Witness Name: Peter Reynolds Foster

Statement No.: 1

Dated: [DATE OF SIGNING]]

Inquiry Ref: [……]

THE PENROSE INQUIRY

Witness Statement of Peter Reynolds Foster, date of birth [redacted], formerly head of research and development at the SNBTS Protein Fractionation Centre 1974 to 2008, formerly senior research scientist at the SNBTS Protein Fractionation Centre 1973 to 1974

I, Peter Reynolds Foster say as follows:-

The covering letter concerning my witness statement on AIDS/HIV states:

"*While your client may derive some assistance from the Preliminary Report, the Report may not include all material relevant to the matters in respect of which a statement is sought, in which case your client should include in the statement any material your client considers relevant to these matters, whether contained in the Preliminary Report or not.*"

The Schedule which describes the Issue in respect of which my statement is sought identifies under item (c) after "*significant progress towards self-sufficiency in the manufacture of blood products by the NHS in Scotland had been made*".

This is one of three aspects on which the 'Issue in respect of which a statement is sought'. Therefore, additional information on "*progress towards self-sufficiency*" and on the establishment of the policy of self-sufficiency by the UK Government may be relevant to the matters in respect of which my statement is sought.

Therefore, I have included in my witness statement additional information concerning self-sufficiency.

My witness statement is in four sections :

A. Additional Information on Self-Sufficiency.

B. A Chronological Response to the Matters Raised.

C. A Non-Chronological Response to the Matters Raised.

D. Appendices.

A. ADDITIONAL INFORMATION ON SELF-SUFFICIENCY

A.1. A Paper Entitled "Self-Sufficiency and the Supply of Blood Products in Scotland (with particular reference to the treatment of Haemophilia A): Author Dr P R Foster, October 2010.

I have prepared a paper on self-sufficiency and the supply of blood products in Scotland to assist the SNBTS in responding to enquiries from the Penrose Inquiry and wish to include this document with my witness statement (Section D. Appendix I) as it provides information which is not contained in the Preliminary Report.

My paper includes:

- the development of policies on self-sufficiency,
- planning for self-sufficiency,
- progress towards self-sufficiency in Scotland,
- the amounts of blood products used in the treatment of haemophilia A in Scotland annually in the period 1978-1984, including the use of cryoprecipitate as well as Factor VIII concentrates from both the SNBTS and from commercial sources,

- the annual availability of blood products for the treatment of haemophilia from the SNBTS from 1975 to 1987 in relation to average clinical use in the UK,

- comparisons with other countries, including England & Wales.

Although the Preliminary Report addresses this topic, there is material in my paper which has not been included in the Preliminary Report and which may be of assistance to the Inquiry.

A.2. The Policy of the United Kingdom Government on Self-Sufficiency

The policy of the UK Government in support of the principle of self-sufficiency provided the foundation on which "*significant progress towards self-sufficiency in the manufacture of blood products by the NHS in Scotland*" was made.

According to the Preliminary Report (para 5.20), this policy was established by the UK Government in 1974.

In December 1980, the new UK Government of Mrs Thatcher announced its support for principle of self-sufficiency. However, this decision was not automatic and was made only after a trades union (ASTMS) campaign against a proposal by the Government to privatise BPL (Elstree) and an investigation undertaken by journalists from Granada Television (World in Action).

I had a direct involvement in both of these activities.

A 2) i ASTMS

When I learned of the plan to privatise BPL from colleagues at BPL, I informed Mr Gordon Craig, Scottish Divisional Officer of ASTMS. The information that I provided resulted in Parliamentary Questions being put to the Minister of Health, Dr Vaughan, which led ultimately to a House of Commons debate of 15 December 1980 on the Blood Transfusion Service in which Sir George Young confirmed the Government's support of the principle of self-sufficiency.

I have a number of personal documents concerning the ASTMS campaign (see Appendix V).

I wrote again to Mr Craig on 25 January 1981 to encourage the Parliamentary Committee of ASTMS to visit PFC following their visit to BPL. This was arranged by Mr Craig and a delegation from ASTMS visited PFC on 26 June 1981 where, I understand, they were briefed by Mr Watt on the potential capabilities of PFC. It was following this briefing that Mr Craig wrote an article concerning PFC in Medical World (para 10.64).

A 2) ii. <u>World in Action</u>

I attended a meeting at BPL in September 1980 where Dr Lane, Director of BPL, described how Beecham's had visited BPL and were "*about to sign on the dotted line*". He appeared depressed and resigned to the sale of BPL to Beecham's.

