The Archer Inquiry

"To investigate the circumstances surrounding the supply to patients of contaminated NHS blood and blood products; its consequences for the haemophilia community and others afflicted; and suggest further steps to address both their problems and needs and those of bereaved families".

Independent Public Inquiry Report

On

NHS Supplied Contaminated Blood and Blood Products

The Rt Hon Lord Archer of Sandwell QC - Formerly Solicitor General - Chairman

Dr Norman Jones FRCP - Emeritus Consulting Physician to St Thomas' Hospital, London

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Published: 23 February 2009

www.archercbbp.com

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TERMS OF REFERENCE

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MEMBERS OF THE TRIBUNAL

The Rt Hon Lord Archer of Sandwell QC - Formerly Solicitor General - Chairman

Dr Norman Jones FRCP - Emeritus Consulting Physician to St Thomas' Hospital, London

Ms Judith Willetts - Chief Executive of the British Society for Immunology

GLOSSARY OF TERMS

ALT	Alanine Aminotransferase
AIDS	Acquired Immune Deficiency Syndrome
AHG	Anti-Haemophilia Globulin
BPL	Blood Products Laboratory
CDC	Centre for Disease Control
CSM	Committee on Safety of Medicines
DDAVP	Desamino-D-Arginine-vasopressin
DHSS	Department of Health and Social Services
ELISA	Enzyme-linked Immunosorbent Assay
FDA	Food and Drug Administration
GRID	Gay Related Immunodeficiency
HCDs	Haemophilia Centre Directors
HEP C	Hepatitis C
HIV	Human Immunodeficiency Virus
IU	International Units
NANB	Non A – Non B Hepatitis
NHS	National Health Service
PCP	Pneumocystis Carinii Pneumonia
PFL	Plasma Fractionation Laboratory
PFC	Protein Fractionation Centre
PUPs	Previously Untreated Patients
RHAs	Regional Health Authorities
SNBTS	Scottish National Blood Transfusion Services

UK	United-Kingdom
UKHCDO	United-Kingdom Haemophilia Centre Doctors' Organisation
USA & US	United States of America
vCJD	variant Creutzfeldt-Jacob Disease
WHO	World Health Organisation

INTRODUCTION

Throughout the 1970s and the first half of the 1980s, many in the UK who suffered from haemophilia were treated with blood and blood products which carried what came to be known as Hepatitis C, and some 4,670 patients became infected. Between 1983 and the early 1990s some 1,200 patients were infected with HIV, also through blood products. These infections had caused at least 1,757 deaths in the haemophilia community by the time this Inquiry started in February 2007, and more have occurred subsequently.

By the mid 1970s it was known in medical and Government circles that blood products carried a danger of infection with Hepatitis and that commercially manufactured products from the USA were particularly suspect. By the mid-1980s there were warnings of a similar situation in respect of HIV. But the products continued to be imported and used, often with tragic consequences. The reasons for the chain of decisions that led to this situation, and the alternative options which might have given rise to a different outcome, have been debated since that time.

Many of the victims were deprived of their livelihoods, and families of their principal earners, while the other financial consequences were far reaching. Some provision has been made for meeting the consequent financial needs, but it has been seen as less generous than the benefits made available in other countries which faced similar disasters.

There is a widely felt need for an airing of the questions to which the experience has given rise and of the lessons to be learned. The UK Haemophilia Society has

campaigned for a Public Inquiry since 1988, with encouragement from the World Federation of Haemophilia. The Rt Hon the Lord Morris of Manchester, AO, QSO, the first Minister for Disabled People, both in the UK and the world, has repeatedly raised the issue, successively in the House of Commons and the House of Lords, with support from colleagues of all parties.

However, successive Governments have declined to establish a Public Inquiry. Their view was articulated succinctly by, among others, Lord Warner the Minister of State at the Department of Health who said in answer to a question on 12 January 2006:[1]

"We do not consider that a Public Inquiry is justified as we do not believe that any new light will be shed on this issue as a result".

Inevitably, it was widely suspected that there was something to hide. Secrecy fosters suspicion.

Nevertheless, Lord Morris of Manchester believed that, not only would a Public Inquiry yield some lessons for the future, but also that it may help the victims and those bereaved to come to terms with their experience.

Accordingly, on 19 February 2007, he announced that The Rt Hon Lord Archer of Sandwell QC, Lord Turnberg and Ms Judith Willetts had agreed to serve on an Independent Public Inquiry, with Dr Norman Jones as a Consultant.

[1] At column 299 in Hansard

The terms of reference are:

"To investigate the circumstances surrounding the supply to patients of contaminated NHS blood and blood products; its consequences for the haemophilia community and others afflicted, and further steps to address both their problems and needs and those of bereaved families".

We understand this to include consideration of lessons to be learned.

Sadly, in the course of the Inquiry, Lord Turnberg was compelled by a family tragedy to withdraw from the Inquiry, and was replaced by Dr Norman Jones, to whom the other members of the Inquiry would like to record their gratitude. We would also like to record our appreciation of the contribution made by Lord Turnberg.

It should be made clear that, although not appointed by the Government, this is nonetheless a public inquiry, as we hope to have demonstrated. It is, however, not a statutory Inquiry, under the Inquiries Act 2005. The principal consequence is that we had no power to compel anyone to give evidence or to produce documents. Nevertheless over 300 witnesses submitted statements, 64 of whom gave oral evidence, and we have been presented with more than 20,000 documents.

Without the resources which would have been available to a Government appointed Inquiry, we did not have the assistance of Counsel to the Inquiry, nor the support staff who would have facilitated our task. We wish to record our debt to Mr Vijay

Mehan, an Associate Solicitor with Messrs Fentons Solicitors LLP, who alone shouldered the administrative work entailed, and without whom our proceedings would not have been possible.

We estimate that the total cost of the Inquiry, including publication, will be less than £75,000. No member of the Panel has received or will receive any remuneration. The venues for our meetings and hearings were provided at the House of Lords by courtesy of Black Rod, Lieutenant General Sir Michael Wilcox.

We are indebted to all those who gave evidence, written and oral, especially victims and their families. All witnesses are recorded in the Appendix. Written evidence has continued to be submitted late to us by those anxious to assist us, as new information has been discovered, and this has continued until our report was virtually finalized. It has not been possible to invite oral evidence relating to these submissions, but where they appeared reliable and relevant we have endeavoured to incorporate them.

At the outset we wish to make it clear that we are as independent of the Government as we are of the Haemophilia Society. Our task has been to listen to a great deal of evidence from the victims and others, to read many papers and documents and to express our own conclusions. There is no hidden agenda.

We have been financed by the generosity of a number of donors. None of these is connected with the pharmaceutical industry, and none stood to gain from any outcome of the Inquiry.

The Department of Health maintained its view that the Inquiry was unnecessary, and declined to provide witnesses to give evidence in pubic, but they supplied documents which we requested, responded to questions from us and sent representatives to three private, informal and unminuted meetings.

During the course of our Inquiry, the Scottish Government announced that it was appointing a statutory Public Inquiry into the transmission of Hepatitis C and HIV through blood and blood products. We fully understand that, given the Opinion of Lord Mackay of Drumadoon in the Petition of Rosaleen Kennedy and Jean Black, the Scottish Government felt constrained to appoint a Public Inquiry. We are told that the Scottish Public Inquiry will consider our Report. We had already received evidence about events in Scotland during the relevant period, and have held discussions with representatives of the Scottish Government, but we are reluctant to trespass on ground to be explored by the statutory Public Inquiry and have therefore refrained from making judgments on events in Scotland, except where they impinge on situations throughout the United Kingdom.

The past cannot be undone. Nothing can rescue the victims and their families from what they have already suffered. But a review of the events and decisions that led to the tragedy may assist in coming to terms with the consequences, and might suggest ways in which Government may address those aspects which it is not too late to rectify. While hindsight, by definition, operates after damage is done, it may reveal important lessons for the future. We consider that to be more important than apportioning blame.

CHAPTER 1 – HAEMOPHILIA

Haemophilia is a bleeding disorder caused by a deficiency of a protein essential for the normal clotting of blood. Consequently even minor injuries may lead to prolonged bleeding, which may also occur spontaneously. Bleeding into joints is common, leading to severe pain and eventually to permanent damage to the joint. Haemophilia is hereditary and is confined almost exclusively to males. It is, however, transmitted through the female line. The severity varies substantially from patient to patient.

Bleeding disorders may arise from deficiency of one of a number of such protein factors in the blood. Deficiency of Factor VIII causes Haemophilia A. Less common is Haemophilia B, caused by deficiency of Factor IX, which tends to be more serious than the A form. A range of other bleeding disorders result from deficiencies of other clotting factors, e.g. Von Willebrand's disease[2].

Haemophilia can seriously diminish the quality of life. Prior to the availability of effective treatment, the condition caused episodic crises requiring urgent medical treatment, together with restriction of schooling, employment capacity and ability to travel. It could affect the patient's entire family, since the disruption of the patient's home and working life could require a disproportionate share of attention, and impose psychological strain on all concerned. It diminished life expectancy, particularly by reason of bleeding into the brain or gastro-intestinal tract. A study in 1960 indicated that patients with severe forms of the condition could not normally expect to live beyond 25 years.

[2] Von Willebrand's disease is a bleeding disorder caused by either quantitative or qualitative deficiency of a protein termed vonWillebrand Factor (vWF). Both hereditary and acquired forms of the disease exist. It can be treated with Factor VIII concentrate complexed with vWF or, in less severe cases, with DDAVP.

Provision for the treatment of haemophilia lay in the first instance with the Area Health Authorities. Professor Savidge described the arrangements for us. He explained that in the 1960s the Department of Health issued a circular describing a 3-tier provision: -

"So you had the lowest tier, which was associate centres, which in essence were general haematology departments that looked after one, two, three, four patients…there were about a hundred at the time. Then you had your haemophilia centres which looked after about twenty to thirty patients and they numbered some ten to sixteen, and then you had the so-called reference centres, which was the top of the heap".

In the late 1960s, Haemophilia Centre Directors formed the United Kingdom Haemophilia Centre Directors' Organisation (The UKHCDO). Its function was to collect and co-ordinate data on haemophilia patients and their treatment. It was a voluntary, unincorporated association of physicians, with its Executive Committee consisting of Directors of the largest and most influential Haemophilia Centres, from the Royal Free and St Thomas' Hospitals in London, together with Edinburgh, Glasgow, Belfast, Cardiff, Manchester, Newcastle, Sheffield and Oxford. The membership was drawn from about 100 centres. In the early 1990s it developed a regional structure, but in the earlier years meetings were on a national basis. Recommendations and advice on important issues were conveyed to Government and to relevant national committees and organisations by informal communications. It appears that there was little feedback.

While doctors caring for haemophilia patients were achieving coordination, the patients were pursuing a similar objective, with advice provided by concerned doctors. In 1950 the UK Haemophilia Society was established, with charitable status. It provides information and support for patients with haemophilia or related disorders, and their families, and acts as their advocate to Government and other Authorities. At present it has 17 local groups and 4,113 members. It estimates that about half of severe haemophilia sufferers are members or registered supporters. Some 12,000 people use the website each year, and there are about 2,000 telephone calls annually to their Helpline. Similar societies exist in other countries; there is a European Haemophilia Consortium and a World Federation of Haemophilia. There are also a number of separate campaigning groups, such as Tainted Blood and the Manor House Group, to whom we are indebted for helpful information.

Before 1965, there was no known effective treatment for haemophilia, and until the 1940s treatment usually consisted of bed rest and cold compresses. There were experiments with snake venom. Episodes involving severe loss of blood could be compensated by blood transfusions, but these were not a form of treatment for the condition itself, since Factors VIII and IX form a minute proportion of the body's blood content, and the amount of blood required to rectify the deficiency would be so massive that the circulatory system would have difficulty in coping. Transfusions were a lengthy process, requiring visits to hospital or treatment centres and entailing frequent interruptions to daily living.

In 1965 a group of researchers in Stanford University, USA, discovered that by freezing plasma and then thawing it slowly, they could produce a residue rich in Factor VIII known as cryoprecipitate. It had ten times the concentration of the Factor VIII, produced naturally by the body, could be injected at home and stored in domestic refrigerators. But it could take a long time to thaw, a frustrating disadvantage if the patient was suffering, and it was not easy to transport on long journeys.

In the late 1960s it was discovered that if cryoprecipitate was dissolved, treated chemically and subjected to a centrifugal process, it produced a crystalline powder, which had ten times the clotting power of cryoprecipitate, and when dissolved in sterile water, could be injected at home. This became known as Factor VIII concentrate. The disadvantage was that to be processed economically it required a substantial amount of plasma, pooled from a large number of donors, thus increasing risk of transmission of infection from any one donor.

From the early 1970s, therefore, Factors VIII and IX became available in concentrated form. They could be stored in domestic refrigerators, carried conveniently on journeys, and injected when and where required. The quality of life for patients was significantly improved, and there was promise of a new dawn. The Reverend Prebendary Alan Tanner, whose son died in 1998 in consequence of both HIV and Hepatitis C infections, explained:

"We were greatly comforted by the discovery of cryoprecipitate by Professor Judith Post in the USA in the 1960s. It meant that for the first time they could isolate Factor

VIII and inject it almost immediately following a bleeding episode. It was a very clumsy procedure…in these kinds of plastic bags, and the nurses had to exercise great patience in extracting it by syringe. They took ages to do it but it was all worthwhile because then it could be injected immediately there was a bleeding episode.

The complications were, in the very nature of the case, being cryoprecipitate, it had to be kept at very, very low temperatures, and you needed facilities to be able to deal with that.

The next step really was miraculous, when we came across Factor VIII concentrate because that did away with the clumsiness of extracting it all from the cryoprecipitate bags. It was just….put in solution into a syringe.

The important thing is that the boys and men were taught how to administer this by themselves, intravenously, and all the doctors would know that was a tremendous breakthrough".

Mr Chris Hodgson told us:

"I clearly remember my first infusion of commercial Factor VIII in 1973…I could hardly believe the small amount and speed of the treatment compared to my previous treatment with bags of cryoprecipitate".

It is not surprising that there was a rising demand from doctors and patients for Factor concentrates. But funding was dispersed to Regional Health Authorities, and thence to District General Hospitals, as part of their overall budgets. Consequently, few resources became available for what became known among haemophilia doctors as "Replacement Therapy". The annual requirement of Factor VIII was initially estimated at 40 million units. By 1984 it had increased to 80 million units, and by 1994 160 million. By reason of the underestimate, the United Kingdom acquired a reputation for offering very low levels of factor replacement compared with other European countries. This proved to be false economy, since it led to continuing joint and muscle damage, and other long-term problems, involving additional charges on the NHS. There was little margin to respond to any call for increased supplies, with the consequences discussed in subsequent chapters.

CHAPTER 2 – THE TRANSMISSION OF HEPATITIS

It had been recognised since the 1930s that a virus from a blood donor could be transmitted to a recipient of blood or blood products. Shortly after the Second World War, Dr J Garrott Allen, a surgeon at the University of Chicago, who managed the University Blood Bank, had found that in order to maintain supplies, he needed to buy blood and plasma donated by prisoners, sold on by the prison authorities. He found that the incidence of Hepatitis among haemophilia patients was related to the increase in the use of prison plasma, and began to research the phenomenon.

