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REPORT

of the

TRIBUNAL OF INQUIRY

into

THE BLOOD TRANSFUSION SERVICE BOARD

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ón
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,
nó tríd an bpost ó
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,
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Tribunal of Inquiry
Appointed by instrument of
the Minister for Health
dated the 24th day of October 1996
Sole Member
The Honourable Mr. Justice T. A. Finlay

Tribunal Office
63/64 Adelaide Road,
Dublin 2.
Tel: 6628740
Fax: 6628856

6 March 1997

Michael Noonan T.D.
Minister for Health
Department of Health
Hawkins House
Hawkins Street
Dublin 2

Dear Minister,

I enclose herewith my Report as sole member of the Tribunal appointed by Order made by you on the 24th of October 1996, pursuant to resolutions of Dáil Éireann and Seanad Éireann each passed on the 17th October 1996, to enquire into the circumstances surrounding the contamination of blood and blood products in accordance with the Terms of Reference contained in the Said Order.

Yours sincerely

Thomas a. Finlay

The Honourable Mr.
Justice T.A. Finlay
Sole Member of the Tribunal.

Registrar: Noel D. Doherty; Solicitor to the Tribunal: Claire Loftus.

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Part I

Introduction

Introduction

The examination of the individual human suffering and hurt occasioned by the infection of Anti-D and other blood products with hepatitis C has been for all of us who have been engaged in the work of this Tribunal, a deeply distressing and very emotive experience.

Our task however has been to ascertain the facts which have been referred to us and reach the conclusions requested in an entirely detached and unemotive manner leaving aside great sympathy felt for the victims.

That task has been eased by the courage and indeed moderation with which the victims have given their evidence and by the wholehearted cooperation which has been afforded to the Tribunal by all parties involved in it and by their legal representatives.

I personally owe a great debt of gratitude to the legal team representing the Tribunal James Nugent SC, Rory Brady SC, Dara Foynes BL, Claire Loftus, Solicitor and David Ainscough, Solicitor, for their skill and dedication not only in the presentation of the evidence but also in the vast preparatory work involved in the interviewing of witnesses and the analysis of a truly vast number of documents. In this last mentioned task, they were assisted by Emily Egan BL and Tara Burns BL.

I also gratefully acknowledge the skill and experience of Noel Doherty BL, Registrar of the High Court who contributed so much to the smooth running of the Tribunal hearings.

The contribution made to the Tribunal by the administrative and clerical staff was afforded without stint, courteously and was of very great value indeed.

Karl Martin, Higher Executive Officer ensured the completely smooth operation of the office created for the Tribunal and managed the many physical requirements of the Tribunal hearings without a single hitch.

Dan Ryan, Staff Officer, efficiently carried out the essential task of bookkeeper and Colm Grace and Tom Walsh, Clerical Officers, amongst their general office administrative duties discharged the mammoth task of photocopying involved in the preparation of the Tribunal's various and numerous books of evidence.

Marie Heffernan and Madeline Loughlin, Clerical Assistants were the office secretaries answering the phones and typing with great speed and precision the extensive documentation necessarily created for the Tribunal as well as this Report and its preliminary drafts.

Thomas A. Finlay

Thomas A. Finlay
Sole Member of the Tribunal

6th day of March 1997

Chapter 1

Terms of Reference

Pursuant to a Resolution of Dáil Éireann passed on the 17th of October 1996 and to the Resolution of Seanad Éireann passed on the 17th of October 1996, the Minister for Health, Michael Noonan TD, on the 24th day of October 1996 made an Order appointing a Tribunal, to which the Tribunals of Inquiry (Evidence) Act 1921 (as adapted) and the Tribunals of Inquiry (Evidence) (Amendment) Act 1979 applied, to enquire urgently into and report and make such findings and recommendations as it saw fit to the Minister for Health on the definite matters of public importance set out at paragraphs 1-9 of the Resolutions passed by Dáil Éireann and Seanad Éireann aforesaid.

The matters referred to in paragraphs 1-9 of the said Resolutions (which are hereinafter referred to as Terms of Reference) are as follows:—

1. The circumstances in which Anti-D, manufactured by the Blood Transfusion Service Board (BTSB), was infected with what is now known as Hepatitis C and the implications, thereof, including the consequences for the blood supply and other blood products.

2. The circumstances in which the BTSB first became aware that Anti-D, manufactured by the BTSB, had become, or might have become, infected with what is now known as Hepatitis C.

3. The implications of the discovery at 2. above, the action taken by the BTSB in response to the discovery and the adequacy or otherwise of such action including the consequences for the blood supply and other blood products.

4. The response of the BTSB to a letter of the 16th December 1991 from the Middlesex Hospital, London in relation to Human Immunoglobulin — Anti-D and the adequacy of such response including the consequences for the blood supply and blood products.

5. Whether the National Drugs Advisory Board in carrying out its functions in advising on the grant of a manufacturing licence for Anti-D under the Medical Preparation (Licensing of Manufacture) Regulations 1974 and in advising on the grant of Product Authorisations under the European Communities (Proprietary Medicinal Products) Regulations 1975 carried out its function properly.

6. Whether supervision of the Blood Transfusion Service Board and the National Drugs Advisory Board, in respect of the matters referred to in paragraphs 1-5 above, was adequate and appropriate in the light of:
   (i) The functional and statutory responsibilities of the Minister for Health, the Department of Health and the Boards.
   (ii) Any other relevant circumstance.
7. Whether Anti-D was a therapeutic substance for the purposes of the Therapeutic Substances Act, 1932 and the regulations made pursuant to it and whether the grant of a manufacturer's licence during the years 1970-1984 would have been appropriate and could have prevented the infection of human immunoglobulin Anti-D with Hepatitis C.
8. The relevance to the foregoing of any further documents, testimony or information not available to the Expert Group, which became available subsequent to the completion of the Group's report.
9. The questions raised by the family of Mrs. Brigid McCole, in their open letter published on October 9th, in so far as these questions relate to the Terms of Reference above.

The "questions raised by the family of Mrs Brigid McCole in their open letter published on October the 9th" which relate to the Terms of Reference contained in paragraphs 1-8 hereof are as follows:—

(1) Why did the Blood Transfusion Service Board use plasma from a patient undergoing therapeutic plasma exchange when it was unsafe to do so?

(2) Why did the Blood Transfusion Service Board ignore the ample warnings of jaundice, hepatitis and adverse reactions to Anti-D in 1977 and again take no steps when they were informed of the infection of Anti-D with Hepatitis C on the 16th December 1991?

(3) Why did the Blood Transfusion Service Board not inform the infected women in 1991 and why did they not report the infection to the Department of Health as they were obliged by law to do?

(4) Why was the Blood Transfusion Service Board permitted to manufacture Anti-D unlawfully and without a licence under the Therapeutic Substances Act, 1932 from 1970-1984?

The full terms of the Order made by the Minister for Health on the 24th of October 1996 are contained in appendix A of this report.

Chapter 2

Procedures adopted by the Tribunal

Summary of procedures adopted by the Tribunal.

1. *Parties represented.*

The Tribunal was represented by a team of lawyers and the following parties were granted by the Tribunal full representation before it, that is to say:—

The Positive Action, a Company limited by guarantee
The Family of the late Brigid McCole
The Blood Transfusion Service Board (BTSB)
The National Drugs Advisory Board (NDAB), now known as the Irish Medicines Board
The Department of Health and the Minister for Health
A team of lawyers nominated by the Attorney General to represent the Public Interest.

The following associations or bodies were granted limited representation before the Tribunal:—

Transfusion Positive
The Irish Kidney Association Ltd
The Irish Haemophilia Society
Crumlin Hospital

The following persons who were witnesses were granted representation in connection with the giving of their testimony:—

Dr Stephen O'Sullivan
Dr John O'Riordan
Dr James Kirrane
Ann Kelleher

The orders drawn in relation to representations are annexed at Appendix B.

2. *Documents*

All the parties to the action brought by the late Brigid McCole against the BTSB and others in the High Court agreed that documents discovered by them in those proceedings should be made available to the Tribunal for the purposes of its task.

In addition, orders for discovery of documents relevant to the Terms of Reference and not already discovered in those proceedings, were made against the following:—

The BTSB
The NDAB
The Department of Health.

Orders for discovery of documents were also made against:—

Positive Action
The Coombe Hospital and
Crumlin Hospital

In addition other individuals and the societies representing the victims of the Hepatitis C infection also supplied the Tribunal with documents on request.

3. *Work preparatory to the taking of evidence*

It was decided by the Tribunal at the outset that it, for the purpose of taking evidence, would divide the Terms of Reference into two separate groups. Accordingly, it was directed that evidence would first be taken, both oral and documentary relevant to items number 1-4 inclusive and item 9 of the Terms of Reference and that subsequently evidence would be taken both oral and documentary in regards to items number 5-8 inclusive of the Terms of Reference. This was a general division and not rigorously adhered to.

The legal team representing the Tribunal studied the entire of the documentation available to it together with statements of evidence supplied to it by the various witnesses and as a result prepared prior to the 2nd of December 1996 (when the taking of evidence commenced), a document in the form of a "Statement of Facts" concerning the matters arising under Terms of Reference 1-4 and number 9, which was served on the other parties concerned seeking their agreement or dispute with the facts as itemised.

4. *The taking of evidence*

Over a period of 11 days between the 2nd and 17th of December, the Tribunal sat and took evidence from a total of 29 witnesses in relation to the Terms of Reference 1-4 and number 9.

The Tribunal team of lawyers then carried out a similar exercise with regard to the documents and statements concerning Terms of Reference numbers 5-8 inclusive and served a series of documents in the form of "Statement of Facts" on the parties concerned prior to the 13th January 1997.

The examination of witnesses recommenced on the 13th of January 1997 and continued over a period of 13 days until the 30th of January 1997. The Tribunal sat on two subsequent days to hear submissions by Counsel on behalf of the parties concerned.

With the exception of a limited number of occasions when, by agreement, statements of witnesses were read, witnesses gave sworn evidence.

With the exception of a limited number of witnesses who had been victims of infection by Hepatitis C, all witnesses were in the first instance questioned by Counsel representing the Tribunal.

No formal proof of the documents discovered was required except in cases where their authenticity was challenged and the Tribunal has had regard to such documents produced by the parties as appear relevant.

The names and occupations of the witnesses called in evidence before the Tribunal are contained in Appendix C of this report. It should be noted that a number of these witnesses had evidence relevant to more than one issue arising before the Tribunal and in their case would have been recalled on one or more occasions to deal with the issues then being considered.

Chapter 3

Introductory information

It appears convenient before dealing with the issues before the Tribunal to set out in a very brief form some introductory information which is relevant to the considerations arising.

The BTSB

The BTSB is a statutory corporation established by an Order made by the Minister for Health in 1965 pursuant to the Health (Corporate Bodies) Act, 1961. It took over the assets, liabilities and rights of the National Blood Transfusion Association which had been set up in 1948. Its main function relevant to this inquiry is:

> *"to organise and administer a blood transfusion service including the processing and supply of blood derivatives or other products and also including blood group and other tests in relation to specimens of blood received by the board"*

It also has a function of making available blood and blood products.

It is administered by a Board of Management, members of which are all nominated by the Minister for Health who also nominates the Chairman.

In the period relevant to this inquiry it was firstly staffed by a National Director and Deputy National Director, both of whom were consultant doctors and who were supported by other medical, scientific and administrative staff.

In 1986 an Executive Consultant, who was an accountant, was appointed to the staff and became the Chief Executive Officer and so remained during the rest of the relevant period.

Theoretically the BTSB was intended to be self financing but in fact and in practice it required the sanction of the Department of Health in fixing the prices of its services and its products and required the financial subvention from the Department of Health for major capital investment in premises, equipment or major staff changes. During the relevant period it was quite clear that such matters as the introduction of new systems of screening or viral inactivation required the prior sanction of the Department of Health where, as was usually the case, they required the acquisition of significant new equipment and possibly staff.

In 1965 there were two other Blood Transfusion services in existence, one in Cork and one in Limerick. The Cork Service amalgamated with the BTSB in 1976 and the Limerick Service amalgamated with the BTSB in 1991.

The NDAB

The NDAB was established by an Order made in 1966 by the Minister for Health pursuant to the Health (Corporate Bodies) Act, 1961. It was a statutory board, the members of which and the Chairman of which were nominated by the Minister and it was financially subvented by the Department of Health.

Its main functions on its establishment were to organise and administer a service for obtaining and assessing information as regards the safety of new and reformulated drugs and in particular the toxicity and other adverse effects; to organise and administer a service for obtaining and assessing reports on the adverse effects of drugs; to advise in general on the safety and quality control of drugs and other functions concerning the dissemination of information and recommendations with regard to the standards concerning drugs. It did not at that time have any statutory powers of inspection. Subsequently, in 1974, certain functions of advice to the Minister concerning the licensing of the manufacture, importation and distribution of drugs and standards of manufacturing practice were added to its functions. It also became involved in advising the Minister with regard to Product Authorisation of drugs and medicinal products. It was not a licensing authority at any time. It did in fact carry out inspections of the BTSB from time to time as will appear later.

The NDAB ceased to exist on the coming into effect of the Irish Medicines Board Act, 1995 and the functions previously carried out by it together with other functions are now vested in the Irish Medicines Board.

Anti-D Immunoglobulin

Anti-D Immunoglobulin (Anti-D) is a manufactured blood product used to prevent RH Haemolytic Disease. At the end of a pregnancy of a woman with RH Negative blood whose foetus is RH Positive, separation of the foetus from the womb involves the leaving of RH Positive blood in the mother's system. She can then develop anti-bodies for the purpose of destroying the red cells, in the foetal blood, which remain in her system. These anti-bodies remain in her blood system and if she again becomes pregnant with a rhesus positive foetus, the already established anti-bodies will cross the placenta and attack the red cells in the foetus and destroy them. This can lead to severe damage and possibly the death of the baby. The injection of Anti-D into the mother within 48 hours of the end of the pregnancy prevents the mother from developing these harmful anti-bodies.

In instances where the prevention of the harmful anti-bodies has not been successfully achieved after the end of a pregnancy by the injection of Anti-D, it may be necessary for a mother who retains anti-bodies in her system and becomes pregnant again to have a therapeutic course of plasma exchange

prior to the birth of her child for the purpose of removing from her blood the anti-bodies and substituting for them compatible plasma.

The therapeutic use of Anti-D became generally available in the late 1960's and production of it was commenced by the BTSB in Ireland in 1970. As appears from research carried out by the Expert Group and published in its report of January 1995, it is estimated that over 100 babies were born dead in Ireland each year up to the introduction of Anti-D and many more would each year have been born gravely handicapped or gravely injured by reason of RH Haemolytic Disease. The existence of that disease in newborn children and its consequences has, by reason of the introduction of Anti-D, been for practical purposes eliminated.

Hepatitis

Hepatitis is a virus infection primarily infecting the liver and frequently, though not inevitably, linked to visible signs of jaundice. Jaundice may also arise from causes other than viral infection of Hepatitis. In general Hepatitis was one of a small number of diseases which it was known were capable of being transmitted by the transfusion of blood or blood products.

Hepatitis C

By 1975 two types of Hepatitis had been clearly identified and characterised by the medical and scientific professions. One was known as Hepatitis A and one was known as Hepatitis B.

By 1975 a somewhat unreliable and imprecise test for the existence of the virus of Hepatitis A in blood had been developed to the extent of being available in research laboratories.

By 1975 however, in regard to Hepatitis B, a test for the existence of that virus in blood, which was considered substantially reliable, had been developed and was generally available.

In addition, by 1975, it was generally accepted in medical and scientific circles dealing with the virus of Hepatitis and in particular by specialists dealing with the transfusion of blood, that a form of Hepatitis virus affecting humans which was neither A nor B did exist. It was not even known with certainty at that time whether this virus was a single type or merely a group of more than one type of Hepatitis virus which was not Hepatitis A and not Hepatitis B. It was known at that time scientifically as Hepatitis (non-A, non-B), and includes the type of Hepatitis now known and identified as Hepatitis C. Its identification as a single type of Hepatitis virus did not occur until the late 1970s or early 1980s and even fairly reliable methods of testing for it were not available until the late 1980s though they have in reliability and precision fairly rapidly improved in the years since 1990. Since 1993, a reliable test dividing Hepatitis C into sub-types has been developed.

Method of manufacture of Anti-D by the BTSB

Anti-D as manufactured by the BTSB since 1970 was intended for injection intravenously as distinct from Anti-D used in a number of other countries which was injected intramuscularly. The manufacture of Anti-D at all material times by the BTSB was based on a system of manufacture developed by Professor Hoppe, Director of the Central Institute for Blood Transfusion in Hamburg.

This method was one employing ion exchange chromatography together with an ethanol precipitation step which was considered beneficial in helping to inactivate any Hepatitis viral material that might be contained in the plasma being fractionated. The process of fractionation as part of the process of the production of Anti-D consists of the separation of Anti-D immunoglobulin from other proteins in the plasma.

Part II

Terms of Reference 1-4

BTSB were not using the plasma and was never subsequently informed that they were.

Patient X was never asked for her consent to the use of plasma taken from her in the course of this plasma exchange treatment for the manufacture of any blood product. In a statement to the Tribunal she stated that she would not have given her consent because she had earlier in her life been infected with Tuberculosis. On the 28th of September 1976 a supply of exchange plasma was in fact received by the BTSB from Crumlin Hospital having been taken from Patient X and was included in five batches of Anti-D manufactured between the 4th of October 1976 and the 4th January 1977 which were issued by the BTSB between the 31st January 1977 and the 6th April 1977.

A table outlining these and further details is contained in Appendix D.

Subsequent examination of these batches, made in later years when testing for Hepatitis C became scientifically possible, indicated that none of them was infected with Hepatitis C.

Patient X had a reaction to a transfusion on the 4th November 1976. The evidence is that this was not a reaction which might normally be associated with some virus infection, but was rather a reaction, not abnormal in persons who have received transfusions, arising from some incompatibility in the blood transfused. The fact however, of a reaction was made known to the BTSB, and the treatment by plasma exchange was suspended for a short time.

On the 17th November 1976 Patient X became jaundiced and was diagnosed as having developed Hepatitis. This fact was made known to the BTSB and in his evidence, Dr McGuinness stated that he was fairly certain that he had told Dr Walsh of that fact.

An application was made by the Coombe Hospital to the BTSB on the 17th November 1976 to have a specimen of the blood of Patient X tested for Hepatitis B and on the form seeking that test, the "clinical data/relevant treatment" column was filled in as follows: — "mild jaundice, recent history of multiple plasma exchanges? Hepatitis?" That test for Hepatitis B in the blood proved negative. The result of it, attached to the form of application, was returned from the BTSB to the Coombe Hospital signed by Dr O'Riordan, the National Director. On the same date specimens of the blood of Patient X were sent by Dr O'Riordan to be tested for Hepatitis B by Dr Dane of the Middlesex Hospital.

By the 15th of November 1976 four batches of anti-D had been manufactured by Mrs Cunningham, which included the plasma taken from Patient X on the 28th of September 1976. Mrs Cunningham's evidence was that she was then told by Dr. Walsh to hold those 4 batches as a specimen of Patient X's blood had been sent for testing because of her reaction to a transfusion. It appears more likely that the reason given to Mrs. Cunningham at that time would have been that the patient had been observed to have jaundice and/or had been diagnosed as having hepatitis.

It was necessary as part of the therapeutic plasma exchange which was being given as treatment to Patient X that those involved in the treatment would keep a check on the extent to which it was being successful, in other words,

on the extent to which the rhesus anti-bodies were still retained in the blood of Patient X. This was known as quantitative testing and was usually carried out after each plasma exchange. Between the 19th November 1976 and the 8th December 1976 on ten separate occasions, samples of the plasma of Patient X were sent by the Crumlin Hospital to the BTSB for the purpose of having this quantitative test carried out and each of them was apparently reported on by a form signed by Dr Wilkinson, the Deputy National Director. In each of those ten forms, a column providing for a statement of the clinical diagnosis of the patient concerned had the words "infective Hepatitis" contained in it.

It cannot therefore be doubted that by the middle of December 1976, the entire senior medical staff concerned for the BTSB with this question of the plasma obtained from Patient X, that is to say Dr O'Riordan, Dr Wilkinson and Dr Terry Walsh, were all aware of a diagnosis of infective Hepatitis and the display of jaundice by the patient.

Notwithstanding this knowledge, further supplies of plasma were obtained from Patient X on the 10th, 17th and 19th January 1977. These supplies of plasma or part of them were included in pools of plasma used to manufacture batches of Anti-D on dates between the 14th February 1977 and 4th July 1977. The total number of batches manufactured during that period was 16 of which 8 when tested in later years when testing for Hepatitis C became possible, proved to be infected with the virus of Hepatitis C.

The number of doses of Anti-D contained in each batch varied significantly depending upon the amount of plasma used in each batch but, for those manufactured from plasma obtained, inter alia, from Patient X in January 1977, the number of doses on average varied between about 250 and something over 400 per batch.

In the month of July 1977, the BTSB was informed by the Rotunda Hospital of the existence of 3 patients of that hospital who in the month of May 1977 had received doses of Anti-D after childbirth, all of which were from a particular batch, namely batch 238 in which the plasma of Patient X had been used and each of whom had subsequently been diagnosed as having Hepatitis. Communication was made with the General Practitioners attending upon these three patients after the birth of their children all of whom suggested to the BTSB that their Hepatitis might be associated with having been the recipient of the doses of Anti-D.

On the 25th July 1977, Mrs Cecily Cunningham who was in charge of the laboratory where the Anti-D was manufactured, received an instruction not to use Patient X's plasma in any more donor pools. By that time the last of the 16 batches of Anti-D in which Patient X's plasma was included had been manufactured, but not all of them had yet been issued. Her evidence was that she received no instruction as to what she was to do with the already manufactured batches of plasma to which Patient X's plasma was a contributor which had not been issued, or with those which had been issued but not yet been used. She accordingly continued to issue the batches which had already been manufactured.

On the targeted Lookback it was established in evidence that the late Mrs Brigid McCole was on the 5th November 1977 inoculated with Anti-D taken from batch 250 which was one of the batches manufactured from plasma to which the plasma of Patient X had been contributed and was one of the batches issued in 1977 which, subsequently on testing, was established as having been infected with Hepatitis C.

Mrs Cunningham's evidence was that she did not seek any particular instruction about those matters and her recollection was that she probably received this instruction from Dr Walsh, though having regard to his evidence of being on holiday in July of 1977, it is more probable that the instruction was received from Dr O'Riordan or possibly from Dr Wilkinson.

On the 11th August 1977, further specimens of blood of the women who had been reported from the Rotunda Hospital as having received Anti-D in the Rotunda Hospital and subsequently developed Hepatitis, together with specimens of plasma taken from Patient X and 16 samples of batches of Anti-D to which plasma from Patient X had been contributed including batch number 250, were sent to Dr Dane at the Middlesex Hospital Medical School for further testing. The reports on these tests were negative and on the 2nd September 1977, Dr Dane wrote to Dr O'Riordan expressing his opinion on the result of these tests. Part of the contents of that letter were as follows:

> *"I saw no virus or antigen particles. We have frozen the specimens away for future reference and if and when any test is developed which is likely to solve the mystery, we will take them out again.*
>
> *The negative RIA tests already reported to you confirmed that you are not dealing with Hepatitis B, which is all we could really hope to do for you at this stage"*

In August and November 1977 two further women who had received anti-D injections in the Coombe hospital in June and August respectively from batches which were identified as having been contributed to by Patient X were reported by their general practitioners as having suffered from hepatitis and jaundice, and concern was expressed by the doctors as to the possible connection between that and the anti-D injections which they received. Further reports of a like kind were received by the BTSB in the months of November and December 1977 concerning two further women who had received anti-D in Holles Street Hospital in October 1977 from 2 further batches, each of which was again a batch contributed to by Patient X. A table setting out the above reports made to the BTSB can be found at Appendix E.

A body known as the BTSB Scientific Committee in the years 1976 and 1977 and for some time afterwards, met usually once a week. It had an agenda prepared by or on the instructions of Dr O'Riordan. The attendance included at this time, Dr O'Riordan, Dr Wilkinson, Dr Walsh Mr Sean Hanratty, Technical Officer who has since died, Mrs Cunningham, Mr Cann, Chief Technical Officer and Dr Kirrane, a part-time consultant attached to the BTSB.

Unfortunately no minutes of any description were kept of the meetings of this committee and it seems to have been particularly informal, more of a discussion group than a meeting capable of, or in fact, reaching definite decisions.

From the items on the agenda however, and from such recollection as has been possible to obtain in evidence of what occurred at the meetings of the Scientific Committee in 1977, it is clear that the question of the plasma obtained from Patient X, the condition of jaundice and Hepatitis reported with regard to Patient X and the complaints of the recipients of Anti-D from batches donated in part by Patient X who had developed Hepatitis after being dosed with the Anti-D, were all matters discussed on a number of occasions at meetings of the Scientific Committee during the year 1977 and in particular it would appear, from July 1977 on.

The evidence at present available of what was discussed and, to whatever extent it may have occurred, decided at meetings of the Scientific Committee on this topic, is extremely poor but it is clear that no decision was taken at any time to either prohibit the further issue of batches of Anti-D derived in part from the plasma obtained from Patient X or to recall batches which had already been issued, although a decision was taken as indicated in July, not to manufacture any more batches.

One of the documents made available by the BTSB before the Tribunal was a list of the destinations of doses derived from batch number 238 to which reference has already been made. The number and destination of each dose from that batch throughout the country is recorded by apparently one of the persons working in the dispatch office of the BTSB at that time.

None of the surviving members of the Scientific Committee could give any assistance to the Tribunal as to what the purpose of the compilation of this list was. It seems to be a likely conclusion that this was brought into existence with a possible view to a total recall of the product. On the other hand it is possible that the Committee was considering making an enquiry as to whether, in addition to the reports of hepatitis and jaundice in persons who had received the anti-D doses in Dublin, there were other reports from any of the hospitals or nursing homes outside Dublin to which this particular batch 238 had been sent.

Standards of conduct which should have been applied in relation to Patient X

1. It is a fundamental principle of the indications for rejection of a donor of blood that a person with a history of viral Hepatitis or jaundice of unknown origin, shall be excluded permanently as a blood donor. This was agreed by all the witnesses called from the BTSB and any other technical or scientific witnesses who gave evidence.

2. A period of at least six months should elapse from the date of the last infusion or injection of blood before a person receiving a transfusion of blood or blood components is accepted as a donor. This is stated again in the notes for the Guidance of Medical Officers of 1972 as being to protect the donor and protect against the transmission of Hepatitis.

3. A fundamental ethical standard of conduct is that a blood donation should not be taken from any person without his or her informed consent.

4. An abnormal reaction to the injection of blood or a blood product should be reported to the National Drugs Advisory Board. This is an obligation which would apply amongst others to the Blood Transfusion Service Board.

5. It was a fundamental principle of blood transfusion and the preparation of blood products that should any question be raised of any substance concerning the safety of a product, even without convincing proof of infection, it should be totally recalled and supplies of it destroyed.

Wrongs committed in the treatment of Patient X by the BTSB

1. A suspicion notified to the BTSB of either jaundice or Hepatitis having developed in Patient X, was a reason in itself why no plasma taken from her should have been included in any batch of manufactured Anti-D. If plasma taken from her had already been included in a batch, that batch should have been destroyed and if any doses from it had been issued they should have been recalled. It was accepted by all the medical and technical staff of the BTSB in 1975 that the process of manufacturing Anti-D immunoglobulin, could not and did not constitute any guarantee of the removal of all forms of Hepatitis virus. This was also the unanimous view of the International Blood Transfusion and Blood Service Scientific Experts.

   Having regard to that belief and that knowledge, there was no room for proceeding upon a theory that jaundice or Hepatitis in the donor of blood might not be a virus which would remain after the production of a blood product such as Anti-D.

2. It was a serious breach of ethical conduct to have taken the plasma removed from Patient X for use in the manufacture of blood products without having obtained her informed consent. As a result of this particular breach, Patient X has understandably been deeply distressed by the knowledge that, even though entirely innocently and without blame on her part, she has in fact been a source of infection for so many other women.

3. The failure on the part of the National Director of the BTSB who must be the person with this particular responsibility, either to notify the NDAB or the Board of Management of the BTSB of the complaints or suspicions notified to him and to the other members of the Scientific Committee between July 1977 and December of 1977 by General Practitioners attending on recipients of Anti-D that it had caused to those recipients the quite abnormal reaction of developing Hepatitis, was a grave dereliction of duty. It is not possible to avoid the conclusion that had this duty been performed, by the reporting of the matter either through the NDAB to the Department of Health or through the Board to the Department of Health, it would have led to a proper examination of the problem at that time, and notwithstanding difficulties which then existed for testing against the existence of Hepatitis C, might have avoided much of the damage which was occasioned by this incident.

   The events which had occurred between November 1976 and September 1977 concerning the plasma donated by Patient X and used in the batches of Anti-D issued were, as they were properly described in the letter from Dr Dane to Dr O'Riordan of 2nd September 1977, "a mystery". The existence of such a mystery constituting as it did, a mystery or question as to the safety of the product that had been issued should have resulted in the recall and destruction of that product.

Responsibility

It is clear that from the documentation, and from the oral evidence given both by officers of the BTSB and independent witnesses involved in blood transfusion outside Ireland, that the major responsibility in connection with the safety of the raw material consisting of the donations of blood rests with the medical staff of the Blood Transfusion Service.

This being an incident in which the contamination of the eventual blood product arose from a total failure to adhere to the standards of donor selection as distinct from any question of an intervening contamination in the course of production or manufacture, the greater responsibility must lie with the medical staff.

With regard to the individuals involved in the medical staff at that time, they are: Dr O'Riordan, the late Dr Wilkinson, Dr Terry Walsh and Dr Kirrane, a part-time consultant.

Dr O'Riordan

Dr O'Riordan was the first National Director of the BTSB when it was established in 1965. Evidence before the Tribunal establishes that he was a widely recognised expert in questions of blood transfusion and of the manufacture of blood products, respected as such not only in Ireland but in many countries abroad as well. He served as National Director until his retirement in 1986. He will be 83 years of age this March.

It was clear that Dr O'Riordan was requested by the Expert Group to meet them and to provide them with such information and assistance as he could in the task that they were carrying out. He denies a recollection of that invitation and request but it is clear that it was made to him. He did not accede to that request nor does he appear to have taken any steps at that time to ascertain what information they might require or whether he could give it.

He was requested as were all the other witnesses involved to give to the Tribunal a statement of his evidence and to make himself available for a consultation prior to the taking of his evidence, with counsel acting for the Tribunal. He did not accede to that request, he did not supply any statement of evidence and did not come to any meeting. It was suggested on his behalf that his memory might have failed to the extent that he would not be a competent witness.

A subpoena was then served upon him to give evidence and at the very commencement of the proceedings of the Tribunal, legal representation on his behalf was granted to him and the lawyer concerned informed the Tribunal that it might be that he could offer evidence which would indicate that his client was not fit to give evidence. It was indicated by the Tribunal that if such evidence was forthcoming, it would be heard and tested. No such evidence was offered to the Tribunal and Dr O'Riordan answered the subpoena and came and gave evidence. Broadly speaking, his evidence was to the effect that with regard to the particular events with which the Tribunal was especially concerned to obtain evidence from him, that is to say the events of 1976 and 1977, which are already set out in this report, he had no real recollection and could not be expected to answer any questions about them when he had not got available to him any documents, notes or other matters which he would have left behind him in the BTSB. On enquiry he did not ever look for those documents to assist him in giving evidence as other witnesses have had to do, nor did he purport to understand what issues the Tribunal was investigating. His memory with regard to some other matters, not directly relating to the Terms of Reference, but relating to his period of office in the Blood Transfusion Service Board as for example, his activities as a member of various research bodies in Europe, was quite good. The conclusion which the Tribunal must reach is that Dr O'Riordan was not prepared to reveal the extent of his knowledge of most of the matters with which the Tribunal is concerned, and was certainly not prepared to refresh his memory, as he could have done, by consulting documents arising from the time from the events that happened. Conclusions with regard to his responsibility must therefore to a large extent be based on the evidence which appears credible and is obtained from documents and from the evidence of other people.

That conclusion must be that he bears the major responsibility for what occurred in 1976 and 1977, which was the largest single event contributing to the infection of Anti-D with Hepatitis C. The nature of his responsibility derives, in the view of the Tribunal, not only from the fact that he was the senior medical officer involved but also from two other facts, one being the extent of his properly deserved reputation as an expert in this field as well as

the authority he wielded as National Director, and the other being what is clearly derived from the evidence of independent people as well as people employed in the BTSB at that time, that he was a person with a strong and dominant personality. He was, it would seem, the person who above all others, should have recognised the danger of what had occurred and, irrespective of whether it should have occurred at all or not, should have taken steps to prevent it causing damage. If he was not strong in an intention to do that, it was difficult for more junior and less experienced persons to change the course of events though they should have attempted so to do.

Dr Wilkinson

Quite obviously Dr Wilkinson as the Deputy National Director must also be considered to have had responsibility but it is particularly difficult to quantify that or to compare it with the responsibilities of others having regard to his death, and because of the potential injustice that would arise from blaming a person who had never had an opportunity of defending himself. There is no evidence however, that he carried to any of the meetings of which some evidence is given, discussion of any particular point of view on this issue.

Dr Terry Walsh

Dr Walsh, though the most junior of the three medical officers who were whole-time in the BTSB, was in fact the officer with a particular responsibility for donors and for the system of blood donation. It would appear from the evidence of Dr McGuinness that it was directly with Dr Walsh that the arrangement of the taking of the plasma was first made and although Dr Walsh in evidence accepts that, he says that he certainly would not have been able to make a decision of that description without the authority of Dr O'Riordan. Be that as it may, it seems that he was clearly in important neglect of his duty in failing, as he appears to have done, to make a firm contribution suggesting the destruction or non-use of the plasma obtained from Patient X as soon as he learnt of her Hepatitis and jaundice which was at an early stage.

Dr. James Kirrane

Dr. James Kirrane is a medical doctor and a consultant in pathology who in the year 1968 was working as a lecturer in University College Dublin under Professor Harman, who at that time was a member of the Board of the BTSB. He was appointed to the BTSB as a part-time consultant to advise the BTSB of the establishment and operation of two new laboratories. One of those was a tissue typing laboratory and the second was a protein fractionation laboratory. This part time appointment was one which involved a single visit each week and was an appointment which Dr. Kirrane retained until the end of the year 1985 when he resigned.

On his evidence he was closely involved from the time of his appointment with the establishment of the fractionation laboratory involved in the production of Anti-D and with the processes of fractionation. This was the laboratory which was under the control of Mrs. Cecily Cunningham.

By 1976 his activities appeared to have become confined to attending on most weeks the meetings of the Scientific Committee and in spending some short time before each meeting in the laboratories with the establishment of which he had been associated. He would receive a copy of the agenda of the meeting as he arrived at it. He did not keep notes of what went on at the meetings.

The evidence of Dr. Kirrane was to the effect that at no time had he been involved in any aspect of donor selection with regard to blood transfusion and that he did not have either an expertise or a particular responsibility with regard to the safety of the raw material, but was involved with the question of the process and procedures involved in the laboratories, with particular reference to the fractionation.

In the year 1977 he was consulted by one of his colleagues Dr. Lennon in the Mater Hospital who was treating two female patients who were amongst those who had been recipients of Anti-D and who had developed jaundice and hepatitis. He was, according to his own evidence, consulted about their further treatment but was also requested to contact the BTSB concerning them. He stated that he gave information to Dr. Walsh concerning these two patients, who were among those previously referred to in this report as having been reported to the BTSB, but did not give a detailed account of their condition or of any views held as to the origin of the jaundice and hepatitis from which they were suffering.

He further stated in evidence that he did not remember being informed at the scientific meetings, which he apparently regularly attended during 1977, of the fact that Patient X, the source of the exchange plasma, had been diagnosed as suffering from either hepatitis or jaundice. He did remember being informed that patients who reported a reaction from Anti-D during that year to the BTSB had been described as suffering from jaundice.

His recollection of any discussion which was had at the several meetings was extremely poor although he did admit that there must have been a discussion having regard to the agenda of the meetings at which he attended.

He does not suggest that he made any particular recommendation concerning the course of action which should be taken and he could not recollect hearing of any decision either to suspend the use of the plasma which had been obtained or to send specimens to the Middlesex hospital for testing.

Dr. Kirrane described his contact with the BTSB at that time as "sketchy" and this would appear to be an accurate description of it. Notwithstanding the fact that he was not directly involved in any question of donor selection or in the questions of virus contamination of the blood or blood products, he had a duty as an independent consultant attached to the BTSB to press for further investigation of possibly serious adverse reaction to the blood product Anti-D, of which he had been informed in the Mater Hospital, and of which he was informing the BTSB. Had he done so the damage might have been avoided or limited.

Mrs. Cecily Cunningham

Mrs. Cunningham holds the degree of Master of Science from Trinity College Dublin and has been since 1974 the principal biochemist employed in the BTSB. She had been involved in the very beginning in the setting up of the fractionation laboratory for the making of Anti-D in 1970. She was in effect at all material times the biochemist in charge of that laboratory.

As such she would not have had any direct responsibility for donor selection nor for the obtaining of plasma for the purpose of the production of Anti-D. Her superior in 1976 and 1977 would have been Mr. Cann who was the Chief Technical Officer at that time in the BTSB.

Both Mrs. Cunningham and Mr. Cann were members of the Scientific Committee and attended its meetings regularly. With regard to the incident surrounding Patient X Mrs. Cunningham maintained throughout her evidence that she had never been informed that Patient X who was contributing the plasma used for the making of Anti-D, displayed signs of jaundice and/or was diagnosed as having infectious hepatitis.

She does agree that she was aware that there was evidence that some of the recipients of Anti-D particularly those obtaining doses taken from batches nos. 238 and two other batches numbered 250 and 252 respectively, all of which batches contained plasma to which the plasma taken from Patient X had been contributed, were reported as having developed jaundice after having received the doses of Anti-D.

Having regard to the oral and documentary evidence which is available concerning the discussions which undoubtedly took place in the year 1977 concerning these batches of Anti-D and having regard to the tests, of which it seems clear Mrs. Cunningham was aware, which were made at the Middlesex hospital at the request of the BTSB, not only of the Anti-D content but of blood taken from Patient X, it is not acceptable that Mrs. Cunningham was unaware of the diagnosis of hepatitis and the display of jaundice sustained by Patient X at the time the plasma was being taken from her.