Following the meeting, I visited a friend in London and mentioned the Government plan to sell BPL to Beecham's. Shortly after returning to Edinburgh I received a phone-call from a Mr Laurie Flynn. Mr Flynn explained that he was a journalist with World in Action; he had worked on the World in Action programmes of 1975, which had dealt with the topic of imported blood products (para 5.106) and had learned of the Government plan to privatise BPL from my friend. He was interested in undertaking an investigation and sought assistance from me. I told him everything that I knew of the privatisation plan and at his request gave him the names and contact details of people who might be able to assist him with his inquiries.

Mr Flynn subsequently contacted me a number of times to ask me to explain various technical matters and to advise me of the progress of the investigation, which was being undertaken by himself and his colleague Mr Michael Gillard.

In November 1980, Mr Flynn phoned to tell me that a World in Action programme was scheduled for transmission, but that he was required to seek a comment from the Minister of Health prior to transmission. He then phoned back to tell me that on learning of the investigation by World in Action, the Minister of Health had arranged a

parliamentary question to be put to him to which he responded "*…we have concluded that there is no place for a commercial company in the management of service, which depends on volunteer donors."* (Hansard, 26 November 1980, written answers column 102; Department of Health, FOI releases, document numbers 1965, 1966, 1967 and 1968).

The World in Action programme that had been scheduled for transmission was cancelled and the sale of BPL was not carried into effect (para. 6.97). Subsequently, on the 15th December 1980, in a House of Commons debate on the Blood Transfusion Service, Junior Health Minister Sir George Young stated "*The principle of self-sufficiency is one that the Government fully endorse."* (Hansard, 15 December 1980, column 187).

On 22nd December 1980 a revised version of World in Action entitled 'The Blood Business' was broadcast. In the revised programme, the reporter (Mr Flynn) commented "*The surprise "U turn was announced in a Written Answer to a Question conveniently tabled by a backbench conservative MP."* (transcript of World in Action transmission of 22 December 1980, Department of Health, FOI Releases, document number 1998).

A 2) iii <u>Impact on Scotland</u>

Although the proposal to sell BPL (Elstree) to Beecham's Pharmaceuticals is described in the Preliminary Report (para 6.97), the potential impact on Scotland is not considered.

The Preliminary Report does refer to a paper from DHHS official Dr Diana Walford (para 10.60, ref 67) in which Dr Walford warned:

"*The principal medical worry is presented by Beecham's intention to import plasma for fractionation. Unless it were Beecham's intention to process such plasma in an entirely separate plant or with complete duplication of all facilities in a single plant, it would be impossible to prevent contamination of the UK material with imported hepatitis viruses."* and "*If the DHSS did not agree to Beechams fractionating*

imported plasma other than in a separate plant etc, Beechams would probably feel constrained to obtain the necessary extra volume of plasma by buying it in the UK. That is, it is likely that the company would establish plasmapheresis centres in this country for paid donors and thereby seriously undermine the voluntary donor principle in the UK."

As well as signally a move away from the principle of self-sufficiency by the UK Government, the paper from Dr Walford also demonstrates that the proposal threatened to increase the risk of transmission of blood-borne infections. An increased risk of hepatitis transmission via commercial concentrates was already known (para. 6.94, ref 113) and plasma imported from the USA, at this time, would unknowingly have been contaminated with HIV.

It is difficult to imagine that the loss of Government support for self-sufficiency together with the promotion by Government of commercial manufacture in the UK, in conjunction with the Blood Transfusion Services of England & Wales, would not have had some impact in Scotland, although the degree to which patients in Scotland would have been affected is a matter of conjecture.

B. A CHRONOLOGICAL RESPONSE TO THE MATTERS RAISED

B 1 1981

I first became aware of AIDS from a television programme in late-1981 in which a strange illness amongst homosexual men in the USA was described. Although the cause of the illness (referred to at that time as Gay Related Immune Deficiency – GRID for short) was not known, the use of recreational drugs by homosexual men was put forward as the most likely cause.

B 2 1982

i) ISBT Congress, Budapest, 1-7 August 1982

On Thursday 5 August 1982, I attended a symposium at a joint meeting of the 19th Congress of the International Society of Haematology (ISH) and the 17th Congress of the International Society of Blood Transfusion (ISBT) which began at 17.00 hours

and was entitled "*Present and future research challenges in haemophilia treatment*". At this symposium, the chairman, Dr Aledort, reported that three people with haemophilia had developed pulmonary infections characteristic of AIDS. My memory of the proceedings is that this report passed without comment and with no interest being shown by the delegates present. I assumed that these patients must have been homosexual men who were also haemophiliacs. Nevertheless, I noted this observation in my report of the Congress.

