

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

(9.30 am)

THE CHAIRMAN: Good morning. Yes, Ms Dunlop.

MS DUNLOP: Sir, we have Dr Perry with us again today.

Dr Perry has provided a statement on topic B2 and it's [\[PEN0160460\]](#).

DR ROBERT PERRY (continued)

Questions by MS DUNLOP (continued)

MS DUNLOP: Dr Perry, you begin by talking about

self-sufficiency very generally. If we can look at page 2, please, you say that:

"It was accepted that prescribing doctors were free to exercise their own judgment in the choice of either SNBTS or commercial products, preserving the important principle of clinical freedom. Whilst SNBTS and haemophilia directors collectively embraced the goal of self-sufficiency, the use of NHS products was not and could not be enforced by SNBTS."

So I think what you are saying is the bottom line was that if doctors preferred commercial products they were free to use them?

A. Yes, that was certainly very much my understanding at the time, that, although there was this goal of self-sufficiency and there was strong encouragement, I think that the principle of clinical freedom was at

1 that time really quite a sacred principle that was
2 respected by all parties, I think.

3 Q. You were speaking as at your arrival in the early 1980s?

4 A. Yes.

5 Q. What about --

6 THE CHAIRMAN: Where did the principle come from?

7 A. I think this was quite a widely practised principle
8 amongst the medical profession. I think also there was
9 an important acceptance, even at that time, that the
10 manufacturer of the medicine shouldn't be closely
11 involved in specific decisions concerning treatment of
12 patients because that would create a potential conflict
13 of interest, and where the principle of clinical freedom
14 came from, I'm sorry, I probably can't enlighten you too
15 much but it was certainly very prevalent then.

16 THE CHAIRMAN: Already your answer has complicated the
17 situation by bringing in additional dimensions. I can
18 well understand that the clinician in actually carrying
19 out clinical work could assert -- and it might only be
20 an assertion -- that it was essential for the
21 patient/clinician relationship that the clinician should
22 have complete freedom as to the decisions he took and of
23 course with it, the accountability that complete freedom
24 implies.

25 But before it can become an aspect of general

1 practice, it has to be accepted in some way by others
2 and there may be limits that have to be drawn. And in
3 this case I would be very interested, and will be in due
4 course, to know the attitude of government in Scotland
5 to this principle, since from what you have said
6 already, clinical freedom could cut across government
7 policy. So that's one thing we have.

8 The next element that you have introduced is
9 an assimilation of the position of the national producer
10 with the position of commercial manufacturers and
11 producers of products. So immediately one has a more
12 complex situation emerging.

13 My role is to try to find out what the reality was,
14 Dr Perry, and I'm not sure that simply saying there was
15 a principle of clinical independence or autonomy, or any
16 of the other expressions we have used, takes me terribly
17 far unless I know the basis on which it was done. Can
18 you help or did you just inherit it?

19 A. Clearly I just inherited it and whether I can help we
20 will see soon. It was certainly the case that the
21 Scottish Home and Health Department were very strong
22 supporters and proponents of self-sufficiency, that's
23 recorded in a number of discussions, in a number of
24 documents, although the absolute clear policy statement
25 is a little bit elusive.

1 What they consistently fell short of was demanding
2 that haemophilia doctors would use NHS products, and
3 I think there are a number of references from memory in,
4 certainly the meetings between SNBTS and haemophilia
5 directors, where there was an acceptance that doctors
6 should be free to prescribe products in the best
7 interests of their patients and they wouldn't wish to
8 change that principle.

9 I'm not sure that takes us forward but that was very
10 much the prevalent position. So my job as
11 a manufacturer was to seek to persuade our colleagues in
12 the haemophilia community that our products were
13 suitable, they were acceptable, there was a reliable
14 supply, so it was a process of persuasion, not a process
15 of instruction.

16 THE CHAIRMAN: That's something I will have to look at quite
17 closely in your report.

18 A. Sure.

19 THE CHAIRMAN: Yes, Ms Dunlop?

20 MS DUNLOP: Dr Perry, I put to you the proposition that if
21 doctors preferred commercial products, they were free to
22 use them and you agreed with that. I wondered what the
23 position was if the patients preferred commercial
24 products.

25 A. I think again, from my perspective as a manufacturer,

1 I don't think I can speak authoritatively on that
2 particular topic.

3 Q. All I'm trying to get is your understanding of the
4 situation which applied when you arrived in 1981. So
5 the products you were producing, were they really to
6 fill that part of the demand which was represented by
7 doctors who were happy to use your products and patients
8 who were happy to? So if the patients had wanted
9 commercial products, they wouldn't have been using
10 yours. Is that your sense of it?

11 A. My sense of it when I arrived in SNBTS was that the role
12 of this relatively new centre then in 1981 -- it had
13 only been opened in 1975 -- its job was to meet the
14 demands in Scotland for all plasma products, including
15 Factor VIII, Factor IX, albumin, immunoglobulin and so
16 on, and as I have said on a number of occasions,
17 certainly not within the Inquiry, but self-sufficiency
18 as it was well-known at the time, although perhaps
19 ill-defined, was the only game in town and our job was
20 certainly not to interface with patients but to do
21 everything we possibly could to provide a supply of
22 products for treating patients that were acceptable,
23 obviously to the treating doctors but also to the
24 patients; but we didn't have, as a manufacturer, any
25 direct relationship with the patients. I think that

1 would have been seen as quite improper.

2 Q. Right. Just to read on through your statement, you were
3 asked, as were a number of other witnesses, about
4 specific snapshots in the unfolding history in the early
5 1980s. One of those is the UKHCDO meeting of
6 13 September 1982, and we do have a note which looks as
7 though it's your note of that meeting. It's
8 [\[SNB0017431\]](#). Do you recognise that? Does that look
9 like something that you will have prepared?

10 A. Perhaps if I can see the content, yes.

11 Q. I suggested to others that sometimes we can tell from
12 the typeface. This looks like a sort of typeface that
13 I have seen on documents for which you were responsible.

14 A. It could be.

15 Q. Right.

16 A. It could be but it might be helpful to see the content.

17 Q. Certainly. Look at page 3 of [\[SNB0017431\]](#), which is actually
the

18 first page of text. Whoever prepared this note has
19 recorded that they were writing down matters of
20 relevance to PFC. There's a bit of mention of
21 preliminary issues and then number 3, the hepatitis
22 working party. We know that Dr Craske presented results
23 of that study that he had been conducting, quite a small
24 study, but if you read on to the following page, 7434,
25 if it's you, you have written a table, drawn a table,

1 and we can see from the table that from those who had
2 had no previous concentrate, a total of nine people,
3 when they had their first concentrate, all nine of them
4 got non-A non-B hepatitis?

5 A. Indeed.

6 Q. You have done a little symbol beside the nine and a note
7 underneath saying:

8 "Seven out of the nine received NHS concentrate."

9 A. Yes, my answer to your first question is my best guess,
10 that this is not my document.

11 Q. Oh, right.

12 A. And I don't recall attending the meeting. That doesn't
13 mean to say that I wasn't there, and the reason I say it
14 doesn't look as though it's my document is that by the
15 time of that meeting I had only been in post about
16 a year and I think some of the quite complex technical
17 issues that were being discussed here seem to have been
18 very coherently presented in this report, and that may
19 not have been the case had I written the document. I'm
20 not trying to deny any knowledge of it but I don't think
21 this is a report written by myself unless you are going
22 to come on at the end and see my signature on the
23 bottom.

24 Q. No, we don't have that but I think you were there
25 actually.

1 A. Okay.

2 Q. But I don't think anything turns on this, Dr Perry.

3 I was just going to say that if it had been your note,
4 you haven't noted down anything about AIDS. There was
5 a discussion of some sort about AIDS at this meeting but
6 I rather suspected that the person who wrote this note
7 had felt that it wasn't covered by the introductory
8 statement that this note is on matters of relevance to
9 PFC.

10 A. Okay.

11 Q. If you didn't write it, you certainly won't remember --

12 A. It doesn't look like the style in which I would have
13 presented the data with the paragraph numbers, with the
14 margin and so on. It doesn't look like the sort of
15 structure I would have taken for the report but, as
16 I say, I can't be sure but it looks to have much too
17 high a level of really quite technical scientific
18 content for me at that stage in my career in blood
19 transfusion to have competently written.

20 I think there were probably other people from SNBTS
21 at the meeting. It could well have been written by
22 Dr Foster, for instance. I don't know whether he was at
23 the meeting.

24 THE CHAIRMAN: Could we see the previous page just briefly?

25 MS DUNLOP: Yes, certainly. 7433. We listed in the

1 preliminary report those who attended from Scotland and
2 they were Dr Boulton, Dr Forbes, Dr Ludlam, you
3 Dr Prentice, Dr Sharp and Dr Vosylius. It is not
4 Dr Boulton's note because we have his note as well.

5 A. No.

6 Q. That was why it seemed likely that it was yours but it
7 doesn't matter. It was a long time ago, Dr Perry.

8 A. It is a long time ago and I'm sorry, I can't with any
9 authority remember whether it is my note. It may have
10 been.

11 Q. Can we go back to the statement in that case, please?

12 That's [\[PEN0160460\]](#) and now that we have mentioned the
13 meeting of September 1982, we can go on to the third
14 page. You have made some general comments about the
15 situation as it stood at that time and you have referred
16 on page 3 to the stated SHHD policy for
17 self-sufficiency. Do you see that reference? It's
18 almost three quarters of the way down the page. This is
19 obviously something that we can ask Professor Cash about
20 and I plan to do that. He is obviously coming today as
21 well.

22 A. Yes.

23 Q. But since you have made a brief mention of this already
24 this morning, I just wondered what your recollection was
25 of any formal statements of policy?

1 A. Well, certainly at that time, I think as a number of
2 other people have suggested throughout the course of the
3 Inquiry, there is no defining moment where a clear
4 policy comes out of the Scottish Home and Health
5 Department that we can, should and will be
6 self-sufficient.

7 However, there are policies and there are quite
8 clear statements in which both the UK Government and
9 I think SHHD embraced formal statements by bodies such
10 as the World Health Organisation, which stated quite
11 clearly that countries should strive for
12 self-sufficiency in blood and blood products. And
13 I think from memory it wasn't until the late 1980s that
14 a clear statement -- or the mid 1980s or the late
15 1980s -- that the Scottish Home and Health Department
16 made a very, very clear and unequivocal statement.

17 I haven't got the reference for that or the detail
18 but I have certainly heard that in discussion with
19 people like Professor Cash that it took that long.

20 In the meantime, certainly from the perspective as
21 a senior manager in SNBTS, there was absolutely no doubt
22 in my mind, and certainly in the minds of the staff that
23 worked with me, that for all practical purposes
24 self-sufficiency was what we had been set up to deliver
25 and achieve, and indeed there were a number of

1 references in regular meetings of haemophilia directors
2 and SNBTS directors at their annual meetings, where the
3 importance of self-sufficiency and using NHS products
4 whenever they were suitable and available, was certainly
5 the goal for the Scottish Health Service.

6 Q. Right. We then asked a question which has been
7 superseded, about who attended various meetings, so we
8 can move beyond that on to the following page, and this
9 is in relation to Dr Galbraith's recommendation to cease
10 importation of American commercial products. You
11 haven't found any evidence that SNBTS directors were
12 aware of the recommendation or its rejection and you go
13 on to say you are not aware of any discussion taking
14 place in SNBTS or SHHD in response to this information:

15 "This is not wholly surprising since SNBTS had no
16 involvement in or responsibility for importation or use
17 of commercial product. It is highly unlikely that SHHD
18 would have taken a contrary view to DHSS."

19 I just wanted to ask you about that. Firstly, are
20 you describing something that in practice happened, that
21 SHHD tended to take the same line as DHSS?

22 A. On this specific topic, I think the whole issue of
23 commercial importation -- this is a licensing issue.

24 Q. Yes.

25 A. This is a product licensing issue and product licensing

1 matters at that time, and still, are based on a UK-wide
2 body, which is now called MHRA, and I'm unclear of any
3 mechanism, any practical or realistic mechanism that
4 SHHD could have used to have taken a contrary view to
5 DHSS. We talk about the DHSS/MHRA but in fact it is a
6 body -- I think the licensing body itself -- I think I'm
7 correct in saying this -- is composed of UK Health
8 Ministers, and that's ministers from Ireland, Scotland,
9 Wales and England, and it's enacted through
10 a secretariat basically, a expert group that happens to
11 be based in London.

12 Q. Fine.

13 A. So I can't think of a mechanism where SHHD could have
14 said, "We wish to revoke or remove the licence for these
15 products because we think they are unsafe". They would
16 have been party to the decision that was taken on
17 a UK-wide basis.

18 Q. Right. I understand the point you make and that relates
19 to the formal situation. I suppose, though, there might
20 have been the possibility of a line, perhaps in a letter
21 from the chief medical officer for Scotland or something
22 like that. I wondered if the comment you are making
23 here went so far as to say that there would be nothing
24 coming from SHHD which differed in any kind of policy
25 sense from what was being said in DHSS. Is that also

1 the case?

2 A. I understand the question. Again I can't remember any
3 significant issue where a particular view was taken by
4 DHSS on a very specific topic, such as whether a product
5 should be licensed or used in the UK, and SHHD or the
6 chief medical officer issuing a statement which
7 contradicts the view taken by the DHSS or the CMO in
8 England.

9 I can't remember any instant of that taking place
10 but theoretically it would have been possible for SHHD
11 to have issued an instruction or a recommendation. It
12 would probably have had to have been a recommendation
13 that, "We no longer wish to use these products in
14 Scotland". Because that would have been contravening
15 the UK licence, and I think that would have created all
16 sorts of difficulties in legal terms and anticompetitive
17 behaviour and so on.

18 Q. Just thinking in the generality, though, there could on
19 occasions be scope for a different line being taken in
20 Scotland if the situation on the ground was different in
21 Scotland.

22 A. Sure. Yes.

23 Q. But in practice you think that that, at least in this
24 context, would have been unlikely?

25 A. In practice in this context I think it would have been

1 very unlikely from where I stood. I would have been
2 very surprised to have found SHHD taking a contrary view
3 to DHSS. Whether or not SHHD were aware of the letter
4 from Dr Galbraith and had a separate discussion, which
5 led them to a conclusion which was similar to DHSS,
6 I really don't know.

7 Q. Just to speak not in the general but in the particular,
8 the different situation on the ground in Scotland, in
9 the early 1980s, was that there weren't the same
10 problems of supply. So if the line in DHSS was being
11 influenced to some extent by shortage of product, NHS
12 product, that would be a condition that wouldn't apply
13 in Scotland, or at least not with anything like the same
14 force.

15 A. Indeed, had the UK been close to self-sufficiency then
16 there may well have been a different outcome because, as
17 I understand it now, Dr Galbraith was suggesting we
18 cease import of US products and that proposal was
19 rejected on the basis that -- I think it simply says on
20 grounds of supply: that if that were to happen, one
21 would have to wind back all the progress that had been
22 made in terms of home therapy and improved treatment for
23 haemophilia. But I would agree with your proposition
24 that had the wider UK been closer to a degree of
25 self-sufficiency, then it would have been, I think,

1 a more realistic proposition to have enacted that.

2 But again, it would have been a licensing authority
3 decision.

4 Q. You go on to make mention of increasing recognition of
5 the possible causal relationship between AIDS and US
6 commercial products and you conclude that section in
7 which you have discussed the possibility of a ban, which
8 we know didn't happen. You then answered a succession
9 of questions, some of which aren't really relevant to
10 you because they are about clinical treatment of
11 patients. You didn't go to the meetings in Karolinska.
12 On to the next page, thank you.

13 Do you remember Mr Watt circulating documents round
14 PFC, perhaps copying particular pages he wanted people
15 to read and annotating them?

