HAEMOPHILIA

CONSIDERATION OF CRIMINAL PROCEEDINGS IN RESPECT OF THE USE OF CONTAMINATED BLOOD PRODUCTS

Submitted 17 April 2003

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Area 9
'H' CID Operations
Strathclyde Police

SCOTTISH HAEMOPHILIA GROUPS FORUM LETTER DATED 05.12.02

CONSIDERATION OF CRIMINAL PROCEEDINGS IN RESPECT OF THE USE OF CONTAMINATED BLOOD PRODUCTS

CHRONOLOGY/BACKGROUND

In a letter dated 5 December, 2002 (Appendix 1) a Mr GRO-A GRO-A, a representative of the above forum and a "severe" haemophiliac wrote to Chief Constable Andrew Cameron, Central Scotland Police.

Mr Cameron is President of ACPO Scotland and Mr GRO-A requested that he instigate enquiries to establish whether the supply of blood products to haemophiliacs in Scotland may merit a criminal investigation.

In a letter dated 24 December Mr Cameron wrote to ACC Graeme Pearson, Strathclyde Police, Secretary ACPOS Crime Standing Committee. He requested examination of Mr GRO-A letter to establish whether this was a matter for Scottish Police Forces to pursue.

On 16 January Detective Superintendent Stephen Heath, Strathclyde Police 'H' CID Operations was allocated the enquiry. His remit was to review circumstances and establish whether any crime may have been committed. The views of the Crown Office were requested.

Detective Superintendent Heath established that a similar review had recently occurred in England and Wales. Rather than duplicate investigations a copy of their report and any subsequent response from the Crown Prosecution Service was requested.

During the intervening period other matters led to the reprioritisation of the Haemophilia Review. On 5 March, 2003 Detective Superintendent Heath met with Mr GRO-A and colleagues at Stirling Police Office.

On 10 March the Crown Prosecution Service Advice Document was received and following a telephone conversation with Mr W Gilchrist, Deputy Crown Agent (28.03.03) the report was forwarded to his office.

ADDITIONAL ENQUIRIES – SCOTLAND

In this Review reference will be made to the CPS Advice Document together with the study of four Scottish cases where "causation" and the audit trail of blood products supplied to an individual can apparently be shown.

The CPS document provides a clear background to haemophilia, its treatment and the production and supply of blood products. It is not considered necessary to repeat details contained in that report which are common to the United Kingdom.

There are two areas where criminality may have occurred:-

- The continued supply of blood products to haemophiliacs when awareness existed that such supply was likely to lead to the recipient sustaining life threatening or seriously debilitating infection.

- The blood testing of haemophiliacs for such infections without their knowledge or permission and subsequent failure to notify those who tested positive.

Such action is alleged to have caused infection transference to family members and to have deprived haemophiliacs of the knowledge to seek treatment or alter their lifestyles.

MEDICAL KNOWLEDGE/AWARENESS

Paragraph 1.10 (2) of the CPS report indicates a chronology of known publications and medical studies. The following additional publications and studies are considered relevant:-

1966 Dr J Garrot Allen, Stanford University School of Medicine, published and presented the following to the American Surgical Association. Extract:-

"The paid donor is often a cloistered resident of skid row where he and his colleagues enjoy frequently the practice of the communal use of unsterile needles and syringes for the self administration of drugs .... There are also other unsanitary practices that prevail among this kind of population which favour repeated exposures to infectious hepatitis as well. Still another contributing factor higher in this group than in the general population is that of alcoholism which appears to make such individuals more susceptible to an initial infectious or serum hepatitis.

These paid donors have been variously described in many other papers as narcotics, dope addicts, liars, degenerates, unemployed derelicts, prison narcotic users, bums, the faithless, the undernourished and unwashed junkies, hustlers and ooze for booze donors. Many are said to give fictitious names and addresses to sell their blood to different blood banks and to traffic in black markets of social security cards rented for 25 cents or so to serve as identity cards at blood banks."

1996 Plasmapheresis Conference

The conference highlighted a number of health risks to donors and the following.

"In many states blood obtained from prisons is used for commercial purposes. The first plasmapheresis programme started by Cutter Laboratories, a pharmaceutical firm of Berkeley, California began in a prison setting. In Georgia in 1966/7 a local hospital seeking blood and a pharmaceutical firm were "clashing head on" for the rights to obtain blood from prisoners in the Reidsville State Prison. By 1968 bids or tenders were being made in various

areas by pharmaceutical firms operating plasmapheresis methods and other commercial interests for monopoly rights over prison blood.

In terms of ethical principles therefore there is a fundamental difference in the official policies adopted in regard to prison donors in the United States and England".