ii) The copy of my report which is cited in the Preliminary Report (para 8.14, ref 13) is complete, except for a set of abstracts which were appended. The abstract of Dr Aledort's presentation (S-23-1) made no reference to AIDS. I submitted my report of the Congress to Mr Watt, the Director of PFC, and sent a copy to Dr Smith at PFL Oxford, as he had not attended the Congress. I do not know the extent to which my report was distributed by Mr Watt.

iii) MMWR When I attended the ISBT Congress, I had not read the account of these cases in the 26 July issue of MMWR (para 8.12). Although PFC subscribed to MMWR, delivery of the journal from the USA was slow and, on receipt, it was first circulated to Mr Watt and to Dr Cuthbertson before being returned to the PFC library for general use. I do not remember reading this article at that time.

iv) In late-1982 I saw another television programme on AIDS in which a parallel was drawn with hepatitis, a comment which led me to believe that a blood-borne infectious agent was the most probable cause of the syndrome.

v) Further articles were published in MMWR in December 1982 (para 8.16, ref 16). I do not remember if I read these articles at that time.

B 3 1983

i) Early in 1983, I was invited by Dr Ludlam to give a talk to his department on progress towards the development of non-infective blood products. During my presentation on 8 March 1983 (para 11.113, ref 161), I referred to the possibility that AIDS might be caused by a blood-borne infectious agent. I do not remember if I commented specifically on risks associated with commercial products as opposed to UK-derived products. As commercial products were derived from USA-donors and

the epidemic of AIDS was much more advanced in the USA than elsewhere, I believe that this would have been self-evident.

ii) Because of the possibility that AIDS might be caused by a blood-borne infectious agent, I wrote a memo to Mr Watt on 3 May 1983 suggesting that our strategy on the development of heat treatment should be re-considered as all patients might be vulnerable to infection with AIDS, in contrast to the situation with NANBH where most people with haemophilia were already believed to have been infected (para. 11.123, ref 178). This meant that we should be planning to develop an effective heat treatment process that could be applied to all of the Factor VIII concentrate produced not just to a proportion of the product.

iii) Galbraith Recommendation. I was not aware of the recommendation on 9 May 1983 from Dr Galbraith (para. 8.24) that blood products from the USA should be temporarily withdrawn from use, nor that his recommendation was considered by the Committee on the Safety of Medicines Biologicals sub-committee at its meeting on 13 July.

iv) ASTMS On 9 June 1983 I wrote to ASTMS Divisional Officer Mr Gordon Craig to express my concern over the continued importation of blood products from the USA in light of AIDS and the extent to which the PFC facility was underused. Mr Craig forwarded my letter to Ms Sheila McKechnie, Health and Safety Officer at ASTMS Head Office, who represented the Trades Union Congress (TUC) on the Advisory Committee on Dangerous Pathogens (ACDP). I was subsequently invited by Ms McKechnie to assist her with correspondence between Mr Clive Jenkins, General Secretary of ASTMS, and the DHSS in which Mr Jenkins was questioning the continued importation of blood products from the USA.

This correspondence can be seen in Appendix VI.

I am aware that in May 1983 Dr F Boulton , Deputy Director of the Edinburgh Regional Transfusion Centre, engaged in communication with Professor Bloom concerning the position of the UK Haemophilia Centre Directors Organisation on this topic (para 8.29).

v) Congress of the World Federation of Hemophilia, Stockholm, 27 June-1 July 1983
Following a recommendation by Dr Cash, I was invited by Dr Mannucci to give a presentation on '*Improving the yield of factor VIII'* at the WFH Congress that was held at the Karolinska Institute on the outskirts of Stockholm. At the WFH Congress, Dr Evatt of the USA Centers for Disease Control, gave a very detailed account of the situation concerning AIDS. In particular he explained that none of the known haemophilia cases had any other risk factor, such as homosexuality or iv drug abuse.

Although delegates received a book of abstracts on arrival at the Congress, the abstract from Dr Evatt (no. 220) was blank, leaving delegates with no record of his presentation other than any notes they might have taken. The proceedings of the Congress were published some 12 months later (Scandinavian Journal of Haematology 1984, 33, Suppl. 40).

vi) Congress of the International Society of Thrombosis & Haemostasis, Stockholm, 2-8 July 1983. The ISTH Congress took place at the International Conference Centre in the centre of Stockholm. It was a much larger gathering than the WFH Congress and encompassed a much broader spectrum of topics. Delegates were provided with a book of abstracts on registration which, like those of the WFH Congress, had been submitted some 6 months earlier. Unlike the WFH Congress, the proceedings were not published.

vii) I returned from Stockholm on 11 July to discover that Mr Watt had resigned from his post of PFC Director and that he would be leaving in about 6 months (he actually left at the end of December 1983). Because of its importance, I decided to summarise the main points relating to AIDS in two memo's to Mr Watt (para. 8.37, ref 59), prior to writing a full report which would cover both Congresses.