16 A. Yes.

17 Q. Do you remember that?

18 A. Oh, yes, it was one of the major means of
19 communication.

20 Q. Right.

21 A. And very effective in some ways.

22 Q. Do you remember it particularly in association with this
23 topic, the topic of AIDS and blood products?

24 A. I don't remember anything specific from that particular
25 topic but it is quite likely, if Mr Watt had been at

1 that meeting, he would have communicated some of the key
2 outcomes; if there was a report, then he would have
3 annotated it and I would have probably seen it and
4 I don't recall.

5 Q. You go on to talk a bit more about the Committee On the
6 Safety of Medicines and you tell us in the paragraph
7 beginning, "at this time ..." that Mr Watt's membership
8 was in a personal capacity rather than a representative
9 role of the respective organisations or countries. And
10 the proceedings were conducted under strict
11 confidentiality.

12 I just wondered if you could explain to us so that
13 we have a complete grasp of what was at stake, the
14 meeting on 13 July 1983, which was considering
15 Dr Galbraith's suggestion that the import of products
16 from the United States should be banned. So there is
17 this proposition that the licence for particular
18 products should be withdrawn because they aren't safe or
19 safe enough. How does confidentiality bite in that
20 context?

21 A. Well, again from my own experience of sitting on the
22 Committee on Safety of Medicines, I think the
23 confidentiality requirement of all those attending the
24 meeting was an umbrella for all activities and all
25 discussions. I think it applied to -- this would have

1 been an unusual meeting for the Committee On the Safety
2 of Medicines because their primary goal was to receive
3 licence applications from individual manufacturers,
4 large dossiers of information, and the committee would
5 then discuss whether or not, on the evidence presented,
6 these were suitable for licensing. This was a more
7 policy issue. But certainly from my own experience
8 I think the meeting was always introduced by the
9 chairman and in introducing the meeting, he would
10 certainly emphasise the importance of confidentiality.

11 I can't remember whether we had to sign on a regular
12 basis that that was the case but we were certainly in no
13 doubt as members of this committee that these
14 discussions were between those four walls and the
15 content of the meeting shouldn't be shared outside it.

16 Although I wasn't at the meeting obviously, I think
17 that would have applied to this meeting as well.

18 I think primarily for the reason that the committee
19 would have taken the view that any discussion concerning
20 the possibility of withdrawing licences of commercial
21 organisations had a very major commercial component, and
22 was not a matter for discussion outside its committee.

23 Q. Obviously you can contribute some insight here because
24 you served on the committee between 1986 and 1990?

25 A. Correct, yes.

1 Q. Effectively replacing Mr Watt?

2 A. Yes, I think there was a gap -- I think Mr Watt retired
3 in 1986 and I was asked to participate in the meeting.
4 I don't think it was a direct replacement but I think
5 there was always a wish on the committee to have
6 a reasonable territorial representation from the
7 different parts of the UK and I was seen as somebody who
8 knew something about fractionation and plasma products.
9 So it wasn't a direct replacement.

10 Q. Indeed Mr Watt had continued to sit on the committee
11 even though he was no longer at PFC.

12 A. He did.

13 THE CHAIRMAN: Was membership of the committee published?

14 A. Yes. My understanding is that although there was no
15 such thing as the Internet then, it would have been in
16 the public domain who actually sat on the committee and
17 what the secretariat was. How easily it would have been
18 able to get that information I'm not sure, but it
19 certainly wasn't a secret.

20 THE CHAIRMAN: I have some knowledge of committees that are
21 admitted to exist but the membership is kept strictly
22 secret in order to avoid lobbying or any possibility of
23 indirect influence or pressure. It wasn't like that?

24 A. My best understanding is that the membership was in the
25 public domain, although the discussions were clearly and

1 very explicitly felt to be confidential.

2 MS DUNLOP: I suspect you now know, Dr Perry, that Mr Watt
3 was at the meeting of 13 July 1980.

4 A. Yes.

5 Q. That information has filtered through to you?

6 A. Absolutely, and indeed, just following on your
7 statement, I certainly have no recollection of Mr Watt
8 coming back and briefing either myself or anybody else
9 on the nature and the content of the discussion.

10 Q. Dr Perry, you probably know this too, but in the end
11 this is a Scottish Inquiry and we are not examining UK
12 matters, and you said yourself licensing is a UK matter.

13 A. Sure.

14 Q. On to the following page, please. You have answered
15 some other questions about international gatherings and
16 your perception, having been around at the time -- and
17 this is section 3.3 -- is that it is an accurate
18 impression to say that there was a strong desire to
19 continue using the products.

20 A. Yes.

21 Q. You say that in terms:

22 "Despite the uncertainty and often conflicting
23 scientific opinion, there was a strong desire to
24 maintain the level and quality of treatment offered by
25 concentrate products."

1 A. Absolutely.

2 Q. I wasn't immediately sure what you were meaning but
3 I think, in the following sentence, what you are really
4 saying is there didn't have to be a choice between
5 commercial or NHS concentrate because there was ample
6 NHS material?

7 A. I think that was the clear implication.

8 Q. Yes.

9 A. Unless there was specific patient-related requirements
10 for a different product to that which was supplied by
11 the SNBTS, and I think we have heard from people far
12 more expert than I that occasionally individual patients
13 may have an idiosyncratic reaction to a particular
14 product, in which case the NHS product is not going to
15 be suitable so an alternative would have had to have
16 been found in that circumstance.

17 Q. Yes. Can we move on to the next page, please?

18 I wanted to ask you one or two questions about
19 supply, Dr Perry. This looks to have been something you
20 investigated in 1983 and 1984, supply and stock?

21 A. Yes.

22 Q. Can we have a memo, [\[SNB0073984\]](#), please? We have
23 looked at this already this week, Dr Perry.

24 A. Yes, I remember it well.

25 Q. Good. What led to it?

1 A. I think at that stage my responsibility was still for
2 quality management and so on. So I did not have
3 a direct role in stock control and so on. That wasn't
4 part of my brief but it was a fairly small team in PFC
5 with the knowledge that self-sufficiency or meeting the
6 needs of the NHS in Scotland was a primary objective.
7 I can't remember exactly what led to it but I remember
8 in the course of signing batches off for clinical use,
9 which was part of my role, I noticed that we seemed to
10 be having an extraordinarily high throughput of
11 Factor VIII in particular and other products, and I then
12 in conjunction with the then production manager,
13 Mr Grant, decided to do a little more detailed analysis.
14 Primarily from the point of view that if stock levels
15 became too high, then product would outdate because the
16 shelf life was only two years. So if you had more than
17 two years' stock you were inevitably making product
18 which was never going to be usefully used.

19 I can't remember the exact process I used but it was
20 basically using data collected by the production
21 manager, and I thought this was of particular interest
22 to the SNBTS because at that time we were still,
23 I think, issuing product on what I recall was a system
24 called a pro rata system, in which regions of Scotland
25 got back product in proportion to the amount of plasma

1 that they issued. It was my view at that time that (a),
2 we had more than enough product in Scotland to meet
3 effectively the unconstrained needs of the haemophilia
4 population in Scotland. We had very large stocks, which
5 were growing. But also, with the knowledge that there
6 was a very substantially less degree of self-sufficiency
7 in England and Wales, that there was an opportunity to
8 provide some of this surplus product, which I perceived
9 it to be at the time, to colleagues in England and
10 Wales.

11 The objective at this time -- certainly in my mind,
12 and of colleagues -- was basically every bottle of
13 product that you could supply, made from UK or Scottish
14 donors in our case, prevented the requirement for
15 importation of product from the US. I think generally
16 the view was that if we did from time to time have
17 a surplus in Scotland, then it was our duty to offer
18 that to wider UK colleagues.

19 So this was basically doing the sums and making this
20 proposition to the SNBTS, that we had very, very large
21 and substantial stocks and it basically led to the sort
22 of actions that I have described.

23 Q. Dr Perry, even coming to this topic cold, as it were, as
24 most of us have, one doesn't need to think for very long
25 before realising that there must be quite complicated

1 issues involved in stock of blood products, more
2 particularly where the stock sits, how much stock should
3 be in each place --

4 A. Yes.

5 Q. -- down the supply chain. And by how much stock, I mean
6 in terms of how many months' supply.

7 A. Yes. Absolutely.

8 Q. Did PFC have experts on these sort of questions or was
9 it more sort of trial and error?

10 A. I wouldn't describe them as experts. It was nominally
11 the responsibility of the production manager reporting
12 to the director to manage stock and issue to customers
13 basically. But you are absolutely right, the
14 complexities, I think as evidenced by some evidence that
15 has been given this week to the Inquiry, that there is
16 a reconciling the stock figures against the various data
17 sets that are available was quite difficult at the time,
18 and even within PFC, when you asked what is the stock
19 level within PFC, it's a simple question but often used
20 to give rise to a very complex answer.

21 I think in this memo I refer to the sausage machine
22 and that implies that the manufacturing process for
23 Factor VIII probably takes, from plasma being entered
24 into process on day one, the product probably doesn't
25 get released for another four months. So at any point

1 in time, the Factor VIII product is at various stages of
2 release and testing and so on. The stock figures that
3 are often quoted as PFC stock only relate to the product
4 that was held in the warehouse, which was immediately
5 available for clinical use, ie had been released, had
6 been labelled, had been signed off and was ready for
7 dispatch.

8 But often, certainly during the early 1980s, there
9 were problems of that. We had warehousing problems. We
10 had with limited cold storage. So in a period of high
11 productivity, for instance, the sausage machine -- the
12 plasma would still be going into process and through
13 this period we can see that the level of plasma being
14 processed was massively increasing, but we didn't have
15 room to accommodate the product in the finished product
16 cold store at 4 degrees and therefore the intermediate
17 product would build up as a high stock, which was close
18 to the point of being ready to use but wouldn't have
19 actually been entered into finished stock figures.

20 So one has to exercise extreme caution when we
21 looked at stock figures. We had to then. We were
22 looking at the whole picture and often, for strategic
23 planning purposes, if you were looking at stock and
24 requirements for plasma and so on, you would look at the
25 entire contents of the sausage machine, and that, in

1 fact, is what I'm doing in my memo of November because
2 there I say there is 7 million units at various stages
3 of processing.

4 Q. Yes.

5 A. In addition, as we know, there was stock held at
6 regional transfusion centres, which were effectively the
7 retail outlets for our products. They were the
8 interface with the haemophilia doctors. They supplied
9 the product. So even for a small organisation like
10 SNBTS, you are absolutely right, the whole business of
11 maintaining stocks and controlling stocks and so on was
12 fairly complex and it wasn't computerised.

13 THE CHAIRMAN: Dr Perry, I'm not sure about the complexity.
14 Branch stock control is not unknown in the commercial
15 world, but I wouldn't have thought it was possible
16 without proper returns and records.

17 A. Yes.

18 THE CHAIRMAN: Was there a recording system in place?

19 A. There was.

20 THE CHAIRMAN: Did that extend to stocks at the local RTCs?

21 A. At the regional transfusion centres? In all honesty
22 I don't think the formal system of managing stocks
23 within PFC extended to the regional transfusion centres.
24 It was very simple because we only had five stock
25 centres, which were in the major cities of Scotland.

1 Certainly the reports that I used to see at the time
2 concerned primarily the stocks held at PFC.

3 THE CHAIRMAN: Do you have any recollection of stock
4 reconciliation exercises being carried out that would be
5 comprehensive in the sense of including RTCs and stock
6 in the hands of patients?

7 A. Yes, I think, certainly when I became director in 1984,
8 and of course I would say this, I significantly extended
9 the whole business of surveillance of stocks to include
10 RTC stocks because it was such an important area of
11 stockholding, particularly when we introduced the batch
12 dedication system, for instance, in 1985. That required
13 a significant outposting of stock from a central
14 location in Edinburgh to the individual centres that
15 were feeding the needs of the haemophilia directors.

16 THE CHAIRMAN: Perhaps we should take it chronologically and
17 Ms Dunlop has not come to that point yet.

18 A. Sure.

19 THE CHAIRMAN: But is it implicit in that you found
20 deficiencies in the stock control system when you took
21 over that position?

22 A. Well, like yourself, sir, I thought that in order to
23 plan the levels of production and the levels of plasma
24 and so on that were required, it was necessary, when
25 looking at stock, to look not just at the stock which

1 was held in PFC but also the stock that was held in the
2 regional transfusion centres, because that was
3 ultimately all SNBTS stock. So in the reports that
4 I subsequently used to give to directors, it always
5 included the total stock, which included the material
6 held in the so-called retail outlets for SNBTS.

7 MS DUNLOP: Dr Perry, will there have been notions of what
8 number of months' stock needed to be held in each place?
9 I'm not asking you to remember what they were but you
10 used the term "surplus" so you would be thinking
11 presumably, "We need to have a year's stock or something
12 at PFC", and you would work out that you had more than
13 that. Was that how it operated?

14 A. Yes.

15 Q. You did, I think, at this time, prepare some additional
16 documents. One of them is [\[SNB0073985\]](#). Actually we
17 have been told this is Mr Grant's writing, not your
18 writing.

19 A. Yes, that's correct. Yes, I believe it is, yes.

20 Q. If we turn to the next page of this document, this being
21 a document dated 4 November 1983, we can see that there
22 is a note of the stock that was then held in the
23 regional transfusion centres, the five Scottish centres
24 and Belfast.

25 A. Yes.

1 Q. That seems to link back into the content --

2 A. Indeed, and I think this is part of the exercise that
3 I carried out, with significant assistance from
4 Mr Grant, because it was at that point that I thought it
5 was important to find out what the
6 regional transfusion centre stock was. So, yes, this is
7 an early example of capturing stock levels from regional
8 transfusion centres.

9 Q. Quite interesting to see the Glasgow figure of 900,000
10 units.

11 A. Hm-mm.

12 Q. If we just follow this on a little bit in time, can we
13 look at [\[SNB0015252\]](#)?

14 This, I think, has a reference to the amount of
15 stock held in Glasgow, at least I'm hoping it does. Can
16 we scroll through it, please? This is 2 February, 1984.
17 We see paragraph 5(i). There is a discussion of the
18 amount of production. If we can go up a little bit,
19 please:

20 "Trends over the last five years indicated that the
21 SNBTS production of Factor VIII concentrates may be
22 exceeding clinical demand in that current stocks at
23 regional transfusion centres appear to be increasing."

24 A. Yes.

25 Q. That certainly seems to have been a perception in the

1 spring of 1984. Then if we look at May 1984, which is
2 [\[SNB0074393\]](#). This is one that gives quite a startling
3 figure.

4 A. Yes.

5 Q. You have obviously seen this recently too, have you?

6 A. I have indeed, yes. Yes, I remember it from the time as
7 well because ...

8 Q. It would be good if you just told us what you remember.

9 A. Oh, I just remember, as it indicates, this was fairly
10 soon after me taking over as acting director of PFC, and
11 one of the first things that I thought it was necessary
12 to do was, given the, at that time, really quite secure
13 position in terms of product supplies, it seemed to me
14 that we needed to review or we had the opportunity to
15 review the so-called pro rata system and simply issue
16 product in relation to what was required in different
17 regions. We didn't have to have this relationship, in
18 terms of the product we received, we didn't have to have
19 that as a relationship with the plasma that was entered.

20 So this was part of a process of really speaking to
21 colleagues, and Donald Hopkins was the consultant who
22 was in charge of these stock control aspects in Glasgow,
23 and I asked him for basically clear updated information
24 on what the stock levels were, and I remember, when
25 I got this letter back, following the phone call, I was

1 really quite shocked, surprised and to an extent
2 delighted that we had so much outposted stock which gave
3 us a great deal of flexibility in terms of planning. It
4 was a very significant piece of information and
5 certainly the stock level in Glasgow was much higher
6 than I would have thought it would have been.

