CHAPTER 4

THE GLOBALISATION OF BLOOD, FAILURE TO ACHIEVE SELF-SUFFICIENCY AND THE IMPACT ON THE UK HAEMOPHILIA COMMUNITY: A CRITIQUE OF A GOVERNMENT REPORT

> The most practical method of reducing the hazard of serum hepatitis from blood is to stop using blood from prison and Skid Row donors.
>
> (J. Garrott Allen, M.D. *Annals Of Surgery*, 1966)

Introduction- Background To The Self- Sufficiency Report 2006

In 2006 the Department Of Health (DOH) released a report entitled *Self- Sufficiency In Blood Products In England And Wales: A Chronology From 1973 to 1991* (*SSR*) (see Appendix A1 for full report). The definition of self-sufficiency in this case is the ability to produce and supply enough blood and blood products to cover the needs of UK patients as referred to in the *SSR*. The DOH report was published in direct response to a haemophilia "Bad Blood" campaign run jointly by the Newcastle *Journal* and Haemophilia Action UK.[1] The report was much anticipated by the UK haemophilia community in the hope that it would provide some answers to the many questions on how haemophiliacs came to be infected with HIV and hepatitis C (HCV) previously referred to as non-A, non-B hepatitis (NANB) through their NHS treatment.[2] In 2001 former Health Minister Lord David Owen gave an interview in the Newcastle *Journal* recalling his parliamentary commitment to self-sufficiency in blood products back in 1975 on the

grounds of "medical safety" and expressed his anger by questioning past Government policy in the following statement:

> I was absolutely staggered to discover years later that what I had promised had never been done. It was argued they (the government) had run out of cash but why? My commitment was to become self-sufficient and to find the funds whatever the cost. This was a parliamentary commitment I had made, not just an internal administrative matter. Once a decision has been taken it is perfectly legitimate for a new minister to change it, but only if they tell parliament and that never happened. (Houldcroft, August 2nd, 2001)

It was Owen's interview with the *Journal* that finally sparked a reaction from Government that same year and the newspaper reported, "the Department Of Health has now agreed to re-examine all valuable documentation after copies of the Journal's Bad Blood Campaign was sent directly to Tony Blair by the President of the Haemophilia Society, Lord Morris," (IC Newcastle Website, Dec 5th 2001). The haemophilia community had fought for years for a full and open public inquiry while Government repeatedly rejected haemophiliacs' demands insisting that there was no evidence of wrongdoing and offered instead an "internal, informal review." The *SSR* took several years to compile, was subject to repeated delays during which time more haemophiliacs died from their treatment, and the report was undertaken without consultation with any of the interested parties.

The basic conclusions of the report were that although the UK Government had failed to achieve self-sufficiency in blood products no individual or Government department was found to be at fault for this failure, or for exposing haemophiliacs to a greatly increased risk of viral infection from imported plasma products sourced from "high-risk"

donors.[3] One of the aims of this study is to provide a critique of the *SSR,* to contest Government findings, examine the manipulation of facts and the withholding of key safety information from NHS patients. The Haemophilia Society, the national organisation set up to represent the haemophilia community released a press statement voicing their own dissatisfaction with the report, Chief Executive, Margaret Unwin, stated that,

> The Society has pointed out that there are glaring holes in the document- there is no mention of what information was given to patients about the safety of products so that they could give informed consent to treatment at the time. The report also mentions testing new products on previously untreated patients to determine whether they were still transmitting blood borne viruses and again does not make clear whether they were told of the risks or any given alternatives. (Unwin, Haemophilia Society Website, 28th Feb, 2006)

It is not argued here that the infection of haemophiliacs with HIV/HCV was entirely preventable but there is compelling evidence to suggest strongly that infection rates could have been significantly reduced had appropriate safety measures been adopted. It is important to point out here why I have chosen to critique only one report and why this particular report is so significant. The *SSR* is the only major report to look at the issue of self-sufficiency from the 1970s onwards. For the first time the Government has produced a review that brings together a collection of internal blood policy documents not previously seen by the general public after application was made under the Freedom Of Information Act (FOI). Self- sufficiency wasn't an issue that the Government wanted to be scrutinised in the public arena as this would have highlighted inefficiency and maladministration as detailed by former Health Minister David Owen in his complaint to

the Parliamentary Ombudsman (see Appendix A2). It has always been difficult in the past for academics to critique Government blood policies thoroughly without the necessary documents from the UK and abroad being made available to the public, even so many are still missing. My critique looks at past Government policies by studying documents within the *SSR* alongside my own collection of papers gathered over many years.

This chapter attempts to illustrate how organisations handled the contamination crisis once the haemophilia population became infected and raises ethical questions with regard to haemophilia treatment. My study examines the medical establishment from a Foucauldian perspective as identified in Peterson and Bunton (1997, p. 99) who state that "power as it operates in the medical encounter is a power that provides guidelines about how patients should understand, regulate and experience their bodies." By examining medical documents in my analysis of the report I aim to look at the extent to which this power is exercised by the medical profession and the State in gaining control over a patient's body in relation to their haemophilia treatment. This study also draws on the theory of Richard Titmuss (1970) who analysed the impact of the blood donor as a commodity in relation to economic versus social good.

My critique of this report is not only a review of the written content of the *SSR* but is also a textual analysis of some of the material that is excluded. I examine the politics of deceit by deconstructing the Government version of the "truth", namely the presentation of erroneous information as accurate fact and by challenging the view that this narrative must be accepted simply because the report emanates from an official body. Although I interpret evidence up to 1991 I have chosen to focus mainly on documents before 1985. This was the period prior to the introduction of heat-treatment (which eliminated HIV

and hepatitis viruses from factor concentrates) a time when haemophiliacs were most at risk of becoming infected.[4] It is important to note that hepatitis C was still being transmitted to the general population through whole blood transfusions until the introduction of an HCV test in 1991 (see section - *Testing Of Blood For HIV And Hepatitis C*). However any haemophiliac receiving whole blood at this time would very likely have already been infected with HCV through treatment with factor concentrates.

It is argued that the *SSR* which is described by the author as "at times contradictory and incomplete" (p. 28) is written in a way that makes it difficult for some haemophiliacs and non- health care professionals to understand. This is an example of the power of language used by professionals to control lay persons as identified in the work of Foucault (1980) who described the "politico-medical hold on a population" where the physician places himself as the "expert" in an almost unquestionable position of authority. The *SSR* which was supposed to address questions from the haemophilia community makes extensive use of politico-medical terminology to disempower and confuse the reader. It is not difficult however for educated and informed campaigners to dissect the content and see through the Government's diversion tactics of focusing on pages of facts and figures of treatment output (*SSR*, p. 13-27) which could have easily been summed up in one word a *failure* in terms of self-sufficiency whilst Government downplayed the key issue of safety. The sourcing of evidence is poor in that whoever compiled the material for the report (the Government has never identified the author) failed to work with other key organisations during the collection of evidence stage despite the fact that campaigners offered to share their own documents to ensure that the *SSR* was as accurate as possible. It is argued that this was a deliberate ploy to censor

sensitive material. If the Government had taken key evidence from campaigners they would have been forced to acknowledge incriminating material. The author of the *SSR* chooses a careful selection of extracts from the documents that are presented in the report to avoid showing successive governments in a negative light and the wider health issues are often hidden. The *Chronology Of Events* (*SSR*, p. 42-44) is also incomplete due to the exclusion of key documents which were "inadvertently" destroyed (Connon, 2006).