1966 Hepatitis among prison inmate plasmapheresis donors in 3 state prisons – by Ronald F Johnson, CDC Public Health Services, US Department of Health, Atlanta

The study highlighted the hepatitis risk of using prison plasma donors. The risk was far higher than in the general population of America. (American prisons were a common source of donors for plasmapheresis to make plasma products for haemophiliacs). In the UK collection of blood from within a prison population was banned on the grounds of safety.

1968 Journal of American Medical Association "Transfusion Hepatitis Arising from Addict Blood Donors" by Stephen N Cohen MD and William J Dougherty MD. Warned of hepatitis risk from using addict donors at US blood banks.

1968 British Medical Journal 20 April "The Price of Blood" by Arie Zuckerman warned against using imported plasma from paid donors on safety grounds.

1970 First evidence of Non A Non B Hepatitis (NANB)

1970 A pivotal book entitled "The Gift Relationship" by Richard Titmuss published by Allen and Unwin.

The book compared the UK Blood Transfusion Service with the US and commented strongly on the failures of the American system to protect against Hepatitis. The book is frequently quoted in the field of haematology and was referred to by Dr Owen, the Health Minister in 1974 when endeavouring to gear the Health Service in the UK to become self sufficient in the production of blood products.

1972 Serum Hepatitis and the Paid Donor by Martell J Dailey MD, Williamston, NC, USA.

The article indicated a clear link between paid blood donors and a greatly increased risk of hepatitis.

1972 Journal of the American Medical Association, 31 July. Hepatitis and clotting factor concentrates, University of California, Los Angeles.

The article documented concern over increased risk of hepatitis infection in the United States observed by haemophiliacs following use of the new treatment clotting factor concentrates.

1973 Britain licences the import of plasma concentrates from the US.

Prior to this year Cryoprecipitate used to treat haemophiliacs. Originated from small pools of donors who were volunteers and unpaid. Incidents of Hepatitis in general population very low in the United Kingdom at that time (National Blood Transfusion Service statistics).

1975 World in Action documentary "Blood Money".

Contributors included Dr Arie Zuckerman, a hepatitis expert who visited 10 plasmapheresis centres in the US who supplied products to the UK. The programme commented:-
"the estimated hepatitis rate from imported American factor concentrates is 100%."

1975 (2 August) – Lancet Article

This is an expansion of comment made in the CPS Advice document and is relevant to some of the Scottish cases.

The outcome of the study indicated that amongst others the following measures might lessen the likelihood of infection.

- Commercial Factor 8 concentrates should be reserved for the treatment of life threatening bleeds in all haemophiliacs and for covering major operations.

- If used for treatment commercial concentrates should be reserved for severely affected haemophiliacs since they are more likely to be immune to Hepatitis A and B. Treatment should be carried out by experienced staff who are aware of the risks of using large pool concentrates.

1975 World Health Organisation Guidelines: The Collection Fractionation Quality Control and Uses of Blood and Blood Products

"Countries with a low incidence of Hepatitis should not use whole blood or blood products obtained from source material collected from an area in which there is a high incidence of Hepatitis".

1975 Outbreaks of Hepatitis directly linked to imported factor concentrates. Several studies published.

UK Haemophilia Centre Directors issue guidelines recommending that children are treated with older, safer Cryoprecipitate. Adults not given this choice.

Late 1970's Seven Year UK Study launched under Professor Preston et al on Liver Disease and Haemophiliacs.

Government ask UK Haemophilia Directors Association to store information on suspect batch numbers. Certain US products and companies are identified as high risk.

1981 Non A Non B Hepatitis. Book by R J Gerety.

Examined infectivity levels from prison plasma. Symptoms identified for acute and chronic NANB.

Early 1980's Warnings from US regarding haemophiliacs dying from Immune Problems.

1982 Centre for Disease Control, Atlanta.

Consensus of experts that Aids blood borne. US plasma companies warned to stop using high risk donors.

1983 Public Health Laboratory Service (PHLS).

Writes to UK Government calling for urgent withdrawal of all US blood products manufactured after 1978 - risk of Aids.
First cases in US and Spain of Aids symptomatic haemophiliacs. Common factor is the use of US concentrates.
Wales – first report of Aids in UK haemophiliac.

25.11.84 Mail on Sunday Article – Susan Douglas.

Links Aids to haemophiliacs and US blood products. Causes medical furore. Author subsequently censored by Press Association.

1983/84 Haemophilia Society communicates with Health Department requesting that supply of imported products continue "No Alternative" argument (discussed later in this review document).

1985 Haemophiliacs tested for HIV virus (often with knowledge or permission).

1,263 eventually test positive nationally. Many are not informed. A high percentage are now dead.

