ADVOCATE DEPUTE

CONSIDERATION OF CRIMINAL PROCEEDINGS IN RESPECT OF CONTAMINATED BLOOD PRODUCTS

This report asks for Crown Counsels' instructions as to whether the complaints made by a Mr GRO-A a haemophiliac, as to the circumstances surrounding the supply of blood products to haemophiliacs, should be investigated by the police.

A number of haemophiliacs became infected with HIV and more particularly hepatitis C as a result of contaminated blood products. A letter from Mr GRO-A representing the Scottish Haemophilia Groups Forum was sent on 5 December 2002 to Andrew Cameron, Chief Constable, Central Scotland Police, in his capacity as chair of ACPO Scotland, requesting that the police consider whether the supply of blood products to haemophiliacs merited criminal investigation. In January 2003 Detective Superintendent Stephen Heath of Strathclyde Police was allocated the enquiry. He has sought further instructions as to whether the enquiry should continue.

In compiling this report I have had the benefit of Detective Superintendent Heath's report, information from the Scottish Executive Health Department, an Advice Note from the CPS, London to Dyfed-Powys Police who carried out a similar review in England and Wales, and information from various sources in connection with proceedings in other jurisdictions.

Background

Haemophilia is a hereditary disease that is found in approximately 400 men living in Scotland. It is not found in women. It is a bleeding disorder which results from an inability to produce Factor VIII. Factor VIII is a coagulant which assists blood clotting. As a result of a lack of the clotting agent, any bleeding is potentially fatal to the haemophiliac. Haemophiliacs are treated by a Factor VIII concentrate which is introduced to the body either intravenously or subcutaneously. This concentrate was until recently produced from pooling human plasma from multiple donors. It is thought that if just one of the donations used in the manufacturing pool was infected

with hepatitis (and perhaps also HIV) then the whole batch made from that pool could be infected and the each of the recipients of blood products from it, vulnerable to infection. In the mid to late 1970's Factor VIII took over as the main treatment for haemophiliacs from an older less effective treatment, cryoprecipitate.

Hepatitis C was first isolated in 1989, although it was known to exist from the late 70's onwards when it was known as "Non-A Non-B Hepatitis" (NANB). It is a blood borne virus that causes inflammation of the liver. The inflammation does not reverse and tends in 75% or so of cases to cause chronic liver disease which leads to serious illness and at times death. It is known to be a precursor of liver cancer. Although the symptoms can be treated, there is no cure. According to the Scottish Executive Health Department, 15 HIV negative patients have died of liver disease in the last 15 years having been infected by hepatitis C.

HIV is a virus that destroys or damages the body's immune system. As I understand it to this develops into AIDS in every case, with fatal consequences. The possibility that blood products could spread the virus was raised in 1982.

As will be explained below, the Secretary of State for Scotland had responsibility for the provision of health services in Scotland at the material time. He did this through provision of health services through local health boards and, in the provision of blood products, the Scottish National Blood Transfusion Service (SNBTS).

The Allegations

It is alleged by Mr GRO-A on behalf of the Scottish Haemophilia Groups Forum that haemophiliacs were infected with Hepatitis and HIV/AIDS by being treated with contaminated blood products. Successive governments and health authorities were aware that there were risks associated with these treatments but patients were not advised of them. The authorities, whilst knowing of the risks took no remedial action in relation to them, and where they did take action were dilatory about it. The haemophiliacs also complain that they were tested for Hepatitis C/HIVAIDS without their consent or knowledge. They ask whether this merits a criminal investigation.

The Scottish Haemophilia Groups Forum is a pressure group who are knowledgeable in their methods of using the media and applying political pressure. They are actively suing a number of US drug companies in the United States. They have petitioned the Scottish Parliament Health Committee for a public enquiry. This has not met with success. It seems that their complaint to the police is part of their ongoing campaign. It seems to have been made partly to apply leverage to the Executive to set up a publicenquiry

Chronology of Events

There follows a summary of the facts as to the risks associated with the treatment of haemophiliacs as presented in the police and Executive reports, and also from the CPS Advice. A more detailed narrative as to what happened in Scotland follows in the next section.

1966- Studies in the US highlighted the risk of hepatitis from prison plasma donors was higher than in the general population. American prisoners were a common source of donors for plasmapherisis to make commercially available blood products for haemophiliacs. Collection of blood from UK prisoners was banned on safety grounds. Some of the US plasma was being imported into the UK to make blood products. Paid donors in the US often came from what have been described as the "residents of skid row" and also posed a higher infection risk.

1968- Article in Journal of American Medical Association warned of the hepatitis risk from using drug addict donors at US blood banks. On 20 April an article in the British Medical Journal warned against using imported plasma from paid donors on safety grounds.

1970-The first evidence of Non-A Non-B hepatitis was found. A pivotal book called "The Gift Relationship" by Richard Titmuss compared the UK Blood Transfusion service with the US and commented unfavourably on the failure of the US system to protect against Hepatitis. The book is frequently quoted and was referred to in 1974 by the then Health Minister Dr David Owen as the reason why the UK should become self sufficient in the production of blood products.

1972- Various articles in US pointed to research indicating a clear link between paid blood donors and the risk of hepatitis, and made a link between the increased hepatitis levels seen in the haemophiliac population and new clotting products made from plasma. In May Dr W Maycock, of the UK Blood Products Laboratory, acknowledged the risk of hepatitis infection from the use of blood products and acknowledged that the risk was greater where commercial products were concerned.