7 Q. Yes, and enabled you not just to make your forward plans
8 but also to give some of it to patients in England?

9 A. Oh, absolutely, absolutely. So this was all part of the
10 process of saying, "Look, we don't have to divide up the
11 available product in Scotland according to either
12 a population basis or a pro rata input of plasma, we can
13 simply do it on the basis of clinical need". And I
14 think it was very early in 1984 that we abandoned the
15 so-called pro rata system and simply issued to regional
16 centres on the basis of minimum stock levels.

17 So we created a fairly simple system which involved
18 regular reports from the regional transfusion centres on
19 a monthly basis, what their stock levels were. We
20 established what the minimum level was and we would then
21 issue on a monthly basis product to ensure that they
22 were always at or above their minimum stock level.

23 THE CHAIRMAN: Could we look up to see where Dr Hopkins was
24 situated.

25 MS DUNLOP: He was at Law as well.

1 A. He was at Law.

2 THE CHAIRMAN: Do you understand that these returns included
3 the Glasgow Royal Infirmary.

4 A. No, these just included Law BTS. So to the best of my
5 recollection, these particular returns only included the
6 material held by the SNBTS and the
7 Glasgow Royal Infirmary was basically blood bank stock.
8 So there was a further depot, but I think for practical
9 reasons they didn't hold large quantities of product,
10 but significant quantities. Because if
11 Glasgow Royal Infirmary needed a quick delivery of
12 product, it would be a very simple matter to get it from
13 Law to the Glasgow Royal Infirmary.

14 MS DUNLOP: We have heard reference, Dr Perry, to a daily
15 order form going from the Royal Infirmary to Law.

16 A. Hm-mm.

17 Q. You probably don't recollect very much about what the
18 practical arrangements were.

19 A. No, except that, because it was issuing blood as well,
20 there was transportation basically shuttling between the
21 centre at Law and the major hospitals in Glasgow. So it
22 would have been perfectly simple and appropriate to
23 issue on a daily or a weekly basis but I'm not sure of
24 the detailed arrangements they had for transferring
25 stock from Law to the Glasgow Royal Infirmary.

1 Q. Yes. Certainly, as far as concentrates are concerned,
2 that does sound slightly different from Edinburgh, where
3 Professor Ludlam made reference to the van coming
4 monthly. Do you remember that?

5 A. Yes. I think what he is referring to is the PFC van.

6 Q. Yes.

7 A. Actually it was a lorry and I think, again in the early
8 1980s I think it was a sort of monthly trip where the
9 van would collect the plasma from the
10 regional transfusion centre on a monthly basis and it
11 would also have a compartment in the van for delivering
12 the products because they were temperature-controlled
13 product.

14 So I think the deliveries to regional transfusion
15 centres were roughly on a monthly basis. I think
16 subsequently we reviewed that and I can remember a time
17 where I think there might have been weekly deliveries
18 because that was more convenient and required lesser
19 regional stockholding of product.

20 Q. Did the same truck go to and from Law?

21 A. Yes, and Inverness and Dundee and Aberdeen. But the
22 transportation from Law to the Glasgow Royal Infirmary
23 was operated by the West of Scotland Blood Transfusion
24 Service.

25 Q. For all the other centres was it the same convenience of

1 exchange --

2 A. Yes, absolutely. It was there to collect the plasma and
3 to distribute the finished product. If there was
4 periodically emergency issues of a rare product or
5 a shortage, then obviously we had arrangements where
6 vans could be sent up to any part of Scotland and
7 product delivered, but the standard system, I think,
8 from memory, was roughly a monthly cycle.

9 Q. Dr Perry, I wanted to ask you some questions about
10 supply to particular hospitals, and I accept that you
11 are arrived in March 1981 and it may be that some of
12 these were matters that really were determined before
13 you came on the scene, but it is important to us to try
14 to find out as much as we can about why there was
15 a particular pattern of usage at Yorkhill, to start.

16 We have quite lot of information about the use of
17 commercial products in Yorkhill, particularly around the
18 turn of the late 1970s and early 1980s. Do you know
19 anything about that? Do you remember anything about it?

20 A. About the pattern of usage at Yorkhill?

21 Q. Yes.

22 A. Probably not. I was aware fairly early on that there
23 were parts of Scotland that were continuing to use
24 commercial products. This was referred to in various
25 meetings and so on. You know, in terms of my level of

1 awareness, certainly up until I took over as director in
2 1984, I was aware of the fact that there were still some
3 parts of Scotland that were using commercial product,
4 and again I didn't dwell on that too much, it wasn't
5 part of my job to do so. My understanding was that
6 there were some doctors that preferred commercial --
7 this was my understanding.

8 I'm not suggesting it is correct or factually
9 accurate, but my understanding and belief was that there
10 were some doctors that preferred commercial product for
11 one reason or another and indeed, in the very early
12 1980s it was the case that the SNBTS stock levels and
13 supplies weren't as secure as they were two or three
14 years later. I think the early 1980s saw a very
15 substantial ramping up of output and stocks. But
16 I don't remember in detail any discussions or
17 significant reflection on haemo--

18 Q. Do you think it would be accurate to say that that's
19 something that you just took as a given?

20 A. I took it as a fact of life but also took it as a target
21 that part of our job was to increase our performance and
22 output so this was no longer necessary. That was the
23 take-home message for me as the operational manager of
24 the fractionation centre, and indeed I think that's
25 certainly the case with the wider SNBTS.

1 Q. You have already explained a bit about the situation in
2 the West of Scotland to us and the system that applied,
3 I take it, from your arrival, of allocation back to
4 different regions on the basis of the amount of plasma
5 they had supplied; how much flexibility was there in
6 that if somebody rang up and said, "We are terribly
7 short, we have finished our allocation"?

8 A. I think it depended very much on what material was
9 available in the central stockpile. I think the
10 pro rata system was designed, from memory, to include
11 not only this pro rata allocation to regions but I think
12 you might call it bottom slicer, a bottom slice of the
13 total output in a period of time was retained as central
14 stock in PFC to meet that sort of circumstance that you
15 described.

16 The extent to which that flexibility was actually
17 used I don't recall because, as I say, I wasn't directly
18 involved in any detail in the sort of monthly/daily
19 transactions of supply. My job was quality management
20 and quality systems and so on.

21 Q. Did you visit Law from time to time?

22 A. Yes, I visited Law quite early on in my career in the
23 SNBTS, yes, but primarily -- and again I recall this
24 quite vividly -- it was to begin the process of
25 introduction of standard operating procedures and

1 quality management systems and so on, but not in
2 relation to product supplies or pro rata system or
3 product delivery.

4 Q. That was really what I was meaning. I was wondering if
5 when you went to Law there was some sense in which you
6 were there to discuss any difficulties they might be
7 having or, I suppose, any comments or complaints they
8 might want to relay about the product or the amount of
9 supply.

10 A. Not at that stage. SNBTS is a fairly small organisation
11 and there were fairly effective, informal systems but
12 I think it's fair to say if there were substantive
13 concerns from any regional transfusion centre about the
14 supply of plasma products or quality issues and so on,
15 they would have been taken up on a director to director
16 basis.

17 Q. Right. We have heard evidence from Dr Boulton -- and
18 you will know Dr Boulton?

19 A. Yes, indeed.

20 Q. We have seen a lot of correspondence as well involving
21 him and it is clear that he was a sort of middleman or
22 a liaison person in Edinburgh between Dr Ludlam in the
23 haemophilia centre and PFC and he was assisting
24 Dr Ludlam to obtain the stock he required for the
25 treatment he wanted to give patients?

1 A. Yes.

2 Q. Who was the equivalent of Dr Boulton for the West of
3 Scotland, or was there not one?

4 A. I think, as Dr Boulton suggested in his evidence -- and
5 I did have a chance to read it very briefly last
6 night -- I don't think there was an immediate or direct
7 equivalent to Dr Boulton. I think Dr Hopkins, who was
8 a consultant in the West of Scotland, was in some ways
9 responsible for managing stock levels and the blood bank
10 and so on, but in terms of the clinical interface,
11 I don't think there was a personal in the West of
12 Scotland who worked closely in a clinical sense with the
13 haemophilia doctors.

14 I think, if there were equivalents it was people
15 like Isobel Walker and John Davidson in
16 Glasgow Royal Infirmary, but they weren't SNBTS staff,
17 they were part of the Glasgow blood bank. The
18 difference, as I'm sure you know, between Edinburgh and
19 Glasgow is that Edinburgh did not only the blood
20 collection and testing and processing and so on, but it
21 also ran the blood bank. In the West of Scotland, it
22 collected the blood, did the processing and testing but
23 the blood bank was run by the health board.

24 Q. Just lastly, the whole issue of allocation pro rata, who
25 monitored that overall? Was there somebody at PFC whose

1 job it was to do the calculations for plasma --
2 A. Yes, it was basically the production department.
3 Certainly, when I joined in 1981, it was very clear that
4 that's what they did. I think there were other much
5 more formal arrangements on at least an annual basis.
6 I remember there being meetings of the directors and
7 they were called the pro rata meetings, and part of
8 their function on an annual basis was to look into the
9 future, work out the best requirements for demand, apply
10 the formulas that existed and give colleagues in the
11 wider regional transfusion centres some idea of how much
12 product they might expect in the coming 12 months.

13 So there were very formal agreements an allocations
14 and how much would be held at central level in PFC and
15 how much would be distributed and on what sort of
16 frequency. So there was a very formal process and that
17 process was chaired by Professor Cash and the regional
18 directors attended that. At the end of that meeting
19 there would be a clear definition of what the plasma
20 intake target was, what the plasma processing target
21 should be, what the product output was likely to be
22 based on yield calculations and so on, and how much
23 regional centres could be expected to receive of not
24 only Factor VIII but Factor IX, albumin and
25 immunoglobulin products. It covered the whole range of

1 products.

2 Q. Thank you, Dr Perry.

3 THE CHAIRMAN: Mr Di Rollo?

4 Questions by MR DI ROLLO

5 MR DI ROLLO: Dr Perry, can I just take you back to
6 a question that you were asked at the beginning about
7 clinical judgment and doctors being free to exercise
8 their own judgment.

9 I think in your statement the passive voice is used.
10 It says:

11 "It was also accepted that prescribing doctors were
12 free to exercise their own judgment in the choice of
13 either SNBTS or commercial products preserving the
14 important principle of clinical freedom."

15 Can I ask you just exactly who accepted that?

16 A. I think the whole of the senior management of the SNBTS
17 accepted that as a reality of the world that we lived
18 in, and we were not operating a totalitarian system
19 here, that required prescribing doctors to use what they
20 were given basically. And I think that principle was
21 certainly embraced by Professor Cash and certainly
22 embraced by the regional transfusion service directors.
23 And certainly -- I wouldn't say embraced by myself, I'm
24 not a doctor -- but I certainly accepted that that was
25 part of the world in which we operated.

1 Q. I take it that in terms of when that was accepted, that
2 was something that when you joined the organisation,
3 that acceptance was in place and continued throughout.
4 Is that correct?

5 A. It was an acceptance of that principle but in a sense it
6 was a driver for minimising the requirements for doctors
7 to exercise that freedom by obtaining commercial
8 product. Our objective was to make the SNBTS product
9 the product of choice in both quality and quantity, to
10 meet the needs of haemophilia directors. So it wasn't
11 just a complete free-for-all; there were very close
12 relationships between the directors of the Scottish
13 Transfusion Service, whose job it was to collect the
14 plasma and make the product, and the haemophilia
15 directors who were the users. And as we know, there
16 were regular meetings between these groups to plan the
17 future.

18 Q. How do you reconcile this idea of clinical freedom with
19 the principle of self-sufficiency?

20 A. It is a difficult reconciliation. That's absolutely
21 right. I think for true self-sufficiency, which I don't
22 think any organisation has truly achieved, for all sorts
23 of technical and clinical reasons, there will always be
24 an occasion when the range of products that you make,
25 certainly in the complex area of blood transfusion and

1 plasma products, won't be the right one for a particular
2 patient.

3 So you will never achieve 100 per cent but I think
4 for self-sufficiency to be substantively achieved, it
5 has to be, in my view, an exercise that's undertaken not
6 only by the supplying organisation but by the receiving
7 organisation as well. There has to be a will and
8 a determination to achieve this thing called
9 self-sufficiency or close to it.

10 Q. So in order to sign up to self-sufficiency truly, the
11 clinicians have to sign up to. They have to say, "We
12 are going to use Scottish plasma"?

13 A. Yes, they have to be part of the process that says, "We
14 understand why we want to be self-sufficient; we realise
15 the advantages of this and we will work as closely with
16 you as we can to make that happen."

17 So it does require a prescribing doctor to say,
18 "I am part of the Scottish Health Service, I must do the
19 best for my patients, but I am also part of a process
20 which I believe in, which is to do everything we can to
21 avoid the unnecessary use of products which are perhaps
22 less safe than those provided by the NHS".

23 Q. Scotland is a relatively small community, a small place.
24 All the clinicians that are active in this area and the
25 SNBTS, they all know one another, they all meet

1 together, they all discuss these matters?

2 A. Indeed, as indeed the SNBTS doctors and the haemophilia
3 doctors did. In fact I think it's a matter of knowledge
4 to most people here that there were regular meetings
5 between the SNBTS directors and the haemophilia doctors
6 to effectively plan for self-sufficiency or at least to
7 work out how best to meet the needs of patients in
8 Scotland.

9 Q. Can I ask you about the next part of your statement.

10 You are dealing with licensing matters and one of the
11 things you say in your statement is that:

12 "It is likely and appropriate that ..."

13 This is on the third page of your statement:

14 "It is likely and appropriate that this formal
15 position would have informed the policies and decisions
16 of treating doctors."

17 And what you are referring to there is that the
18 licensing of products -- I think the idea in your
19 statement -- please correct me if I am wrong -- is that
20 the fact that a commercial product was licensed would
21 inform the doctor or the clinician as to whether or not
22 it was appropriate to use that material; in other words,
23 if it was licenced, then it was all right to use it. Is
24 that what you are suggesting?

25 A. I think that's what the licensing system is intended to

1 achieve. It's intended to give prescribing doctors
2 clear indications that the product is safe, it's
3 efficacious, its risk/benefit balance has been properly
4 and objectively assessed and it is suitable for use,
5 absolutely.

6 Q. I have to say that -- and as far as I have heard any
7 evidence -- and I will be corrected if I'm wrong --
8 I don't hear the directors telling us, the ones that
9 have given evidence, that the fact that the commercial
10 product was licensed actually made any impact on their
11 decision-making at all -- obviously, it's a requirement
12 to use it because you can't use it if it's not licensed,
13 but that that again had an impact in their decision as
14 to whether or not to use it. In fact the reverse
15 appears to be true. Quite a number of doctors have
16 indicated that, notwithstanding the fact that the
17 commercial product was licensed, they chose not to use
18 it because there were specific risks in relation to
19 that?

20 A. Yes.

21 Q. Do you want to comment on that?

22 A. Only to say that at that particular time I think the
23 licensing and the continued licensing of products was
24 part of the confused world that we operated in.

25 I think, as we have discussed previously, the notion of

1 removing licences for these products on the basis of
2 what we now describe as a precautionary principle would
3 have created so much disruption in the treatment of
4 patients that it was considered an inappropriate thing
5 to do.

6 I would still take the view that the licensing
7 system was and is set up to establish that products can
8 and should still be used safely in clinical use. That
9 doesn't preclude an individual doctor for a whole number
10 of reasons not using a particular product. But I agree,
11 that there is a slight conflict there. The system, you
12 know, as we now know, was not as effective as it might
13 have been but the consequence of creating a safer
14 environment was to expose patients to no treatment at
15 all, certainly with concentrates.

16 Q. Do you know if any doctors took the view that the
17 material from PFC should not be used because it wasn't
18 licensed, in the sense that it had Crown immunity?

19 A. No, I don't recall that being a specific concern.
20 I think colleagues, haemophilia director colleagues,
21 periodically expressed concern, particularly in terms of
22 their liability and the fact that it was a product that
23 was made under Crown immunity and what were their
24 liabilities in case anything went wrong. I think that
25 was an issue and there were some issues, which are well

1 documented, concerning some concerns that people like
2 Professor Ludlam had in terms of doing clinical trials
3 on behalf of SNBTS and what safeguards were in place for
4 patients and doctors in the event that the clinical
5 trial created a problem or an adverse event for
6 a patient.