Hepatitis is an inflammation of the liver, with loss of functioning liver cells. A number of viruses are among the causes. Until the late 1960s the two principal viral forms were labelled A and B. Hepatitis A virus is usually transmitted in food and water. Hepatitis B virus is commonly transmitted through blood products, and the sharing of syringe needles, although it can be transmitted sexually. Both types of virus multiply in the liver. Symptoms of Hepatitis B are not usually manifest until the end of an approximately 90-day incubation period. In the acute phase it frequently gives rise to jaundice. Other symptoms include fever, fatigue, loss of appetite and muscle pains. Hepatitis can result in cirrhosis, and so lead to death from liver failure.

The virus responsible for Hepatitis B was identified in 1967, and that for Hepatitis A in 1973. But in the mid 1970s it transpired that neither the A nor B virus could account for Hepatitis in some patients, giving rise to the term “non-A non-B” Hepatitis (NANB), which was later identified as “Hepatitis C”. This is known to be responsible for the major proportion of Hepatitis infections from blood products and from sexual

activity. We were told that it was not initially thought to be a serious condition, and warnings of the risk of Hepatitis NANB encountered a somewhat dismissive response. This is not surprising given the lengthy period of many years between infection and manifestation of its more serious consequences, together with the absence of symptoms at the time of infection.

In the United Kingdom, blood was acquired by advertising for donors, who gave their blood on a voluntary basis. In the United States many blood banks operated commercially. It was the practice for entrepreneurs to collect blood from donors who were induced to donate by payment. Having purchased the blood, the commercial companies either processed it themselves or, more usually, sold it on at a profit for processing by others. It was estimated that at least almost half of blood donations in New York came from paid blood donors.

This practice meant that in the USA a large proportion of the blood donated came from those most in need of money, and there was a high correlation between that group and those whose lifestyles made them particularly susceptible to infections and least likely to have received treatment. It was also a group most tempted to conceal relevant details of their medical history, and to give false answers to questions on the subject. In the United States a substantial portion of blood donations came from those in prison. In the 1970s the blood industry in the USA was not subjected to statutory or other forms of regulation.

Dr J Garrott Allen later moved to Stanford University Medical School, where he published his findings in the journal “California Medicine”. For some of his studies he

surveyed sectors of the community popularly known as "Skid Row" inhabitants, "whose use of alcohol, drugs and unsterilised needles made them prime Hepatitis carriers"[3]. His findings provoked a national debate. He began corresponding with the Department of Health, Education and Welfare in the United States. But the blood industry constituted a powerful lobby, and nothing was done.

However, anxiety was spreading. On 29 July 1969 the New York Times carried an article by Walter Rugaber, entitled "Prison Drug and Plasma Projects Leave Fatal Trail". In 1970, the New York Times wrote of the "transfusion roulette" played by the blood industry. In 1971 the US National Blood Transfusion Service began routinely to screen donors for Hepatitis B. Indeed, it was the discovery that recipients of blood from donors free of Hepatitis B were nevertheless contracting Hepatitis that alerted doctors and researchers to the existence of Hepatitis NANB. Nor was the problem confined to the USA. In 1971 the Canadian Red Cross Society ceased to collect blood donations from prisons.

Dr Allen sent some of his findings to Professor Richard Titmuss of the London School of Economics. Titmuss subsequently wrote a book, "The Gift Relationship", published in 1970, expanding on the dangers of taking blood from paid donors. It was widely read in the USA and the United Kingdom.

On 6 January 1975, Dr Allen wrote to Dr William Maycock, then Director of the United Kingdom Blood Transfusion Service, expressing anxiety about blood products from paid and prison donors and asking a number of questions about the

[3] Douglas Starr, Blood: Chapter 12, page 221 – Time Warner Paperbacks; New edition (6 Jul 2000)

processing of blood donations in the UK. He mentioned two American commercial companies whose products were reported as carrying a high rate of infection. On 8 December of that year Dr Maycock was interviewed on the "World in Action" programme on BBC television.

In the course of the interview he said:

"After the expert committee[4] gave its advice in 1973 there was so to speak a sudden demand; where, quite clearly this couldn't be met overnight, a lot of reorganisation had to be carried out which involved accommodation, equipment and staff which is clearly going to take a considerable time. One could have left it and said well we will get round to this when we have made our arrangements or one could say we will meet the need now by importing. Having decided to become self sufficient, this in fact is what happened".

He was asked:

"Was it in your view ever possible that we could have produced Factor VIII concentrate much earlier in Britain given the work that was done on some of the processes associated with it?"

He replied:

[4] See page 28

"Well it's always easy to look back and see what might have been done; I think had certain decisions and certain things been made and certain things not happened we obviously could have done this". He was referred to Allen's letter and was asked:

"Do you think in that case that perhaps we might have been somewhat complacent about these risks?"

He replied:

"No, I don't think so. I think the quality of this material was controlled both here and in America". His view was not universally shared among the medical community.

Professor Arie Zuckerman of the World Health Organisation, working at the University of London, held a different opinion, which he expressed succinctly in the same programme:

"It is well recognised that the commercial donor carries a considerably greater risk of transmitting Hepatitis than the volunteer donor and indeed there are two World Health Organisation (WHO) recommendations now stating that efforts must be made to stop the commercial practice of the collection of blood."

By the mid 1970s, the danger of contamination from blood products was widely known in medical circles within the United Kingdom, and the particular dangers attendant on US commercial products were recognised.

CHAPTER 3 – PROCUREMENT AND CONTROLS

It has long been a fundamental principle of medical practice in the United Kingdom that subject to certain overriding constraints a doctor is free to prescribe whatever treatment is considered best for the patient. This requires the patient's consent, although it may in some circumstances be implied.[5] Again, if the treatment carries a financial cost, any body, such as the NHS, which meets or contributes to the cost may place a limit on the expenditure involved.

A doctor is free to obtain the necessary medication from any chosen source, although where bulk purchasing carries advantages in price reduction or guarantees of supply, it would be unwise not to consider those arrangements. Admittedly, this would subject him to a degree of constraint, since it would require conformity with what others wished to purchase. Markets of this nature are influenced by the marketing techniques of the various suppliers.

Within the medical profession, as in most professions, information on recent research and the availability of new treatments, together with reports of relevant committees, is circulated through medical journals, conferences, other professional meetings, material from vendors of commercial products and informal conversations.

An overriding restriction is imposed by the Medicines Act 1968, a measure introduced following the Thalidomide tragedy. Section 7 of the Act provides:

[5] See Chapter 7

"Except in accordance with a Licence granted for the purposes of this Section (in this Act referred to as a "Product Licence") no person shall in the course of a business carried on by him, and in circumstances to which this sub-section applies –

(a) Sell, supply or export any medicinal product or

(b) Procure the sale, supply or exportation of any medicinal product or

(c) Procure the manufacture or assembly of any medicinal product for sale, supply or exportation".

Subject, therefore, to certain exceptions provided by the Act, unlicensed products are not available in the United Kingdom.

Applications for licences are considered by the "Licensing Authority" consisting of the Secretary of State for Health in England and Wales, the Minister of Health and Social Services in Northern Ireland, and the corresponding Minister in Scotland, any one of whom may perform licensing functions. The Act provided for the Medicines Commission, consisting of experts, to advise Ministers. The Medicines Commission subsequently became the Committee on the Safety of Medicines.

Applications for licences were submitted to the Medicines Division of the DHSS, and new drugs and major changes in usage were referred to the Committee on the Safety of Medicines. Its Biological Sub Committee first considers biological products. Since membership embodies formidable expertise, it would be very unusual for a Secretary of State not to accept its advice.

In deciding whether to grant a licence and on what conditions, the Committee considers efficacy and safety. It normally also considers the quality of the product, the method of preparation and the standard of packaging and labelling.

Section 9 of the Medicines Act provides an exemption permitting a doctor to procure and administer a product for a particular (named) patient, even if no product licence has yet been granted. This became known as the "named patient basis" and is used, among other purposes, for researching the effects of the product on a patient.

The system of licensing was complicated by the doctrine of Crown Immunity. This had its origin in the Middle Ages, arising from the legal principle that the Sovereign could not be called to account in his or her own court, and since the existing courts were the Queen's, the Crown could not be prosecuted in the English courts. Crown institutions such as the Blood Products Laboratory (BPL), which produced Factor VIII concentrate, were therefore immune from the provisions of the Medicines Act 1968. There was some doubt whether Crown Immunity applied in Scotland, but the first Director of the Plasma Fractionation Centre (PFC), the Scottish facility for processing blood products, argued that it ought not to be exempted from the statutory provisions, and he was authorised to apply for a manufacturing licence in the normal way. Crown Immunity was abolished in 1991.

Originally doctors and clinical institutions purchased Factor concentrates directly from suppliers. In England there were facilities for processing blood collected from donors in the country. There was the Blood Products Laboratory at Elstree (BPL), established in 1954 as part of the Lister Institute of Preventive Medicine, and the

Plasma Fractionation Laboratory (PFL) at Oxford, both owned and controlled by the NHS. To supply Scotland's needs there was the Protein Fractionation Centre (PFC) at Edinburgh. The English laboratories obtained their blood from the Blood Transfusion Service, and did not purchase commercial products.

Initially, haemophilia centres received blood products produced by BPL, in proportion to the amount of plasma supplied by the District Health Authority. This accounted for some 40% of their needs. The remainder came from commercial suppliers predominately from the United States. The suppliers, dealt with the person who handled contracts on behalf of the District Authority. Professor Savidge told us:

"It all depended who felt they could possibly get the best deal out of the commercial companies. So you would perhaps have a rather cavalier pharmacist who would negotiate on behalf of the district hospital because it was district money...the local blood transfusion directors within the districts, sometimes would take responsibility for the purchase of it and store it within the hospitals. So it was very much something which was hit and miss, but invariably the people that actually did the negotiation were those who notionally took responsibility for the budget".

These resources were incapable of meeting the demand for Factor concentrate, and there were complaints that patients were not being adequately supplied. In 1974 a number of senior doctors, supported by the UK Haemophilia Society, asked the Government to fund the purchase of commercial Factor concentrates from the United States, where they had been licensed in the previous year. This was a more expensive method of procurement, but was needed if the shortfall was to be met.

The Government's response was to negotiate a central supply contract, administered by the DHSS, for sale to authorised clinicians and Haemophilia centres. In March 1979, the arrangement was terminated and individual Health Authorities were authorised to purchase directly from suppliers, but by then, many lives had been significantly affected.

CHAPTER 4 - SELF-SUFFICENCY

By 1973, the desirability of national self-sufficiency in the supply of blood products was appreciated and four key issues emerged. First, the UK was unable to meet the rising need for plasma from its own blood donors. Secondly, even had the plasma been available, processing facilities for blood products were inadequate to meet the demand. Thirdly, it was known that blood products carried a risk of infection with Hepatitis, and that the risk from concentrate was greater than that from cryoprecipitate, although the advice available to the DHSS admittedly varied in the degree of urgency with which it was conveyed. But for most purposes, the majority of haemophilia doctors and patients preferred Factor concentrate to cryoprecipitate, for the reasons explained in Chapter 1. Fourthly, while no blood products, not even those from the National Blood Transfusion Service, could be guaranteed to be free of risk, it was known in the early 1970s that US commercial products carried an increased risk of infection. Indeed, some patients had become aware of this in various ways and were refusing treatment with those products, although the majority of patients had no idea of the danger.

There was therefore a consensus that the United Kingdom should aim to become self-sufficient in blood products.

Since the Second World War, blood donations had been collected from some developing countries where medical services were scarce, and a disturbing range of diseases was prevalent. In addition to the risk of spreading infection, it was clear that not only did this represent an exploitation of poor countries, but also it deprived those

countries of blood supplies of which they themselves were in need. In 1974, the World Health Organisation circulated a questionnaire to some of its most affluent countries, and discovered that the practice of seeking blood donations from the poorest counties was increasing.

The commercial imports were more expensive than UK products, since the price included payment to donors and profit for the companies. There were suggestions that American commercial companies might be licensed to collect and process plasma in the United Kingdom, but there was anxiety that they might introduce payments for donors, and it would be difficult for the NBTS to collect blood donations on a voluntary basis while other donors were receiving payment.

It is difficult at this distance in time to determine which of the above motivations was predominant in the minds of policy makers. The Rt Hon Lord Owen, Health Minister in the then Department of Health and Social Security, was concerned primarily with the risk of infection from imported commercial products, although he was also mindful of the cost of the imported products, which were imposing a heavy and increasing financial burden on Area Health Authorities. The question of cost may have loomed larger in the minds of officials. The Departmental publication "Self-sufficiency in blood products in England and Wales", published in May 2007, stated:[6]

"Although in 1975 cost and loss of the volunteer donor system was cited as the major motivating factors for the push towards self-sufficiency, by the middle of 1978 concerns over the methods of plasma collection and safety of imported blood

[6] "Self-sufficiency in blood products in England and Wales: a chronology from 1973 to 1991"

products were also reported to re-enforce the need for self-sufficiency in blood products".

This carries the surprising implication that it was not until 1978 that officials appreciated the concerns over infections from imported blood products. If that is so, it represents a serious oversight in the Department, or serious distortion of priorities. The destruction of the Departmental papers of Lord Owen and The Rt Hon Lord Jenkin of Roding has precluded us from investigating further the Departmental thinking and the extent to which ministers were made fully aware of the facts[7].

Whatever the motivations, the UK was confronted with a problem, and a number of possible solutions. In 1973 the Department of Health convened a group of experts to assess the likely future requirements of Factor VIII concentrate. It met on 20 March 1973, and quickly agreed that the UK should become self-sufficient in the shortest possible time. It estimated that to achieve self sufficiency would require 400,000 donations of blood annually, of which 275,000 should be used for Factor VIII concentrate.

This estimate was surprisingly low. First, it failed to take into account the escalating demand for concentrate, as its advantages became widely known. Secondly, the estimate was based on an assumption of the concentrate yield per litre of plasma which overlooked certain technical problems associated with large-scale manufacture. A working group chaired by Dr Rosemary Biggs estimated that at least 500,000 donations would need to be dedicated to the manufacture of Factor

[7] See Chapter 8

concentrate, and a meeting of Haemophilia Directors in January 1974 endorsed this. Nevertheless, the Department adopted the estimate of 275,000 donations.

At a meeting of the expert group in May 1976, it was accepted that the original estimate was insufficient, but it was agreed that there should be no revision of the target until the original target had been achieved. One reason for the absence of urgency was that it was unlikely that any additional finance would be available.

There seems little doubt that at that time the Department of Health considered that the determining factor in achieving self-sufficiency was the supply of blood and plasma available from donors. Little attention appears to have been given to the second limiting factor, namely the capacity within the UK for processing any increase in the volume of blood donated.

On 9 July 1974 Dr David Owen, stated in a written answer to a Parliamentary question:

"The supply of Factor VIII is at present insufficient for the optimum treatment of haemophilia patients. I hope that it will be possible to increase our supplies, and meanwhile product licences were issued last year to two firms to market imported Factor VIII in the UK".