1973-The UK licensed imported plasma from the US. The DHSS Expert Group on the Treatment of Haemophilia acknowledged that there was at least a theoretical risk of hepatitis infection from the concentrate. Prior to 1973, Cryoprecipitate was used to treat haemophiliacs in the UK. This originated from small pools of UK donors who were unpaid volunteers. At that time the incidence of hepatitis was low in the general population in Britain which meant that using cryoprecipitate made in the UK was less "risky". It was however, significantly less effective as a treatment.

1974- Dr Maycock (the CPS do not know whether this is the same Dr Maycock as acknowledged the risk of hepatitis infection in 1972) was given a warning (unfortunately unspecified in the source document) The rate of infection from commercial donors was ten times greater than that from voluntary donors

1975-An article in The Lancet studied the hepatitis risk to UK haemophiliacs. The outcome of the study indicated that *inter alia* the following measures might lessen the likelihood of infection;

1. Commercial Factor VIII concentrates should be reserved for the treatment of life threatening bleeds in all haemophiliacs and for use during life threatening operations.
2. If used for routine treatment commercial concentrates should be reserved for severely effected patients as they were more likely to be immune to hepatitis A and B. Treatment should be carried out by experienced staff who were aware of risk of using pooled concentrates. A TV documentary the same year commented that the estimated hepatitis rate from imported American Factor concentrates was 100%. Dr Owen participated in the programme and recognised the greater risk involved in using commercial products. World Health Organisation Guidelines were promulgated indicating that countries with a low incidence of Hepatitis should not use blood or

blood products obtained from a source collected in an area in which there is a high incidence of hepatitis. Also this year a number of hepatitis outbreaks were reported in the UK and as a result UK Haemophilia Centre Directors issued guidelines that children should be treated with cryoprecipitate.

Late 1970's- Central Government asked the UK Haemophilia Centre Directors Association to store information on product batch numbers. Certain US products and companies were identified as high risk. The results of this exercise were to be studied by a team headed by Dr Preston.

1980- The Under Secretary of State for Health "noted" the risk of hepatitis from imported products.

1981- Research identified symptoms for chronic and acute NANB hepatitis from products made from prison plasma in the US. Warnings started to surface in US regarding haemophiliacs dying from immune problems.

1982- A consensus of experts at the Centre for disease control in Atlanta, US said that AIDS is blood borne. US companies warned to stop using high risk donors for production of blood products.

1983- The Public Health Laboratory Service in the UK wrote to the Department of Health urging a withdrawal of all US blood products manufactured post 1978 due to a risk of AIDS. In the US and Spain AIDS symptomatic haemophiliacs presented and the common factor was found to be US concentrates. In Wales there was the first report of AIDS in a UK haemophiliac. An article in the British Medical Journal highlighted findings that commercial concentrate was more infectious than NHS concentrate and further suggested that there had been an increase in the infectivity of NHS concentrates following an increase in the size of the UK donors pool. In late 1983 SNBTS prepared a batch of pasteurised Factor VIII for clinical evaluation

1984- The first patient in clinical evaluation for SNBTS pasteurised Factor VIII suffered

an adverse reaction, and the trial was abandoned. The Plasma Fractionation Laboratory (PFL) in Oxford (a pilot plant laboratory for Bio Products Laboratory in Elstree) managed to dry heat a Factor VIII product to 80°C for 72 hours. It was expected that this would give greater protection against HIV. There was no indication whether this temperature would have an effect on the agent responsible for Non A Non B hepatitis, not at that time recognised as hepatitis C. The Scottish National Blood Transfusion Service decided to keep trying to develop a different method. In December 1984 the SNBTS were able to heat treat a year's supply of Factor VIII at sufficient temperatures to render it HIV-safe.

During 1983 and 1984 the Haemophiliac Society communicated with Health Department asking that the supply of imported blood products continue as there was "no alternative" treatment to treat their condition.

1985- At around this time it is alleged that haemophiliacs were tested for HIV, often it is said, without their knowledge or permission. 1,263 were tested across the UK. A high percentage are now dead. Heat treatment of all English blood products to eliminate HIV and hepatitis began. The Scottish National Blood Transfusion Service was around 18 months behind England in producing a heat-treated product which eliminated the hepatitis C virus. Some hospitals indicated that non heat treated products were to be used up first. Some areas heated blood to the wrong temperature and viruses were not eliminated. The results of the study launched in the late 70's by Dr Preston *et al* (supra) concluded that the majority of liver disease in haemophiliacs is *probably* as a result of NANB hepatitis and predicted increased problems in the future. In September of that year BPL began to heat treat all of its Factor VIII at 80°C for 72 hours. This accounted for 25% of the requirement in England and Wales. The balance was made up from commercial concentrates.

1986 - In August 1986 SNBTS produced the first trial batches of their new Factor VIII product, heat treated to 80°C for 72 hours. In September a BPL/PFL preliminary report was published which indicated that heat treatment of Factor VIII at 80°C for 72 hours might prevent the transmission of NANB hepatitis.

1987 – During March 1987 the clinical trial of the SNBTS Factor VIII product (heat treated at 80°C for 72 hours) was completed. In April SNBTS Factor VIII product (heat treated at 80°C for 72 hours) was available for clinical use.

1988 - In the October 1988 *Lancet* the full results of a study were published showing that heat treatment of Factor VIII at 80°C for 72 hours was effective against NANB hepatitis.