She states that she was aware of a reaction suffered by Patient X after one transfusion of blood and she stated her belief that the testing of Patient X's blood carried out at the request of the BTSB arose from this reaction. That is plainly inconsistent with the evidence which was before the Tribunal to the effect that reactions from incompatibility of transfusions of blood are quite usual and frequently occur, being generally considered by those involved in blood transfusion medicine as being by no means abnormal.

Mrs. Cunningham agrees that she received an instruction from Dr. Walsh to hold the plasma in November of 1976 after this reaction had been reported and at a time when the first set of samples were sent to Middlesex for testing. This was apparently the first time such an instruction had ever been issued to her in relation to any batch of Anti-D.

Subsequently in July of 1977 she was again instructed not to use any more of the plasma derived from Patient X for the purpose of making Anti-D. She states that she did not receive any instruction to discontinue issuing the

batches derived from Patient X which had already been made. She had no recollection of finding this instruction peculiar and there was no suggestion that she sought any clarification of it. She therefore continued to issue batches of the Anti-D obtained in part from Patient X right up to the end of the year 1977.

Mrs. Cunningham does not bear as great a responsibility for the contamination of the blood supply with Hepatitis C derived from the incident of Patient X as do the medical staff at that time employed by the BTSB. She does however bear an important and serious responsibility nonetheless. Once the instruction had been given to her in one instance to hold for a period the plasma derived from Patient X and in the other instance to discontinue the making of Anti-D from it, having regard to her qualifications and experience, she clearly owed a duty to have these two matters clarified if she did not understand the reasons for them, and should have insisted, as far as was within her power to do so, that no further batches of Anti-D so made should be issued or made available.

Other possible sources of infection of Anti-D with hepatitis C virus

It was suggested in the evidence of Dr. Stephen O'Sullivan that an incident which occurred in the year 1975 in the laboratories of the BTSB was the cause of the infection of the Anti-D with Hepatitis C.

Dr. O'Sullivan was a biochemist who worked with the BTSB between 1973 and 1979.

He gave evidence that on an occasion in 1975, the date or month of which he could not now recollect, he became aware that Mrs. Cunningham, who was then in charge of the fractionation laboratory for Anti-D, had removed a number of doses of Anti-D from a freezer which had broken down in that laboratory and placing them for storage in a freezer situated in the microbiology laboratory, in which doses of reagents containing active virus for testing against hepatitis B were already placed.

He stated that upon his protesting against this procedure, which was quite clearly in breach of the necessary sterility involved in the treatment of, and storage of, blood products, the doses of Anti-D were removed, some form of disinfectant matter placed on them, and were again put back into the Anti-D laboratory and eventually were issued in the ordinary way.

Mrs. Cunningham agreed that this occurred though there was some dispute with regard to detail.

It is quite clear that this was an extremely serious breach of what should have been a fundamental distinction between the sterile laboratory, such as the anti-D laboratory where blood products were manufactured and stored, and the laboratory which stored what would be the contaminating agents such as reagents for the testing against viruses, in this instance the virus of hepatitis B.

From the evidence which was not in dispute it is clear that this incident having occurred, the proper standard of safety would have been that the doses

so removed, even for a short time and even though not brought into the presence of opened bottles of reagent, should have been destroyed and not issued or used. This was not done and it constitutes a serious breach of safety precautions by Mrs. Cunningham and, on her evidence that her action in retaining it and reissuing it was approved by the medical staff, a serious breach by them of the standards which they should have applied.

Having regard however to the fact that the possible contamination, if it did occur, of these batches would have been with hepatitis B, and having regard to the very compelling evidence in respect of the connection between the donations of plasma obtained from Patient X, the series of contaminated batches which were made up from it, and the infection with hepatitis C of recipients of those batches, it is quite clear that this was not a cause, either great or small, of the infection with hepatitis C of the Anti-D supplies in the BTSB. It is relevant only as an example of inadequate standards of safety observed by the people involved in it.

There is however one other incident connected with the production of Anti-D which, later than the events surrounding Patient X, clearly made a contribution of a significant kind to the infection of Anti-D with the virus Hepatitis C. This incident was known in the proceedings before the Tribunal as the position with regard to Donor Y.

Donor Y

Donor Y was a patient who underwent a course of therapeutic plasma exchange in St. James's Hospital which commenced on the 2nd of August of 1989. Between that date and the 30th of August 1989 she made 10 donations of plasma. These donations were subsequently tested for hepatitis C and they proved to be negative. A table outlining these and further details relating to the manufacture of Anti-D are contained in Appendix F.

On the 13th of September 1989 Donor Y received a unit of plasma supplied by the BTSB which, must now reasonably be assumed to have been HCV positive. The subtype of the virus so identified was subtype 3 which is different from the subtype 1B virus which the donations from Patient X introduced into the blood supply and blood products of the BTSB. The probability must therefore be that the infection of Donor Y with the hepatitis C virus arose from the failure to detect a donor carrying the hepatitis C virus before the introduction of hepatitis C screening in October 1991.

Between the 29th of September 1989 and 25th of October 1989, twelve further donations of plasma were taken from Donor Y. These were frozen and retained for contribution to pools of plasma for the later manufacture of Anti-D.

Between January 1991 and January 1994 these donations of plasma were included in a total of 46 batches of Anti-D.

Of those 46 batches which were tested for Hepatitis C on the PCR test subsequent to 1994, 20 proved to be positive and 23 produced a result which was technically classified as being "infectivity cannot be ruled out". Of the 46 batches, 43 were issued between March 1991 and February 1994. Of the 43

that were issued, one was subsequently returned in the recall of February 1994.

By 1989 the BTSB had introduced a precaution against the infecting of plasma used for Anti-D with either the hepatitis B virus or the HIV virus. This precaution was that none of the plasma obtained from a patient undergoing therapeutic plasma exchange prior to the birth of a child was to be used for inclusion in any production of Anti-D, until such time as that patient, subsequent to the birth of the child, had passed tests for both Hepatitis B virus and HIV virus.

Donor Y was apparently not so tested shortly after the birth as was the requirement and, on the 22nd of February 1990, Mrs. Cunningham wrote to Dr. Walsh asking him to ensure that Donor Y was tested for these two viruses in order that she could use the plasma for manufacture. Following that letter Donor Y was not asked to come in for a test nor was she tested.

Mrs. Cunningham again wrote to Dr. Walsh making the same request on the 1st March 1991, but Donor Y was again not tested and was in fact not tested until the 8th of November 1991, at which time she was tested not only for Hepatitis B and HIV but also for Hepatitis C.

Notwithstanding the absence of any test for hepatitis B and HIV after the birth of the child, Mrs. Cunningham in fact commenced manufacture of anti-D from the plasma donated by Donor Y on the 14th of January 1991 and commenced to issue the doses of Anti-D so made from March 1991. On the testing of Donor Y in November 1991 her testing was negative for all three viruses concerned, including, the Hepatitis C virus.

Having regard to the subsequent testing of her plasma and to the investigation of the batches of plasma to which she contributed, it is now accepted by the BTSB that the passing of the test for hepatitis C by Donor Y in November of 1991, merely indicated that she had by that time as is described in medical terms, sero converted for Hepatitis C. That is to say that she had by then developed sufficient anti-bodies against the virus with which she had been infected to destroy the virus in her blood stream.

In 1992 4 tests were carried out on plasma which had been taken from Donor Y in 1989 and they proved positive for Hepatitis C.

The result of these tests should of course have been immediately communicated to Mrs. Cunningham who was in charge of the anti-D laboratory and she should have then taken 3 steps. She should have:

1. Ceased to use any remaining plasma from Donor Y in the production of anti-D and should have destroyed the plasma;
2. She should have ceased issuing any batch of anti-D to which the plasma of Donor Y had been contributed and;
3. She should have recalled as far as possible all batches of anti-D already issued to which the plasma of Donor Y had been contributed.

Mrs. Cunningham denied in evidence being informed of more than one of the positive tests on the plasma of Donor Y which were made in 1992 but

admitted that she was informed of one test which was dated the 24th of July 1992. She stated in evidence that she believes she was informed orally that this was a false positive test and to use her own words simply "ploughed on" with the manufacture. The evidence was that after the date in July 1992 when Mrs. Cunningham admits she was aware of a positive result to the hepatitis C test on the plasma of Donor Y, 18 further batches of Anti-D containing that plasma were manufactured and 21 issued.

Responsibility in connection with the infection derived from Donor Y

The evidence does not support a positive responsibility for the infection of Donor Y except insofar as that may arise from the question of the failure to introduce a Hepatitis C screening system into the BTSB before October 1991 which is dealt with later in this report. It is probable that she was infected by a contribution of blood from a donor who had concealed a likely source of infection in his blood.

Dr. Walsh was clearly at fault in not arranging for the testing of Donor Y for hepatitis B and HIV prior to when she was tested in November of 1991. In particular it was wrong of him to have failed to have regard to the two reminders by letter which he received from Mrs. Cunningham. However that failure to have Donor Y tested in regard to hepatitis B and HIV did not have any harmful effect insofar as she never was positive for either of those two viruses.

Again Mrs. Cunningham was clearly in breach of the standards adopted by the BTSB for the safety of their product in proceeding to manufacture Anti-D from the plasma of Donor Y notwithstanding the fact that she had actually reminded Dr. Walsh of the necessity to have Donor Y tested for HIV and hepatitis B and this had not been done.

Though that is a clear sign of an indifferent approach to safety in the manufacture of the product, it was not the direct cause of any harm.

In July 1992 however, Mrs. Cunningham was in direct and clear breach of the safety standards, which had been accepted by the BTSB at that time, in proceeding to make anti-D out of Donor Y's plasma after that plasma had proved positive for hepatitis C on a test. Oral communication or any other communication of the view of somebody that the test might have been a false positive test would be no excuse for using the plasma having regard to the risks involved.

There does not appear, apart from that failure on the part of Mrs. Cunningham, to have been any safe system for communication between the testing laboratory for screening plasma and the laboratory presided over by Mrs. Cunningham which made the Anti-D. Such communication should have been in unambiguous written form and rigorously adhered to. Responsibility for this omission must be on Dr. Walsh then the Chief Medical Officer, and the then Chief Technical Officer Mr. Sean Hanratty (now deceased).

Why did these events infecting Anti-D with Hepatitis C occur?

It has been possible to ascertain with reasonable certainty the events which actually happened concerning the Anti-D taken from plasma of Patient X and the Anti-D taken from plasma of Donor Y.

It has also been possible with reasonable certainty to reach conclusions concerning the chain of causation between these events and the widespread infection of Anti-D with Hepatitis C virus.

The breaches of safety rules and standards involved in those events and the persons responsible and the measure of their responsibility, are matters which have already been set out in this Report. It remains to attempt to answer the obvious question as to why all these things occurred.

None of the persons from the BTSB involved in these events who are still available to give evidence offered any form of explanation as to why they occurred.

The nearest any evidence went to an explanation was an answer given by Dr Terry Walsh when asked why the Scientific Committee reacted as it did to the complaints of women, who after injection with Anti-D, had developed jaundice/Hepatitis. In answer to that question he replied "It was preferred obviously to believe that the infection at the time was infectious hepatitis rather than a product related problem".

Conclusions as to why these events happened must therefore be very largely indeed a matter of speculation with its attendant frailties.

The setting up of a national self-sufficient blood transfusion service in the 1960s and the 1970s in a country the size of Ireland, was a very great and beneficial scientific achievement.

The development of a self sufficient unit for the production of Anti-D made exclusively from the plasma of Irish voluntary donors in sufficient quantities to meet the entire needs of the country was a particularly noteworthy and splendid aspect of that development, of which Dr O'Riordan and his colleagues were justly and understandably proud.

For the supply of home produced Anti-D to fall short of requirements at any time so as to involve its replacement or supplementation by imported products, would have been a major admission of failure.

Originally the source of plasma for the making of Anti-D was designed to be from contributions from post menopausal women who could safely contribute every three months. This proved apparently insufficient and a group of voluntary male donors was enlisted who were Rhesus Negative and were immunised with Rhesus Positive red cells to produce the necessary anti-bodies. Donations could not be accepted from such donors at shorter intervals than every six months, a precaution associated both with their own health and with the safety of the product.

If plasma could be used from a patient undergoing therapeutic plasma exchange, which involved an exchange 3 times per week for approximately 25 weeks and yielded exchange plasma in quantities of 7-9 litres per week, a very substantial quantity of plasma would be obtained which would be very much

greater indeed than could ever have been obtained from a single male volunteer.

Not even the proven advantage in the strength of the plasma obtained from male volunteers, would offset the significant advantages of such a large and regular source of supply.

Anxieties as to the maintenance of the supply of plasma for manufacture of Anti-D would be greatly eased by the use of donations in general from therapeutic plasma exchange patients.

As already set out, the use of plasma from such a patient who was receiving exchange transfusions 3 times per week was in the teeth of the BTSB's own guidelines against using blood from a donor within 6 months of that donor's receipt of a blood transfusion, guidelines which followed standards generally accepted by the blood transfusion profession.

It seems likely that the reason this was done was that the medical and technical staff involved believed that the method of production of Anti-D involving an ethanol step, would probably inactivate any virus. None of those who gave evidence purported to have believed that the production of Anti-D even involving the ethanol step, guaranteed the destruction of any virus but it appears possible that in deciding to use plasma from a plasma exchange patient they were relying on the chance that it would.

Even this speculation does not explain why, upon learning of the diagnosis of jaundice/hepatitis in Patient X, they persisted in taking and using the plasma.

This can only be explained by a decision to ignore the fact, which they knew, that a form of non-A, non-B hepatitis virus existed capable of being transmitted by transfusion for the presence of which no proper test had yet been developed.

Such a possible theory is consistent with the decision in November 1976 to "hold" the batches already made until tests for Hepatitis B had been made on the samples taken from Patient X and once they proved negative to continue manufacturing and issuing the Anti-D.

The subsequent failure properly to react to the complaints made to the BTSB during 1977 of jaundice occurring in recipients of Anti-D batches which had been contributed to by Patient X, seems likely to have been partly caused by an absolute ignoring of the existence and/or importance of non-A, non-B Hepatitis and partly by a fear of a dramatic confession of failure which a recall of the product at that stage would have entailed.

With regard to the position upon the receipt of the letter of the 16th December 1991 from the Middlesex Hospital, the reaction of Dr Walsh, and to a lesser extent of Mrs Cunningham, to that letter can only be construed as a blank refusal even to contemplate the consequences of what had been done in 1977 and a vague hope that by ignoring the problem it would go away.

With regard to Donor Y, the major reason why these events occurred was:—

1. because a refusal to recognise the consequences of what had been done in 1976 and 1977 meant that plasma from therapeutic plasma exchange patients was still being used, and;
2. Mrs Cunningham ignored the warning arising from any form of positive Hepatitis C test, due apparently to her indifference.

Chapter 5

The Consequences of the infection of Anti-D

"The implications of the infection of Anti-D with Hepatitis C including the consequences for the blood supply and other blood products"

It is necessary to divide the issues arising under this part of Term of Reference number 1 into certain sub-categories that is to say:

(1) *The medical consequences and characteristics of Hepatitis C as a viral disease.*

(2) *The human consequences of being infected with the disease of Hepatitis C.*

Medical consequences and characteristics of the disease of Hepatitis C

Evidence was given before the Tribunal of the medical consequences and characteristics of Hepatitis C by Dr John Hegarty, who is a Consultant Hepatologist and Medical Director of the Liver Unit in St Vincent's Hospital. Dr Hegarty in the course of his practice has treated almost 200 patients suffering from the effects of Hepatitis C as a result of the receipt of Anti-D and in addition has had a substantial number of other patients who have been infected with Hepatitis C as a result of contaminated blood transfusions.

The evidence of Dr Hegarty, in respect of which there was no conflict, may thus be summarised.

Hepatitis C is a viral infection usually transmitted from one person to another by blood to blood contact known medically as parenteral contact. It is possible, though very rare, for it to be transmitted from person to person by sexual intercourse, and it is also possible that a child born of a mother infected with Hepatitis C may be infected itself with the virus, though this is also very rare indeed.

There is no real possibility of Hepatitis C being transmitted from one person to another by any form of social contact including the sharing of towels or food containers or other ordinary family social contacts. However precautions to eliminate such risks are advocated.

Hepatitis C is known as a sub-clinical disease, that is to say that a person being infected with it and therefore at the acute stage of the disease, may well

produce no symptoms which could be related to it, and may suffer no difference in their condition other than a mild flu like condition for a relatively short time.

30-40% of persons who are exposed to an infection of Hepatitis C will overcome that infection by producing anti-bodies in their own system which will clear their system of the virus. In the remaining 60-70% of persons who have been infected with Hepatitis C, the infection will persist and become chronic but the effects of such a chronic infection vary enormously from individual to individual. At one end of the scale the liver may be mildly inflamed and the disease may progress no further. At the other end of the scale continuous inflammation of the liver may result in the formation of scars within the liver which themselves may progress to cirrhosis of the liver and ultimately liver failure. Quite apart from the potential effect of infection by Hepatitis C on the liver, a number of symptoms may arise quite separately from damage to the liver and these principally are as follows:—

(a) Generalised aches and pains mainly to the hands, shoulders, hips and knees.

(b) Fatigue which can be profound and which can interfere with occupation and social life.

(c) Skin problems, blisters and rashes.

(d) A feeling of tired and gritty eyes.

(e) Over or under activity of the thyroid gland which may lead to fatigue and weight loss on the one hand or to weight gain and depression on the other. This abnormal activity of the thyroid gland, when it is a consequence of Hepatitis C, is capable of control by medication.

Of the persons who have developed chronic Hepatitis C infection since exposure to Anti-D from 1977 who have become patients of Dr Hegarty, 6% have developed cirrhosis of the liver and 25% have developed fibrosis. The majority of these persons have some degree of inflammation of the liver.
Hepatitis C is now one of the most common viral infections affecting the liver and the amount of research on medicines and treatment concerning it going on throughout the world is very extensive indeed. It is the view of Dr Hegarty that it is extremely probable that within the next five years or so medication for the control and elimination of the disease and its consequences will be developed much more effectively than presently exists.

On the present availability of medication for control or eradication, the general prognosis which Dr Hegarty would give is firstly, that patients who at present display fibrosis of the liver will probably ultimately develop cirrhosis. Persons who have developed neither cirrhosis nor fibrosis (and of the patients with which Dr Hegarty is concerned that would appear to be 69%) are not at risk from developing advanced liver disease in the next 5-10 years.

The effects of cirrhosis can be bleeding from varicose veins in the gullet, the accumulation of fluid within the abdomen and lower limbs and in some

instances intermittent confusion caused by the circulation of toxins in the brain which would be normally cleared by a properly functioning liver. A minority of patients who suffer from cirrhosis arising from any cause and therefore including those who suffer from cirrhosis arising from Hepatitis C can go on to develop liver cancer.

The present treatment for liver damage caused by Hepatitis C infection is by anti-viral agents such as Interferon or Ribaviran. In general 30-40% of persons thus treated over a 6-12 month period will have a sustained response to this treatment whereby the virus is permanently eliminated. In the case however, of persons infected with Geno-type 1B Hepatitis C (and that is the Geno-type of Hepatitis with which the Anti-D products were infected as a result of plasma taken from Patient X) that response rate drops to 10-15%. The anti-viral treatment does have side effects such as severe flu like symptoms, aches, pains and nausea, and 30% of persons who are commenced on those treatments have either to alter to taking a reduced dose or to abandon the treatment altogether because of the side effects.

This treatment is more effective if given to persons who for a shorter time have been suffering from liver damage consequent upon infection from Hepatitis C. Thus the earlier a person infected with Hepatitis C is diagnosed as being so infected and diagnosed as having some damage to the liver as a result of that infection, the more likely treatment is going to be to have good consequences.

In the event of liver failure arising from the damage to the liver caused by the disease of Hepatitis, a liver transplant operation can be carried out. Apart from the ordinary risk of such an operation, some Hepatitis C virus infection will occur in the transplanted liver and the long term survival of patients who have transplantation as a result of the Hepatitis virus is less than a person with a liver transplant arising from some other cause. It is worth noting that Hepatitis C victims are not always suitable transplantees. This fact can render the disease a terminal one.

The human consequences of infection by Hepatitis C

Ms Jane O'Brien who was a founder member of Positive Action and is now the Chairperson of that group: Ms Paula Kealy who is a member of Positive Action; Mr Gerard Hogan, himself a victim of infection by Hepatitis C, having received a blood transfusion in 1979 and now secretary of Transfusion Positive; an anonymous witness who was a person who had kidney failures and who had undergone a kidney transplant and had become infected with Hepatitis C; Ms Rosemary Daly who is administrator with the Irish Haemophilia Society; and Ms Brid McCole, daughter of the late Brigid McCole, all gave evidence to assist the Tribunal in reaching conclusions concerning in particular the human consequences of infection by Hepatitis C. A brief summary of the effect of that evidence is as follows:—

Before diagnosis

Persons affected by Hepatitis C which has not yet been diagnosed have very frequently suffered from a profound and inexplicable fatigue. This was often accompanied by deep depression. Such depression and fatigue had the effect of significantly limiting if not entirely excluding a social life outside the family home. This had, obviously, serious effects on the personal relationships within the home and in particular spouses found it difficult to relate to a partner who constantly complained of tiredness and lassitude but who was not being diagnosed or recognised by the medical profession as suffering from any particular illness. Some of those who underwent these problems were conscious of even family treating them as if they had become hypochondriacs. Many expressed a feeling of deep personal failure and a lack of self esteem due to what appeared to be an unexplained incapacity to look after themselves and their family.

After diagnosis

The initial reaction of very many people who were infected with Hepatitis C to the diagnosis of that disease was one of relief. What had been inexplicable was now readily explained. After the initial relief however, the fatigue and limitation of activity and capacity and social life remained. In other instances there has been a feeling of shock and fright upon discovery of the existence of the disease of Hepatitis C and it has led in some instances almost to a refusal on the part of the person diagnosed to admit the diagnosis even to themselves.

Other major problems include the following:—

(a) *Personal relationships*

Personal relationships became difficult and young persons had a particular difficulty in this regard. If at the outset of a relationship they informed the other party of their infection, the relationship usually ended. If on the other hand they allowed the relationship to develop without informing the other party, then when they eventually did so inform them, they were usually treated as being guilty of a breach of trust. In established relationships no guarantee could be given to the parties that infection could not be passed from one to the other through sexual relations.

(b) *Work*

Infected persons applying for jobs are significantly disadvantaged if there is a medical examination prior to engagement. Employers are unlikely to engage somebody who they know will be likely to suffer from fatigue and depression. Prospects of promotion are also greatly limited. Firstly the person themselves have not the energy or ability to take on further or more responsible work. Secondly an employer is not likely to promote somebody whose work output is likely to reduce.

Persons working in the health care and food industries feel that they are likely to be dismissed in the event of their condition being discovered and persons with the infection feel that employment in those industries is not an option for them.

Some instances were quoted of persons who, having applied for employment after they had been diagnosed as being infected with Hepatitis C, were interviewed and told that they would be further considered after a medical examination, refused to go for the medical examination, either for fear of being refused the job for that reason or sometimes for fear that other people including their own family would discover what they did not already know, namely that they were suffering from the disease.

(c) *Financial*

Persons infected with Hepatitis C find it impossible to get life assurance. They also have great difficulty in obtaining mortgages or long term loans. In some instances married women who were anxious to become joint owner of a family home on a mortgage, and who were able to contribute to it with their earnings as well as those of their husband, were refused and the house had to be taken out in the name of the husband alone and the mortgage based on his earnings only. Many infected persons when they have to take periods off work are not paid during those periods.

(d) *The Diet*

Infected persons have to carefully watch their diet so has to reduce foods high in iron content therefore certain foods such as red meat, shellfish, green vegetables have to be severely limited or avoided.

(e) *Treatment*

The treatment for Hepatitis C which has caused severe liver disorder is by anti-viral injection as has already been set out. Infected persons are taught how to inject themselves. The injection is into the abdomen. Even when it has been learned, this process can be both painful and intensely upsetting and sometimes the injected area becomes over perforated and creates its own problems. Furthermore, distress can be caused in the family by the constant reminder of the person's condition by the storage of the injecting materials in a fridge or other suitable place. These disadvantages of treatment are of course in addition to the side effects of treatment already set out.

Different Groups of sufferers

Individual groups of sufferers have individual problems over and above those above set out which are common to them and they may be summarised as follows:—

(a) *Anti-D recipients*

The children of mothers who became infected by the administration of Anti-D bear a sense of guilt for their mothers infection. They believe that were it not for the fact that their mothers had become pregnant with them, that their mothers would not be suffering from the infection. In addition, the death of Mrs McCole had a particular effect on this group of women. In addition to the personal sadness which many of them felt as having known her as a member of Positive Action, her death had the effect of significantly reducing the consolation or re-assurance which medical practitioners had been able to give to these women concerning their own condition.

(b) *Sufferers from kidney failure*

Persons suffering from kidney failure require significant transfusions at any time when they are on dialysis. In addition they also require significant transfusions in the process of kidney transplant. It was through such infusions that the infection was passed to this group of people. Following kidney transplants, it is impossible to go on to the viral treatments now available to try and ameliorate the condition of Hepatitis C. Such treatment would have the effect of activating the immune system of the person so as to combat the Hepatitis C virus. After transplant however, it is important that the immune system be suppressed so that the body does not reject the transplanted organ. Accordingly kidney transplant patients have to allow the Hepatitis C virus to take its course without effective treatment.

(c) *Haemophiliacs*

The infection was passed to haemophiliacs through the blood products which they are required to use in the treatment of their disorder. In many instances, parents would have injected their children with the necessary blood product and therefore, in effect, would have injected their children with the disease. In these cases those parents feel a burden of guilt, though no doubt it is one which is in no way justified. In families in this community, the disorder is often carried by many male members of the same family. Accordingly many members of the same family can be infected with Hepatitis C. Haemophiliacs have also previously been infected through blood products with HIV virus. New treatment for that virus requires the suppression of the immune system. Haemophiliacs who have been doubly infected by HIV and Hepatitis C cannot avail of that new treatment or if they do, must sacrifice the possibility of obtaining a treatment for the Hepatitis C. It was stated in evidence that the knowledge of their infection by Hepatitis C has frequently come to Haemophiliacs at a time when they were just coming to terms with knowledge of their previous infection with HIV virus and achieving some optimism concerning that condition and thus came as a particularly bitter and ironic blow.

A further difficulty of the Haemophiliacs who have become infected with Hepatitis C, is that the monitoring of the progression of the disease is normally carried out by liver biopsy and whilst there are conflicting medical views with regards to the safety of this, it is in many instances not advised as it could lead to dangerous internal bleeding.

(d) *Transfusion recipients*

Transfusions are normally only required by persons who have significant injuries or illnesses. It is particularly distressing for these persons to have overcome those serious illnesses and/or injuries, only to find that in so doing they have been infected with Hepatitis C. Transfusion victims of Hepatitis C include men, women and children and for young people in particular, the bleakness of a future with progressive chronic Hepatitis C is especially distressing.

Public perception

There is a significant public misconception about the Hepatitis C virus which causes difficulty and embarrassment to the persons infected with it. Firstly, there is a misapprehension that Hepatitis C, known in medical terms as HCV, is associated in some way with what is commonly known as Aids and is known in medical terms as HIV. Secondly, there is a misapprehension that the infection is easily transmissible by normal social contact. Thirdly, there is a belief apparently that it is in some way connected with drug abuse. Fourthly, when it has proceeded to the level of serious liver damage including cirrhosis, some of those infected with it have been apprehensive that they will be considered as possibly being guilty of abuse of alcohol if they are talked about as having cirrhosis of the liver. The result of these misapprehensions tend to make persons with Hepatitis C very secretive about their illness. In some cases the sufferers have not yet informed members of their close family circle. This deprives them of the natural support and sympathy which they should have.

Children

Persons with the Hepatitis C infection have found it difficult to decide whether or not their children should be screened for the Hepatitis C virus. On one hand they incline towards having the children screened so that if they are infected they can be monitored and where appropriate treated at the earliest opportunity. On the other hand they do not want to impose on their children all the difficulties which they have experienced and which have been dealt with above. Many find it impossible to advise whether it is better to know or not to know that one is affected by this virus. Common to all the groups and individuals whose evidence came before the Tribunal of the effect on them of having been infected with Hepatitis C, was a deep seated anger

and resentment that it should have apparently been inflicted upon them by the Blood Transfusion Service.

Numbers of persons affected by the infection of Anti-D with Hepatitis C and the consequential infection of blood and other blood products

It may never be possible to arrive with any great precision at the calculation of the number of persons who have been affected by developing Hepatitis C virus, resulting from the infection of Anti-D with that virus.

It is certain that they include not only persons who received contaminated injections of Anti-D but, since it is clear that a very substantial number of persons who received injections of Anti-D subsequently became donors of blood themselves, the persons eventually infected include persons who were transfused or injected with blood or blood products contaminated with Hepatitis C as a follow on from the original infection of the Anti-D product.

The problem of arriving at precise figures is aggravated by the fact already noted in this Report that Hepatitis C is a disease which may be, for a sustained period, silent in the sense of being a sub-clinical disease showing few recognisable or identifiable symptoms in the first instance after it has been contracted.

One of the consequences of that fact has been that, up to the introduction of Hepatitis C screening for donors, not even a rigorous examination of the past history of a prospective donor and a truthful reply by such donor to the questions asked would necessarily reveal circumstances which should have been recognised as creating the possibility of infection by Hepatitis C. In some instances therefore, persons as a result of receiving a transfusion of blood or an injection of a blood product became infected with Hepatitis C entirely unconnected with the immediate or long-term consequences of the infection of Anti-D with Hepatitis C.

Subject to these considerations, there are two sources of evidence available to the Inquiry with regard to the number of persons who appear to have been infected. Neither would purport to be either precise or complete and it is necessary to set them out as clearly as possible for the purpose of trying to establish the general scope of the tragedy which arose from these events.

The up to date results of the BTSB Targeted Lookback as of February 1997

The medical consultants at present working in the BTSB namely Dr Joan Power, Dr Emer Lawlor and Dr Joan O'Riordan, at the request of the Tribunal, have supplied a number of figures arising from the targeted lookback, in reply to specific questions raised by the Tribunal. These figures and the explanations of them, some of which are quite technical, are contained in Appendix G of this Report.

For convenience, an abbreviated summary of them is set out in this chapter.

(a) *How many persons were infected with HCV as a result of receiving the 1977 infected Anti-D.*

A total of 757 persons showed evidence of infection with Hepatitis C past or current, on laboratory screening, of which it is possible approximately 18, may constitute a false testing result.

Of these 757 people, 390 have persisting circulating virus.

In addition 74 recipients of 1977 Anti-D have been surveyed, who had an episode of jaundice after receiving the dose but do not show any reaction to Hepatitis C on testing.

Of the 390 recipients with detectable circulating HCV virus, 294 showed the same type, namely type 1B, as that transmitted by the contamination arising from the use of the plasma of Patient X.

(b) *How many persons were infected with HCV from receiving the 1991 infected Anti-D.*

97 persons in this category show evidence of Hepatitis C infection with a possible approximate 6 arising from false testing.

Of these, 44 have detectable virus. Of these 44, 26 have had viral typing carried out showing type 3, the HCV type transmitted by the 1991 Anti-D as a result of the use of the plasma from Donor Y.

Almost 30% of those who received BTSB Anti-D in the later years have not yet presented for screening.

(c) *How many persons who were infected by the 1977 and 1991 Anti-D became blood donors.*

103 Anti-D recipient donors have been identified of which 62 show continuing viral presence.

(d) *How many blood donations did these persons give.*

504 potentially infectious donations were given by donors exposed to Hepatitis C by BTSB Anti-D. 606 potentially infectious labile components prepared from these donations were issued. Of this 606, an estimate can be made that 359 would have issued from donations given by the 62 donors of the 103 who show continuing viral presence.

(e) *How many persons were infected as a result of receiving blood or blood products donated by such persons*

Of the estimated 359 labile components from positive donors, 209 have been traced of which 189 were used. Of these 189, 104 recipients have been identified as having died and 85 are living. Of those that died, the cause of death so far ascertained in the vast majority of cases, does not appear to be related with infection with Hepatitis C. Of the 85 recipients of these components who survive, 76 attended for screening, 61 of whom have evidence of exposure to Hepatitis C and of those 61, 30 show evidence of continuing viral presence.

(f) *How many Anti-D recipients have been screened for Hepatitis C.*
The total is 62,667 to date under the Anti-D recipient/HCV programme.

(g) *How many recipients of blood or blood components or products from infected Anti-D donors have been screened.*
102 recipients of labile blood components prepared from donations where the donor was positive, have been screened. Recipients from plasma-derived products have been screened for Hepatitis C by their attending clinicians, and some in the Optional Transfusion Recipients Screening Programme, but the source of the Hepatitis C has not yet been ascertained.

(h) *How may persons have availed of the optional screening programme.*
12,176 persons have so availed.

(i) *How many persons tested positive under this programme*
80 persons screened positive in relation to current or past infection with Hepatitis C on this programme of which approximately, 14 may be a false testing.

(j) *How many persons who have thus proved positive can be linked to the receipt of the infected Anti-D either directly or indirectly*
849 persons have been identified as proving positive and linked directly or indirectly to infected Anti-D. 467 of those show evidence of continuing viral presence.

(k) *How many persons who have screened positive or HCV positive without any link direct or indirect to the infected Anti-D and subsequent donations of blood by those Anti-D recipients*
300 persons come within this category.

Other evidence of approximate number of persons affected.

Other more general evidence was given of the numbers which appear to have been infected which is of assistance in putting into context the detailed figures already set out.

In a submission made by Positive Action to the Oireachtas Womens Rights Committee dated 12th April 1995, a copy of which was made available by Positive Action to the Tribunal, the number of women believed to have been affected as a result of the infection of Anti-D with Hepatitis C was 1,069. This figure was adopted and mentioned again in the terms of a figure of more than 1,000 by Counsel on behalf of Positive Action opening their submissions to the Tribunal.

Ms Rosemary Daly, Administrator with the Irish Haemophilia Society gave evidence that out of its present membership of 500, 210 have become infected with Hepatitis C.

Transfusion Positive which is a Group formed of persons who have been infected with Hepatitis C as the result of blood transfusions or the injection of blood products other than what might be described as the specialised groups already referred to, in November 1996 represented 250 people who had become infected by Hepatitis C.

Representatives of the Irish Kidney Association informed Counsel for the Tribunal in consultation that what was described as a conservative calculation of 50 of their members suffering from kidney disease had become infected with Hepatitis C.

Chapter 6

Steps which might have been taken before 1994 to diminish the effect of the infection

The implications for the blood and blood supply of steps which might have been taken between 1977 and 1994

Screening for Hepatitis C

Clearly the consequences and implications of the infection of the blood and blood products of the BTSB by Hepatitis C was affected, with regard to the extent of the damage caused, by the date on which the BTSB introduced screening for the Hepatitis C virus.

The screening for the Hepatitis C virus was in fact introduced by the BTSB at the commencement of October 1991. An issue arose during the course of the Tribunal's Inquiry as to whether an effective method of screening for Hepatitis C could and should have been introduced prior to that date. If it were, quite clearly, it would have had the effect which the introduction of the screening in 1991 did have, of curtailing the increasing spread of the Hepatitis C into the blood and blood products of the BTSB.

By the year 1987 there was a general appreciation in the medical and scientific circles concerned, of the prevalence of what was then known as Hepatitis non-A, non-B as a post-transfusion risk of blood transfusion. The only test then apparently known which might pick up in the blood of a donor the existence of this Hepatitis non-A, non-B virus, was a non specific test known as the ALT Test. In short, this was a test for the increase of a liver enzyme which could be caused by Hepatitis but could also be caused by other factors such as alcohol intake, exercise and obesity. Where that test was allied to tests for Hepatitis B and Hepatitis A, it could point towards a condition of Hepatitis non-A, non-B. By 1987, surveys conducted in the USA where there was a relatively high incidence of Hepatitis C in the general population to start with, indicated that ALT testing of donors of blood effected something in the region of a 40% reduction of the incident of Hepatitis C. Testing by ALT however, undoubtedly entailed a substantial proportion of false positive results indicating to a person informed of them that they had the disease of HCV when they hadn't and false negative results which might reassure a person that they had not the disease when they had, and which also of course permitted the entry of Hepatitis C virus into the blood supply by the person who was a donor.

By Resolution made on the 15th July 1987, the BTSB decided to seek the approval of the Department of Health for the introduction of ALT testing. This was done on the recommendation of the CEO, Mr Keyes. On the 16th July 1987, Mr Keyes informed the Secretary of the Department of Health of the Resolution by the Board of the BTSB and enclosed his report to the Board setting out the advantages of ALT testing and a summary of the countries in which it had been introduced and those in which it had not been introduced. In that letter he sought the permission of the Department of Health for the introduction of the testing. This was not forthcoming and no letter was produced before the Tribunal indicating the reasons of the Department in not agreeing at that time.

On the 19th April 1988, the CEO brought this matter again before the Board of the BTSB, mentioning in connection with the desirability of introducing a test for non-A, non-B Hepatitis, an EEC Directive on Product Liability which it was suggested would make the BTSB liable in the event of a failure to introduce screening for Hepatitis C It appears that this information was also conveyed to the Department of Health though no letter conveying it has been produced before the Tribunal.

On the 26th September 1989, the CEO of the BTSB, Mr Keyes wrote to the Secretary of the Department of Health, a letter which commenced as follows:—

> *"You will recall that I wrote to you on a number of occasions concerning non-A, non-B Hepatitis and the possible introduction of ALT testing. There has been a development in this area in so far that a more definitive marker for non-A, non-B has now been developed".*

The letter then enclosed a copy of a report dated 5th September 1989 from the Chief Medical Consultant to the Board, namely Dr Walsh, together with certain further details concerning the new test prepared by Mr John Keating, a Senior Technical Officer. On behalf of the Board, Mr Keyes sought the approval of the Minister for the introduction of this new Hepatitis C test. This test which subsequently became known as the ELISA First Generation Test was being developed in the USA by a commercial firm known as Ortho Diagnostics and it was claimed to be capable of detecting 80% of carriers of HCV virus. The information was that approval of it as a test from the Food and Drug Administration of the USA was expected soon.