7 I don't recall at any time doctors simply saying --
8 or haemophilia doctors withdrawing from the process of
9 self-sufficiency, as it were, on the basis that these
10 products were made under Crown immunity and they didn't
11 operate within the UK licensing system.

12 Q. Not withdrawing but just expressing concern or being
13 worried about that. That wasn't expressed to you at any
14 rate?

15 A. I don't recall it being a major feature of the
16 landscape. I think what we were trying to do, and
17 collectively, was to do everything that we could to make
18 sure that we maximised the availability of products to
19 treat patients from Scottish plasma, certainly in this
20 period in the early 1980s.

21 Q. If that's right, then that would possibly tend to
22 suggest that the licensing or otherwise doesn't really
23 come into this decision, clinical decision?

24 A. No, I think my issue about licensing, informing doctors,
25 would have been primarily, you know, perhaps a more

1 important issue in England and Wales, but also, I think,
2 just as part of the general background of
3 decision-making, the fact that the UK licensing
4 authority, which has very substantial experts on it --
5 these are not lay people, these are highly experienced
6 professionals -- if they take the view that a product is
7 safe, then that is a reasonable baseline to start from.

8 Q. Right. You indicated, I think, at one stage of your
9 evidence that in the early 1980s there was a ramping up
10 of product in relation to performance and output. What
11 I wondered is, are you aware of concerns that were
12 expressed about availability and, more importantly, in
13 relation to quality of PFC material by clinicians? Was
14 that articulated to you?

15 A. I think there were concerns in the early 1980s. I think
16 there were solubility issues. Yes, I was aware of
17 those.

18 Q. You were aware of them at the time?

19 A. I was aware of them at the time and I was also aware
20 that under the leadership of Peter Foster we were doing
21 everything we can to actually improve the so-called
22 quality of the product. But we were aware that our
23 products in some respects were less user friendly --
24 I think the term has been used -- than some other
25 commercial product.

1 Q. But, notwithstanding that, certain clinicians were able
2 to use exclusively NHS product?

3 A. Absolutely.

4 Q. Just one point in your statement. Again it's the
5 third page. It's just the page we are on, yes.

6 Just to emphasise one point, you say:

7 "However, SNBTS medical and scientific staff would
8 have held personal and speculative views on AIDS and
9 there was periodic informal discussion on the topic but,
10 in absence of both the formal requirement or
11 responsibility for it to intervene or advise on the use
12 of licensed commercial products and the paucity of
13 scientific information available, it did not, to the
14 best of my knowledge, express a formal view or make any
15 specific relations."

16 I think this is in connection with the issue of
17 decision-making at the beginning of 1983 or just shortly
18 after the beginning of 1983.

19 A. That's right, yes.

20 Q. And really what you seem to be saying is that there
21 wasn't a formal requirement for SNBTS at that time to
22 make any specific decision about matters and it didn't
23 have any specific, as it understood it, responsibility
24 to intervene or advise at that time. That's correct, is
25 it?

1 A. I think it was certainly my understanding at the time
2 and probably still is, with the benefit of hindsight,
3 that it wasn't any part of SNBTS's job to define the
4 overall -- again this goes back to the clinical freedom
5 issue. Our job, as a collector of blood and plasma and
6 manufacturer of plasma products, was to do just that.
7 Our job wasn't to become the judge and jury on all the
8 products that should be used in Scotland. So it
9 certainly wasn't part of the role of PFC.

10 Q. So where is this responsibility then? If it's not
11 SNBTS, where do you say it is?

12 A. In terms of deciding which product is best for each
13 patient?

14 Q. No, I think really --

15 A. Whether or not a commercial product should be used?

16 Q. -- used?

17 A. I think the responsibility (a), rests with the licensing
18 authority, that's what the system was set up for but
19 also with the prescribing doctor, with any additional
20 information that they have over and above the license
21 status of a product to decide whether it is the best
22 product to use.

23 Q. What about PFC product? Where is the responsibility
24 there?

25 A. For using PFC product?

1 Q. Yes.

2 A. I think formally that rests with the Secretary of State
3 for Scotland as it was at the time, but also the
4 responsibility for using it rested with the haemophilia
5 doctor on the basis of the status that the product had.

6 Q. Just two other matters I want to ask you about.

7 THE CHAIRMAN: Just before you leave that, Mr Di Rollo. You
8 have dealt quite a bit with the use of licensed
9 products. I wondered whether you wanted to ask any
10 questions about the use of products on a named-patient
11 basis, whether Dr Perry might know anything about that.

12 MR DI ROLLO: I'm quite happy to -- perhaps you would be
13 better to ask the precise question because I don't think
14 I had specifically in mind. So I would be grateful.

15 THE CHAIRMAN: Are you aware of products being used on
16 a named-patient basis?

17 A. I'm aware of the system that allows products to be used
18 on a named-patient basis.

19 THE CHAIRMAN: Would you like to tell Mr Di Rollo what the
20 system was then.

21 A. What the system was then? I think the system was -- and
22 again, I'm not an expert but I think a clinician or
23 doctor is always free to use a drug to treat a patient
24 whether or not it's licensed if he believes and can
25 justify that that's in the patient's interest. I think

1 the downside to it, which is clearly an issue if you are
2 a prescribing doctor, is that if you do take that
3 decision, then the responsibility is wholly yours for
4 the outcome and the consequences of that, whereas if it
5 is a licensed product or it's a product in clinical
6 trial you are using, so long as you prescribe the
7 product in the right circumstance and use it in the
8 right way, then the responsibility is very much shared,
9 if not more wholly owned by the licensing authority
10 because they are the people that have taken the expert
11 view that the drug is safe, efficacious and can and
12 should be used.

13 MR DI ROLLO: I'm grateful for that, chairman.

14 Just two other matters I want to ask you about
15 relating to the use of PFC product. Just in terms of
16 its manufacture, was there a stage at which package
17 inserts were included with the material which warned of
18 the risk of AIDS from products?

19 A. Yes.

20 Q. When was that?

21 A. I can't remember from memory but it would have been --
22 I'm sorry, I would need to look those data up but
23 I think the SNBTS has done a lot of work on leaflets and
24 when they were inserted into the particular products but
25 I think it is a matter of record and I'm very happy to

1 come back with the answer to that question.

2 Q. Somebody is telling me that this is a matter of record

3 so no doubt we can find out, but perhaps we can -- I'm

4 told it's coming.

5 A. Okay.

6 Q. The other matter is, was there ever a time, in your

7 knowledge, that there was a surplus in Scotland or even

8 a sort of self-sufficiency before that point was

9 reached, where Scottish material was exported to

10 England?

11 A. Hm-mm.

12 Q. There was?

13 A. I'm sorry, maybe I jumped forward with your question.

14 Q. Sorry.

15 A. Was there a period before we had a surplus?

16 Q. Yes.

17 A. Where product was exported to England?

18 Q. That you are aware of.

19 A. I can't remember that being the case, although that

20 doesn't preclude the possibility that occasionally,

21 maybe not Factor VIII but other products may have been

22 supplied to colleagues in England and Wales.

23 Q. Thank you very much.

24 THE CHAIRMAN: I think we know that at one stage PFC did

25 hold plasma that had been sent by England, when the

1 scope of Scottish production was still under discussion.

2 A. That's right.

3 THE CHAIRMAN: If we limit Mr Di Rollo's question to a time
4 when product from Scottish plasma might have been sent
5 to England, does that help you to be more particular?

6 A. Well, I think the English plasma that you refer to was,
7 I think, so-called recovered or outdated plasma and
8 wasn't used for coagulation factor manufacture. I think
9 it was primarily used for albumin. Our generous
10 colleagues in England and Wales said, "We don't
11 necessarily want the product back". But in terms of
12 excluding that from the equation, again I have no
13 immediate memory today of an example of SNBTS exporting
14 significant quantities of plasma products to colleagues
15 in England and Wales. Although periodically that may
16 well have happened. Certainly, as we know, we did in
17 late 1984.

18 THE CHAIRMAN: Late 1984?

19 A. Actually in mid 1984 I think the transfer actually took
20 place, and that was roughly 2 million units.

21 THE CHAIRMAN: Thank you.

22 MR ANDERSON: I have no questions.

23 THE CHAIRMAN: Mr Sheldon?

24 Questions by MR SHELDON

25 MR SHELDON: Just two matters, if I may.

1 Doctor, you mentioned that it was perhaps not until
2 the mid or late 1980s that the Scottish Home and Health
3 Department made a clear, unequivocal statement about
4 self-sufficiency and I just wondered what kind of
5 statement you had in mind there.

6 A. A clear policy statement from SHHD, that is part of Her
7 Majesty's government in Scotland, that we will be
8 self-sufficient. I can't place that in time. This is
9 actually as a result of a fairly recent conversation
10 I had with Professor Cash, who felt this was the first
11 time that we had a clear statement from the Scottish
12 Home and Health Department on self-sufficiency.

13 I think until that point, the references to
14 self-sufficiency -- certainly Professor Cash would argue
15 and perhaps myself to a certain extent -- were that it
16 was never absolute government policy -- or it was never
17 clear to us that it was government policy -- that we can
18 and should navigate towards self-sufficiency, although
19 all the indications, all the suggestions, the culture,
20 the meetings, the process that was put in place,
21 indicated that self-sufficiency was the target.

22 Q. I just wondered really whether you had in a mind
23 a public statement?

24 A. No, just basically a clear written statement that
25 self-sufficiency was part of the Scottish Government's

1 priorities for the service.

2 Q. Yes. Could we look, please, at a document, it's
3 [\[SNB0015160\]](#). This is the minutes of a meeting of the
4 SNBTS directors and the haemophilia directors on
5 21 January. I don't think that you are there, Dr Perry.
6 Certainly not in terms of the list of those who were
7 present.

8 A. No, I wouldn't have been at that stage. No.

9 Q. But we see Dr Cash is there --

10 A. Yes, and Mr Watt, my predecessor.

11 Q. Indeed. Could we just look, please, at the third page
12 of that document, page 3? In the second paragraph down
13 we see:

14 "Concern was again expressed about the amount of
15 commercially produced Factor VIII that's still being
16 purchased."

17 It's perhaps just worth noting that about half way
18 down that paragraph, Dr Ludlam indicates that the
19 reasons for the use of commercial material in Edinburgh
20 were partially clinical and partially a policy of
21 conserving a cushion of NHS Factor VIII. But it's clear
22 that commercial material is still being used.

23 A. Yes.

24 Q. Then if we move down the page, I think it's the second
25 last paragraph.

1 A. Indeed, yes.

2 Q. We see that the chairman, who I think is Dr Bell of
3 SHHD --

4 A. Yes, it was Dr Bell, yes.

5 Q. -- stressed that:

6 "The SNBTS had been set up to have the capability to
7 cope with all Scottish requirements ..."

8 Reading short:

9 "... and that in terms of national policy, the
10 purchase of commercial product should be avoided so far
11 as possible."

12 So would you agree that really, at least in terms of
13 what I suppose one might regard as a private meeting, as
14 opposed to a public statement, nevertheless it's
15 a fairly clear statement that what SNBTS is about is
16 self-sufficiency and indeed the avoidance of commercial
17 product?

18 A. I would agree with you. I'm not suggesting that there
19 were never any clues coming from SHHD concerning our
20 status and I would agree, there are a number of other
21 references in meetings of this type where the
22 self-sufficiency requirements are actually mentioned.
23 I think what myself and colleagues were concerned with
24 is, if you then pursue that had a little further and
25 say, "What does self-sufficiency actually mean?" --

1 because I think, you know, in the real world you are
2 just saying "self-sufficiency"; it can mean all sorts of
3 different things to different people and from
4 a government perspective, it could be an open cheque
5 book. And Dr Bell was an extremely able and good
6 colleague and friend of the SNBTS, and I would expect
7 him to say this, and he passionately believed in this
8 particular process, but I think if one tried to probe
9 that further and say, "Can we have a clear statement
10 from Scottish Home and Health Department what they
11 actually mean by that, ie what actions arise from that
12 policy, what are our orders in terms of meeting
13 self-sufficiency," I think that always fails to
14 materialise.

15 Q. Perhaps I could just pursue that a little further then,
16 because I think at one point in your evidence you
17 indicated that whatever the situation about public
18 statements about self-sufficiency and so on, you all
19 felt that that's the goal you were working towards.

20 A. Hm-mm, absolutely.

21 Q. I think that perhaps appears from the minutes of this
22 meeting: that everybody perhaps takes on board that
23 self-sufficiency is a desirable goal.

24 Can I just ask you then: what was the goal that you
25 took yourself to be working towards in terms of

1 self-sufficiency?

2 A. Meeting most, if not all the needs for plasma products
3 in Scotland, with the exception of occasional rare
4 products, individual patients who had idiosyncratic
5 reactions to the product that we had on offer. We would
6 fully accept that it would certainly be justified to use
7 a non-NHS product.

8 And I think we quantified it. In the absence of
9 a clear statement -- which in some senses is
10 understandable, but in the absence of that statement we
11 tried to quantify -- because planning self-sufficiency
12 is a quantitative concept not a qualitative one -- and
13 we established targets of 2.75 million units per million
14 population and so on, as navigational systems to guide
15 our activities.

16 I think the way we generally tried to get
17 a collective agreement on what self-sufficiency was --
18 and I think primarily through the communications of
19 Professor Cash -- was to officer proposals to the
20 Scottish Home and Health Department, particularly at
21 these annual meetings, and seek their agreement that
22 2.75 million international units was an appropriate
23 target, and more often than not, Scottish Home and
24 Health Department would agree that subject to
25 availability of funding, of course, but that was broadly

1 how the process would work.

2 Q. Yes.

3 A. But as far as I was concerned as an operational manager
4 in PFC, self-sufficiency was about maximising our output
5 and as I've said previously, every bottle of product
6 that we could make from Scottish donors avoided the
7 importation of a product from other sources, which we
8 held and believed were less safe. That was the culture,
9 that was the ethos, that's what drove the team at PFC.

10 THE CHAIRMAN: We will have a break now. You will bear in
11 mind that there were public statements in 1984 in
12 England and in Scotland in the preliminary report at
13 paragraphs 10.148 and then again at 10.155 to give you
14 the timeframe.

15 (11.10 am)

16 (Short break)

17 (11.31 am)

18 THE CHAIRMAN: Mr Sheldon?

19 MR SHELDON: Thank you, sir.

20 Dr Perry, I wonder if I can just take to you another
21 document. It is [\[SNB0015252\]](#). I think this is a set of
22 minutes, again of the joint directors, a meeting at
23 which this time I think you were present.

24 A. Yes.

25 Q. This is 2 February 1984 and again Dr Bell is in the

1 chair. Perhaps we could look, please, at page 2, the
2 second page of the document. Right at the foot of that
3 page, we see that Dr Cash is asking members to consider
4 whether, given present SNBTS production of Factor VIII,
5 it was necessary to purchase commercially unless
6 exceptionally a superior product was available. And
7 then over the page there appears to be some discussion
8 about the use of commercial products. Dr McDonald and
9 Dr Hann contribute. Again Dr Ludlam indicates he
10 required to have a small stock of higher purity
11 commercial material for a very few patients.

12 A. Indeed.

13 Q. I think we have heard there may be circumstances, where,
14 for example, patients with inhibitors may require
15 particularly high purity Factor VIII. Is that your
16 understanding?

17 A. Yes, and I think maybe small children, but that's my
18 understanding: a patient that requires large volume
19 treatment. And that would typically be an inhibitor
20 patient who might not be able to tolerate the
21 relatively lower purity SNBTS or NHS product.