The product licences had of course been granted on the recommendation of the Committee on the Safety of Medicines. The Committee had weighed the respective risks, on the one hand, of treatment with blood products carrying a disturbing danger

of infection, and on the other of leaving a substantial number of patients without access to Factor VIII concentrate. There were a number of possible ways of alleviating the problem, as set out below, but the Committee does not seem to have considered them.

On 22 January 1975, in a further written Parliamentary answer, Dr Owen said:

"The amount of Factor VIII materials including cryoprecipitate produced within the National Health Service is not sufficient, and in particular, there is an immediate need to provide more human Anti-Haemophilia Globulin (AHG) concentrate, which is now the preferred treatment for haemophilia patients. There is also increasing demand for certain other blood fractions.

At present part of the demand for AHG concentrate is being met by imported material, but this is very expensive and for reasons which I well understand, Health Authorities feel that they cannot afford to buy as much as they would wish to, given the various claims on their resources.

I believe it is vitally important that the National Health Service should become self-sufficient as soon as practicable in the production of Factor VIII, including AHG concentrate.

This will stop us being dependent on imports and make the best-known treatment readily available to people suffering from Haemophilia. I have, therefore, authorised

the allocation of special finances to boost our own production with the objective of becoming self-sufficient over the next few years".

A Departmental minute dated 17 March 1975, and approved by Dr Owen, reads:

1. "Immediately after the decision was taken in December last to invest £0.5m of special finance in AHG concentrate production, provisional targets of plasma production were drawn up for each of the 14 Regional Transfusion Centres. These were then circulated to Regional Transfusion Directors and discussed with them at a special meeting on 19 February. The target has now been revised and we shall be asking Regional Health Authorities next week to indicate the amount of money required for extra staff, equipment, transport, and adaptation of accommodation. A copy of our draft circular letter is attached (Appendix 1 needs some revision). We shall process these returns as speedily as possible.

2. The timetable for starting up this programme is likely to depend on the time taken for: -

   (a) Delivery and installation of three Sharples centrifuges at Blood Products Laboratory. The quoted delivery period is six months; this is evidently the key factor determining the speed with which we can get on; we shall pursue this to see if we can shorten the period.

(b) Adaptation of premises at Regional Transfusion Centres and the Blood Products Laboratory; at the latter laboratory recruitment and training of staff may be a problem.

(c) There is a possible risk that delivery and installation of certain other items of equipment, e.g. freezers for plastic bags and refrigerated vehicles, may also add to the time taken; this will not be known until information is received from the suppliers".

On 8 July 1975, in a further written answer Dr Owen said:

"I have allocated additional funds so that regional blood transfusion centres can produce more plasma for increased production of this material, i.e. Factor VIII concentrate. I hope that the first effect of the action we have taken will be felt by the end of the year and that the National Health Service will be self-sufficient in this material within two to three years".

A minute by Dr Owen dated 11 July, and apparently requested by him in consequence of his briefing for that answer, reads:

1. "Dr Owen has commented on PQ 3474: - "Once again we are a 2-3 years timescale. I have asked if we can improve on this. Can I have a note?"

2. This is the timescale which Dr Owen gave in a reply to a PQ from Mr John Spence on 22 April. Since then, as a result of our discussions with regions, we have given them targets which would produce plasma from 337,000 blood

donations. This is some 20% more than the total of 275,000 recommended by the Expert Group on haemophilia but this figure must be regarded as the minimum.

3. All regions, except two, have now indicated when they expect to achieve their share of the target of 337,000. The position may be summarised as follows:

The two regions which we are at the moment uncertain will provide another 45,000 donations i.e. 13% of the target.

4. The main reason why the programme cannot be completed earlier is that in four regions extensive alterations have to be made to the Transfusion Centres before they are in a position to provide more plasma. In one case the work will take six months, in two cases one year, and in the fourth 21 months. There is no scope for reducing these periods. Arrangements are in hand to purchase centrally those items of additional laboratory equipment requested by RTCs. First deliveries are expected within 2-3 months and the programme is unlikely to be held up on this score. We are having difficulties about the date of delivery of three Sharples centrifuges for the Blood Products Laboratory but we are pursuing this and hope to resolve the matter soon.

5. We are taking steps to clarify the position of the two regions whose ability to contribute to the programme are at present uncertain. From the point of view of the NBTS it is desirable, if it is at all possible, that all regions should take part. If the two regions in question can be brought in we hope that they

will be able to achieve their target by about the end of 1976. However, if they cannot participate we will have to consider allocating the funds provisionally earmarked for them to other regions able to provide more plasma than they have at present undertaken to do.

6. It is difficult to be precise in estimating a date for achieving self-sufficiency, not least because not all are agreed as to what constitutes self-sufficiency; some Haemophilia Centre Directors envisage prophylactic treatment whereas the department's programme is based upon home treatment of those patients for whom treatment at home can be recommended. It remains to be seen whether RTCs will be successful in persuading clinicians to accept a steadily increasing proportion of blood in this form of concentrated red cells; this may be a possible limiting factor. AHG concentrate has not previously been prepared in the NHS on the scale envisaged and this in itself will almost certainly give rise to some problems.

7. However, accepting these qualifications, the figures in paragraph 3 suggest that we can improve on the previous estimate of achieving self-sufficiency within 2-3 years. We can now say that we expect to be self-sufficient within 2 years or, alternatively, that within about a year we will be able to meet some two thirds of present requirements and become self-sufficient in 1977".

In a management note, Dr Owen commented:

"This is excellent and I recognise that everyone is doing everything possible. I believe we should keep up the pressure. Can I be kept informed on the Centrifuges and also the two regions – why are there difficulties and what can be done? I would not easily accept that they should not contribute."

An international consensus was emerging. In May 1975, the World Health Organisation passed a widely circulated resolution, urging all countries to aim at self-sufficiency. It urged member states:

"To promote the development of national blood services based on voluntary non-remunerated donation of blood and enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and the recipients of blood and blood products."[8]

On 29 April 1976, at the congress of the World Federation of Haemophilia in London, Dr Owen addressed the ethical aspect of the question. He said that self-sufficiency in Factor VIII products was expected to be reached in mid-1977. He spoke of the danger of developing a modern society, "where values are solely conditioned by the market place, where 'what is the price?' and 'what is something worth?' predominate".

As the answer on 8 July 1975 explained, the purpose of allocating the additional funds was to enable regional Blood Transfusion Centres (BTCs) to produce more plasma, and an annual target was fixed at 275,000 donations earmarked for the

[8] World Health Assembly. *Resolution 28.72*. Geneva: WHO, 1975.

Factor VIII concentrate and 100,000 for cryoprecipitate. In a letter to Dr Owen dated 16 June 1988, The Rt Hon John Moore, then Secretary of State for Health and Social Services, stated that the additional £500,000 made available to the regional BTCs in 1975 had increased donations from 2.9 million units in 1975 to 11.8 million in 1977.

But even had the target been sufficient for the purpose, the BPL facility at Elstree did not have the capacity to process an increased volume of plasma. The laboratory at Elstree had been developed in stages over a number of years, since its establishment as a research facility for the Lister Institute, who had continued to manage it. There were three principal manufacturing departments, each operating as a separate unit, with no integrated operation. The scale of production had escalated since it had been established. Those in charge were scientists, well qualified in research, but with little experience in large-scale manufacturing. There was a serious shortage of space for quarantining of new materials, or cold storage, or for proper storage of packaging and warehousing, and manufacturing facilities were inadequate.

The structure for allocating finance did not encourage the provision of adequate resources. Funds for the BPL were channelled through the Department of Health, and there was no mechanism for claiming re-imbursement from the Health Authorities for expenditure on expanding production facilities, although it was they who would benefit financially if they were relieved of the cost of purchasing imported concentrate. Yet there is no evidence that they were asked to do so at the time.

Jenny Willott, MP commented to us:

"So they are generating more blood donations but actually there is nothing that can be done with the blood. And it is going to waste because they have more than they can actually process".

Even had there been no interruption of the manufacturing process, the volume of plasma resulting from the injection of funds could not have been processed. But there were additional problems relating to the safety of the product. A draft submission to Ministers prepared by an official and dated December 1979 included the sentence:

"Moreover products derived from paid donor plasma are known to carry a ten fold increase in the risk of transmitting hepatitis over the risk from products derived from voluntary donations."

A subsequent draft by a more senior official deleted the reference to a ten-fold increase, and substituted "a greatly increased risk of Hepatitis". In May 1979 there had been a General Election and a change of Government. The incoming Government spent some time in exploring the possibility of commercial involvement in the future of BPL, but appears to have rejected the option on grounds both of cost and of the danger that commercial companies might wish to introduce payment to donors.

The problems escalated. In July 1979, the Medicines Inspectorate visited BPL. They reported that the buildings were never designed for the scale of production envisaged. They commented:

"If this were a commercial operation we would have no hesitation in recommending that manufacture should cease until the facility was upgraded to a minimum acceptable level."

BPL was rescued by Crown Immunity. Among their recommendations the Inspectorate advised:

"Under no circumstances should production of any product be increased under the existing manufacturing conditions."

The Government decided to introduce a complete redevelopment programme at Elstree, but meanwhile, interim measures were undertaken to increase production. At a meeting in Glasgow of the Haemophilia Centres Directors Organisation on 30 September 1980, it was stated that £1million had been authorised by ministers to improve the facilities, and that BPL aimed to double the existing output. In the event the sum set aside was augmented to £1,300,000. The work began in July 1981, and it was completed in November 1982.

However, the improvement in facilities was accompanied by a restructuring in management, which does not appear to have been carefully considered, possibly because it was intended only as a temporary measure. In October 1979, responsibility for management by the Lister Institute was terminated, and as an interim arrangement, the Department of Health assumed direct responsibility. A draft paper by an official in February 1981 included a disturbing criticism.

"The chief difficulties over these temporary arrangements are that management is too diffuse with too many people exercising a fragmented responsibility; management is insufficiently and not continuously coordinated; at RHA level particularly the task of management is largely an addition to the normal work of those who are carrying it out; and that those responsible have very little experience in the management of facilities of the kind concerned. Responsibilities are vested in the department for which it is not equipped; and which had in principle been elsewhere. Consequences of these difficulties are, for example, that the Directors of the laboratories are required to work without adequate policy guidance and without sufficiently expert monitoring of their laboratories' performance it is often difficult to reach fairly elementary policy decisions and to ensure that they are implemented; and that attention to the management of the laboratories may have to be dropped from time to time in order to deal with other pressing matters". The paper was severely redacted by superior officials before submission to ministers.

The Government then made plans for a complete redevelopment programme, and in November 1980 Dr Gerard Vaughan, the Minister of State at the Department of Health, announced in a written answer to a Parliamentary question that £21 million had been allocated for the purpose. The target date for completion was January 1986. Work began in May 1983, and the cost had by then escalated to £52 million. It was in fact opened on 29 April 1987.

Meanwhile, the existing plant continued production, relying on Crown Immunity to dispense with all the requirements of the Medicines Act, but was able to meet only about 40% of the national requirements.

To address the shortfall in Factor VIII production, a number of options were available, ranging from using alternative products to reducing the risk of infection for each individual patient: -

1) The PFL at Liberton in Edinburgh possessed the capacity to process a substantial volume of plasma in excess of Scotland's needs. A joint committee had been established in 1973 to coordinate policy in England and Scotland, and at a meeting of the Haemophilia Centre Directors in January 1977, it was announced by the Department that proposals were being considered to direct plasma from England to Liberton to produce concentrate for use in England. But first, this would have required a substantial outlay on additional facilities at Liberton, and secondly, the proposal would have entailed shift working, and discussions between the Government and the unions about pay and conditions were never resolved. We have not been able to discover the issues on which the talks foundered but one factor appears to have been a difference of view between Dr Lane, who was shortly to be appointed Director of BPL, and who was anxious to retain the work at BPL, and some officials at the Department, who favoured involving Liberton. In the event, this option was not adopted.

2) Doctors could have reverted to cryoprecipitate instead of continuing to use Factor VIII concentrate. In a paper prepared in May of 1983 for the Biological Sub-Committee of the C.S.M., Dr N S Galbraith, Director of the Public Health Laboratory Service, advised that all products made from blood donation in the USA after 1978 should be withdrawn until the risk of AIDS transmission had

been clarified. On 13 July 1983 the Biological Sub-Committee considered this possibility. It concluded that this would give rise to a problem of supply. The minutes declared:

"Moreover the perceived level of risk does not at present justify serious consideration of such a solution. Efforts are however being made to secure UK independence of foreign supplies of clotting Factor concentrate. This should reduce markedly although not eliminate, the risks to recipients of these products". It is therefore clear that the risk was appreciated. We have heard suggestions that the decision to continue with US produced concentrate arose at least partly from patient demand. It seems clear that patients would have been reluctant to return to the use of cryoprecipitate, but in many cases were not given an informed choice and they relied on doctors for information and advice.

Professor Savidge commented:

"I really think that it is asking a little bit too much to put the responsibility on to the patients' backs and to say that they insisted, because they were advised, or they should have been advised".

We know of no suggestion that either Government or the professional bodies sought to recommend this course.

3) In Chapter 6 we consider the possibilities of encouraging research on screening and heat treatment, but it is doubtful whether effective results could have been achieved by the mid-1970s.

4) While serious cases of haemophilia required urgent treatment, for some with mild haemophilia the condition was not necessarily life threatening, and the balance of risk between treating the patient with products carrying a danger of infection, and leaving him or her untreated varied from patient to patient. Many doctors continued to treat patients prophylactically, as opposed to administering treatment only when a bleed actually occurred. The risk of infection was therefore incurred even when there was no immediate necessity. Again, it appears that in many cases patients were not offered the choice.

Mr Haydn Lewis, a sufferer from mild haemophilia, told us:

"I had kicked my big toe, rather painful but certainly nothing that I could not have contained by just going home and sticking my foot in a cold bath of water or something. I suggest that the treatment was given not under the premise that it was a life threatening situation in any shape or form and I would suggest that many mild haemophiliacs experienced the same procedure. The only reason I was given that product, I might suggest, was that until then I had not received any commercial products so I met the criteria".

5) Professor Ian Franklin described for us a system in use at the large teaching hospital where he served as a consultant haematologist from about August 1982. Each patient was supplied with Factor concentrate from one specific batch dedicated to that patient, until the batch was exhausted. The potential infection to which the patient was exposed was therefore limited. The system depended on careful record keeping. He explained that when he had arrived at the hospital, the system had already been in place for some time. But we have not heard evidence that this practice was widespread.

The Advisory Committee of the NBTS established a working party on Plasma Supply to consider future requirements. It reported in the middle of 1981. It stated that the existing capacity of BPL and PFL was 15 million international units (iu) per year, and that when the work on interim expansion at BPL, planned for completion in 1982, was completed; production of Factor VIII concentrate would reach 30 million iu. In 1982 there was a further revision of the required production targets for BPL. The PTC was allocated a target for plasma amounting to 435,000 kilograms per annum. It was thought that the savings in the need for commercial products would offset the additional cost. A paper presented to the Advisory Committee showed that there was a substantial increase in demand for Factor VIII concentrate from 14 million iu in 1980 to 22.5 million iu in 1981. In 1983, for the first time since 1974, more NHS concentrate was used than commercial.