Experimental testing by the BTSB on the ALT testing of a relatively small sample of 50-70 blood donors each day which had been carried out since January 1988, had created a rejection rate of approximately 3% where it was suggested that this new test would result in a rejection rate of only 0.5%.

As a result of that letter, a meeting was held on 12th December 1989 between Mr D. Mulligan of the Department of Health and Dr Rosemary Boothman of the Department of Health, with representatives of the BTSB, to deal inter alia with the question of Hepatitis C screening. A memorandum of that meeting made by Dr Boothman shortly after it, indicates that the view

of the Department of Health was that the question of Hepatitis C screening would require further detailed review.

On the 7th February 1990, the CEO of the BTSB wrote to the Secretary of the Department of Health stating that the Board on the 17th January noted with extreme concern that the approval of the Minister to the implementation of Hepatitis C testing as recommended by the Board, had not been received. The letter mentioned concerns with regard to the public liability insurance of the Board which was not satisfactory in the absence of testing, but did point out that the Board's principal concern related to patients. An immediate meeting with the Minister via a deputation was requested.

In February 1990, Dr Alfie Walsh then Chief Medical Officer (CMO) of the Department of Health attended a symposium on Hepatitis C in London. In a subsequent memorandum written shortly after the meeting, he reviewed the views expressed at the meeting and in particular the reservations expressed by some of the contributors with regard to any nationally introduced test on the basis of the extent of false positive reactions which it might yield and the concern of the blood donors, who if they tested positive, could not be told by the Blood Transfusion Service involved, as to what that really meant. Concern was also expressed and is reflected in the memorandum of Dr Walsh about the result of false negative results for the testing. The view was then expressed by Dr Walsh that the BTSB should not introduce this test ahead of the UK and the US, neither of which countries had so far introduced it. As a result of that meeting and memorandum, Mr O'Dwyer, the Assistant Secretary of the Department of Health, Dr Alfie Walsh of the Department of Health and Dr O'Dwyer of the Department of Health met Mr Keyes the CEO and Dr T. Walsh the Chief Medical Consultant of the BTSB to discuss the position with regard to HCV testing. It is clear that at that meeting the BTSB was still pressing for the introduction of that testing but, at the request of the Department, decided to defer a decision until a further meeting had taken place. Dr Alfie Walsh undertook at that meeting to make contact with the Department of Health in the United Kingdom to establish their position.

Dr Walsh did so contact Sir Donald Acheson, Chief Medical Officer of the Department of Health and Social Security in the United Kingdom, and by a lengthy letter on 2nd March 1990, was advised that on the advice of a committee on viralogical safety of blood, that the Department of Health in the UK had decided not yet to introduce the test which had been newly developed on the basis that there was insufficient scientific information about it to advise its routine introduction, and on the basis of anxieties that still existed with regard to the consequences of false negative and false positive results.

In May 1990, Dr Terry Walsh attended a meeting of the committee of experts on Blood Transfusion and Immuno Haematology of the Council of Europe in Madrid and as a result reported to Dr Alfie Walsh, CMO of the Department of Health that the consensus of opinion at that meeting of experts was that the testing then available for HCV would significantly increase the safety of the blood supply and that the great majority of countries would be testing by the end of 1990.

After receipt of that letter, Dr Alfie Walsh made further contact with Dr Rayman of the UK Department of Health and as a result of advice received from him, expressed the view that it was not yet appropriate to introduce testing and communicated that view to Dr Terry Walsh.

In July Dr Alfie Walsh was informed by the UK Authorities that they would probably shortly recommend that screening of blood would commence on the basis that reliable, confirmatory tests were becoming available. He then recommended to the Department by a minute addressed to Mr Devitt, the Assistant Secretary, on the 24th July 1990 that screening for Hepatitis C should be commenced in Ireland at the same time that it was commenced in the United Kingdom. Dr Alfie Walsh retired as Chief Medical Officer on 2nd August 1990 and was succeeded by Dr Niall Tierney who was appointed to that position in November 1990.

On the 19th November 1990, Dr Terry Walsh of the BTSB wrote to Dr Tierney stating that he had just returned from a joint ISBT/AABB meeting in Los Angeles and that the information presented at various symposia and papers there, confirmed the value of the Hepatitis C testing in preventing post-transfusion Hepatitis. The letter then concluded with the following paragraph:—

> *"I would therefore again strongly recommend that the Department sanction the introduction of this test and make available to the Board the necessary resources required to implement testing for Hepatitis C to further safeguard the health of blood transfusion recipients".*

To that letter Dr Tierney replied on the 23rd November noting what was said about the testing and saying that it would be helpful to have some indication of what resources, both capital and revenue might be required. In fact certain estimates had previously been made by the BTSB at the request of the Department of Health in regard to what might be involved for some form of Hepatitis C testing.

On 1st February 1991, Dr Terry Walsh wrote again to Dr Tierney, on this occasion confirming that he had spoken to Dr Gunson, the National Director of the UK Transfusion Service and that he had advised him that the Department of Health in the UK had now formally approved the introduction of HCV screening in the United Kingdom. It was stated in the letter that it was hoped that screening would commence in April, but because of the Gulf War, it was expected that the actual date when screening would be formally required would be in June. He again stressed the necessity for introducing HCV screening in Ireland.

Dr Tierney received a communication from the Department of Health in the United Kingdom indicating that approval had now been given to the introduction in the UK of Hepatitis C testing by the Blood Transfusion Service and it would probably commence on 1st July. This letter was received at the end of March 1991. On the 29th May 1991, Dr Tierney noted at the end of a memorandum dealing with this topic, *"it would seem that we have little alternative other than to introduce this procedure"*.

It does not appear that any decision was made as a result of that advice coming from the CMO of the Department of Health and certainly none was communicated to the BTSB though further discussions took place between officials of the Department of Health and the BTSB with regard to the possibility of screening. Eventually by letter dated 3rd September 1991, written by Mr Devitt, Assistant Secretary of the Department of Health, the BTSB was directed by the Minister to commence Hepatitis C testing on the 1st October 1991. That direction was complied with and the testing commenced at the commencement of October.

Conclusions from the above facts

It appears clear from the detailed facts, a recital of which in summary form are above set out, that the BTSB from late in 1987 were pressing and pressing quite strongly and urgently for the introduction of Hepatitis C screening. It is equally clear from the entire of the correspondence and dealings between the BTSB and the Department of Health over the period from late 1987 to September 1991, that there was no conceivable question of their being entitled to introduce such screening on a national level as distinct from the research or exploratory pilot scheme which they did operate, otherwise than with the consent of the Minister for Health. The BTSB cannot, it would appear, be faulted for want of pressing forward not only their demand or request for permission to introduce Hepatitis C screening, but also the reasons behind that and the material which would have justified it.

Having regard to the considerations which the evidence supported concerning the difficulties of introducing the ALT Test which was non specific and which permitted of substantial false positives and false negatives, and the disadvantages from every point of view including the peace of mind and concern for donors who might be tested either falsely positive or falsely negative, as well as the effect of the supply of blood for the entire blood service, it seems clear that the Department of Health was justified in delaying consent to the introduction of a National Hepatitis C screening so long as the only form of test available was the ALT Test.

As soon however, as what has now become known as the ELISA First Generation Test became available and recognised as reliable and as soon as there followed onto it a second generation ELISA Test by way of confirmatory testing, it would appear that the sound and solid reasons for refusing to permit the introduction of Hepatitis C screening had disappeared.

There does not appear on the evidence before the Tribunal to have been any logical reason, concerned with the position of donors of blood and/or with the position of recipients of blood and blood products and the safety of those products, why the introduction of Hepatitis C screening by the BTSB in Ireland should be tied by date to the introduction of similar screening in the United Kingdom.

There were good reasons why the Department of Health in reaching a decision on this matter should have regard to any technical and expert advice

given not only by authorities in the United Kingdom but by authorities in blood transfusion in any other countries who were concerned with the same issue. In these circumstances, it appears that it would have been quite permissible and safe for Hepatitis C screening to have been introduced in Ireland in the beginning of the year 1991 when the reliability and safety of the test concerned appears to have been universally acknowledged.

The Department of Health would appear to bear responsibility for the delay between that time and the commencement of October 1991 in the introduction of that screening as it was due entirely to their refusal to authorise its introduction at the commencement of 1991 that caused it to be delayed.

Evidence before the Tribunal is that if an earlier permission had been given, it was possible for the BTSB to have introduced Hepatitis C screening on a national scale within one full month of obtaining that permission. When they received permission in September 1991, they in fact commenced screening in October 1991.

Unfortunately, evidence adduced before the Tribunal indicates the probability that a number of persons may have been infected with Hepatitis C from the transfusion of blood or blood products between February and October 1991 who might have avoided infection had screening been introduced at the earlier date.

Responsibility

The decision of the Department of Health to direct or permit the introduction by the BTSB of Hepatitis C screening was necessarily an administrative decision made in the name of the Minister. On the evidence before the Tribunal, it would appear that this decision would have been reached by the Secretary of the Department, Mr Hurley in particular, on the advice of Mr Devitt, who was then Assistant Secretary with special responsibility for secondary care including the BTSB and Mr O'Dwyer who was then Assistant Secretary with special responsibility for finance. The communication of it to the BTSB on the 3rd September was made by Mr Devitt. It is clear however that it was a decision which to a considerable extent relied upon the advice of the Chief Medical Officer of the Department of Health who, at the relevant times up to August of 1990 was Dr Alfie Walsh, and from November of 1990 was Dr Niall Tierney. Certainly the decision of the CMO that it was appropriate from a medical point of view to introduce the screening was a necessary pre-condition to a decision to direct or permit its introduction.

As indicated above it appears that the policy which had been laid down by Dr. Alfie Walsh in July of 1990 that hepatitis C screening should be introduced as soon as it was introduced in the UK must be construed from a medical point of view as being a view that reliance would be placed on the medical approval of it by the UK blood transfusion service. Once that approval had been given as was notified to Dr. Tierney by letter from Dr. Terry Walsh of the 1st February 1991, there no longer remained any medical reason why the Chief Medical Officer of the Department of Health in Ireland should not have

signified his consent to the introduction of hepatitis C screening by the BTSB.

Dr. Tierney must therefore bear some responsibility for so much of the delay in the introduction of hepatitis C screening as may have been contributed to by his failure to signify consent to that course between February 1991 and the 29th of May 1991.

With regard to the administrative decision evidence was given by Mr. O'Dwyer, now Secretary of the Department of Health and in 1991 an Assistant Secretary with responsibility for finance, that he had included in the budgetary provisions in the Department of Health for the year 1991 the probability that Hepatitis C screening would be authorised for the BTSB during that year and the necessity in arriving at the amount of the usual contingency fund. He therefore insisted that at no stage in the year 1991 was finance a delaying or impeding factor with regard to the introduction of Hepatitis C screening,

It does not appear that at any time the fact of such contingency financing having been included in the budget was made known to the BTSB, and in fact evidence from Mr. Ahern whose task it was in 1991 to open negotiations with the BTSB with regard to the possible cost of screening indicates that he was not aware of it either, and that in fact he was drafting memoranda based on the desirability of avoiding the payment of any subvention for the purpose of setting up the screening. When the screening was set up in October 1991, largely by reason of the relatively short time it would be in operation before the end of the calendar year, it was not necessary to make any grant in 1991, though a grant of an additional £100,000 was made in 1992 to cover the special expenditure in the previous year.

The BTSB was not informed of the decision of Dr. Niall Tierney at any time between the 29th of May 1991 and the 3rd of September 1991. It seems clear therefore that the administrative side of the Department of Health must bear the major responsibility for the delay which appears to have been unnecessary and unwise having regard to the safety advantages of introducing hepatitis C screening between the earlier part of 1991 and October 1991.

Steps towards the introduction of Solvent Detergent as a method of viral Inactivation for Anti-D

Towards the end of 1989 the BTSB had entered into an arrangement with a firm known as Octapharma in Germany for the manufacture by that firm of the blood products known as factor VIII and factor IX which are used in the treatment of haemophilia. That arrangement included at that time the use of a viral inactivation system of a solvent detergent to increase the capacity of the production of the blood product to eliminate as far as possible viral infection, including all forms of hepatitis.

As a result of that experience the BTSB sought information with regard to the possibility of introducing into their production of anti-D a solvent detergent to achieve viral inactivation. On the 28th of November 1989 Mrs. Cunningham wrote to the New York Blood Centre making inquiries as to whether they had developed a solvent detergent capable of being applied to the production of anti-D. On the 14th of December she received a reply from the New York Blood Centre indicating that they were willing to license all qualified fractionators to use their solvent detergent system and that following the execution of what they described as their standard licence agreement, one or more representatives of the BTSB would be welcome to come to the workshop at the New York Blood Centre and in effect be instructed on how, pursuant to the licence, to introduce the system in Ireland. That letter Mrs. Cunningham replied to on the 16th of January 1990 asking for further details regarding the licence agreement with a view to proceeding as had been suggested. There does not appear to have been any reply to that letter and certainly none was produced before the Tribunal.

The next documentary reference to this question was a lengthy memorandum prepared by Dr. T.J. Walsh and dated the 11th of May 1992 presented to the Chairman and members of the BTSB and the Chief Executive Officer, Mr. Keyes. That memorandum dealt with the problem of viral inactivation in the production of anti-D and in effect recommended the introduction of a solvent detergent inactivation. It mentions that the New York Blood Centre have developed this technology and may be prepared to license its use and states "the principal biochemist (Mrs. Cunningham) has been instructed to contact the NYBC to further explore this possibility and the outcome will be reviewed as soon as possible". That memorandum clearly carries the meaning that the contact with the NYBC and the instruction to Mrs. Cunningham to further explore that possibility were relatively recent events, whereas the events which occurred and are witnessed by the correspondence in 1989 and the beginning of 1990 would seem to be the events referred to.

Mr. Keyes gave evidence and stated that he had gone, whilst on holiday in the United States, to visit the New York Blood Centre in 1991; that he had ascertained from them that their method of solvent detergent was being used in Canada for the purpose of providing viral inactivation in the manufacture of Anti-D, that manufacture being in a form similar to that used by the BTSB and, of particular importance, creating a product which was intravenously injected. He stated that on his return from that visit he came to the conclusion that it would probably be better to have plasma fractionated by that firm in Canada than to try and introduce the solvent detergent method into the fractionation being carried out in Ireland. Mr. Keyes who has no note or memorandum dealing with that visit, whenever it occurred, was also in the United States, he agrees, in 1992 and though he seemed very positive that his visit to the New York Blood Centre was in 1991 it is possible that he was mistaken as to the year. A visit by him there in 1991 and the realisation that there was an option of sending the plasma away to have it fractionated in Canada was quite inconsistent with the report made by Dr. Walsh to the

Board on the 11th of May 1992. It would also appear to be inconsistent with a letter which Mr. Keyes wrote to the Board on the 21st of July 1992. In that letter he refers to the Chief Medical Consultant's Report to the Board in May and refers also to the new solvent detergent system of viral inactivation being available from the New York Blood Bank but that the cost was substantial. He then proposed sending the Chief Biochemist and the Senior Technical Officer to Winnipeg to study the methods there and report back. In the letter he suggests that having obtained this information the Board will have to decide whether it wishes to continue its own operation or indeed to consider contract fractionation.

As a result of that letter the Board authorised the sending of Mrs. Cunningham and Mr. Keating to RH Laboratory Inc Winnipeg, Canada, where the solvent detergent was being applied to the production of intravenous anti-D under the trade name of WinRHO. The work then being carried out in Winnipeg was not beyond the stage of clinical trials and subsequent evidence established that this product with the solvent detergent process applied to it was licensed for the first time in Canada in 1993 and for the first time in the United States of America in 1994.

After the visit of Mrs. Cunningham and Mr. Keating to Canada and their report thereon, a decision was undoubtedly made towards the end of 1992 or at the very commencement of 1993, that in all probability the better method of introducing a solvent detergent inactivation process in Ireland, was to send plasma to Canada and have it fractionated on contract with solvent detergent inactivation. This view was largely based on what was considered to be significant shortcomings in the equipment and process in Ireland for the purpose of introducing this new system into them. In 1993 the BTSB had pending with the NDAB, who had been advising the Minister on it, an application made to the Department of Health for a product authorisation in respect of the manufacture of Anti-D, with the solvent detergent process applied to it, and were in that year in effect altering the application so as to try and convert it into an application for the import of the finished product from Canada, made of plasma exported to Canada by the BTSB for that purpose. That application was being studied and considerable detail with regard to the manufacturing process etc. was obtained and being considered by the NDAB at the end of 1993.

Conclusions from the above facts

There does not appear to be a full explanation of the long delay between January of 1990 and May of 1992 in pursuing this question of obtaining the services in one way or another of the New York Blood Centre for the purpose of introducing solvent detergent into the manufacture of anti-D to be used in Ireland. Dr. Walsh gave evidence that difficulties had arisen with regard to factor VIII and factor IX which were being manufactured by the Octapharma firm in Germany and that the question of the introduction of a solvent detergent into the production of anti-D required caution. That evidence appears

correct but hardly justifies the very long gap between January 1990 and May of 1992.

After the further consideration of this matter in July of 1992 and in particular after the visit of Mrs. Cunningham and Mr. Keating to Winnipeg in August of that year, the BTSB appears to have proceeded with reasonable speed in trying to firstly, reach a decision as to the precise way in which the solvent detergent would be introduced and secondly, to arrange for its introduction.

Evidence independent of the BTSB was given by Dr Bowman before the Tribunal, which indicates that the WinRHO product was first licensed after the completion of its clinical trials in Canada in 1993 and was first licensed by the FDA in the United States in April 1994.

Whilst it is possible that if this search for an appropriate method of introducing solvent detergent inactivation into the manufacture of anti-D had been energetically pursued in the years 1990 and 1991, a properly tested product might have been available sometime in 1993, that is by no means certain and it is improbable that it could have been available earlier. In these circumstances whilst both Mr. Keyes and Dr. Walsh must bear some responsibility for a delay in pursuing this particular matter it does not appear to have been the cause of significant harm.

Chapter 7

The response by the BTSB to the letter of the 16th December 1991

Term of reference number 4

The response of the BTSB to a letter of 16th December 1991 from the Middlesex Hospital, London in relation to human immunoglobulin Anti-D and the adequacy of such response including the consequences for the blood supply and blood products.

The letter of 16th December 1991 from the Middlesex Hospital referred to in this Term of Reference was the culmination of correspondence between the Middlesex Hospital and the BTSB which was shortly as follows:—

On the 15th August 1991 Ms Moya Briggs of Middlesex Hospital wrote to Mr Keating of the BTSB stating that in August 1977 they had received material from the BTSB to investigate the possible implication of Hepatitis B virus in cases of Hepatitis following inoculation with Anti-D. The letter then continues:—

> "*From his results Dr Dane concluded that HBV was not involved and the remains of the samples were frozen in our NANB files. We are now in a position to carry out a very sensitive PCR assay for the presence of Hepatitis C RNA devised by my colleague, Dr Jeremy Garson. I am writing to enquire if you would be interested in our looking for HCV in the frozen material. It might be nice to be able to close the book on that particular incident or at least to write another chapter. The samples I have are.....*"

The letter then sets out the names of the people from whom samples were taken and they consist of Patient X and three of the persons in respect of whom complaint had been made that after inoculation by Anti-D, they had developed Hepatitis, being the persons reported by July 1977. The other samples mentioned in the letter are samples of the 16 batches of Anti-D, all of which had been contributed to by the plasma taken from Patient X. The letter concluded with the following sentence:—

> "*We are very keen to see if we can detect HCV RNA in these and it might be worth a collaborative publication somewhere but that would be for you in Dublin, BTC to decide*"

That letter was replied to by Dr Walsh on 4th October 1991 in the following terms:—

> *"Further to your letter dated 15th August (received 11th September) to Mr John Keating, re. Anti-D immunoglobulin, I believe that it would be interesting to carry out the investigation that you propose. When this has been done, we would be interested in reviewing the findings with you".*

On the 16th December 1991 Dr Jeremy Garson, Senior Clinical Lecturer in Virology in the Middlesex School of Medicine, wrote to Dr Walsh stating that Ms Briggs had asked him to take on the further investigation of what he describes as "the intriguing Anti-D/Hepatitis story".

He then set out in technical terms the results of a series of tests by different methods for Hepatitis C which had been applied to the samples he had received in 1977 and which are described above in this part of the report. The results of those tests and the findings arising from them were in short as follows. The sample taken from Patient X and the samples taken from the three women who had received Anti-D contributed to by Patient X and themselves developed symptoms of Hepatitis, all showed positive for the virus Hepatitis C. The samples of the 16 batches showed reaction of a positive nature to the virus Hepatitis C in nine cases. In the remaining seven cases the reaction shown to the virus Hepatitis C was technically described as being "just below the cut off" which indicates grounds for suspicion of infectivity. Dr Garson then summarised those findings by saying that taken together, they strongly suggested that Hepatitis C virus contaminated Anti-D was responsible for the "outbreak". Dr Garson then asked that in order to clarify the situation further, Dr Walsh would answer the following questions and they are:—

(i) On what dates were the McG, B and R samples taken and precisely how long was this after they received the Anti-D? The dates of onset of Hepatitis would also be of interest.

(ii) The Patient X sample is dated 17th January 1977. How long before or after she gave blood for Anti-D was this? Why was Patient X selected as the likely "culprit" in retrospect what if any risk factors for HCV infection did she have? Are any other blood samples from Patient X available for us to test?

(iii) Can you confirm that all sixteen batches of Anti-D contain material donated by Patient X? Was there any evidence of Hepatitis in the recipients of batches 237, 240, 250 and 252 in which we have detected HCV — RNA.

(iv) What size were the donor pools for these Anti-D batches and how exactly was the Anti-D IVIgG preparation made? Were any virucudical steps included in the manufacturing process? How do we explain

the absence of similar Anti-D related Hepatitis outbreaks before and after the 1977 incident?

(v) Is there any chance of us obtaining later or current blood samples from the three recipients and/or their children and spouses? Is it known whether any of the recipients went on to develop chronic Hepatitis or other long term sequelae? Was a report of the 1977 incident ever prepared or published and if so may we have access to it?

With that letter, Dr Garson enclosed a copy of the test results which are summarised in the letter. To that letter, Dr Walsh wrote a reply dated 16th January 1992 in the following terms:—

> "*I have received your fax dated 16/12/91 and have commenced gathering the information you requested. Obviously with the time lapse involved, we will not be able to answer all the questions but when I have collated all the available information I will contact you again. It may indeed be simplest to meet to discuss this in London in the next month or so*".

There was no further letter written by Dr Walsh or anyone else in the BTSB to Dr Garson concerning the queries raised in the letter of 16th December 1991 and Dr Walsh did not visit Dr Garson to discuss the contents of that letter or any replies with him/

The evidence of Dr Walsh concerning this letter may thus be summarised.

He agrees that he received the letter and says that he did not recall upon receipt of it the events of 1977 but he merely had a vague recollection that there had been a problem in 1977. He stated that he was now totally unhappy with his own response to the 1991 fax and in fact, at one part of his evidence, said that he was devastated by his response to it. He stated that it did not make a big impression on him as being a serious and dangerous matter, that he had recently been able to introduce screening for Hepatitis C and he thought that this was an interesting scientific matter to be followed up. He agreed that he went to London shortly after receipt of this letter but that he did not go to see Dr Garson about it and explained that by saying that he gave the letter to Mrs Cunningham asking her to fill in the information requested in it and that she hadn't yet given it back to him by the time he went to London. He took no further action of any description concerning the letter.

Mrs Cunningham gave evidence that Dr Walsh did not show her the letter when it arrived but asked her to collect and give the information required in the letter to him and she says that she did that within 24 hours. She did not then see the letter but saw the results of the samples that had been tested. Some time later Mrs Cunningham says that she asked Dr Walsh how he got on with his discussions in London and he more or less cut her out, that he was curt and that she got an indication that he did not wish to discuss the matter anymore, that he was discussing it elsewhere. She stated that was her impression but not as a recollection of what Dr Walsh said.

Dr Emer Lawlor was a Consultant Haematologist and first joined the BTSB as a locum part-time consultant haematologist on the death of Dr Wilkinson in November 1988. Her duties were dealing with donor queries, dealing with Platelet Pheresis and very specifically, being involved in looking after the bone marrow register which was just being set up at the time she joined the BTSB. She was not of course in any way associated with the BTSB in 1976 and 1977, nor had she any knowledge in 1991 of what had occurred at that time. No evidence has been given that Dr Lawlor was aware of the letter of 16th December 1991 but she volunteered certain facts concerning it. She stated that in December 1991, she went in to see Dr Walsh and that he told her that they had got a fax from Middlesex about a problem with Anti-D in 1977 and it looked as if, while they had thought it was Hepatitis A, it was Hepatitis C. She then went on to say that when she heard that she realised that there was a problem as Hepatitis C is a silent disease and therefore it was likely that there were more than six women involved. Dr Walsh had mentioned to her that six women were involved. She did not ask any further questions and Dr Walsh said to her that he would pull out the file and would get the information that was requested in the fax and he would come back and "we would sit down and discuss it". Dr Walsh had also told her at that time that there was a donor to the pool who had either, he said, Hepatitis or jaundice. She said that Dr Walsh did not come back to her and that it slipped her mind. When asked did she ever discuss it with him again she replied, "No, I was very busy, one of my children was quite ill over Christmas and then after Christmas I was very busy with teaching and attending meetings and it just totally slipped my memory and he never came back to me. It is something that I deeply regret".

The other evidence relevant to this issue is that nothing was done by anybody concerning this fax other than what has been summarised in this chapter until it arose again in January and February 1994 when the whole question of the infection of Anti-D had arisen.

It is quite clear that the response of the BTSB to this letter of 16th December 1991 was non existent and totally and completely inadequate. It is equally clear that the consequences for the blood supply and blood products of this inadequacy was that a procedure for testing recipients of Anti-D derived from plasma manufactured in the years 1976 and 1977 could have been initiated two years before it was, and that upon the necessary result of such screening, namely information concerning the further donations by such recipients of blood to the blood transfusion service, that there could have been a large scale recall of products two years before that became possible and by these and other steps much infection of recipients of blood and blood products with Hepatitis C would have been avoided.

In addition, recipients of infected blood and blood products could have been diagnosed and treated two years earlier than they were.

The Responsibility

There is no evidence that any other person working in the BTSB was made aware of the contents of this faxed letter of 16th December 1991 or of the information it contained.

The major responsibility must rest on Dr Walsh who had the knowledge of what had occurred in 1977, had the scientific and medical knowledge to understand fully the implications of the information contained in the faxed letter, and had the clearest obligation to react to it in a major manner for the purpose of trying to secure as far as possible the safety of the product which was being manufactured and distributed and of course as importantly if not more importantly, to secure medical attention to those who may have been already infected by it. He has, in his own evidence, described himself as being devastated in now considering his lack of reaction to this letter, and his responsibility could without exaggeration be described as massive.

Having regard to the conclusions reached above in this report concerning the position of Mrs Cunningham in relation to the events of 1976 and 1977, it would appear that she must also bear some responsibility for not having gone further than she did in trying to ascertain whether any further action would be taken arising out of this letter. Her responsibility however, is significantly less than that which obviously belongs to Dr Walsh.

Dr Lawlor, who had no knowledge of the events of 1976 and 1977, and who had no direct concern with this letter or with any information that might be required in order to answer it, seems to bear a sense of guilt concerning her failure to revert to Dr Walsh about it. She has stated in her evidence that she should have taken the matter up again, because she did realise that it might be a problem larger than a problem concerning six women. The reasons why she did not do so, she gives, as a complete lapse of memory of a short and quick incident at a time when she was extremely busy both professionally and domestically and this seems understandable and acceptable as an explanation. In addition she could never have anticipated that Dr Walsh would have taken no action at all, on foot of the letter. It is understandable that she should carry a sense of regret that she did not follow up the matter with Dr Walsh but this ought not to be confused with a sense of guilt. It would be unreal and, therefore, unjust to impose upon Dr Lawlor, in respect of this incident, any responsibility.

Chapter 8

The response of the BTSB to the crisis in 1994.

Terms of Reference numbers 2 and 3

In Chapter Four of this Report, the circumstances under which the major infection of Anti-D with Hepatitis C arose from the use of the plasma from Patient X were dealt with. Of necessity in dealing with that, the Report has dealt with a series of facts and events from which a conclusion must be drawn that the BTSB should have become aware at that time that Anti-D was probably infected with Hepatitis which was neither A nor B.

In so far as the events of that period are concerned, its implications and consequences have already been dealt with and in so far as Term of Reference number 3 refers to the response by the BTSB to the "discovery" in 1977 of the infection of Anti-D with Hepatitis C, there was no response as there was no admission or acceptance of such a discovery.

The second time at which again the BTSB should have been aware of the likelihood that Anti-D had become infected with Hepatitis C was when use was made of the plasma donated by Donor Y. The absence of that awareness and therefore the absence of any response to it is also dealt with in Chapter Four.

The receipt by the BTSB of the letter from the Middlesex Hospital of 16th December 1991, was a further occasion when it can be said that they were made aware of the infection in 1977 of the Anti-D product with Hepatitis C, and another occasion on which there was absolutely no response to that awareness, with the consequences for the blood supply and blood products which are set out in Chapter Six of the Report.

In dealing with Terms of Reference numbers 2 and 3 therefore in this Chapter, it is necessary to deal first with the circumstances in which in 1994 the BTSB became admittedly and plainly aware of the infection of Anti-D with Hepatitis C, and with the action taken by it in response to that discovery and the adequacy or otherwise of such action. Considerations of the adequacy and appropriateness of the supervision exercised by the Department of Health over the BTSB in regard to their actions in response to the awareness in 1994 of the infection of Anti-D with Hepatitis C, which come within Term of Reference number 6, fall to be considered in Chapter 13.

The circumstances in which the BTSB in 1994 became aware of the infection of Anti-D by Hepatitis C

Dr Joan Power, a Consultant Haematologist took up office as Regional Director of the BTSB in 1989 for the Cork region, and from February 1991 was Regional Director for the province of Munster.

After the introduction of screening for Hepatitis C in October 1991, Dr Power took steps to set up a research survey of Donors who had tested positive in the Munster area for Hepatitis C, with a view to investigating for Viraemia in the donors and where established, recommending hepatology referral with a view to identifying the possible source of the Hepatitis C virus infection in the donors and identifying the viral types present in the donors.

In the course of this survey, Dr Power in January 1994, identified a possible link between a Munster female donor of blood who had tested positive in relation to Hepatitis C, and an Anti-D inoculation which she had received some sixteen years before.

Dr Power brought this information as part of an interim report on her survey, to the Medical Consultants' Meeting of the BTSB which was held on January 19th, 1994. After discussion at that meeting, Dr Walsh agreed that there had been some difficulty with the Anti-D programme in the late 1970s and undertook to review that and also the position of donors testing positive for HCV in the region outside Munster.

Further investigations took place both by Dr Walsh and Dr Power after that date and Dr Walsh in particular turned up and communicated to Dr Power, the results of the tests, a report of which he had received in December 1991 from the Middlesex Hospital. Further discussion of these issues took place at a special Consultants' Meeting on January 26th and at Medical subcommittee meetings on February 3rd and February 9th. At the latter meeting which was attended amongst others by Dr Boothman of the medical section of the Department of Health, who was a member of the Board of the BTSB, it was agreed that the information presented was strongly suggestive of a causative relationship between the 1977 non-A, non-B episode associated with Anti-D, and the HCV detected in female donors in the Munster donor study. It was agreed that that information should be forwarded in the form of a report, to Dr Boothman and also to the Board of the BTSB for their next meeting. Dr Walsh stated that he had already advised the CEO and also the Chairman of the Board.

Questions had arisen with regard to the safety of the current stock of the BTSB, and a number of samples of the stock of Anti-D currently held by the BTSB were sent to London for testing and on the 17th February 1994, a letter was written by the CEO of the BTSB to the Secretary of the Department of Health enclosing a copy of a report on Anti-D and Hepatitis C and requesting an urgent meeting with officials of the Department.

This meeting took place on the 17th February 1994 and further meetings followed on succeeding days, that is to say the 18th, 19th and 20th February 1994. Problems arising and the information available including preliminary

results of tests on stocks of Anti-D other than those which had been made in 1976/1977, and in particular on some associated with Donor Y, were obtained from London. At these meetings there was planned:—

(i) a media release to be made on the 21st February

(ii) the institution of a national screening programme to be carried out by the BTSB

(iii) a total recall of the product; and

(iv) an immediate substitution for it of Anti-D manufactured by WinRHO in Canada.

These actions and many others are all to be considered in the next section of this report dealing with the adequacy of the actions taken by the BTSB after the discovery of this situation in February 1994.

Action taken by the BTSB in response to the discovery in February 1994 that Anti-D manufactured by it had become infected with Hepatitis C.

The immediate action taken by the BTSB was as follows:—

1. The commencement of a screening programme for all women who had been recipients of Anti-D from the commencement of its manufacture in 1970 up to the present. Contact with these women was organised through direct contact by letter from records in some instances, by appeals made through the media, by contact with maternity hospitals and by communication made by courier to General Practitioners on the date of the first public announcement of the infection of Anti-D and of the screening programme. By early March 1994, 24,000 women had given blood samples which were in the process of being tested and by May 1994, approximately 52,000 women had been tested.

2. The immediate recall of all stocks of Anti-D which had been issued and were still unused. This was to be effected by telephone communication made with each of the individuals or institutions to which doses had been sent followed by a letter.

3. The replacement product available on the 22nd February 1994 was imported WinRHO Anti-D from Winnipeg, Canada, which was free from infection and had been treated with a solvent detergent. This replacement Anti-D was delivered to all the individuals and institutions which required it and this was done immediately after the public announcement of the infection of Anti-D. At the same time, all manufacture of Anti-D in Ireland by the BTSB ceased and has not been resumed.

4. Arrangements were made for the taking of samples for testing by General Practitioners as an alternative to the taking of samples and testing by the BTSB at the option of any person who wished to be tested in that

way and arrangements were made through the Department of Health to discharge any fees connected with that testing.

5. The BTSB conveyed to the Department of Health and in conjunction with the Department of Health to the public at large in February 1994, the events that had occurred and the risk that persons who had received Anti-D treatment could be infected with Hepatitis C.

6. Arrangements were made upon the results of the testing being obtained and proving to be positive on the first test, that is to say positive for antibodies, for further testing and information and counselling to be given to the person concerned. If upon subsequent tests a positive reaction remained, then the person was referred to organised specialist clinics for further investigation, and where appropriate, treatment.

7. There was a significant communication commenced and maintained with the Positive Action Group, referred to below. Information was given to the Group concerning the disease, its effects and consequences and also the services and facilities that were available.

8. Arrangements were made firstly on an ex gratia basis by the BTSB and secondly, on an ex gratia basis by the Department of Health, for the reimbursement of expenses for women in relation to obtaining testing and, where appropriate, referral and further treatment.

9. A Targeted Lookback Programme was planned and put into operation at the commencement of 1995. This involved seeking to trace the donors of infected blood, the blood or blood products into which their donation went and the recipient of such blood or blood products.

10. A series of meetings was organised and advertised throughout the country for the discussion of the effects of Hepatitis C and on the entire question of the infection of the Anti-D and publicity was given to such meetings and information given to women who attended them.

11. Close liaison was made by the medical staff of the BTSB with hospitals and in particular with haematologists and hepatologists concerned in the investigation and treatment of the persons affected with the Hepatitis C.

12. In September 1994, a new Chairman, Mr Holloway was appointed to the BTSB and, from 1995 on, a major reorganisation and expansion of the BTSB took place which included the taking account of recommendations made by the Expert Group set up by the Minister for Health in March 1994 to enquire into the infection with Hepatitis C and into the BTSB itself, and also the report of a firm of accountants and business consultants with special experience in blood transfusion services in the UK named Bain which was issued in April 1995. The consultant medical staff of the BTSB has been substantially enlarged and further enlargements are in the process of being made. Structures within the organisation and communication between the administrative side and the medical side and

within the medical and administration sides, have been very substantially improved. A Quality Manager has been appointed and plans are made, and shortly to be implemented, for a total re-siting of the premises of the BTSB, hopefully to put them in close proximity to a teaching hospital. Joint appointments between hospitals and the BTSB and haematology users committees in hospitals have also been initiated to improve the relationship between the BTSB and the research and clinical branches of medicine.

The adequacy of the action by way of response taken by the BTSB to the discovery of infection of Anti-D in February 1994.

Early in 1994, a number of women who had been infected with Hepatitis C as a result of having received Anti-D treatment, came together and formed a group for the purpose of supporting each other; and the purpose of presenting to the BTSB and the Department of Health, points of view and concerns arising from the infection which they had received, and from the reaction of both the BTSB and the Department of Health to that infection. They also took independent advice and obtained independent information concerning the disease of Hepatitis C and its probable consequences including the appropriate treatment for it.

This group which became known as the Positive Action Group was in regular communication both with the Department of Health with the BTSB and its individual officers. They made suggestions for change and alteration during the course of the action taken from 1994 up to the present. Some of these changes were either speedily, or in other cases with some significant delay, put into effect. Positive Action have been represented throughout the Inquiry and have presented criticism of the actions of the BTSB as well as criticism of the adequacy and appropriateness of the supervision of that action by the Department of Health before the Inquiry. The main substantial criticisms of the BTSB which have been made and which the Tribunal considers it appropriate, to deal with separately, are as follows:—

1. It was contended that having regard to the fact that it was the BTSB which had as it is said, quite unnecessarily and very wrongfully inflicted the victims of this Hepatitis C with the virus, that they should never have undertaken or been allowed to undertake the screening process which was admittedly necessary once the infection had been discovered, but that it should have been carried out by some other group or institution independent of the BTSB.

   The screening process which involved the screening, testing and further testing and counselling of something over 60,000 women and which of necessity had to be carried out with the utmost possible speed could not, on the evidence before the Tribunal, have been carried out by any body other than the BTSB. The sense of grievance of the victims of this infection that they should be subsequently examined by, and at

times counselled and informed by, the very people who had caused their damage, is humanly understandable. There was, on the evidence however, no other group who had the capacity of conducting the screening of this size and of this extent urgently. The screening in itself was an essential task but there must necessarily have been attached to it, a targeted lookback. This, having regard to the fact that the entire of the records system and knowledge of the system and records concerning the manufacture and destination of batches of Anti-D rested with the BTSB, made them by far the most speedy persons to carry out that as well.