1985 Heat treatment of blood products introduced to eliminate virus (see Scottish landmark dates contained in subsequent section of this report).

Scotland allegedly lagged behind England in heat treatment. Some hospitals indicate that non heat treated products are used up first. Some companies heat treat at the wrong temperature.

1985 Refer to previous entry entitled Late Seventies – study by Dr Preston et al published in the Lancet. The article is entitled "liver disease in haemophiliacs – under estimated problem".

Study concluded that the majority of liver disease in haemophiliacs was probably a result of NANB hepatitis. Predicts future increased problems and hopes for safer synthetic treatment.

NB:- HIV litigation by haemophiliacs founds on the premise that if warnings had been heeded re hepatitis contamination and safety precautions taken then risks from Aids would have been drastically reduced.

1989 NANB isolated and officially designated Hepatitis C

Testing for Hep C
UK Government does not utilise first generation Hep C test in 1989 as they indicate there are too many false positive tests. Other European countries utilise the test. Many haemophiliacs secretly tested with first generation test and then with second generation test 1991/92.

Many not told of positive results until 1994 or later.

Such testing is against GMC published guidelines.

1991 HIV Litigation/Hepatitis waiver.

Ex gratia Government payment with no acceptance of liability. Solicitors agree to this deal and files are sealed for 30 years (Appendix 2 – Kenneth Clarke's statement).

HIV settlement haemophiliacs sign the waiver that they will take no further action. Haemophiliacs indicate that they were informed by solicitors that Hep C *"nothing to worry about"* and *"less of a problem that Hep A and B"*.

They now allege that they signed on this basis and contest the 30 year seal of documents. Many Scottish haemophiliacs did not sign the waiver and still received the financial settlement.

Haemophiliacs refer to a letter from John Horam then Health Minister dated 12.03.66 in response to a question regarding Government knowledge of Hep C when the waiver signed. Extract:-

"Although it is correct that more information on the natural history of Hep C is becoming available ..... At the time of the HIV settlement it was known that in some cases NANB (now Hep C) could lead to serious liver disease and some deaths had already occurred in UK haemophiliac patients."

Haemophiliacs also refer to the House of Lords ruling in 1984 stating that a patient has the right to know of substantial risks involved in taking treatment.

1993 France – Special court created to try ministers for alleged crimes re supply of contaminated blood products and Aids testing.

1994 Many haemophiliacs told they have Hepatitis C. 99% of those with HIV have Hep C.

1995 Haemophiliac Society launches Hep C campaign for recompense package. Initial campaign excludes haemophiliacs who are co infected with HIV and Hep C. This splits the haemophiliac community and bad feeling still exists. (Now includes all haemophiliacs following significant pressure from haemophiliac breakaway groups.)

Hepatitis C now overtaking HIV as biggest killer of haemophiliacs in Europe and United States.

1996 Concern expressed re the possibility of CJD being transferred via blood products.

1998 British Plasma banned over CJD issue.

Pressure groups via media drive the case of haemophiliacs on a number of issues. Private Eye, Guardian and others publish articles. Meridian TV documentary "Blood Brothers".

1999 March – French Prosecutions. French Health Minister found guilty of manslaughter. Two doctors also convicted and received jail sentences.

2001 Haemophiliacs informed that they have been exposed to the theoretical risk of exposure to CJD as blood has been used from donors who subsequently died of Variant CJD.

2001 May Haemophilia Action UK meet with Lord Hunt to present campaign aims.

2001 July Response from Lord Hunt refusing public enquiry.

2001 Canada Public enquiry and criminal investigation.

Red Cross found legally negligent over donor sourcing. Criminal charges pending for plasma brokers and others.

2001 Eire Public enquiry. Lindsay tribunal ongoing.

2002 Haemophilia Action UK increases campaign work and employ US solicitors to sue US plasma companies on a no win no fee basis which does not involve legal aid.

Police in England and Wales requested to consider criminal investigation.

Italy brings criminal charges against health officials and plasma companies.

2003 Haemophilia Action UK launch campaign to stop international trade utilising blood products from paid donors in line with EC proposals.

2003 MAIN OBJECTIVES – HAEMOPHILIA ACTION UK

- Recombinant safe treatment for all haemophiliacs
- A full and open public enquiry
- Recompense on a parity with Eire
- Justice through the UK legal system and explore Human Rights Act
- US litigation. UK haemophiliacs versus US plasma companies
- Haemophilia Action UK calls for a world-wide ban on the use of paid donors and resulting products.

SCOTTISH LANDMARK DATES – RECENT HISTORY

24.10.2000 (Appendix 3)
Scottish Executive publishes results of fact finding exercise re the alleged delayed introduction of heat treatment of Factor 8 in Scotland.