In 1987 Lord Owen learned that the objective of self-sufficiency in blood products had not been achieved. He wrote on 17 November to the Rt Hon John Moore,

then Secretary of State for Social Services. Mr Moore replied on 21 January. The fact that the reply required eight weeks of research suggests that self-sufficiency was not a priority theme in the Department. He said:

"It is interesting to note that when you made your statement in 1975 our consumption of Factor VIII was about 8.2 million units per annum, of which 3.2 million were produced by the NHS. As so often happens with healthcare, a successful treatment generates increased demands, and today, with the widespread use of home-therapy, Factor VIII demand is nearer 80 million units". He added that Elstree was by then producing 25 million units. Of the £500,000 dedicated to the self-sufficiency drive in 1975, he wrote:

"The £500,000 helped the output increase from 3.2 million units to 12.8 million between 1975 and 1977; however the total demand for Factor VIII increased from 8.2 to 27.4 million units in the same period so that the proportion of commercial product needed remained roughly the same". It seems clear that as UK production increased, it was constantly chasing the increasing requirement, which continued to disappear around the next corner. The accelerated provision, which might have caught up with the target, was never made.

Lord Owen has suggested to us that, having told Parliament on 8 July 1975 that the target was to achieve self-sufficiency 'within two to three years'; the fact that the target had not been achieved should have been made known to Parliament. We have not been able to trace a specific formulation of the convention, but it is generally agreed that if Parliament has been led by ministerial statement to

expect a particular event, it should be informed if the expectation is not fulfilled. The problem appears to have been that if the Government is chasing a moving target, all that could have been expected was that when the approximate target date was reached, the attention of ministers should have been drawn to the situation. But we have been unable to trace from the evidence now available what, if anything, ministers were told. Understandably, neither Lord Owen nor Lord Jenkin is able to recollect details, without access to the missing ministerial files.

Lord Owen subsequently corresponded with a succession of Parliamentary Ombudsmen, urging them to investigate the reasons for the failure to achieve self-sufficiency, and the consequences for haemophilia patients, but was told that there was no prima facie evidence of maladministration.

By the mid-1980s, heat-treated products were becoming available (see Chapter6), and it was considered safe to use commercial concentrates from the USA. But meanwhile, a substantial number of haemophilia patients had been infected.

In the 1990s, a new blood-born infection had appeared. Variant Creutzfeldt-Jacob Disease (vCJD)[9] had been identified in blood donated within the United Kingdom, and therefore subsequently UK-donated plasma ceased to be used. The Department of Health purchased a commercial plasma supply company in the

[9] CJD is a fatal brain disease first reconisged in the 1920s. In 1996, doctors reported a variant of the disease, vCJD.

United States, and the United Kingdom now employs American commercial plasma for its needs. Thus ended the quest for self-sufficiency.

CHAPTER 5 – AIDS: A NEW THREAT

In the early 1980s a new illness appeared in the USA. There was a sudden increase in cases of Pneumocystis Carinii Pneumonia (PCP) among men. In June 1981 the US Centre for Disease Control (CDC) at Emory University recorded five cases among gay men and the number rose rapidly. Common to these cases was an unexplained failure of the immune system. Its prevalence among the gay male community caused the condition to be known as "gay related immunodeficiency" (GRID). It was later recognised that the disease was not confined to homosexuals.

Dr Bruce Evert, of the CDC, sounded the alarm. He alerted the Public Health Service, the National Haemophilia Foundation and fractionation laboratories, and published his findings in the Morbidity and Mortality Weekly Reports, a publication that was widely read internationally. The Public Health Service established an emergency working group. The group did not quickly reach agreement on the nature of the condition, but a surveillance programme was established to monitor blood recipients and particularly haemophilia patients. They named the condition "Acquired Immune Deficiency Syndrome" (AIDS).

On 3 February 1982 the New Scientist reported that haemophilia sufferers were at risk of contracting the condition. In the summer of 1982 some haemophilia patients in the US were diagnosed as suffering from AIDS. In January 1983 an editorial in the New England Journal of Medicine suggested that cryoprecipitate should be used in preference to Factor concentrates. On 30 April 1983, the Lancet recorded eleven

cases of haemophilia sufferers in the USA contracting AIDS, and three similar cases in Spain.

On 4 January 1983, the Centre for Disease Control convened a conference of doctors, representatives of the blood industry, gay groups and others. By then there was evidence that haemophilia patients and others who were not gay could develop AIDS.

Dr. N. S. Galbraith, Director of the Communicable Disease Surveillance Centre (part of the Public Health Laboratory Service) in the United Kingdom reviewed the literature on the subject and investigated the cases. At the same time there came a report of a haemophilia patient in Wales who had contracted AIDS. On 9 May 1983, Dr. Galbraith submitted a report to the DHSS, postulating that AIDS, of which little was then known, was probably caused by an infectious agent with a long incubation period. He warned that many more haemophilia patients might have been infected, but that symptoms may not yet have appeared. He suggested that the cause might lie with blood products from large pools of donors whose lifestyles were leading to a higher-than-average risk of the condition. He proposed a temporary stay on all blood products from the USA.

Little was known of the nature of the disease, except that some were persuaded that it was transmitted through blood. The scientific community was cautious in drawing premature conclusions. The Medical Research Council in the United Kingdom did not convene a working party on AIDS until October 1983. There were suspicions

that the condition was caused by a virus, and the virus responsible was identified in late 1983 and early 1984. It became known as HIV.

There was no clear consensus among researchers and doctors, nor was there any source of authoritative advice. Virology was then a very young study, practised in hospital Pathology Departments, as a branch of microbiology. The United Kingdom Haemophilia Centres Directors Organisation (UKHCDO) had established an informal arrangement for Dr John Craske, a virologist working in Manchester, to supply advice when requested. In those circumstances, it might have been expected that caution should have prevailed, but the advantages of Factor concentrate appear to have overridden the need for decisive action.

By 1984 it was known that the HIV virus could lead to "full blown" AIDS, characterised by the impairment of the immune system, and so leading to recurrent infections, and often finally to fatal diseases. Sometimes the symptoms appear only after a number of years. The onset may be retarded, but the replication of the virus is usually relentless. It is now known that individuals differ widely in their chance of developing the full-blown syndrome of AIDS after infection with HIV. This heterogeneity is believed to have a genetic basis. The Inquiry is not aware of any research into the possibility that the genetic make-up of a patient with haemophilia might influence their susceptibility to AIDS after infection with HIV.

We have heard distressing evidence about the effects for the patient of acquiring AIDS. Little was known of the new disease, except that it could be a death sentence. It was believed to be highly infectious, and anyone known to be suffering

from it was ostracised. There developed what has been described as a "leprosy culture". Within the family the patient would frequently be provided with his or her own plate, dish, eating utensils and towel, which were kept strictly isolated from the rest of the family. Originally, sufferers might be labelled as gay, at a time when homophobia was widespread. At the same time, since it was known that the sharing of needles could transmit the condition, it was frequently assumed that sufferers were drug addicts. They were insulted in the street, and their homes were sometimes daubed with graffiti. Their children were victimised at school, and fellow employees would refuse to work with them. There were even instances where hospital staff declined to enter rooms occupied by AIDS patients, leaving food outside the door, and labelling body samples as high risk. Cases were reported of consultants declining to see patients.

The panic did not extend to the Government, nor to all sections of the scientific community, whose imperturbability veered in the opposite direction. There was a reluctance to recommend any action until more evidence was available. It is understandable that they were reluctant to impose restrictions on choice without more evidence, but the danger signals might have indicated some precautions.

On 1 May 1983, an article by Susan Douglas appeared in the Mail on Sunday, referring to "killer" blood from high-risk donors and the danger of AIDS. Her article was referred by a haematologist to the Press Council, who held that it was "extravagant" and "alarmist".

In July 1983, further reports of AIDS led the UKHCDO to recommend treatment for haemophilia patients with cryoprecipitate, in preference to Factor concentrates, for the treatment of children under four, and for previously untreated patients (PUPs) who would hopefully be free of infection prior to that time. But the CSM warned that there would probably not be a sufficient supply of cryoprecipitate for all haemophilia patients.

On 12 August 1983 the Government agreed to circulate advice warning practising homosexuals and intravenous drug addicts not to give blood. But the tendency was to cool the discussion rather than to exacerbate it. There was little sense of urgency in commissioning advice. An expert Advisory Group on AIDS was not convened until 1985. Individual practitioners were subjected to conflicting advice.

In November 1983, the Secretary of State for Health, The Rt. Hon Kenneth Clarke, told Parliament, doubtless on Departmental advice:

"There is no evidence that AIDS is transmitted by blood products".

At the AGM of the UKHCDO in December 1983, Professor Bloom is minuted as reporting that "he felt there was no need for patients to stop using the commercial concentrates because at present there was no proof that the commercial concentrates were the cause of AIDS", and this view appears to have been endorsed in the ensuing discussion. In the same month, following press reports, Mr John Maples, MP wrote enquiring about the Government's assessment. In a reply dated

13 December 1983, Lord Glenarthur, a Parliamentary Under-Secretary of State, commented that:

"The cause of AIDS is as yet unknown and there is no conclusive proof that the disease has been transmitted by American blood products. Nevertheless, I would like to assure your constituent that the Government is committed to making this country self-sufficient in blood products. Over £2 million has already been spent on improving the production facilities of the Blood Products Laboratory at Elstree, Herts, and a major redevelopment programme is under way. When this is complete the Central Blood Laboratories Authority will have a new laboratory of a size capable of meeting the demands of England and Wales for blood products. Meanwhile, in the absence of a satisfactory alternative, we shall be dependent upon imports from the USA for an adequate supply of Factor VIII. While there is as yet no test for AIDS, such imports, prepared from plasma collected after March this year, will be subject to new Regulations initiated by the US Food and Drug Administration, designed to exclude donors from high-risk groups, (e.g. persons with symptoms and signs suggestive of AIDS; sexually active homosexual or bi-sexual men with multiple partners; intravenous drug abusers). Although future supplies of Factor VIII both for export and for use in America will be manufactured from plasma collected in accordance with these Regulations, there is still a quantity of stock, which has been made from "pre-March" plasma. The FDA has recently decided not to ban the use of such stocks because to do so would cause a crisis of supply. The same considerations apply here".

It is surprising that even when the new Regulations were in operation, existing stocks were not withdrawn either in the USA or in the United Kingdom.

CHAPTER 6 – REDUCING THE RISK

The danger of infection from blood products was directly related to the size of the donor pool from which the blood or plasma was collected and to the lifestyles of the communities from which donors were drawn. But researchers were investigating measures to eliminate, or at least to reduce, the risk of transmitting infection. Their efforts fell basically into three categories. First, care could be taken to select only donors who were unlikely to be infected. Secondly, tests could be applied to the plasma or resulting product to detect infections and thirdly, procedures were being developed for de-activating any infective agents.

1. Hepatitis

a. <u>The screening of donors</u>

It had long been the practice of Blood Transfusion Centres to question potential donors about their medical histories, but often a disease had not been diagnosed. Moreover paid donors in the United States, used by commercial processors, had a financial interest in concealing any disqualifying medical condition.

In the USA, blood was treated as a commercial commodity, and there were disputes as to the constitutional propriety of interfering by legislation in free competition between suppliers. Only in 1978 did the FDA introduce a requirement that blood banks and plasma collectors should state on the labels whether donors were paid, or were volunteers, leaving consequent action to purchasers' choice. As a result whole

blood from paid donors virtually disappeared from the retail market, although manufacturers of blood products continued to use it.

Until 1978 the screening of American donors, therefore, consisted of appeals for self-exclusion by groups which were at risk of spreading infection, a request which, when addressed to paid donors, was less than realistic. Some campaigners regarded it as a denial of human rights, particularly for gay men, and opposed even this form of donor screening. Not until 1983 did commercial companies question donors about their medical histories.

Tests were available to screen potential donors for Hepatitis B as early as 1970, although they were not sufficiently sensitive to be infallible. The Scottish National Blood Transfusion Service (SNBTS) introduced these tests in that year. In England, BPL followed in 1971. No test was available specifically for Hepatitis C until 1989, when the virus was isolated. Until then reliance was placed on what became known as a "surrogate test", based on blood enzyme levels. This test was not an accurate one, and sometimes gave a false positive result. However, it was widely considered to provide a useful, if not infallible, indication. It was introduced in the USA and in many European countries. Indeed, West Germany was making use of it in 1965.

The United Kingdom delayed testing until a specific test (as opposed to a surrogate test) became available. Even then, although such a test was in use in Japan in 1989, and in the USA, Australia and most European countries in 1990, the United Kingdom delayed introduction until the product had been approved by the Food and Drug Administration (FDA) in the USA, and it was not introduced into the United

Kingdom until September 1991. In a case before the High Court in 2001, Mr Justice Burton considered the steps which were legitimately required before a product was made available in the United Kingdom. He said:

"I am satisfied that it was not appropriate, or legitimately expectable, that the screening should wait until after FDA approval, if as I am satisfied should have occurred, sufficient evaluation has taken place to allow for the United Kingdom's own decision to be made, like that in France and other countries which started prior to the FDA approval within the United States".

He stated:

"I have concluded that surrogate testing should have been in place by March 1988 and thus, like France, the United Kingdom would have run the new routine screening alongside the surrogate tests from 1 March 1990 onwards.[10]

b. Reducing or eliminating infectivity

Detecting the virus in the donor was a significant step in protecting recipients. Perhaps even more important was discovering methods of reducing or eliminating sources of infectivity. By the 1970s manufacturers of Factor concentrates were seeking ways of rendering them safe from Hepatitis NANB. Shortly after Factor VIII concentrate became available, experiments were proceeding with heat treatment as

[10] A and Others V. National Blood Authority and another (2001) 3 All.ER.289, at page 357seq

a method of killing pathogens. Research was taking place in the PFC at Edinburgh in the early 1970s, and similar work was proceeding in the USA and in Germany.

It was beset by problems. Heating to temperatures, and for periods, sufficient to destroy the virus could destabilise the product. In order to prevent this, "stabilisers" were added, but they also stabilised the virus. It was only in the early 1980s that a method was discovered in Germany of using as stabilisers sugar-based elements, which did not have this effect.

A further problem was that since there was no specific test for Hepatitis NANB until 1989, it was difficult to judge the success of the inactivation process, without subjecting patients to treatment with the product and monitoring the results. Test results on chimpanzees proved not to apply accurately to humans.

Nevertheless, in March 1983 the first patent for heat-treated product was granted in the USA, and heat-treated products imported from commercial sources were available for distribution in Scotland by the end of 1984. The SNBTS then recalled untreated Factor VIII concentrate stored in hospitals and where possible, concentrate distributed to patients, and subjected it to heat treatment.

The risk of infectivity was reduced stage by stage. In a letter to all Haemophilia Centre Directors dated 11 January 1982, Professor Bloom and Dr Rizza stated that at least four commercial companies were about to introduce "preparations of Factor VIII and possibly Factor IX that have been processed in an attempt to reduce the risk of transmitting Hepatitis B and non A non B".