Conclusion

The Tribunal is therefore satisfied that the decision to undertake the task of national screening itself and the general manner in which it was carried out, subject to certain reservations which will later be dealt with, was an adequate and proper reaction by the BTSB to the knowledge of the infection in 1994.

2. The challenge to the adequacy of the recall of the contaminated Anti-D was mainly on the basis that it was insufficiently complete and that there were insufficient checks on its completeness, the result being that approximately ten doses of Anti-D were injected into recipients after the 21st February 1994 from the Anti-D manufactured and issued before that date. Of these ten doses, subsequent research has discovered the recipients of nine of them in which cases fortunately, no sign of infection seems to have occurred. It was not possible to trace one recipient.

   In the original meetings between the BTSB and the Department of Health, the Department of Health was assured by the BTSB that it had a regular system of recall which had been put into operation before, when some products had some doubt about them, and that they would carry it out on this occasion. The Department accepted that assurance.

   The method of recall was, as has been indicated, a telephone call made mostly personally by Dr Walsh or some of the other medical staff, to each of the institutions concerned followed by a letter written on the same day in a circular form merely stating that for quality control reasons, it was requested that the Anti-D be returned. This was of course received subsequent to the media release indicating the contamination of Anti-D with Hepatitis C.

   The proper standard to be applied to any recall procedure in the circumstances which became know in February of 1994, was to assume that any dose issued could be lethal in the sense that it could cause wholly unnecessary, very serious and potentially fatal disease. In these circumstances, it would appear that a system of recall consisting merely of telephone conversations very frequently to one individual in a large institution followed by a letter, was insufficiently safe as a method of recall. An obvious additional and, it would appear, very necessary precaution and one which was quite practical, would have been that since the BTSB

was aware of the relatively limited number of institutions and individuals who were in possession of the outstanding doses of Anti-D, that actual collection by someone with a vehicle should have been made after the communications recalling the Anti-D. A system should then have been put in place of checking the doses taken back against the total stocks outstanding, ensuring that all issued stocks had been effectively recalled. In fact it would appear that 9 doses were administered after the recall.

In one instance of a Nursing Home in Limerick which was managed by Sr Ann Kelleher, it was established that no phone call was made at all before April 1994 and that no letter was ever sent. By the time that phone call was made, the doses of Anti-D which were in the nursing home had been used quite innocently and without any blame on the part of those responsible for that nursing home.

Conclusions

The Tribunal is therefore satisfied that the procedure for recall carried out was not in all the particular circumstances of this discovery of infection adequate and, that it should have included a physical recall and a checking against dispatch records of the dosages recaptured.

3. The criticism of the action of the BTSB in providing as they did, by the weekend of the 19th and 20th of February 1994, a sufficient supply of imported Anti-D from WinRHO in Winnipeg, Canada for distribution, was challenged on two grounds only. The first was that they represented to the Department of Health when informing them of their intention to make use of this imported product, that it had been licensed by the FDA of the United States whereas a licence from the FDA of the United States was only pending and was not granted until April, although it was licensed in Canada. The second challenge to it was that it had not been approved by the Licensing Authority in Ireland as a product for import, at the time when it was imported.

   No evidence was adduced of any description challenging the validity, safety or efficiency of this product which is still in use in Ireland and as far as the experts who gave evidence before the Tribunal are concerned, and they would include a number of persons involved with haematology in Ireland, it has created no difficulties. It was wrong of the BTSB, as they admit that they did, to inform the Department of Health on the 17th or 18th February, that this was licensed by the FDA. The falsity of that fact was reported to the Minister for Health by Senator Mary Henry who had made separate enquiries concerning it, and he then caused further enquiries to be made and the Department was informed of the true position by the BTSB.

   Before the end of 1993 as already indicated in this report, the BTSB was in active negotiations with the NDAB to try and obtain through WinRHO sufficient information for it to advise the Minister on an application to import this particular product into Ireland. The amount of

documentation and information required for such an approval, was very substantial indeed. This process was continued with both urgency and energy between the Department of Health, the NDAB and the BTSB after February of 1994, and a licence for import was granted in April of 1994.

Conclusion

There can be no doubt that it was absolutely essential that the BTSB should have available and ready for delivery, a substitute product for injection to women requiring an Anti-D injection within 48 hours of the birth of a child, at the same time as they recalled the Anti-D previously issued by them now suspected of being infected. Either a delay in the recall of the Anti-D issued so as to permit completion of the licensing of the WinRHO product or a gap between the recall and the availability of a standby product, would have done a very substantial, unnecessary harm. The only inadequacy of this particular action in response to the discovery of the BTSB was not to have fully informed the Department of Health about the licensing situation in the United States of America, though that was not, of course, the main issue.

4. A separate criticism of the setting up of the screening process by the BTSB apart from that already dealt with above, arose from the complaint of the Irish Council of General Practitioners who stated that they were put into a very difficult situation by not having been given some days notice of the public announcement of the infection with Hepatitis C and an opportunity properly to be instructed with regard to the consequences and implications of that, so as to be in a position more amply to advise their patients who might come to them immediately after the announcement.

   As already mentioned, the package of information to the General Practitioners went out contemporaneously with the public announcement and undoubtedly in many instances probably was not received until after a number of patients had communicated with their General Practitioner. Dr Dunne, the President of the Council, had been notified of the position on Saturday 19th February but it was not possible to communicate with his colleagues nor was it possible to even get a comprehensive list of General Practitioners and their addresses still in practice in Ireland so as to communicate earlier than the date on which the communication was made.

   Conclusion

   The decision not to delay the press and media announcement so as to communicate with the General Practitioners, was a difficult decision and the consequences of their not being given forewarning was obviously going to cause problems for them and, to some extent, distress for their patients as well. This decision was defended before the Tribunal on the grounds that the inevitable leakage of information neither complete nor

accurate, which was likely to occur if two or three days as suggested was placed as a postponement so as to inform the General Practitioners fully of the situation before informing the public, would have caused more alarm and distress than anything else. Bearing in mind the balance between these two contentions, the Tribunal is satisfied that notwithstanding its disadvantages, the contemporaneous sending of packages of information to the General Practitioners and the making of a public announcement was the better choice and was an adequate response by the BTSB to that particular problem.

5. A criticism of the manner in which, and the extent to which, the information concerning this infection of Anti-D with Hepatitis C was conveyed to the Department of Health and to the public by the BTSB in February 1994, arises from an assertion that the publicity involved was insufficiently clear in identifying the possibility or likelihood that batches of Anti-D manufactured from 1991 onward from plasma to which Donor Y had contributed were infected as well as those which had been manufactured in the earlier period of 1976 and 1977.

   The explanation offered by the BTSB with regard to that matter was that as of 17th and 18th February 1994, they had only got a very tentative testing result of these samples. To identify it as a particular risk, was they say, not warranted at that time and would have caused an unnecessary alarm. The screening programme in any event was intended to cover everyone who had had an Anti-D injection since 1970 and therefore it was likely that most people who had the more recent injections would eventually come forward for screening. Tests on the material involved in the Donor Y situation were ongoing from February onwards and eventually the position became more certain than it was at that time. In particular the BTSB relies on the fact that it submitted to the Department of Health, a letter dated the 8th of April drafted by Dr Power and Dr Lawlor as a circular letter to General Practitioners pointing more certainly to suspect doses manufactured from 1991 onwards, but that the Department of Health would not agree to its circulation.

   The Department of Health's grounds for refusing that apparently were that it was insufficiently precise in its scientific proof. Overall the balance between causing undue alarm and giving fair warning which again arises on this issue is not easy to strike, but it appears probable that by April of 1994, in the form of a communication to General Practitioners at least, people should have been informed as to what the position then was, that there was strong likelihood that some of the batches manufactured from 1991 on and coming from the plasma donated by Donor Y, would be infected. There are grounds for saying that the suspicion of such an infection might quite well have been mentioned though possibly not highlighted in the original media release on the 21st February 1994, but in that case the balance seems to be appropriately one of caution rather than of risking alarming a greater number of people.

There was not any significant evidence, though it is not a matter on which evidence might easily be obtainable, of persons who were in any way damaged or prejudiced by the failure to communicate this particular piece of information earlier than it eventually became a matter of public knowledge.

The officers of the BTSB and in particular Dr Power and Dr Lawlor in fact, after the refusal of the Department to sanction the letter of 8th April, took energetic steps, on the evidence before the Tribunal to communicate this general information to hospitals and to meetings of General Practitioners and others so as to give it the greatest possible currency.

Conclusion

The suspicion quite strongly expressed on behalf of the victims of this infection with Hepatitis C, was of course that the BTSB were seeking as far as it might be still possible to do so, to cover up what they had done and not done and the extent of the problem which they had caused. The suspicion of a desire to cover up is one which is sufficiently plausible to require careful consideration. The evidence before the Tribunal was that Dr Walsh before, even going to the Department on the 17th February 1994, had gone to London with specimens from the batches of Anti-D made from 1991 onward which were suspect by reason of the history of Donor Y and that he had had them preliminarily tested in London. The results of those tests came back on the 18th February and were made known to the Department of Health at the continuing meetings which were being held on that day and on the subsequent days before the media releases of the 21st. The pressure put by Dr Lawlor and Dr Power through Mr Keyes on the Minister for Health to agree to the letter to the General Practitioners of the 8th April, allied to Dr Walsh's own conduct in seeking to have these tests made before 17th February 1994, would appear to be quite inconsistent with any real intention of covering up the possibility of later infected doses of Anti-D. The Tribunal is not satisfied that the reaction of the BTSB on this particular issue was inadequate.

6. The arrangement made for the screening of persons who had been recipients of Anti-D by the BTSB and the continuance of that screening by further test where preliminary positive results had occurred, associated with information and counselling also carried out by the BTSB, with referral to specialised clinics for further investigation and treatment only occurring when there were positive indications of a HCV virus in the blood, was heavily criticised. Positive Action made the point both at the time when this screening procedure was started and before the Inquiry, that it was quite inappropriate for the people who had been the cause of the infection from which these women were suffering, to be any way in control of or organising their counselling. It was stated that obviously

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the women were hostile and could not be expected to benefit from counselling from the people who they felt had done them so much harm. It was further asserted that there was a constant suspicion that the purpose of the counselling, which included questioning concerning possible causes of infection by HCV other than the receipt of Anti-D, was not intended to support them but rather was an attempt to cut down the amount of harm for which the BTSB was responsible. A separate criticism of this screening procedure and in particular of the timing of the ultimate referral, arose from a dispute between the Hepatologists involved in the treatment in persons found to be infected with Hepatitis C, and the BTSB, as to the proper stage at which such a referral should take place.

(a) Counselling

From an early stage, certainly by June of 1994, Positive Action on behalf of its members was making clear both to the BTSB and to the Department of Health its objections to the counselling of women by the BTSB who were found to have reacted positively to a test for the Hepatitis C anti-bodies and were pressing for independent counselling. The dissatisfaction with the counselling provided by the BTSB as already indicated, was partly due to the fact that they were seen as the origin of all the trouble. It was, on the evidence also to some extent probably contributed to by the fact that quite clearly these people who had unfortunately become infected with Hepatitis C expected to get clear and certain information as to what the future prognosis was going to be. On the evidence, that was not available to them in full having regard to the fact that knowledge about the infection, its consequences and its progress was developing and increasing all the time in the years 1994 to the present and that certainty of prognosis was not on many aspects then available. Efforts were made to try and create counselling independent of the BTSB even for those who had not been referred for treatment to specialist clinics. In the Dublin area from May 1994, the Well Woman Centre at the request of and funded by the Department made themselves available for this counselling. It was necessary of course that they should obtain as much information as possible about the disease of Hepatitis C from the BTSB before starting on the counselling. Similar problems with regard to counselling in the Cork area were experienced, and there an organisation was set up in March 1994, whereby a counsellor who was not in any way an employee or officer of the BTSB would be made available to persons who had tested positive for the Hepatitis C. The evidence of Ms O'Brien on behalf of Positive Action was that that failed because he, Mr Hogan, had been introduced to the women by the BTSB as a person available to give them counselling and was therefore associated by the women with the BTSB. It would seem however that his services were availed of

to some extent. It was replaced in November 1995 by a service provided by private counsellors arranged by the BTSB. Independent counselling services in other areas of the country were arranged at various locations from February 1995.

Together with these forms of counselling, meetings were organised by the BTSB around the country and particularly out of Dublin for both individual one to one counselling and counselling in groups. Criticism has been made of these meetings as well, but the evidence would indicate that they were, in many instances, well attended and that the medical staff of the BTSB particularly Dr Power and Dr Lawlor saw them as being quite successful.

Conclusion

With regard to this criticism of the attitude of the BTSB to counselling, the conclusions from the evidence would appear to be as follows:- the BTSB probably underestimated the extent of the anger and hostility which the facts revealed in February 1994 had caused to the victims of Hepatitis C. Apart from the option which was provided for women who wished to be tested and therefore to be counselled by their own General Practitioner, it would have been extremely difficult to set up a general independent counselling service either in Dublin, Cork or in other areas with any reasonable speed in February of 1994. If however, the BTSB had realised as they should have done, the difficulties that were likely to arise from their doing their own counselling for those screening positive, and had in the very first instance commenced to arrange for independent counselling and to seek general assistance from the medical professions involved for that purpose, it seems likely that the counselling situation which eventually became satisfactory to the victims in late 1994 and 1995 could probably have been put into operation at a somewhat earlier time than it was. To that extent it would appear that this particular reaction of the BTSB to the events of February 1994 was inadequate.

(b) *Clinical assessment of those testing positive to Hepatitis C.*

The controversy under this heading was as follows:—

By letter of the 27th July 1994 written by Dr M.J. Whelton of the Cork Regional Hospital, Chairman of the Hepatology Group to Dr Tierney, Chief Medical Officer of the Department of Health the recommendations of that Group were that the following Groups should be offered clinical assessment:—

(1) PCR Positive

(2) RIBA Positive

(3) Those with abnormal liver function tests, and

(4) Recipients of blood donated by women infected by Hepatitis C as a result of Anti-D immunisation.

The letter continues, "The Group feels strongly that to exclude any of these Groups would be incorrect and might be construed as negligence".

That letter was submitted by Dr Tierney to the BTSB and Mr Keyes the CEO of the BTSB replied to it on the 17th August 1994 stating that the attitude of the BTSB was as follows:—

1. Women who are both RIBA positive and PCR Positive are being referred for hospital investigation.

2. Women who are RIBA positive and PCR Negative are undergoing an extensive testing programme over a short period of time. Women with strong RIBA reactions which do not reduce over the follow up period will be considered for hospital investigation.

3. Women with abnormal liver function will be referred for hospital investigation.

4. The Board will carry out, as soon as possible, a targeted look-back on women who tested positive for Hepatitis C and who have donated blood. The first step will be to identify the women in question, and the second step will be to identify the products from these women and the hospitals they were sent to. The third step will be to identify the recipients of these products and a programme will be put in place for such recipients.

The letter concludes "*The Board would like to thank Dr Whelton for these recommendations and any other views that he may wish to make in relation to the matter will be welcome*".

Put in its simplest terms the controversy arising between the Hepatologists and the BTSB at that time was that the BTSB had the view that if persons had reached the stage only of reacting to tests on the basis of having Hepatitis C anti-bodies in their blood stream as distinct from a test revealing the existence of Hepatitis C virus, they should first be monitored by further testing for a period before being sent for any referral for treatment to Hepatological Units.

The philosophy behind that point of view was stated to be that they should be regarded as well people rather than patients at that stage. On the other hand the point of view being put forward by the Group of Hepatologists was that it was safer at the earlier stage that they should be referred for further clinical assessment and investigation.

Conclusion

Having regard to the fact that the BTSB at that time had already been made aware of the complaints made by Positive Action on behalf of a number of the victims of this infection with regard to their further testing and counselling by the BTSB after an original positive test for Hepatitis C anti-bodies, it would appear that they were most unwise to pursue their particular clinical assessment of this situation in the face of the clinical assessment of the Hepatologists. The advantage should have been clear to the BTSB of making an earlier referral, and therefore easing the concerns of the people who had been affected. The matter was eventually resolved in a way which appears to have been satisfactory to the persons who had been victims of the Hepatitis C in 1995, but the delay until that time would appear to have been unnecessary. The particular reaction of the BTSB to this aspect of referral and counselling must therefore be deemed to have been inadequate.

7. A further criticism arose concerning the counselling and information given and not given to persons, who upon screening, were positive for Hepatitis C. It arises in part from the evidence of one known to the Inquiry as Donor L and is in respect of matters occurring before 1994. It also appears to have arisen in relation to other people after 1994 of which evidence was given by Ms Jane O'Brien of Positive Action.

Shortly the evidence of Donor L was as follows.

He underwent cardiac surgery in 1980 and subsequent to that became a blood donor. He gave blood donations in 1986, 1987, 1988, 1989 and 1990. In 1991 he gave a blood donation in April. All these donations were given in the Limerick unit of the BTSB. Having received a donor notification card, he again presented himself to give a donation of blood in December 1991 and did so. He was aware that a screening had been introduced in October 1991 but did not receive any communication as to whether to not his blood had been tested nor any result of any test.

He presented again in April 1992 as a result of a donor notification card and again as a result of donor notification cards in August 1992, December 1992, April 1993 and July 1993.

In November 1993 he received a letter from Dr Power which in effect informed him that on a screening of his blood donation of the 28th July 1993, that the test suggested that he may have been exposed to the virus of Hepatitis C in the past. It also stated that a sample sent to the Virus Reference Laboratory in Dublin concurred with that opinion. She further went on to point out that this test was used in reducing the risk of post transfusion Hepatitis but it did not indicate whether or not the donor had any virus left in his body but a further test was now available and suggesting that he should subject himself to that test.

Donor L did subject himself to that further test and as a result of it, was referred to the Hepatology Unit at University College, Cork, had a liver biopsy in 1994, and again in 1995, and was then put on a course of Interferon in August 1995. At the stage when Donor L gave evidence, he stated that he was responding well to the that course of treatment and that all the indicators were favorable, the PCR was negative and the virus load had dropped significantly. This witness expressed considerable distress and considerable anger at the fact that, as subsequently transpired, he had in fact tested positive to HCV antibodies on the first occasion after testing was introduced, namely in December 1991 and from that onwards up to the receipt by him of the letter of November 1993, on the occasions mentioned when donations of blood were taken from him, he was at no time informed that they were being used for the purpose of testing only, nor was he informed that any form of positive test had arisen.

He was never given an opportunity of deciding whether he should have further confirmatory tests or whether he should seek treatment at any stage before November of 1993. He was under the impression that he was still making valuable donations of blood to the service from December 1991 up to November 1993, something which he apparently valued out of a sense of gratitude for blood transfusions which he had at the time that he underwent cardiac surgery in 1980.

Dr Power gave evidence concerning this matter and in effect her evidence was that she felt that even the HCV screening that was available in 1991, was insufficiently precise to warrant the risk of upsetting the donor who was tested in the ordinary, way as was Donor L, by informing him of a positive result and that the best course to adopt was to continue screening his blood on a regular basis by sending him an ordinary donor's notification card from time to time to see whether the apparent reaction would vary and also apparently in the hope or expectation that confirmatory testing of a more certain kind would come available very soon. Dr Power denied that this occurred through inadvertence or want of care, but was, she said, a conscious decision which with great difficulty she made concerning the position of donors screening positive on the introduction of the test in October 1991. It was apparently a decision which she implemented as a general policy and not merely in one case.

Evidence indicated that during the same period, that is to say after the introduction of screening in 1991, this was not the policy pursued in the area outside Munster in respect of which Dr Walsh had personal supervision and there does not appear to have been any attempt between Dr Walsh, who was the Chief Medical Consultant and Dr Power, who had the responsibility for the Munster area, to have agreed on a procedure or even to have discussed rights and wrongs of either procedure. Dr Walsh apparently did inform people of the consequences of positive tests. Ms O'Brien of Positive Action gave evidence of general instances

of a similar policy having being applied in the Munster area and in particular in one instance having being applied subsequent to 1994 and in particular one woman was tested "border line" according to the test results which were now known and the blood she had donated was not used but was discarded but she was never informed of the position. She was eventually informed in 1996 that whilst her blood was healthy and the "border line" results had disappeared in so far as they were positive, that it could not be accepted because of the result of the screening process.

Conclusion

An ethical view was expressed by some of the doctors giving evidence before the Tribunal that even in the relationship of a blood transfusion doctor to a donor as distinct from the relationship of a doctor to his or her patient, that there was an ethical obligation to inform a person who had tested positive in any fashion of that fact, lest they wish to make the choice of having further investigation or treatment. Dr Power did not agree with that interpretation of the ethical position. The reaction consisting of the introduction of this system after the introduction of Hepatitis C screening in 1991, and after the knowledge of the infection of the blood supply which came to the BTSB in 1994, appears to be quite an inadequate response to the responsibilities which they had towards donors. There was the distress and frustration which a donor naturally felt at having, as he or she thought, made valuable donations of blood only to find that over a sustained period they were discarded. Then there was the major problem that they should have had an opportunity of earlier investigation in depth of the extent, if any, of their infection with Hepatitis C and earlier treatment. The medical evidence accepted by the Tribunal as already shortly set out, indicated that in any case where the Hepatitis C infection advanced to being the cause of liver damage, that the earlier intervention took place the more likely it was to be successful. The operation of this system therefore must be taken to be quite an inadequate reaction to the screening of 1994 and even though not strictly coming within the Term of Reference of a reaction to the knowledge of the Hepatitis C infection of Anti-D, is of importance in relation to that, in the instances of some of the women who came within that category.

8. Certain further complaints on individual matters connected with testing and screening of the victims of Anti-D were also dealt with at the Inquiry. They may be listed as follows. The method of counselling and consultation with regard to testing was often insensitive, examples given included the fact that questionnaires to be answered included the question as to whether the women had, had their ears pierced for jewellery.

A further complaint was from women who, when tested, did not receive the result of their test at the time promised nor any intervening explanation before what was frequently a delayed response. Complaint

was also made that they were never given the written record of their test though they were informed in general terms what the result of it was.

There was also a complaint with regard to the quality of that information and in many instances it was insufficiently clear, particularly for people who were often upset.

A further complaint was that when promised a repeat testing within a particular time, that frequently this did not happen and that no explanation was given as to a long delay.

With regard to these items they appear to fall into two categories. One was quite clearly a lack of administrative efficiency, insufficient contact kept between a person being tested, to indicate the availability of personnel and testing arrangements for further tests, a failure possibly to confirm in some form of writing the results of tests and in particular, apart from scientific records of what was found, the general consequence of it. The other items arise from what has already been partly dealt with, the feelings of suspicion and hostility which these people who had been infected through Anti-D with Hepatitis C, had towards the BTSB, at the time that they were being tested and information given to them.

It would appear that there was significant substance in the questions of the amount of delay and in the poverty of communication in this testing. The most probable explanation, on the evidence, was a lack of staff to deal with the sudden numbers which came after February 1994. As already indicated, evidence would suggest that this was not due to any lack of resources which apparently the Department of Health committed to the BTSB, but rather the significant difficulty of obtaining appropriate staff. Much of the communication with those who were tested and the arrangements for the testing had to be done by medical staff and whilst junior medical doctors were recruited, it was not easy to get appropriate people.

Complaints about the insensitivity of the questionnaire obviously arise from the fact that what was given to them would presumably be a questionnaire which was necessary from a medical point of view in order for certainty of diagnosis with regard to what the cause of the Hepatitis C infection was. Here again a careful attempt to explain it was probably was not done, having regard to the numbers involved, and would have removed the problem.

Conclusion

Whilst the complaints made under these and other individual headings in the evidence concerning the counselling, information and screening by the BTSB after 1994 are very understandable and have obviously caused hurt and concern to the people who make them, having regard to the task that was being undertaken, and having regard to the conclusion which the Tribunal has reached that it had to be undertaken by the BTSB, the reaction in these matters is some, but not a significant,

addition to the general inadequate reaction which has been noted in not procuring independent counselling earlier.

9. A criticism was made at the Inquiry by Positive Action which centred around a dispute concerning the efforts of Positive Action to communicate, through or with the assistance of the BTSB with other persons who had been infected with Hepatitis C as a result of inoculation with Anti-D. Apart from this major dispute, there was considerable evidence from both Positive Action and medical staff of the BTSB that personal relations between people who had been involved on both sides was good, and that a reasonably strong level of communication was kept up during the entire of the relevant period between Ms O'Brien in particular, on behalf of Positive Action and other members of that Group, and in particular Dr Power and Dr Lawlor.

The controversy about communication in the first instance arose in the following way.

On the 6th April 1994, Ms Jane O'Brien had an interview with Dr Lawlor in which she requested that the BTSB would address to all the people, whom their records showed had been recipients of Anti-D during the relevant period, a letter in the following terms:—

> "*Dear Friend,*
>
> *We are writing to you as fellow Hepatitis C/Anti-D sufferers. We know the personal suffering, fear and isolation you may be going through. This letter which is kindly being distributed by the Blood Transfusion Service Board is to judge interest in establishing a support group for Anti-D women. Such a group would enable women to form contacts with others in the same situation living in their area. It would help greatly if you would complete the following questionnaire to enable us to build up a wider picture of the situation*"

It was signed by Ms O'Brien and by certain other people who were members of the emerging group. The questionnaire sought the name, address and phone number of the person concerned, their age, the number of their children, the dates on which they received Anti-D and where, particulars of what testing had taken place, a question as to whether their children had been tested and whether their partner had been tested and then a question as to whether they would be interested in attending a meeting of the Anti-D support group and then a question as to the nearest large town to their address.

The discussion, pursuant to which that letter was sent to Dr Lawlor for distribution, was one at which Dr Lawlor expressed the view that the writing of such a letter by the BTSB might be quite acceptable and would be a good idea. In reply however to that letter, she wrote to Ms O'Brien in the following terms:—

"Thank you for your letter of 18th April and our further telephone conversation. I have consulted my colleagues for discussion as the issues involved are complex and need careful consideration by all concerned parties before a comprehensive answer can be given. I will come back to you with the Board's considered response before the end of next week".

The response of the Board to this letter was given to Ms O'Brien by Dr Lawlor in a letter of 3rd May, the relevant portions of which are as follows:—

"The BTSB welcomes the establishment of a support Group to bring together those women who may have contracted Hepatitis C through the administration of Anti-D and may wish to contact other women in the same situation. The Board recognises that this issue has raised many an emotional and personal fears as well as clinical concerns. However the Board is not in a position to formally endorse any one Group or individual and will continue to facilitate all Groups and individuals equally to the best of its ability.

What does this mean in practice? On the positive side it means that the Board can facilitate your Group by providing as much information as possible to your members. Since the first RIBA tests came back from the laboratories, the Board consultants and medical staff have been advising individuals on the nature of Hepatitis C and its effective management in their individual cases. The Board has no difficulty in continuing to provide such specialist help for a Group such as yours.

The Board cannot and will not provide any Group with details of any individual cases. We are legally bound to protect the confidentiality of all donors and recipients and this principle applies especially in the case of women who received Anti-D. If individual women chose to share their concerns with others in the same situation, that is their prerogative.

Your request therefore that the Board issues letters and questionnaires on your behalf creates difficulties on both principles I'm afraid. To issue such a letter would be to endorse formally your group ahead of others. It might also alarm some women to receive a letter from your group that had been distributed by the Board. While you know and I know that individual women's names would not be in the possession of the self help group. The individual women would not be so sure. The Board is not prepared to cause further distress. There is a precedent for this situation. The Board has no formal participation in the haemophiliac support group, the Irish Haemophilia Society nor did it ever help target members. It does however provide valuable assistance in terms of expertise and information. I hope this is of some assurance to you."

At a subsequent date in or about the month of September 1994, the BTSB agreed to have available in all areas where women coming for screening, notices from Positive Action, which gave them the opportunity of getting in touch with the other victims who were members of that Group, and in April 1995 circular letters were distributed.

With regard to the letter of 3rd May which is quoted extensively above, it was suggested by Counsel on behalf of Positive Action that the reasons there given for declining to circulate the letter and questionnaire were so transparently insubstantial that they indicated that the refusal of the BTSB to adopt that course must have had a wholly different purpose. The purpose suggested was that they were anxious at all costs to prevent women who were victims of the infection getting together and sharing their experience and indignation.

The evidence before the Tribunal from a number of different sources concerning the strong desire of a number of victims and potential victims of the infection by Hepatitis C at the beginning, and even at much later stages after the whole series of events had become largely public matters, to retain anonymity was quite strong. Examples were given individually of persons who still had not conveyed the information that they were infected by Hepatitis C to their family and close friends. The very desire for anonymity fully understood and fully yielded in the affairs of the Tribunal to some persons who had become unfortunate suffers of this infection, indicates that point of view.

It is the view of the Tribunal therefore that there was considerable substance in the concern expressed in this letter by the BTSB that a letter in the terms which were being proposed and a questionnaire, added to it, would if addressed to recipients of Anti-D, give some of them at least the impression that the confidence owed to them by the BTSB as to their identity had been breached.

The evidence of Ms O'Brien was that she was quite prepared that a letter without a circular could have been circulated.

Conclusion

What would appear to have been safe even having regard to the desire by the BTSB not to appear to have broken the confidential obligations they had to each person who had received Anti-D, was to leave open letters available for people to take away, and to put notices in the areas where sufferers were visiting the BTSB premises indicating the existence of the Group and the way in which it could be communicated with.

The BTSB was inadequate in its reaction to this request for the circulation of a letter in April 1994 by failing to provide a reasonable alternative before September of 1994 and April of 1995.

Part III

Terms of Reference 5-7

Chapter 9

The Manufacturer's Licence

Term of Reference No. 5

Whether the National Drugs Advisory Board in carrying out its functions in advising on the grant of a Manufacturing Licence for anti-D under the Medical Preparations (Licensing of Manufacture (Regulations) 1974 carried out its functions properly.

The Facts

By Statutory Instrument No. 225 of 1974 made by the Minister for Health in exercise of the powers contained in the Health Act 1947 as amended by the Health Act 1953 it was provided that subject to certain exemptions not relevant in this case, no person should manufacture for sale any medical preparation except in accordance with the licence granted by the Minister referred to as a Manufacturer's Licence. This Statutory Instrument was made on the 12th of July 1974 and was to come into operation on the 1st of October 1975.

On the 28th of February 1975 the BTSB applied to the Department of Health for a manufacturing licence. The Department of Health sought the advice of the NDAB in respect of that application and on the 17th of July 1975 the Board of the NDAB decided to recommend the granting of the licence. This decision was communicated to the Department on the 9th of September 1975 and apparently a further communication was made on the 26th of September 1975, of what can only be regarded as a confirmatory recommendation made by the NDAB on the 23rd of September 1975. The Minister for Health granted the licence on the 1st of October 1975.

The evidence of the inspections prior to the recommendation by the NDAB for the granting of this licence was that in November 1973 Mr. O'Dowd, who had been appointed an inspector on the pharmaceutical side with the NDAB in October 1972, made an inspection of the premises and equipment of the BTSB. In a report made of that inspection he described it as not being a full inspection, but that he felt that "it was tactically better to leave that to be done with licensing as a good relationship was more desirable at that stage". In the course of the inspection however Mr. O'Dowd, who was an extremely experienced person in regard to quality assurance from a pharmaceutical point of view, was well satisfied with the standards of care, safety and sterility provided for in the process and in the equipment at the BTSB.

On his evidence he paid two further visits between that time and July of 1975 with a view to passing on information about good manufacturing practice and drawing attention to requirements for personnel in management positions in relation to "qualified person" functions. He gave evidence that the combined effect of these three inspections would be more representative of the true position than the full inspection would have been.

The licence granted by the Minister for Health on the 1st of October 1975 was for a period of three years the maximum permitted under the Regulations, and would therefore have expired on the 1st of October 1978.

On the 17th of October 1978 the NDAB communicated a recommendation for the renewal of this licence to the Department of Health, although it would appear that no actual application for a renewal had been received from the BTSB. Pursuant to that recommendation, a licence was granted on the 30th of November 1978 by a document which was backdated to the 2nd of October 1978 and which was received by the BTSB on the 4th of December 1978.

No particular inspection had been carried out by Mr. O'Dowd or by anyone else of the BTSB premises in respect of this renewal of the manufacturing licence. Mr. O'Dowd's evidence was that he was on a number of occasions visiting the premises of the BTSB, but was doing so largely for the purpose of discussion concerning an intended move of the premises from Pelican House in Leeson Street, where they were then operating, to new premises in Mespil Road. His evidence however was that in the course of those discussions he did in fact make enquiries and acquaint himself with the manufacturing processes with regard to all the products which the BTSB was making at that time, including of course anti-D.

The evidence of Mr. O'Dowd was that the inspections he carried out for the purpose of the manufacturing licences were not applied, as would be product authorisation inspections, to any particular product nor to the quality or safety of a product, but were rather applied to the processes being used under the protocols which applied and the compliance with them in the various laboratories, and that the equipment and procedures were correct to make a safe form of manufacturing.

In particular he stated that it was his understanding that he did not have, in regard to blood products, any duty to enquire into or pass judgement on the procedures for donor selection. That, he asserted, would be a matter for medical inspection or for medical consultation, and unless he was specifically asked to report on the facts concerned he would not do so.

The licence granted in 1978 was of course renewable. It expired on the 2nd of October 1981 and was renewable on that date.

On the 9th of October 1981 the NDAB at a Board meeting, decided to recommend the renewal of the manufacturing licence and this recommendation was conveyed to the Department on the 12th of October 1981. On the 16th of October 1981 the BTSB applied for a renewal of the licence and on the 9th of February 1982 a document granting the licence backdated to the 2nd of October 1981 was issued from the Department of Health and was received by the BTSB on the 10th of February 1982.

Between the granting of the licence in October 1978 and the granting of the licence with effect from the 2nd of October 1981 the BTSB had moved from the premises in Pelican House to the premises in Mespil Road. Inspection of those premises in the course of their construction and equipment had taken place between 1978 and 1981 by Mr. O'Dowd as an inspector on behalf of NDAB. On the 13th of October 1981, Mr. O'Dowd carried out a full inspection of the premises on Mespil Road and of the manufacturing processes taking place in them. He was, he states, fully satisfied with the processes, their safety and the procedures being used. This inspection and the report issued and apparently submitted to the Board of the NDAB after it had taken place was of course subsequent to the date on which the recommendation of the NDAB for the renewal of the licence was communicated to the Department. This position was defended on behalf of the NDAB and also to an extent on behalf of the Department, by an assertion that had there been any difficulty or unresolved query arising on this inspection, the licence even though only recently renewed could have been immediately revoked. This licence again expired on the 2nd of October 1984 when it fell to be renewed.

On the 31st of August 1984 the Department of Health warned the BTSB that their manufacturing licence was due for renewal on the 2nd of October 1984. On the 20th of September 1984 the BTSB applied for a renewal of the licence. On the 20th of September 1984 the NDAB decided to recommend the renewal of the licence to the Department of Health and this was communicated to the Department of Health on the 28th of September 1984. On the 15th of November 1984 Department of Health issued a licence backdated to 2nd October 1984 and communicated that fact to the BTSB on the 20 November 1984.

That decision of the Board of the NDAB on the 20th of September 1984 was made at a meeting at which a general decision was made that in respect of any cases where companies holding a manufacturing licence had not been inspected by the inspector by that date and if the licence was to expire on the 1st of October 1984, that the Board should recommend the renewal of those licences and provide for an inspection to be undertaken by the Boards' inspector over the coming months. It was also decided to try and initiate a programme for the inspection of manufacturers at least once a year.

Mr. O'Dowd carried out an inspection of the BTSB on the 15th of November 1984 and found that there were no changes in personnel, equipment or premises since his last inspection, which would have been the inspection of 1981, and that the areas involved in manufacturing and distribution "are functioning very efficiently and operation of them has proved to be much easier than in the old premises."

He recommended that the licence be renewed.

On the 1st of October 1987 the NDAB decided to recommend to the Department a grant of a renewal of the licence and that decision was communicated to the Department on the 7th of October 1987. On the 23rd of October 1987 the BTSB applied for a renewal of the licence. On the 17th of November 1987 by a document backdated to the 2nd of October 1987 the

renewal of the licence was granted. This fact was communicated to the BTSB on the 18th of November 1987. An inspector from the NDAB had inspected the BTSB premises on the 14th of July 1987 and apparently was satisfied with the manufacturing processes involved. The licence granted with effect from the 2nd of October 1987 was again for a period of three years and became renewable on the 2nd of October 1990.

On the 27th of September 1990 the NDAB decided to recommend the granting of a renewal of the licence and that was communicated to the Department on the 28th of September 1990. By a document dated the 2nd of October 1990 the Department granted the renewal of the licence and a decision was communicated to the BTSB of that fact on the 31st of October 1990. The BTSB had not applied for a renewal of that licence. The NDAB had not carried out an inspection of the BTSB premises, prior to making that recommendation, since 1987.

On the 17th and 18th of November 1992 Mr. John Lynch, an inspector appointed by the NDAB in September 1987, carried out a very full inspection of the BTSB premises. This arose in relation to questions concerning the importing by the BTSB of blood products which had not got a product authorisation. It was not directly related to the renewal of any manufacturer's licence but was in fact a very thorough examination which dealt with all the activities and procedures of the BTSB. The conclusions relevant to the issues arising on this inquiry contained in that report were: firstly, that in general the procedures of blood collection, plasmapheresis component separation, micro biology and blood grouping were satisfactory; secondly, that the preparation of anti-D was well documented and the hygiene standards were well maintained; thirdly, that the layout of the unit and the filtered air supply did not meet current requirements of good manufacturing practice. The fact that the final solution was not sterile-filtered immediately prior to filling was considered to be a critical deficiency which should be remedied at an early date. That report was dated February the 18th 1993.

On the 29th of July 1993 the NDAB decided to recommend a renewal of the BTSB licence to the Department and that was communicated to the Department on the 27th of August 1993. On the 2nd of October 1993 the Department granted renewal of the licence.

Summary of these facts

Between 1975 and 1993 seven manufacturing licences pursuant to the regulations of 1974 were issued by the Department of Health to the BTSB. Of these, those in 1978, 1981, 1984 and 1987 were all backdated, that is to say they were issued subsequent to the date on which they fell due for renewal.

In the case of two of them, that is to say 1978 and 1990, there was no inspection on behalf of the NDAB since the issuing of the last licence before recommendation for renewal was given to the Department.

In two instances 1981 and 1984, the inspection relative to the recommendation for the renewal took place after the recommendation had been made.