1989- NANB was isolated and designated Hepatitis C. The UK government did not use the first generation Hepatitis C test, in contrast with other European countries, as it indicated that it provided too many false positive tests. Many haemophiliacs are said to have been secretly tested anyway, and then tested again with second generation test in 1991/1992. Many allege that they were not told of positive results until 1994. This is against General Medical Council guidelines.

1991- HIV Litigation/Hepatitis Waiver. An *ex gratia* payment was made by the UK government with no acceptance of liability. The files were sealed by the then government for 30 years. HIV settlement haemophiliacs signed a waiver that they would take no further action. They claim their solicitors advised them that Hepatitis C was less of a problem than hepatitis A and B. This is being contested in the civil courts, as is the 30 year seal on the documents. Many Scottish haemophiliacs claim they did not sign the waiver but were still given the financial settlement.

1993- A French Court began to hear evidence in a case against ministers for alleged crimes in relation to supply of contaminated blood products and secretive AIDS testing. The results of tests were published confirming the clinical safety of both SNBTS and BPL products as regards hepatitis C transmission.

1994- Many haemophiliacs were told they had hepatitis C. 99% of those found to have HIV had hepatitis C.

1995- The Haemophiliac Society in the UK launched a campaign for compensation. Hepatitis C overtook HIV as biggest killer of haemophiliacs in Europe and the US.

1999- The French Health minister was found guilty of manslaughter. Two doctors received prison sentences as a result of the French trial.

2000- The Scottish Executive published the results of a fact finding exercise in respect of the alleged delay in the introduction of the heat treatment of Factor VIII in Scotland. No fault was found. The report concluded that the Scottish National Blood Transfusion Service made "reasonable progress" in developing products with reduced viral risk relative to activity elsewhere.

2001- The UK Government refused to hold a public enquiry. In Canada a public enquiry and criminal investigation found the Red Cross negligent over donor sourcing. Criminal charges are pending against donor brokers. In Eire, the Lindsay Tribunal began to hear evidence. The tribunal's terms of reference were to establish which blood products caused hepatitis, and whether the safeguards to prevent infection were adequate.

2002- Haemophilia Action UK started US litigation. Dyfed-Powys police began a criminal investigation in England and Wales into the treatment of haemophiliacs. In Italy, charges were brought against health officials and plasma companies. The Lindsay Tribunal reported. It recommended that blood products supplied to Haemophiliacs should be of the highest standard and safest nature available, and that record keeping and communication should be better. The Tribunal was reluctant to make further recommendations due to the historical nature of the evidence and the changes in personnel and procedures that had been made since the events that the evidence disclosed.

2003- 2 Irish blood bank officials are charged under section 23 of the Offences Against the Person Act 1861 which relates to administering or causing to be administered a dangerous or noxious "thing" thereby causing grievous bodily harm. The allegations concern the administration of Anti-D to rhesus negative women. The Scottish Health Minister declined to hold a public enquiry on the basis that he had not seen any evidence that clinicians or officials had acted wrongfully.

The Scottish Position

Prior to embarking upon a discussion of the Scottish position, it is important to note that the scientific community world-wide shares information through the publication of research papers. Papers are subject to a process of peer review before they are published. Sometimes, information is shared at conferences before a paper has been published. This is the means by which Scottish ministers, officials and doctors were to discover what the most up to date developments in regard to haemophilia.

As noted in the chronology, blood products are made safe against viruses such as hepatitis by heat treating them. There are two ways to do this. The first way is to wet-heating the blood to a certain temperature, otherwise known as pasteurisation; the second means by which the product can be protected is by dry-heating, which involves freeze-drying a product, then subjecting the dried product to heat. The product is reconstituted with water for use.

According to the Scottish Executive Health Department examination of the subject, (Hepatitis C and Heat Treatment of Blood Products for Haemophiliacs in the Mid 1980's) the crucial factors in this are the temperature to which the product is heated and the length of time for which it is heated. They go on to state,

> "It was apparent to us from the contents of the published scientific papers included with SNBTS's submission that subjecting Factor VIII to heat treatment was a far from straightforward matter. Improperly controlled heating of plasma proteins can cause them, in lay terms, to cook; this changes their nature and spoils the product for human use. An additional technical complication arose from the view that the purification of Factor VIII (separation of the Factor VIII component from other material in plasma) was important in working out the process of heat treatment."

Following upon the earliest research from Germany in 1980 which suggested that pasteurization was effective in removing the hepatitis B risk from Factor VIII, SNBTS research on pasteurisation began in 1981. Current Haemophilia Centre Directors have recalled that in 1983, Scotland was approaching self-sufficiency in

Factor VIII, in accordance with Scottish Health Service Policy that Scotland should be self-supporting in blood products including Factor VIII concentrates for the treatment of haemophiliacs.

In 1983, SNBTS established that commercial firms were investigating dry heat treatment of Factor VIII at 60°C. SNBTS carried out preliminary tests of their own but found that the commercial methods were less effective than their own. They got to the stage of conducting a clinical trial of pasteurised Factor VIII but when the first patient to be examined suffered an adverse reaction they abandoned the trial.

In late 1983, HIV was isolated as a blood-borne virus. It was first cultured for research in March 1984. The focus on heat treatment shifted towards the optimal method to eradicate HIV, since this was now recognised as the biggest threat to haemophiliacs. SNBTS decided to explore further the options available should HIV be found to be sensitive to dry heat treatment. They made further measurements of the behaviour of their Factor VIII when subjected to heat treatment, which were completed in October 1984.