Meanwhile, by December 1986, BPL had developed a product, referred to as 8Y, which appeared to retain its effectiveness despite elimination of the NANB virus. It was released routinely from April 1987, and by 1988 tests had confirmed that 8Y was free from Hepatitis because recipients did not develop raised transaminases. Of course, no product can be guaranteed to be totally safe, either from Hepatitis or AIDS, and there are substantial variations in the degree of risk. BPL were world leaders in the new technology, but, about 70% of Factor VIII used in England prior to 1988 was imported, and commercial suppliers did not use the methods employed in the production of 8Y.

By the end of the 1991, therefore, blood products manufactured in the UK were as safe from infection with Hepatitis C as current technology could make them, although this was not necessarily true of all imports.

2. AIDS

a. <u>The screening of donors</u>

The testing of donors for AIDS (as opposed to self-exclusion) proved an even slower process. Initially, it could be done only by keeping a careful record of particular batches of donations, from donor to recipient, and monitoring the recipients subsequently to receiving the treatment. In the United Kingdom the practice appears to have varied among different hospitals and treatment centres. In the case of the large donor pools required for the bulk production of Factor concentrates it was simply not practicable.

b. The testing of products

There was no one moment when a conclusive breakthrough for reducing or eliminating AIDS was achieved. Research into the effects of heating products was being conducted in a number of centres. In March 1983 the first patent for heat-treated product was granted in the USA, and heat-treated products imported from commercial sources were available for distribution in Scotland by the end of 1984. The SNBTS then recalled untreated Factor VIII concentrate stored in hospitals and where possible, concentrate distributed to patients, and subjected it to heat treatment.

For AIDS there was no question of detecting pathogens in the product until the virus was identified in 1984. On 2 March 1985 the US authorities licensed a test for blood samples referred to as the "ELISA" test (enzyme-linked immunosorbent assay). It was not infallible, but excluded much infected blood. It was licensed in the United Kingdom in October 1985, and from June 1986 all donations processed by the BPL were screened for HIV.

c. Reducing or eliminating infectivity

The availability of heat treatment, already described, was found to be effective for eliminating the HIV virus, and UK products were virtually free from HIV after 1988. Sadly, the appearance of vCJD raised further concerns, with the consequences already described.[11]

[11] See page 45

CHAPTER 7 – THE DOCTOR/PATIENT RELATIONSHIP

The Inquiry heard many complaints that during the 1970s and 1980s patients were often not given adequate information about the options for their treatment and the associated risks. In particular concerns were voiced about the paucity of information given to many patients concerning the following issues:

1. The growing concerns in the late 1970s among doctors treating haemophilia patients about the possibility that blood products could transmit harmful viruses, and the uncertainties existing in this area. Patients were often not informed about these anxieties until late in the day, if ever.

2. The relative risks of treatment with different blood products, notably the comparative risks of cryoprecipitate and Factor VIII concentrate. Therapy was also available in the form of DDAVP[12], which did not involve the use of blood products. This analogue of vasopressin could be useful in the management of less severe bleeds, but was effective only in patients with mild haemophilia. Haemorrhages in patients with haemophilia varied from relatively minor to life threatening. The relative risks of the bleed and its therapy varied accordingly, but several witnesses stated that this was often not explained to the patient before a choice of therapy was made. For instance Mr Stephen Wintle, the husband of Mrs Colette Wintle who suffered from a mild form of haemophilia, and who had been treated with substantial quantities of US concentrate,

[12] DDAVP (Desmopressin or Desamino-D-Arginine-vasopressin) is a synthetic analogue of vasopressin, the naturally occurring antidiuretic hormone. It is helpful in the treatment of mild haemophilia and of von Willebrand disease.

posed the question to the Inquiry, "...then why use a high-risk product on a low-risk patient?" Mr GRO-A told the Inquiry, "If I had the choice to use Factor VIII with the risk of infection with three life-threatening viruses, or the choice of joint damage and arthritis I would of course have chosen the latter. I was never given any choice".

3. When tests for HIV became available they were often used without patient consent. Even if this is understandable given the medical professional mores of that time, the results of these tests were often not disclosed to patients or their relatives. When patients were informed of the test results this was sometimes done without sensitivity or appropriate advice. The Inquiry heard of one patient who, when told that he was HIV positive, was urged not to tell his wife. She proved to be already infected. A haemophilia patient, Mr Burgess, told the Inquiry that after being informed that he was HIV positive, "...at no point were we offered counselling." On the same day the Inquiry heard from Laura, daughter of Mr Burgess, a moving and disturbing account of the disruption of family life caused by her father's infection with HIV and Hepatitis C.

4. The Inquiry was told, both by patients and by the UK Haemophilia Society, of the lack of patient involvement in decisions to monitor the effects of new therapies on, for instance, liver function tests. Such follow-up studies would have seemed prudent to doctors at that time, but the failure to inform the patients gave rise to resentment. Again Mr Stephen Wintle told the Inquiry, "I

feel very badly let down on behalf of my wife and myself in the way she and her fellow haemophiliacs were used as, I consider, guinea pigs".

Several medical witnesses, to whom the Inquiry is much indebted, readily acknowledged mistakes made by doctors in the unfolding of this tragedy. The Inquiry understands that the medical profession has since learned important lessons. Communication and transparency are today much better in the doctor/patient relationship than 30 years ago. Lord Owen told the Inquiry that, "there has been a sea-change in what we consider the rights of a patient…". In this context it is worth noting that the Royal College of Physicians now has a Medical Director of Patient Involvement.

Several factors appear to have been operative in limiting patient participation in decision taking in the 1970s and 1980s. Sources of information about their diseases which were available to patients at that time were far more limited than they are today. The flood of medical information and opinion now provided by the media was then a mere trickle. Patients had no access to computer medical information sources. Patient associations and similar organisations, representing consumer interests, were then in their infancy. In these circumstances patients had to rely on their doctors, both for information and advice.

In the early days of the AIDS epidemic doctors were themselves ill informed about it, as available information was fragmentary and uncertain. For instance, the disease was considered for a time to be limited to those practising homosexual intercourse. It is understandable that ignorance about AIDS was

widespread in its early years as, in some ways, it presented a novel challenge to medical science. In these circumstances doctors advising HIV positive patients operated from an inadequate knowledge base, which is always difficult and may lead to unwarranted dogmatism.

Between the mid 1970s and mid 1980s supplies of Factor VIII concentrate produced in the UK were completely inadequate to meet demand. Clinicians were thus faced with a dilemma: whether to use US commercial blood products, increasingly under suspicion of transmitting viral infections, or not. The Inquiry heard from a number of patients who, without consultation or informed advice, were given the American products, sometimes for relatively minor bleeds. One doctor, asked why he had chosen this option without patient consultation, replied that he had considered it "...worth the risk". Whatever the merits of this decision the Inquiry believes that the patient, who has most at stake, should have input into such decisions after being as fully informed as possible.

The relationship between doctors and their patients in the 1970s appears to have been paternalistic. Patients had few options other than to trust their doctors, while in the medical profession the duty of care of a doctor for his patient was considered to be absolute, conferring a mantle of total responsibility.

Nevertheless, from the evidence it heard, the Inquiry has no doubt that a significant number of patients with haemophilia received advice and information from their doctors in ways that today would be unacceptable. Responsibility for

this regrettable fact lies in the practice and customs of the medical profession at that time.

While the importance of clear information and informed consent is now recognised as having applied in the case of Hepatitis C, it was AIDS, and the consequences of a positive test, which focused discussion on the principles involved. Professor Maxwell Franklin explained:

"The emergence of AIDS was a turning point in the expectation that people expect to be asked and consent obtained, before important life changing investigations are performed. Prior to AIDS implied consent was the doctrine. A person came to you with a problem and this gave consent to do all necessary tests to investigate it…after AIDS, consent is required".

Standards expected of doctors have become much more explicit, since the Medical Act, 1978. Section 35 of the Medical Act, 1983, provides:

"The powers of the General Medical Council shall include the power to provide, in such manner as the Council think fit, advice for members of the medical profession on-

(a) Standards of professional conduct,

(b) Standards of professional performance

(c) Medical ethics".

The Council has availed itself of these powers to formulate advice on the importance of patient consent.

The Council offers guidance in a document entitled "Good Medical Practice". It is not a body of rules, but a set of principles and values on which good medical practice is founded. The advice is not enforceable by statute, but if a doctor seriously or persistently fails to follow the guidance, he may be judged unfit to practise, or suffer other appropriate sanctions.

In May 1988 the GMC set out guidance in relation to HIV and AIDS, in a document entitled "HIV infection and Aids: the Ethical Considerations" and under a section headed "Consent to Investigation or Treatment" declared:

"It has long been accepted, and is well understood within the profession, that a doctor should treat a patient only on the basis of the patient's informed consent. Doctors are expected in all normal circumstances to be sure of their patient's consent to the carrying out of investigative procedures involving the removal of samples or invasive techniques, whether those investigations are performed for the purposes of routine screening, for example in pregnancy or prior to surgery, or for the more specific purpose of differential diagnosis. A patient's consent may in certain circumstances be given implicitly, for example by agreement to provide a specimen of blood for multiple analysis. In other circumstances it needs to be given explicitly, for example before undergoing a specified operative procedure or providing a specimen of blood to be tested specifically for a named condition".

"The GMC believes that the above principles should apply generally but that it is particularly important in the case of testing for HIV infections, not because the condition is different in kind from other infections, but because of the possible serious social and financial consequences which may ensue for the patient from the mere fact of having been tested for the condition".

The importance of involving patients when making clinical decisions is underlined by a recent publication by the General Medical Council, 'Consent: patients and doctors making decisions together'.[13]

[13] May 2008

CHAPTER 8 – THE LOST DOCUMENTS

In November 1987 Lord Owen learned that the objective of national self-sufficiency in blood products had not been achieved, and initiated the correspondence referred to in Chapter 4. He then sought access to the papers relating to his period as minister, which had of course been retained by the Department. It is clearly recognised that a former minister is entitled to consult documents which formed the basis of his decisions as a minister. The current Ministerial Code, published by the Cabinet Office in July 2007, reads (paragraph 2-9):

"By convention and at the Government's discretion, former ministers are allowed reasonable access to the papers of the period when they were in office…subject to compliance with the Radcliffe rules (section 8, 10) former ministers may have access in the Cabinet Office to copies of Cabinet or Cabinet Committee papers which were issued to them when in office, and access in the relevant department, to other official papers which they are known to have handled at the time".

It came as a surprise to Lord Owen to be told that the papers had been destroyed "under the 10-year rule". We have made inquiries, but have been unable to identify "the 10-year rule". But it would be strange indeed if any rule prescribed that documents should be destroyed after a given period of time without some responsible official considering whether they might prove relevant to future discussion or inquiry. Since in 1987 there was continuing public discussion of the self-sufficiency policy, and of the reasons for failure to achieve the objective, it should have been obvious that the papers in question might prove relevant to

ongoing issues. In June 2006, the Department of Health commissioned a review "to access the extent and content of documents held by the Department of Health in relation to non-A non-B Hepatitis". The outcome of the Review was published in May 2007. It includes a table entitled "The Chronology of Events". And one item reads:

"1986: Research identifies the need for retrospective NANBH studies, recognising that the initial disease might be quite mild but progression to symptoms associated with severe disease may be very protracted". And by September 1988, it had transpired that the discussion was not concluded. Another item reads:

"September 1988: the UK was not self-sufficient in plasma products due to errors in estimating both the amount of plasma stockpiled and the net yield for Factor VIII production at BPL and could not expect to be so for a couple of years".

We have been unable to ascertain who carried out the destruction of the papers, and who gave the instructions. But the conclusion appears inescapable that some official made a decision which he or she had no authority to make, or that someone was guilty of a serious error of judgement. The consequence is that Lord Owen has done his best to recollect details of events a quarter of a century ago, but both he, and we, have been deprived of the primary sources.

Lord Jenkin of Roding was Secretary of State for Health and Social Security for two years from 1979 to 1981. He explained to us that the Minister of State of the Department was Sir Gerard Vaughan, MP who, sadly, is no longer alive. Since Sir Gerard was a doctor, Lord Jenkin delegated to him the handling of matters relating to

blood and blood products used by the NHS, asking only to be kept informed of important developments and matters arising in Parliament.

In October 2004 Lord Jenkin was asked to attend a meeting of the All Party Group on Hepatitis. In consequence, it was suggested to him that he might ask to see the papers which were presented to him during his period in office. Accordingly he wrote to Lord Warner, the Parliamentary Under Secretary of State, requesting certain papers. In his reply, Lord Warner stated that officials had carried out a search, but could find no trace of the papers described. He added:

"The Government takes the issues of haemophilia and blood products very seriously and has great sympathy for anyone who has suffered harm as a result of NHS treatment. Ministers do understand the hardship and great distress that people with haemophilia and their families have suffered from both HIV and Hepatitis C, and deeply regret that so many people were infected through blood products". He added that, notwithstanding the ex gratia payments: "the position with regards to accepting liability has not changed"[14].

Lord Jenkin pursued the matter by making an appointment to see Sir Nigel Crisp, the Permanent Secretary. On 10 March 2005 Lord Warner wrote further to Lord Jenkin, explaining that he had not meant to convey that the Department held no records on the treatment of Haemophilia patients and blood safety, and offering to discuss the papers required. Enclosed with the letter, no doubt by oversight within the Department, was a Departmental note from the Blood Policy Team explaining that

[14] See Chapter 9

the original reply had been drafted by the correspondence unit "using a number of standard lines", and adding that the new draft "seeks to reassure Lord Jenkins [sic] that the Department of Health does operate an effective management system".

On 13 April 2005 Lord Jenkin met Sir Nigel, who apologised for the original reply. Lord Jenkin was left with the clear impression from their subsequent conversation that all the files bearing upon the issue of contaminated blood products had been destroyed, and that this had been done "with intent, in order to draw a line under the disaster". We enquired whether Sir Nigel was available to give evidence to us as to whether this was what he intended to convey, but were informed that he is now on an extended visit to another part of the world. However, he added that there were files available in the Records Office, and that staff were seeking to identify those which may be helpful. Lord Jenkin was subsequently able to inspect some of them. He discovered no files relating to the source of infection, but his inspection confirmed that the Department was aware that Hepatitis C had been identified, and that blood and blood products used for transfusions were routinely tested for contamination. He subsequently received from the Department two bundles of documents. One of these was to be treated as confidential.

He tabled a Parliamentary question:

"Whether the Department of Health's report 'Self-sufficiency in Blood Products in England and Wales', published on 27 February 2006, is a complete account of the circumstances leading to the infection of National Health Service patients with HIV and Hepatitis C due to contaminated blood products".

Lord Warner replied on 19 April 2006:

"My Lords, the Report published on the 27 February examined key issues around self-sufficiency in blood products in the 1970s and early 1980s. The review was commissioned following suggestions that implementation of what was called "the self-sufficiency policy" in blood products in this period might have avoided haemophiliacs being treated with infected blood products. The report makes it clear that it was based on surviving documents from 1973, but that self-sufficiency would not have prevented infection from haemophiliacs with Hepatitis C".