22 Q. We then have a paragraph where Dr Bell emphasises again
23 that the aim of SNBTS and national policy was for
24 Scotland to be self-sufficient:

25 "... and although the department would not wish to

1 intervene in what clinicians prescribed, it was not
2 sensible to purchase imported material when suitable NHS
3 product was available."

4 A. Indeed.

5 Q. You have talked a little bit in your evidence about the
6 idea of clinical freedom. Is that an issue which
7 appears to be in Dr Bell's mind in that little passage?

8 A. Well, I would imagine that's -- knowing Dr Bell as
9 I did, he would choose his words very carefully when
10 discussing these issues. And he, I think, like SNBTS,
11 was a strong advocate of self-sufficiency but he is
12 also, I wouldn't say a strong advocate but he recognised
13 that this so-called clinical freedom issue was an
14 important consideration, and it certainly wouldn't have
15 been a position of the Scottish Home and Health
16 Department to try and force-feed haemophilia doctors and
17 their patients with a product that they didn't want.

18 So I think, yes, he would have embraced
19 self-sufficiency very enthusiastically but he would have
20 also embraced the important element, that the Scottish
21 Home and Health Department did not wish to intervene in
22 clinical decisions and product choices of haemophilia
23 doctors. So, yes, it's in that sort of difficult zone
24 between the two.

25 THE CHAIRMAN: At this stage who controlled the budget?

1 A. The budget for the SNBTS was controlled, effectively by
2 the Scottish Home and Health Department through the
3 Common Services Agency. The budget for commercial
4 purchase would have been in 1984, to the best of my
5 knowledge, that would have been health boards.

6 Q. And the health boards received their money from?

7 A. The Scottish Home and Health Department.

8 THE CHAIRMAN: Yes.

9 MR SHELDON: Just thinking a little bit more about issues of
10 clinical freedom and self-sufficiency, doctor, was there
11 any discussion at this meeting, or indeed any other that
12 you can recall, about the extent to which the amount of
13 Factor VIII that haemophilia clinicians prescribed
14 should be or could be reined in or controlled?

15 A. No, I think during this period we were -- well, I can
16 perhaps only speak for myself, but from a PFC
17 perspective, our understanding at that time, that demand
18 for plasma products was and would continue to increase.
19 And part of the challenge was to actually respond to the
20 quantitative increase in product requirement and also
21 the qualitative increase in product requirement, ie
22 introduction of heat treatment and all these other
23 safety factors that were being considered.

24 So I don't think there was any discussion in these
25 meetings to try and control the activities of

1 haemophilia directors to fit the product that was
2 available. The discussion was primarily about how we
3 could meet our ambition to be largely or as
4 self-sufficient as possible in the supply of coagulation
5 factor products to treat patients in Scotland.

6 I think there were periodically discussions about
7 increased usage, and I think haemophilia doctors were
8 perhaps not called to account but they were asked to
9 explain why the demand for Factor VIII was rising on
10 a year on year basis, but I don't think it was with the
11 specific intention, either from SHHD or anyone else, to
12 say that too much was being used. But I think they were
13 putting a mark down that we are interested in
14 quantitative increases for the reasons that I have
15 discussed. Self-sufficiency, if not defined and scoped
16 out, is basically an open-ended process with
17 a potentially infinity sum of funding required. So it
18 was --

19 THE CHAIRMAN: Dr Perry, at the end of paragraph 5 there is
20 a paragraph:

21 "It was also pointed out that an accurate assessment
22 of future need could only be made if commercial
23 processes were fully identified and taken into account."

24 Do you remember who made that point?

25 A. Dr Bell -- no, I don't remember, no.

1 THE CHAIRMAN: It's a fairly obvious point.

2 A. It's a fairly obvious point and it could well have been
3 made by Dr Bell and perhaps what Dr Bell -- if it was
4 him and it reads as though it was him -- he would have
5 been certainly familiar with the important requirement
6 of understanding what the total usage of Factor VIII was
7 including commercial product, knowing that that was
8 a problem or an issue.

9 MR SHELDON: Can I just finally, in relation to this
10 document, ask you for your recollection, if any, of the
11 context of that discussion. Was that discussion about
12 commercial products and the use of commercial products,
13 a discussion in the context of cost or a discussion in
14 the context of risk?

15 A. I think it was a discussion -- from memory -- and this
16 is one of perhaps a number of occasions where this type
17 of discussion would have taken place, and I think
18 typically it would have been led by Professor Cash who
19 was the national medical director, we would have had
20 information. It might not have been accurate but we
21 knew that whilst SNBTS had substantively achieved its
22 goal of making enough product quantitatively for
23 treating patients in Scotland, there was still
24 commercial purchase, and our view, as I have described,
25 was certainly that one vial of NHS product made avoids

1 the importation of a less safe US product. And so
2 I think it was probably risk-driven but also financially
3 driven.

4 I think Professor Cash -- I think he did lead this
5 particular discussion -- was challenging, I think, his
6 colleagues, haemophilia director colleagues, to
7 effectively justify the use of commercial product when
8 there was a suitable NHS product available, but that
9 would have been also trying to establish whether there
10 was any particular problem with the SNBTS product.

11 Q. Thank you. Just one final matter.

12 You mentioned some issues about the licensing of
13 medicines and so on and indicated that that appeared to
14 be a UK matter. The possibility was floated, I think,
15 by Ms Dunlop about a letter or recommendation from SHHD
16 about the use of imported concentrates. You have given
17 some evidence about clinicians' attitude to the
18 licensing system and so on, and I just wondered -- and
19 if you don't feel comfortable answering this question
20 please do say -- I just wondered what the reaction might
21 have been if we had a Scottish letter or Scottish
22 recommendation saying, "Don't use imported
23 concentrates", in circumstances where in fact there was
24 a valid UK licence?

25 A. Well, I think it would be highly speculative of me to

1 comment. (a) I can't imagine the circumstances, either
2 legal or otherwise, in which such a statement could have
3 been made, given that the UK licensing authority was the
4 UK licensing authority, and for Scotland to declare UDI
5 and to have a separate offline process, which is second
6 guessing the CSM, in itself is difficult.

7 Having said that, if that curious process could have
8 been achievable, I'm not sure what the reaction would
9 be. I think if there was very substantive evidence --
10 I think colleagues, certainly haemophilia doctors and
11 perhaps even SNBTS, would have wanted to see the
12 evidence for that particular decision to be clearly laid
13 out. Although, at that time, the SNBTS and patients in
14 Scotland were in substantially better position in terms
15 of NHS supplies than they were in England. So I guess
16 in a sense it would have been manageable. I just can't
17 conceive of the circumstances in which such a statement
18 might or could have been made, in my experience. That's
19 not to say that there isn't a mechanism there for doing
20 that. But a CMO letter, for instance, second guessing
21 the views and decisions and clear position on the
22 Committee on Safety of Medicines, I think would have
23 caused some chaos in the system actually.

24 Q. All right, thank you.

25 A. Certainly for the licensing authority.

1 THE CHAIRMAN: It is not necessarily a bad thing.

2 A. But I speculated.

3 THE CHAIRMAN: Yes. I don't think I want you to speculated
4 too much further on that. There are constraints but of
5 course, as you have pointed out yourself, there was
6 a very different factual position in Scotland as against
7 England, which perhaps shouldn't have influenced the
8 Committee On the Safety of Medicines.

9 Ms Dunlop?

10 Further Questions by MS DUNLOP

11 MS DUNLOP: There was one other question I wanted to ask

12 Dr Perry and I forgot. May I ask it?

13 THE CHAIRMAN: Certainly.

14 MS DUNLOP: Dr Perry, this is about licensing, and if you
15 don't know or don't remember, please just say so. You
16 were asked a bit about named patient usage of a product
17 and that it's also possible to get a product for
18 clinical trials in advance of its having been licensed.

19 A. Correct.

20 Q. If however, a product has gone to -- well, then it would
21 be the Committee on Safety of Medicines -- and actually
22 a licence application has been refused, does that change
23 things or is that product still available for use on
24 a named-patient basis or for trials?

25 A. It could still be available on a named-patient basis or

1 the clinical -- or the refusal of the licence could be,
2 for instance, that the Committee On the Safety of
3 Medicines wants more clinical data. So the fact that
4 a licence has been -- unless it's on very clear safety
5 line, ie, "You are transmitting disease to patients as
6 a result of this product" -- in which case I don't think
7 the licence application would go to the Committee On the
8 Safety of Medicines. But there are a number of examples
9 of products being submitted for licence and the
10 licensing authority saying either, "We want more
11 clinical data" or, "We want more validation data" or,
12 "We want more pharmaceutical data" and so on. Or simple
13 things like, "We want your product information leaflet
14 to be changed". So there are a whole range of scenarios
15 in which a product can be refused a licence and continue
16 to be used, either on a named patient basis or in
17 a clinical trial, with a view to the submission being
18 made at a later date.

19 Q. Right. If the grounds for refusal had related in some
20 kind of way to safety -- say, the committee had thought
21 unjustified claims were being made about the product or
22 something like that -- in a practical sense that might
23 put doctors off using it.

24 A. Yes, that would -- and it's certainly directly
25 applicable to the applications for heat-treated

1 Factor VIII in 1984. I wasn't on the committee at that
2 time but my understanding was that the Committee On the
3 Safety of Medicines took the view that the apparent
4 claims for safety, improved safety of the products, were
5 not justified by data. I think they would have had in
6 their mind also their concern about, as I think has been
7 rehearsed a number of times by people far more
8 knowledgeable about this area than I, that the downside
9 of heat treatment was unknown. So without any evidence
10 of upside risk or upside reduction in risk in terms of
11 virus safety, there was this genuine concern about the
12 downside risk of damaging the product and creating
13 inhibitors.

14 Q. So formally it would still be available --

15 A. Absolutely.

16 Q. -- but on the ground it might have altered the way in
17 which the product was seen?

18 A. Absolutely. Or they could simply be asked to reduce or
19 modify their claims. So if you submitted a licence
20 application and said, "This product is better than
21 product Y because it reduces the risk of hepatitis", to
22 say that you would need to give clear evidence, and
23 I think they were perhaps suggesting that it reduced the
24 risk of hepatitis in their applications but the data
25 didn't support it.

1 Q. Thank you.

2 THE CHAIRMAN: Ms Dunlop, I'm slightly concerned that there
3 may be some loose ends at the moment about the
4 productive capacity of PFC over this period when stocks
5 appear to have been rising dramatically. Is this
6 something you will be coming back to at some stage?

7 MS DUNLOP: You mean the 83/84 period, sir?

8 THE CHAIRMAN: Yes.

9 MS DUNLOP: I wasn't proposing to, sir, because I don't see
10 it relating to the circumstances in which anyone
11 acquired infection.

12 THE CHAIRMAN: Well, it doesn't but we have now had quite
13 lot of evidence about very large stock build-ups over
14 this period and I just want to be clear, if there is
15 a sort of physical explanation for that, we get it, but
16 I will do it myself. Don't worry.

17 Dr Perry, we know that there was a very significant
18 investment in England in 1982 at Elstree and I have also
19 seen a programme of developments in Scotland. Could you
20 pinpoint, just in a few sentences, what was happening
21 that might have had a bearing on productive capacity in
22 1982 through to 1984?

23 A. I think there was a programme of investment. We were
24 installing major new dispensing equipment, product
25 filling equipment, to meet modern standards. That's one

1 example. We were restructuring the production
2 department, relocating, labelling and packaging,
3 improving the storage capability within the envelope of
4 the building we had. So there were a range of
5 improvements, structural improvement's, that were going
6 on within the centre, probably primarily in response to
7 the so-called Flint and Purves advice,
8 Medicines Inspectors' report in 1979 and 1980 and the
9 subsequent visit by Messrs Ayling and Haythornthwaite.

10 So they are the two immediate very substantive
11 exercises that spring to mind. It was basically
12 a restructuring of the production department to make the
13 flow better and you can't manufacture pharmaceuticals in
14 a building site. So it required quite significant
15 periods of closedown, which in itself required to build
16 stocks to cover those periods, because I think the key
17 feature of self-sufficiency is that you can't have it
18 this month and then abandon it next month. It is for
19 ever.

20 THE CHAIRMAN: But there was nothing in that answer to
21 suggest that the actual throughput would have been
22 significantly increased once the modifications had been
23 made.

24 A. No. These were mainly quality improvements to improve
25 standards of good manufacturing practice and so on.

1 I think there were some elements of improved
2 productive capacity, for instance automated filling
3 lines and so on gave you the opportunity to slightly
4 increase batch size and reduce the labour component of
5 sterile dispensing and so on. But they weren't designed
6 to increase volume throughput.

7 THE CHAIRMAN: So the apparent dramatic increase from
8 900,000 units to 4.5 million units in storage in Glasgow
9 certainly wouldn't be explained by changes in the
10 productive capacity of PFC.

11 A. Well, I think part of the dramatic improvement in
12 stocks -- and it was quite dramatic -- over a relatively
13 short period of time was a combination of more plasma,
14 still within our capability at the time, quite dramatic
15 improvements in yield as a result by Dr Foster. And
16 I think the combination of those two factors led our
17 production to fairly quickly, over a period, 1981 to
18 1984, exceed the then current clinical use of our
19 particular product, and that's what led to the stock
20 build-up which has been discussed in 1984.

21 THE CHAIRMAN: One of the contributions made by Dr Foster
22 was eventually persuading people that the quality of
23 plasma sent to PFC was important in relation to yield.

24 A. Yes, it was a ten-year process, I seem to remember.
25 I don't think it was a one-off event.

1 THE CHAIRMAN: Thank you. Dr Perry, thank you very much.

2 A. Thank you.

3 MS DUNLOP: Our next witness is Professor Cash, sir.

4 (11.52 am)

5 PROFESSOR JOHN CASH (continued)

6 Questions by MS DUNLOP (continued)

7 THE CHAIRMAN: Good morning, Professor Cash.

8 MS DUNLOP: Good morning Professor Cash. I think it's still
9 good morning.

10 A. Yes.

11 Q. I want to ask you some questions about the topic that we
12 call B2. You have provided a statement for us in
13 relation to that topic and you have also provided
14 a sheet of supplementary comment.

15 I want to go back to the 1970s and to ask you about
16 risks of concentrates generally, which in the 1970s, as
17 we understand it, really meant hepatitis, as a perceived
18 problem.

19 This is a version of your statement which has some
20 handwritten questions on it but I think for ease of
21 reading everything that comes after, we need the
22 questions too. It's [\[PEN0150273\]](#). Can we go to page 2?

23 Towards the bottom of the page we can see some
24 response from you and it's in bold. You say in a
25 paragraph numbered 2 that you think the first public

1 warning in the UK concerning the potential dangers of
2 commercial concentrates came from the SNBTS, and you
3 refer to what is actually your letter. Perhaps we could
4 have that. That's [\[LIT0010245\]](#).

5 When you were here before, Professor Cash, I think
6 you wondered if the television programme might have been
7 a response to the suggestions of the danger, but it
8 actually looks as though your letter was in response to
9 the television programme because it was December 1975
10 and here is your letter on 24 January, I think it is.
11 24 January 1976.

12 You have no doubt looked at this letter again
13 recently?

14 A. Yes, some months ago, yes.

15 Q. Right. I just wanted to ask you particularly about the
16 sentence which we see at the top of the right-hand
17 column, so we need to go up again. It's that sentence
18 about the level of a potential lethal virus into the
19 whole community being deliberately increased.

20 One or two witnesses have wondered about the use of
21 the word "deliberately". I wondered if on reflection
22 you didn't really mean "deliberately" but perhaps
23 "knowingly", or do you want to stick with
24 "deliberately"?

25 A. I personally wouldn't see much deference between

1 "knowingly" and "deliberately" but perhaps lawyers
2 would. But there is no doubt in my mind that the policy
3 that was coming through into England and Wales, that
4 this wasn't by accident, it was a very deliberate policy
5 that was being developed, and so I'm pretty relaxed
6 about changing it from "deliberately" to "knowingly",
7 but I don't personally see any difference. The people
8 that knew were the civil servants and there is evidence
9 of that that we have.