Haemophiliacs have expressed a feeling of anger and betrayal at the way in which the Government and other institutions such as the medical profession have dealt with the contamination of their community. The Haemophilia Society and haemophilia led campaign organisations question the accuracy of the report and are challenging the findings that are based on incomplete records.[5] In order to do so they have requested full access to the evidence used in the *SSR* under FOI and to all documents originally held by solicitors acting for infected haemophiliacs. (Government documents were sent to legal firms in the late 1980s as part of an information exchange during the UK haemophilia HIV litigation against the DOH).

In 1991 Justice Ognal the presiding judge in the HIV litigation had advised that the Government must submit all their blood policy documents to be viewed in court. On hearing this opinion and after years of legal wrangle the Government decided to settle claims out of court providing haemophiliacs with an "ex-gratia" payment and avoided any embarrassment of having potentially damaging documents revealed to the general public. Much of this evidence which was excluded from the *SSR* and went unseen by haemophiliacs for many years was recalled by the Government in recent months and they have now decided which papers to release to the public and which documents they wish

to withhold on commercial grounds under the FOI Act. This goes against the Government statement that all the evidence pertaining to the infection of haemophiliacs is already in the public domain. As Margaret Unwin of the Haemophilia Society is keen to point out,

> The Government has already admitted that it has shredded many of the documents that refer to the time period in question, but that still doesn't explain the strange assortment of references they have made in the report- ranging from clinical journals to the Sun Newspaper. (She goes on to say) This document is greatly flawed and has, I believe been produced to deflect the call for a wide-ranging public inquiry into the whole issue. The report has been produced internally, informally and very poorly by the Department of Health. It is not public, not an inquiry and merely reflects the views of the Department itself. (Haemophilia Society Website, 26th Feb, 2006)

The Globalization Of Blood: Haemophilia And The Introduction Of Factor Concentrate Treatment

Britain's initial introduction to the globalization of blood was a very positive experience. Starr (1999) documents the success of the *Plasma For Britain* programme set up in 1940 in cooperation with the Blood Betterment Association and the American Red Cross. Charles Drew (the first African America to be awarded a Doctor of Science degree) supplied Britain with shipments of plasma from the US and prided himself on the highest standards of safety virtually eliminating viral contamination in blood supplies (Red Gold Website, date not stated).[6] Over the next three decades Britain strived to develop its own blood collection service with a view to becoming self-sufficient in blood products and utilized a volunteer unpaid donor system. Haemophiliacs however experienced discrimination with regard to their treatment and were subjected to a much lower standard of safety than other NHS patients that required blood. In 1973 the UK government began licensing factor concentrate products from large American

corporations. The importation of plasma/plasma products continues to this day as it is no longer possible to use white cell plasma from UK citizens because of the risk of new variant Creutzfeldt- Jacob Disease (v CJD).

Prior to the introduction of testing for HIV and hepatitis viruses the medical profession and Government bodies acknowledged that the single most effective measure to minimise the risk of blood borne diseases was the careful screening of plasma donors and the need to use volunteer donors as opposed to commercial donors on the grounds of safety (Titmuss, 1970).[7] The emphasis however during the 1970s and early 1980s was profit over safety and blood became an extremely lucrative commodity. Titmus, an expert on the welfare state placed the selling of blood in the wider context of the global economy and went so far as to predict future ethical dilemmas (which are now present reality) when he stated:

> Short of examining humankind itself and the institution of slavery- of men and women as market commodities- blood as a living tissue may now constitute in Western societies one of the ultimate tests of where the "social" begins and the "economic" ends. If blood is considered in theory, in law, and is treated in practice as a trading commodity, then ultimately human hearts, kidneys, eyes and other organs of the body may also come to be treated as commodities to be bought and sold in the marketplace. (Titmuss, 1970, in revised edition, Oakley and Ashton 1997 p.219)

From the early 1970s haemophiliacs in many UK hospitals were repeatedly treated with US blood products manufactured from the plasma of "high-risk" commercial donors which included prison and "skid-row" donors. Craske (1975) reported a rise from 3 to 50% in cases of hepatitis in his UK patients after the introduction of American plasma products in haemophilia treatment. U.S. companies also had a history of importing raw

plasma from Central and South America and shipping it to Europe where it was made into factor concentrates to be used by UK haemophiliacs (Gould, 1975). [8] This exploitation also highlights the north-south divide where those in the poorer countries of the southern hemisphere were viewed in terms of the market value of their blood and used to supply the markets of the north with little regard for the health of the donor.

Prior to the invention of factor concentrates UK haemophiliacs were treated with cryoprecipitate. This was manufactured from single donor units (*SSR*, p. 5) and was therefore considered safer than factor concentrates pooled from thousands of donors which increased the hepatitis risk.[9] The Government have on many occasions tried to use the argument that had haemophiliacs not been treated with factor concentrates they might have died from bleeding (*SSR*, p. 12). This might well have been the case with the earlier treatment using whole blood and fresh frozen plasma ***prior*** to 1960 and ***before*** the use of cryoprecipitate (see SSR, p. 5) however it is important to note that many haemophiliacs did not receive their first factor concentrates until adulthood and had survived for many years using cryoprecipitate. It could be argued that as Government (DOH) had both failed to estimate the correct level of treatment needed and failed to achieve adequate production levels of cryoprecipitate and factor concentrates within the UK then the Government could have been putting haemophiliacs at risk of death. I contend that the Government realised the implications of its failure to achieve self-sufficiency and sanctioned the use of "high- risk" products from the U.S. to supplement UK produced plasma products.

Factor concentrates which were produced from large pools of donor plasma i.e. 10,000 donors" in the UK (*SSR*, p. 5) and up to 60,000 in the US were however acknowledged to

be a more convenient treatment for haemophiliacs (Treatment Of Hemophilia Website, date not stated). Patients could be taught to inject themselves with "home treatment" using small amounts of these freeze dried products mixed with sterile water to prevent bleeds wherever possible whereas taking cryoprecipitate meant a visit to hospital often after bleeding had started and undergoing extended treatment. Many haemophiliacs have stated that had they known the risks from imported factor concentrates they would have chosen to remain on cryoprecipitate until such time as a process could be introduced to eliminate hepatitis and later HIV in plasma concentrates which was eventually the case in the mid 1980s. Haemophiliacs also had a right to abstain from using treatment if they felt the risks were too great.[10] The vast majority of haemophiliacs however were never given the information they needed in order to make an "informed" choice which is integral to a partnership of trust and respect between doctor and patient as is pointed out by Faulder (1985, p. 27). Faulder supports Foucault's work on power inequality in the clinical setting by arguing that "if the doctor does not confide in the patient as the patient confides in the doctor, then the relationship is unequal and unjust."