14.03.2001
Scottish Parliament Health and Community Care Committee. Debate on Hep C and treatment of blood products for haemophiliacs (meeting 8.2001)

"BENEFITS OF TREATMENT OUTWEIGHED RISKS"

This is a "defence" raised by Doctors, Politicians and Plasma companies indicating that the withdrawal of commercially produced blood products would have had a more life threatening impact on haemophiliacs than continued supply.

It is relevant to note that between 1969 and 1974 prior to widespread usage of Factor concentrates 71 haemophiliac patients died, not all from haemophilia. During a subsequent 5 year span following adoption of Factor 8 concentrates, 413 haemophiliacs died from HIV. 99% would also have been co-infected with Hepatitis C and these figures do not include deaths from that virus.

Appendix 4 is a Parliamentary response from Tony Newton, Minister of Health, dated 11 January, 1988 to a related question from Frank Field MP. The response provides an understanding of this view.

The argument was rejected in US and Canadian litigation cases. Additionally haemophiliacs argue that prior to the use of commercially produced blood products Cryoprecipitate fulfilled their treatment needs, ie, there were alternative treatment methods available which were much less likely to result in recipients contracting life threatening diseases.

EXAMPLES OF INDIVIDUAL SCOTTISH CASES

Case A

GRO-A resides in New Zealand. In July 1980 then 7 years of age, he was on holiday in Scotland with his family.

He is a severe haemophiliac who had always been treated with Cryoprecipitate. In early August 1980 he suffered a "bleed" and was taken by his father to Yorkhill Hospital, Glasgow. His "bleed" was treated by the use of Factor 8 commercial products. This was the first time he received Factor 8 although he subsequently received Factor 8 in New Zealand in 1987.

In 1985 having returned to New Zealand it was discovered GRO-A had contracted HIV and Hepatitis C. It is the reporting officer's understanding that this was the first case of HIV to be discovered in New Zealand.

Following 19 years of enquiry and investigation throughout the world by his father it has been established that he was infected at Yorkhill Hospital. The hospital have accepted that the contamination occurred there but have denied liability. His father has batch numbers of the product which came from the Armour Plasma Company, USA.

He has been offered a high six figure dollar sum in settlement with no acceptance of liability.

Mr GRO-A indicates he has evidence that Yorkhill Hospital were aware in early 1980 that contaminated blood products had been purchased by them. He feels strongly that his son was unnecessarily contaminated and should have been informed of Yorkhill's awareness of their possession of such blood products.

It may be the case that others treated with the same batch numbers have suffered similar problems.

Case B

Robert Mackie (53) is a severe haemophiliac who resides in the GRO-A area of Scotland. He is a vociferous individual and due to his style of personal campaigning has over the years alienated himself from several hospitals and their staff.

Until 1978 he received Cryoprecipitate treatment. He subsequently self injected Scottish National Blood Transfusion Service (SNBTS) produced Factor 8.

On 7 June, 1981 he suffered a bleed in his left elbow and attended Edinburgh Royal Infirmary. He was treated with commercially produced US Armour Products Factor 8. This is the one and only time he received imported Factor 8. He sustained a short term bad reaction to the treatment. He later continued self administrated use of SNBTS produced Factor 8.

In 1984 he began experiencing flu like symptoms and aware of the contaminated blood scare felt that he may have contracted some form of blood borne infection.

Because of this he had previously altered his personal lifestyle to avoid the possibility of passing any such infection to family members.

Mr Mackie indicates that prior to and after 1984 he was constantly in touch with the Haematology Department at Edinburgh Royal Infirmary to ascertain whether he had contracted any blood borne viruses.

His position is that he was not informed until 1987 that he had been infected with HIV. Additionally he indicates he was not formally informed until January 2003 that he had contracted Hepatitis C.

He has official letters which confirm this position and that he was tested positively for HIV in 1984 and Hepatitis C when testing was developed in 1992.

He indicates that he did not give permission for his blood to be tested in this manner.

Mr Mackie has a letter from Dr C A Ludlum, Consultant Haematologist, The Royal Infirmary of Edinburgh dated 17 September, 1987 sent to his solicitor which states:-

"in my opinion he became infected with HIV as a result of transfusion of batch 023110090 of SNBTS Factor 8".

This indicates that the American imported product was not the cause of his infection and tests for HIV on Mr Mackie indicate he was anti HIV negative on 27 March, 1984 and positive on 29 May, 1984. This apparently ties in with the dates during which he was supplied with the above batch number.