I did not complete a full report due to other commitments but, in addition to my memo's relating to AIDS, I did write a report of my visit to the fractionation plant of Kabi Pharmaceuticals in Stockholm. I do not know the extent to which these reports were distributed by Mr Watt.

viii) Committee on the Safety of Medicines, Biologicals sub-committee, 13 July 1983.

According to his CV, Mr Watt, Director of PFC, was a member of the Biologicals sub-committee of the Committee on the Safety of Medicines from 1976 to 1986. As a member of this committee, he was acting in a personal capacity as an invited expert, not as a representative of either the SNBTS or Scotland. Mr Watt regarded these meetings and their proceedings as strictly confidential. He never discussed them with me nor, to the best of my knowledge, with anyone else at PFC. I do not know if he attended the committee meeting on 13 July 1983 as the minutes that I have seen have been redacted. I do not know if the proceedings were notified to anyone in Scotland.

The redacted minute does indicate that one member did not attend and their apology is noted. I do not know if this absentee was Mr Watt or not.

The redacted minute does indicated that a number of DHSS officials were in attendance. I do not know if any officials from SHHD were in attendance, nor if they were informed of these proceedings.

MHRA have declined a request from SNBTS for a non-redacted copy of this minute.

C. A NON-CHRONOLOGICALRESPONSE TO THE MATTERS RAISED

To provide a clear response, I have annotated the Schedule from the Penrose Inquiry to highlight the specific questions contained within the Schedule. I have then listed the questions separately and provided an answer to each question.

C 1. Schedule Annotated by Dr P R Foster

Schedule

Issue in respect of which a statement is sought

AIDS/HIV

The use of commercial products in Scotland, including the continuation of such use after:

(a) international realisation that these carried a risk of AIDS;

(b) the proposal by Dr Galbraith of the Public Health Laboratory Service in May 1983 that use in the UK should be stopped; and
(c) significant progress towards self-sufficiency in the manufacture of blood products by the NHS in Scotland had been made.

Sections of Preliminary Report which may assist when preparing statement

Chapter 8, "HIV and AIDS".

Matters to be included in the statement

SNAPSHOTS and LANDMARKS

1. The first point at which the topic can really be focussed is at the beginning of 1983, when there was a meeting at St Andrew's House of the Directors of SNBTS and the Haemophilia Directors (see paragraph 8.17 of Preliminary Report and copy minutes attached).

By this point, in relation to increasing awareness of AIDS, there are three specific references in the Preliminary Report:

i) The MMWR of 16 July 1982, in which an editorial note commented in relation to 3 cases of AIDS in heterosexual haemophiliac patients (see paragraph 8.12 and copy article attached):
".. the occurrence among the three hemophiliac cases suggests the possible transmission of an agent through blood products …"

ii) the reference to these cases at the congress in Budapest in August 1982, which Dr Foster attended. He subsequently prepared a report, which we do not have in full (see paragraph 8.14).

iii) the meeting of UK Haemophilia Centre Directors (UKHCDO) in Manchester on 13 September 1982, at which the condition was mentioned along with a reference to the possibility of involvement of commercial blood products (see paragraph 8.16).

In the minutes of the joint meeting on 21 January 1983 is recorded the following passage:

> "6 (a) Acquired Immune Deficiency Syndrome (AIDS)
> Dr Cash drew members' attention to recent articles in the United States, and also in the Observer and the Lancet, about this problem. An MMWR extract (CDC, Atlanta) had been circulated with his paper. Dr Ludlam informed members that in the UK a letter and questionnaire had been sent out to haemophilia directors."

In relation to the continuing use of commercial products, the previous joint meeting of the Directors of SNBTS and the Haemophilia Directors on 30 January 1981 (copy of minutes attached) had discussed the use of commercial products. There had been reference to a Council of Europe recommendation that member states should be self –sufficient.

Page 5 of the minutes of the meeting of UKHCDO on 13 September 1982 refers to an "encouraging rise" in the amount of NHS factor used in the figures for 1981, but there had been no change in commercial use.

There was continuing use of commercial products in Scotland in the face of approaching self-sufficiency (achieved in 1983 – see attached copy memo of 18 November 1983). 1 a By the beginning of 1983, was there any recognition that the arrival of AIDS, and its possible connection with (US) commercial blood products, required a re-assessment of the risks/benefits associated with the use of commercial rather than NHS product? 1b Why was there no discussion about the possible connection between AIDS and commercial blood products?