In April 1984, an American company published a patented method for the pasteurisation of Factor VIII. SNBTS noted that the Plasma Fractionation Laboratory (PFL) in Oxford, which was a pilot plant laboratory for Bio Products Laboratory, managed to dry-heat an experimental preparation of Factor VIII product to 80°C for 72 hours. It was expected that this would provide greater protection against HIV. SNBTS noted that this product was 10 times more purified than their own Factor VIII , which was believed to be the reason why the heat treatment was successful, without spoiling of the product. At that time there was no indication whether this degree of heat treatment would have any effect on hepatitis viruses (and since the causative agent of NANB hepatitis had not been isolated, it could not be tested for directly).

In November 1984, SNBTS learned of reports that HIV was sensitive to 68°C dry heat for 1 hour. In December 1984 they were able to heat-treat a year's supply of their Factor VIII product at 68°C for 2 hours, thus rendering it HIV-safe. In

January 1985 they were able to begin dry heat treatment at this temperature for 24 hours, and in the same month SNBTS began to specify and procure equipment to a similar specification to that used in England. The initial delivery of equipment was in July1985. By July 1986, SNBTS had enough stocks of Factor VIII to stop production but still maintain sufficient supplies to the health service, so they could concentrate on trialing other types of heat treatment.

Meanwhile, in March 1985, PFL at Oxford were heat-treating all of their Factor VIII, some at 80°C. In May 1985 Bio Products Laboratory (BPL) in England were doing the same. By September 1985, all PFL/BPL Factor VIII was being heat treated at 80°C for 72 hours. This amounted to a quarter of the requirement in England and Wales for Factor VIII.

SNBTS were also attempting to develop the technical processes which would produce a Factor VIII product able to withstand dry heat at 80°C without spoiling. In Autumn 1985, they developed a more highly-purified Factor VIII, but it was unable to withstand heat treatment at 80°C. They therefore concluded that it must be the process of freeze-drying which was crucial when it came to the tolerance of the product to dry heat, rather than higher levels of purity. In February 1986, SNBTS management endorsed the approach of their scientists to concentrate on 80°C dry heat.

In August 1986, SNBTS produced the first trial batches of their new Factor VIII product treated at 80°C for 72 hours. In September 1986 came a preliminary report that treatment of the BPL Factor VIII product at 80°C for 72 hours might prevent the transmission of NANB hepatitis SNBTS undertook a clinical trial of their own Factor VIII product in March 1987. In April 1987 they made it available for routine clinical use.

The first production of 80°C dry-heated Factor VIII in England was March 1985. A preliminary clinical report issued in September 1986 suggested that 80°C dry heat treatment was indeed effective against NANB heptitis. According to the Health Department, while the

> "scientists involved would doubtless have been reasonably confident before then that they were at least heading in the right direction, but they could not know for sure that this form of heat treatment would be effective until after the product had been in clinical use."

That appears in the circumstances to be fair comment. The full results of this trial were not published until October 1988. However, SNBTS Factor VIII had been in routine clinical use from April 1987. SNBTS say that in 1987 they supplied 89% of Scotland's Factor VIII needs. In 1988, they were able to supply all of Scotland's needs. In contrast, they estimate that outwith Scotland over half the UK's Factor VIII concentrate requirement in 1988 was still being supplied with products being heat treated at 60-68°C.

After the HCV virus was isolated and identified in 1989, results were published in 1993 confirming the clinical safety of both the Scottish and English produced products as regards HCV transmission.

Up until 1988, Scotland was not self sufficient in blood products. As a result haemophiliacs were also treated with commercial products during this time. One of the main complaints made by the haemophiliacs relates to the risks involved in this. These were acknowledged in leaflets to patients. However, one wonders what doctors were supposed to do in the treatment of haemophilacs. Whilst cryoprecipitate could be used to treat "mild" haemophilia, the Haemophila Centre Directors in Scotland told the Health Department that these alternative treatments also had side effects such as thrombosis and anaphylactic shock. The treatment was a matter of clinical judgement. In addition, whilst "mild" haemophilics do not bleed spontaneously, they do not heal if they are injured. In these circumstances they needed life saving Factor VIII treatment to stop the bleeds.

Case Studies

The police report outlines a number of case studies (p8 *et seq.*) To a large extent these do not assist consideration of this matter. Whilst the police say they have seen

documented evidence to suggest that there is an audit trail tracing the infection of the individuals concerned to imported factor VIII, the times of infection of cases A-C are before the time when SNBTS were able to heat treat products and Scotland was not self sufficient in blood products. As shown above, that there were risks involved in the treatment of individuals with commercial products was known, but it is thought that doctors and officials had little choice but to treat the patients with commercial product. It is also uncertain how robust the "proof" is.

Potential Crimes

Having briefly set out the factual background, one can move forward to examine the legal framework. As noted earlier the allegation made by the haemophiliacs is that the authorities knew of risks in their treatment but carried on supplying and administering it regardless. If it were the case that the authorities knew that there were risks attendant to treatment of individuals with blood products the potential offences could be as follows;

(i) Assault

An assault is an intentional act upon the person of another (*Macdonald 115*). An assault cannot be committed recklessly or negligently *(Lord Advocates Reference (No. 2 of 1992) 1992 SCCR 960).* From the known facts presented above there is no suggestion that patients were intentionally infected. For an assault to be relevant there would have to be an intention to infect another person with a virus. In the absence of any evidence that patients were deliberately infected the crime of assault is irrelevant.