NOTE:-
It is Mr Mackie's position that several haemophiliacs including members of his family received the SNBTS product around that time and have subsequently died. He indicates that a donor to this batch was traced and established to be a homosexual HIV carrier. This has not been verified by the reporting officer.

Appendix 5 indicates opinion of senior counsel in the case of two Scottish brothers GRO-A and GRO-A both of whom have subsequently died. Mr Mackie supplied this document to the reporting officer indicating that the GRO-A contracted Aids from the same SNBTS batch provided to him by Edinburgh Royal Infirmary. His position is that their wives also contracted Aids and may also have died.

Case C

Bill Wright (44), resides in GRO-A and is a mild haemophiliac.

He is an active individual and in May 1986 whilst rock climbing sustained an injury to his thigh. He attended his GP who advised him to rest his leg. A few days later he suffered a re-bleed on the site and experienced severe pain. He attended Edinburgh Royal Infirmary Casualty Department.

Due to the pain he was administered Entinox, a gas inhaled painkiller. His subsequent recollection of events is therefore unclear.

He does however recall that following several hours of waiting he was administered an injection which he now knows and can prove was Factor 8. This is the one and only occasion he received Factor 8.

The next day he was visited by Dr Ludlum who informed him he had been administered Factor 8 and stated he had a "fifty per cent chance of contracting NANB Hepatitis".

Following a period of recuperation and some 6 weeks later having consumed alcohol he felt nauseous and began vomiting.

He returned to hospital and underwent a series of tests. There were indications he had contracted NANB Hepatitis which he alleges was described to him as *"as no big deal"*.

He married in August of that year and for some time had unprotected sex with his wife until Hepatitis C was categorised in 1991.

He was thereafter diagnosed as having chronic active Hepatitis C.

It is not known whether his wife or his child have contracted Hepatitis C.

In 1996 via solicitors and in order to prevent time bar he served a summons on Lothian Health Board and the Secretary of State for Scotland.

Proceedings are not currently active.

Case D

Case D is one of the four cases referred by the Haemophiliac Forum to the reporting officer.

The subject is a 16 year old boy resident with his family in an isolated community in Scotland. The community are apparently unaware of his situation and the family fear they will be ostracised should his case receive publicity and details of his medical condition published.

Currently they are represented by Frank McGuire of Thompsons Solicitors, Berkeley House, 285 Bath Street, Glasgow. Mr McGuire is a solicitor specialising in civil law and it is understood he recently acted for a number of asbestosis victims.

The reporting officer has been in contact with Mr McGuire on several occasions during this review. He has fully explained the nature of the review and that his client was referred by the Forum as a case meriting investigation.

Following discussion the reporting officer sympathised with Mr McGuire's client's position and indicated provision of anonymity at this stage of the investigation. Mr McGuire has been obstructive failing to return calls and to supply any details regarding his client's condition or treatment history.

It is understood that Mr McGuire is currently involved in litigation with a number of companies and institutions. A possible criminal investigation might therefore negatively impact on any financial settlement.

As his client was not born until 1986 and apparently has a number of blood borne viruses apparently arising from Factor 8 treatment, he is clearly a case meriting investigation.

SUMMATION – SCOTTISH CASE SELECTION

The cases studied are understood to represent a "snapshot" of numerous cases which have not been examined by the reporting officer.

All of the individuals and families concerned are motivated, educated and via an organised pressure group are knowledgeable in methods of utilising the media and applying political pressure.

In the cases studied the reporting officer has viewed documentary evidence which indicates an audit trail of their receipt of Factor 8.

CONCLUSION

This document is not intended as an evidential police report, but an overview of circumstances to aid decision making in establishing whether a criminal enquiry is merited.

Clearly any criminal enquiry would have implications for the Crown and the Scottish Police Service which may include the following:-

- The compilation and provision of a clear remit in terms of reference to the Senior Investigating Officer.
- Considerable media and public interest.
- The establishment of a centrally located HOLMES incident room.
- Staffing to facilitate a full major incident structure utilising resources drawn from across the Scottish Police Service.
- A lengthy international investigation.

GRO-C

STEPHEN HEATH
DETECTIVE SUPERINTENDENT
AREA 9 'H' CID OPERATIONS
STRATHCLYDE POLICE

17 April 2003

APPENDIX 1

MR GRO-A 'S LETTER

DATED 05.12.2002

4532/02/cc

GRO-A

GRO-A

Chief Constable Andrew Cameron,
Central Scotland Police,
Police Headquarters,
Randolphfield,
Stirling,
FK8 2HD.