2. The further developments which had taken place since the meeting of 21 January (all referred to in the preliminary report) included:

i) the meeting at Heathrow Airport on 24 January 1983, at which there was discussion of AIDS (see paragraphs 8.18 and 8.19). By this time there were said to have been 10 cases in patients with haemophilia in the USA.

ii) the article in the New Scientist in February 1983, again linking AIDS and blood products (see paragraph 8.20 and copy article attached).

iii) articles in the Lancet of 29 January (see paragraph 8.21) and 2 April 1983 (see paragraph 8.23 and copy articles attached).

iv) the UKHCDO meeting of 13 May 1983 at which it was, in effect, recognised that some restriction of the use of concentrates was warranted (see paragraph 8.26).
2 iv) a It is noteworthy that there appears to have been no Scottish representation at this meeting. Glasgow and Edinburgh were supposedly reference centres by this time – should they not have been invited? 2 iv) b Was there in fact a reluctance to involve them (see comments in letter dated 8 August 1985 referred to in paragraph 8.36, footnote 55 regarding their status)?

v) the meeting of the SNBTS co-ordinating group on 24 May 1983, at which precautionary steps were again discussed (see paragraph 8.28).

vi) Dr Galbraith of the Public Health Laboratory Service specifically recommended on 9 May 1983 that blood products from the USA should cease to be used (see paragraph 8.24). In his letter to the DHSS he said:

"I have reviewed the literature and come to the conclusion that all blood products made from blood donated in the USA after 1978 should be withdrawn from use until the risk of AIDS transmission by these products has been clarified. Appended is a paper in which I set out my reasons for making this proposal."

There must have been knowledge in Scotland of this recommendation from Dr Galbraith. It was referred to at the English Directors' meeting of 18 May 1983, which was attended by Dr Ruthven Mitchell. He prepared a note of the meeting (see copy attached) which must have been circulated within SNBTS. 2 vi) a Presumably it was sent to Dr Cash, whose apologies were tendered at the meeting? Moreover, Dr Gunson attended the next Scottish Directors' meeting on 14 June (see paragraph 8.33) and must have known of the proposal, albeit he had not been present at the English meeting. 2 vi) b Was there ever any thinking along these lines in Scotland?

There were meetings of the Directors on 14 June and the Factor VIII Safety sub-committee on 15 June (see paragraph 8.34). AIDS was discussed at both, in terms which imply an acceptance that a blood borne infectious agent was involved.
2 vi) c Was there any recognition that cessation of use of products from the USA would eliminate the risk from that source? 2 vi) d If not, why not?

vii) On 24 June, Professor Bloom and Dr Rizza wrote to Dr Ludlam with recommendations (see paragraph 8.36). In essence, these prioritised the protection of mildly affected haemophiliacs and children. 2 vii) a Did Dr Ludlam disseminate this advice round the haemophilia centres in Scotland? 2 vii) b Was there any gathering of Scottish haemophilia clinicians to discuss the situation? 2 vii) c Was there any different advice issued in Scotland? 2 vii) d What, specifically, was the practice in relation to the treatment of children in Scotland? 2 vii) e Is it the case that large amounts of commercial concentrate were used at Yorkhill?

In retrospect, it is probably the case that the risk of infection correlated with the amount of concentrate received. 2 vii) f Was any attempt made to formulate strategies for reducing the amount of concentrate, particularly commercial concentrate, used by moderately or severely affected haemophiliacs? 2 vii) g What use was made in Scotland of DDAVP?

viii) 2 viii) a Which Scottish haemophilia clinicians attended the WFH & ISTH meeting in Karolinska between 27 and 29 June 1983 (see paragraph 8.37)? 2 viii) b Was Dr Foster's report of the meeting distributed beyond PFC?

ix) Dr Galbraith's paper was discussed at the Biologicals sub-committee of the Committee on the Safety of Medicines in London on 13 July 1983 (see paragraph 8.41). 2 ix) a Was there any Scottish representation at this meeting? 2 ix) b Were its proceedings notified to anyone in Scotland?

3. In the second half of 1983, there was the first WHO Europe conference on AIDS, entitled "AIDS in Europe, Status Quo 1983" in Aarhus, Denmark, between 19 and 21 October (see paragraph 8.57 and copy note of meeting). There was also a meeting of UK Haemophilia Centre Directors (UKHCDO) in Manchester on 17 October 1983 (see paragraph 8.61) and the WHO Conference in Geneva, 22 – 25 November 1983 (see paragraph 8.65).

i) 3 i) Who attended the Aarhus conference from Scotland?

ii) 3 ii) Was information from the Geneva conference in 1983 disseminated beyond SNBTS?

iii) In relation to the UKHCDO meeting and various communications from or relating to the Haemophilia Society around this time, the emphasis appears to have been strongly on maintaining the use of commercial concentrates. 3 iii) a Is this an accurate impression? 3.iii) b Did haemophilia clinicians from Scotland agree that patients should not be encouraged to revert to cryoprecipitate for home therapy?

iv) 3 iv) Did haemophilia clinicians in Scotland follow the advice from the Geneva conference to avoid non-essential use of blood or blood products?

v) 3 v) More generally, was there an awareness of Scottish patients with AIDS? We are aware of a comment from an unnamed GU specialist to the effect that in 1983, patients were arriving in his/her clinic with symptoms of AIDS (copy of part of thesis by Bennett/Pettigrew attached). From the BMJ article dated 11 February 1984, it

appears that the first Scottish AIDS death was December 1982 (copy of article attached).