In no instance would there appear on the evidence to have been an inspection which could be described as relating to the manufacturers' licence on more than one occasion in the three year period involved.

On four occasions the BTSB does not appear to have applied for a licence either within the appropriate time or at all. A chronology of the events relating to this Licence is contained in Appendix H.

Conclusions

The view of the Board of the NDAB, on the recommendation of Mr. McGuinn Chief Pharmacist of the Department of Health and a board member, as expressed at their meeting of 20 September 1984 was that for the purpose of advising properly on the granting of a licence under the Medical Preparations (Licensing of Manufacture) Regulations of 1974, that it would have been necessary for their Inspector to pay one visit each year at least to the premises where such manufacturing procedures were carried out. Quite clearly that was not done in any year in any period of licensing from 1975 to 1993. Mr. O'Dowd's explanation for his failure to carry out this minimum number of visits of inspection to the BTSB during this period was that he was, from the time of his appointment in 1972 until 1987, the sole pharmaceutical inspector employed by the NDAB. During that period a number of different factors had led to a massive increase in the workload of a pharmaceutical inspector attached to the NDAB. These included increasing legislative control of medicinal products, the inclusion of veterinary products, and a great increase overall in the number of companies manufacturing medicinal products of one description or another in Ireland or seeking to import them and the variety of products manufactured by them. These factors and the resources available to the NDAB will be dealt with in a separate part of this report.

A proper exercise of its functions in relation to these licences would have been an annual inspection, the last of which was carried out and reported on in good time before the date for renewal, so as to permit to the Board of the NDAB time for full consideration of its contents. That requirement would however have also involved a proper system of early application by the BTSB and an early and formal request from the Department for advice, neither of which appears to have existed.

Chapter 10

The Product Authorisation

Term of Reference No. 5

Whether the NDAB in carrying out its functions in advising on the grant of Product Authorisations under the European Communities (Proprietary Medicinal Products) Regulations 1975 carried out its functions properly.

The Facts

On the 15th of December 1975 the Minister for Health pursuant to Section 3 of European Communities Act 1972 made regulations entitled European Communities (Proprietary Medicinal Products) Regulations 1975 being Statutory Instrument No. 301 of 1975. The material provision of those regulations was that with effect from the commencement dates shown in respect of the classes of Proprietary Medicinal Products in the schedule to the regulations, such products should not be placed on the market unless they complied with the provisions of Council Directive 65/65 EEC Council Directive 75/318 EEC and Council Directive 75/319 EEC. Anti-D was by its description a medicinal product listed at No. 2 (e) of the Schedule to those Regulations to which there applied a commencement date of the 1st of April 1983. Upon the making of these regulations it was accepted apparently by the Minister for Health who was the competent authority in the State for the purpose of the Council Directives referred to: the NDAB to whom was delegated by the Minister for Health the function of advising by way of recommendation on the necessary product authorisation arising under the Regulations; and by the BTSB, that these Regulations applied to anti-D and made it obligatory for the BTSB to obtain a licence to be known as a Product Authorisation in respect of the anti-D manufactured by them. Such licence would be for a period of 5 years and would therefore expire on the 1st of April 1988.

The European Communities (Proprietary Medicinal Products) Regulations 1975 (S.I. No. 301 of 1975) were revoked by virtue of the European Communities (Proprietary Medicinal Products) Regulations 1975 (Revocation) Regulations 1984 with effect from the 1st of October 1984. This Revocation Order was of course made pursuant to Section 3 of the European Communities Act 1972 as had been the original order of 1975.

The Minister for Health pursuant to the provisions of the Health Act 1947 as amended by the Health Act 1953 and pursuant to the Misuse of Drugs Act

1977, on the 3rd August 1984 made regulations entitled Medical Preparations (Licensing Advertisement and Sale) 1984. At Section 4 of those Regulations it was provided that a person should not in the course of a business carried on by him sell any medical preparation or procure the manufacture for sale of any medical preparation except in accordance with the licence granted or renewed by the Minister under those Regulations, to be referred to as a Product Authorisation. The date upon which that provision became effective for any particular product was provided for in a Schedule and, having regard to the category of product which would include anti-D, the date by which Section 4 of these Regulations became applicable to the product anti-D would appear to be the 1st of April 1989.

By section 11 of these Regulations of 1984 it was provided that an authorisation granted or renewed pursuant to the Regulations of 1975 and in force immediately before the commencement of these Regulations should continue in force and have effect as if it were a Product Authorisation granted under the 1984 Regulations.

By the same section it is provided that an application made pursuant to the 1975 Regulations which had not been determined prior to the making of the 1984 Regulations should be treated as if it were an application for Product Authorisation under the 1984 Regulations. Again both the Department of Health, the NDAB and the BTSB acted upon the basis that these Regulations clearly applied to anti-D and that an application made by the BTSB on the 12th of December 1982 for a Product Authorisation pursuant to the Regulations of 1975 which was still pending and had not yet been determined, should be deemed or treated as an application under the 1984 Regulations, pursuant to Section 11 of them.

There are very substantial grounds for reaching a conclusion as a matter of law that the 1975 Regulations never applied to anti-D as a product. The reasons for that conclusion are shortly these. The 1975 Regulations apply to Proprietary Medicinal Products and not to any other medicinal products. By Article 1 of EEC Directive 65/65 which governs the interpretation of the Regulations of 1975, a Proprietary Medicinal Product is defined as "any ready prepared medicinal product placed on the market under a special name and in a special pack". All the evidence before the inquiry indicates that anti-D was never placed on the market under a special name and was never in a special pack, but was just a general medicinal product whose name indicated what it consisted of . The provisions of Article 2 of the 65/65 EEC Directive applied Chapters II to V of it only to proprietary medicinal products and they are the chapters which are relevant. EEC Directive 75/318, referred to in the Regulations of 1975, deals with standards and protocols in respect of the testing of proprietary medicinal products and is not relevant to any of the issues arising here or to anti-D. By virtue of Article 34 of the EEC Directive 75/319, it is provided that Chapters II to V of Directive 65/65 EEC, and that Directive did not apply, inter alia, to proprietary medicinal products based on human blood or blood constituents. These provisions which remained unaltered by

and indicating that incidentally the authorisation for anti-D was due for renewal shortly. In November 1991 the BTSB requested from the NDAB the appropriate application form and documentation for the renewal of the anti-D authorisation. By letter dated the 18th of December 1991 the Department of Health reminded the BTSB that the product authorisation with regard to anti-D would expire on the 1st of April 1988 and set out in some detail information which would be required in order to renew the authorisation. By letter dated the 2nd of February 1993 the BTSB applied to the Department of Health for renewal of the Product Authorisation and enclosed Part 1 of the information requested in the NDAB Guidelines. There was no evidence that any action was taken by either the NDAB or the BTSB in respect of that application. A "one page renewal" was supplied by the NDAB to the Department of Health at its request in late February 1994 and a purported renewal under the 1984 Regulations was granted backdated to the 1st of April 1988. The circumstances surrounding the execution of this document are dealt with later in this report as a separate item but it had no legal effect of any description nor was it based on any particular examination of the product or of the procedures by which it was produced.

It was agreed however by both the NDAB and the Department of Health before the Tribunal that a system of "one page renewal" had been permitted in the following circumstances. If an application for a renewal of a Product Authorisation was made and the Department of Health had not determined it by the time that more than 5 years had elapsed since the expiry of the previous authorisation then a system was permitted of a renewal of the previous authorisation for a period of 5 years. Such a renewal was issued by a one page document extremely brief and formal in character. Such "one page renewals" , the evidence was, were only intended to be issued contemporaneously with an ordinary full renewal based on appropriate documents and information for the next five years. A chronology of the events relating to this Product Authorisation is set out in Appendix I.

Conclusions

Upon the assumption on which the parties were all working of the applicability of the 1975 Regulations and the necessity for a consistently renewed Product Authorisation in respect of anti-D from the 1st of April 1983 up to the date in 1994 when its manufacture was ceased, it is quite clear that the NDAB very substantially failed in its obligations to carry out the sort of inspection and examination of the product which would have been appropriate. By virtue of Article 7 of the 65/65 EEC Directive there was an obligation imposed on the Member States to take all appropriate measures to ensure that the procedure for granting an authorisation to place a Proprietary Medicinal product on the market was completed within 120 days of the date of submitting the application and there is a proviso for in exceptional cases, extending that by a further 90 days but informing the applicant of such extension before the expiry of the 120 days. Quite obviously in relation to the

application made on the 12th of December 1982 by the BTSB this obligation was not fulfilled. Pharmaceutical assessment of the application by the BTSB was in February 1984.

When that process did commence firstly there was very significant delay on the part of the BTSB on a number of occasions in answering queries and supplying requested information. On the other hand it is clear that on the evidence of Mrs. Rafter who was dealing with the pharmaceutical side of this application that by reason of the pressure of work upon her at that time, having regard apart from anything else to the introduction for so many other medicinal products of this necessity for licensing on the 1st of April 1983, she simply was unable to catch up with the task of adequately dealing with the application by the BTSB. It is clear both from her evidence and the documentation of meetings had with the BTSB discussions and papers prepared by them that the examination of the products involved at that time for pharmaceutical assessment was extremely thorough and very detailed.

Dr. Scott, who was then the Medical Director of the NDAB and who has since unfortunately died, was the person who carried out the medical assessment. Her evidence is not available and the evidence of Mrs. Rafter is that Dr. Scott would frequently have not kept minutes or notes of meetings which she had.

Mrs Rafter was in a position to say that there was a very thorough medical examination of these products by the NDAB.

In short, it would appear that the breakdown in the carrying out of its proper and necessary functions in regard to product authorisation by the NDAB in the period concerned, which was a very substantial breakdown, consisted of very long delays in getting to the task at hand rather than any inefficiency or want of care in the carrying out of the actual tasks.

Chapter 11

The Therapeutic Substances Act 1932

Whether Anti-D was a therapeutic substance for the purpose of the Therapeutic Substances Act 1932 and the Regulations made pursuant to it.

The Therapeutic Substance Act 1932 was an Act to regulate the manufacture, import and sale of therapeutic substances and of relevance to the issues arising on this Inquiry, created an obligation on any person who was manufacturing for sale any therapeutic substance to which the Act applied, to obtain for the purpose, from the Minister for Health, a licence. By Section 7 of the Act it was provided that for any person to manufacture for sale any therapeutic substance to which the Act applied, without holding a licence was unlawful, and that a person who acted in contravention of that Section was guilty of a criminal offence.

Under the principle of strict interpretation of a criminal statute it therefore is necessary, if Anti-D is to be held as a matter of law, to be a therapeutic substance to which the Act of 1932 applies, that the definitions contained in that Act and the Regulations made thereunder would be strictly construed. Unless they unambiguously coincided with the product Anti-D, the Act could not apply to it.

The therapeutic substances to which the Act applied are set out in the schedule to the Act and there is a power granted to the Minister for Health by subsequent order to add other substances. The only relevant part of the Schedule to the Act itself is, that it is said to apply to "the substances commonly known as vaccines, sera, toxins, antitoxins and antigens".

The then Minister for Health enacted the Therapeutic Substances (Amendment) Act Regulations 1939 on the 9th September 1939 by virtue of Statutory Rule and Order 1939 number 253. At Section 2 of that Order it is provided as follows "every therapeutic substance of animal origin intended for injection which is not a therapeutic substance specified in the schedule to the Therapeutic Substances Act 1932 is hereby declared to be a therapeutic substance to which the said Act applies".

By Statutory Instrument number 149 of 1955 entitled Therapeutic Substances (Amendment) Regulations 1955, the then Minister for Health on the 29th July 1955 made an order providing that "the Therapeutic Substances (Saorstat Éireann) Regulations 1934 (SR and O 1934 no. 365) shall be amended by the addition to the second schedule thereof of the following part:

Part 5 — provisions applicable to immune serum globulin (human)

1. Immune Serum Globulin (human) is soluble protein which is derived from human plasma serum or tissue and has specific anti-bacterial, anti-viral or anti-toxic activity. Its proper name is "IMMUNE SERUM GLOBULIN (HUMAN)" or such other similar name as may be approved by the Minister.

2. Each batch of immune Serum Globulin (Human) shall be derived from material pooled in accordance with the requirements of the Minister.

Submissions made to the Tribunal asserting that the Therapeutic Substances Act 1932 applied to the manufacture for sale of Anti-D by the BTSB, were framed, in the alternative, on three allegations;

(i) that the Act of 1932 was applied to Anti-D by virtue of the Act itself as a "sera",

(ii) that it was applied by virtue of the Therapeutic Substances (Amendment) Regulations 1939 (SR and O 1939 no. 253) as being a therapeutic substance of animal origin intended for injection which is not a therapeutic substance specified in the schedule to the Therapeutic Substances Act 1932.

(iii) that the Act of 1932 applied to Anti-D by reason of the provisions of the Therapeutic Substances (Amendment) Regulations 1955 (SI. no. 149 of 1955).

(i) With regard to the first submission, I have come to the conclusion that on the evidence before the Tribunal, Anti-D Immunoglobulin cannot be described unambiguously as sera so as to bring it within the provisions of the schedule of the Act of 1932. Dr Barker who is an authority with experience in the World Health Organisation, the Food and Drug Administration of the United States of America, and the Red Cross on blood transfusion plasma collections, plasma derivatives, and the manufacturing and regulatory practice with regard to these matters, when asked as to whether Anti-D was a sera answered as follows:- "Anti-D is in sera or can be extracted out of sera as it is done in fractionation" and having been asked the question again "so it would be sera?" his reply was "yes, it is a component of sera". Even if the schedule to the Act of 1932 applied the Act simpliciter to "sera" amongst other things, these answers would appear to rule out the possibility of interpreting it as unambiguously applicable to Anti-D. It is of importance however, in relation to the interpretation of that Act, that the phrase used as already quoted for the therapeutic substances to which the Act applies under the relevant paragraph number 1 of the schedule, is the substances *commonly known* as vaccines sera, toxins, anti-toxins and antigens. There is no evidence before the Tribunal that Anti-D immunoglobulin was ever commonly known either by the medical profession or by any other group as a sera and indeed references made by a number of different experts with regard to Anti-D and

its making and matters concerning it did not appear to make any use of the word sera as a common description of it.

The conclusion must therefore be that the Act of 1932 by virtue of the schedule attached to it, did not apply to Anti-D.

(ii) With regard to the Regulations of 1939, it was submitted that they should be construed so as to apply the Act of 1932 to Anti-D, on the grounds that the word "animal" used in Section 2 of those Regulations must be deemed to have included human beings and that therefore Anti-D is a therapeutic substance of animal origin intended for injection.

With regard to this submission, there is a relevant provision of Section 13 of the Interpretation Act 1937 which provides that where words used in instruments introduced under a statute have also been used in the statute they must be read to have the same meaning as they have in the principal Act. By virtue of sub-Section 3 of Section 7 of the Act of 1932, it is firstly provided at sub-clause (a) that the Section should not apply to a preparation, by a registered medical practitioner for any of his own patients, or for and at the request of another such practitioner, of a therapeutic substance to which the Act applies, if it is specially prepared with reference to the condition and for the use of an individual patient. Then at sub clause (b), also excluded from the application of the Act is a preparation, by a registered veterinary surgeon for any animals under his care, or for and at the request of another such surgeon, of a therapeutic substance to which this Act applies if it is specially prepared with reference to the condition and for the use of an individual animal. This is quite clearly a use of the word "animal" to exclude human and indeed is an example of a section in which the position of humans there described as patients is dealt with in one sub-clause and the position of animals presumed to be under the care of a veterinary surgeon is dealt with in the other.

Applying the principle of Section 13 of the Interpretation Act 1937 as must be done to the interpretation of the Regulations of 1939, it is clear that they cannot apply under any circumstances to Anti-D which is a substance of human origin.

Though it is not relevant to the legal interpretation of these Acts and Regulations, it is not without practical importance that when in 1984 the Department of Health for the first time suggested to the BTSB that it required a licence pursuant to the Act of 1932 in respect of its manufacture of Anti-D, a query was raised by Dr O'Riordan on behalf of the BTSB as to the grounds on which that was being asserted. The reply received from the Department of Health was to the effect that the Act applied to it by virtue of the provisions of the 1939 Regulations as a substance of animal origin used for injection.

(iii) There remains the assertion that the Act of 1932 was applied by virtue of the 1955 Regulations. Here again it is necessary to apply the test outlined above in this chapter as to whether the words used in the Regulations unambiguously apply to Anti-D. The evidence before the Tribunal with regard to the effect and purpose of the use of the substance Anti-D clearly indicate that it is not intended for nor does it have the effect; of destroying any bacteria;

of destroying any virus; or of destroying any toxic material. Its purpose rather is to prevent the interaction of a particular blood group in the mother with a particular blood group which is in the foetus which she is carrying in her womb. On that evidence it cannot be said to have specific anti-bacterial, anti-viral or anti-toxic activity.

This legal interpretation of the Regulations of 1955 is to a significant extent confirmed by the evidence of Mr McGuinn, the Chief Pharmacist employed by the Department of Health. He stated that he could not see this description as applicable to Anti-D and that in fact there was at the time of 1955, a specific therapeutic substance which is properly described in this part of the Regulations of 1955 and which had the name of Immune Serum Globulin (Human). His evidence on this matter was challenged by Counsel on behalf of Positive Action who suggested to him that whether he intended it or not, his evidence was favorable to the position of the Department of Health who had not sought up to 1984 at least, to apply the Act of 1932 to Anti-D. The Tribunal is quite satisfied that Mr McGuinn gave his evidence wholly independently of any such considerations and as a person with considerable expertise of both practical and scientific kind in relation to the precise issues which arose on this question. It appears therefore that as a matter of law, the Regulations of 1955 also did not apply to Anti-D. Therefore there are no grounds for saying that a licence pursuant to the Act of 1932 was at any time required for the substance known as Anti-D.

Conclusions

The answer to the first two questions raised in Terms of Reference number 7, namely whether this Anti-D was a therapeutic substance under the Act of 1932 and the Regulations made pursuant to it and the question of whether a grant of a Manufacturer's Licence during those years 1970 — 1984 would have been appropriate must be answered in the negative, because quite clearly if the Act did not apply to it, the granting of a licence pursuant to it would have been wholly inappropriate and of no legal effect.

Having regard to the evidence which was taken before the Tribunal on the question of the relevance, as distinct from the strict legal application, of the Act of 1932 and its Regulations to the making of Anti-D, it may be of assistance to state certain conclusions which have been reached by the Tribunal and, whilst they do not bear on the legal interpretation of the Act and Regulations, to an extent set out the factual and practical situation surrounding them. On consideration of the Act of 1932 and the Regulations made thereunder, it is clear that its general structure was an Act, for the purpose of controlling the manufacture for sale of therapeutic substances, which is relatively short and general in its provisions, merely indicating the areas where control would be necessary, and which was followed up from time to time over the period of 60 years while it still remained in force with Regulations made by the Minister for Health to deal with the developing area of therapeutic substances for use both in human and animals. A simple example of this

particular form of development are the Therapeutic Substances (Amendment) Regulations of 1945 (SR and O no. 121) which deal in considerable detail with penicillin.

This view of the legislative structure of the Act to an extent confirms views expressed by Mr McGuinn amongst others, that even if the Act of 1932 had by its own Schedule or by of one or other of the Regulations relied upon, been applied as a matter of law to the product Anti-D, the standards and regulations in existence for testing the process of manufacture, would have been quite insufficient by 1970 or 1980 for the purpose of dealing with the scientific developments which had occurred at that time.

It is of importance that the Act itself and the only regulations relied upon by those asserting that the Act of 1932 applied to Anti-D, were all enacted before Anti-D and the method of its preparation had been discovered by the medical profession.

Part IV

Terms of Reference No. 6

Chapter 12

Supervision of the NDAB by the Department of Health

Whether supervision by the Minister for Health and the Department of Health of the National Drugs Advisory Board in respect of its functions in advising on the Grant of Manufacturing Licence for Anti-D under the medical preparation (Licensing and Manufacture) Regulations 1974 and in advising on the grant of product authorisations under the European Communities (Proprietary Medical Products) Regulations 1975 was adequate and appropriate.

Relationship between the NDAB and the Minister for Health.

As indicated in chapter 3 of this report the NDAB was set up by the Minister for Health in 1966 by virtue of the National Drugs Advisory Board (Establishment) Order 1966 made pursuant to the Health (Corporate Bodies) Act 1961. It was a Statutory Corporate Body and was controlled by a Board, each member of which was appointed by the Minister, and presided over by a chairman appointed by the Minister. The Minister had a right to request any member of the Board to resign and a right to appoint a new chairman at any time to the Board. The Minister had a right, which he exercised, to add to and alter the functions of the Board by Statutory Instrument.

The Board could appoint so many officers and employ so many servants as the Board should at any time think proper and necessary, but must comply with any directions given by the Minister relating to the procedure to be followed. The Minister had a right to declare that with regard to any particular office or employment that the power of making an appointment to it by the Board should not be exercised except with his consent.

The only source of income which the Board had was in respect of applications for amendment of certain licences or product authorisations for medicines for use by humans, the fees on which were payable to the Board and not to the Department of Health. Fees payable in respect of applications for authorisations or licences or for the renewal of authorisations or licences were, up to the dissolution of the Board, paid to the Department of Health. Since 1985 the Board had added to its functions the exercise of powers as a competent authority, with the implementation of an EEC Directive relating to the marketing of veterinary medicinal products. By virtue of that function it was from that time also in receipt of the fees payable upon application for licences

and product authorisation in regard to those products. The total however, of such fees would never have been more than about £200,000 and effectively therefore the entire cost of the carrying out of its functions by the Board fell to be provided by subvention from the Department of Health.

The members of the Board whose number, originally 12, was eventually increased to 19, carried out their services to the Board without remuneration.

It is clear that in effect the relationship between the Minister and the Department of Health and the NDAB was one in which it was possible for the Minister and Department to exercise complete control over the personnel and composition of the Board and over the functions which were allotted to the NDAB and the staff and other resources of which it could avail in order to discharge those functions.

Staff and Workload During the Relevant Period

Mr. Brendan Murphy who was secretary of the NDAB from 1974 till his retirement in 1996 gave evidence of the workload and the staff available to the Board during that period. At the time he joined as secretary in 1974 the officers of the Board consisted of one Medical Director Dr. Scott who also was effectively the Chief Executive of the Board, one pharmacist and one inspector, the secretary and a senior adverse reactions officer. In addition there were five clerical staff of all grades. In that year in addition to the ordinary work of an advisory nature which the Board was carrying out at the request of the Minister for Health it acquired two new responsibilities. It became the adviser to the Minister for Health with regard to applications for product authorisations pursuant to regulations introduced by the Minister in 1974, and also quite separately it became the adviser to the Minister on applications for Manufacturing Licences for Medicinal Products pursuant to regulations also introduced in 1974.

Applications for product authorisations commenced with a number of 50 in 1974, rose to 272 in 1975 and then in 1976 to 1,195. In 1976 the backlog at the start of the year had reached 108 and this rose sharply in 1977, 1978 and 1979 until it was over 1,000 in 1979. By 1983 the backlog was over 2,000 and remained from the years 1985 to 1995 in excess of 2,000. The board also had responsibility in relation to the renewal of product authorisations and by 1985 the backlog at the end of the year in this regard had risen to over 1,000. A consistently high backlog remained from 1986 until 1995 when it had reached over 2,000. The number of new applications was 347 in 1986 and with some figures of over 1,000 it eventually reached 1,298 in 1992 but reduced to 715 in 1995.

Regulations imposing on the Boards functions as the competent authority in respect of veterinary medicinal products, came into effect in 1987 when a total of 172 applications were received which had to be advised upon. This figure rose in the following year to over 300 and in the intervening years between then and 1995, a backlog built up of applications for both new, and

review of existing, applications totalling at times over 1000 and being 832 at the commencement of 1995.

In addition to this burden of work the NDAB was during the same period involved in:—

1. Inspections and advice concerning clinical trials.

2. Applications for manufacturing licences and for the renewal of them.

3. Applications for wholesale licences and,

4. The sampling and analysis of medical products for human medicines and for veterinary medicines.

The staffing level of the Board remained the same in 1975 as it had been in 1974 but was increased in 1976 by the addition of one pharmacist and two clerical grades. By 1978 a Deputy Medical Director had been appointed as had a Medical Assessor. In addition the number of pharmacists had been raised to four but there was still only one inspector. An Assistant Secretary and two additional clerical grades had been added to the staff.

The evidence of Mr Murphy was to the effect that these additions in no way met the requirements which the Board then had for staff and particularly for technical staff. His evidence was to the effect that Dr Scott, who was during all this period, both the Medical Director and in effect the Chief Executive Officer, a Chief Executive Officer not being appointed to the Board until 1995, worked, on his estimate, for something like 80 hours in most weeks on the affairs of the Board. In 18 years whilst he worked with her she had not taken any form of annual leave. Dr Scott retired in 1991 and no successor to the position of Medical Director was appointed before 1995. Two additional Medical Assessors had been appointed in 1988 and this number was increased to five in 1994. The second inspector was not appointed until 1987 and two inspectors remained working during that year and that situation continued in the years 1988 and 1989. By 1990 however, the situation had reverted to only one inspector working.

There was ample evidence before the Tribunal that these levels of staff, particularly on the technical side, available for the carrying out of the work in both the medical and pharmaceutical fields which had to be carried out, was quite inadequate at all times from 1975 onward up to the end of the activity of the National Drugs Advisory Board.

Further it is quite clear from the correspondence between the NDAB and the Department of Health over that period that this situation was consistently made known to the Department of Health and that urgent applications were made during very large parts of the period concerned by distinguished voluntary Chairmen of the NDAB as to the absolute necessity for increasing its technical staff. On a number of occasions the difficulty of increasing the technical staff was a refusal on the part of the Department to sanction an increase. On other occasions an increase was sanctioned but at a level of salary which

clearly failed to attract persons who were considered competent to carry out the tasks.

The only explanation for this want of resources for such a sustained period in the NDAB which was put forward on behalf of the Department before the Tribunal, was that the NDAB could have made better use of the resources which it had and that the Department was examining a reorganisation of it. No detailed evidence was put forward before the Tribunal as to what these failures in the use of resources might have been and even if they existed there does not appear to be any good reason why having regard to the fullness of the powers of control which the Department of Health had over the NDAB, why they could not have been remedied without delay when they first appeared.

It was proved that in 1991 the Government had accepted in principle the alteration of the activities and status of the NDAB which in fact has been enacted by the Irish Medicines Board Act of 1995. It was submitted that the delay in the introduction of that legislation after the acceptance of the principle was a contributory cause to the failure of the NDAB to carry out its functions adequately in respect of the BTSB. It does not appear likely that this is so. If the enactment of the Irish Medicines Board Act 1995 at an earlier stage had, coinciding with it, a provision of sufficient and ample resources to the new Board to carry out the functions which it would be carrying out in relation to the regulation, licensing and control of the Medicinal Products and Veterinary Products, then of course it would have solved the major problem which existed. Such increased resources could however have been provided for the old Board and it was capable of making use of them. There is an obvious advantage in the major provision of the Act of 1995 which vests in the same body, the Licensing authority and the authority to make inspection and enquiry in order to reach a conclusion as to whether a licence should or should not be granted. The division of the Licensing Authority and the Inspecting Authority between the Department of Health and the NDAB which existed up to the passing of the Act in 1995 was, not however, a significant contributor to the difficulties of the NDAB because, on the evidence available, the Department of Health exercised its discretion with regard to the granting of licences or of authorisations without question on the recommendation of the NDAB.

Conclusion

Having regard to the facts above set out the conclusion which must be reached is that in the years from 1975 to 1994, successive Ministers of Health and the Department of Health failed adequately and appropriately to supervise the NDAB in the exercise of its functions concerning the licensing of the manufacture of products by the BTSB and the authorisation of products by the BTSB in that they failed to provide to the NDAB the appropriate and sufficient resources for carrying out those functions properly.

A further question arises of considerable importance and it is as to whether, if the failure adequately and appropriately to supervise the NDAB during this period had not occurred, and if as a consequence the NDAB's carrying out of its functions concerning the BTSB under the manufacturing and product authorisation codes had not failed to be adequate, would the major infection of Anti-D with Hepatitis C have been avoided, or the consequences of it have been significantly reduced.

Having regard to the findings already contained in this report as to the sequence of events which caused the major infection of Anti-D with Hepatitis C, it is clear that it was not the processes being used for the manufacture of that product nor the systems availed of for its storage, distribution or dispatch that caused this infection, but rather the clearest breaches of:—

(i) a number of standard operating procedures in relation to donor selection;

(ii) well established rules for action resulting from complaints of abnormal reaction to an injection of the product, and;

(iii) a total ignoring of the proper standard of recall and destruction which should be applied to a suspect product.

It does not appear that the type of inspection, even if regularly and adequately carried out, associated either with the manufacturing licence or with the product authorisation would have, except by some form of chance, have revealed the particular facts surrounding the use of Patient X's plasma. It is somewhat more likely that an inspection regularly carried out and the questioning that might have been involved in it for either of those two purposes, could have revealed some of the information concerning reaction of recipients of the Anti-D over this period in 1976 and 1977.

Furthermore, there certainly would appear to be a likelihood that if all the persons involved, as they appear to the Tribunal to have been involved, in dealing with the entire incident concerning Patient X, were aware that they would on a regular basis have to face questioning from an inspector dealing with a manufacturing licence or a product authorisation, that it was possible that they might have been less content to make the decisions and avoid the making of further investigations as they did.

To that extent, but to that extent only, it would appear that failure of the Department to supervise the NDAB with regard to these matters and the consequential failure of the NDAB properly to carry out its duties of inspection and assessment in this context has contributed to the infection of Anti-D with Hepatitis C.

It should be noted that detailed particulars of the number of staff employed by the NDAB in the period 1974 to 1995 and a number of tables of the major items of work carried out by the NDAB during that period are appended to this report in Appendix J.

Chapter 13

Supervision of BTSB by the Department of Health

The adequacy and appropriateness of the supervision by the Minister for Health and the Department of Health of the BTSB in respect of its actions in response to the discovery of the Hepatitis C infection of Anti-D in February 1994.

In considering this issue arising under Term of Reference number 6, the Tribunal has broadly interpreted the supervision by the Minister and Department of the BTSB so as to include action which was taken or should have been taken by the Minister and Department to enhance or support action taken by the BTSB in response to the discovery of the infection.

Background

Before considering the issues arising it is necessary to put them into context by having regard to the background against which the Minister and Department were obliged to work on this occasion.

They were dealing with what has been properly described by some of the witnesses as the most devastating calamity of a public health nature which had occurred since the foundation of the State. They were also dealing with a particular form of calamity, namely a major infection of a nationally distributed blood product of which not only had there been no previous experience in Ireland and therefore no pattern of conduct or reaction created in Ireland but which had not been experienced in any other European country either.

What had to be done

It was put by Counsel for the Tribunal to both the then Minister for Health, Mr Brendan Howlin TD and to the then Secretary of the Department, Mr Hurley and they agreed, that the action which they had to, either ensure was carried out, or carry out themselves could be put under seven broad headings and these were as follows:—

1. That no further infection should if possible occur to anybody.
2. That an Anti-D product clearly free from infection must replace the one that had existed, and be immediately available.

3. That they must find out who already was infected.
4. That they must as far as possible sustain confidence in the BTSB and in the blood supply.
5. That they must arrange treatment, counselling and help for the victims of the infection.
6. That they must find out what in fact had happened and,
7. That they must deal with problems which clearly were within the BTSB and its organisation.

The facts

Against that background and having regard to those headings, the following are the facts established before the Tribunal:—

1. *Prevention of further infection*

   The evidence was that the Department had been assured on the 17th and 18th February 1994 that the BTSB would immediately recall all the doses of Anti-D which had been issued and which had not yet been used. That they would do so by immediately telephoning each of the individuals or institutions to which they had been sent and following that up with a letter. They were assured that this was a procedure for recall which had been operated previously by the BTSB successfully. That procedure was apparently accepted and there does not appear to have been any query raised with regard to the success or completeness of that recall until in July 1994 the BTSB reported to the Department that in a limited number of instances, the recall had not been successful. It does not appear that the Department reported that fact to the Minister who says that he has no recollection of being so informed although further queries were raised by the Department.

   Conclusion

   A conclusion has already been stated in this Report that the BTSB's recall procedure was not adequate having regard to all the circumstances. A similar conclusion appears to arise in respect of the supervision of that recall procedure by the Department of Health. Having regard to what was at stake and to what the Department has stated had so recently been revealed to them of the standards of care for safety which had been displayed by the BTSB, it would appear that the proper and adequate supervision of the action of the BTSB at that time would have been: firstly, to insist on a more complete recall including a physical recapture of the doses; and secondly, to provide for an immediate checking and reporting to the Department literally in a matter of days of the successful completion of the recall.

2. *The replacement by a safe Anti-D product.*

As has already been set out in this report, the BTSB were, by February 1994, in active negotiation with the NDAB and relatively far advanced in seeking a licence for the import of the WinRHO product for intravenous injection of Anti-D. On the 18th February 1994, they assured the Department of the adequacy and safety of this product and apparently informed them that it had been licensed both in Canada and by the FDA in the United States. As already indicated, this latter piece of information was incorrect and, upon that fact being conveyed to the Minister by Senator Henry, he directed further stringent enquiries concerning the product. Minutes of meetings had and communications made between the Department of Health, the NDAB and the BTSB in the weeks immediately following the 18th February 1994 establish that examination of this product, the manner in which it was made and its safety and effectiveness was urgently and strenuously progressed so as to permit firstly, of assurance that it was a safe replacement for the infected Anti-D and secondly, to legalise its importation by a licence for that purpose. These investigations were completed in April 1994 and as already indicated, the product has proved safe and efficient.

Conclusion

Having regard to these findings, the Tribunal concludes that the supervision of the Minister and Department in regard to this matter was adequate and appropriate.

3. *To find out who already was infected.*

The major accusation of want of supervision in this context made against the Minister and Department was to the effect that the BTSB should not have been permitted to carry out the screening at all. The conclusions reached and already set out in this Report with regard to the adequacy of the reaction by the BTSB in undertaking the screening, clearly indicated that to have attempted to have the screening carried out by any other group, individual or institution would not have been feasible and would not have been appropriate conduct on the part of the Minister and Department.

A separate criticism was made during the course of the inquiry as to what was described as a failure to oversee that screening and in particular a failure to ensure that the targeted lookback which was a necessary part of the screening, was initiated earlier that it was in 1995. A further criticism was of the form of the screening whereby victims screened by the BTSB and found on the first or preliminary test to be positive indicating the existence of Hepatitis C anti-bodies but not the existence of Hepatitis C virus, were kept within the control and treatment of the BTSB, and not referred for further screening to Hepatologists or clinics.

With regard to the actual screening programme, the documents and communication between the Department and the BTSB, disclose a constant flow of communication in the early months of 1994, informing the Department of the extent of the screening and the number of persons who had been persuaded to come and submit themselves to the tests. Enquiries from the Department were, on the evidence, adequate to ensure that there was no unnecessary delay in this process and it is agreed by both the BTSB and the Department in evidence that the Department had sanctioned any resources that could be obtained in the way of additional staff. There were difficulties in obtaining properly qualified people, necessary for this purpose were immediately agreed to by the Department.

With regard to the second criticism namely a failure on the part of the Department to push forward the lookback programme, the position would appear to be that the Department was in 1994 pressing, and relatively strongly pressing, for the initiation of this programme. The evidence also establishes however, that the setting in place of the programme was not something which could safely or usefully be done without considerable arrangements and without considerable planning. It clearly was best done by the BTSB itself and in a sense the completion to a very large extent of their screening programme and the obtaining of the results from that, was the necessary platform from which it could be launched.

The third criticism with regard to the question of screening is that directed towards the procedures whereby many of the victims who tested positive for antibodies continued to be screened by the BTSB instead of being referred on to clinics or Hepatologists. The details of how this controversy arose in early 1994 have already been dealt with in Chapter eight of this Report dealing with reaction of the BTSB towards discovery in 1994 of the infection. The conclusion is there expressed that the BTSB should have agreed to the request of the Group of Hepatologists for referral of patients on their criteria basis rather than on the basis which the BTSB were putting forward.

Conclusions

With regard to the general criticism that the Department failed adequately to oversee the Screening and Targeted Lookback Programme, the evidence of the communications between the Department and the BTSB with regard to this programme at all relevant times would appear to the Tribunal to indicate an adequate and appropriate reaction. Consideration has been given in this context in particular to the criticism contained in the evidence of Dr Power, that whilst there was plenty of contact between the Department and its officials and the BTSB during the course of this programme, contact was always in the form of ad hoc meetings and there should have been structured, regular meetings with

agendas. To an extent, Dr Power gave this as a view for the purpose of contemplating if it ever should occur, the way to deal with a similar situation in the future and the conclusion of the Tribunal would be that to dub the absence of it a lack of adequate or appropriate supervision by the Department of Health, would be unduly to avail of hindsight. As the position was developing and as the various urgent matters were being dealt with, the form of communication would appear to the Tribunal to have been adequate. With regard to the particular criticism of delay by the Department in putting forward the Targeted Lookback Programme, it has already been indicated that the Department was pressing relatively strongly for this to be commenced on the one hand and it was necessary on the other hand if it was to done properly that careful planning and use of the material daily arriving from the Screening Programme, would be utilised.

In Chapter eight of this Report the conclusion has already been stated to the effect that the BTSB should have agreed to the approach put forward by the Group of Hepatologists in July 1994. Having regard to the fact that the communication from Mr Whelton on behalf of the Group of Hepatologists, was made directly to the Chief Medical Officer of the Department of Health, the Tribunal concludes that the Department should at that stage not merely have submitted the matter for the comment of the BTSB but should, after taking the view of the BTSB, have specifically directed the adoption of the programme as proposed by the Group of Hepatologists. The failure to do so constitutes an inadequacy and inappropriateness of supervision.

4. *To sustain confidence in the BTSB and in the Blood supply.*

It is appropriate to consider this heading in conjunction with heading number 7 namely the necessity for the Department to deal with the problems within the BTSB at that time.

Obviously the first steps to be taken in order to sustain confidence in the BTSB and the blood products and blood supply was to give the maximum possible publicity to assurances that the product now being supplied in substitution for the infected Anti-D which had been withdrawn, was safe and proper. These public assurances were given both by the Department by the statements of the Minister in the Oireachtas, and by the BTSB itself and there was in effect no criticism nor can there be a criticism of those statements and assurances.