As noted earlier there is also a complaint made about the testing for illnesses without the consent of the victims. It is thought in the case of surgical procedures consent is a defence (see Gordon "The Criminal Law of Scotland" para 29.40). However, in order to be valid, the consent must be freely given. There is no authority that the concept of "informed consent" is part of the criminal law, and it is suggested that if the consent is obtained by fraud then there may be in law a crime of dishonesty, though this issue has never been explored in Scotland (see *R v. Richardson (Diane) [1999] QB 444* for

the position in England). It is thought that haemophiliacs had blood drawn regularly for other purposes, to which they have consented. The issue would therefore be in relation to the use put to the blood rather than the taking of the blood itself. Any potential offence would be one of dishonesty. Haemophilia Centre Directors deny that they put blood to purposes other than those that patients were advised of. There is no case that I am aware of that suggests that this is an assault and therefore one is lead to conclude that assault is not a relevant crime for the purposes of this complaint.

(ii) Reckless Conduct

Reckless conduct that causes injury is an offence (*Harris v HMA 1993 SCCR 599*). The *Harris* case supported the view that the standard of recklessness that required to be shown was that set out in *Paton v HMA 1936 JC 1.* In that case, the Lord Justice Clerk (Aitchison) said at page 22,

> "…it is now necessary to show gross, or wicked, or criminal negligence, something amounting, or at any rate analogous, to a criminal indifference to consequences, before a jury can find culpable homicide proved."

Whilst this dictum is not without its difficulties, in particular in its use of epithets such as "wicked" and "criminal", which lead to an element of tautology, its basic premise is that there must be an indifference to the consequences. In *Cameron* v *Maguire* 1999 J.C. 63, a case involving culpable and reckless discharge of a firearm, Lord Marnoch, delivering the opinion of the court reaffirmed the *Paton* test and reformulated it thus

> "recklessness so high as to involve an indifference to the consequences for the public generally".

In the context of the treatment of haemophiliacs, if knowledge could be brought home to a person that there were risks to haemophiliacs' health involved in the licensing, supply and administration of blood products, and if it could be proved that the products continued to be licensed, supplied and administered in the face of those known risks, and that could be said to involve an indifference to the consequences for haemophiliacs, that person may have the requisite *mens rea* to be criminally liable.

In the circumstances therefore, if the facts matched up to the test set out above reckless conduct could be a relevant crime in this context.

(iii) Culpable Homicide

Culpable homicide is the unlawful killing of another in circumstances short of murder. *MacDonald Criminal Law of Scotland* (5th ed.) at p.96, describes three kinds of culpable homicide in Scotland. Any situation involving haempphiliacs is likely to concern the third of these three kinds of culpable homicide, namely "homicide from negligence, or from rashness in the performance of lawful duty".

In *Hume* (*Bell's Ed.*) Vol.1 pps.233-4 he describes this form of culpable homicide, sometimes called "lawful act" culpable homicide as follows;

> "It has already been mentioned, and it does not seem to stand in need of further illustration, that it is culpable homicide, where slaughter follows on the doing even of a lawful act; if it is done without that caution and circumspection which may serve to prevent harm to others."

It seems that the requisite test to be used derives from *Paton* (supra), that is "criminal indifference to the consequences". A person may be charged with culpable homicide if knowledge could be established that there were risks to haemophiliacs' health involved in the licensing, supply and administration of blood products, and if it could be proved that the products continued to be licensed, supplied and administered in the face of those known risks, if that could be said to involve an indifference to the consequences for haemophiliacs.

A further issue arises here in respect of reckless conduct and culpable homicide. Assuming that haemophiliacs consent to their treatment with blood products what effect would this have? According to cases such as *Khaliq v H.M. Advocate 1984 J.C.84* and *Ulhaq v HMA 1991 SLT 614*, involving the sale of what may broadly be described as kits for the inhalation of volatile substances, and *Lord Advocate's Reference (No. 1 of 1994) 1995 S.C.C.R. 177,* involving the supply of drugs to an individual who died as a result of ingesting the drugs, the fact that the substance (or in this case, the blood product) was taken voluntarily was held not to have broken the causal chain between the reckless supply and the consequence. While this may be slightly different from consenting to medical treatment, the principal is the same. The

crucial fact is that the supplier (or licenser or person administering the treatment) knew the use to which the substance would be put. In these circumstances it is submitted that consent, like voluntary consumption in *Khaliq* and subsequent cases makes no difference.

(iv) Health and Safety at Work etc Act 1974

An employer may be potentially liable under the Health and Safety at Work etc Act 1974 section 3(1). Section 3(1) states: -
"It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety"
The Act imposes a duty on employers, so far as is reasonably practicable, to conduct their undertakings in such a way as to ensure persons who are not in their employment who may be effected by their undertakings are not exposed to risks to their health and safety. Not to safeguard this class of person is an offence in terms of section 33(1)(a). Health Boards and government departments can me said to be employers for the purposes of this section, and haemophiliac patients are persons not employed by them

As will be shown when looking at "Potential Accused" below, the application of this section is severely restricted in practical terms by section 48 of the same act which means that the section does not apply to the Crown. For non-Crown bodies there is a statutory defence available under section 40.