4. By the early part of 1984, there appears to have been caution in Scotland in relation to the use of commercial products from abroad. But "small amounts" of commercial products were still purchased. 4 a Why was this necessary?

We also need to ascertain what happened in practice re the use of heat treated concentrates in Scotland in 1984. 4 b When were physicians able to begin using heat treated commercial concentrate?

C 2. My Response to Questions in the Schedule

Question 1a By the beginning of 1983, was there any recognition that the arrival of AIDS, and its possible connection with (US) commercial blood products, required a re-assessment of the risks/benefits associated with the use of commercial rather than NHS product?

ANSWER

Early in 1983, I was invited by Dr Ludlam to give a talk to his department on progress towards the development of non-infective blood products. During my presentation on 8 March 1983 (para 11.113, ref 161), I referred to the possibility that AIDS might be caused by a blood-borne infectious agent. I do not remember if I commented specifically on risks associated with commercial products as opposed NHS product. As commercial products were derived from USA-donors and the epidemic of AIDS was much more advanced in the USA than elsewhere, I believe that this would have been self-evident.

Question 1b Why was there no discussion about the possible connection between AIDS and commercial blood products?

ANSWER

I do not remember being involved in any discussion about the possible connection between AIDS and commercial blood products. I do not know if discussions took place in which I was not involved. If not, I do not know why not.

Question 2 iv) a It is noteworthy that there appears to have been no Scottish representation at this meeting. Glasgow and Edinburgh were supposedly reference centres by this time – should they not have been invited?

ANSWER

According to the non-redacted minute (appendix III) Dr Ludlam was present at this meeting.

Question 2 iv) b Was there in fact a reluctance to involve them (see comments in letter dated 8 August 1985 referred to in paragraph 8.36, footnote 55 regarding their status)?

ANSWER

See answer to question 2 iv) a above.

Question 2 vi) a Presumably it was sent to Dr Cash, whose apologies were tendered at the meeting?

ANSWER

I do not know if this document was sent to Dr Cash or not.

Question 2 vi) b Was there ever any thinking along these lines in Scotland?

ANSWER

On 9 June 1983 I wrote to ASTMS Divisional Officer Mr Gordon Craig to express my concern over the continued importation of blood products from the USA in light of AIDS and the extent to which the PFC facility was underused. Mr Craig forwarded my letter to Ms Sheila McKechnie, Health and Safety Officer at ASTMS Head Office. I was subsequently invited by Ms McKechnie to assist her with correspondence

between Mr Clive Jenkins, General Secretary of ASTMS, and the DHSS in which Mr Jenkins was questioning the continued importation of blood products from the USA.

This correspondence can be seen in Appendix VI.

I am aware that in May 1983 Dr F Boulton , Deputy Director of the Edinburgh Regional Transfusion Centre, engaged in communication with Professor Bloom concerning the position of the UK Haemophilia Centre Directors Organisation on this topic (para 8.29).

Question 2 vi) c Was there any recognition that cessation of use of products from the USA would eliminate the risk from that source?

ANSWER

I was not present at either the meeting of the Directors on 14 June or the meeting of the Factor VIII Safety sub-committee on 15 June. I was not a member of these committees. I do not know if there was any recognition at these meetings that cessation of use of products from the USA would eliminate the risk from that source.

Question 2 vi) d If not, why not?

See my response to question 2 vi) c above.

Question 2 vii) a Did Dr Ludlam disseminate this advice round the haemophilia centres in Scotland?

ANSWER

I do not know if Dr Ludlam disseminated this advice to haemophilia centres in Scotland.

Question 2 vii) b Was there any gathering of Scottish haemophilia clinicians to discuss the situation?

ANSWER

I do not know if there was a gathering of Scottish haemophilia clinicians to discuss the situation.

Question 2 vii) c Was there any different advice issued in Scotland?

ANSWER

Advice was issued by the Council of Europe on 23 June 1983 in Recommendation R (83) 8 (Appendix III). I was not aware of this Recommendation at that time. A draft version of this recommendation was included amongst documents that were released by the Scottish Executive Department of Health in December 2005. I do not know the extent to which this draft or the final version, were distributed in Scotland.