5/12/02

Dear Mr Cameron,

I am a representitive of The Scottish Haemophilia Groups Forum.I got your contact details from the ACPOS wesite and I hope this is the correct way to start communications with you.
The reason I am writing is one which is very serious and wide ranging. I am not an expert in the subject but all of the following, I believe to be true.I am not sure if you are aware of the subject I am writing to you about so, I will start at the start.
I am a 27 year old, severe haemophiliac (a blood disease where the clotting factor is missing) and I, like others, have for many years been treated with blood derived medical products such as Factor VIII and IX.
There are two main sides to this subject. The first being, during the seventies and eighties successive governments ignored warnings that importing blood products from American Pharmeceutical Companies was at best, unwise and at worst, criminal. The worst scenario proved to be true, as they harvested their blood stocks from some of the most medically dangerous sources possible, including the gay communities of San Francisco in the 70's and 80's, inner city jails, down and out drop in centers, skid row etc It was even proven that they actively targeted gay men, as their blood had a very high incidence of Hepatitis B and they would use it for a HepB vaccine. However they then used the surplus to give to Haemophiliacs. To make matters worse, one of their Doctors pioneered a heat treating process which would have eliminated all of these virus' around 1971, but they fired him for trying to introduce an unnecessary expense into the production process.
I am involved with a large law firm from San Francisco who are sueing these companies on a no win, no fee basis, which is the only way we could possibly manage it. The firm have already taken action on behalf of 8,000 American haemophiliacs and have won out of court settlements of around $700,000 each. Incidentally, recently the Canadian Police have charged the Armour blood company, the Canadian Red Cross, and 4 doctors with various offences including criminal negligence resulting in bodily harm etc. The same infections have happened all over the world with these American products, including at York Hill Hospital, Glasgow, where I was treated from age 18 months to 10 years. During this time 66 children contracted HIV and HepC, of which, only 19 are still alive apparently.
The doctor who treated us, a Dr Willoughby, left in the early eighties, as the AIDS epidemic was being indentified, with a question mark over his conduct and emmigrated to Australia.
The thing is, people in Scotland were told that it was only York Hill Hospital that used the American products, but in the last few weeks, a Glasgow Proffessor has said that many hospitals all over Scotland used these products – a statement that would correlate with many patients'

accounts. We have taken this point up with MSPs but I would also like to know if this is a matter for the police?

The second part of this subject, involves what was happening during this time in the UK. In Scotland, our Executive maintains that they brought in this heat treating process as early as was possible, in 1987.
However, we do not believe this is true, because in France it was introduced in 1984, 3 years earlier than Scotland, and this is still seen as criminally late. In fact, their former Prime Minister, Health Minister and many transfusion services officials were put on trial and although the Prime Minister was not found guilty, the rest were and have served jail sentences and had large fines imposed.
We actually have much information which shows that our Blood Transfusion Services, Government Health Ministers and Haemophilia Center Directors (Doctors and Professors) knew of the dangers, but were willing to keep quiet and carry on using unsafe products.
One letter from these Blood Bank Meeting Minutes which I have in my posession is from a Dr Contreras and says –
"If we consider that half of the blood transfusion recipients are dead one year post – transfusion, then the cost effectiveness of anti-HCV screening of blood donations should be critically reviewed"
There is a stream of information like this, although the more damning meeting minutes are locked in a Library in Westminster, and have been refused to us.
Despite years of campaigning, there has never been a Public Inquiry into all of this and we have never been allowed legal aid, so basically all effective legal and political avenues have been closed to us.
Recently though, in England, a Haemophilia group have been talking with the English ACPOS eqiuvalent and they have been looking into whether or not there is enough evidence to warrant an investigation.
This is essentially what I am writing to you, to ask for. We have tried absolutely everything to get to the bottom of what actually happened and I'm afraid the general consensus among the Haemophilia community is that this is a cover up.
If you can let me know what your thoughts are on the possibility of an investigation of some sort I would be extremely grateful.

Yours Sincerely,

GRO-A

GRO-A

TOTAL P.03

APPENDIX 2

KENNETH CLARKE

STATEMENT

20.09.1990

Department of Health
Richmond House
79 Whitehall
London SW1A 2NS

PRESS RELEASE

Telephone 071-210 5963

48/D24/90

90/466

20th September 1990

KENNETH CLARKE'S STATEMENT ON COURT OF APPEAL JUDGEMENT CONCERNING HAEMOPHILIACS

Kenneth Clarke, Secretary of State for Health, today issued the attached statement on the judgement of the Court of Appeal concerning action brought by a number of haemophiliacs.

[ENDS]-

"It is an appalling tragedy that so many haemophiliacs were infected by HIV as a result of their NHS treatment. For this reason, the Government has quite uniquely paid the victims at least £20,000 each to help with their problems and we have paid more in cases of hardship. We have made it clear that we will review our expenditure of £34 million so far and top up the funds of the Macfarlane Trust if that becomes necessary.