Lord Jenkin enquired about the destruction of Departmental files.

Lord Warner replied[15]:

"We regret that the papers were destroyed in error, which was, I think, explained to the noble Lord in a meeting with the former Permanent Secretary to the Department of Health. I think that it has been explained to him on a number of occasions that there was no deliberate attempt to destroy past papers. We understand that many of the papers were unfortunately destroyed but I have to say that that did not take place under this government".

Baroness Barker asked:

[15] Reply given on 26 May 2006

"My Lords, does the Minister accept that the report, which contains no information about what patients were advised at the time and no information about what Government policy was on blood donations from high-risk groups, is an unsatisfactory report and will not help to move this policy or this practice forward".

Lord Warner replied:

"My Lords, the document is helpful in setting out the chronology and the changes in scientific understanding during this period, which had a considerable impact on policy under successive Governments on blood products and their use with haemophiliacs. There was a lot of clinical uncertainty in the early days in identifying Hepatitis C. The document sets out clearly those clinical and scientific uncertainties. It gives an extensive 158 references to other documents, on which it relied".

In addition to the ministerial papers of Lords Owen and Jenkin, two other instances of misfiling or mishandling have been identified. The first example arose in connection with the litigation consolidated in 1989 by the "Multi-Party Group"[16]. A substantial number of documents were removed from Departmental files and provided to solicitors acting for the Department which were a party to the action. Some of them were photocopied and copies provided to solicitors acting for the claimants. After the litigation was concluded, folders thought to contain the documents which had been removed were returned to the Department, but when in January 2005, the Department received a request under the Freedom of Information Act for some of the records, it was discovered that they were missing.

[16] See Chapter 9

The resulting publicity led to the return in May 2006 by a firm of solicitors acting for claimants in the litigation, of the photocopies of 610 documents with which they had been provided. This appeared to result in searches within the Department for files that had not been registered, meaning that their content had not therefore been previously recorded. Consequently, a further 4,629 documents were discovered. These were in addition to the copies returned by the solicitors. It follows that 5,239 documents or photocopies were recovered, and it is thought that the majority of the missing documents have now been located.

The second instance of the mishandling of documents arose in connection with a number of files relating to the Advisory Committee on the Virological Safety of Blood between May 1989 and February 1992 which were found to be missing. It was the subject of an internal audit review, which reported in April 2000. Staff who may have been involved were interviewed, but they were seeking to recollect details and events up to eight years previously. It appears that the files were closed in February and March 1993 and marked for review five years from the date of the last paper in each file. But in July 1993 they were marked for destruction. They were in fact destroyed over a period from July 1994 to March 1998. The decision to mark them for destruction took place when the Department was undergoing major reorganisation, in accordance with the Functions and Manpower Review.

The audit review concluded that there was either a delegation of responsibility without proper instructions, or an assumption of responsibility by someone who had not been authorised. The files should have been recalled when it was known that

they might be relevant to the litigation. It was also judged that the periods assigned for review were shorter than should have been assigned.

The audit review made a number of recommendations. In particular, it recommended that new and existing staff should receive training in the importance of record keeping, and guidance in what is required. In many cases it noted that record keeping is seen as an onerous and boring job.

It is not surprising that some of those who gave evidence to us suspected that there was an exercise in suppressing evidence of negligence or misconduct. We have not been able to interview any of those responsible, and even had we done so, recollections may have been eroded by the passage of time, but we have discovered no evidence of malicious destruction of relevant records. Comment on the standard of record keeping at the period in question is not within our Terms of Reference. But had an official Public Inquiry been established while recollections were fresh, the suspicions might have been addressed.

CHAPTER 9 - GOVERNMENTAL RESPONSE: FINANCIAL RELIEF

The shattering effects of contracting Hepatitis or HIV are frequently exacerbated by the consequential loss of earning capacity and pension rights, and the increased expenses of everyday living. The patient may require additional heating, a special diet, and assistance with transport. Health, travel and life insurance may be refused, or offered only at enhanced premiums. There may be consequent inability to meet existing commitments, such as mortgages. Patients are often unable to share household chores, and there may be a need for domestic help. Nor are the consequences confined to the patient. They may extend throughout the family.

Mrs Colette Wintle, who was infected with Hepatitis C through treatment for haemophilia, told us:

"I was forced to retire from working part-time, aged 38, on the grounds of ill-health, and I now have no pension to retire on because of not being able to work".

Mrs GRO-A, who became a full-time carer for her husband, GRO-A after he had been infected with HIV, told us:

"During the time I cared for GRO-A, most of the 17 years of my adult life, I lived on means-tested benefits. Following his death, I also have to endure life on means-tested benefits, not even being recognised for widows' pension status. This was available to all blood-contaminated widows apart from those in England".

As it became clear in the 1980s that many haemophilia sufferers had been infected with Hepatitis, or with HIV, and patients became aware of the financial consequences that often followed, the UK Haemophilia Society, supported by MP's, began to lobby Governments to provide financial relief for those affected, particularly for the victims of HIV infection.

On 16 November 1987, following a lobby of Parliament by the Haemophilia Society, The Rt Hon Tony Newton, then the Minister of Health, now Lord Newton, announced that the Government recognised the "wholly exceptional position of haemophiliacs", and that it was proposed to make an ex gratia payment of £10 million. It would take the form of a discretionary charitable trust, that would be charged with making payments to haemophilia patients who had been infected with HIV from contaminated NHS blood products, and who were in need, and to their dependants. The Trust was called "The Macfarlane Trust", commemorating Professor R G Macfarlane, who had conducted early research at Oxford into the treatment of haemophilia.

Its purposes were set out in a trust deed, and, within those purposes, payments were to be made at the discretion of the trustees. Four trustees were to be nominated by the Department of Health and were to include one Haemophilia Centre Director and a social worker. There were to be six additional trustees representing the Haemophilia Society, two of whom would be "user trustees", i.e. persons who qualified as beneficiaries of the Trust. The composition of the Board was subsequently revised. The appointees of the Haemophilia Society were reduced to

four, and the Board itself appointed four additional trustees, of whom two could be user trustees.

The Government held out no expectation of further funding. Few of the 1,246 victims who registered claims were expected to survive beyond five years and, given provident investment of the initial funding, it was considered possible to make annual disbursements amounting to £2 million.

Accordingly, monthly payments were made to beneficiaries, towards the expenses imposed by HIV, together with an annual supplement to meet seasonal outgoings such as additional fuel costs in cold weather. Discretionary payments could be made to meet incidental expenses. The Trust received a further grant from the Government to meet administrative outlay. The system has subsequently been changed to one in which the Trust applies each year for the expenses which it is likely to incur. Of the original registrants, about 370 are still alive, together with 42 "infected intimates". There was therefore no stated lump sum or periodical payment to which beneficiaries were entitled as of right. Anyone seeking relief had to apply to the Trust and establish that he or she was in need of relief for specific purposes.

This method of providing relief was flawed in two ways. First, to provide money on an ad hoc basis to beneficiaries who could point to specific needs savoured strongly of poor relief. Victims, some of whom before they were infected had enjoyed high living standards and were capable of substantial earnings, were now required, as they saw it, to go cap-in-hand and beg for discretionary relief. However sympathetic and sensitive the Trustees, the victims felt patronised. Secondly, victims of HIV also

continued to feel that there remained an element of stigma attached to the condition, and sometimes felt embarrassed in discussing it.

Meanwhile, some of the victims were questioning whether those whose activities, or inactivity, brought about the disaster might be held responsible in law to compensate for the damage. In the United States victims were bringing proceedings against the manufacturers of the commercial blood products in question, and there were substantial awards of damages. Victims in the United Kingdom began to seek legal advice. One major difference between the two countries was that in the USA there was no equivalent to the NHS, which, in the United Kingdom, had usually supplied the infected products.

There were some actions against individual Health Authorities, but the majority of the claims were against the NHS and the BTS. We have endeavoured to trace the many actions, but no records were held centrally, and the information is patchy.

In 1989 a number of victims who had been infected with HIV, and had begun proceedings against the Department of Health and the BTS, consolidated their claims. They became known as the "Multi-Party Group" and the number of claims amounted to some 970. They alleged that the Department of Health had been negligent in failing to address the inadequacies of the fractionation plant at Elstree, in importing products which were known to be at risk of infection and in failing to provide timely surrogate testing.

On 26 June 1990, Mr Justice Ognal, the judge assigned to the case, indicated his view that justice would be best served by a negotiated settlement of the action.

Negotiations were encouraged by a further development. The defendants had disclosed to the plaintiffs in the normal manner a substantial proportion of the documents which they held and which, in their view, were relevant to the issues raised, but in respect of some they claimed public interest immunity. On 31 July 1990, Mr Justice Rougier held that, nevertheless, most of those documents, too, should be disclosed, and on 20 September of that year his order was upheld by the Court of Appeal. The Government, for whatever reason, was reluctant to disclose the documents in question, and this seems to have encouraged a negotiated settlement.

In November 1989, the Government agreed to make to the Macfarlane Trustees a payment of a further £42 million of which £24 million was set aside for the plaintiffs. This was sufficient to enable them to provide an ex gratia sum of £20,000 to beneficiaries of the scheme. They were therefore no longer living from hand to mouth, but were enabled to a limited extent to plan their expenditure and meet some more substantial commitments. It was agreed that there were to be continuing negotiations, and in 1991, further payments were made according to individual family circumstances.

But the agreement was conditional upon the signing of a waiver, renouncing the right to make further claims through litigation, in respect not only of infection with HIV, but also of Hepatitis. At that time, many of the recipients were not aware that they had

been infected with Hepatitis, since the long incubation period of Hepatitis C was not fully understood. A number of witnesses have expressed resentment that recipients of payments to address the consequences of HIV should have been required to renounce any right of action in respect of Hepatitis C, although it was known to the Department that they were at least potentially at risk of having been infected with the Hepatitis C virus. It is hardly surprising that, since there had been litigation, entailing mutual disclosure of documents, there are suspicions that the authorities may have been aware that some patients had been tested for Hepatitis C, with positive results, of which they had not been informed by their doctors. Mr Haydn Lewis commented:

"I found it pretty disgraceful to ask them (the patients) to sign a waiver to disregard any future responsibility when at that time they actually knew that I was infected with it". He was not then himself aware of the test. Furthermore, there remained the expectation that victims of HIV could look forward to a very limited lifespan. We have heard of solicitors advising clients, no doubt on the evidence then available, "take it and enjoy it while you can".

These lump-sum payments are administered by two separate trusts, known respectively as "Macfarlane Special Payment Trusts 1 and 2". For the moment there remains a substantial need for the discretionary and ad hoc payments originally envisaged.

The Macfarlane Trust and the Macfarlane Special Payment Trusts address the needs of haemophilia sufferers who have been infected with HIV. But they have no power to assist those who do not suffer from haemophilia but who have been treated

with NHS blood or blood products for other reasons, and have consequently suffered from HIV infection. Following the establishment of the Macfarlane Trust, a number of people who were not haemophilia sufferers, but who had suffered infections from blood or blood products, began proceedings against the Department of Health, based on similar allegations. One of the allegations was a failure to test either blood donors, or blood collected from untested donors, and applications were made on behalf of the plaintiffs for details of the individual donors who had contributed to the blood donations in question. The prospect of breaching the confidentiality assured to blood donors could have discouraged them from volunteering donations, and in consequence there were discussions leading in 1993 to a Government subvention of £500,000, to establish what became the Eileen Trust.

This is a much smaller trust than its Macfarlane counterpart. It has only 27 registrants. However, the number is increasing and there is reason to believe that there may be many more who would qualify for registration, but since in most cases they were not originally diagnosed as suffering from an ongoing disorder, their cases were not followed up, and often neither they nor their doctors are aware of the cause of their infection. It has been suggested that the Government might be more positive in recommending that patients who were treated with NHS blood or blood products between 1973 and 1986 should be tested for HIV.

Because the purposes of the Eileen Trust do not fall within those of the Macfarlane Trust, it is funded separately and administered by a full-time administrator and part-time staff. The Trustees of the Skipton Fund (see p83) also serve as Trustees of the Eileen Trust.

The Eileen Trust received a further grant of £500,000 in 2001, and the Government now funds it at an annual rate of £178,000, but it has ceased to provide additional money for administrative expenses, which are met from its general income. Registrants receive sums, including special payments, at the same level as registrants of the Macfarlane Trust, but the capital payments have not been increased since 1991.

Furthermore, an anomaly has arisen with the passage of time. Beneficiaries of the Eileen Trust who were married with children when they were infected now receive annual payments amounting to £60,000, while those who were infected at an earlier age receive only £21,500. Not only have they been subjected to a longer period of illness, but also their payment is not increased even if they subsequently marry and have children.

Until 2003 there was no separate financial provision for those who had been infected with Hepatitis C, although the outcome of A and Others –v- National Blood Authority and Another was seen as a likely precedent for future negotiations[17]. On 29 August 2003 following the publication of the Ross Report[18], the then Secretary of State, the Rt Hon John Reid MP, announced the establishment of a fund to make payments to those who had been infected with Hepatitis C. He explored whether the fund could be administered through the Macfarlane Trust, but since the purposes of the fund did not fall within the objects of the Trust, separate arrangements were required, and the Skipton Fund was established. The name was taken from Skipton House, a building in London occupied by the Department of Health.

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[17] See page 56
[18] September 2002: Expert Group on Financial and Other Support – Parliamentary Report

The Fund is administered by a company established for the purpose, which operates under an agency agreement with the Department of Health. To those who qualify, it makes lump-sum payments of £20,000, with a further £25,000 for those who establish that the infection has led to severe liver disease. We have not been able to discover how these figures were calculated. We were told that they were the Department's figures, and that there had been no negotiations.

By May 2007, there had been 3,751 first-stage payments, amounting in total to a little over £75 million. And there have been 600 second-stage payments amounting to a further £15 million. The Fund continues to pay first-stage payments at the rate of about 20 per month and second-stage at about 8 per month. It is expected that the proportion of second-stage to first-stage payments will rise over time. The Government provides money as required, since the rules leave no discretion to the Directors of the Fund. After some discussion it was agreed that the payments are not to be taken into account for the calculation of means-tested benefits. Those doubly infected, with HIV and Hepatitis C, qualify for payments from both the Macfarlane Trust and the Skipton Fund. We were told that anyone suffering from haemophilia during the 1970s who was treated with blood products, and who subsequently developed Hepatitis C is regarded as having been infected by those blood products.

Those who administer the Fund admit that they are totally dependent on the medical advice which they receive. Some hospitals are reluctant to support claims from patients who have been cleared of the virus, and whose condition could not now be confirmed by a test. Others appear to give the benefit of the doubt to the patient.

However, there is an Appeals Panel, which includes a hepatologist and a haematologist, and is chaired by a lawyer.

The scheme is not made retrospective for dependants of people otherwise eligible who died before 29 August 2003, when the Trust was established. For those who died between 29 August 2003 and 5 July 2004 the payments are made to their estate. But payments are made in respect of those dying after the latter date only if the victim had applied to the Fund before dying. In consequence, many widows are excluded from the benefit of the Fund.