Question 2 vii) d What, specifically, was the practice in relation to the treatment of children in Scotland?

ANSWER

I do not know the practice in relation to treatment of children in Scotland, except for a minute of a meeting of the Haemophilia Directors, SNBTS Representatives and officials of the SHHD that was held on 29 November 1984 (para 8.104, ref 159) which records:

"*Dr Gibson reported the anxiety felt by parents of haemophiliac children treated at RHSC Glasgow, where imported factor VIII had been used until relatively recently.*"

Question 2 vii) e Is it the case that large amounts of commercial concentrate were used at Yorkhill?

ANSWER

I do not know the amounts of commercial concentrate that were used at Yorkhill.

Question 2 vii) f Was any attempt made to formulate strategies for reducing the amount of concentrate, particularly commercial concentrate, used by moderately or severely affected haemophiliacs?

ANSWER

I do not know if any attempt was made to formulate strategies for reducing the amount of concentrate, other than the Council of Europe Recommendation R (83) 8 noted in my response to question 2 vii) c above.

Question 2 vii) g What use was made in Scotland of DDAVP?

ANSWER

I do not know what use was made in Scotland of DDAVP.

Question 2 viii) a Which Scottish haemophilia clinicians attended the WFH & ISTH meeting in Karolinska between 27 and 29 June 1983 (see paragraph 8.37)?

ANSWER

I do not know which Scottish haemophilia clinicians attended either the WFH Congress at the Karolinska Institute, Stockholm, on 27 June to 1st July 1983, or the ISTH Congress at the Stockholm International Conference Centre on 2 to 8 July 1983. The proceedings of the 1983 WFH Congress are available (Scandinavian Journal of Haematology, 1984, vol. 33, Supplement 40).

Question 2 viii) b Was Dr Foster's report of the meeting distributed beyond PFC?

ANSWER

I do not know if my reports from these meetings in Stockholm were distributed beyond PFC.

Question 2 ix) a Was there any Scottish representation at this meeting?

ANSWER

According to his CV, Mr Watt, Director of PFC, was a member of the Biologicals sub-committee of the Committee on the Safety of Medicines from 1976 to 1986. As a member of this committee, he was acting in a personal capacity as an invited expert, not as a representative of either the SNBTS or Scotland. I do not know if he attended the committee meeting on 13 July 1983, as the minutes that I have seen have been redacted. The redacted minute does indicate that one member did not attend and their apology was noted. I do not know if this absentee was Mr Watt or not.

The redacted minute does indicated that a number of DHSS officials were in attendance. I do not know if any officials from SHHD were in attendance.

MHRA have declined a request from SNBTS for a non-redacted copy of this minute.

Question 2 ix) b Were its proceedings notified to anyone in Scotland?

ANSWER

Mr Watt regarded these meetings and their proceedings as strictly confidential. He never discussed them with me, nor, to the best of my knowledge, with anyone else at PFC. I do not know if the proceedings were notified to anyone in Scotland.

The redacted minute does indicated that a number of DHSS officials were in attendance. I do not know if any officials from SHHD were in attendance, or, if not, if they were informed of these proceedings.

MHRA have declined a request from SNBTS for a non-redacted copy of this minute.

Question 3 i) Who attended the Aarhus conference from Scotland?

ANSWER

I do not know who attended the Aarhus conference from Scotland.

Question 3 ii) Was information from the Geneva conference in 1983 disseminated beyond SNBTS?

ANSWER

I do not know if information from the Geneva conference was disseminated beyond SNBTS.

Question 3 iii) a Is this an accurate impression?

ANSWER

I had no involvement with either the UKHCDO or the Haemophilia Society and was not directly involved in any of these meetings or communications. Nevertheless, I was aware that the Haemophilia Society was advising both the Government and its own members that commercial products should continue to be used.

In September 1983, I was invited by my trades union, ASTMS, to comment on a letter from The Lord Glenarthur, Joint Parliamentary Under Secretary of State at the DHSS, to Mr Clive Jenkins, General Secretary of ASTMS, dated 26 August 1983, which noted "*Haemophilia Society is aware of the situation and has in fact made known to me its opposition to any move to ban American FVIII.*" (Department of Health, file 334/16 vol 2, document number 35). See also my response to question 2 vi) b above.

Also in September 1983 I was invited by my trades union , ASTMS, to comment on a letter, dated 4 May 1983, from the Haemophilia Society to its members which advised that it would "*be counter-productive to alter our treatment programmes radically.*" (para 8.25, ref 32). This letter was included in the agenda papers for a meeting of the Advisory Committee of Dangerous Pathogens (ACDP/83/P9) on which Ms Sheila McKechnie of ASTMS represented the Trades Union Congress (TUC). See also my response to question 2 vi) b above.