Section 40 says (in terms) that in any proceedings for an offence consisting of a failure to comply with a duty to do something so far as is reasonably practicable it shall be for the accused to prove that it was not reasonably practicable to do more than was in fact done to satisfy the duty. As will be shown below, whether in the circumstances those involved in the treatment of haemophilia had any other option but to treat the patients is very doubtful. As such, they would have done all that was reasonably practicable and would be able to satisfy the statutory defence.

Potential Accused

(i) The Secretary of State for Scotland and the Scottish Office

In terms of the National Health Service (Scotland) Act 1978 section 1(1) the Secretary of State for Scotland was responsible (during the material time) for providing effective Health services, including the prevention, diagnosis and treatment of illness. This includes responsibility for the Scottish National Blood Transfusion Service (s10). These responsibilities have now passed to the Scottish Ministers in terms of section 117 of the Scotland Act 1988.

It has not been suggested that the Secretary of State as an individual is guilty of assault or reckless conduct even by the campaigners themselves. There is no suggestion that the Secretary of State's actions in facilitating the supply of blood products are *ultra vires*. Any case to be made out against the (then) Secretaries of State would have to be in their capacity as Secretary of State. Therefore there would clearly be significant difficulties in attributing the knowledge of what happened vis a vis blood products to the holders of this post. More importantly all of this assumes that a causal link can be made between decisions taken at Ministerial level and the administration of contaminated products to individual haemophiliacs. It would be very difficult to show that a haemophiliac contracted a disease from a particular product never mind to attribute responsibility for this to a ministerial decision.

It is thought that there is a general principle of Crown Immunity, which prevents the Crown from being prosecuted, and that this still applies to Ministers of the Departments of State and to their Ministries. Whilst the Crown Proceedings Act 1947 removed many of the privileges in respect of the government in respect of litigation, that act had no application to the criminal law. There is a presumption in legislation that the Crown are not bound unless that is expressly stated. It is suggested that this can only be because the general privilege still exists and would apply here.

There are cases in which unlawful actions by servants of the Crown have been held to be actionable (prior to the 1947 Act) in civil law. For example in *Feather v The Queen (1865) 6 B&S 257.* However, the unlawfulness referred to seems to relate to

questions of *vires.* In their decisions in respect of haemophiliacs, unless there was malice, the Ministers (and the department) were acting *intra vires.* Such authority is therefore not relevant.

In England, it has been suggested that the Minster has none of the Crown's privileges or immunities on the basis of *M v Home Office [1994] A.C. 377.* In that case it was held that the Secretary of State and his Department could be liable for contempt of court. However, in the analysis of Lord Woolf (at pp 424 *et seq*), who gave the leading judgement, this was to reflect the essential nature of the relationship between the executive and the judiciary. The purpose of a finding of contempt was to ensure that orders of the court were obeyed, in order that the executive branch was subject to the law. Such proceedings were not "essentially personal or punitive". Lord Woolf went on to say, in parenthesis,

> " it would clearly not be appropriate to fine or sequestrate the assets of the Crown or a government department or an officer of the Crown acting in his official capacity."

Whilst it is dangerous to confuse punishment with principle, it is suggested that a finding against a minister or department in order to enforce an order of court is in a different category to a finding of guilt in the criminal law, which is still governed by the common law and results in immunity.

As such it is submitted that no prosecutions could be brought against ministers for decisions made in their capacities as ministers of state.

The same principal would operate as far as the Scottish Office itself is concerned.

In any event, section 2(8) of the National Health Service (Scotland) Act 1978 means that most liabilities that the Secretary of State would have in this regard are transferred, by primary legislation, to the respective Health Boards (which are considered below).

(ii) Civil Servants

Since Crown Immunity protects the Minister and his Ministry, attention may then fall upon the officials within the relevant departments who proffered the advice to the ministers. Three potential issues arise here. Firstly, if these officials only offered advice to Ministers who took it, is there a proper causal connection? Arguably they could be guilty on an art and part basis by counselling or procuring an offence. The second question then arises as to whether it is competent to charge a person who caused or procured an offence in the absence of charges against the principal actor, the minister. It is submitted that this is no *legal* bar to the bringing of proceedings. It is possible to commit a crime on an "art and part" basis where one could not be the principal actor (e.g. *Vaughan v HMA 1979 SLT 49* where it was held that it was competent to be art and part guilty of incest in relation to person that was not related to the accused. See also section 293 of the Criminal Procedure (Scotland) Act 1995). It is also competent to try a secondary actor on an indictment alleging art and part conduct with a principal actor who has been acquitted (see e.g. *Duffy v HMA 2000 SCCR 195*). There seems to be no impediment in law to prosecution of officials.

Assuming that the first two questions were answered in the affirmative, the third question would then arise. Is it in the public interest? There may be some reluctance to take proceedings against a public servant who gave advice to the Minister who was ultimately responsible for taking the decision, when the shield of immunity protects that Minister. It is submitted that this would be inequitable and not in the public interest and therefore no proceedings should be taken in these circumstances even if an offence could be proved.

(iii) The Licensing Authorities and the Committee on Safety of Medicines

Under section 30 of the Medicines Act 1968, blood products, which are medicines cannot be supplied or imported to the UK without a licence. The responsibility for the licence lies with a Licensing Authority in terms of section 6 of the 1968 Act. This authority is made up of the UK Ministers responsible for Health. They are advised by an expert group, the Committee on Safety of Medicines, which is appointed to give advice regarding issues of safety, quality efficacy etc. Licenses are granted in terms of sections 19 and 20.