Meanwhile, the Macfarlane Trustees were finding that the original prediction of an early death for their beneficiaries had (happily) been unduly pessimistic. But paradoxically, a longer lifespan itself brought additional problems, since their savings were evaporating by reason of deteriorating health and longer term needs. Consequently, the longer term commitments of the Trust were escalating and their reserves were being depleted. In 2003 the Department of Health agreed to fund a review, carried out for the Trustees, of the probable future needs of their beneficiaries. The consequent report was entitled "A Full Life – Not Just Existence". It concluded that Government funding of the Trust should rise to £7 million annually, linked to the cost of living index, for the five years beginning April 2006. This would represent an increase of nearly 100%, and it gave rise to a meeting with the Minister of State, Caroline Flint, MP. In a follow-up letter dated 26 July 2006 she said:

"I am satisfied that an increase of £400,000, approximately 11%, to the Trust funding will maintain an appropriate level of support to their remaining registrants and is

within the current level of Government funding that is available. This will bring the funding each year to £3,754,000 for the Macfarlane Trust and £177,000 for the Eileen Trust (assuming a 90/10 split on the current ratio of their size). Both these figures include provision for administrative costs".

The Macfarlane and Eileen Trusts are now able to provide monthly payments consisting of a standard rate of £255, and higher rates varying between £300 and £500 for those in receipt of income support. In addition, there are two annual payments for specific outgoings such as additional heating costs in winter and family holidays in summer. Further, grants may be made to cope with disability, building adaptations and respite care.

However, the Macfarlane Trust continues to find difficulty in matching its resources to the needs of its beneficiaries, and to the financial relief afforded to those of similar circumstances in other countries. In November 2006, the Trustees presented to the Department of Health a survey of the needs of beneficiaries, given the existing situation, entitled "Funding Long Term Survival". Its conclusion was that provision should be made for annual disbursements in the order of £7.5 million.

In evidence to us, Mr Roddy Morrison, Chairman of the UK Haemophilia Society said:

"The Government must conclude a financial settlement that will fully recognise their (the victims') loss potential and its effect on their current living standards. It should be a full and final settlement, which will replace all the myriad of current

arrangements. These payments must be independently adjudicated for each individual and should be paid directly. There should be no more trusts or funds and that is in no way a criticism of the individual trust and funds; they were set up as they were set up, but that is not what we want going forward. One of the key points here is that the people affected feel that they have been denied control over their own futures. In order that they can begin to regain their independence, settlement levels should be based on recognised legal norms. A settlement should assess the losses and loss potential of individuals, bereaved relatives, dependants and those cleared of Hepatitis C naturally. Carers, many of whom have sacrificed their careers, should be assessed separately from their partners".

But while the Trustees of the various funds are arguing the need for further funding, they are threatened with a reduction in the existing levels. In November 2006 the Macfarlane Trust received a letter from the Department of Health which stated:

"I explained the financial difficulties facing the Department, and I am being asked to reduce all budgets. Nevertheless, I am aiming to secure the same level of funding for 2007/2008 as 2006/2007". Mr Christopher Fitzgerald, the current Chairman of the Macfarlane Trust, commented to us:

"We are charged with a duty under a trust deed to relieve the needs of beneficiaries. We cannot perform that duty unless adequate financing is provided, and to do that the politicians have got to recognise the fundamental change that has taken place in the needs of our beneficiaries, resulting from the fact that they now are expected to survive for a full life span, God willing, whereas, when the commitments were

originally given, they were all expected to be dead within 4 to 5 years. And there are realities here, new realities, that are going to continue and must be recognised".

The Government recently told the Trustees of the Eileen Trust that the first port of call for financial support should be the benefit system and that the function of the Eileen Trust should be to provide top-up payments. Mr Peter Stevens, Chairman of the Eileen Trust commented to us:

"The benefit system is not in my opinion well suited to provide for people with multiple medical conditions, who are permanently unable to work because of those medical conditions. Increasingly, the benefit system is being designed to encourage people to go and do some work".

It is not surprising that comparisons are often made between the financial provision made available in the United Kingdom and that which operates in Ireland. The population of Ireland is approximately one-tenth of that of the United Kingdom and the proportion of people infected with Hepatitis C and HIV to the total population is about the same. In 1987 the Irish Haemophilia Society concluded a survey of haemophilia patients who had been infected with HIV, to ascertain their needs and requirements, and in consequence it published a booklet in 1988 entitled "Aids, Haemophilia and the Government". In 1989 the Irish Government established a trust fund with a sum of £1 million. It was similar in structure to the Macfarlane Trust and was similarly flawed. The Irish Haemophilia Society believed that the solution lay in substantial lump-sum payments. In 1991, the Irish Government set out a scale of payments to persons infected through contaminated blood with HIV. Payments were

made to a single person of £77,000, £101,000 to a married person with dependant children, £94,000 to a married person with no dependent children, and £20,000 to the parents of a deceased person.

From 1992, attention in Ireland turned to haemophilia patients who had been infected with Hepatitis C, and the Government established a Tribunal, the Hepatitis C Compensation Tribunal, to assess the loss and damage suffered in consequence of infections. There was not a scale of lump-sum payments, as in the case of HIV. Each case is assessed individually, and the Tribunal may award a lump sum as the final award, or make interim awards where a final assessment is not possible. Mr Brian O'Mahony, the Chief Executive Officer of the Irish Haemophilia Society, told us that payments have ranged from 14,000 Euros to 3,100,000 Euros, the average payment being 853,636 Euros. Payments have been made to 2,200 claimants, and amount in total to 778 million Euros.

In view of comparisons made between financial provisions in England and Ireland the United Kingdom Government sought to distinguish the situation in the two countries. In the House of Lords on 11 December 2003, Lord Warner, speaking on behalf of the Government, said:

"In Ireland and Canada, for example, compensation schemes were paid because the blood authorities were both found to be at fault. Indeed in Canada, criminal prosecutions were filed against those responsible. It is important to state that, despite our decision to make ex gratia payments, the position with regard to accepting liability has not changed. The payments are made on compassionate

grounds and are not compensation. With that in mind, the payments cannot be expected to take account of loss of earnings or compare with positive damages awarded by the Courts in other countries".

On 25 March 2004, he sought to clarify the position:

"My understanding of the position in Ireland, which has been corroborated by officials in the Department of Health and Children in Dublin since my last utterances on the subject in the House, is that the Irish Government set up their Hepatitis C compensation scheme following evidence of negligence by the Irish Blood Transfusion Service. A judicial inquiry, the Lindsay report, found that "wrongful acts were committed". It is important to stress that the blood services in the UK have not been found to be similarly at fault. Compensation has therefore been given in very different, specific circumstances in Ireland that do not apply in the UK".

The Minister's briefing from the Department appears not to have been wholly clear. To distinguish between the situation in the United Kingdom and that in Ireland on the basis that the Official Inquiry in Ireland had made certain criticisms of the Irish Blood Transfusion Service is a curious argument, since successive Governments in England have declined to establish an Inquiry, and so have precluded any possibility of comparing the comments of an Official Inquiry in Ireland and an Official Inquiry in England. The payments by the Irish Government were equally made without an admission of liability. However, recipients were required to sign waivers, as in England, exempting the Government from further claims. Certain criticisms were

made of the 1997 provision, particularly that no relief had been made available for those infected with HIV, but these were addressed in an amending Act in 2002.[19]

Ms Carol Grayson, who provided the Inquiry with a great deal of helpful information, supplied us with a letter written to her on the 26 February 2004, by an Assistant Financial Officer in the Public Service in Ireland, in reply to a question about the basis of compensation by the Hepatitis C and HIV Compensation Tribunal. It includes the following:

"As you rightly point out, compensation for persons with haemophilia was made on compassionate grounds, without legal liability on the part of the State – he (the Minister) acknowledged extraordinary suffering endured by persons with haemophilia who were infected, and by their families".

Schemes to provide financial support for haemophilia patients who had suffered infections have been established in Canada, New Zealand, Hungary, Italy, Spain and Sweden. In Canada, payments ranged from $10 to $100,000. In Italy, monthly payments are made ranging between the equivalent of £600 and £900, and there has been a single payment of £465,000.

It is not our function to decide issues of legal liability, and we do not presume to do so. But we are impressed by the arguments which have been presented to us for more generous assistance to mitigate the financial hardship endured by many victims. We have made certain criticisms of acts or omissions which, in the past,

[19] Hepatitis C Compensation Tribunal (Amendment) Bill, 2002

may have contributed to the disasters and the consequences, and which continue to blight the lives of victims and their families. But it is not on these observations that the arguments rest.

It is understandable that those infected and their dependants should have sought in the first instance to apportion blame, and to seek a remedy through litigation, and no less understandable that successive Governments should have denied that they, or their predecessors, were at fault. For the present purpose, we ignore that issue. We believe that in this situation, legal argument addresses the wrong questions. First, it frequently focuses on marginal issues, such as whether proceedings are barred by the Limitation Act, 1980, or whether the claimants have in some way renounced their right to bring proceedings. Secondly, the outcome is often decided by such chances as whether proper records were kept and are still available, or whether a vital witness is still alive. And thirdly, it often fails to address the real issue, namely of human need. The purpose of civil law is not to punish negligence or wrongdoing, but to compensate for undeserved suffering.

The arguments for no-fault liability in certain categories of claim have been deployed and debated at least since the 1960s; first, the expense of pursuing a legal remedy, or of resisting it, would be saved. Secondly, the lottery described above could be replaced by a more rational outcome.

It has been argued that those who embark on an activity carrying a risk of injury to someone else should bear the cost of compensating victims, even in the absence of fault, and that they can avoid the burden of meeting substantial claims by taking out

appropriate insurance. In New Zealand an instance of the principle may be found in relation to road accidents. A narrow application of the argument is that those who undertake an activity for profit should compensate those who suffer in consequence, even if no fault can be established. That is the premise which underlies the Consumer Protection Act, 1987 although, as we have seen, the exceptions and provisos which Parliament felt to be necessary, have given rise to substantial arguments. In any event, that is not the situation where the Government provides a service such as the NHS.

A version of the argument which has been suggested to us by a number of witnesses is that the Government is under an obligation to compensate victims simply because, through its agents and irrespective of fault, it supplied patients with blood or blood products which caused the damage. The argument appears to be that anyone who, however innocently, is the occasion of harm to another, should compensate the victim. Traces of that proposition appeared in legal cases of Anglo-Saxon England, but they did not survive the analysis of professional judges in the 12th Century, and we do not believe that in the contemporary world that proposition is arguable. We believe that the real foundation of the case for Government action is that a Government has a duty to ensure to all its citizens, so far as possible, a reasonable life, free from the "five giants" addressed in the Beveridge Report, in 1942, one of which was poverty.

Lord Warner's answer on 25 March 2004[20], whatever the facts on which it was based, is open to more fundamental criticism. It carries the startling implication that

[20] See page 89

unless a Government is in some way responsible for a misfortune befalling a group of its citizens, it is under no obligation to relieve it. That doctrine has only to be stated to stand refuted. The very purpose of Government is to protect its citizens, so far as possible, from life's vicissitudes, and to afford them the best achievable quality of life. It is not in the position of a citizen who may, if he chooses, remain indifferent to the misfortunes of a neighbour in which he had no hand.

We do not recommend payments on an individual means-tested basis, but we are here discussing certain categories of people who are more likely than the average to be in financial need. We recommend that membership of any of those categories should be the criterion for receiving substantial assistance. We do not recommend that such payments should be construed as an admission by the Government that previous Governments, or the BTS, were at fault.

Where poverty is widespread, even though not universal, among a limited and readily defined category of citizens, and particularly where it is attributable to a specific misfortune, we believe that they are entitled to look to the Government for redress. Since a means-tested solution is an undeserved affront to their dignity, we believe that it should take the form of a standard payment or payments adequate for the purpose. On 21 November 2002, in the House of Lords, Lord Akner elaborated on the argument.

"My Lords, how does the noble Lord differentiate between this case and the extensive compensation paid for victims of crime? There is no obligation on the Government to provide a penny piece for victims of crime, but in the past, it was

provided on the same basis as the ordinary civil liability. Subsequently it went to a tariff system. Many millions of pounds are provided for victims of crime. Why is there a differentiation between them and the haemophiliacs whom we are discussing?"

Where the support embodied in private charity is not applicable, we believe that a compassionate Government should provide it.

CHAPTER 10 GOVERNMENTAL RESPONSE: ADDITIONAL MEASURES

Addressing the consequences of infection with Hepatitis or HIV in terms of the need for the provision of financial relief is a necessary step. However, further steps are required to meet the wider needs of the haemophilia community.

We have examined in Chapter 9 the Government response to this serious issue in terms of the financial arrangements made through the Macfarlane Trust, the Skipton Fund and the Eileen Trust, and the reasons why we contend that these arrangements are flawed. It is now necessary to consider the measures that could and should be taken in addition to payments to individuals and their families.

Campaigners have been working for years to raise awareness of the plight of these patients in order to present the case for an adequate and reasonable response to their suffering and that of their families. This suffering has never been sufficiently acknowledged, nor the consequences of it addressed. It affected, and continues to affect, all aspects of the victims' lives - physical, emotional, social and, of course, financial.

The priority must be to address the fundamental questions. The first of these is a consideration of what can be done to provide some degree of closure for those who have suffered and their families, and what action Government should take. Through no fault of their own, the ability to lead a normal life has been taken away from them.

We heard evidence from Mrs Sue Threakall, who told us:

"We will only be able to move on and truly live our lives when we know the truth has come out and everything possible has been done to address this catastrophe".

In addition, it is vital that those lessons are learned for the future and that we can ensure that a tragedy of this nature and scale does not occur again. We can learn many lessons from Ireland. There, following the publication of the Lindsay Report, a model was devised that addressed a number of issues, and recommendations were made accordingly.

Initially, we propose that a statutory advisory committee is established. This committee must be representative and its members should include specialist haemophilia clinicians, individuals from the Haemophilia Society and a representative from the Department of Health. Such a group would ensure involvement by medical experts and, most importantly, it would guarantee the involvement of members of the haemophilia patient community. The committee would provide a formal, statutory structure within which patients have a voice in decisions regarding treatment and options for care. We consider the formation of such a committee, with its mechanism for consulting with patients, to be essential. Such committees or councils operate successfully in Canada, Ireland, Japan, Thailand and the USA. The committee would require proper resourcing, with adequate provision and administrative support.

It is now widely recognised that good practice in healthcare provision involves patient representation. The following is taken from a recent report entitled, European

principles of haemophilia care[21]:

"Clinicians and patient representatives must be part of national and/or regional haemophilia care decision-making in partnership with ministers for health and social affairs and those organisations that deliver haemophilia care". This report has recently been endorsed by The World Federation of Haemophilia and the European Haemophilia Consortium.

Involvement in decision-making through consultation and participation would be a much needed step forward for the haemophilia community. However, while access to this democratic process is essential, we must also consider their access to adequate health and support services.