The Politics Of The Paid Donor And The Infection Of Haemophiliacs With Hepatitis Viruses

Since the 1970s there had been a long running debate amongst health professionals about the need for the UK to become self-sufficient in the collection of blood and manufacture of plasma products for haemophiliacs on the grounds of safety. Titmuss (1970) had documented his concerns exploring the fact that where donors were paid for their blood

this attracted individuals who were less worried about their own health and suitability to donate and more focused on the financial reward offered to them. He noted that:

> In the United States in 1970, blood group identification cards are loaned at a price to other sellers; blood is illegally mislabelled and updated; and other devices are adopted which make it very difficult to screen and exclude as donors drug addicts, alcoholics, and carriers of hepatitis, malaria and other diseases. (Titmuss, 1970, p.129)

The UK on the other hand had a system of volunteer unpaid blood donors that donated blood not for remuneration but for altruistic reasons. Further concerns about paid donors were raised by Martel Dailey MD (1972) in a letter to an American medical journal. He began by quoting personal communication from respected surgeon Dr J Garrott Allen,

> To the editor- The probability of a recipient developing serum hepatitis (SH) is 10 to 50 times greater when the blood donor is a commercial donor. (*JAMA*, 24th July, 1972, Vol 221. No 4)

Owen supported the evidence provided by Titmuss and Garrott Allen when he spoke at length about his commitment for the UK to become self- sufficient in blood products by mid-1977 acknowledging in his own words "the terrible risks associated with importing blood" (Houldcroft, *Journal,* Aug 2nd 2001). He recalls having to fight hard on this issue in parliament but stated that, "no-one argued against me on the grounds of medical safety- it was purely a case of money." It is argued here that the Government's reliance on imported plasma products was in fact false economy, the *SSR* actually states that the primary goal of self-sufficiency was to "reduce reliance on expensive imported

treatment" (*SSR*, 2006, p.1) this statement also emphasises the fact that the Government placed economy over safety. Klein (1994) provides a wider picture of patient treatment issues during the 1970s documenting the "politics of disillusionment" within the NHS at a time of economic crisis, financial cutbacks and growing militancy towards Government from the medical profession. This supports the concerns repeatedly raised by campaigners that the Government failed to commit adequate financial resources for UK plasma production. Haematologist, Dr Peter Jones, interviewed for a documentary programme "The Blood Business" *World In Action* (1980) voiced his own anxiety with regard to underinvestment in haemophilia care and also claimed that the level of product demand for factor concentrates was known by Government years earlier however the UK output remained insufficient to supply the needs of patients.

I contend that the title of the *SSR* is itself misleading and incorporates a level of government "spin" in that the author of the report uses the positive phrase "self-sufficiency in blood products" so readers might at first sight assume that this had actually happened. It is argued that the report should have used the phase "failure to achieve" or "lack of" self-sufficiency to accurately reflect the negative content of the report in the title. The Haemophilia Society state that,

> Reading the report- which does not have a named author- it appears to be a fairly blatant attempt to gloss over the details of the events of the time and even to lay blame at the door of the patients themselves. (Unwin, Haemophilia Society Website, 28th Feb, 2006)

It is argued here that this is a common tactic used by government and the medical profession to absolve itself of responsibility for flawed decision making and avoid potential litigious action by shifting responsibility onto individuals.[11] Government officials in an attempt to divert from their own failure to estimate and produce the correct level of treatment needed for the haemophilia community have portrayed haemophiliacs as "demanding" attempting to place the blame for shortages onto patients themselves. (I will explore further the issues around inadequate treatment production at a later stage in this chapter). It is important to note however that the risk of viral infection from blood products before 1985 was so high that during HIV legal proceedings both lawyers for haemophiliacs and lawyers defending the DOH accepted that on the balance of probability haemophiliacs would most likely have become infected through their NHS haemophilia treatment.

This study contests the argument sometimes put forward by Government that there were not enough volunteer blood donors in the UK to achieve self-sufficiency. I support my viewpoint by drawing on the work of Titmuss (1970) who studied a variety of reports on supply and demand from 1948 and noted "what is particularly striking is the orderly, progressive and sustained rate of growth in the number of blood donors, blood donations and supplies to hospitals." He also suggests that had there been shortages of blood, "one obvious answer would have been to have bled donors more frequently than twice a year," (p. 94-95). He noted that the UK had a very strict standard of bleeding donors only twice a year whereas the U.S. bled donors up to 5 times a year and there could have been some flexibility in this area.

In the 1970s Owen was very clear in his view that "medical safety" had to be prioritised over economy. It is important therefore to examine documents written before 1973 the year importation of blood products began in order to establish the dangers known by Government at that time. The *SSR* chronology provides only vague entries from 1970 up to the end of 1973 (*SSR*, p. 42) and fails to mention known high risks related to the newly introduced factor concentrates particularly those imported from the US. Owen's name is barely mentioned within the *SSR* despite the fact that he has written a number of letters of complaint to the Parliamentary Ombudsman accusing the Government of "gross maladministration" (telephone conversation with Owen 2001). He has repeatedly tried to establish the facts around the breaking of his parliamentary commitment and was a key figure with regard to self-sufficiency policy. When Owen tried to access his Government papers from the period he was in office as Health Minister he was informed that they had in fact been pulped. (see Appendix A3 and A4).

The Government with access to both researchers and resources has failed to emulate campaigners and document evidence of risk prior to 1973 easily obtained from medical journals of that era which remain available through any medical library in the UK. Cohen and Dougherty (1968) detailed a study on narcotic addicts and suspected addicts that sold blood at a local proprietary blood bank in America and exposed the donors as the significant source of serum hepatitis. The study concluded that "the risk of it (hepatitis) developing in recipients of blood known to have been donated by convicted or suspected narcotics addicts was 70 times that in the controls" (*JAMA,* Feb 5th, 1968: Vol 203, No 6). This is only one of dozens of medical and health journal studies that linked outbreaks of hepatitis to commercial blood donors prior to 1973. Titmuss (1970) documented a

clash between a local hospital and a US plasma company fighting for the right to bleed prisoners as far back as 1966. This once again highlights commercial venture taking priority over patient safety. In 1971 Kliman et al wrote an article on hepatitis and HAA (Australian Antigen testing) for hepatitis B and echoed the findings of Titmuss stating that,

> The HAA- positive donor does differ from the general population of blood donors, and in this finding is the hope that as we identify high-risk populations, the overall risk of hepatitis from the blood collected will be diminished. The elimination of prison donors is a case in point although it must be admitted that there was abundant evidence that this was a high-risk group before HAA testing. (*New England Journal Of Medicine*, Sept 30, 1971)

A meeting of the Expert Group On The Treatment Of Haemophilia 1973 (see Appendix A5) was held at the UK Government's own offices and identified the increased risk of hepatitis once the number of donors in the plasma pool was increased, and also the importance of screening for hepatitis B in blood and blood products.[12] Factor concentrates were noted to be "expensive" and deemed to be "in limited supply" and that "the limiting factors are the capacity for production (and the cost) of this preparation." The minutes of the meeting emphasised the importance of "reducing and as soon as possible ending purchase from foreign sources." Haemophilia campaigners ask the following questions:

1. How could US factor concentrates from "high-risk" sources be licensed for treatment as safe by licensing authorities in the UK?
2. How could treatment from such "high-risk" sources manufactured from plasma pools of up to 60,000 in the U.S. be licensed by UK authorities *before* processes were developed to eliminate hepatitis viruses?
3. Why were patients and their families not told of the very high viral risks linked to factor concentrates?