"In my opinion, on the factual information before me at the moment, this tragedy was no-one's fault. The doctors and staff gave the patients the best medical treatment available in the light of medical knowledge at the time. The patients could have died then if they had not received that treatment. When the blight of AIDS first struck haemophiliacs suffered the same appalling consequences throughout the western world.

"Today's judgement will enable the Judge to see a further batch of documents in addition to those already disclosed. I am advised that they do not contain anything which will reveal that anyone was at fault.

"It may be argued that we should pay compensation to the victims regardless of whether anyone in the Health Service or the Department of Health was negligent or to blame for the tragedy. I believe it would have very grave consequences for medicine in this country if compensation was paid whenever a patient who had been treated properly by his or her doctors later suffered awful side-effects or died. We rely on the clinical judgement of the medical and other professions when patients are treated. This principle of only paying full compensation when negligence is proved is not unique to the case of the haemophiliacs. It could arise over and over again whenever a patient suffers a harrowing experience after receiving treatment.

"In the USA, the practise of medicine is now dominated by these issues of compensation and their resources for health care cut back as a result. That should never happen here.

APPENDIX 3

SCOTTISH EXECUTIVE

NEWS RELEASE

24.10.2000

CAS

SCOTTISH EXECUTIVE

Information Directorate

St Andrew's House
Regent Road
Edinburgh EH1 3DG

Telephone: 0131-244 1111

News Release

24 October 2000

BLOOD PRODUCTS AND HEPATITIS C
- FACTFINDING EXERCISE PUBLISHED -

Health Minister Susan Deacon has concluded that Scotland's national blood authority was not negligent in its efforts to remove the risk of contracting Hepatitis C from blood products in the 1980s.

The announcement follows an exhaustive fact-finding exercise into the heat treatment of blood products in the mid 1980s, the report on which has been published today.

The Minister asked officials to undertake this exercise last year after concerns had been raised that haemophiliacs who contracted the Hepatitis C virus through blood products in Scotland need not have been exposed to such a risk.

The report concludes that the Scottish National Blood Transfusion Service (SNBTS) worked actively during the 1980s to find a way of eliminating the Hepatitis C virus. This virus, much better understood today, had begun to pose a threat in infecting vital blood products - such as Factor VIII - the potentially life saving product used by haemophiliacs.

The report confirms that the SNBTS did not develop successful heat treatment until after the Bio Products Laboratory (BPL), their counterparts in England had done so. The report concludes, however, that the technical processes involved were complex, and that the method used by BPL was not actually proven to eliminate the virus until after SNBTS had also managed to develop a comparable method.

Ms Deacon said:

"The cases of people contracting Hepatitis C in the 1980s are a real human tragedy. I have listened carefully to the points raised with me and have given the matter very careful consideration.

"Having studied all the facts, I have concluded that there is no evidence that the relevant authorities did anything other than their best for patients. As a result I do not believe that the NHS should pay compensation for non-negligent harm to those haemophiliacs who contracted Hepatitis C during the period covered by the report.

"When I announced this exercise I stressed that we would – as a new Executive – take a fresh look at the evidence. And we have done this.

"But we have seen no new evidence and nothing to demonstrate that compensation is owed. I fully understand that there will be disappointment at the outcome. However, our decision is one based on the facts as they stand before us now – some 20 years on. Medical treatment is always complex and often involves a balance of risks, not least the necessity of using blood products to protect the lives of haemophiliacs.

"I do not, for one moment, want to underestimate the suffering which has occurred in these cases. But the sad fact is that the evidence shows that nothing further could have been done to avoid this unforeseen outcome given the level of scientific knowledge at that time.

"Last month's publication of the Scottish Needs Assessment Programme (SNAP) report on Hepatitis C, sponsored by the Scottish Executive, shows how important it is to ensure that we improve our understanding of the prevention and treatment of Hepatitis C. It must now be Scotland's priority to ensure that treatment and care are put in place for all of those people infected."

Commenting on the results of the factfinding exercise, Professor Mike Greaves, Professor of Haematology at Aberdeen University said,

"The development of factor VIII concentrates represented a major advance in the management of the life-threatening bleeding disorder haemophilia A. Use of concentrates in treatment has had an overwhelmingly beneficial effect on the crippling long-term consequences of recurrent bleeding and has saved lives. An important and sometimes tragic side effect of this treatment has been the transmission of the virus responsible for Hepatitis C.

"The Scottish Executive has produced a carefully researched and detailed report on the events relating to the introduction of heat treatment of factor VIII concentrate for use in haemophilia in the 1980s. The information provided to patients with haemophilia about the risks of contracting hepatitis from blood products at that time has also been investigated. It is clear that the technical challenge of producing virus-free factor concentrates was substantial.