In addition to these documents and the documents cited in the Preliminary Report, I am aware of additional documents in which the position of the Haemophilia Society is described.

In a letter to the Baroness Marsham of Ilton dated 30 August 1983, The Lord Glenarthur noted "*My officials have been in close touch with the Haemophilia Society about the AIDS problem and we are al very grateful to them for the constructive and responsible attitude they have taken. Naturally this is a matter of great concern to them; but they did not support the cries from some quarters to ban the import of Factor VIII because they accepted that the possible risk from AIDS must be balanced against the obvious risk of not having enough Factor VIII.*" (Department of Health, FOI releases, document number 2735).

In a fact sheet for members concerning AIDS (HÆMOFACT A.I.D.S. Release No. 2) dated 22 September 1983, the Haemophilia Society advised "*Our message remains unchanged THE ADVANTAGES OF TREATMENT FAR OUTWEIGH ANY POSSIBLE RISK. BALANCE THE RISKS for yourself, but we would state again that*

the risk of AIDS is tiny compared with the risks from untreated bleeding episodes." (Department of Health, FOI releases, document number 1553). See also Guardian of 28.9.83 (para 8.53, ref 83).

In my opinion, these documents, together with those cited in the Preliminary Report, demonstrate that the impression is accurate.

Question 3.iii) b Did haemophilia clinicians from Scotland agree that patients should not be encouraged to revert to cryoprecipitate for home therapy?

ANSWER

I do not know what haemophilia clinicians from Scotland agreed.

Question 3 iv) Did haemophilia clinicians in Scotland follow the advice from the Geneva conference to avoid non-essential use of blood or blood products?

ANSWER

I do not know if haemophilia clinicians followed the advice from the Geneva conference to avoid non-essential use of blood or blood products.

Question 3 v) More generally, was there an awareness of Scottish patients with AIDS?

ANSWER

I was not aware of Scottish patients with AIDS at this time.

Question 4 a Why was this necessary?

ANSWER

I did not know that "small amounts" of commercial products were still being purchased. I do not know why this was necessary.

Question 4 b When were physicians able to begin using heat treated commercial concentrate?

ANSWER

I do not know when physicians in Scotland were able to begin using heat treated commercial concentrates.

At its meeting of 14 September 1983, the Committee on the Safety of Medicines Biologicals sub committee rejected an application from Hyland/Travenol/Baxter concerning its dry heat treated Factor VIII, Hemofil T and criticised the company for making unsubstantiated claims concerning AIDS.

At its meeting of 7 March 1984, the Committee on the Safety of Medicines Biologicals sub committee approved an application from Behringwerke concerning its pasteurised Factor VIII, Haemate P. However, according to an expert advisor to the DHSS "*This material has never been available in sufficient quantities to be used in the UK and even now is very difficult to obtain."* (Department of Health, Self-Sufficiency in Blood Products in England and Wales, reference no. 123).

At its meeting of 4 July 1984, the Committee on the Safety of Medicines Biologicals sub-committee rejected an application from Armour Pharmaceuticals concerning its dry heat treated Factor VIII, HT Factorate.

A number of heat treated commercial concentrates were approved for use in the UK during February 1985 (Department of Health, FOI releases, document no. 3449).

According to the expert advisor to DHSS (ref 123, Self-Sufficiency in Blood Products in England and Wales) "*Only one of them (Hemofil T) was available for Clinical trials in UK.*" and " *In the event heat-treated commercial concentrates were not available in substantial quantities until late 1984.*"

According to the medical literature, patient samples from the clinical trial of Hemofil T were tested for HIV in late-1984 and found to be negative (Mannucci P. J Thrombosis Haemostasis 2003, 1, 2065-2069). A comparison with results from patients who had been treated with unheated commercial concentrate suggested that the heat treatment employed in the manufacture of Hemofil T was effective

against HIV. These results were published on 2 February 1985 (Rouzioux et al. Lancet 1985, 1, 271-272).

D DOCUMENTS APPENDED

Appendix I: Self-Sufficiency and the Supply of Blood Products in Scotland (with particular reference to the treatment of Haemophilia A): Author Dr P R Foster.

Appendix II: Minute of the HCDO meeting held on 13 May 1983 (non-redacted).

Appendix III: Council of Europe Recommendation R (83) 8.

Appendix IV: Curriculum Vitae, including a pdf listing authored PFC R&D Reports.

Appendix V: Personal Correspondence with ASTMS Concerning Privatisation of the Blood Products Laboratory, Elstree (BPL).

Appendix VI: Personal Correspondence with ASTMS Concerning Blood Products and AIDS.