10 Q. Sorry to jump about but can we go back down to get the
11 bit immediately before that. So back down to the bottom
12 of the page.

13 A. Yes.

14 Q. "... no doubt that the import into the UK ..." We can
15 read on for ourselves about that being an unequivocal
16 pathway. Then if we read up to the top, the level of
17 a potentially lethal virus into the whole community was
18 being increased.

19 Given what happened in the early 1980s, when an
20 actually lethal virus was introduced, when you looked
21 back at the letter, did it seem to you that you had been
22 something of a prophet?

23 A. I wouldn't dream that I'm a prophet. I would simply say
24 that, looking at the word -- I'm aware that people have
25 talked about that I suggested it exaggerated -- the

1 programme, and I think I would say without any shadow of
2 doubt, it was an exaggeration and I can explain why that
3 was so.

4 But I wouldn't see myself as some prophet, a prophet
5 of doom. I just think if you have a process -- I'm not
6 sure whether -- in 1969 I did my own World in Action.
7 I had a WHO travel fellowship and spent three and a half
8 months in the States looking very carefully at all
9 aspects of their transfusion service, made a lot of
10 hugely important friends over there, that were immensely
11 important in the later years. And one of the things
12 I did when I was in California was to go into the
13 Cutter -- it was Cutter, not Hyland -- skid row area,
14 and this is in San Francisco, as I recall, and --
15 I mean, I thought the film was pretty gentle on that.
16 What I saw was just obscene. It was just obscene.

17 So the film didn't surprise me. I thought it had
18 exaggerated because if you ask, "Did that reflect the
19 total input of commercial plasma into the US system," it
20 did not. Indeed, as John Prothero, in the second disc
21 of that programme, who was in the Haemophilia Society,
22 said, there were companies -- and there were
23 companies -- who claimed -- and I actually believed them
24 at the time -- that they didn't use these sort of donors
25 at all, that they used university campus people. And if

1 you look at the latest, which is many years later, PCR
2 Hepatitis C studies on old batches of commercial
3 concentrate, to my astonishment -- these were held in
4 NIBCS -- some of them were negative. And that does
5 indicate that there were sources of the commercial that
6 in fact may be on a par, in terms of safety, with the
7 voluntary paid donor. So I felt the programme did
8 exaggerate the point. It was also very dominated by
9 Harry Zuckerman, whom I knew very well. He was very
10 much a B virus man.

11 Q. Yes, I think we appreciate the point that much of what
12 was being discussed and what was being used as an
13 example of the problems that might occur was actually
14 Hepatitis B rather than non-A non-B. But I think
15 perhaps you have partly answered my next question, which
16 was going to be what you meant, if you can remember, by
17 saying that the absolute magnitude of the problem was
18 exaggerated and overdramatised?

19 A. Well, very briefly I'll repeat that they were suggesting
20 that all plasma that was used in commercial concentrates
21 was coming from skid row. That wasn't true.

22 Q. Okay. I think some people who have read the letter, and
23 it has obviously been scrutinised a lot recently, but
24 some people have thought that you were referring to the
25 numbers of people who would get hepatitis.

1 A. No.

2 Q. And as we look back now --

3 A. No, no, no. I cannot claim that --

4 Q. -- there was a suggestion of that in the programme, that
5 doesn't count as an exaggeration?

6 A. Quite.

7 Q. That wasn't what you were getting at --

8 A. No, it was the skid row.

9 THE CHAIRMAN: Could I just ask you about your reference to
10 recent studies? We have heard about a study reported by
11 Minor. Is that what you have in mind? It is suggested
12 that five out of 46 --

13 A. It could be Phil Minor but Peter Simmonds and
14 Chris Ludlam I think were engaged.

15 THE CHAIRMAN: I have done it too.

16 A. And I think it's Lancet, sir, and it's a beautiful
17 study.

18 PROFESSOR JAMES: There was a Minor letter, which perhaps is
19 the one you are referring to, in 1990, that we saw
20 a couple of days ago, where from memory, they tested 46
21 American pools and found four or five of them negative
22 for HCV by the very early tests of 1990.

23 A. Right. Certainly I think Phil Minor -- he is NIBCS, is
24 Phil.

25 PROFESSOR JAMES: Yes.

1 A. And I think he obtained the samples for Peter Simmonds
2 to do the PCR.

3 PROFESSOR JAMES: Very possible.

4 A. I think he did the first, but I think he was doing
5 antibody. I think he was doing ELISAs and picked them
6 up that way. But Peter Simmonds is deemed -- did
7 PCRs --

8 THE CHAIRMAN: If you can give us references later to your
9 sources, that would help.

10 A. Could somebody chase me on that? I shall forget.

11 MS DUNLOP: Can we go back to Professor Cash's statement,
12 please. The other reference you make in paragraph 2 is
13 to work at the end of the 1970s and to there being
14 a need for prospective studies. Just to clarify for the
15 record that the reference seems to be the published
16 proceedings of the symposium on unresolved problems in
17 haemophilia.

18 A. That's correct, in Glasgow.

19 Q. Yes, and I think we can actually bring up the reference
20 concerned. It's [\[DHF0030649\]](#). You, Professor Cash,
21 surmise that perhaps the book, which I happen to have
22 here -- but the book wasn't published until 1982 and
23 that would seem to be correct but the actual symposium
24 was 1980.

25 A. Yes.

1 Q. And I think we have confirmed that your reference is
2 actually to the first paper in the book, which is the
3 work of Dr Craske. In your supplementary paper you
4 agreed that that is correct. And we can see your words,
5 the words that you quote on page 7 of your version. If
6 we could go to page 7. I think it might be page 11 in
7 the book but if we go to page 7.

8 At that point, Dr Craske was thinking that there was
9 an increased risk from commercial Factor VIII compared
10 with NHS Factor VIII. No firm conclusion could be drawn
11 until prospective studies had been carried out. So by
12 prospective studies, presumably, looking at ideally
13 previously untreated patients and monitoring them from
14 the time of their first administration of concentrate
15 onwards.

16 A. Yes, and may I say -- and I am very interested in
17 seeing, I haven't read it all -- Chris Ludlam's
18 transcript. Very interesting. I think it's probable
19 that Ludlam was sitting on -- I say "probable" because
20 I wasn't clinically involved -- sitting on a population
21 of haemophiliacs in the UK that were relatively unique,
22 ie they had not been exposed to commercial concentrates
23 at all. And doing prospective studies, you would need
24 either to have this very slow -- the PUP concept of
25 previously untransfused patients and/or you could add in

1 a group of patients that had not had commercial, and my
2 view -- I didn't feel strongly about this -- of
3 John Craske's conclusion is that was a really tough nut
4 to expect the haemophilia directors to go on and do
5 a prospective study.

6 That was a conclusion. And I'm just pointing out
7 that that was as late as 1980, that there was caution
8 among the clinical teams and John Craske was really,
9 although not a clinician, very closely involved with the
10 haemophilia doctors in the UK, that they were saying --
11 and later they clearly, when AIDS came, they were
12 reticent to ascribe too much danger of the commercial
13 concentrates versus the non, whereas I have to say,
14 because I think it was pretty evident, I was at the
15 other extreme end of that.

16 Q. Just to round off this point for the moment, because
17 I think we will need to come back to it when we are
18 looking in more detail at Hepatitis C, but there is
19 quite a lot of material from the first half of the
20 1980s, including Dr Craske's own work, to show that the
21 attack rates for non-A non-B with NHS concentrates were
22 very high as well. Can we look particularly at
23 a letter, [\[SNF0012890\]](#).

24 This is a letter from you to Dr Forbes. Slightly
25 frustratingly we haven't been able to find any response

1 to the letter or any written record of Dr Forbes' data,
2 but the letter does give us a hint as to what was in the
3 information, when it says:

4 "You advised the working party that you had data
5 which indicated that the results from the Oxford study
6 were identical to yours."

7 The Oxford study, I think, is a reference to
8 Dr Craske's work in which he looked at 26 patients --

9 A. I think so.

10 Q. -- and found that all nine treated with concentrates for
11 the first time acquired non-A non-B hepatitis, and that
12 included all of those who were given NHS product. But
13 just perhaps to take it shortly for the moment, do you
14 still think that it was possible that the Scottish
15 product had a lower infectivity than the commercial
16 products for non-A non-B?

17 A. I wonder if -- I will "if" and "but" a lot in
18 a moment -- but I wonder if I can just remind you what
19 I said on my previous appearance and that is that one of
20 the things that struck me throughout this period was our
21 clinical colleagues -- and John Craske, for instance,
22 although that's not strictly true -- took no cognisance
23 of the notion that the viral load -- and I would like to
24 stress "load", the amount of virus per syringe or
25 whatever -- could be a significant factor in the final

1 outcome. Certainly from my physiology days when I did
2 an extra degree, dose response curves were very
3 important. I'm retired and I have little access now to
4 libraries and time, but I am aware, and I have papers
5 that will demonstrate that in the HIV context viral load
6 is absolutely critical as to whether you pass on --
7 whether the recipient will in fact get it.

8 I never escaped the conclusion that -- when the
9 haemophilia directors said and John Craske said, when
10 you get to a pool size of NHS product, you will get the
11 same infectivity, and what that tells us is that the NHS
12 product probably had two viruses per ml and the
13 commercial had 2,000 viruses per ml. Yes, indeed, they
14 would both produce evidence of hepatitis.

15 The real question is -- and I never came to any
16 conclusion about this -- was the clinical pathological
17 outcome of having a mild attack of hepatitis with just
18 two viruses versus 20 or 200 -- was it any different?
19 And I don't think those studies were ever done.

20 Q. Right.

21 A. And thus, I think, viral load -- I don't see it
22 appearing in the preliminary report or anything so
23 far -- as being an issue in relation to the commercial
24 concentrates.

25 Don't forget -- I shouldn't say this -- but a lot of

1 the commercial stuff was from plasma phoresed. So if
2 you had a group of people who were HCV or HIV positive,
3 you would be stacking in a bigger volume of contaminated
4 material. This is nothing to do with pool size at the
5 moment. So load, I think, is an issue which needs to be
6 explored and considered.

7 Q. Thank you.

8 I wanted to turn, Professor Cash, to ask you about
9 questions of policy, in particular self-sufficiency.
10 The first reference I wanted to take you to, just to
11 sketch the background, is Hansard, which I think is at
12 [\[PEN0120185\]](#). In the end I think it was three
13 references we looked at from January and February 1975,
14 where there was a statement by Dr David Owen in the
15 House of Commons, and we can see that at the bottom of
16 that page. He says:

17 "I believe it is vitally important that the
18 National Health Service should become self-sufficient as
19 soon as practicable in the production of Factor VIII
20 ..."

21 We know too that there were international
22 statements, particularly the Council of Europe, but
23 I think your position is, in short, that there wasn't
24 a formal policy statement for Scotland. What would we
25 be looking for, because I notice that the way it was

1 expressed by Dr Owen was that it was the NHS, the
2 National Health Service, that was to become
3 self-sufficient. He perhaps was very careful not to say
4 England or the UK. He said the National Health Service.
5 That surely meant and was understood as meaning the
6 whole of Britain?

7 A. Yes, I wouldn't -- being an Englishman, I would demur
8 from that, but you then have to say, "What's on
9 offer?" -- if he said, "I believe we must get to the
10 moon tomorrow," you then say, "How are we going to do
11 that?" And if he has an aeroplane with a rubber band to
12 run it and a propellor, clearly it doesn't mean very
13 much. We were in a situation -- and I think I wrote
14 about it at the time -- in which David Owen's statement,
15 when you looked at what they were going to do to achieve
16 their self-sufficiency -- and I was reminded in this
17 World in Action thing that I had a look at again --
18 Sir William Maycock is on the second disc. He was
19 signed up to the notion at the time of the
20 World in Action that by 1977 they would be home and dry.
21 Anybody that had the remotest knowledge would have known
22 that, forgive me, there wasn't a cat in hell's -- they
23 were clearly not on the same planet, as my friend,
24 Graham Scott, used to say.

25 Q. I think you made that point in your letter, your 1976

1 letter?

2 A. Is that right?

3 Q. Yes.

4 A. So I would presume, because we may be coming to this
5 later, that what the Secretary of State for Health said
6 in London applied to Scotland. However, in Scotland we
7 knew that -- well, by then we were way past, even by
8 then -- which we can talk about at another time. But by
9 1975, we had taken off in terms of motoring. Our
10 friends south of the border hadn't woken up. They
11 didn't know anything was happening.

12 What I wanted as a Scottish national medical
13 director was an assurance -- and it's a long saga, I am
14 afraid -- an assurance from my colleagues in the
15 Scottish Office that don't worry about David Owen, we
16 are past that, but really are we going to get sorted out
17 and become seriously nationally self-sufficient in
18 Scotland. That became a major issue, which, as far as
19 I'm concerned, the Scottish Office did not declare their
20 hand until late 1988.

21 Q. Well, because you have made these points in your
22 statement, Professor Cash, we did do a bit of research
23 so that we could try to assemble as complete a picture
24 as possible. Can we have firstly our letter, the
25 Inquiry team letter, which is [\[PEN0150051\]](#)?

1 Obviously, we are asking people who weren't around
2 at the time to do some research on this. So no doubt
3 it's like a form of archaeology that they had to do,
4 going back and digging out files and searching, but just
5 to let you see the letter. Two questions were posed in
6 this letter to the Scottish executive and we have the
7 reply, which is [\[PEN0150100\]](#). Now, for the moment,
8 I just want to look at the first part only, the first
9 paragraph:

10 "Blood policy files from 1974 to 1989 have disclosed
11 one document."

12 Just to look at it to show that really it's not
13 perhaps the answer to the question, at least not an
14 entire answer to the question. It's [\[SGH0027195\]](#). It
15 is issued from the Scottish Office in -- I think it must
16 be 1986, although it seems to be number 169 of 85 but
17 given that it gives results up to the end
18 of December 1985, that would suggest it was issued in
19 1986.

20 The context of it is that screening of donated blood
21 for antibodies to HTLV-III has been in place for three
22 or four months. This is Norman Fowler making reference
23 to the results of the first few months and saying that
24 he wants to emphasise a need for a steady increase in
25 blood donations in 1986 as part of the drive towards

1 achieving self-sufficiency in blood products.

2 So would you accept that this is a reference to an
3 aim of self-sufficiency but it seems to be 1986, and
4 it's a joint statement from Norman Fowler on behalf of
5 all the health ministers in the UK?

6 A. Yes. I have a problem, to be absolutely honest. In
7 1977, June thereof, I was in New York at the World
8 Federation of Haemophilia congress. I had been invited
9 over there by Louis Aledort -- his name appears a lot in
10 these documents -- to give a talk on really the subject
11 that I had presented in 1975, I think in Helsinki. The
12 basis of this was that the notion of self-sufficiency,
13 national -- was a runner, we could do it, and this is
14 what you needed and so on and so forth. And this was in
15 fact in New York, a repeat, with an update.

16 This is a rather dramatic tale but only once in my
17 life I have been elbowed off the rostrum in the middle
18 of my talk. The person who did this was the chief
19 executive of Immuno, Dr Eibl.

20 Q. E-I-B-L. I've seen that name before.

21 A. He is about six foot four in his socks and he bounced me
22 off the rostrum and with his finger pointing to this
23 huge array, vast auditorium of haemophilia patients --
24 a significant number I subsequently discovered were from
25 the UK -- doctors, scientists, carers, social workers

1 and so on and so on, made it very clear that what I was
2 saying was nonsense, and I won't go into that, but the
3 last thing he said was:

4 "And we can assure you ..."

5 Meaning the commercial sector:

6 "... that the UK Government does not accept that the
7 WHO commitment to self-sufficiency is a runner, and what
8 John Cash is saying is a load of nonsense -- and then
9 came the runner -- and the UK Government, we know, does
10 not support him."