"It is clear that the need for the rapid development of safer products was recognised by SNBTS and that timely and concerted efforts were made to this end.

"The report from the Scottish Executive represents a thorough and balanced assessment of the complex clinical and scientific problems surrounding the issue of the development of the safe and effective factor VIII concentrates which are essential for the treatment of haemophilia A."

NOTE TO NEWS EDITORS

1. The remit of the exercise was to examine evidence about the introduction of heat treatment in Scotland for factor VIII in the mid 1980s, to assess whether Scottish haemophilia patients were exposed to the risks of the hepatitis C virus longer than they should have been, given the state of knowledge at the time and to examine evidence about the information given to haemophilia patients in the 1980s about the risks of contracting hepatitis C virus from blood products.

2. CHRONOLOGY

Late 1983 – SNBTS prepare batch of pasteurised Factor VIII for clinical evaluation

January 1984 - First patient in clinical evaluation for SNBTS pasteurised Factor VIII suffers adverse reaction, and trial is abandoned.

1984 - 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 (NANBH) – not at that time recognised as hepatitis C. The Scottish National Blood Transfusion Service (SNBTS) decided to keep trying to develop pasteurisation.

December 1984 - SNBTS were able to heat treat a year's supply of Factor VIII at sufficient temperatures to render it HIV-safe.

September 1985 - BPL heat treating all of its Factor VIII at 80°C for 72 hours. This accounted for 25% of the requirement in England and Wales.

August 1986 - SNBTS produced the first trial batches of their new Factor VIII product heat treated to 80°C for 72 hours.

APPENDIX 4

PARLIAMENTARY RESPONSE

11.01.1988

DEPARTMENT OF HEALTH AND SOCIAL SECURITY
Richmond House, 79 Whitehall, London SW1A 2NS
Telephone 01-210 3000

From the Minister for Health

PO(3)9042/4

Frank Field Esq MP

11 JAN 1988

Dear Frank,

Thank you for your letter of 17 September about the use of Factor VIII by haemophiliacs. I am sorry for the delay in replying.

It may be helpful if I explain the structure established for the care of haemophilia patients in this country which was set out in a Health Circular in 1976. Designated Haemophilia Centres were listed where doctors with the particular expertise in this blood disorder were available to treat patients. This organisation still exists and directors of Haemophilia Centres meet regularly to pool information and expertise. Close contact with this group is maintained by the Department to ensure that our policies in this area reflect their professional view.

The first report of 3 haemophiliacs with an opportunistic pneumonia which was later associated with AIDS was published in the United States of America in July 1982, and it was to this that my reply to your Parliamentary Question on 5 May last year referred. Our records show that because of what was then considered the 'remote possibility' that there might be a connection between AIDS and commercial blood products, Haemophilia Reference Centre Directors responded swiftly by agreeing in September 1982 to establish a mechanism for collecting data in the UK. The details of this programme were sent to the Department in April 1983. At that time there were no known UK cases and even in the USA fewer than 10 haemophiliacs were suspected to have AIDS. Meanwhile, a Haemophilia Centre Director, through the Bulletin of the Haemophilia Society in the first quarter of 1983, advised haemophiliacs to continue to use Factor VIII because the risk from bleeding episodes far outweighed any risk of getting AIDS.

Briefing prepared for Ministers on media stories about AIDS in May 1983 indicated that, while there was no conclusive proof that AIDS had been transmitted by blood products, medical opinion tended to favour the theory that an infective agent such as a virus might be responsible. In July 1983, Lord Glenarthur stated in a Lords reply that, despite the absence of conclusive evidence, the Department was considering the publication of a leaflet indicating the circumstances in which blood donations should be avoided. Such a leaflet, asking those thought to be in a high-risk group for AIDS not to give blood, was circulated through the National Blood Transfusion Service in August 1983. There was regular contact by officials with Haemophilia Centre Directors, the Haemophilia Society, the Medical Research Council, and the World Health Organisation amongst others during this period.

Monday 11 January 1988

Written Answer

PQ 3013/1987/88
Han Ref: Vol
Col

31 Mr Frank Field (Birkenhead): To ask the Secretary of State for Social Services,
W when he will answer the letter sent by the honourable Member for Birkenhead on 17th September 1987, concerning the date Ministers were first informed of the dangers of HIV infection from contaminated blood products and asking for details of professional advice given to haemophilia centres regarding these dangers in 1983.

MR TONY NEWTON

I am replying to the hon Member today.

GRO-D

GRO-D

GRO-D

GRO-D

GRO-D

GRO-D