Given the interrelation between the ministers and officials it is suggested that the same considerations apply here as apply in the case of ministers and civil servants as noted above. Proceedings appear to have little prospects of success, and how far they are in the public interest is in doubt.

(iv) The Health Boards and The Common Services Agency

The Health Boards in each area were responsible at the material time for the provision of health services as delegated by the Secretary of State (National Health Service (Scotland) Act 1978 section 2). The Scottish National Blood Transfusion Service was responsible for provision of blood products to those health boards. The Scottish National Blood Transfusion Service is a division of the Common Services Agency. The Agency is set up by section 10 of the 1978 Act. As far as I am aware, the health boards that were in existence at the material time still exist today, although some of their primary functions in relation to provision and management of hospitals have been transferred by the National Health Service Community Care Act 1990 to NHS trusts. Careful consideration would have to be made of the relevant legislation to see if responsibilities for the functions that we are interested in here (i.e. blood services) have transferred, however, what follows in the generality is equally applicable to whatever body is responsible (The National Health Service (Residual Liabilities) Act 1996 transfers liabilities to Trusts Health Board or the Secretary of State in the event of the original body ceasing to exist).

According to the legislation (s2 (8)) Health Boards shall, notwithstanding that they exercise functions on behalf of the Secretary of State, be entitled to enforce any rights acquired, and shall be liable in respect of any liabilities incurred in the exercise of those functions in all respects as if the Health Board were acting as a principal.

A Health Board is a body corporate in terms of Schedule 1 paragraph 1 of the 1978 Act. The Common Services Agency, which is responsible for SNBTS, is a body corporate in terms of Schedule 5 paragraph 1 of the 1978 Act. The principles of corporate liability such as they exist in Scotland, would govern any criminal liability that the Health Board might attract. These rules are now to be found in *Transco PLC v HMA (unreported, Appeal No: XC392/03.)* In that case the Crown sought to

prosecute a limited company for culpable homicide. The culpable homicide charge libelled that the company had knowledge of certain risks, and with reckless indifference to the consequences failed to act upon them. The consequence of these omissions was said to be a fatal explosion in which 4 people died. The knowledge of the particular risks, and the consequent omissions was to be attributed to the company by various collective bodies and three "posts" which were in charge of various aspects of the company's operations, in particular safety. Knowledge could not be brought home to an individual natural person, since because of the timescale during which the risks became apparent and the omissions took place, personnel moved on and as a result of corporate restructuring the collective bodies changed in nature and composition, a fact representing the reality of corporate life (whether in limited companies or public corporations).

It was held that there was no reason in principle why a legal person could not be charged with a common law crime (per lord Osborne at para [21] and per Lord Hamilton, with whom Lord MacLean agreed, at para [56]). The crucial thing, however, was how this liability was attributed to the corporation. The only way of attributing liability was via the "identification doctrine." Following *Tesco Ltd v Nattrass [1972] A.C. 153* the principle of the "directing mind and will of the company" was how liability was to be attributed. Since all powers in a limited company stemmed (in terms of the Companies Acts) from the board of directors, this controlling mind and will could come from a group of individuals where they act collectively. However, Lord Hamilton went on (at para [63]),

> "It is at the next stage that, in my view, the Crown case inevitably breaks down. It is acknowledged that no individual, and no group of individuals acting collectively, at any time acted (or failed to act) with a state of mind which could amount to that degree of culpability which, according to the modern law, is a prerequisite of the crime of culpable homicide. The Crown case can succeed only if it is legitimate to attribute to the appellant company states of knowledge or awareness of individuals or groups which from time to time constituted the controlling mind of the company and to regard such knowledge and awareness as, in effect, "banked" with the company so that, when other individuals or groups subsequently having and exercising the directing mind and will of the company acted (or failed to act), the company is

> treated as having so acted (or failed to act) with the accumulated states of knowledge and awareness of all those hitherto having and exercising the directing mind and will. In my view, such attribution is not legitimate. It is inconsistent with the identification theory which proceeds on the hypothesis that it is possible to ascribe to the company the state of mind of a natural person (or of a plurality of natural persons acting together)."

The effect of this decision is that in order to find a corporation guilty of an offence, there must be an individual (or group of individuals), at a senior level of the company, who can be said to be the controlling mind and will of the company, who can be shown to be guilty of the offence. The reality of this is that whilst it is technically possible to prosecute a corporation, it is in practice impossible to do so.

It is understood that individuals and groups of individuals, who may or may not be taken to be the controlling minds, took the decisions taken in health boards and at the SNBTS All of the health boards took similar decisions but the reality is that given the timescale involved it is suggested that there is next to no chance of successfully prosecuting a health board or of the Common Services Agency.

Against this background, the converse is also true. It stands to reason that if one cannot identify a controlling mind and will, in order for a body corporate to be convicted, then there is no prospect of identifying an individual official or doctor against whom there is sufficient evidence.

The causation issues that are described above in terms of the Ministers and Officials would also apply. How can it be proved that the hepatitis or HIV was caused by a product which was contaminated and supplied or administered by the body corporate.

It is suggested therefore that there is no prospect of finding enough evidence against a health board.