It is argued throughout this study that the DOH failed in its duty of care to provide sufficient funding to invest in adequate production facilities to provide the safer UK plasma products for haemophiliacs. As Owen has stated once he left his position as Health Minister no-one in Government carried out his parliamentary commitment. Many haemophiliacs recall that the DOH and its doctors actively encouraged the use of the new innovative treatment (factor concentrates) which was meant to improve the quality of life for haemophiliacs. The promotion of these new products by medical staff alongside the failure of the Elstree blood processing plant to reach the required levels of treatment output in the UK had thus created a market that Government owned facilities could not supply. "At present, UK production is considerably less than the required amount of the freeze dried preparation" (DHSS Meeting, 1973, see Appendix A5). The Government does not address this area of investigation sufficiently and refuses to accept any responsibility for its failings. It could be argued here that UK doctors did attempt to challenge DOH policy on importing blood products as stated by Dr Mark Winter who

recalls that representation was made to Government on this matter both in 1975 and 1978 (Meridian documentary, 2000). However despite safety concerns the medical profession continued to prescribe "high-risk" imported treatments without consulting patients on the risks associated with their treatment.

In 1975 a well respected television documentary programme "Blood Money" *World In Action* (parts 1 and 2) investigated the self-sufficiency issue taking a look back at Elstree which had been established in the mid-1960s and should have covered the treatment needs of the English and Welsh haemophilia community.[13] A copy of the "Blood Money" documentary was presented to Lord Hunt by campaigners at a meeting at the DOH but was not included in the *SSR* although the later *World In Action* documentary "The Blood Business" (1980) was included, (*SSR*, p.7). A reporter from the 1975 documentary made this comment about Elstree:

> the completion was delayed by administrative changes, building hold-ups and disagreements among doctors about whether (factor) concentrates were the best way to treat haemophiliacs. The plant was finally ready in the early 1970s but by then because of the popularity of home treatment, the amount it needed to produce had shot up to 10 times the original estimate. To fill the gap England imported factor concentrates. ("Blood Money" *World In Action*, 1975)

In "Blood Money" an investigative journalist interviewed several haemophiliacs and their families from the north-east of England about their treatment. The television crew travelled to the US after a hepatitis outbreak in UK haemophiliacs and traced the factor concentrates used by these patients back to the plasma collection centres. The *Times* published an article 12 months prior to this program which noted that in the United States

90% of transfusion associated hepatitis was caused by hepatitis NANB (*Times*, Nov 12th 1974). The "Blood Money" team were accompanied in their travels by Dr Arie Zuckermann a leading hepatitis expert who described a Hyland blood collection facility in Los Angeles as "an offense to human dignity" noting that donors were "derelicts" and "alcoholics" that any British physician would have "rejected straightaway " (Starr, 1999, p. 235).[14] Zuckerman (1968) had already expressed his concerns about the greatly increased hepatitis risk from paid donors years earlier (*British Medical Journal*, 20th April 1968 p.174-175). The UK government however chose to support the commercial practices of US domestic blood policy rather than support self-sufficiency in the UK and it could be argued that these policies reflected many of the wider commercial ventures between the two countries which continue to this day.

William Maycock the person in charge of producing Factor VIII concentrates in England and senior advisor to the Department of Health on blood transfusion policy was interviewed in 1975 on the same "Blood Money" documentary programme in which the following exchange of opinions took place:

> **Reporter. (Question)** Was it in your view ever possible that we (the UK) could have produced Factor VIII concentrate much earlier in Britain given the work that was done on some of the processes associated with it?
>
> **William Maycock (Reply)** Well, it's always easy to look 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.
>
> ("Blood Money" *World In Action*, 1975)

The exclusion of the "Blood Money" documentary from the *SSR* after it was accepted by the Lindsay Tribunal in Eire to assist Irish haemophiliacs in their version of a public inquiry has increased the mistrust of haemophiliacs in the UK Government to provide an objective and accurate history of the events leading up to haemophiliacs' contamination with HIV/HCV. This adds to the anger felt by many within the haemophilia community that they were used as "guinea pigs" for studying infectious diseases and officials had little care for their wellbeing. It is argued that the Government blatantly ignored the safety guidelines laid down by the World Health Organisation (1975) not to use paid donors from countries such as the US with a higher incidence of hepatitis in the general population than the "home" country, in this case the countries within the UK. The following letter from a staff member at the Viral Diseases Division, Bureau of Epidemiology to the Director, Centre for Disease Control, (CDC) Atlanta, US shows that the American Government responsible for disease prevention and monitoring at the highest level were aware of the type of donor used within the US prison system (see Appendix A6). The letter was marked "For administrative use, limited distribution, not for publication." The following statement appeared,

Summary

Over a 2 –week period in February- March 1974, 11 clinical and 8 subclinical hepatitis cases were detected among prison inmates at the Kansas State Penitentiary. The majority were HbsAg – (hepatitis B) positive. Investigations revealed that 18 of these 19 cases were in prison plasma donors at the prison plasmapheresis center; however risk of hepatitis could not be definitely associated with the plasmapheresis operation, since intravenous drug abuse- including the sharing of equipment –was commonly practised by plasma donors. (Centre For Disease Control, Document, 24th July 1975)

The UK government appears to have absolved itself of any responsibility in its part in sanctioning treatment manufactured from prison plasma despite repeated warnings from hepatitis experts. In 1975 Dr J Garrott Allen supported Zuckerman's findings (1968) in a letter to Dr William Maycock (see Appendix A7) describing one US product as "extremely hazardous with a 50 to 90 per cent rate of icteric hepatitis developing from it." He writes of his concerns related to an emerging strain of hepatitis which is not hepatitis A or B, which appeared in "high-risk" donors. Garrott Allen stated that,

> Whatever this agent may be, it still seems to be more frequently encountered in the lower socio-economic groups of paid and prison donors.... (and) until we understand this problem better, I would hope Great Britain would give some thought to what the purchase of Factor VIII and IX from the United States tends to do to our attempts to secure a volunteer program. (Garrott Allen letter, 1975)

An adjournment debate in the Commons, (*Blood Transfusion Service,* 1980) illustrates that the UK Government continued to be fully aware of the type of "high-risk" donors used and the increased hepatitis risk from imported products yet there was still no move to withdraw US plasma as Government had also continued to fail to invest enough money to produce adequate treatment supplies in the UK.

Hepatitis C; Risk-Taking, Research, And Reinfection

Craske et al (1975) and (1978) documented outbreaks of hepatitis in the UK haemophilia community following on from the importation of American plasma products.[15] Many

haemophiliacs claim that haematologists failed to tell them about the seriousness of being infected with NANB hepatitis and this is a source of a great deal of anger as detailed in the replies to my questionnaires which examine testing for hepatitis C without a patient's knowledge and consent. Even well into the 1990s some doctors were still claiming hepatitis C was "nothing to worry about" during face to face contact with patients yet for years unbeknown to most haemophiliacs the medical profession had been studying the haemophilia population in relation to this infection.