The second major step to sustain the confidence of the public in the BTSB and in the blood supply, would be to take steps to ensure that the organisation and running of the BTSB would be such that it could be recognised by those who are dealing with it as having an efficient and safe control. The following are the steps which appear to have been taken in that regard and it is necessary to consider not only their adequacy but also to consider the speed with which they were taken.

(a) Mr Keyes, the Chief Executive Officer of the BTSB was due to retire in 1994 but was specifically requested by the Department to continue his service into the following year. The conclusion must be that this was a wise decision. There is much evidence that the morale of people working in the BTSB was completely shattered in February 1994 even amongst those who had no conceivable responsibility in relation to what had occurred. It now had to face a major screening programme, something which it had never undertaken before and which imposed great strains upon it and upon the people involved in administering it. In particular the two medical officers with special responsibilities for this screening programme, namely Dr Power and Dr Lawlor were, on the evidence, put to a very great strain indeed in carrying out the work that was necessary. At the same time it was essential that all the other activities of the BTSB be maintained at a normal rate and with as much efficiency as possible.

(b) The Chairman of the BTSB retired in the summer of 1994 and the Minister for Health appointed as Chairman, Mr Holloway who had very extensive useful experience in the public service and who was especially charged, on taking the Chairmanship, to improve in particular the level of communication between the BTSB and the Expert Group and also with the Department of Health and also to improve the communication at various levels within the BTSB.

(c) Among the major tasks imposed on the Expert Group when it was set up in March 1994 was to make recommendations to the Minister with regard to any matter relating to the BTSB which the Group considered necessary, with particular reference to systems and standards in place for donor selection, the manufacture and use of Anti-D and any other aspect of systems and standards and for other purposes. The Expert Group in its report issued in January 1995, made extremely valuable recommendations concerning the structure, approach and staffing of the BTSB and its internal organisation. In addition the Minister for Health had sought from Bain & Company a firm of auditors and accountants, who had special experience in the United Kingdom in blood transfusions services, a report on the systems and organisation of the BTSB and on matters which could be implemented to improve them. The result of that survey became available shortly after the publication of the Expert Group Report.

(d) Dr Terry Walsh, Chief Medical Consultant retired in April 1995. On the 1st April 1995, Professor Shaun McCann who was then and still is a Consultant Haematologist in St James Hospital, Dublin and Professor of Haematology in Trinity College, was appointed as National Medical Director of the BTSB for an interim or limited period. In evidence he explained that he was given two major things to do. One was that in April 1995, the blood supply might be in danger as a

result of the adverse publicity associated with Hepatitis C and he was asked to try to maintain an adequate blood supply. Secondly, he was asked to try and give some general advice as to the reorganisation particularly of the medical aspects of transfusion medicine both to the BTSB and also on a national basis. Professor McCann remained as National Medical Director of the BTSB until November 1996 and oversaw during that period major changes in the internal arrangements and structures of the BTSB and in its relationship with the medical profession in general and with the users of blood products in particular, all of which formed part of the recommendations of both the Expert Group and the Bain Report. In particular new consultant appointments to the BTSB are linked with university teaching hospitals. In addition during that period of Professor McCann's activities as National Medical Director, the clinical service of the BTSB has been maintained at a very high level. For the period of 20 months, January 1995 to August 1996, the BTSB has issued 239,841 red cells, 114,058 units of platelets and 54,590 units of plasma to hospitals in the country. In addition 230 corneas and 55 heart valves were issued and bone marrow donors found for patients. The supply of blood from blood donors was maintained and in fact increased during that period.

(e) Mr Liam Dunbar who is a qualified RGN, holds a diploma in Health Economics and is a member of the Institute of Health Service Managers, was appointed as Chief Executive Officer of the BTSB in April 1995. He was appointed to that post having been Chief Executive Officer of St James Hospital, Dublin for 10 years since 1985 and he was specifically requested by the Minister for Health to assume the position of CEO of the Blood Transfusion Service Board so as to reorganise it.

Upon appointment Mr Dunbar in effect proceeded immediately to implement the recommendations of both the Expert Group and of the Bain Report in regard to a major reorganisation of the BTSB. This included the proper structuring of the Consultants' Group and of the Medical Committee and, as Chief Executive Officer, Mr Dunbar is a member of both these Groups. The medical matters immediately dealt with are set out in Appendix K to this Report as are the management matters which were immediately undertaken by Mr Dunbar. A reorganisation plan based on the needs of the BTSB over a period of 5 years or more, was prepared by Mr Dunbar in conjunction with the Chairman, Mr Holloway and the Medical Director, Professor McCann and was approved by the Board of the BTSB and by the Department of Health in May 1996. It was presented and explained to the staff and their representatives in the following weeks and they committed their support to it.

This reorganisation plan resulted in part from a series of consultations with staff to obtain their views towards the future reorganisation. In addition a development plan was created which identified a 3 year implementation period together with the capital and revenue costs involved in that, and was prepared and submitted to the Department of Health in July of 1996. Details of the development plan for the period 1996 to 1999 are set out in the Appendix L attached to this Report.

The review of the building requirements of the BTSB has been carried out in accordance with the Report by the British Medicines Control Agency issued in February 1995 with regard to the Board's facilities in Dublin. This was followed by a report from an engineering firm, Jacobs Engineering with regard to the capacity of the BTSB to achieve its guidelines in good manufacturing practice in it's present location. As a result of this it became clear that the only resolution to the problem was to construct a new blood transfusion headquarters in Dublin to the maximum proper standards, and the Department of Health and the Board of the BTSB and its senior staff have agreed on this fact.

The siting of buildings provided for the BTSB in a close relationship to a teaching hospital is one of the desired developments which is considered to be of great importance. Plans are at present being actively considered with regard to the siting and construction of the buildings which the Department has agreed in principle must start as soon as possible.

Conclusions

(a) The decision to extend the term of office of the Chief Executive, Mr Keyes made by the Minister and Department was, in the view of the Tribunal, a wise decision. The continuity of his direction was, for a period at least, essential in the view of the Tribunal for the effective continuance of the activities of the BTSB which have been outlined above.

(b) The appointment of Mr Holloway as a new Chairman with the specific responsibilities which are noted again appears to have been an adequate and appropriate step to take. His appointment commenced in September of 1994 and he took immediate steps which appear to have been substantially effective to increase the communication by the BTSB, both to the Expert Group and to the Department. He was also substantially involved in the decision made by the Department of Health to employ the services of Bain & Company for a survey and report on the entire structures and arrangements internal to the BTSB. This was therefore an adequate and appropriate reaction.

(c) The Tribunal concludes that it was a reasonable and adequate approach for the Minister and the Department to await the result of the examinations of the BTSB and its internal structures, being conducted by the Expert Group and by Bain & Company, before implementing the necessary alterations in those structures, in some of the staffing levels, and in the procedures for communication between administration and staff and between scientific and administrative officers in the BTSB. This aspect of their supervision was therefore adequate and appropriate.

Conclusions (d) and (e)

The appointment of Professor Shaun McCann as National Medical Director of the BTSB in April of 1995 and the appointment at the same time of Mr Liam Dunbar as its Chief Executive Officer, were both immensely wise and advantageous steps for the Minister to take. The alterations they jointly made in the structure, relationship and apparently in the morale of the BTSB have been extremely advantageous. The alterations in the medical structure and in the relationship between the BTSB and other medical services, and the management and physical reorganisations proposed, in many instances already implemented as a result of their joint activity, has manifestly improved the entire situation as far as the BTSB is concerned. There did not appear to be any significant criticism before the Tribunal as to the appropriateness of the steps which were being taken. The criticism that occurred was a suggestion that these steps should have been taken much sooner after February 1994 than they were.

The Tribunal has carefully considered those submissions which were quite forcefully advanced but has reached a conclusion that having regard to the matters which had to be done as a matter of urgency by the BTSB from February 1994 on, in relation to screening and targeted lookback as well as to the maintenance to the existing service, that any more impetuous and therefore more rapid intervention with the entire organisation than that represented by the appointment in April 1995 of Professor McCann and Mr Dunbar and the reorganisation which they undertook, would have been more likely to impede progress in the BTSB than to assist it. Having regard to that conclusion it appears to the Tribunal that in the context of these questions, the supervision of the BTSB by the Minister and Department of Health has been adequate and appropriate.

5. (a) *Treatment, counselling and help for the victims of the infection.*

In March 1994, the then Minister for Health, Mr Howlin put into place a hospital service providing assessment and treatment, including prescribed medication, free of charge for persons affected by Hepatitis C. That hospital service was provided in six designated hospitals:—

(i) St James' Hospital, Dublin

(ii) Beaumont Hospital, Dublin

(iii) Mater Hospital, Dublin

(iv) St Vincent's Hospital, Dublin

(v) Cork University Hospital

(vi) University College Hospital, Galway.

The question as to at what stage of testing victims of Hepatitis C should have been referred to Hepatitis C units has already been dealt with in Chapter Eight of this Report in so far as that deals with the action of the BTSB. In this chapter of the Report, dealing with the supervision of the BTSB by the Minister and Department, whilst there was evidence from time to time during the period since treatment first started in 1994, of apparent deficiencies in individual places and in individual units with regard to the treatment and some more general complaints of insensitivity in some units, the overall picture appears to be that the treatment in so far as treatment has been developed by the medical professional in general for this unfortunate disease, was adequately provided in these units.

With regard to the question of treatment however, a much more serious and long-term problem has been the approach of the medical services provided by the State to the long-term treatment of sufferers with Hepatitis C. That has been carefully presented and strenuously argued on behalf of the victims of infection directly or indirectly connected with Anti-D by the Positive Action Group. As a result of a consultation with them and with the other Groups representing sufferers from Hepatitis C, a Bill which eventually became known as the Health (Amendment) Bill 1995 was introduced and passed by both houses of the Oireachtas and came into operation on the 23rd September 1996.

The services to be provided free of charge to eligible persons, that is to say sufferers from Hepatitis C arising from the blood products are as follows:—

(a) General Practitioners, medical and surgical services in relation to all medical conditions by General Practitioners chosen by the eligible persons themselves.

(b) Prescribed drugs, medicines, medical and surgical appliances.

(c) Nursing services specified in Section 60 of the Health Act 1970.

(d) The home help service specified in Section 61 of the Health Act 1970

(e) Dental ophthalmic and aural services and dental, optical and aural appliances.

(f) Counselling services in respect of Hepatitis C and such other services as may be prescribed.

For the purpose of carrying these services into effect, the Minister for Health has arranged for the eight Health Boards to appoint a Liaison Officer, each to act as a contact point for individuals and with the various interest groups whose members will be availing of services under the Act.

(b) *Counselling*

This Report in Chapter Eight dealt with the action of the BTSB concerning counselling and with the criticism made of that. It is clear on the evidence that the Department of Health were at all material times kept aware of the criticism of the BTSB counselling which was being made in particular by Positive Action on behalf of its members. Evidence was given that in addition to all other forms of communication and coming within the extended meaning of counselling, that the Department of Health received a very large number of written communications from sufferers which were dealt with, and in which whatever action by agencies could be organised, was provided. In addition telephone calls were also received in very large numbers which were given priority response. The ultimate provision of counselling of a satisfactory nature which was achieved eventually in the year 1995 in most areas in the country, was largely due to the intervention of the Department of Health, but a criticism still existed that this was done too slowly and that an earlier intervention in the problems of counselling should have taken place. The counselling services that were put in place when they were put in place independent of the BTSB, were of course funded by the Department of Health.

(c) *Help for the victims of the infection*

The necessity of help for the victims of the infection in so far as it relates to the responsibility of the Minister and Department of Health, would seem to fall into three sub-categories. Firstly it was important that support for Groups formed to support and assist the sufferers from the Anti-D infection and its consequences, such as the Positive Action Group, should be provided. Secondly, the immediate expenses of attending for, and travelling to, testing and for treatment required to be dealt with. Thirdly it was appropriate that some mechanism of compensation for what had been wrongfully done to the victims should be provided.

(i) Support for Groups

Evidence was given of good communication between the Positive Action Group in particular, and the other Groups as well, with the officials of the Department of Health and with successive Ministers of Health concerning all the problems arising as a result of this infection. In addition substantial financial support was given to all the organisations involved with victims of the infection. In particular in framing the legislation previously referred to for health care, the views and suggestions of the various groups were obtained and considered.

With regard to the immediate expenses, an ex gratia expenses scheme was put into operation by the BTSB and funded and organised by the Department of Health as early as February 1994 to alleviate the hardship that might be experienced by any person diagnosed as Hepatitis C positive and to enable people to obtain the appropriate screening and treatment. That scheme was extended in July 1995 to blood transfusion recipients. It has been critised in the first instance on the basis that it was insufficiently publicised and that some of the people entitled to avail of it were not aware of its existence. It has however apparently worked reasonably satisfactorily since that time.

(ii) Compensation

The Government by a declaration of policy issued in December 1994, committed itself to fair compensation for women infected by Hepatitis C virus from Anti-D.

A decision was taken in April 1995 to establish as a matter of urgency, a Tribunal which would assess compensation on an ex gratia basis in respect of Anti-D recipients who were infected with Hepatitis C and partners and children of theirs who were also infected.

After the announcement of this decision, a series of meetings took place in relation to the provisions of the scheme of compensation. The views of Positive Action were according to the evidence given by the Minister for Health, Mr Noonan, taken on board as far as possible in the formulation of the scheme and the Government announced the scheme in June 1995. In September 1995 the scheme was extended to included persons who had contracted Hepatitis C from a blood transfusion or other blood products.

In September 1995, the membership of the Compensation Tribunal was announced and the main elements of the Health Package which eventually became the Health Amendment Act 1996, were also announced. Positive Action expressed

themselves as unhappy with some elements of the compensation scheme. Further negotiations took place, including negotiations between lawyers representing the State and those representing the Groups involved and eventually amendments were made and an amended compensation scheme was approved in December 1995. A Compensation Tribunal was established on the 15th December 1995. In November 1996, a further amendment was made to the scheme, giving a claimant of an award made by the Tribunal, up to one month after the publication of the Report of this Tribunal of Inquiry to decide whether to accept the award. Evidence was given that the Compensation Tribunal has to date received 1,653 applications, it commenced regular hearings on the 11th March 1996 and has heard 233 cases. The awards made range from £15,200 to £453,904 and a sum of approximately £25.9m has been awarded in compensation so far.

In addition to these specific items dealing with treatment, counselling and health, two other steps have been taken which are of relevance. The first is that in November 1996, a statutory Consultative Council on Hepatitis C was set up to advise and make recommendations to the Minister for Health on all aspects of Hepatitis C including health and counselling services and the funding organisation and delivery of those services. In addition the sum of £1m has been made available to the Health Research Board over the next five years for the purpose of providing for research programmes in connection with Hepatitis C.

In September 1995, a National Optional Testing Programme was established whereby any blood transfusion and blood product recipient who wished to avail of testing for Hepatitis C, could attend their General Practitioner and he could forward a blood sample taken from such person to the BTSB.

Conclusions

With regard to the issue of treatment, the major criticism has been that the arrangements for it, publicity surrounding those arrangements and the certainty of them, came too slowly, rather than that the eventual programme which is now in statutory form, was particularly inadequate. It was certainly wise and of value that there should have been relatively full and lengthy consultation both with Positive Action and other interested Groups concerning the final or eventual Health Care Package. It is easy to understand the urgent desire of people who suffered this tragedy to have some sense of security for their future. There are many aspects of that future, for example

employment, insurance and the other matters that have been mentioned in which absolute security cannot be provided, though compensation may attempt to make up for the difficulties which face victims of this disease. The desirability of providing a secure Health Care Programme into the future and doing so urgently, was therefore very obvious.

On balance the position would appear to the Tribunal to be that the Health Care Package, when finally provided, was appropriate and that it was, when provided, adequate but that some element, though not a great one, in the delay in bringing such a package into statutory form, was not an adequate response to the particular urgency which attached to that task. Particular delay which appears relevant to this is some part, though of course not all, of the period from the time when the Health (Amendment) Bill 1995 was approved by the Government, and the time when it came into operation on the 23rd September 1996. Subject to that inadequacy, it would appear that in general the supervision by way of additional provisions by the Department and Minister for Health of the necessary arrangements for treatment of victims of Hepatitis C was adequate and appropriate.

With regard to counselling, the problems arising were brought to the notice of the Department of Health and the Minister for Health in the summer of 1994 and steps were then taken to try and solve the problem arising from the inappropriateness, as Positive Action saw it, of counselling by the BTSB. Subject to the matter already dealt with concerning the referral of people at an earlier stage than was being operated, the steps taken by the Department and Minister in order to try and solve the problems of counselling, would appear to have been adequate and appropriate.

With regard to help for the victims the support given to Positive Action both in communications with them and in funding, and to the other Groups, would appear to have been adequate subject to one reservation. When the problem of the circulation, to sufferers of Anti-D, of information concerning Positive Action surfaced in April 1994 and was made known, as it apparently was to the Department, the Department should then have rapidly insisted on some compromise arrangement which would not breach the confidentiality owed by the BTSB to victims of Hepatitis C, but would have let people who wanted to know of the existence and arrangements with Positive Action. Something similar to what eventually became established by 1995 could then have been introduced at an earlier time. Reaction to that particular problem must therefore be considered as being inadequate.

With regard to the compensation for the victims of infection with Hepatitis C two criticisms are made, one was that it was too slowly

introduced and the other is that it is a "no fault" system of compensation, that it has not been enshrined in a statute, and does not involve an apology by, or finding of wrong against, the BTSB.

It appears to this Tribunal that the main necessity was to ensure that further harm and loss would not occur to persons who had suffered from Hepatitis C by reason of the absence of a system of relatively rapid determination of the compensation to which they were entitled. It was correct for that to be introduced on the basis that it was an alternative only to a right to sue in the Courts, and that even the processing of a claim before the Compensation Tribunal should not be a bar to taking the option of suing in the Courts. That being a necessary characteristic to be attached to a scheme of compensation, it would appear an adequate and reasonable reaction to the particular problem that it should be on a "no fault" basis. The absence of a statute enshrining it does not appear to have had any practical effect from the point of view of the object which it is desired to achieve.

With regard to the speed with which it was introduced, it quite clearly required considerable negotiations over a sustained period with the interested Groups and has already been once amended on further negotiation. To have introduced it earlier would apparently have led to the possibility that people would in large numbers have decided not to avail of it. As finally introduced, it has been, as the figures show, substantially availed of. The reaction therefore on this ground also must be considered adequate.

6. *To find out what in fact had happened.*

In March 1994, the then Minister for Health, Mr Howlin, established the Expert Group to examine and report to him amongst other things the following:—

> "*All the circumstances surrounding the infection of the Anti-D Immunoglobulin product manufactured by the Blood Transfusion Service Board,*" and "*the systems and standards in place for donor selection, the manufacturing process and use of the Anti-D Immunoglobulin produced by the Blood Transfusion Service Board*".

This constituted the immediate and certainly timely response of the Department of Health and of the Minister to the obligations to find out what happened. The appropriateness of it is challenged upon the following basis. Evidence was given by the Officers of the Department of Health and particularly by Mr Devitt, the Assistant Secretary with special responsibility for the BTSB and Mr Hurley, the Secretary of the Department that in the lengthy meetings held over the weekend of the 17th to 21st February 1994 when the fact of this infection of Anti-D first became known to the Department of Health, that they had significant

difficulty in obtaining the full facts from the BTSB and its officers and that they had to, as it were, extract rather than be given facts as they wanted them.

This was disputed and disputed quite strenuously on behalf of the BTSB who apart from simply denying that they had been slow in giving the information, stated what the impression they got at these meetings was that Officers of the Department of Health appeared to expect to be given with great certainty all the characteristics of the disease of Hepatitis C and in particular the prognosis that was attached to it, whereas nothing like certainty in regard to those matters was available at that time.

The assertion is made that once that was the impression of the Officers of the Department, that it gave great strength to the concept of appointing a Judicial Inquiry with powers of compelling witnesses and documents, rather than any other form of Group to examine the question of what happened and why. The decision to be made at that time was clearly a decision by the Minister for Health himself. It was made as a result of lengthy discussions at a conference at which the Minister, his Special Advisor Dr Collins, the Secretary of the Department Mr Hurley, and Mr Devitt the Assistant Secretary with special responsibility for the BTSB were present. Evidence was given by all those who attended of what occurred on that occasion. Mr Devitt undoubtedly favoured the setting up of a Judicial Tribunal and expressed as his main reason for that, what he considered to be the unsatisfactory nature of co-operation of the BTSB at the meetings which over the last few days had been held. Neither Mr Hurley nor Mr Collins apparently expressed any particular recommendation to the Minister but both of them pointed out the advantages and disadvantages of an Expert Group which was the only obvious alternative, and equally of the Judicial Tribunal. Amongst the advantages expressed with regard to an Expert Group was that it was on experience likely to be much more speedy than several Judicial Inquiries had been that had occurred. Regard was had to a recent experience of the Department of Health when an Expert Group enquiring into a child care incident of incest in the country had reported within 9 weeks with a comprehensive report. A contrast was expressed between that a very lengthy Judicial Inquiry that was still pending.

Mr Howlin in evidence stated that after hearing the views expressed at that conference, he carefully considered the advantages and disadvantages of both a Tribunal and of an Expert Group, and that he decided that in the interests of speed and efficiency that he would prefer to appoint an Expert Group and this he immediately did have and consulted the appropriate members.

That Group got to work straight away and was assisted by an officer seconded to it from the Department of Health — Mr. Fergal Lynch. It

interviewed people and obtained written submissions and written documents from people and reported in January of 1995. As already indicated, amongst its functions were recommendations with regard to the re-organisation and arrangements for the BTSB. The personnel of the Group consisted of Dr. Miriam Hederman O'Brien, Chairman, Dr. Alastair Bellingham, Professor of Haematology at the King's College School of Medicine, London and President of the Royal College of Pathologists, and Dr. Caroline Hussey, Lecturer in the Department of Industrial Microbiology UCD.

Conclusion

Having considered the evidence as to how the decision was formed and the basis on which it was formed, and looking at the situation as it was at the time the decision had to be made, this Tribunal is satisfied that the decision of the then Minister for Health., Mr Howlin to set up an Expert Group was an adequate and appropriate response to the problem of trying to find out what actually had happened in regard to this infection of Anti-D.

A separate criticism was made based on the fact that by July of 1994 the Expert Group reported that it was receiving inadequate cooperation and information from the BTSB.

The evidence was that Mr. Holloway when appointed a new Chairman of the BTSB as has already been indicated, was specifically charged with the task of ensuring that full co-operation should be given to the Expert Group. He applied himself to that task and the Expert Group finally reported that it had received full co-operation from the BTSB. The suggestion was made that when the report of a lack of co-operation in July of 1994 was made to the Minister for Health, that he should then have set up a judicial inquiry. His reply to that was to the effect that to defeat or abolish the functions of the Expert Group at a time when it was substantially into its task would have been quite improper and inefficient.

Conclusion

The Tribunal concludes that the decision to force the BTSB, through the appointment of a Chairman specially charged with that task, to co-operate with the Expert Group which was made by the Minister in July of 1994, was an adequate and appropriate reaction and that to have set up a judicial inquiry at that time would have been quite inappropriate.

A further suggestion was made arising out of the revealing of the quantitation reports concerning the plasma from Patient X which mentioned infective hepatitis and which were discovered by the BTSB in March of 1996 in the action being brought against them that at that time the then

Minister for Health, who was Mr. Michael Noonan, should have immediately set up a Tribunal of Inquiry on the basis that he should have then known that the BTSB had not co-operated with the Expert Group which it should have and that the unease of the victims and the unease of the public would justify a judicial inquiry.

Conclusion

This Tribunal has in chapter fourteen of the report set out the views which it has formed concerning the effect of these quantitation reports containing the words "infective hepatitis", on the general conclusions with regard to what occurred on this occasion. Having regard to those views it finds that the refusal of the Minister in March of 1996 to set up a Tribunal of Inquiry was quite adequate and appropriate.

7. *That they must deal with problems which clearly were within the BTSB and its organisation.*

In dealing at 4 with the obligation of the Minister of the Department to supervise the BTSB so as to sustain confidence in it and in the blood supply, the obligation mentioned at 7 to deal with the problems within the BTSB has also been dealt with and does not require further comment here.

Part V

Terms of Reference No. 8

Chapter 14

Information not available to the Expert Group.

The relevance to the foregoing of any further documents, testimony or information not available to the Expert Group which became available subsequent to the completion of the Group's Report.

It is necessary shortly to set out a number of factors which affect the issues arising under this Term of Reference. The Expert Group's Report was published early in 1995 as a result of information obtained from the various parties involved in the matters in issue, by discussions with individuals, and by the obtaining by the Secretary of the Group, Mr Fergal Lynch, of documents from the various parties. It did not of course have any power to direct discovery of documents nor to compel the attendance of witnesses to it. It did not take "evidence" in the sense of having formal examination and cross examination of persons supplying information to it.

The position of the Inquiry conducted by this Tribunal was of course in relation to its powers, entirely different. It had a power which it exercised of compelling discovery of documents by all relevant parties and compelling the attendance of witnesses. It had the services of a legal team, who having examined all the documents, consulted with the witnesses, then examined them, and they were subjected to cross examination by various other interested parties.

Quite apart from these major differences in the procedures available to the Tribunal as distinct from the Expert Group, in the meantime litigation had been commenced by the late Brigid McCole against the BTSB and others in which discovery of documents had been ordered. This introduced into each of the parties or institutions involved, the necessity for independent lawyers to examine in their entirety the documentation available relevant to issues arising in that action, many of which were common to issues arising on the Terms of Reference of this Tribunal. Quite apart from the availability of the documents so discovered to this Tribunal, the witnesses from the various parties giving evidence before the Tribunal had themselves an opportunity of considerable value to refresh their memory as to details from perusing the documentation discovered by them and by others.

As a consequence of these major differences a very great deal of detail became available to the Tribunal which was not available to the Expert Group. Some of it would have had no real relevance to the Terms of Reference but simply be part of a continuous narrative of events, other parts of it had some but little relevance to the issues, and some had significant relevance.

In dealing with this Term of Reference therefore the Tribunal has sought to identify important matters which became available to it and which were not available to the Expert Group and to identify those which have a definite and significant relevance. These matters are as follows:—

Statement of Patient X

The Expert Group did not have the benefit of any statement in writing or orally from Patient X. Accordingly they did not know that Patient X had not been asked for nor had she given her consent to the use of her plasma in the manufacture of Anti-D. The relevance of that fact which became known to the Tribunal did not bear on the actual causation of the infection of Anti-D by the use of the plasma from Patient X, but it did have a bearing on the breach by the BTSB of a very significant ethical standard which should have been observed by them in relation to donors of blood and it did also have a bearing on the consequent additional distress which was suffered by Patient X.

Quantitation Reports marked "Infective Hepatitis" dated November and December 1976

In approximately the month of March 1996, Dr Emer Lawlor while searching the files and documents in the BTSB in relation to the action brought by the late Brigid McCole, by chance found a box of documents and, noticing the name of Patient X upon them brought them for consideration. This box of documents contained copies of the quantitative testing applications made in respect of the plasma exchange of Patient X in November and December 1976 which are referred to in Chapter 4 of this Report. They were immediately discovered and the fact of their discovery became public. It is quite clear that the existence of these particular documents and of the diagnosis of "infective hepatitis" written on them was not information which was available to the Expert Group.

Documents which were available to the Expert Group on the evidence before the Tribunal were firstly, a document dated 25th February 1994 and which was signed by Dr Terry Walsh, Dr Emer Lawlor and Dr Joan Power and which reads as follows:—

> *"The medical consultants wish to record that Dr E. McGuinness contacted Dr Walsh and Dr Lawlor on Thursday 24th February 1994 after review of his patient's case notes as requested by Dr Walsh. Dr McGuinness advised that a history of hepatitis had been reported by him to the Board. On foot of this information, Dr Walsh reviewed the Anti-D 1977 file together with Dr Lawlor and Power at 7pm. The information revealed was reported in full by Dr Walsh to the CEO in a written report.*

This was sent by the CEO to the Department on Friday 25th". The document then contains a note about arrangements for a convening of the Medical Sub-Committee to discuss this new information.

The Expert Group also had available to them the letter written by Mr Keyes CEO of the BTSB to the Secretary of the Department of Health on 25th February 1994 which apparently was the sending of the Report referred to in the document, signed by the three consultants of the BTSB. That letter deals with specific batches of plasma and the dates on which they were made and then states as follows:—

> *"Further to more detailed examination, it emerges that the Board had, in fact, been informed that the patient had an episode of jaundice early in the course of her treatment which led to an initial investigation of her Hepatitis B status. These investigations were reported on 9/12/76 and showed no evidence of Hepatitis B. As Hepatitis B was excluded, it is apparent that it was then decided that the plasma from the patient could be used in production of Anti-D.*
>
> *It was not until July 1977 that the clinical reports of Hepatitis (jaundice) in Anti-D recipients were first recorded at which time production of Anti-D from the patient's plasma had ceased and there is no evidence in laboratory log books of production of Anti-D using that plasma beyond the 4/7/77. On receipt of the clinical information in July/August 1977 further investigations to exclude Hepatitis B were carried out. These studies, including EM and immunoEM were reported in early September 1977 as being negative for Hepatitis B."*

It is clear from the terms of the Report of the Expert Group that they were aware that the normal practice of the BTSB was not to use blood donations from persons with a history of jaundice of a potentially infective origin. The meaning of jaundice of a potentially infective origin would appear to have been amplified by a letter quoted by the Expert Group in their Report in which the BTSB defined jaundice not related to infectious causes as being "ie neo-natal jaundice, gallstones etc". cf. Report, paragraph 3.60, page 35. The Expert Group was also informed of the more general provision operable from May 1968 in the BTSB that the practice of accepting donor volunteers who have at any time had infectious hepatitis or jaundice of unknown origin is to be discontinued forthwith. cf. paragraph 361, page 35.

The conclusion reached by the Expert Group and stated at paragraphs 3.62 and 3.63 of the Report at page 36, concerning the origin and prime cause of the infection of Anti-D in 1976 and 1977 is in its effect though possibly not in its terms, very similar indeed to the conclusion reached by this Tribunal in Chapter 4 of the Report.

The conclusion must therefore be that, whilst undoubtedly the existence of these quantitative reports and their contents was of considerable relevance at the Inquiry before this Tribunal, that it does not constitute new dominant or

fundamental medical evidence. It does permit of an assessment of the particular responsibility which must be attributed to the late Dr Wilkinson who signed each of these reports, but it does not form a foundation for any particular conclusion which would not have been reached without them in regard to the general wrong doing involved in the use of the plasma from Patient X.

This issue with regard to the relevance of these quantitation reports was raised as a criticism of the Department of Health and of Mr Noonan, the Minister for Health, at the time of their becoming known in March 1996, in that they were not reacted to in the form of immediately setting up a Tribunal of Inquiry. That criticism was of course based on the assertion made that they were of fundamental importance and that they altered the entire situation concerning the events which had happened in 1976 and 1977. Evidence was given that both Mr Noonan and the Minister for State, Mr O'Shea took the attitude in reply to questions in Dáil Éireann, that this did not constitute any fundamental difference in the information available with regard to the wrongful use of Patient X's plasma.

Having regard to the conclusions above reached, this attitude would appear to have been correct.

One page renewal of February 1994

A significant amount of evidence became available to the Tribunal from officers of the Department of Health and of the NDAB concerning the issue of a "one page renewal" of the Product Authorisation for Anti-D to the BTSB in February 1994, which was clearly not available to the Expert Group.

This evidence may be summarised as follows.

Mr Michael Collins, who was employed as a Clerical Assistant in the Department of Health in 1994 worked in the Medicines Division. His immediate superior officer was Ms Madeline Meade and his superior officer over that again was Mr Thomas O'Neill, a Higher Executive Officer. Mr Collin's work involved acknowledging receipt of Product Authorisation applications and renewals, and receipting and acknowledging the appropriate fees. He also did photocopying, filing and other tasks assigned to him. He stated that on what he believes was the 23rd February 1994, he found on his desk the file relating to the Anti-D Product Authorisation of the BTSB. Other evidence would indicate that this file had been taken out of its ordinary filing situation by Mr McGuinn of the Department of Health for some purpose unrelated to the question of any one page or any other renewal of the authorisation, and had been simply left back on Mr Collins's desk.

Mr Collins before replacing the file in its proper position looked at it and noticed that there had not been any renewal of the Product Authorisation for more than five years. He brought that to the attention of his superior Mr Thomas O'Neill and stated that he was then instructed to request a one page renewal form from the National Drugs Advisory Board. As a result he phoned the NDAB and spoke to Deirdre McKeever, employed by the Board and

asked her to supply a one page renewal to the Department of Health. He had not before requested a one page renewal nor had he encountered one and he stated that he did not do this of his own initiative.

The evidence before the Tribunal was that, in regard to one page renewals which are already referred to in Chapter Ten of this Report, when they were issued by the Department contemporaneously with a fully supported renewal for the period after the lapse of five years, that the form of them was actually filled in on paper headed the Department of Health by the NDAB.

The next relevant witness was Ms Madeline Meade who was an Executive Officer in the Medicines Division in February 1994 and she would have been Mr Collins's immediate superior and reported to Mr O'Neill. She recalls a phone call being made by Mr Collins in her presence to the NDAB in which he requested a one page renewal and stated that he was doing so on behalf of Mr Tom O'Neill. She had no recollection of seeing the document coming to the Department of Health nor had she any recollection of dealing with it afterwards. She was asked as to whether she thought it strange that Mr O'Neill had instructed Mr Collins to apply for a one page renewal in respect of a product that had been withdrawn from the market and stated that she thought it was strange that Mr Collins should be making a phone call in connection with a document, that is to say the one page renewal, as normally he only dealt with applications.

Ms Deirdre McGeever gave evidence that she was in February 1994 a Grade 4 administrative assistant with the NDAB and responsible to the Secretary. On the 23rd February 1994 she received a phone call from Mr Michael Collins of the Department of Health asking for a one page renewal for Anti-D. She stated that Mr Collins would have given her the name of the product, that is to say Anti-D and the product authorisation number which was all the information she required for this very short document known as a one page renewal. She then gave instructions to a typist to type a one page renewal for the production authorisation for the Anti-D. She checked it after it had been typed and it was sent as far as she knew, back to the Department of Health.

Mr Tom O'Neill gave evidence that in 1994 he was a Higher Executive Officer in the Medicines Division of the Department of Health and that one of his functions was in relation to product authorisations. He was the most senior officer in charge of the issuing of product authorisations in the Medicines Division of the Department and would be answerable to an Assistant Principal who at the time was Mr John Gillen. He gave evidence that Mr Collins told him that the Anti-D file showed that there was a period when the product authorisation was out of date and that the second product authorisation was in fact due. Mr O'Neill denied that at the time of this conversation he knew that there was a matter of considerable controversy in relation to the Anti-D. When asked what he told Mr Collins to do, Mr O'Neill answered as follows:—

"I did not tell Mr Collins to do anything. I told him what would be done in the circumstances. I told him that in circumstances where there was that long a period, we would have to issue a "one page renewal document".

Under further questioning he stated that he had understood that Mr Collins was asking what would be done when a new licence was being issued for the future period. Subsequently, Mr O'Neill agrees that he signed the one page renewal which had been sent by the NDAB to the Department. He stated that the document was presented to him, in amongst many others documents and that he signed it without reading it. Mr O'Neill stated in the course of his evidence that part of the Medicines Division's function over which he presided was the issue of reminders to bodies that their Product Authorisation was due for renewal.

It is clear from the provisions of paragraph 5.23 of the Expert Group Report, on page 84, that the information before the Expert Group was that the issuing of this one page renewal of the Product Authorisation for Anti-D in February 1994, was done as part of a normal procedure and was not done for the purpose of deflecting attention from the previous absence of a Product Authorisation.

The evidence before the Tribunal leads inevitably to a different conclusion. That conclusion is that Mr O'Neill, who would have had the immediate responsibility as part of the functions of the Medicines Division, of which he was the senior officer, did in fact direct Mr Collins to seek a one page renewal from the NDAB and did in fact knowingly sign that document when it was returned to him. Evidence of other members of the Department of Health, who might be involved in this area, superior to Mr O'Neill, has satisfied the Tribunal that they had neither knowledge nor any part in that transaction.

The Tribunal is satisfied that it was an irregularity and an impropriety to which only Mr. O'Neill contributed and that it had no more sinister purpose than an attempt to escape being blamed for not having carried out the function of reminding the BTSB of the necessity to apply for renewal of their product authorisation, something which to put the matter in context should not have been an obligation on the part of the Department of Health as it was the duty of the BTSB to remember when they should apply.

Oral Evidence of General Practitioners who treated recipients of Anti-D in 1977.

It is clear that the Expert Group did not have the oral evidence of general practitioners who treated the recipients of Anti-D from the batches supplied to by the plasma of Patient X in 1977 and in particular would not have had the benefit of their views as to the suspicion they had at that time concerning the possible connection between their patients' jaundice and hepatitis and their receipt of Anti-D. In addition the Expert Group did not have evidence which this Tribunal had from Ms. Jane O'Brien on behalf of Positive Action to the effect that Positive Action are now aware of a significant number of women who have proved positive to hepatitis C as a result of having received

doses of Anti-D from the 1977 batches, and who did have experience of jaundice. Some of them were hospitalised for it after the receipt of the Anti-D, although they did not report this matter to the BTSB at that time. The evidence of the doctors combined with the evidence of Ms. O'Brien has permitted this Tribunal to reach a very firm conclusion that no real attempt at all was made by the BTSB to investigate the complaints which they did receive and, as already indicated in chapter 4 of the Report, it also supported the view, that had the medical officers of the BTSB, as they should have done, made even an enquiry from the doctors and institutions to which the suspect batches had been sent they would have probably got significant corroboration of the fact that they were infected.

The Expert Group in its conclusions on this issue has concluded that the attempts to investigate these complaints were inadequate but they would not have had such compelling evidence of that fact as was produced by these two pieces of evidence.

Documentation concerning Donor Y

It appears that the Expert Group did not have sight of the documentation concerning the manufacture of Anti-D from plasma taken from Donor Y which was available to the Tribunal as a result of discovery made by the BTSB. As a result they were not able to reach the conclusion which this Tribunal has reached, that the BTSB manufactured and issued Anti-D from the plasma of Donor Y before Donor Y had been tested for either HIV or Hepatitis B, contrary to what was, at that stage, their own standard. Secondly, that the BTSB manufactured and issued Anti-D notwithstanding the fact that plasma from Donor Y had tested positive for hepatitis C on four separate occasions.