11 I was bundled off, went out and had a coffee and
12 coming next to me while I was having a coffee came a man
13 who introduced myself as John Prothero, whom we saw, who
14 was a haemophiliac. And he was a senior guy in the UK
15 haemophilia centre and John and I had a lot of
16 interesting chat and he brought me back to reality and
17 he finally said:

18 "You need to know, John, that what Eibl said out
19 there actually we believe, that is the UK Haemophilia
20 Society, that is there isn't a cat in hell's chance that
21 the NHS will get anywhere near, in England and Wales,
22 self-sufficiency."

23 And he said:

24 "We now know that we have to have Factor VIII. So
25 what we are doing is pursuing the government to let us

1 have it, commercial sources."

2 So despite all the talk in England and Wales of
3 self-sufficiency, if you looked at what they were doing
4 and you go through the blood transfusion advisory
5 committee papers, they just weren't in the hunt, and
6 they were told this. I wrote to Ed Harris. You have
7 them on your big database, this.

8 So nothing was new. They just didn't come to
9 Scotland to really look and see how it was being done,
10 not that they should do, but they just weren't that
11 interested. So, yes, you can bring me -- I'm sure there
12 are far more papers than this. I'm sure I have some
13 which -- "We are committed to self-sufficiency", but
14 again, when you look at what they are proposing and
15 what's on the ground, it just doesn't add up and didn't.

16 Q. All right. You are drawing a distinction, which we
17 understand, between words and deeds. I suppose some
18 might say that for Scotland the words might be missing
19 but the deeds were there, and there does seem to have
20 been an awareness among all those working in the field
21 that self-sufficiency was what was being sought.

22 Indeed, Dr Perry used the phrase, "The only game
23 in town".

24 A. That's right.

25 Q. Can you have a look please, firstly at [\[SNB0104452\]](#).

1 This is a congress in Budapest in 1982 and this is
2 actually Dr Foster's report of proceedings, but you were
3 there too.

4 A. Hm-mm.

5 Q. And if we look at page 10, we see your name. There is
6 a paragraph numbered 4:

7 "Other Factor VIII presentations."

8 It says:

9 "In discussing the problem of achieving
10 self-sufficiency from an all voluntary blood donor
11 programming, Cash gave details of the SNBTS programme to
12 meet clinical demands into the 21st century."

13 We have that, and I also just wanted to show you
14 what Dr Foster said to us. Can we go to the transcript,
15 please, for 10 May, at page 44? I think we need to go
16 down towards the bottom of the page. In fact the
17 context of this passage, Professor Cash, is that we were
18 imagining the attempt to achieve self-sufficiency as
19 being like a runner in a race, who is chasing the person
20 in front and never even managing to draw alongside
21 because just as you nearly do, the runner pulls ahead.
22 And it becomes more elaborate when you start to think
23 that the person behind is running uphill all the time as
24 well.

25 A. Absolutely.

1 Q. Anyway, no doubt it is not a particularly original
2 analogy. You will see that towards the bottom of this
3 transcript it is said that:

4 "It might be difficult to find express statements of
5 a policy of self-sufficiency for Scotland by politicians
6 or by Government."

7 There doesn't seem to be any doubt that everybody
8 knew that that was the aim for Scotland, and Dr Foster
9 said at the 1981 meeting -- I think this is the joint
10 meeting:

11 "There seemed to be quite a consensus and complete
12 agreement that that was the objective we were all
13 working towards."

14 So I suppose my question is: if the words weren't
15 there for Scotland, did it matter because everyone was
16 just getting on with trying to achieve it?

17 A. It mattered hugely, and when we get to the realisation
18 that in 1982 I submitted a paper to the CSA, the blood
19 transfusion committee, saying "Look --" I mean, I have
20 a picture, this amazing picture we produced of our
21 predictions that took us to 1997. I don't know whether
22 you are aware of the picture.

23 Q. Well, I don't know if you mean literally a picture. You
24 mean a graph?

25 A. Yes, a graph. I have a picture of our predictions and

1 then from Peter's stuff, Peter Foster's, what actually
2 happened. And it's very interesting to see that. But
3 the point I'm making is that in 1982 it was already
4 clear to me and my colleagues that if we were going to
5 stay in the self-sufficiency mode -- and we were moving
6 in 1982 into a surplus for a period of time -- but we
7 saw ourselves as the thing -- like any other, we needed
8 to warn the Scottish Office that we needed other sources
9 of plasma. And our first port of call at that stage --
10 although I was aware of the work of Claus Hogman in
11 Uppsala, which was optimal additive solutions. Our
12 first port of call until that arrived was to introduce
13 a plasmapheresis programme. And all I can tell you is
14 that if you take that request -- and it was in the
15 public expenditure survey, the request that we made --
16 it was ignored until 1988. And in 1988 we fell off the
17 cliff because our plasma -- we needed to boost our
18 plasma.

19 So although the directors -- and Bob Perry with his
20 no other show in town routine he used to tell us
21 about -- were all working their socks off. So we had
22 within a service a clear policy that we were running
23 for. The real question is, it was never very clear to
24 me at least whether, when the chips were down, my mates
25 in the Scottish Office shared that vision. And I took

1 a view, which may be completely wrong, that one of their
2 fundamental problems was here in St Andrew's House, that
3 down the road in London was an organisation that by any
4 standards was a disaster, and this, in my view -- and
5 I had some evidence for this -- was becoming
6 a increasing embarrassment and was quite tough for the
7 Scottish Office people.

8 Q. Which was the disastrous organisation in London?

9 A. The National Blood Transfusion Service in terms of
10 plasma supply and their fractionation setup. Yes. They
11 were not delivering. 60 per cent plus of the needs of
12 their patients was having to come from commercial
13 sources.

14 Q. There were some formal statements towards the end of the
15 1980s. You were referring to that and --

16 A. What, you mean in Scotland?

17 Q. Yes, for Scotland.

18 A. Yes, indeed.

19 Q. Just to put in front of you a paper. You may have seen
20 it recently or you may not. It's a paper that you
21 enclosed with a letter, [\[SNB0061686\]](#). We need to go to
22 the first page in, please. Although it is the next
23 page, it must have a separate reference, [\[SNB0061687\]](#).

24 No.

25 THE CHAIRMAN: Try the one ahead.

1 MS DUNLOP: Well, this page is definitely 1687 and I had
2 assumed that, given it's the enclosure with the letter
3 it would follow, but that was obviously a fallacious
4 assumption.

5 THE CHAIRMAN: I am just suggesting 85 because sometimes
6 when they are loaded they are adjacent but in reverse
7 chronological order.

8 MS DUNLOP: I have printed it out, sir, and it has the
9 number on it so that must be its number. It's just it's
10 not there. We will come back to it.

11 There was a Department of Health statement in
12 1990 -- and we have looked at that this week,
13 Professor Cash. When we have loaded in our document we
14 will look at what you were saying around about 1990.
15 Just to look at what the Department of Health were
16 saying, that's [\[SGH0050501\]](#), in October 1990.

17 A. Yes, that's the chief medical officer.

18 Q. Yes.

19 A. And as my recollection goes, because I wrote in the BMJ
20 about it or something, this was a document on its way to
21 the UK Haemophilia Society.

22 Q. Well --

23 A. It's from the CMO, England.

24 Q. That definition of self-sufficiency, the one that we see
25 in the last sentence, when you saw that, did that

1 surprise you?

2 A. No.

3 Q. You had better explain.

4 A. I don't wish to be too contentious but I think what
5 emerged in the 1980s is that the commercial sector --
6 I mean they told me this, that they could be absolutely
7 assured that the market in England and Wales would
8 remain one in which they played major roles, and it was
9 my understanding -- and I can give you some reasons for
10 this -- that this was a comfortable position from the
11 point of view of government. This is forgetting about
12 AIDS or anything like this, but this is taking us into
13 the early 1980s. So the notion of the public sector,
14 down there, BPL, up here, PFC, dominating the scene down
15 there, not only was not happening but actually
16 politically was not something that people were
17 comfortable with.

18 As a consequence of which the commercial people
19 envisaged they would retain a significant amount of the
20 market for Factor VIII, despite all the talk, all the
21 letters, all the statements made by Sir George Young,
22 now a member of the current cabinet, in 1980. Despite
23 all this, this was the belief.

24 And in due course, the chief medical officer came
25 out with this and by then the clinicians down there

1 were -- there was lots of other evidence: the Galbraith
2 decision and so on and so forth -- that they were
3 absolutely hooked to the commercial stuff, despite the
4 fact that they said -- and I think they did, the
5 clinicians -- "We want NHS stuff", they weren't going to
6 get it.

7 So there is no doubt that this came as no surprise,
8 not only because what he was saying, the overriding
9 factor is clinical freedom, and I took a view -- and I
10 wrote about this -- that when the chips are down, the
11 overriding thing is about money, and clinical freedom
12 will take a second seat.

13 So I was not surprised when I saw this and I wrote
14 about it and said I was, however, dismayed.

15 Q. Was the sort of notion that we see encapsulated in the
16 last sentence on the screen ever your understanding of
17 self-sufficiency, as you were pursuing it in Scotland in
18 the late 1970s and early 1980s?

19 A. No. I felt we had a moral obligation -- this is the
20 transfusion service -- to deliver what I saw -- Charlie
21 Forbes said when he puts his hand up, whenever, at any
22 time of day or night, like a surgeon waiting for a.

23 Q. At the drop of a hat, I think he said.

24 A. He wanted it, just there. And my view was that was got
25 to be our job, our goal. If you look at the UK

1 haemophilia directors' minutes, you will see time and
2 time again, every two or three years or every year
3 sometimes, they would issue recommendations on the
4 products that they would recommend people using. And
5 every time, until about 1989, I think, they said, "Our
6 number one priority is from products that come from
7 unpaid donors". They then later wanted heat treatment
8 and so on and so forth. And that was their clinical
9 choice in terms of a corporate body and the government
10 just didn't deliver. There is no doubt whatsoever that
11 the CMO London's comments in 1990, in my view -- I was
12 very distressed about it because I believed they
13 reflected clearly the reality -- and I knew
14 Harold Gunson was very distressed by it too, I might
15 add, very distressed by it -- they reflected the problem
16 they were in.

17 Q. Professor Cash, I wanted to change the subject now,
18 although we will obviously, when we have the full paper
19 into court book, which will be very shortly, go back and
20 look at it. But if I could change the subject and ask
21 you about Yorkhill, more particularly about the choice
22 of product with which to treat children with haemophilia
23 at Yorkhill.

24 You will know, I'm sure, that we have discovered
25 a position whereby Yorkhill hospital in Glasgow was

1 using large amounts of commercial concentrate and even
2 in 1980 it looks as though, from the usage reported to
3 them and they have passed on to us, that in 1980 only
4 about 20 per cent of what they were using was from PFC.
5 They were using a lot of a product, Factorate, made by
6 Armour.

7 A. Yes.

8 Q. Can we go to your statement again, please, page 6. We
9 asked you about this and you give us some information in
10 paragraph 2 there. That was your recollection, that the
11 haemophilia centre director at Yorkhill preferred
12 commercial concentrates to the PFC NHS product.

13 You did suggest that we asked Dr Aileen Keel about
14 this, and we did try to find out about Dr Keel but
15 Dr Keel's work at Yorkhill was between July 1981 and
16 January 1983, when she was employed there as a leukaemia
17 research fund fellow. So our understanding is that work
18 was in connection with leukaemia.

19 Just to put this in context to explain why we are
20 asking about it, it looks from the statistical
21 information that we have as though 21 boys became
22 infected with HIV through their treatment at Yorkhill,
23 possibly in the very early 1980s. Doing the best one
24 can to interpret the data, there does seem to be
25 a connection with this use of commercial product.

1 So questions for the Inquiry involve matters such as
2 when Dr Willoughby -- for it's Dr Willoughby we are
3 talking about -- made the choice to use commercial
4 product, why he made it and why he wasn't using PFC
5 product.

6 So can I start by asking you just a little bit about
7 Dr Willoughby? He wasn't at the joint meeting on
8 30 January 1981. We have the minutes of that, we have
9 looked at that several teams. He was represented at
10 that by Dr Pettigrew. There doesn't seem to have been
11 any discussion specific to Yorkhill. How well did you
12 know Dr Willoughby?

13 A. Not at all, really.

14 Q. How many times did you meet him?

15 A. I'm not sure I ever did. But that's my recollection at
16 the present time. But I have read some of the
17 transcripts and his colleagues seem to think he was
18 a very energetic and good doctor, but I have honestly no
19 recollection of meeting him but I may be quite wrong.
20 You are now going to show me a letter, I imagine, from
21 1972, are you? I have no recollection and I apologise,
22 sir, for having no recollection.

23 Q. Sadly for us but it will be a relief to you, we don't
24 have anything of that nature.

25 A. That's very disappointing.

1 Q. We have looked very thoroughly in our database for
2 information that might shed some light on all of this.
3 Most of the material that we have about Dr Willoughby --
4 and we don't have much -- seems to show his involvement
5 in matters to do with anti-D and cell separators. There
6 is one exchange, however, which is interesting, an
7 exchange of correspondence from 1977. Can we look first
8 at [\[SNB0071075\]](#), please?

9 This is a Dr Easton, a senior registrar. Can we
10 look right at the top, please, just so we can see the
11 heading.

12 A. Thank you.

13 Q. It's the haematology department at Yorkhill.

14 A. Yes.

15 Q. And on 22 February 1977 Dr Easton is writing to Mr Watt
16 and he tells Mr Watt that they are trying the effect of:

17 " ... administering Factor VIII concentrate
18 prophylactically to a few severely affected
19 haemophiliacs. These are patients who would probably go
20 on to home therapy at a later stage."

21 What's perhaps slightly puzzling is the reference to
22 cost because it wouldn't have cost anything to Yorkhill
23 to use PFC product, as I understand it.

24 A. No.

25 Q. So do you think that he is thinking about cost in

1 general terms, taking into account the cost of launching
2 this form of treatment?

3 A. I have to say I have no idea but if you look carefully
4 at, for instance, the UK haemophilia directors
5 organisations' minutes -- you need to look very
6 carefully -- there are occasions when somebody has leapt
7 up and said, "I'm opposed to this public sector, let's
8 move everything out into the private sector and really
9 create a marketplace". I have to say that that was not
10 a view that was not in Scotland. Some of the
11 tensions -- and I wonder, when I read that now, was this
12 a poor senior registrar being hounded by a chap -- I had
13 never met Dr Willoughby -- that was very concerned about
14 public sector, civil servants, costing an arm and a leg:
15 "It would be much cheaper to the nation if we went and
16 bought it."

17 I'm not for a moment suggesting that's relevant to
18 Willoughby. By jove, it was not an unknown view among
19 some individuals in that area. So I wouldn't wish to
20 comment about that at all as far as ...

21 Q. Just for the record, because we are interested in this,
22 you did get a reply, which I think took the letter at
23 face value and answered the questions. It's
24 [\[SNB0071083\]](#). So the letter is engaging on ideas of
25 cost --

1 A. Yes.

2 Q. -- albeit, as Mr Watt says, it's difficult to be
3 precise.

4 A. Can I just interject and say -- this reminds me, seeing
5 this, that it doesn't appear in the preliminary report
6 at all; no reference to what I regarded as absolutely
7 critical work we did on what I called "value for money".

8 What we did was -- not "we" did; we brought in
9 independent financial people, to simply ask the
10 question: would it be cheaper for the NHS in Scotland to
11 purchase all this stuff we are making or would it be
12 more expensive? I'm not sure whether you are aware of
13 this story. There is a lot of data in the -- I think
14 you call it the "court book", is it, the large database,
15 in which they demonstrated that in fact if you looked at
16 the bottom line, the work we were doing saved the
17 Scottish Health Service ú7.5 million a year. That was
18 in, whenever it was, the mid 1980s.