Walford (1980, see Appendix A8) expressed her concerns a decade earlier and wrote to the UK Blood Products Laboratory that NANB hepatitis "can be rapidly fatal or can lead to progressive liver damage." Although this letter is referred to in the *SSR* (p.15, [98]) in relation to "demand" for factor VIII there is no inclusion of this particular statement as the Government have tried to claim that they were not aware of the dangers associated with NANB until around 1983. A report from the Haemophilia Centre Directors Hepatitis Working Party 1980-1981 (see Appendix A9) recorded once again the higher risks of hepatitis from imported treatment with "a 4-20 times higher incidence of overt non-A, non-B hepatitis (NANB) associated with US commercial concentrate compared with NHS" (p.1). The study noted 283 episodes of hepatitis in haemophiliacs recorded by Haemophilia Centre Directors and stated that several patients had experienced repeated attacks of hepatitis and were being ***re-infected*** with one or more strains. The report also found that "70-80% of cases of NANB hepatitis were associated with the first dose of concentrate a patient received" (p. 2) yet the parents of small children and adult haemophiliacs recall that they were repeatedly told not to worry about the safety of their treatment and if they were told anything at all, hepatitis was compared

in seriousness to being similar to "a dose of the flu." The 1980-81 report was also a study of factor concentrate treatment brand by brand examining American treatment and UK treatment as well as the hepatitis infection rates over a 6 year period. There appears to have been a total disregard for the fact that had patients been made aware of the 90% NANB hepatitis risk associated with transfusion of US products (Wright, *Times,* Nov 12th 1974) they may have wished to reject imported treatment and return to cryoprecipitate made from small numbers of UK volunteer donors. (The risk with UK factor concentrates however was now also starting to rise with an increase in the size of the donor pool). Haemophilia campaigners ask a further question on safety,

4. How could the DOH have sanctioned the use of UK factor concentrates manufactured from large donor pools *before* processes were developed to eliminate hepatitis viruses?

An international symposium held in Glasgow in 1980 covered the subject of haemophilia treatment and hepatitis risk whose findings were published in 1982. Craske speaking on behalf of the Public Health Laboratory stated that "hepatitis B was strongly correlated with the use of factor concentrates made from ***large*** plasma pools and spoke of the increased risk of infection with NANB hepatitis from ***commercial*** plasma products" (HIV Haemophilia Litigation Claim, 1990, p. 30). Craske noted that "of the 138 cases where the transfusion history was known 103 cases of NANB hepatitis had been associated with concentrate but only 7 with cryoprecipitate" (HIV Haemophilia Litigation

Claim, 1990, p.52). Craske concluded here that there was "a ***high-risk*** from the use of factor VIII or IX that the patient will contract non-A, non-B hepatitis."

Gerety (1981) supports concerns over the increased risk of patients acquiring hepatitis through commercial products. He examined non-A, non- B hepatitis in his book of the same name which includes chapters on haemophiliacs and donor sourcing yet there is no reference to this text in the *SSR*. A journal article by Gerety (1982) is included (*SSR*, p.6) yet there is careful selection of material taken from this article to mention only the minimal risk of viral infection from albumin and immunoglobulin while carefully excluding any mention of the known danger of NANB hepatitis from factor concentrates at this time. Gerety (1981) notes that the transmission rate of hepatitis in haemophiliacs was around 1.8% in the UK ***before*** the use of imported treatment prepared from ***large*** pools which utilized ***paid*** donors, after importation the risk jumped to 17.7%. Shortly after this book was published Haemophilia Centre Directors recorded at a meeting in 1982 that surveillance into hepatitis in haemophiliacs was being carried out in the UK. Craske was documented in the minutes as stating the importance of continuing to collect data on "suspect" treatment batch numbers received by patients that developed hepatitis. He also stated that he would be "most interested to receive samples of liver from patients who came to autopsy where there was evidence of chronic liver disease" and his hope that Haemophilia Directors would "continue to report cases of chronic hepatitis to the Working Party on the appropriate form" (UKHCDO Minutes, p, 20, see Appendix A 10).[16] Requests from haemophilia campaigners for the full data collected on hepatitis C surveillance under the FOI Act have been met with anger and avoidance tactics from both the Government and the medical profession.

In 2002 as part of a legal challenge to Government I requested a chronology of the history of NANB hepatitis from a medical expert in order that my husband Peter Longstaff could challenge a "hepatitis waiver" that appeared in the 1991 HIV litigation (see section *Testing For HIV And Hepatitis C: Delays, Devious Deals And Dangerous Practice*). Professor Eric Preston a specialist in liver disease who is well respected for his research into hepatitis in haemophilia patients provided a report for Queens Council (QC). When the *SSR* was published in 2006 I was able to compare Preston's findings to those in the *SSR* and discovered several discrepancies. The Government report fails to recognize the seriousness of NANB hepatitis until 1982/83 yet Preston reported for Queens Council that back in 1978,

> Even at that time, our patients exhibited a wide spectrum of chronic liver disease, including hepatic cirrhosis. We expressed the view that the chronic liver disease was attributable to non-A, non-B hepatitis. We concluded that histological liver disease is common in haemophiliac patients and is probably related to clotting factor concentrate replacement therapy.

These findings were published in the *Lancet* by Preston et al (1978). It was a well established fact at that time that hepatic cirrhosis and liver disease could lead to death so this is rather more serious than the suggested likeness to "a bout of flu" the term used by some doctors to explain hepatitis to haemophiliacs. Haematologists go so far as to record the fact that "there are no further deaths directly or indirectly attributed to liver disease in the past year" (Haemophilia Centre Directors' Hepatitis Working Party Report, 1980-81, p.1). A study by Galbraith et al (1979) supported the findings by Preston and his colleagues on the serious nature of NANB hepatitis. The Government report however fails to document the significance of these findings in the *SSR* and in the *Chronology*

there is no entry whatsoever for the year 1978, the year the Preston study was published. In the *SSR Conclusions* section the report states,

> The prevailing medical opinion in the 1970s and early 1980s was that NANB (hepatitis) was mild and often asymptomatic. Therefore, as always, patients with haemophilia, their parents, and doctors, were required to balance the improvements in quality of life and the dangers of bleeding against the risks of treatment. (*SSR*, p. 28)

Patients have questioned why even up to the late 1990s some were still being told that hepatitis C was "not a problem." Patients that did raise concerns were often labelled totally inappropriately as the "worried well" by "panicking professionals" eager to playdown their infection by implying that patients' concerns were unfounded. Many of the "worried well" are now dead.[17]

What is very disturbing for haemophiliacs is the fact that they appear to have been used in trials to test out infectivity of treatment however as Harriet K Beecher points out "A study is ethical or not at its inception; it does not become ethical because it turned up valuable data" Henry K. Beecher (quoted in Faulder, 1985, p. 75). The following information on haemophiliac studies appears in a letter from haematologists Rizza and Bloom (1982),

> It is therefore very important to find out by studies in human beings to what extent the infectivity of the various concentrates has been reduced. The most clear cut way of doing this is by administering those concentrates to patients requiring treatment who have not been previously exposed to large plasma pools. Those patients are few in number but a study along those lines is being carried out at Oxford to determine the infectivity of factor VIII concentrates produced by the Plasma Fractionation Laboratory, Oxford and Blood Products Laboratory, Elstree. This study shows that it is possible to demonstrate infectivity using quite small numbers of previously untreated patients. (Rizza And Bloom Letter 1982, see Appendix A11)

As haemophilia is an hereditary condition and most haemophiliacs are diagnosed in the first years of life, previously untreated patients would generally be very small children or mild haemophiliacs as opposed to those considered to have moderate or severe haemophilia. In Foucauldian terms this experiment can be viewed as an abuse of clinical power where doctors have access to key information which is not passed on to patients resulting in an abuse of human rights.