Had that documentation been available to the Expert Group they would clearly have been in a position to reach a definite conclusion, as the Tribunal has done, of causation between the plasma of Donor Y and the infection of batches, and of the completely wrongful issue of those batches which they were unable to do on the information before them.

Evidence of Donor L

The evidence of Donor L which is referred to in Chapter 8 of this Report, was not available to the Expert Group nor was the associated relevant evidence of Ms Jane O'Brien in respect of members of the Positive Group who had been tested and retested by the BTSB and had not been informed of the results of these tests. This evidence as is indicated in the conclusions reached in Chapter Eight, constituted evidence of a serious, inappropriate and improper reaction to a particular problem in the first instance with regard to Donor L, arising not directly from the discovery of the infection of Anti-D with Hepatitis C but rather from the introduction of the Hepatitis C testing. In the case of some of the women victims of Anti-D referred to in the evidence

of Ms O'Brien, it was more directly relevant as concerning the reaction to the discovery of the infection of Anti-D with Hepatitis C. Some of the events of which this is evidence would appear to have occurred after the completion of the Report by the Expert Group and the issues it related to do not appear to have arisen in that Report.

It has a further relevance to the subject matter of the Inquiry by the Tribunal in that it indicates as one aspect of it, an inadequate communication existing up to the recently introduced reorganisation in the BTSB in the communication and structure as between the Munster region and the rest of the country.

Part VI

Term of Reference No. 9

Chapter 15

The McCole Family's questions answered

Term of Reference No. 9

"The questions raised by the family of Mrs. Brigid McCole, in their open letter published on October the 9th, insofar as these questions relate to the terms of reference above".

The questions raised by the family of Mrs. Brigid McCole in the open letter published on October the 9th which relate to the Terms of Reference of this Tribunal are those at paragraphs numbered 1 — 4 inclusive.

Question number 1:

Why did the Blood Transfusion Board use plasma from a patient undergoing therapeutic plasma exchange when it was unsafe to do so?

A detailed set of conclusions with regard to the subject matter of this question are contained in Chapter 4 of this Report but to summarise them it appears to the Tribunal that the reason why the Blood Transfusion Service Board used plasma from a patient undergoing therapeutic plasma exchange when it was unsafe to do so was that the Medical Consultants of that Board were particularly anxious not to admit of any breakdown or failure in the production of Anti-D arising from any shortage of plasma, and were anxious to supplement the supply of plasma which could be obtained from other donors. They therefore took a chance that the procedure of production of the Anti-D would destroy any virus that might be transmitted by the plasma used.

Question number 2:

Why did the Blood Transfusion Service Board ignore the ample warnings of jaundice, hepatitis and adverse reactions to Anti-D in 1977 and again take no steps when they were informed of the infection of Anti-D with hepatitis C on the 16th of December in 1991?

The detailed conclusions reached by the Tribunal which constitute the answers to these two questions are contained in Chapter 4 and Chapter 7 of this Report but to briefly summarise them, they are as follows. The ignoring by the BTSB of the ample warnings of jaundice, hepatitis and adverse reactions to the Anti-D in 1977 were probably caused in part by the wrongful

ignoring by the medical consultants of the BTSB and the technical staff of either the existence or the importance of what was then known as non-A non-B Hepatitis (and what is now known as Hepatitis C). Another cause was a considerable fear of what a dramatic confession of failure a recall of the product, which was the proper reaction to these warnings, would have involved. With regard to the failure of the BTSB to take steps when they were informed of the infection of Anti-D with hepatitis C on the 16th of December 1991, the conclusion reached in Chapter 4 of this report may again be summarised as being that this failure was simply caused by a blank refusal to contemplate even the consequences of what then clearly appeared to have been done wrongly by the BTSB in 1977, and a sort of vague and irresponsible hope that the problem might go away.

Question number 3

Why did the Blood Transfusion Service Board not inform the infected women in 1991 and why did they not report the infection to the Department of Health as they were obliged by law to do?

In a sense the entire of this question is answered both in detail in Chapter 4 of the report and in the summarised and brief answer which is given to question number 2. Informing either the women who were infected or might have been infected in 1991 after the letter from the Middlesex hospital had been received or informing at that time the Department of Health or the NDAB of that infection would have involved facing up to the consequences of the wrong that had been committed in 1977, something the relevant officers of the BTSB were not prepared to do.

Question number 4

Why was the Blood Transfusion Service Board permitted to manufacture Anti-D unlawfully and without a licence under the Therapeutic Substances Act 1932 from 1970 to 1984?

For the reasons set out in Chapter 9 of this report the Tribunal has concluded that as a matter of law the Therapeutic Substances Act 1932 and the Regulations made pursuant to it did not apply to the production of Anti-D at any time.

It is not easy to summarise these conclusions but in effect they are that Anti-D was not commonly known as a "sera" so as to be affected by the Act by virtue of the Schedule to the Act itself when it was passed in 1932. Apart from that only two Regulations could possibly apply the Act to the product Anti-D. The first of those in time was the 1939 Regulations. These regulations applied the Act to a "therapeutic substance of animal origin intended for injection". The Act of 1932 had used the word "animal" in a manner distinguishing it from the word "human". By law it was necessary to interpret the 1939 Regulations so as to give effect to that distinction and accordingly

they could not apply the Act to Anti-D, because Anti-D is a therapeutic substance of human origin.

The third possible application was that under the Regulations, the Act was applied to an Immune Serum Globulin (human) which was defined as a soluble protein derived from human plasma serum or tissue having specific antibacterial, anti-viral or anti- toxic activity. In order for a substance to come within that definition its purpose would have to have been the destruction of bacteria, viruses or toxic or poison elements in the body. The purpose of Anti-D was to deal with a reaction between 2 different blood groups and it had no purpose or activity dealing with bacteria virus or toxic substances. Accordingly the 1955 Regulations could not be held to have applied the Act to Anti-D.

Part VII

Conclusion

Chapter 16

Recommendations

Based on the facts found and the conclusions reached the Tribunal makes the following recommendations:

Development Plan

1. The portions of the development plan for the period 1996 — 1999 which have not yet been implemented should be implemented without any delay. In particular the provisions of a new site, buildings and equipment for the Dublin unit of the BTSB, preferably located in close proximity to a teaching hospital, should be undertaken immediately. Appropriate renewal of the premises and equipment in the Cork unit, whether by major overhaul and reconstruction or by the provision of new premises, should also be immediately commenced. The target date of 1999 for the completion of the development plan of which evidence has been given to the Tribunal should be regarded as a date not to be extended except for the most unavoidable reasons.

Monitoring of the B.T.S.B. by the Irish Medicines Board

2. The Minister for Health should pursuant to the powers vested in him by the Irish Medicines Board Act 1995 require that the Irish Medicines Board in exercise of its functions concerning the BTSB provided for by section 4(1)(l) of that Act should do the following things:

   (a) carry out not less than two separate full inspections and investigations directed to both medical and pharmaceutical issues each year of the premises and procedures of the B.T.S.B. related to the safety and quality of its services and products.

   (b) By a separate report made annually inform the Minister for Health of the result of these inspections and investigations and of any reports of abnormal reactions to blood or blood products received by the Irish Medicines Board from any person or institution.

   The Minister should cause this annual report to be made available to the public and should cause a copy of it to be sent to the Blood

Service Consumer Council, the institution of which is recommended in this report.

Reporting of Abnormal Reactions

3. A Statutory procedure specially providing for the reporting of abnormal reaction to transfusion or injection of blood or blood products should be formulated by the Irish Medicines Board after consultation with the BTSB and, with the medical and nursing professions and agreed with the Department of Health. The obligation on the caring professions to report such abnormal reactions should be one to report contemporaneously to the BTSB and to the Irish Medicines Board.

   The BTSB should have an obligation to report such abnormal reactions of which it becomes aware to the Irish Medicines Board irrespective of whether or not a report has also been otherwise made of such reaction to that Board.

   An abnormal reaction to the transfusion or injection of blood or blood products should be precisely and comprehensively defined in this scheme. Failure by any employee of the BTSB to report such abnormal reaction if committed intentionally or by gross negligence should be a criminal offence.

Blood Service Consumers Council

4. A major contribution to the maintenance of public confidence in the supply of blood and blood products could, be made by the setting up of a "Blood Services Consumer Council" which would be kept informed of relevant matters concerning that supply and which would have a right to make representations to the BTSB and to the Irish Medicines Board. The composition of such a Council should obviously include representatives of categories of persons who may expect regularly or from time to time to be recipients of blood or blood products such as women requiring Anti-D treatment, haemophiliacs, and sufferers from kidney disease. It should also include representatives of regular blood donors. Some form of representation of or liaison with hospital transfusion committees should be created for the Council.

   The BTSB should be obliged to inform the Council in advance of proposed changes in procedures or methods likely to affect donors or recipients of blood or blood products.

Procedures for the recall of unsafe products

5. The BTSB should forthwith prepare a new standard operating procedure for a recall of any product the safety of which is suspected. This procedure should be submitted for the approval of the Irish Medicines Board and of the Department of Health and when approved should be circulated to all hospitals, nursing homes or medical practitioners who may be users of blood or blood products.

If a recall at any time becomes necessary and it is put into operation, the standard operating procedure and the practical operation of it should immediately be reviewed jointly by the BTSB and the Irish Medicines Board and if necessary amendments or additions to the standard operating procedure for recalls should be made.

Replacement of Blood or Blood Products

6. Arrangements should be put in place which would permit the immediate replacement of blood supplies in the event of the entire stock of the BTSB of any particular blood product becoming defective.

The events which occurred in February 1994 indicate that if it had not been possible for the BTSB to have at such very short notice imported into the country substantial supplies of the safe and appropriate substitute for the Anti-D they had been manufacturing, that even more hurt and damage would have occurred than did as a result of the infection of Anti-D with Hepatitis C. The fact that they were able to make such a rapid introduction of an appropriate substitute arose from the coincidental fact that they had in association with the NDAB, been for some time investigating this product WinRHO with the planned intention of bringing it in as an import into Ireland instead of producing Anti-D themselves. The examinations and investigations of the product and its availability which had taken place in 1993 for that purpose were of course used for the purpose of introducing it as a standby product.

The present legislation with regard to product authorisation for medicinal products appears to impose on the producer of such a product the obligation to license it for import into Ireland. The process of obtaining such a license is necessarily and properly both burdensome and to an extent expensive. It is not to be anticipated that any commercial undertaking would undergo such trouble or expense merely to achieve the status of a standby supplier in the event of an emergency. Consideration should therefore be given to the amendment of the Regulations so as to provide for a "standby" or "emergency" product authorisation obtainable by the BTSB and effective only in an emergency situation. If such a scheme can be provided then the BTSB should be required to ensure that such "standby" authorisations are in place and available in relation to such blood products as Anti-D, Factor VIII and others, an interruption in the supply of which could have very harmful effects.

These are the recommendations which the Tribunal makes concerning the matters arising before it.

Two submissions were made for further recommendations which have been rejected but should be mentioned.

It was submitted by Counsel on behalf of Positive Action that the Tribunal should recommend that its report be sent to the Director of Public Prosecutions so that he could consider instituting criminal charges arising out of it.

It was submitted by Counsel on behalf of the Tribunal as a matter of law and by Counsel on behalf of the public interest also as a matter of law that such a step would be unlawful and inappropriate for a Tribunal of Fact set up pursuant to the Tribunals of Inquiry Act by resolution of the Oireachtas.

The Tribunal is satisfied that these submissions made to it by the Counsel acting on its behalf and by Counsel acting in the Public Interest are valid and correct and for that reason has refused to make any such recommendation. The Tribunal has been at all times a Public Tribunal and the evidence before it has been in public. The Report is a public document. It is open to any public body or officer to have regard to the terms of the report in respect of any duties which he or she has to discharge. It is not part of the function of this Tribunal under its terms of reference to ascertain as to whether any person has committed a criminal offence. It would in the view of the Tribunal be wholly unjust and therefore improper for it to make any particular recommendation concerning the report and the Director of Public Prosecutions. The analogy, which to an extent was relied upon, of the custom known to the Courts of a judge directing the papers in a case before him to be submitted to the Director of Public Prosecutions for consideration is quite false. Firstly and most importantly this is not a Court and is not concerned with the administration of the Criminal Law. Secondly, papers before a Court in an action being heard are not necessarily within the knowledge of the public or available to the public in the same manner as is the report of a public tribunal of inquiry.

A submission was also made by Counsel on behalf of Positive Action that a specific recommendation should be made by the Tribunal that Mrs. Cunningham should not henceforth be employed in the profession or service of the preparation of blood and blood products for transfusion or injection. For very much the same reasons as the Tribunal concluded it would be improper and unjust for it to make any recommendation concerning the sending of the report to the Director of Public Prosecutions, it refuses also that application. This Tribunal does not have the function of deciding whether any person should be employed for any particular purpose or whether the employment of any person should be altered or terminated. It would be improper for it to make recommendations in that context as a result of the Tribunal inquiring into facts on which it has reported.

Chapter 17

Summary of Conclusions

Chapter 4.

1. The primary cause of the infection of Anti-D with Hepatitis C was the use of plasma from Patient X, a person undergoing therapeutic plasma exchange treatment who developed jaundice and hepatitis.
2. The use of this plasma was clearly in breach of the BTSB's own standards for donor selection prohibiting the use of blood or plasma from a person with a history of jaundice or hepatitis, and prohibiting the use of blood or plasma from a person who was recently transfused.
3. The BTSB failed properly to react to reports made to them that recipients of the Anti-D made from the plasma of Patient X, had suffered jaundice and/or hepatitis. They failed, to report that to the NDAB and they failed to report it to the Board of the BTSB itself.
4. The BTSB also failed properly to investigate the possible existence of complaints by other recipients of the dosages of Anti-D which were suspected of being contaminated.
5. The BTSB failed to recall the contaminated batches which had been issued and to prevent the issue of any further batches made from plasma obtained from Patient X.
6. The responsibility for these failures rest to a major extent with Dr O'Riordan, then National Director of the BTSB, also with Dr Wilkinson, since deceased, who was Deputy National Director, and with Dr Terry Walsh, who was the most junior Medical Officer of the BTSB at that time. Dr James Kirrane, who was a part-time Consultant with the BTSB must bear some responsibility for not insisting on a greater investigation of the reaction of patients to the Anti-D. Mrs Cecily Cunningham, Principal Biochemist in charge of the manufacture of Anti-D, must also bear a responsibility.
7. The BTSB acted unethically in obtaining and using the plasma from Patient X without asking her for her consent.
8. A further cause of the infection of Anti-D with Hepatitis C was the use of plasma from Donor Y who was undergoing a course of therapeutic

plasma exchange in 1989 and whose plasma was stored and then subsequently used in 1992, notwithstanding that the stored plasma had then been tested for Hepatitis C and, in four separate tests, had proved positive.

9. This occurred for two reasons; firstly, because Mrs Cecily Cunningham decided to use the plasma, notwithstanding the result of at least one test of which she was informed on the basis that she believed the result was a false positive result; and secondly, because neither Dr Walsh, who was then Chief Medical Consultant, nor the Chief Technical Officer at that time, Mr Sean Hanratty, since deceased, had set up a proper method of communication between the testing laboratory and the manufacturing laboratory with regard to infected material.

10. The main reasons why these wrongful acts were committed were as follows:

    An undue emphasis on the necessity to use plasma from therapeutic plasma exchange patients so as to maintain the supply of plasma for the making of Anti-D; An undue and unsupported belief in the probability that the method of production of Anti-D would inactivate any virus that existed; and a reluctance to admit the possibility of having been wrong and the possibility of a failure of the production of Anti-D which would be involved in the recall of the product.

Chapter 5

1. The conclusions of this Chapter consist of a short description of the medical characteristics of the disease of Hepatitis C, consideration of the human consequences both before diagnosis and after diagnosis dealing with personal relationships, work, financial consequences, dietary implications, and treatment.

2. Special difficulties arising for different groups of sufferers, are treated under the headings of Anti-D recipients, sufferers from kidney failure, haemophiliacs and transfusion recipients. Special problems of public perception of the disease and the possibility of it affecting children are also dealt with.

3. The figures of the number which may have been affected by Hepatitis C as a result of the infection of Anti-D are dealt with in this Chapter, indicating overall figures in the region of 1,000-2,000 broken up into different categories and calculated in different ways.

Chapter 6

1. The BTSB adequately pressed for the introduction of Hepatitis C screening into the procedures of the blood supply service.

2. The Department of Health was not at fault in refusing to agree to the introduction of a Hepatitis C screening by the ALT test in 1989 and 1990.

3. The Department of Health was at fault in failing to agree to the introduction of Hepatitis C screening by the tests then available in February of 1991 and postponing their permission until September of 1991. The responsibility for that failure must rest between the medical and administrative sections of the Department of Health.

4. The BTSB was in delay in pursuing the question of introducing a solvent detergent as a method of viral inactivation for Anti-D in the years 1990 and 1991, but on the evidence it is improbable that a reliable product could have been made available much before February 1994, when it was put on the Irish market.

Chapter 7

1. The response of the BTSB to the letter of 16th December 1991 from the Middlesex Hospital in relation to Anti-D, and the infection of it with Hepatitis C, was completely inadequate and non existent.

2. The persons responsible for that inadequacy and failure to make any proper reaction to that letter, are mainly Dr Terry Walsh and to a limited extent, Mrs Cecily Cunningham.

3. No blame should be attributed to Dr Emer Lawlor, who was made aware of the contents of that letter.

4. It would appear that the reason why the reaction was non existent was a total refusal to face the consequences of what had been done in regard to Patient X in 1976/1977.

Chapter 8

1. The decision by the BTSB to undertake the task of national screening itself in February 1994, was an adequate and proper reaction.

2. The procedure operated by the BTSB for the recall of the contaminated Anti-D in February 1994 was inadequate.

3. The provision by the BTSB of a supply of an imported Anti-D from Rh Pharmaceuticals in Canada by the 20th February 1994, was a proper reaction to the discovery of the infection of Anti-D in February 1994 but they should not have informed the Department of Health that it had been licensed by the FDA of the United States when that was not then correct.

4. The decision of the BTSB to inform the General Practitioners of the infection of Anti-D with Hepatitis C, and the setting up of the screening

programme by sending them an information package at the same time as the public announcement was, on balance, a proper reaction.

5. The action of the BTSB with regard to making information available in February 1994 concerning the possibility of Anti-D made from 1991 onwards, being suspect by reason of the history of Donor Y, was adequate.

6. The reaction of the BTSB to complaints that it was inappropriate for them to counsel the victims of Hepatitis C themselves, which were made in early 1994, was inadequate in that they should have sought assistance from the medical profession, and created independent counselling earlier than it was put into operation in late 1994 and 1995.

7. The BTSB was inadequate in its reaction in failing to agree in July 1994 to the proposals of a group of Hepatologists for the referral of persons proving positive on testing to Hepatological Units.

8. The BTSB was inadequate and incorrect in its treatment of Donor L and other persons who, on Hepatitis C screening, proved positive on early testing by not informing them that their blood was not being used as donations, and by not informing them of the results of the tests.

9. The BTSB was somewhat inadequate, in its reaction to the problems of testing, informing and counselling persons infected with Hepatitis C by reason of insensitivity and also of delay and lack of full information.

10. The BTSB was inadequate in its reaction to a request from Positive Action to circulate a letter in April 1994 seeking contact with other victims of Hepatitis C to the extent that it did not put forward and agree to a compromise form of communication earlier than September of 1994 and April of 1995.

Chapter 9

1. The NDAB was inadequate in carrying out its functions in advising on the grant of a Manufacturing Licence for Anti-D under the 1974 Regulations, in failing to make an annual inspection of the premises and procedures of the BTSB for the purpose of advising the Department of Health.

Chapter 10

1. The NDAB in carrying out its functions and advising on the grant of Product Authorisations under the Regulations of 1975, did not carry out its functions properly but failed in its obligations to carry out the necessary examination and inspection of the product which would have been appropriate.

Chapter 11

1. As a matter of law, Anti-D was not a therapeutic substance under the Act of 1932 nor under the Regulations made pursuant to it and a grant of a Manufacturer's Licence during the years 1970/1984 under that Act of 1932, would not have been appropriate because it would have been of no legal affect.

Chapter 12

1. In the period 1975 to 1994, successive Ministers for Health and the Department of Health failed adequately and appropriately to supervise the NDAB in the exercise of its functions concerning the licensing of the manufacture of products by the BTSB and the authorisation of products by the BTSB, in that they failed to provide to the NDAB the appropriate resources for carrying out those functions.

2. If those resources had been provided and if there had been appropriate inspections and investigations, it is possible that the reactions of the recipients of Anti-D in the period 1976 and 1977 to the contaminated product, would have been revealed and that the persons involved in the BTSB would have made further investigations than they did if they were aware of the likelihood of further inspection and interrogation.

Chapter 13

1. The supervision by the Minister and Department of Health of the BTSB in 1994 in relation to the recall procedure was inadequate in not insisting on a better procedure.

2. The supervision by the Minister and Department of the BTSB, in regard to the replacement product of Anti-D (WinRHO) was adequate and appropriate.

3. The supervision by the Minister and Department of the BTSB leaving the screening to be done by the BTSB, was appropriate and adequate.

4. The Minister and Department did not fail in their proper supervision of the BTSB in failing to press for an earlier start of the Targeted Look-back Programme.

5. The Minister and Department should have agreed to the request made in July 1994 of the group of Hepatologists for referral on their proposed criteria and should have insisted on the compliance of the BTSB with those criteria.

6. The Minister and Department were adequate in the holding of meetings with the BTSB in the year 1994 in regard to the Screening and Targeted Lookback Programmes.

7. The Minister and Department were adequate in their supervision of the BTSB in seeking to reassure the public of the effectiveness and safety of the new Anti-D product.

8. The Minister and Department were adequate in their supervision in requesting the continuance of Mr Keyes as Chief Executive Officer of the BTSB after his retirement date in 1994, for a further year.

9. The appointment by the Minister and Department of Mr Holloway as Chairman of the BTSB in 1994 and the appointment of Professor Shaun McCann, as National Medical Director, and Mr Liam Dunbar, as CEO in April 1995, were appropriate actions done at appropriate times for the purpose of the restructuring and reorganisation of the BTSB, and in particular it was reasonable for the Minister and Department to await the results of the examination of the BTSB and its internal structures, being conducted by the Expert Group and by Bain & Company.

10. The arrangements for treatment of victims of Hepatitis C set up in March 1994 by the Minister and Department in six Hepatology units, were adequate and appropriate.

11. The long term provisions for the treatment, counselling and care of victims of Hepatitis C which were provided by the Health Amendment Act of 1996 were adequate and appropriate.

12. The speed with which the Act of 1996 was introduced was not however adequate and appropriate, even making allowance for the proper consultation with the victims and their representatives before finalising the appropriate scheme. The delay between the end of 1995 and the date on which it became effective in September 1996, was an inadequate reaction by the Minister and Department.

13. In regard to the supervision of the BTSB in relation to the counselling of victims of Hepatitis C, the solutions eventually achieved in the year 1995 were appropriate, but having regard to the importance of this element in the treatment of the victims, the reaction of the Minister and Department earlier in 1994 in failing to insist upon a more rapid putting in place of independent counselling was inadequate.

14. The Minister and Department were in general adequate and appropriate in supervising the BTSB in the steps they took to communicate with and support the groups representing the victims of the Hepatitis C infection including Positive Action. The immediate expenses of obtaining treatment and testing were also generally adequate.

15. In general the provision for compensation by a Tribunal on a no fault basis, as an alternative to and not excluding the right to sue at the time at which it was introduced, constituted a reasonably adequate and appropriate reaction to that particular problem by the Minister and Department.

16. The decision made by the then Minister for Health, Mr Howlin, in March 1994, to set up an Expert Group instead of a Tribunal of Inquiry, was an adequate and appropriate reaction to the facts as they then were.

17. There was no inadequacy or inappropriateness in a decision made by the Minister Mr Howlin in September 1994, not to set up a Tribunal of Inquiry at that time and to permit the Expert Group to conclude its deliberations.

18. The decision of the Minister for Health, Mr Noonan in March 1996 not to set up a Tribunal of Inquiry arising out of the making public of the quantitation reports containing the words "infective Hepatitis" was an adequate and appropriate reaction to the facts as they then were.

Chapter 14

1. The statement of Patient X was not available to the Expert Group and they were unaware of the fact that her blood was taken and used without her knowledge or consent.

2. Quantitation reports which were not available to the Expert Group, did not constitute new, dominant or fundamental medical evidence and would not form a foundation for any particular conclusion which would not have been reached by the Expert Group without the reports, in regard to general wrong doing involved in the use of plasma from Patient X.

3. The evidence of individual members of the staff of the Department of Health and the NDAB with regard to the issue of the "one page renewal" of a Product Authorisation for Anti-D in February 1994, was not available to the Expert Group. If it had been, it would have supported a conclusion that this was quite an improper and wrong attempt to cover up, by an official, rather than part of a normal if undesirable procedure, as it appeared to the Expert Group to be.

4. The oral evidence of General Practitioners who treated recipients of Anti-D from contaminated batches in 1977, was not available to the Expert Group. Neither, on the same topic, was there available to it, evidence which Ms O'Brien of Positive Action gave to the Tribunal, of information now available to her of patients, other than those attended by the General Practitioners, who had received Anti-D from contaminated doses, and who suffered from Hepatitis or jaundice after doing so. Had this evidence been available to the Expert Group, it would certainly have been support for the view already taken by them that the medical officers of the BTSB should have made enquiries from doctors dealing with the suspect batches to ascertain whether any other patients had had reactions.

5. The documentation concerning the plasma from Donor Y was not available to the Expert Group and had it been so, they would have been in a position to make a decision which they were not in a position to make, that the infection arising from that was something that should have been avoided and was due to wrongful practices on the part of the BTSB.

6. The evidence of Donor L and other evidence from Ms O'Brien concerning women who had similar treatment with regard to repeated testing, was not available to the Expert Group and would have enabled them to reach a conclusion that it was an improper practice.

Appendices

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Appendix A

Orders for Representation

Tribunal of Inquiry appointed by instrument of the Minister for Health dated the 24th day of October 1996 pursuant to the Tribunals of Inquiry (Evidence) Act 1921

Whereas at a sitting of this Tribunal held at the Four Courts Dublin 7 on Tuesday the 5th day of November 1996 the following persons attended:

Counsel nominated by this Tribunal to act on its behalf

Counsel nominated by the Attorney General to represent the public interest

Counsel on behalf of the Minister for Health and the Department of Health

Counsel on behalf of the Blood Transfusion Service Board

Counsel on behalf of the National Drugs Advisory Board

Counsel on behalf of the family of Mrs Brigid Mc Cole deceased and on behalf of Positive Action a company limited by guarantee

Counsel on behalf of the Irish Haemophilia Society

Counsel on behalf Transfusion Positive

Counsel on behalf of the Irish Kidney Association Limited

The solicitor on behalf of Dr Steven O'Sullivan

And on hearing what is offered by said Counsel and said solicitor

It Is Ordered pursuant to the Tribunals of Inquiry (Evidence) Act 1921 as amended:

(i) that the following parties do have unlimited representation at the proceedings before this Tribunal:

The Attorney General representing the public interest.

The Minister for Health and the Department of Health.

The Blood Transfusion Service Board.

The family of Brigid Mc Cole deceased.

(ii) that the National Drugs Advisory Board do have representation at the proceedings before this Tribunal — limited to the terms of reference of this Tribunal with which it is concerned.

(iii) that Positive Action do have representation at the proceedings before this Tribunal to such extent as shall be determined by this Tribunal.

(iv) that the question of the representation to be allowed to the Irish Haemophilia Society, Transfusion Positive, the Irish Kidney Association Limited and Dr. Steven O'Sullivan be reserved.

And It Is Ordered that this Tribunal shall next sit on Thursday the 21st day of November 1996 at 2 o'clock in the afternoon at 63/64 Adelaide Road, Dublin 2.

Mr Justice T.A. Finlay
Sole Member of the Tribunal

Tribunal of Inquiry appointed by instrument of the Minister for Health dated the 24th day of October 1996 pursuant to the Tribunals of Inquiry (Evidence) Acts 1921 and 1979

Thursday the 21st day of November 1996

Whereas at a sitting of this Tribunal held on Monday the 5th day of November 1996 an Order was made pursuant to the provisions of the said Acts in the following terms:

(i) that the following parties do have unlimited representation at the proceedings before this Tribunal:

The Attorney General representing the public interest.

The Minister for Health and the Department of Health.

The Blood Transfusion Service Board.

The family of Brigid Mc Cole deceased.

(ii) that the National Drugs Advisory Board do have representation at the proceedings before this Tribunal — limited to the terms of reference of this Tribunal with which it is concerned.

(iii) that Positive Action do have representation at the proceedings before this Tribunal to such extent as shall be determined by this Tribunal.

(iv) that the question of the representation to be allowed to the Irish Haemophilia Society, Transfusion Positive, the Irish Kidney Association Limited and Dr. Steven O'Sullivan be reserved.

And whereas at a sitting of this Tribunal held on this 21st day of November 1996 the following persons attended:

Counsel on behalf of the Tribunal

Counsel on behalf of the Attorney General representing the public interest

Counsel on behalf of the Minister for Health and the Department of Health

Counsel on behalf of the Blood Transfusion Service Board

Counsel on behalf of the National Drugs Advisory Board

Counsel on behalf of the family of Mrs Brigid Mc Cole deceased and on behalf of Positive Action a company limited by guarantee

Counsel on behalf of the Irish Haemophilia Society

Counsel on behalf of Transfusion Positive

Counsel on behalf of Dr Steven O'Sullivan

It Is Ordered pursuant to the provisions of the Tribunal of Inquiry (Evidence) Acts 1921 and 1979:

(i) that Positive Action a company limited by guarantee do have unlimited representation at the proceedings before this Tribunal

(ii) That the applications on behalf of the Irish Haemophilia Society, Transfusion Positive and the Irish Kidney Association Limited for representation as participants in the Inquiry be and the same are hereby refused

(iii) that Dr. Steven O'Sullivan shall be entitled to have representation during the course of his being examined by Counsel on behalf of the Tribunal and that he shall be entitled to ask questions if it is thought appropriate.

Mr Justice T.A. Finlay
Sole Member of the Tribunal

Tribunal of Inquiry appointed by instrument of the Minister for Health dated the 24th day of October 1996 pursuant to the Tribunals of Inquiry (Evidence) Acts 1921 and 1979

Wednesday the 27th day of November 1996

In pursuance of Section 2(b) of the Tribunal of Inquiry (Evidence) Act 1921 the Tribunal hereby grants partial legal representation to the following parties:

The Irish Haemophilia Society

The Irish Kidney Association Limited

Transfusion Positive

upon the following terms:

1. Legal representation at the opening of the oral hearings of the Tribunal.
2. During the course of the Tribunal's deliberations the following shall be provided to the said parties:
   (i) a transcript of the evidence led before the Tribunal on a daily basis
   (ii) proofs of the prospective evidence to be given
   (iii) sight of or copies of such documentation as is necessary to allow the said parties keep themselves informed as to the Tribunal's deliberations.
   [Liberty to apply to the Tribunal in this regard]
3. The right to apply to the Tribunal to be permitted to cross examine any witness before the Tribunal.
4. Such representation as is necessary for the purposes of allowing the said parties be advised in the course of Tribunal's deliberations which shall include Solicitor, Counsel and Medical Consultancy Services as appropriate.
5. The right to attend and be represented at the Tribunal when any of the said parties' witnesses are before the Tribunal.
6. The right to make a closing to the Tribunal.

Mr Justice T. A. Finlay
Sole Member of the Tribunal

Appendix B

Order of the Minister for Health dated 24th October 1996

Tribunal of Inquiry (Evidence) Acts 1921 and 1979

WHEREAS a resolution in the following terms was passed by Dáil Éireann on the 17th day of October, 1996:

"Bearing in mind

(1) The serious public concern about the circumstances surrounding the contamination of blood and blood products and the consequences for the health of a significant number of people

(2) The report of the Expert Group which was published in April 1995 and

(3) The fact that further documents, testimony or other information, not available to the Expert Group, may now be available relevant to some or all of the matters following;

resolves that it is expedient that a Tribunal be established, under the Tribunals of Inquiry (Evidence) Act, 1921, as adopted by or under subsequent enactments, and the Tribunals of Inquiry (Evidence) (Amendment) Act, 1979, to enquire urgently into and report and make such findings and recommendations as it sees fit in relation to the following definite matters of public importance

1. The circumstances in which Anti-D, manufactured by the Blood Transfusion Service Board (BTSB), was infected with what is now known as Hepatitis C and the implications, thereof, including the consequences for the blood supply and other blood products.

2. The circumstances in which the BTSB first became aware that Anti-D, manufactured by the BTSB, had become, or might have become, infected with what is now known as Hepatitis C.

3. The implications of the discovery at 2. above, the action taken by the BTSB in response to the discovery and the adequacy or otherwise of such action including the consequences for the blood supply and other blood products.

4. The response of the BTSB to a letter of the 16th December 1991 from the Middlesex Hospital, London in relation to Human Immunoglobulin — Anti-D and the adequacy of such response including the consequences for the blood supply and blood products.

5. Whether the National Drugs Advisory Board in carrying out its functions in advising on the grant of a manufacturing licence for Anti-D under the Medical Preparation (Licensing of Manufacture) Regulations 1974 and in advising on the grant of Product Authorisations under the European Communities (Proprietary Medicinal Products) Regulations 1975 carried out its function properly.

6. Whether supervision of the Blood Transfusion Service Board and the National Drugs Advisory Board, in respect of the matters referred to in paragraphs 1-5 above, was adequate and appropriate in the light of:

   (i) The functional and statutory responsibilities of the Minister for Health, the Department of Health and the Boards.

   (ii) Any other relevant circumstance.

7. Whether Anti-D was a therapeutic substance for the purposes of the Therapeutic Substances Act, 1932 and the regulations made pursuant to it and whether the grant of a manufacturer's licence during the years 1970-1984 would have been appropriate and could have prevented the infection of human immunoglobulin Anti-D with Hepatitis C.

8. The relevance to the foregoing of any further documents, testimony or information not available to the Expert Group, which became available subsequent to the completion of the Group's report.

9. The questions raised by the family of Mrs. Brigid McCole, in their open letter published on October 9th, in so far as these questions relate to the Terms of Reference above.

And that the Tribunal be asked to report on an interim basis not later than the 20th day of any oral hearings to the Minister for Health on the following matters.

The number of parties then represented before the Tribunal.

The progress which has been made in the hearings and the work of the Tribunal.

The likely duration, (so far as that may be capable of being estimated at that point in time) of the Tribunal proceedings.

Any other matters which the Tribunal believes should be drawn to the attention of the Minister at that stage (including any matter relating to the terms of reference).

And that the Minister for Health should inform the person selected to conduct the Inquiry that it is the desire of the House that the Inquiry be completed in as economical a matter as possible and at the earliest date consistent with a fair examination of the matters referred to it.

And it is the wish of Dáil Éireann that

> all persons employed by the Government Departments and the State Agencies concerned shall give their full co-operation to the Tribunal in its inquiries, and that the Departments and Agencies themselves shall fully co-operate with the Tribunal by providing all documents and information requested of them.
>
> the Minister for Health shall inform the person selected to conduct the inquiry that it is the desire of the House that the anonymity of the victims of Hepatitis C who come before the Tribunal be preserved if they so wish, in so far as that may be possible.",

AND WHEREAS a similar resolution was passed by Seanad Éireann on the 17th day of October, 1996, except that the reference in the Dáil Éireann resolution to "Dáil Éireann" is a reference to "Seanad Éireann" in the Seanad Éireann resolution,

NOW I, MICHAEL NOONAN, Minister for Health, in pursuance of those resolutions, and in exercise of the powers conferred on me by section 1 (as adapted) of the Tribunals of Inquiry (Evidence) Act, 1921, hereby order as follows:

1. A Tribunal is hereby appointed to enquire urgently into and report and make such findings and recommendations as it sees fit to the Minister for Health on the definite matters of public importance set out at Paragraphs 1 to 9 of the resolutions passed by Dáil Éireann and Seanad Éireann on the 17th day of October, 1996.
2. The Honourable Mr. Justice Thomas A. Finlay, former Chief Justice, is hereby nominated to be the sole member of the Tribunal.
3. The Tribunals of Inquiry (Evidence) Act, 1921 (as adapted) and the Tribunals of Inquiry (Evidence) (Amendment) Act, 1979, shall apply to the Tribunal.

GIVEN under my Official Seal, this 24th day of October, 1996.

Michael Noonan,
MINISTER FOR HEALTH.

Appendix C

List of Witnesses called by Tribunal

Witnesses

1. *Dr. Lewellys Barker*
   Physician; Associate Clinical Professor of Medicine at George Washington University School of Medicine; currently working at Division of AIDS National Institute of Allergies and Infectious Diseases.
2. *Dr. Denis Reen*
   Immunologist; Head of Research Laboratory, Our Lady's Hospital Crumlin.
3. *Dr. Eamon McGuinness*
   Consultant Obstetrician/Gynaecologist at St. James Hospital.
4. *Dr. Dermot Carroll*
   General Practitioner.
5. *Dr. Garrett May*
   General Practitioner.
6. *Professor Hans Hoppe*
   Professor of Medicine University of Hamburg; formerly Director of Central Institute for Blood Transfusion Hamburg.
7. *Dr. Peter Conlon*
   General Practitioner.
8. *Dr. Sean O'Toole*
   General Practitioner.
9. *Dr. John Lennon*
   Consultant Gastroenterologist Mater Hospital.
10. *Dr. Stephen O'Sullivan*
    Biochemist; former employee of BTSB.
11. *Francis O'Connell*
    Surgeon; Gastroenterologist.
12. *Dr. James Kirrane*
    Consultant Pathologist, Mater Hospital; Part-time Consultant BTSB.

13. *Dr. Brendan O'Donnell*
Member of Board of BTSB 1966-1984;
County Medical Officer for Kildare 1966-1973;
Medical Health Officer for Dublin 1973 to 1995.

14. *John Keating*
Laboratory Technician BTSB from 1966;
Acting Chief Technical Officer BTSB since 1995.