The group of people affected are living with various health problems as a result of their infections. Their primary condition, haemophilia, has to be managed alongside, in many cases, infections such as Hepatitis C and HIV. The treatment of these viral illnesses is complex and presents a huge challenge in patient care. Following such a programme of treatment places an enormous burden on each patient. Not only is the treatment debilitating, but also other factors are involved, such as the frequent journeys to medical centres. These are costly, time-consuming and exhausting. The emotional burden on the patients and their families is huge.

[21] Haemophilia (2008), 14, 361–374: European Association for Haemophilia and Associated Disorders (EHAD) – Special Article for the Inter Disciplinary Working Group

It is therefore essential that provision for comprehensive health and support services should include access to free healthcare. This should include counselling services for victims and their families, and for relatives of the deceased.

Mr Brian O'Mahony of the Irish Haemophilia Society commented to us:

"I do not believe it is fair that any person with haemophilia who has HIV or Hepatitis C through blood or blood product provided by the state, should have to worry about paying for their healthcare for any part of that condition or any condition that they develop".

The issue of safety in the treatment of these conditions is, understandably, a major concern. Patients need to be represented and to have a voice on any committee selecting suppliers, ensuring that cost is not the sole factor in this decision-making. In Ireland, this is managed highly successfully by a Tender Commission.

This model adopted by the Commission has been shown to be a way of ensuring representation, and has been an efficient process in terms of outcomes. The Irish experience has been that the Department of Health officials were pleasantly surprised at the efficacy of patient representation on the Commission. Rather than the process becoming protracted, it became extremely competitive, with potential suppliers tendering for contracts. Ultimately, this led to the Commission achieving highly cost-effective solutions. Patient representation is therefore seen as both desirable in terms of democratic representation and inclusiveness and essential in order for optimum outcomes to be achieved.

This favourable experience has also occurred in Canada, Australia, Japan, Brazil, Uruguay, Georgia, and Thailand, all of whom have a Haemophilia Society involved in the tender process.

The sourcing and supply of treatment is a key concern for haemophilia patients and in many ways the provision has improved. The availability of recombinant[22] treatment for all is a significant move forward. Again, the involvement of patients in the evaluation of available treatments and the risks associated with their use is essential. Patients must be able to make informed choices about their treatment. Above all, people with haemophilia need access to the safest treatment available, including replacement therapies, at all times.

In order to ensure this, there has to be an efficient, and transparent infrastructure to support the care of haemophilia patients. This, in part, touches on requirements across the NHS, such as the need for the highest possible standards in the creation and maintenance of patient records. In addition, rigorous protocols must be in place throughout the BTS to ensure for example, that when new tests become available for the presence of a virus in blood or blood products, positive results are communicated to all interested parties, including donors.

Those responsible for the provision of care need appropriate opportunities to share information. This, in turn, requires that the relationship between the clinician and the patient is informative and open and that both parties have access to the data and information they require. Fortunately, things have changed since the 1980s and it

[22] Recombinant Factor products are genetically engineered and have the advantage of being free, or almost free, of human plasma derivatives, thereby avoiding contamination with viruses.

would now be expected that a doctor would discuss matters such as test results with a patient. A great deal of work has been done on improving standards of care and professional accreditation throughout the NHS. Members of the medical profession are now trained, monitored and evaluated in a methodical and formal manner, while the Royal Colleges and other bodies provide excellent guidance on good practice.

In addition to the medical challenges they face, the Inquiry has heard that people who have haemophilia, and have been infected with viruses, find it extremely difficult, if not impossible, to take out life insurance, health insurance or to secure a mortgage. Even if funding were not an issue, current providers do not offer suitable products to which haemophilia patients would have access, or which would meet their needs. Many would simply not insure these patients nor provide them with a mortgage. To address this, Government-run schemes could be set up for those affected to ensure that they do not continue to be excluded from access to basic levels of insurance and mortgage provision. These individuals are in a unique position, and one that has been imposed upon them. There is therefore a need to develop and fund unique services and schemes to enable them to lead reasonably normal lives, which is, ultimately, what most of them seek.

Of the various bodies in the UK working to support the haemophilia community, the Haemophilia Society has the longest history. A national charity founded in 1950, it provides essential support and services to the community. It has, through its members, a vast bank of knowledge and expertise. The Inquiry has heard many witnesses express concern regarding the future of the Society. This membership organisation is a vital communication vehicle, a thriving network and a powerful voice

for those with haemophilia. It is best placed to present the needs and views of its membership and to play a part in a National Haemophilia Committee and Tender Commission. The Haemophilia Society is needed by its members, and it would be a tragedy for them if its future were threatened. On the contrary, its future needs to be secure and well funded.

Many members of the Haemophilia Society, and witnesses to the Inquiry, have raised the issue of the need for a formal apology to be made for the infected blood products catastrophe. There has inevitably been discussion of this need. Of course, there will be those who might be concerned that apologies can be meaningless, or that an apology bears with it the notion of liability. However, many of the witnesses who gave evidence have spoken about the need for some sort of apology to be made at the highest level, by which we understand them to mean by Government.

Mr GRO-A, a victim of the tragedy, hopes that:

"Lessons will be learned and justice will be done and the truth about our lives and the lives of those no longer with us can be told. I hope this will bring some sense of closure for all those bereaved and all those still surviving with these viruses and I hope for an apology at the very least".

Without necessarily apportioning blame, the state needs to act responsibly in addressing the tragedy of patients being infected with potentially fatal diseases through NHS prescribed treatment.

It must be remembered that many of the thousands of people with haemophilia who

have been infected with the HIV and Hepatitis C, through the administration of state-provided blood and blood products, have died. Many others are living in poor health, without the assurance of optimum healthcare in the future and with the constant worry of not being able to provide for themselves and their families. They feel that their plight has not been adequately addressed and that they have no forum for consultation. In this context the future of the Haemophilia Society, which, for many members, is their only form of representation, must be secured.

For many, closure can never be achieved. However, there is an overwhelming need for progress to be made and a conclusion to be reached. The recommendations and suggestions in this Report are an attempt, after many years, to address the circumstances and needs of those who have been so tragically harmed.

CHAPTER 11 – CONCLUSIONS

In this Chapter we attempt to draw conclusions from the mass of evidence presented to us. In this endeavour we have been hindered by the long time that has elapsed from the tragic events with which we are concerned. Many whose experience would have been important were not available to the Inquiry. Had a full investigation taken place nearer the time of these events this difficulty would have been avoided. Nevertheless we looked for lessons to be learned in the hope of reducing the likelihood of a similar catastrophe happening again. The problems surrounding vCJD are a reminder that new infections may yet arise with serious results. In pursuance of our objective the Inquiry did not consider it appropriate to apportion blame, especially given the problems attendant on hindsight.

There is no doubt that the infection of so many patients, often with fatal results, is a horrific human tragedy. It was memorably described by Lord Winston as the worst treatment disaster in the history of the NHS, a view with which we agree. Subsequent events have done little to alleviate the hurt of the victims or their families. The haemophilia community feels that their plight has never been fully acknowledged or addressed. In Chapters 11 and 12 we suggest ways in which this sense of injustice might be eased.

We are dismayed at the time taken by Governmental and scientific agencies to become fully alive to the dangers of Hepatitis C and HIV infections, and also by the lethargic progress towards self-sufficiency in blood products in England and Wales. From the promise of self-sufficiency to its attainment took five years in Ireland, but

thirteen years in England and Wales. A prominent factor in this delay was the situation at BPL in Elstree. Not designed for production on the scale that was becoming necessary it also suffered from fragmented management and under-funding. Whether the lack of urgency over much of this period arose from over-hesitant scientific advice or from a sluggish response by Government is now difficult to assess. The availability of extra production resources in Scotland was not pursued and alternative strategies do not seem to have been explored.

The anger and sense of betrayal still present among the haemophilia community was a frequent theme stated by witnesses to the Inquiry. A common cause for resentment was the inadequacy of information presented to patients by their doctors. This is understandable given the medical mores of that time (see Chapter 7); nevertheless it highlights the deficiencies of a paternalistic approach when doctors have to operate from an inadequate information base.

We are satisfied that some patients were subjected to tests without knowledge of their purpose and without their consent, a practice described by some witnesses as being treated as experimental guinea pigs. Such a practice is now condemned by the GMC, except in clearly defined circumstances. But, whether it was done as part of a diagnostic process for a particular patient, or to extend medical knowledge for the benefit of all, we found no indication that the motivation was other than well intentioned. The prescription of products carrying potential risk for patients with mild haemophilia, when safe therapy with DDVAP was available, was ill-advised and sometimes led to serious consequences which were avoidable. We do, however, realise that the potential seriousness of Hepatitis C was not then known, while

understanding of AIDS was rudimentary. This may help to explain the regrettable fact that by not informing patients of their infection with Hepatitis C or HIV their partners were thereby placed at risk. The importance of patient involvement in making difficult clinical decisions is emphasised by these events and is today fully recognised by the medical profession.

The Inquiry considers that a significant burden of responsibility rests on American suppliers of Factor VIII concentrate at the time of this tragedy. Long after alarms had been sounded about the risks of obtaining paid-for blood donations from communities with an increased incidence of relevant infections, such as prison inmates, this practice continued. It is difficult to avoid the conclusion that commercial interests took precedence over public health concerns. We are informed that US regulations in such matters are now much more demanding and we trust that lessons have been learned.

We must now look to the future. We cannot undo the damage done, nor turn back the clock to take a closer view of those past events and decisions. We must address the ongoing needs of those affected and consider how the state can ensure these citizens are recompensed.

A summary of the Inquiry's conclusion follows:

1. A full Public Inquiry into this issue should have been held much earlier to address the concerns of the haemophilia community.

2. The procrastination in achieving national self-sufficiency to avoid the use of high-risk blood products from overseas had disastrous consequences. Had self-sufficiency been achieved earlier the scale of the catastrophe would have been significantly reduced. If in the future concern arises about the safety of blood products this lesson must be remembered.

3. The doctor-patient relationship during the evolution of this tragedy sometimes had unfortunate consequences. The medical profession appears to have made good progress in this area. The importance of patient involvement when making difficult clinical decisions is now appreciated and should not be forgotten.

4. Commercial priorities should never again override the interests of public health.

CHAPTER 12 - RECOMMENDATIONS

We believe that the following recommendations would help to meet the unmet needs of patients with haemophilia and their families:-

1.

(a) A Committee should be established by Statute to advise Government on the management of haemophilia in the United Kingdom. It should have overarching responsibility for:

i) the selection, procurement and delivery of the best therapies currently available and recommended by NICE;

ii) readily available access to any necessary treatment relating to the condition itself or any condition arising from consequent therapy;

iii) all provisions necessary to address the financial and other needs of haemophilia patients.

(b) We set out on page 96 our recommendations relating to the composition of the Committee. We emphasise the importance of patient representation, through nomination by the Haemophilia Society and other bodies working to support the haemophilia community.

(c) There should be a statutory requirement to consult the Committee prior to the introduction of legislation or substantial changes in policy.

(d) Where the Committee deems it necessary, regional sub-committees should be established to exercise prescribed functions falling to the principal committee.

2. Patients with Haemophilia who have received blood or blood products, and their partners, should be tested for any condition identified by the Committee described in 1 above.

3. Every blood donor should be similarly tested following the donation. We understand that at present donations are tested for Syphilis, Hepatitis B, HIV, Hepatitis C, and HTLV. This list must be kept under review.

4. Those who have been infected should be issued with cards entitling the holder to benefits not freely available under the NHS, including free of charge prescription drugs, general practitioner visits, counselling, physiotherapy, home nursing and support services. The card should facilitate access to an NHS hospital bed and specialist servcies.

5. We consider it vital that the Government should secure the future of the UK Haemophilia Society by adequate funding. This should be seen as a matter of urgency.

6. Direct financial relief should be provided for those infected, and for carers who have been prevented from working. We propose that the scheme should have the following characteristics:

a) It should be paid through the Department of Work and Pensions in the same way as existing statutory benefits, so that beneficiaries should receive their entitlements from the Government and not through intermediate sources such as the Macfarlane or Eileen Trusts, or the Skipton Fund. The Government would thus have direct responsibility to the individual beneficiary for providing the necessary resources.

b) Entitlements should be payable if infection is established within the appropriate time-frame. An appeal mechanism should be provided against rejection of a claim and the assessment of the amount due.

c) Entitlement should not be means-tested, but should take the form of an initial capital sum, followed by prescribed periodical payments.

d) There should be no distinctions dependent upon the reason for the treatment with blood or blood products.

e) The anomalies which at present apply according to the age when the recipient was first infected, or when the infection took place or, in the case of dependents, the date of death of the original patient should be rectified. In particular, the Government should review the conditions under which the widow of a patient infected by blood products now becomes eligible for benefit from the Eileen Trust and from the Skipton Fund[23].

f) Payments under the scheme should be disregarded for the purposes of calculating other benefits.

g) There should be a table of amounts payable in the case of double or multiple infections.

[23] See pages 81 and 82

h) We suggest that payments should be at least the equivilant of those payable under the Scheme which applies at any time in Ireland.

7. There is a need for some provision to ensure to patients access to insurance. This could be done either by providing the premiums, or by establishing a separate scheme for the patients in question.

8. In addition, a look back exercise should be undertaken to identify, as far as possible, individuals who may have been unknowingly infected by contaminated blood products and who might still not be aware of this.

APPENDIX - LIST OF WITNESSES

Mr David Amess MP
Professor Christopher Bartlett
Mr GRO-A
Mr Gideon Bullock
Mrs Harriett Bullock
Mr Alan Burgess
Miss Laura Burgess
Mr Oliver Carruthers
Dr Brian Colvin
Mr Philip Dolan
Mr Kelly Duda
Mr Andrew Evans
Mr David Fielding
Mr Nicholas Fish
Mr Christopher Fitzgerald
Dr Peter R Foster
Professor Ian M Franklin
Mr Charles Gore
Ms Carol Grayson
Mrs Mary Grindley
Mr Martin Harvey
Mr Gerald Hilary
Mrs Joan Hilary

Mr Chris Hodgson
Dr Brian Iddon MP
Mr Christopher James
Mrs Doreen Jeffrey
The Rt Hon Lord Jenkin of Roding
Mr Gary Kelly (now deceased)
Mr Gareth Lewis
Mr Haydn Lewis
Mr Robert Mackie
Mrs Alice Mackie
MacoPharma – Ms Larby
MacoPharma - Ms Walicka
Mr Frank Maguire
Mr Andrew March
Mr Stephen Martin-Hanley
Dr Jack Melling
Mr Roddy Morrison
Mr Peter Mossman
Mr Gregory Murphy
Mrs Maureen Murphy
Mr Bruce Norval
Mr Brian O'Mahony
The Rt Hon Lord Owen
Mrs GRO-A

Mr Graham Ross
Mrs Della Ryness-Hirsch
Professor Geoffrey F Savidge
Mrs Janet Smith
Mr GRO-A
Professor Sir Joseph Smith
Mr GRO-A
Mr Peter Stevens
The Rt Rev Prebendary Alan Tanner
Professor Richard Tedder
Professor Howard Thomas
Mrs Sue Threakall
Ms Claire Walton
Ms Jenny Willott MP
Dr Mark Winter
Mr Stephen Wintle
Mrs Colette Wintle