In 1985 Preston and his colleagues followed up their earlier research carrying out liver biopsies in patients and produced a further report which concluded,

> We were able to demonstrate that progressive liver disease is a potentially serious problem in haemophilia, nine of our biopsied patients had hepatic cirrhosis. In our report, we predicted that deaths attributable to liver disease in haemophilia will become more common in haemophiliacs. (Preston Legal Opinion, 2002).

AIDS- A Conspiracy Of Silence: The Contamination Of A Community

It is argued that had the appropriate precautions been taken with regard to the UK achieving self-sufficiency and the appropriate screening of donors in the US in relation to hepatitis viruses alongside the exclusion of paid donors and large plasma pools many haemophiliacs worldwide would not have become infected with HIV. AIDS hit the population of America ***before*** it reached the UK and many other countries (African countries excluded). Therefore many of the arguments presented and documents discussed in the previous sections on hepatitis C can equally be applied to the infection of haemophiliacs with HIV. In 1981 a DHSS letter from Harris (see Appendix A12) to

Prescott in the Treasury office detailed the progress or it could be argued lack of progress in terms of self-sufficiency in the redevelopment of Blood Products Laboratory (BPL) owned by the Government. The following statement appears,

> Although BPL's production has increased steadily over the years and it is currently worth about £11m a year to the NHS, health authorities are obliged to supplement supplies from BPL with expensive, and because of the hepatitis risk, **less safe imported commercial blood products** at a cost of up to £10m annually. (Harris, 1981)

The letter noted that BPL fell "considerably short of the standards of good pharmaceutical manufacturing practice applied by the Medicines Inspectorate under the Medicines Act 1968." Harris states that the Laboratory was inspected by the Medicine's Inspectorate (1979) and he writes,

> The gist of the Inspectorate's report was that conditions of manufacture at BPL were **unsafe and potentially hazardous to patients**. The report concluded, 'If BPL were a commercial operation we would have no hesitation in recommending that manufacture should cease until the facility is upgraded to a minimum acceptable level.'(Harris, 1981)

The Inspectorate recommended complete rebuilding of the plant and the letter stated that self-sufficiency although desirable was a long-term goal.[18] This was a far cry from Owen's parliamentary commitment for the UK to be self-sufficient by 1977. The *SSR* makes no mention of this letter in the chronology although does refer and quote from an adverse Medicines Inspectorate Report in 1979. The *SSR* claims that "the report did not say that the products were unsafe" (*SSR*, p. 24) however the SSR fails to mention the unsafe conditions of manufacture documented in the Harris letter. This is an example of

the author selecting material for the *SSR* which does not give a true and accurate picture of the issues around self-sufficiency and there is also no mention of the increased hepatitis risk and added expense of importing commercial blood products at that time as detailed by Harris. The continuing failure of the UK Government to achieve self-sufficiency was to have disastrous consequences for a generation of haemophiliacs in the 1980s as they learnt for the first time of the link between their "life-saving" treatment and AIDS.

An early report on the possible risk of haemophiliacs becoming infected with the AIDS virus via factor VIII appeared in *New Scientist* (Sattaur, 3rd Feb 1983). The year 1983 was very significant for the haemophilia community in terms of how the news of AIDS, (a new blood borne virus at that time) was handled by the Government, the medical profession and the press. I have documented here an incident that appeared in the *Mail On Sunday* which does not appear in the *SSR* yet is an important part of the history of AIDS in the UK and one that the Government and the medical profession are keen to forget. I question why this important article was omitted when the DOH utilized a later newspaper article on AIDS in the *SSR* from the *Sun* (18th May, 1983). On 1st May 1983 Susan Douglas, a journalist for the *Mail On Sunday* wrote a well-researched and controversial article reporting on the dangers of importing "**killer**" blood from the US due to the sourcing of plasma from "high-risk" donors and the risk of AIDS for UK haemophiliacs. Douglas had identified the first two British haemophiliacs with AIDs which led to a strong reaction from a leading haematologist and a dismissal of her concerns from the Government. A complaint to the Press Council was filed by Dr Peter

Jones Consultant Haematologist at a Newcastle hospital who claimed the report was "sensationalized."

The Government reacted to the article by stating that the evidence presented by Douglas was "too slight for immediate action." The Press Counsel went on to censor the Douglas report as "extravagant" and "alarmist" (Douglas, 1984). This had the effect of temporarily closing down some news stories on AIDS but haemophiliacs had begun to question the risks associated with their treatment and once again were met with the repeated response "not to worry." The national Haemophilia Society responded on 4th May 1983 (see Appendix A13) sending a letter telling members that "the importation of licensed blood products has always been strictly monitored and controlled" and that "it would be counter-productive to alter our treatment programmes radically." Under the FOI Act the name of the author of this letter has been blocked out. Galbraith (1983) based at the Public Health Laboratory Service (PHLS) Communicable Diseases Surveillance Centre was becoming increasingly concerned at his own findings. He wrote a letter on 9th May to the DHSS in London (see appendix A14) which documented the first known case of AIDS in a UK haemophiliac in Cardiff who had been treated with US factor concentrates. This letter is notably missing from the *SSR*, Galbraith expressed his concern over AIDS and informed the DHSS of 11 similar cases in the U.S. and 3 in Spain and warned,

> I have reviewed the literature and come to the conclusion that all blood products made from blood donated in the USA after 1978 should be **withdrawn** from use until the risk of AIDS transmission by these products has been clarified. (Galbraith, 9th May 1983)

Galbraith attached his reasons for the withdrawal of treatment and urged an early meeting with haematologists, virologists and others concerned. He also stated, "I am most surprised that the USA manufacturers of the implicated blood products have not informed their customers of this new hazard. I assume no official warning has been received in the UK" (Galbraith, 9th May 1983.) Here it can be argued that once again commercial interests were prioritized over safety. Galbraith failed to get a positive response to his concerns. A meeting of Haemophilia Reference Centre Directors dismissed his worries declaring that there were was insufficient evidence to withdraw US concentrates although they agreed to review the situation (Bloom and Rizza letter, June 24th 1983, see Appendix A15). Galbraith identified that the first known case of AIDS in a U.S. haemophiliac was in October 1980 although the first recorded case of AIDS in the general US population was in 1978. He attempted to warn the medical profession that although at that time the number of cases might be small that did not mean the risk of infection was small. The national Haemophilia Society funded in part by the American plasma companies responded to the issue of AIDS on the 18th May 1983, the *SSR Chronology* states that the "Haemophilia Society appeal not to ban imported blood products and urge patients not to stop treatment in response to concerns over potential risks" (*SSR*, 2006, p. 44).