15. *Cecily Cunningham*
Technical officer Fractionation Department BTSB from 1968;
Principal Biochemist from 1974.

16. *John Cann*
Chief Technical Officer BTSB — Retired 1987.

17. *Dr. Emer Lawlor*
Part-time post as Consultant Haemotologist BTSB from 1988.

18. *Dr. Joan Power*
Consultant Haemotologist and Regional Director BTSB in Cork from 1989.

19. *Dr. John Patrick O'Riordan*
Former National Director BTSB — retired 1986.

20. *Dr. Terence Walsh*
Senior Medical Officer BTSB 1969;
Assistant Director BTSB from 1976;
Chief Medical Consultant BTSB from 1988;
— Retired 1995.

21. *Dr. John Hegarty*
Consultant Hepatologist; Medical Director Liver Unit St. Vincents Hospital.

22. *Gerard Hogan*
Secretary of Transfusion Positive.

23. *Jane O'Brien*
Chairperson of Positive Action.

24. *Paula Kealy*
Member of Positive Action.

25. *"Witness 1A"*
Member of Irish Kidney Association.

26. *Dr. Ian Donaldson Fraser*
Consultant Haemotologist.

27. *Rosemary Daly*
Administrator of Irish Haemophilia Society.

28. *Dr. David S. Dane*
Retired Consultant Virologist.

29. *Dr. John Craske*
Consultant Virologist.

30. *Timothy Keyes*
Chief Executive Officer BTSB — retired 1995.

31. *Dr. Rosemary Boothman*
Deputy Chief Medical Officer of Department of Health; Member of Board BTSB.

32. *Dr. Alphonsus Walsh*
Chief Medical Officer of Department of Health.

33. *Frank Ahern*
Principal Officer at Department of Health.

34. *Dr. Niall Tierney*
Chief Medical Officer of Department of Health.

35. *Jerry O'Dwyer*
Secretary of Department of Health.

36. *Dolores Moran*
Assistant Principal Officer at Department of Health.

37. *Thomas McGuinn*
Chief Pharmacist of Department of Health.

38. *Laurence Patrick McVeigh*
Higher Executive Officer at Department of Health (Public Health Division) 1973 — retired.

39. *John Gillen*
Assistant Principal Officer at Department of Health.

40. *Maureen Ward*
Higher Executive Officer at Department of Health (Public Health Division) 1977.

41. *James Francis O'Dowd*
Inspector at NDAB — retired 1990.

42. *Michael Collins*
Clerical Assistant at Department of Health
(Medicines Division).

43. *Madeline Meade*
Executive Officer at Department of Health (Medicines Division) 1991 to 1995.

44. *John Lynch*
Inspector Irish Medicines Board (formerly NDAB).

45. *Dr. Harry Hennema*
Pharmaceutical Inspector at Department of Health in the Netherlands — retired 1994.

46. *Deirdre McGeever*
Administrative/Clerical worker Irish Medicines Board (formerly NDAB).

47. *Tom O'Neill*
Higher Executive Officer at Department of Health (Medical Division).

48. *Mary Rafter*
Pharmaceutical Assessor Irish Medicines Board (formerly NDAB).

49. *Dr. Mary Teeling*
Medical Director of Irish Medicines Board
(formerly NDAB).

50. *Prof. Geoffrey Savidge*
Clinical Director, Haemophilia Reference Centre, St. Thomas' Hospital London.

51. *Prof. Ian Temperly*
Professor of haemotology Trinity College Dublin — retired 1995; Member of Board BTSB.

52. *Gerry Guidon*
Principal Officer at Department of Health.

53. *Brendan Murphy*
Secretary of NDAB — retired 1996.

54. *Dr. John Maxwell Bowman*
Medical Director of RH Laboratory.

55. *"Donor L"*

56. *Pauline Coakley*
Quality Assurance Officer BTSB.

57. *Anne Kelleher*
Midwife in Charge, Marian Nursing Home, Limerick.

58. *Senator Mary Henry*
Medical Doctor.

59. *Dr. Michael Turner*
Master of the Coombe Hospital.

60. *Prof. Shaun McCann*
Consultant Haemotologist;
Acting Medical Director BTSB from 1995.

61. *Fionan O'Cuinneagain*
Chief Executive Officer of Irish College of General Practitioners.

62. *Brigid McCole*
Daughter of the late Brid McCole.

63. *Donal Devitt*
Assistant Secretary at Department of Health.

64. *Michael Noonan T.D.*
Minister for Health.

65. *John Hurley*
Secretary of Department of Health 1990 to 1994.

66. *Tom Walsh*
Clerical Officer at Tribunal of Inquiry.

67. *Dr. Tim Collins*
Special Advisor to Brendan Howlin T.D.

68. *Brendan Howlin T.D.*
Minister for the Environment;
Minister for Health 1993-1994.

69. *Tom Mooney*
Assistant Secretary at Department of Health.

70. *Fergal Lynch*
Secretary to Expert Group on BTSB 1994-1995.

71. *Liam Dunbar*
Chief Executive Officer BTSB from 1995.

Appendix D

Patient X: the manufacture of her plasma into Anti-D

Patient X

Relevant Dates Plasma Taken to Make Anti-D	Hepatitis	Batch Manufactured		Last Date Batch Issued
28th September 1976	04.11.76 Transfusion Reaction 17.11.76 X becomes Jaundiced	226 227 228 229 233	04.10.76 12.10.76 08.11.76 15.11.76 04.01.77	31.01.77 15.02.77 29.04.77 06.04.77
10th January 1977 17th January 1977 19th January 1977		236 237 238* 239 240* 241 242 243* 244 245* 246* 247 248	14.02.77 21.02.77 28.02.77 07.03.77 14.03.77 04.04.77 21.04.77 25.04.77 02.05.77 09.05.77 16.05.77	REFILTERED 10.05.77 01.06.77 18.07.77 22.06.77 18.07.77 09.08.77 02.09.77 14.09.77 26.09.77 FOUND UNFIT (26 January 1978)
25th July 1977 Cecily Cunningham told not to use patient X's plasma in donor pool.		250* 251* 252* *Denotes Hepatitis C positive	20.06.77 27.06.77 04.07.77	07.10.77 19.10.77 28.10.77

Appendix E

Table of reports of reactions to the Anti-D product received by the BTSB in 1977

Patient	Doctor	Date Anti-D	Hospital	Date BTSB Informed
HOS	Dr. Sean O'Toole	19/05/77 (238)	Rotunda	August 1977
M McG	Dr. Dermot Carroll	28/05/77 (238)	Rotunda	August/September 1977 + October 1977
J R	Dr. Damian Jennings	30/05/77 (238)	Rotunda	July 1977
S B	Dr. Garret May	24/06/77 (238)	Coombe	8th August 1977
C K	Dr. Peter Conlon	26/08/77	Coombe	22nd November 1977
K B	Dr. Sean O'Toole	04/10/77 (250)	Holles Street	November 1977
C R	Dr. Garret May	26/10/77 (252)	Holles Street	19th December 1977

Appendix F

Donor Y: the manufacture of her plasma into Anti-D

DONOR Y 13th September 1989 — Receives a HCV PCR Positive Unit			
Date of Plasma Donation	Batch No.	Date of Manufacture	Date of Issue
4th August 1989	566	6th May 1991	June/July 1991
29th September 1989	597*	28th July 1992	November 1992
	598*	7th September 1992	December 1992
	599*	14th September 1992	20th January 1993
	600*	2nd November 1992	19th February 1993
	601*	2nd December 1992	5th March 1993
	606*	19th April 1993	3rd June 1993
2nd October 1989	618*	8th November 1993	11th February 1994
	RECALLED		
	1994		
	619	13th December 1993	
	620	17th January 1994	21st February 1994
	621	21st January 1994	21st February 1994 (NOT PASSED)
4th October 1989	602*	14th December 1992	7th April 1993
	603*	1st March 1993	21st April 1993
	615*	12th October 1993	9th December 1993
6th October 1989	613*	23rd August 1993	3rd November 1993
	614*	13th Septembeer 1993	15th November 1993
	616*	18th October 1993	31st December 1993
	617*	2nd November 1993	2nd February 1994
9th October 1989	580*	23rd September 1991	
	582*	11th November 1991	January 1992
	589*	5th February 1992	April 1992
	590*	27th February 1992	June 1992
	610*	28th June 1993	31st August 1993
	611*	13th July 1993	17th September 1993
11th October 1989	604*	8th March 1993	14th May 1993
	605*	19th April 1993	23rd June 1993
	607*	3rd April 1993	5th July 1993
	608*	1st June 1993	16th July 1993
	609*	8th June 1993	11th August 1993
	612*	3rd August 1993	13th October 1993

DONOR Y — *contd.* 13th September 1989 — Receives a HCV PCR Positive Unit			
Date of Plasma Donation	Batch No.	Date of Manufacture	Date of Issue
13th October 1989	561*	4th March 1991	April/May 1991
	564*	23rd April 1991	May 1991
	571*	10th June 1991	October 1991
	578*	9th September 1991	December 1991
16th October 1989	559*	4th February 1991	April 1991
	562*	12th March 1991	May 1991
	563 N.T.	3rd April 1991	May 1991
20th October 1989	572*	17th June 1991	September 1991
	573*	24th June 1991	September/October 1991
	574*	9th July 1991	September/October 1991
	575*	15th July 1991	October 1991
	576*	22nd July 1991	November 1991
	577*	30th July 1991	October/November 1991
	579*	16th September	December 1991
23rd October 1989	558*	22nd January 1991	March 1991
25th October 1989	557*	14th January 1991	March 1991
	560*	12th February 1991	December 1991
27th October 1989	TRANSFUSION REACTION		

8th November 1991 — Y presents herself for testing at the BTSB.
13th November 1991 — Memo to Cunningham from Walsh saying plasma may now be used to make Anti-D Immunoglobulin.
18th February 1994 all Anti-D Stock recalled.

*20 Batches PCR Positive
*Infectivity Cannot be Ruled Out

Appendix G

Numbers of persons infected as of February 1997, provided by the BTSB.

(A) HOW MANY PERSONS WERE INFECTED WITH HCV AS A RESULT OF RECEIVING THE 1977 INFECTED ANTI-D?

704 persons who received 1977 infected Anti-D showed evidence of past or current infection with Hepatitis C con a laboratory screening. A further 53 show a RIBA reaction in which HCV antibodies were not confirmed, which we believe in to either evidence of cleared infection or falsely positive (Ratio 1:0.08 true : false RIBA reactions). However they will be further studied.

309 have persisting circulating virus detectable by PCR at 18 years post infection (55%) and therefore at potential risk, unless there is medical intervention, of progressive liver disease.

However we now have evidence that it is also possible (although apparently rare) for a person to be infected and subsequently lose both detectable virus and indeed detectable antibodies. This happened in the case of Donor Y. While we have no laboratory means of identifying these persons, we have however taken a history of symptoms or signs from those who received BTSB Anti-D. We are thus aware of 74 recipients of 1977 Anti-D who had an episode of jaundice at that time which is most likely to be related to exposure to Hepatitis C. As these persons do not show any reaction on laboratory tests for Hepatitis C an epidemiological study is planned to investigate transient infection which has subsequently cleared.

294 of the 390 recipients with detectable circulating virus by PCR have had viral typing carried out showing type 1b, the HCV type transmitted by 1977 Anti-D.

Some alteration in these figures may occur in the course of further viral typing.

We have previously directly invited known recipients of infected 1977 Anti-D for Hepatitis C screening. However a number of recipients have not yet presented for testing. We are therefore following this up with individual recipients and hospitals with specific attention to recipients of PCR positive batches.

(B) HOW MANY PERSONS WERE INFECTED WITH HCV FROM RECEIVING THE 1991 INFECTED ANTI-D?

72 persons who received 1991 infected Anti-D show evidence of past or current infection with Hepatitis C on laboratory testing. A further 25 show a RIBA reaction where antibodies are not confirmed, which we believe to be falsely positive or evidence of cleared infection (Ratio 1:0.3 true : false RIBA reactions).

44 recipients have detectable virus by PCR at 3 years post infection (61%) and therefore at potential risk, unless there is medical intervention, of progressive liver disease.

26 of the 44 recipients with detectable circulating virus by PCR have had viral typing carried out, showing type 3, the HCV type transmitted by 1991 Anti-D. Some alteration in these figures may occur in the course of further viral typing.

almost 30% of those expected to have received BTSB Anti-d in these later years have not yet presented for screening.

(C) HOW MANY PERSONS WHO WERE INFECTED BY THE 1977 AND 1991 ANTI-D BECAME BLOOD DONORS?

(1) 103 Anti-D Recipient Donors have been identified to date from whose donations potentially infectious components were issued, subsequent to their own exposures to and infection with/HCV. 62 of these donors show continuing viral presence by PCR (60%). This includes one donor, with continuing viral presence by PCR, infected by 1991 Anti-D, with a single potentially infectious donation.

Some minor alterations in these figures may occur in the course of further viral typing.

(2) 1 further donor has been identified who we expect to have been indirectly infected by Anti-D. The transmission route to this contact is uncertain (healthcare worker/household).

(D) HOW MANY BLOOD DONATIONS DID THESE PERSONS GIVE?

(1) 504 potentially infectious donations were given by donors exposed to Hepatitis C by BTSB Anti-D. We estimate that 606 potentially infectious labile components (i.e. Red Cell Preparations, Platelets, Fresh Frozen Plasma) prepared from these donations were issued. the proportion of issues before 1986 from Pelican House, Dublin is an estimate as the despatch dockets from this time are no longer available. The two components issued from the single infectious donation from the 1991 Anti-d infected donor are included in the above. However, both of these have been traced to deceased recipients.

We estimate that 359 labile components were issued from the donations given by the 62 donors with continuing evidence of viral presence by PCR. The proportion of issues before 1986 from Pelican house, Dublin, is estimated as noted above. These components are positively associated with transmission of Hepatitis C to recipients (80% associated risk). whereas transmission of Hepatitis C by donations from donors now PCR negative is rare.

(2) 8 liable components were issued from the further donor we expect to have been indirectly infected by BTSB Anti-D.

Some minor alteration i these figures may occur in the course of further viral typing.

(E) HOW MANY PERSONS WERE INFECTED AS A RESULT OF RECEIVING BLOOD OR BLOOD PRODUCTS DONATED BY SUCH PERSONS?

Of the estimated 359 labile components issued from PCR positive donors, 209 have been traced. 20 of these components have been documented as unused, 104 recipients have been identified as deceased and 85 living recipients have been identified. 76 of the living recipients have attended for screening. In addition 89 recipients of labile components from PCR negative Anti-D donors have been identified /

Deceased recipients of labile components from PCR positive donors were at similar risk of HCV transmission i.e. we can expect that up to 80% of these recipients were infected with Hepatitis C as a result of receiving these components. (12 of 16 cases where liver function tests are available show evidence of possible transfusion associated Hepatitis). the cause of death in the vast majority of cases of deceased recipients probably was not related to infection with Hepatitis C.

(1) 61 living persons have been identified, to date, with evidence of exposure to and infection with Hepatitis C from transfusion of labile blood components from donors infected by Anti-D. Of these 30 show evidence of continuing viral presence by PCR (49%). Some of these were identified in the Anti-D recipient programme but were subsequently identified as recipients of components from Anti-D donors in the Lookback Programme. One was identified in a transfusion associated Hepatitis C Lookback undertaken in Munster in late 1993. The donor implicated in this May 1991 transfusion had not donated after October 1991, but was later identified as a 1977 infected Anti-D recipient.

(2) To date no living recipients have been found of the 8 components issued from the further donor who we expect to have been indirectly infected by Anti-D.

(3) 1 person has been identified in the Optional Screening Programme who was indirectly infected by Anti-D. this person does not show evidence of continuing viral presence by PCR.

(4) The situation with respect to recipients of plasma derived products (such as clotting factor concentrates) from such donations is complex. This is because such products are made from very large pools of donors where Hepatitis C contamination would have been present form donor source other than Anti-D. The importation of such products derived from paid plasma donors outside of this country would have exposed their recipients to a higher viral load in the starting plasma for these products than that from unpaid Irish donors. the viral inactivation procedures applied to such products were not fully effective against Hepatitis C until 1990. However, only 2 of 14 Haemophilia patients born after 1986 are HCV positive. These two patients were recipients of commercial (imported paid donor) in addition to BTSB plasma derived products. 12 of these patients remaining negative for Hepatitis C supports a relatively low viral load in unpaid Irish donors starting plasma from either Anti-D or non anti-D sources.

Overall, these factors serve to significantly diminish the contribution to HCV transmission from infected anti-D to recipients of pooled plasma clotting factor concentrates.

Some minor alteration in these figures may occur in the course of further viral typing.

(F) HOW MANY ANTI-D RECIPIENTS HAVE BEEN SCREENED FOR HEPATITIS C?

62,667 persons have presented for Hepatitis C screening under the Anti-D Recipient/HCV Programme.

This includes 56,151 who attended in 1994, 2,636 who attended in 1995, 3,696 who attended in 1996 and 184 in 1997 to date.

(G) HOW MANY RECIPIENTS OF BLOOD OR BLOOD COMPONENTS OR PRODUCTS FROM INFECTED ANTI-D DONORS HAVE BEEN SCREENED?

(1) 102 living recipients of labile blood components prepared from donations where the donor (PCR positive or negative) was infected by BTSB Anti-D Immunoglobulin have been screened.

While recipients of plasma derived products, such as persons with Haemophilia, have been screened for Hepatitis C by their attending Clinicians and indeed others have attended for screening in the Optional Transfusion Recipient Screening Programme, we do not know the source of their Hepatitis C infection. We would be happy to co-operate with the attending Clinicians caring for

patients with haemophilia in undertaking further molecular biology research.

(H) HOW MANY PERSONS HAVE AVAILED OF THE OPTIONAL SCREENING PROGRAMME?

12,176 persons who believe they have had a history of blood transfusion have presented for Hepatitis C screening under the Optional Screening Programme to early February 1997.

(I) HOW MANY PERSONS TESTED POSITIVE UNDER THIS PROGRAMME?

48 persons screened in the Optional Transfusion Recipient Programme have evidence of current or past infection with Hepatitis C. A further 32 persons have a RIBA reaction where antibodies are not confirmed, which we believe to be a false positive reaction (Ratio 1:0.7 true : false RIBA reactions).

31 of the 37 where PCR result available show evidence of continuing viral presence by PCR (84%).

Only one person with the evidence of past infection, but not continuing viral presence, has been identified in this programme to have been infected by a donor who in turn was infected by BTSB Anti-D Immunoglobulin (as noted in (E) above).

This programme was not and is not expected to be efficient in identifying the untraced Anti-D HCV infectious burden, while there is an associated high level of false positive RIBA reactions.

(J) HOW MANY PERSONS WHO HAVE THUS PROVED POSITIVE CAN BE LINKED TO THE RECEIPT OF INFECTED ANTI-D EITHER DIRECTLY OR INDIRECTLY?

849 persons have been identified with laboratory evidence of exposure to and infection with Hepatitis C which we expect to be related, directly or indirectly, to contamination of BTSB Anti-D Immunoglobulin by Hepatitis C. 467 of these show evidence of continuing viral presence by PCR (55%).

These have been identified under the following programmmes:

(1) Blood Donor/Anti-d Recipient Programmes

1977 infected Anti-D	— 704	(390 PCR positive)
1991 infected Anti-D	— 72	(44 PCR positive)
Anti-D Recipient Contact Programme (of 2,284 contacts screened)	— 11	(3 PCR positive)

(2) Targeted Lookback Programme

Recipients of Transfusion from
Donors directly infected by Anti-D — 61 (30 PCR positive)

(3) Optional Screening Programme — 1 (0 PCR positive)

In addition we can anticipate that others will be identified from the following:

1. Recipients exposed and transiently infected in 1977 will be identified in the epidemiological study of 1977 Anti-D Recipients with a history of jaundice who are no longer infected with Hepatitis C, as noted in (A) above.

2. The Targeted Lookback Programme is ongoing and further living recipient tracing can be anticipated. When this is sufficiently advanced we will also consider the issues pertinent to the study of targeted recipients who are now deceased.

(K) HOW MANY PERSONS WHO HAVE SCREENED POSITIVE ARE HCV POSITIVE WITHOUT ANY LINK DIRECT OR INDIRECT TO THE INFECTED ANTI-D AND SUBSEQUENT DONATIONS OF BLOOD BY THOSE ANTI-D RECIPIENTS?

300 persons have been identified to date with evidence of past or current infection with Hepatitis C without a link, directly or indirectly, to Anti-D contamination by Hepatitis C.

They have been identified in the following BTSB HCV Programmes:

(1) Blood donors

(2) The Anti-D Recipient Programme

(3) The Targeted Lookback Programme

(4) The Optional Screening Programme

as follows;

(1) 116 persons who donated blood to the BTSB have been identified with evidence of past or continuing infection with Hepatitis C virus where this was not related to Anti-D directly or indirectly.

56 of these donors have continuing presence of virus detectable by PCR and are associated with a high risk of transmitting Hepatitis C. We estimate that 503 labile components were issued from these donors (issues pre 1986 from Pelican House, Dublin , estimated). A further 13 donors are expected to be of similar high risk, but PCR is not available. We estimate that 122 labile components were issued from these donors.

However the relevant proportion of these donations which are truly at high risk is not known, in many cases. This is because the

timing of their HCV infection is not known to the BTS, as 23 of these donors (2 Munster, 21 Pelican House) have been lost to date to follow-up and have not attended for BTS consultation. Therefore, all their donations must be treated as potentially infectious, although we know from our experience in this Programme that a significant number of their donations would have been given prior to their infection with Hepatitis C and therefore were not infectious for recipients.

(2) 71 persons have been identified in the Anti-D Recipient Programme, with laboratory evidence of past or current infection with Hepatitis C unknown to date to be related to Anti-D, directly or indirectly, 54 of 64 where PCR result available show evidence of continuing viral presence by PCR (84%).

(3) 66 persons have been identified as targeted living recipients of potentially infectious blood transfusions with laboratory evidence of past or continuing infection with Hepatitis C, not related to BTSB Anti-D, directly or indirectly. Of these, 54 show evidence of continuing viral presence by PCR (82%).

This is an interim position as this Programme is on-going.

Of note both Anti-D donors who had (a) been identified on HCV screening when they presented as blood donors after October 1991 and (b) not reattended as blood donors since October 1991, have been identified and included in the HCV infectious burden. However, only non anti-D donors who have reacted on donor HCV screening after October 1991 have been included in the Targeted Lookback Programme. (We can only use limited indirect means to identify those who have not reattended as blood donors since HCV screening commenced. A phased donor lookback of possible cases of transfusion associated Hepatitis C is being undertaken. This will be subjected to interim review).

Therefore we believe that the contribution to the infectious burden from donors who were not exposed by Anti-D directly or indirectly, is under-represented. Moreover we have seen a higher rate of persisting viral presence in these persons over that seen in recipients of Anti-D infected donations (84% Vs 49%) which must be further studied.

(4) 47 persons identified in the Optional Screening Programme show laboratory evidence of past or continuing infection with Hepatitis C which is not related to Anti- exposure, either directly or indirectly. 31 of these 36 with PCR results available show evidence of continuing viral presence by PCR (86%).

No figure is available for the Hepatitis C infectious burden in the general Irish population, nor is it known what proportion of cases of Hepatitis C virus are acquired by blood transfusion or by

intravenous drug abuse in Ireland. However such figures have been reported for the United States, where less than 4% of cases of Hepatitis C virus are acquired by transfusion and in Australia where 3% of cases of Hepatitis C are acquired by transfusion.

Appendix H

Chronology of events relating to the Manufacturers licence

MANUFACTURING LICENCE M225
(Medical Preparations (Licensing & Manufacture) Regulations)

Year	Date of Application	NDAB Inspection	NDAB Recommendation	Grant by Department of Health
1975	28th February 1975	20/11/73[1]	17th July 1975 *(05.09.75)	1st October 1975
1978	No Application	—[2]	12th October 1978 *(17.10.78)	2nd October 1978 **(30.11.78)
1981	16th October 1981	18/12/79 13/10/81	9th October 1981 *(12.10.81) 29th October 1981	2nd October 1981 **(09.02.82)
1984	20th September 1984[3]	15/11/84	20th September 1984 *(28.09.84)	2nd October 1984 **(15.11.84)
1987	23rd October 1987	14/07/87	1st October 1987 *(07.10.87)	2nd October 1987 **(17.11.87)
1990	No Application	No Inspection	27th September 1990 *(28.09.90)	2nd October 1990 **(31.10.90)
1993	No Application	17 & 18/11/92	29th July 1993 *(27.08.93)	2nd October 1993

1. NDAB Inspector says he made 1 or 2 more visits which are unrecorded.
2. NDAB Inspector says he made numerous unrecorded visits.
3. Department of Health had warned of expiring licences — 31st August, 1984.
4. Letter received and date stamped by Department of Health — 5th October, 1984.

* Date communicated to the Department of Health.
** Date grant issued.

A MANUFACTURING LICENCE WAS VALID FOR 3 YEARS FROM DATE OF GRANT

Appendix I

Chronology of events relating to the Product Authorisation

PRODUCT AUTHORISATION (European Communities (Proprietary Medicinal Products) Regulations, 1975 as Amended)		
Application	NDAB Recommendation	Grant
12th December 1982	5th September 1986	1st April 1983
2nd February 1993	23rd February 1994	1st April 1988

LETTERS FROM THE DEPARTMENT OF HEALTH

1 1st March 1991 — Product Authorisation due for Renewal "Shortly"

2 18th December 1991 — Product Authorisation "Will Expire on the 1st April 1988"

3 2nd February 1993 — Product Authorisation "Will Expire on the 1st April 1993"

A PRODUCT AUTHORISATION WAS VALID FOR 5 YEARS.

Appendix J

Tables on workload and staffing levels at the NDAB

Applications for Product Authorisation to Market Medicinal Products for Human Use 1974-1995

Year	Backlog at Start of the Year	Applications Received	Recommendations Issue to Department of Health	Withdrawn	Backlog at End of Year
1974	—	50	22	1	27
1975	27	272	188	3	108
1976	108	1,195	302	20	981
1977	981	1,028	1,029	70	910
1978	910	1,111	691	163	1,167
1979	1,167	992	518	24	1,617
1980	1,617	722	564	69	1,706
1981	1,706	641	596	140	1,611
1982	1,611	966	468	55	2,054
1983	2,054	895	720	258	1,971
1984	1,971	759	565	80	2,085
1985	2,085	641	464	108	2,154
1986	2,154	711	388	103	2,374
1987	2,374	687	790	134	2,137
1988	2,137	592	655	66	2,008
1989	2,008	659	501	129	2,037
1990	2,037	842	258	130	2,491
1991	2,491	840	393	85	2,853
1992	2,853	589	458	124	2,860
1993	2,860	651	463	632	2,416
1994	2,416	679	383	235	2,477
1995	2,477	623	412	116	2,572
		16,145	10,828	2,745	2,572

Source: Annual Reports.

Applications for Approval of Clinical Trials 1974-1995

Scheme	Year	Backlog at Start of Year	Applications Received	Applications Approved	Applications Withdrawn/Rejected	Backlog at End of Year
Voluntary	1974	3	54	41	7	9
Voluntary	1975	9	82	86	—	5
Voluntary	1976	5	102	95	6	6
Voluntary	1977	6	75	71	10	—
Voluntary	1978	—	79	74	5	—
Voluntary	1979	—	57	54	3	—
Voluntary	1980	—	68	68	—	—
Voluntary	1981	—	55	55	—	—
Voluntary	1982	—	31	30	1	—
Voluntary	1983	—	37	36	1	—
Voluntary	1984	—	64	63	1	—
Voluntary	1985	—	223	204	19	—
Voluntary	1986	—	218	198	20	—
Voluntary	1987	—	238	211	27	—
Voluntary	1988	—	288	269	19	—
Statutory	1989	—	210	205	5	—
Statutory	1990	—	240	228	12	—
Statutory	1991	—	178	176	2	—
Statutory	1992	—	205	203	2	—
Statutory	1993	—	213 (142)	209 (139)	4 (3)	—
Statutory	1994	—	252 (154)	248 (151)	4 (3)	—
Statutory	1995	—	246 (176)	246 (176)	—	—

Source: NDAB Statistics/Annual Report.

Note: Amendments are shown in brackets.

Application for Manufacturing Licences 1974-1994

Year	Applications outstanding at the start of year	Applications received	Recommendations issued to the Department of Health	Applications Withdrawn/ Rejected	Applications Outstanding at End of Year	Amendments Received	Existing Licences Withdrawn	No. of Licence Manufactures
1974	0	22	0	0	22	0	0	0
1975	22	12	30	3	1	0	0	30
1976	1	5	2	0	4	6	1	31
1977	4	8	4	1	7	10	2	32
1978	7	7	8	0	6	16	0	37
1979	6	1	2	1	4	3	1	38
1980	4	4	3	0	5	15	2	40
1981	5	4	3	1	5	10	1	42
1982	5	3	5	0	3	7	2	45
1983	3	6	4	0	5	15	0	49
1984	5	4	2	1	6	14	1	51
1985	6	5	7	0	4	5	7	49
1986	4	5	5	0	4	20	1	54
1987	4	7	4	2	5	13	7	51
1988	5	5	10	0	0	17	3	59
1989	0	6	5	0	1	19	2	61
1990	1	4	2	1	2	20	3	60
1991	3	5	5	1	2	N/A	2	63
1992	2	5	3	2	2	N/A	2	64
1993	2	9	9	1	1	N/A	4	69
1994	1	4	3	1	1	N/A	2	70

Source: Annual Report

Application for Wholesale Licences 1974-1994

Year	Applications outstanding at the start of year	Applications received	Recommendations issued to the Department of Health	Applications Withdrawn/ Rejected	Applications Outstanding at End of Year	Amendments Received	Existing Licences Withdrawn	No. of Licence Manufactures
1974	0	1	0	0	1	0	0	0
1975	1	70	65	2	4	0	0	73
1976	4	8	8	1	3	8	0	73
1977	3	2	4	0	1	4	1	76
1978	1	3	3	1	0	9	4	75
1979	0	4	3	1	1	1	3	72
1980	1	5	2	0	4	2	1	76
1981	4	4	6	0	2	4	2	78
1982	2	7	4	1	4	1	4	78
1983	4	4	3	2	3	6	0	81
1984	3	7	4	0	6	1	1	84
1985	6	3	5	0	4	1	5	82
1986	4	3	2	0	5	1	1	84
1987	5	5	0	1	9	3	3	81
1988	9	60	5	0	64	3	7	79
1989	64	10	55	10	9	2	3	132
1990	9	6	4	3	8	2	0	136
1991	8	6	6	0	8	N/A	7	135
1992	8	11	6	1	12	N/A	13	128
1993	12	10	13	1	8	N/A	9	132
1994	8	7	5	1	9	N/A	1	136

Source: Annual Report

Inspections Undertaken by Board's Inspectors 1974-1994

Year	Inspections of Manufacturers				Inspections of Wholesalers		P.I.C. Inspections	Other Inspections
	New Applications Human Medicines	Veterinary	Existing Licence Holders	Veterinary	New Applications	Existing Licence Holders		
1974	0		0		0	0	0	0
1975	33		0		65	0	0	7
1976	2		29		9	5	0	9
1977	4		28		4	4	6	4
1978	8		29		3	28	7	5
1979	3		18		3	15	8	1
1980	3		15		4	6	4	3
1981	5		24		4	9	6	3
1982	5		11		4	6	5	2
1983	4		12		3	14	5	5
1984	4		26		4	7	18	3
1985	7		16		6	6	13	12
1986	6		24		2	6	6	5
1987	4		24		0	6	10	1
1988	8	18	34	0	33	30	9	9
1989	6	11	34	0	87	15	20	2
1990	4	0	18	12	5	8	21	8
1991	4	3	33	16	7	31	31	6
1992	8	5	29	12	6	31	13	10
1993	12	0	25	9	5	22	26	9
1994	5	1	21	8	5	31	11	6

Source: Annual Reports

Applications for Product Authorisations to Market Veterinary Medicinal Products 1987-1995

Year	Backlog at Start			Applications Received			Applications Approved			Applications Withdrawn/Rejected			Backlog at End		
	Total	New	Review	Total	New	Review	Total	New	Review	Total	New	Review	Total	New	Review
1987	—	—	—	172	6	166	—	—	—	—	—	—	172	6	166
1988	172	6	166	356	9	347	—	—	—	26	—	26	502	15	487
1989	502	15	487	306	18	288	30	11	19	41	—	41	737	22	715
1990	737	22	715	216	22	194	66	1	65	(3)	1	(4)	890	42	848
1991	890	42	848	362	42	320	58	11	47	31	1	30	1,163	72	1,091
1992	1,163	72	1,091	162	42	120	109	24	85	79	1	78	1,137	89	1,048
1993	1,137	89	1,048	60	59	1	144	41	103	83	5	78	970	102	868
1994	970	102	868	56	55	1	110	52	58	84	1	83	832	104	728
1995	832	104	728	50	49	1	147	63	84	121	2	119	614	88	526
Total	—	—	—	1,740	302	1,438	664	203	461	462	11	451	614	88	526

Source: Board Statistics and Annual Reports.

Sampling and Analysis on Medical Products (Human Medicines) 1976-1994

Year	Inspectors' Samples	Products Taken from the Market	Suspected Defective Products	Adverse Reactions Reported	Drug Substances	Product Authorisation Application	Total
1976	50	17	4	3	0	0	74
1977	56	122	4	3	0	0	185
1978	18	172	5	2	0	0	197
1979	11	222	1	5	0	0	239
1980	14	152	7	1	0	0	174
1981	4	162	10	4	0	0	180
1982	23	93	9	5	0	0	130
1983	10	142	14	1	0	0	167
1984	16	141	11	3	0	0	171
1985	2	80	14	6	0	0	102
1986	8	63	6	4	18	51	150
1987	3	26	5	3	19	73	129
1988	0	15	6	3	10	95	129
1989	6	11	4	9	9	107	146
1990	7	7	3	13	2	42	74
1991-199	0	127	10	17	0	91	245
Total	228	1,552	113	82	58	459	2,492

Sampling and Analysis on Medical Products (Veterinary) 1989-1994

Year	Inspectors' Samples	Products Taken from the Market	Suspected Defective Products	Adverse Reactions Reported	Drug Substances	Product Authorisation Application	Total
1989	0	2	1	4	0	4	11
1990	4	0	1	6	0	1	12
1991-199	0	80	3	9	0	34	126
Total	4	82	5	19	0	39	149

Source: Annual Reports.

Number of Staff Employed by the National Drugs Advisory Board 1974-1995

Title/Grades	Year ended 31st December																					
	1974	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995
Medical																						
Medical Director	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	0	0
Deputy Director (Medical)	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Medical Assessor	0	0	0	0	1	1	0	1	1	1	1	1	1	1	3	3	3	3	3	3	5	4.5
	1	1	1	1	3	3	2	3	3	3	3	3	3	3	5	5	5	5	4	4	6	5.5
Veterinary																						
Deputy Director (Veterinary)	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1
Veterinary Assessor	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1
	0	0	0	0	0	0	0	0	0	0	0	0	0	2	2	2	2	2	2	2	2	2
Pharmaceutical																						
Senior Pharmacist	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1
Senior Inspector	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1
Pharmacists	1	1	2	3	4	3	3	4	4	4	4	4	4	3	7	7	5	7	7	6	7	5.5
Inspector	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	2	1	1	0	1	1	1
	2	2	3	4	5	4	4	5	5	5	5	5	5	6	10	10	8	10	9	9	10	8.5
Administration																						
Chief Executive	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Secretary	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Assistant Secretary	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Senior Systems Administrator	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1
Senior Adverse Reactions Off	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1
	2	2	2	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	4	4	5
Clerical — Alll grades	5	5	7	7	9	11	10	11	13	13	13	13	13	17	17	25	25	26	27	32	41	37.5
TOTAL	10	10	13	15	20	21	19	22	24	24	24	24	24	30	37	45	43	46	45	51	63	58.5

Notes: (a) Dr. Allene Scott acted as Medical Director and Chief Executive from 1967 until she retired in March 1992.
(b) Dr. John G. Kelly took up his appointment as Chief Executive in June 1995.
Source: Board's Records/Annual Report.

Appendix K

Medical and management matters immediately dealt with by the CEO in 1995

Medical Matters

These included the following:

(a) Reviewing of Donor screening, Donor questionnaire, Donor selection sample archiving and Blood testing/processing.

(b) Managing the medical issues that arise over time.

(c) Reorganising consultant appointments to include sessions at Dublin teaching hospitals.

(d) Ensuring that all screening programmes for hepatitis C currently underway or to be introduced are properly managed, advising on further developments and screening programmes.

(e) Ensuring that international contracts and E.U. Committee memberships are obtained for consultant staff.

(f) Establishing consultants meetings and formalising Medical Sub-Committees relationship with the Board.

(g) Seeking to ensure Medical/Scientific that meetings are held regularly.

(h) Establishing contact with hospital laboratories and transfusion committees and organising symposium on topics related to transfusion medicine.

(i) Establishing a research ethic within the BTSB and identifying suitable projects.

Management Matters

(a) Review of the organisation structure and preparation of the reorganisation plan.

(b) Preparation of a development plan for discussion and agreement with the Department of Health.

(c) Review and making of proposals on buildings and structural matters.

(d) Review and making of proposals on information Technology System.

(e) Review and making of proposals on vehicle and equipment replacement/new purchases.

(f) Ensuring management of the ex gratia payments scheme within guidelines.

(g) Maintenance of close liaison with the Department of Health.

(h) Ensuring blood collections are maintained and quality issues addressed.

(i) Review of Board's insurance.

Appendix L

BTSB development plan 1996-1999

The development programme for the period 1996 -1999 will concentrate on the following areas in particular:

(a) Establishment of an IT department and implementation of new IT systems.

(b) Medical developments including additional medical manpower.

(c) Strengthening of Quality Assurance department.

(d) Establishment of new Donor Services Department.

(e) Strengthening of finance and audit functions.

(f) Management training and development programme.

(g) Research and development programme.

(h) Introduction of new tests.

(i) Molecular Biology developments.

(j) Additional services such as bone marrow register, bone services and cord cell banks.

(k) Capital Programme incorporating:—
- — new and replacement equipment
- — vehicle replacement programme
- — new transfusion centre in Dublin and examination of the current centre buildings in Cork to establish their suitability as a Regional Centre both now and for the future.