(v) Medical Staff

If a doctor or other medically qualified person administered an infected treatment to a patient who subsequently contracted hepatitis C or HIV, issues of reckless conduct or

culpable homicide would arise if it could be established that that person was aware of the risks and administered the treatment in any event in a way that was indifferent to the consequences

The CPS advice document helpfully lays out some of the key issues that have to be considered in regard to this class of persons (at para3.6). The first of these is the causation problem again. Can it be established that the patient was infected by a particular product (ruling out other possible causes of infection), and if so can it be established that a particular doctor administered that product? It is to be doubted whether anything more than that the treatment was administered under the auspices of a particular hospital or health authority could be established in most cases. However, as can be seen from the case studies, the individuals concerned say they can prove they were infected from a particular product. Whether this can be proved to the satisfaction of a court is not known. Even if it can it does not appear to be indicative of criminal recklessness on the part of the doctors involved.

In the case of those individuals who died, there may well not be post mortem examinations. Where there has been an examination it is likely only to have been done by one doctor. This is only likely to increase the causal difficulties.

The real issue, however, is how can it be established that a doctor, using licensed products to help a life threatening condition was reckless? Was the doctor expected to ignore this expert advice and impose his own view? It is submitted that these questions cannot be adequately answered. Even if the could be answered in the affirmative it is suggested that it would not be in the public interest to prosecute medical staff who are acting in accordance with guidelines.

Other jurisdictions

Proceedings have been considered in some other jurisdictions. As was noted in the chronology there were proceedings in France. These were held before a specially constituted Constitutional Court. The court consisted of politicians as well as judges and is not a "court" in the sense that we would know it in Scotland. It returned convictions against a junior minister and acquittals against the former Prime Minister

and Health Minster, but the voting in the court reflected the political leanings of its members. In Canada proceedings are being considered. In Italy proceedings have begun, bit from what I can gather thee are at the instance of haemophiliacs rather than the state.

In Ireland, proceedings have begun against two senior officials from the Blood transfusion Service. These however, relate to the infection of woman who were given Anti-D to protect them from having rhesus negative babies, and are factually different.

In England, in much the same circumstances there has been no further enquiry because of the overwhelming difficulties that there would be in bringing a case.

It is suggested that nothing can be learned from these proceedings which relate to the different factual circumstances and legal systems in the countries where they were taken. If anything they could be argued to show that the authorities in a number of countries wrestled with the same difficulties as there Scottish counterparts.

Conclusions

The foregoing account is a snapshot of the factual background and the applicable law. It is suggested that from this the following conclusions can be drawn.

There is evidence that hepatitis C and HIV were spread through contaminated blood products. Whether this can be traced in the cases of individuals is another matter. The case studies indicate that some individuals infection can be traced back to particular batches of product. Whilst this may assist in establishing causation it does not take us forward in any other way. In the UK and in particular in Scotland there was not a self sufficiency in home grown blood product to supply the needs of the haemophiliac community. Officials and clinical staff were faced with a situation in which haemophiliacs required treatment which could have been the difference between life and death for individual patients. To combat this they treated the patients with licensed products. They appear to have been in the position where not to treat the patient could have lead to the death of the patient.

All of this is against a background of conflicting expert opinion as to what the side effects of treatment were. When the side effects were fully recognised efforts were made to combat this by heat treatment. Although Scotland was not the first to introduce this and was behind England, it can be seen from the facts outlined above that SNBTS was making progress with their own research. To simply abandon that research, which was progressing satisfactorily and adopt the processes that were being developed elsewhere would have been remiss of them. Those other processes were equally as untested as the SNBTS's own methods. Their efficacy was unknown. It has to be remembered that this was at the cutting edge of research. It is also vitally important to remember that hepatitis C was not isolated and designated as such until 1989, after successful methods of heat treatment were introduced. Against the background of the fact that SNBTS did not know what pathogen they were looking for, as science had not yet progressed to the extent where it had been discovered, their failure to introduce a method of heat treatment cannot be described as reckless.

The benefits of the treatment, and indeed the necessity to treat haemophiliacs outweighed the risks such as they were known. According to the Report of the Lindsay Tribunal in Ireland (at page 98),

> "The Tribunal has formed the view from this evidence that the consensus which existed in the late 1970's and early 1980's that NANB hepatitis was relatively mild or benign did change as the results of studies became available showing the condition to have potentially serious consequences for some people infected by it. A number of experts came to regard it as a serious disease with significant long term consequences, especially and increasingly after approximately 1985. That view did not, however, come to be universally held in the relevant medical and scientific communities until after 1989."

This is the crux of the matter. The prevailing view until 1the late 1980's, by which point Scotland was virtually self sufficient and successfully heat treating blood was that hepatitis C was not life threatening or severe. The treatment was potentially life saving and appropriate research continued.

That is not indicative of recklessness.

In regard to the allegation that haemophiliacs were tested without their consent, there is no evidence of criminal behaviour. At most this is an issue to be taken up with professional bodies.

In the circumstances, the allegations made appear to be appropriate for civil litigation. This is a route that many individual haemophiliacs are following. One of the case studies indicated by the police shows that a criminal enquiry is likely to delay rather than hasten these actions as any admission of liability could have a serious effect on a criminal case. The allegations appear to be made to a large extent as a result of frustrations on the part of haemophiliacs that their calls for a public enquiry have been rebuffed.

Recommendations

It is submitted that there is no evidence whatsoever of any criminal activity in this whole affair. In these circumstances I recommend that Crown Counsel instruct that there be no further enquiry by the police into the allegations.

I look forward to receiving Crown Counsel's instructions.

STEPHEN MCGOWAN
High Court Unit
16 December 2003