In the US the plasma companies were slow to react although a meeting between the Food And Drug Administration (FDA), the Centre For Disease Control (CDC), plasma companies and other interested bodies met on a number of occasions to discuss the problem of AIDS. A plasma company letter from Hink (1st June 1983) advised that gay donors (considered a high-risk population for hepatitis viruses) should voluntarily

exclude themselves from donating plasma (see Appendix A16, Gay Donor Adverts). The letter also stated "there are no data to support the emotional arguments that prison plasma collected from adequately screened prisoners is 'bad'" (Hink letter, 1983, see Appendix A17). Although the FDA went on to tighten up controls on plasma donors both the U.S. and the UK continued to use up old stock on haemophilia patients manufactured from donors known to be high-risk for HIV and hepatitis C and failed to withdraw this treatment (Glenarthur letter, undated, see Appendix A18).

On November 25th 1984 Douglas hit back at the UK Government and medical profession by writing a second article for the *Mail On Sunday* entitled "AIDs: This Scandalous Cover-Up." She noted that there were now 90 cases of AIDS identified in Britain and 38 people had died from AIDS including one of Dr Jones's own patients, Newcastle haemophiliac, Terence McStay. In the same month the American Correctional Association (1984) produced an information bulletin entitled "Plasmapheresis Centers In Correctional Institutions" which noted the strong link between intravenous drug-users in prisons and infection with hepatitis viruses and the AIDS virus. The following statement appears in the document,

> Using "prison" blood is controversial within the plasma industry itself. It is also controversial at the consumer level, especially among the hemophilia population. Medical, ethical, and moral concerns have been voiced publicly; they must be considered in any decision-making process. (American Correctional Association, 1984)

Testing Of Blood For HIV and Hepatitis C: Delays, Devious Deals, And Dangerous Practice

In 1985 the first heat-treated factor concentrates were introduced in the UK which should have eliminated both HIV and hepatitis viruses. A test for the presence of the HIV virus in blood was also available for the first time in 1985 which meant that blood products could be tested as well as the testing of haemophiliacs suspected of being infected with HIV. It was left up to individual doctors whether to tell their patients that they had been infected with HIV (Smithies letter, 1984, see Appendix A19).

A first generation test for hepatitis C in blood was not available until 1989. The UK Government chose not to introduce the first generation HCV test as there was concern over too many false negative and false positive test results, (Preston, Legal Report, 2002). A second generation test became available and was introduced in 1991. During this two year period from 1989 to 1991 it is argued here that the UK Government failed to err on the side of caution and did not introduce the testing of blood donations for hepatitis C earlier as they did not want to waste blood that tested as false positive but might not be infected. During this time however other European countries did test blood and patients for the hepatitis C virus and saved many patients from becoming infected (Murray, Notes for *Panorama* Documentary, 1999, see Appendix A20). In 1991 wide-spread testing of the haemophilia community for hepatitis C did commence with very high infection rates recorded. It became apparent years later that many patients were tested during this period without their knowledge and "informed consent" and were not informed of their positive test results which put wives and partners at risk of infection. It is argued here that this was a dangerous abuse of power by the medical profession.[19] To make matters worse

haemophiliacs also co-infected with HIV recall being made to sign an official Hepatitis Waiver (1991, see Appendix A21) by solicitors acting for them in the HIV litigation which required haemophiliacs not to take further legal action with regard to hepatitis "in the unlikely event" they were infected.[20] Haemophiliacs also recall being advised by their solicitors that hepatitis C "was nothing to worry about" and "less of a problem than hepatitis A and B" this advice was very far from the truth.

The practice of collecting plasma from American prisoners existed for many years with one centre in Arkansas having its licence reinstated even after it was closed down on the grounds of safety in 1984 (Ruddy and Limbacher Jr, 2001). The Arkansas prison plasma program was in fact reopened and ran until 1994 allegedly sanctioned with the authorization of Governor Clinton. It became the subject of a recent documentary "Factor VIII: The Arkansas Prison Scandal" made by American film-maker Kelly Duda (Factor 8 Movie Website, date not stated). Many UK haemophiliacs only realized the true extent of the safety violations regarding plasmapheresis in prisons and the treatment they had received after a screening of the documentary in London in 2006. Haemophilia Action UK campaigners had previously presented two letters to officials in meetings at Westminster offering evidence of past safety violations in the collection of plasma. One letter came from Kelly Duda (2003, see Appendix A22) and the other came from American Linda Miller (2001) whose brother was a regular prison plasma donor at Arkansas State Penitentiary and had died from hepatitis C (see Appendix A23). Miller's letter addressed to Tony Blair was presented at 10 Downing Street by a group of campaigners and MPs. The UK Government failed to respond to both letters. In the 1970s and 80s at a time of gross safety violations in the collection of plasma 1,252 UK

haemophiliacs became infected with HIV and 99% of HIV positive haemophiliacs were also co-infected with HCV. In addition to this many other haemophiliacs became mono-infected with HCV with a total infection rate of hepatitis C in haemophiliacs around 3,000 (Macfarlane Trust, conversation with Martin Harvey, Chief Executive, 2006). Haemophiliacs had been repeatedly exposed to the hepatitis virus from the early 1970s.

Conclusions- Government Failure To Achieve Self-Sufficiency: An Iatrogenic Disaster

The critique of the SSR is an attempt to challenge some of the findings within the report and present an alternative viewpoint by studying documents from Government, the medical profession and other organizations not included in the report alongside the official report. My aim was to identify when information on treatment risks were known, and also to establish the importance of UK self-sufficiency in relation to minimizing viral risk to haemophilia patients. My conclusion is that the exclusion of documents from the *SSR* significantly changes the content and timeline of the report. This study provides documented evidence that treatment risks were known at an earlier time than admitted by Government and that there was also withholding of key safety information from patients by doctors. This amounted to unethical behaviour with regard to failure to obtain informed consent to treatment in relation to "high-risk" products, and failure to achieve informed consent in relation to participation in research studies on factor concentrates when introduced in the 1970s. This behaviour contravened the code of conduct laid out for medical professionals within the Hippocratic Oath (Nova Online Website, date not

stated) and also established by the Nuremburg Code, (National Institutes Of Health Website, date not stated). Faulder (1985) stresses the importance of the patient being adequately aware of what they are consenting to and argues that true informed consent "ensures that they (patients) freely volunteer their bodies, being neither manipulated nor coerced into a trial which they do not understand" (Faulder, 1985, p. 43). Documents from the 1970s onwards show that haematologists were closely involved in developing treatment policies on the use of factor concentrates in cooperation with the DOH and repeatedly breached the moral principle of ensuring that the doctor does not cause the patient harm. It feel it is also important to consider the ethics surrounding the globalization of blood and to highlight the exploitation of donors, in the words of Richard Titmuss:

> The commercialization of blood and donor relationships represses the expression of altruism, erodes the sense of community, lowers scientific standards limits both personal and professional freedom….. (and) places immense social costs on those least able to bear them – the poor and the sick…. The redistribution of blood…. from the poor to the rich appears to be one of the dominant effects of the American blood system. (Titmuss quoted in Seaton, 2005, p.25)

I would conclude that failure to achieve self- sufficiency in UK blood products combined with a reliance on imported plasma products from "high-risk" donors in the US and the use of large plasma pools put haemophiliacs at greater risk of becoming infected with HIV and hepatitis viruses. I also conclude that the use of pooled plasma products (factor concentrates) before the introduction of a viral inactivation process to eliminate hepatitis

and subsequently HIV was a high risk policy in terms of spreading blood borne viruses within the haemophilia community. I believe that the evidence within this study justifies a full and open public inquiry as it contradicts the evidence put forward by Government in the *SSR*. A public inquiry with appropriate terms of reference agreed by all sides would ensure that all relevant documents could be placed in the public domain.

I contend that not only should individuals be able to question official organizations within a liberal democracy but that they should be positively encouraged to do so as it is a healthy response to examine institutions that are empowered to provide services to the people and this action also empowers the people to take some responsibility for their own lives and the lives of others within society. The following chapter in this study looks at the identity and self-image of haemophiliacs and their partners, and examines their thoughts and attitudes towards the organizations that were set up to provide health care and support to the haemophilia community.

Notes

[1] Haemophilia Action UK (formerly Haemophilia North) is an independent campaigner led organization based in Newcastle which was set up to represent haemophiliacs infected with blood borne viruses.

[2] Tests for hepatitis A and B in blood samples were developed in the 1970s. Some haemophiiliacs had already been exposed to hepatitis B and when a vaccine became available developed by Blumberg and Millman it was given to protect haemophiliacs against infection (Inventors Hall Of Fame Website, date not stated)

[3] Plasma-a) the fluid part of milk, lymph or blood, the sterilized plasma used for transfusions (Cassell's English Dictionary (2006, p. 940)

[4] Factor concentrate- Factor VIII concentrates are a commercially prepared lyophilized powder prurified from human plasma to treat patients with haemophilia A or Von Willebrands Disease.
Factor XI concentrates are a commercially prepared lyophilized powder purified from human plasma to treat patients with haemophilia B (Blood Products Website, date not stated).

[5] The Haemophilia Society is the national organization representing UK haemophiliacs. In recent years some haemophiliacs have questioned whether this organization can truly represent them as the Society receives funding in part from international plasma companies involved in litigation in relation to the contamination of haemophiliacs with blood borne viruses and this is often pereceived as a "conflict of interest."

[6]Charles Drew was well respected for tackling not only blood safety but institutional racism in American teaching and medical establishments. Drew had to continually face the "Negro versus white blood" issue in blood collection where use of "negro" blood in the US was either restricted for use in black patients only or banned altogether. Despite the exemplary service provided by Drew, Britain came only partway to addressing the race issue accepting blood from "negro" donors but "labelled the plasma so the users would know the race of its origin" (Starr, 1999, p.98).

[7] Starr (1999) also wrote at length on safety issues surrounding the use of paid donors. He investigated the commodification of blood describing America as the *OPEC* of plasma with the world market value of whole blood in 1998 at $20,000 per barrel in its crude state compared with the market value of crude oil at $13 per barrel. America was identified as the world's biggest exporter of plasma products.

[8] One centre in Belize run by Cuban American doctor Pedro Ramos bled impoverished donors up to 50 times a year against World Health Organisation guidelines which were set up to protect the health of

donors. Harriman (1980) notes that some donors fed their drink and drug habits by selling their blood. A description of a similar plasma collection centre can be found in Starr (1999, p. 234- 6 and 243-5.) The centre had such a poor reputation for safety it was nick-named, (Casa de Vampiros) and was eventually burnt to the ground by a rioting mob.

[9] Cryoprecipitate- (Cryo) is a low purity concentrate of three hemostatic proteins prepared from donated whole blood (Blood Products Website, date not stated.)

[10] During the early 1980s when AIDs was discovered to be infecting factor concentrates some doctors reverted back to prescribing cryoprecipitate for children as "cryo" was considered to be a safer treatment.

[11] When patients accessed their medical records for litigation purposes some haemophiliacs discovered that there were covert and unsubstantiated references to alcohol abuse in their notes. Patients challenged doctors to produce evidence of this and asked the reason why any identified problem had not been discussed openly with them. Even in accurately identified cases of alcohol abuse it is important to establish whether any identified problem came as a consequence of the of the stress of living with HIV/HCV which doctors often ignored.

[12] As freeze-dried concentrates are made from thousands of donations of plasma which are then pooled together, if one donation is infected it can affect the whole pool which is why donor sourcing was such an important issue before a viral inactivation method was developed in 1985 (Blood Products Website, date not stated).

[13] Scotland had a separate collection and production facility and provided much of the treatment for Scottish haemophiliacs although at times Scotland also used imported US plasma. The situation in Scotland requires a study in itself therefore my focus is on England and Wales although I acknowledge that at the time contamination of haemophiliacs occurred Scotland was governed by Westminster.

[14] One Newcastle haemophiliac returned his factor concentrates to his local haemophilia centre after the screening of the 1975 "Blood Money" *World In Action* documentary. He recalled being angry at what he had seen but was falsely reassured that the treatment wasn't coming from "dangerous sources" anymore. After years of silence a spokesperson for the hospital finally admitted in 2005 that the hospital had used treatment from prisons for many years, no formal apology was given.

[15] One haemophiliac agreed to speak to me by phone about his own personal recollection of hepatitis during this time when he was a young teenager. This gentleman had been a resident pupil at Lord Mayor Treloar School where children with disabilities were often sent to be educated. He recalls waking one morning to find his haemophiliac friend "glowing yellow." He stated that pupils were told by the headmaster that there were two types of hepatitis and that those infected had the less serious kind, (he believed this to refer to hepatitis B.) The children identified as being infected with a strain of hepatitis were then given plates with red spots attached to signify infection. This was a precursor for the tragedy that followed often referred to by Lords Winston and Morris in Government Hansard reports as "the worst medical treatment disaster in the history of the NHS."

[16] The UKHCDO Minutes (1982) also noted the appointment of a nursing sister whose post would be funded for two years by four pharmaceutical companies and that this person would work closely with the Haemophilia Society and Haemophilia Centres. This demonstrates the close financial ties to the plasma industry also noted in Starr (1999.)

[17] The term the "worried well" appears in a journal article by Miller, Acton, and Hedge (1988) and refers to patients who test negative for AIDS but have the conviction that they are infected with this virus and display irrational and obsessive behaviour. In the case of haemophiliacs the fear was not irrational as many haemophiliacs actually did test positive for HIV and HCV and were worried because they were sick and dying.

[18] Blood Products Laboratory (BPL) is largely protected against litigation under Crown Immunity.

[19] Haemophiliacs often had their blood tested for clotting levels with consent but testing for HIV/HCV requires pre and post test counseling of patients with appropriate support mechanisms for patients introduced from 1985 the year HIV testing was introduced in the UK. (I was involved in developing good guidelines for practice in HIV testing in Newcastle in 1985 as a practicing nurse). However as my questionnaires reveal good ethical practice was not carried out in many cases. The guidelines are available in General Medical Council (GMC) Serious Communicable Diseases Booklet, (Oct 1997).

[20] Haemophiliacs were informed that if one person did not sign the hepatitis waiver the "ex-gratia" payment for HIV would not be granted to anyone by Government. The solicitors had full access to haemophiliacs' medical records and on reviewing the legal files it was apparent that Government, the medical profession and solicitors on both sides were fully aware of the dangers of hepatitis C and the very high likelihood of haemophiliacs being infected and having progressive liver disease. 99% of haemophiliacs infected with HIV were also co-infected with HCV (GUT Online Website, 2002)