19 One of the astonishing things was, when these papers
20 were produced and lodged with the CSA, they didn't get
21 discussed by the Blood Transfusion Service subcommittee.
22 If you look at your court book, you will see I sent
23 copies of the outcomes to the Scottish Office. I had
24 anticipated getting warm letters of, "Well done chaps,
25 you are doing a magnificent job." But absolutely no

1 response whatsoever.

2 So the whole area of costing, we regarded, if you
3 will allow me to say, as hugely important, and I'm sure
4 John Watt at this date was struggling to make up the
5 figures. We eventually had a group of experts that came
6 in and did it for us and there are a large number of
7 documents which were the outcomes of their work. In
8 1989/1990, the procedure was -- there was a very good
9 reason why this was repeated -- was repeated and instead
10 of 7.5 million, our profit then, it was still there but
11 it was about 1.2 million. There is an interesting story
12 there.

13 Q. All right. Can we just finish looking at this letter?

14 It's quite complicated in its thinking.

15 THE CHAIRMAN: Sorry, could I just have a second before --

16 MS DUNLOP: Well, yes, all right. I have something else --

17 THE CHAIRMAN: -- you go on or are you coming back to this?

18 MS DUNLOP: I'm coming back to what Professor Cash has just
19 said, sir, but for coherence I would like to finish
20 looking at this letter if we might.

21 THE CHAIRMAN: It might be difficult to achieve --

22 MS DUNLOP: Well, right. Can we finish looking at the
23 letter, please? Can we go on to the next page, please?
24 We can see Mr Watt has gone into quite a bit of detail
25 here about cost.

1 A. I see.

2 Q. And the frustrating thing is there doesn't seem to be
3 any more correspondence, nothing else coming from
4 Yorkhill about this. You know, "Well, in the light of
5 what you say, we would like to proceed with PFC
6 product," or anything like that. So I am afraid it's
7 just a bit of a straw if the wind.

8 A. I suspect he is a young senior registrar and Watt has
9 done his classic: he blows you away with a vast amount
10 of information. Busy clinicians, you know, "For
11 goodness sake," you know, and that's how we all are.

12 Q. Right. I do have one letter. It's slightly before the
13 exercise that you were describing a moment ago but
14 I think it may be part of what you were alluding to.
15 I think it's in court book. It should be; it's not on
16 the list. [\[LIT0010394\]](#). You see, this is a letter that
17 Mr Watt sent to the Lancet in 1979.

18 A. Yes.

19 Q. It's about this topic. It does contain some interesting
20 information about costings and it's obviously been sent
21 in response to an editorial criticising the
22 fractionation centres. We can see that on the top of
23 the right-hand side, criticising the fractionation
24 centres for their economic performance and not providing
25 a realistic pricing for NHS Factor VIII concentrate. He

1 goes on to say:

2 "For the past 18 months the cost of Factor VIII
3 concentrate produced from this centre has been 2.4p per
4 activity unit."

5 Then at the end of that paragraph he has got the
6 lowest priced commercial product now available in the
7 UK, which costs 9.5p. Is this the sort of material you
8 were thinking of?

9 A. No, it's very interesting. No, no, I'm being very
10 unkind to my late old friend, John. I'm impressed with
11 the numbers but I'm not at all sure as to the validity
12 of the methodology he has done to get it to that. But,
13 no, we brought in -- please, I can provide you quite
14 easily with the "Value For Money" file if you don't find
15 --

16 Q. We have a lot of documentation, Professor Cash. I'm not
17 at the moment convinced we need more.

18 A. That's fine but all I am saying is these numbers are not
19 part of the study I'm referring to.

20 Q. Right. So I think we have your evidence that work was
21 done, and indeed there is a whole file, the Value For
22 Money file, which records the results?

23 A. It's "Value For Money" -- called that in my filing
24 system.

25 Q. I understand.

1 THE CHAIRMAN: Professor Cash, I'll make my position clear:
2 The preliminary report could never be comprehensive and
3 in part it was intended to be provocative. If it has
4 provoked you into the recollection of something that
5 I have missed entirely, then what I would ask you to do
6 is just send us a note of the title headings, so that we
7 can have a look at it. We need not take time with it
8 now but I will look at it in due course.

9 A. Can I say, sir, that I thought the preliminary report
10 was quite outstanding.

11 THE CHAIRMAN: It may have been but equally it may have been
12 holed below the water line. So if you can provide this
13 data, it will be followed.

14 A. Thank you, sir.

15 MS DUNLOP: Thank you, sir.

16 Returning, Professor Cash, to the theme of
17 Dr Willoughby's reasoning, which is what I was trying to
18 get at, we have seen -- and if you have been keeping up
19 with the transcript, no doubt you have noticed this --
20 that Dr Willoughby made one of, I think, very few
21 interventions that we have found at a UKHCDO meeting,
22 when he referred to the chance of having adults who
23 weren't crippled. Have you seen that in the transcript?

24 A. I think I have.

25 Q. Just for the record, can we have a quick look at it?

1 It's [\[SNB0017296\]](#). It's actually the Glasgow meeting.

2 A. Oh, the 80, yes.

3 Q. Yes. Can we look at page 6, please. It's perhaps
4 difficult to square this with the letters we just looked
5 at from 1977, where, no doubt on instructions from the
6 consultant, Dr Easton was writing and asking what's the
7 cost of all this going to be because here, as I read
8 what Dr Willoughby says, he is really saying this is
9 priceless.

10 A. I think having an adult with no painful joints and
11 serious deformities is priceless. I should say, I don't
12 think -- and again I don't wish -- there weren't doctors
13 who were saying this wasn't worth it. We were really
14 saying, "Do we get the best value for money by going for
15 the public or the commercial people?" This is before we
16 got very worried about viruses and so on.

17 My interpretation of this statement here is that
18 Willoughby is saying from a clinical point of view there
19 is no price that you can put on doing this work; from
20 a taxpayer's point of view there should be a price and
21 there may be a cheaper way of achieving the same end.

22 Q. Did you go to the Glasgow meeting yourself?

23 A. Do you know, I'm fairly sure I did but I can't recall
24 it.

25 Q. Let's just look at the front of the minutes and see if

1 you are shown. Can we go back? It doesn't look like
2 it. Go on to the following page.

3 A. There are the apologies, and I haven't even apologised
4 in that list of names, which is not very good.

5 Q. It is actually not as long a list as many of these
6 meetings.

7 A. Oh, indeed, but the good news is, all you know is, that
8 I haven't apologised. So, in answer to your question,
9 I may have been.

10 Q. Right. One of the pieces of evidence that we have about
11 why the decision was made to use so much commercial
12 product at Yorkhill comes from Dr Pettigrew. Look at
13 the transcript for 5 May, please, and go to page 18.
14 Thank you. Just to let you read that. (Pause)

15 A. Yes.

16 Q. I deduce from everything you have said, Professor Cash,
17 that you are not really in a position to comment on this
18 either.

19 A. Not really, beyond the fact -- as I say, I never met
20 Willoughby. I'm actually not sure -- I'm sure you may
21 come to it but we had really in Scotland great
22 difficulties in getting information -- we had
23 information on the commercial purchasers. This became
24 quite a contentious issue for a while. I actually don't
25 recall myself being aware of what was going on in

1 Yorkhill until I see the preliminary report, and it's
2 very interesting -- or at least I don't recall that.

3 But I think it needs to be appreciated that there
4 were on occasions -- and problems of solubility of the
5 PFC early products, and there is no doubt in my
6 experience that some clinicians reacted, I was about to
7 say, "violently" -- that would be quite wrong -- but
8 reacted very much more strongly about this than others,
9 who seemed very much more relaxed.

10 Certainly, if you ask about the speciality of
11 paediatrics in the 1980s, it was in a very -- just
12 paediatrics, forget haemophilia at the moment -- it was
13 in a very interesting development stage and it would
14 come as no surprise to me, not knowing the guy, that the
15 paediatricians were extremely twitchy if it didn't
16 dissolve quickly or whatever, whatever, it really
17 wouldn't.

18 So I could well see somebody like Dr Willoughby
19 deciding -- and I'm also certain that he clearly thought
20 that home therapy -- and I don't think he mentions
21 prophylaxy at this point because that was the next
22 big... But home therapy was critically important to
23 hitting these very early, as soon as they thought they
24 were bleeding. It was very important.

25 Q. Yes. Of course, there are two different possible

1 problems, aren't there? There is, "I want to use this
2 product and I can't get enough of it, there isn't
3 a reliable supply chain."

4 A. Yes.

5 Q. Or, "I don't want to use this product because I don't
6 like its quality," and it's a little difficult to work
7 out which it is.

8 A. Yes. I don't think we can work it out, at least
9 I can't, because I never met Willoughby, we didn't
10 discuss it. I'm simply saying that there could be what
11 I would say was a fairly benign reason -- I may dispute
12 it -- a benign reason why in fact Willoughby went down
13 this track.

14 Q. Just, I think, before we stop for lunch, because it's
15 also from the early 1980s, can we look at the minutes of
16 the joint meeting in January 1981? That's the meeting
17 at which I said Dr Willoughby was represented by
18 Dr Pettigrew. It's [\[SNB0015055\]](#). You can see there she
19 is in the list of those present.

20 A. Yes.

21 Q. Then we go on to supply and demand. We scroll down.
22 And then on to commercial purchases:

23 "The data provided for 1979 and 1980 show that
24 a significant and apparently increasing quantity of
25 commercially produced Factor VIII was being used and the

1 reasons for this were discussed."

2 What's interesting about it is that there is no
3 mention of where. It doesn't look as though the meeting
4 probed which particular hospital this might be, or which
5 hospitals. So you are saying that you didn't really
6 have an awareness that this was particularly true of
7 Yorkhill?

8 A. I didn't, and I'm not sure -- I mean, I saw something --
9 was it Dr Pettigrew or someone -- in the transcripts,
10 that at that time they only had three patients, or was
11 that Chris Ludlam?

12 Q. In 1980 they had 55.

13 A. I beg your pardon. I can't remember now but I know
14 because it was minuted, there was great -- Arthur Bloom
15 said he was very unhappy about giving the transfusion
16 service information on concentrates, it's minuted,
17 because this would lead to comparisons between practices
18 of doctors and centres and so on and so forth, and in my
19 view at the time, the views of Arthur Bloom at that time
20 on this issue, spread right across and up and into
21 Scotland, and we had difficulty in getting figures. And
22 if you ask me: did you get them from individual
23 hospitals or whatever, whatever, whatever? I actually
24 now couldn't be certain. It is just possible -- and it
25 rings a bell -- that we were only allowed to get them

1 from, say, Chris Ludlam. In other words, he gathered
2 them together and gave us the total figures. That rings
3 a bell, but I think you would need to confirm that with
4 Chris.

5 Q. I think it's slightly beyond that, Professor Cash,
6 because there does seem to have been awareness from
7 various minutes around this time that there were a lot
8 of purchases in the West of Scotland. So I suppose it
9 would really only have been a choice of two: it would
10 either be Glasgow Royal Infirmary or Yorkhill.

11 A. Yes.

12 Q. I just wondered, it might not have been minuted but
13 maybe it was something actually that everybody knew?

14 A. I can't honestly recall, I really can't.

15 Q. The other thing that we should note as we look at these
16 minutes is the reference to cryoprecipitate. You were
17 emphasising the important part cryoprecipitate could
18 play in haemophilia treatment. Actually, what happened
19 to your suggestion is apparent to us all.

20 A. Well perhaps I can just ameliorate some of the pain of
21 my mates. The reason I floated this -- and I wrote
22 about it. I wrote a paper about it, and it went down
23 like a load of lead. And I completely understood this
24 position.

25 May I say, sir, just as an interjection. In the

1 1960s I did a PhD and the man who supervised that was
2 a man you know well in your papers, Howard Davies.

3 Q. Oh, yes.

4 A. And dear old Howard used to insist that on Friday
5 afternoon, if he was going to supervise my PhD research,
6 that I went round with him and looked at haemophilia
7 patients, and I did. It must have been the early 1960s,
8 and I was appalled by what I saw. Apart from the fact
9 that there were a large number of patients on pethidine
10 and had become addicted to opiates because of pain
11 control, they didn't have enough Factor VIII. And I saw
12 very clearly that as cryoprecipitate arrived, that
13 produced an immense revolution, but then when the
14 concentrates -- in terms of clinical practice, this
15 produced.

16 As a person responsible for self-sufficiency, so
17 I thought, I was drawing attention to my colleagues, not
18 just saying, "Keep going with cryoprecipitate, chaps",
19 but cryoprecipitate was much higher yielding than
20 John Watt's PFC's concentrates, and that applies across
21 the world. So if you switched fast from cryoprecipitate
22 to concentrate, from the point of view of
23 self-sufficiency, you were going to need a lot more
24 plasma to stay still. And I actually suggested we gave
25 just a thought before we rushed down that track, and

1 that's all that that was really about.

2 If you want to know where that actually took place,
3 talk to a Pim van Aken, because the Dutch did exactly
4 that.

5 Q. We have certainly seen reference to continuing use of
6 cryoprecipitate in Belgium, and at the joint meeting in
7 1983 you yourself made that point, that there was a lot
8 of cryoprecipitate still used in Belgium.

9 A. Yes. So in other words, from the point of view of
10 plasma yields -- and again the preliminary report
11 doesn't go into this in great detail -- but it was
12 a massive issue in its own right, the whole question of:
13 how on earth do you get the plasma in the volume and
14 quality we needed to do whatever we were going to do?
15 And this was just an effort.

16 In actual fact, it was killed, was cryoprecipitate.
17 (A), the clinicians didn't want to know, and they
18 weren't unique in Scotland. You can argue they made
19 a grave error of judgment, but they were our customers.
20 But what really, really killed it was the medicines
21 inspectors came in and closed the freeze-drying plant in
22 the West of Scotland that we were going to use for
23 cryoprecipitate, if that's the way the clinicians wanted
24 to go.

25 Q. Sir, I think that would be a convenient moment at which

1 to stop.

2 THE CHAIRMAN: Yes. I might just remind you that you did
3 make a contribution at a joint symposium of the
4 Royal Society of Edinburgh and the College of Physicians
5 in 1972, when I think you spoke about cryoprecipitate,
6 and perhaps we are not entirely comfortable with the
7 knowledge of fractionation becoming a dominant factor.
8 It is not in the preliminary report --

9 A. No, can I say, yes, I came from the background of the
10 plasma suppliers; I was a centre director. And I became
11 increasingly alarmed that we couldn't cope with the
12 needs of plasma and also the yields of fractionation.

13 THE CHAIRMAN: We will get to these things at an appropriate
14 time.

15 A. But I was a great supporter of the practice.

16 (1.06 pm)

17 (The short adjournment)

18 (2.00 pm)

19 THE CHAIRMAN: Yes, Ms Dunlop?

20 MS DUNLOP: Sir. In the interval it has become possible for
21 us to turn the page of that document, so we should just,
22 I think, to finish off the discussion, look at
23 [\[SNB0061687\]](#).

24 The date of this, Professor Cash, appears to be the
25 beginning of 1990, and I'm guessing from the numbers on

1 the bottom left of the page it looks as though that
2 might mean some sort of drafting date or draft as at
3 15 January 1990. Does that look like --

4 A. Yes, I think so.

5 Q. -- the way one should understand that --

6 A. I think that's right.

7 Q. -- footer there?

8 Just to pick up your views on the whole
9 self-sufficiency question as at 1990. Obviously, I do
10 not know the period that we are really looking at in
11 this topic but I refer to it really only because it
12 makes some reference to matters in retrospect.

13 So you are referring, I think, in the
14 first paragraph to the fact that there wasn't a policy
15 statement when SNBTS wanted one in the early 1980s. Is
16 that right?

17 A. Yes, yes. I don't know whether there is any paperwork
18 to prove that but, yes, that's clearly what I'm saying.

19 Q. Whereas you want to say in July 1989 --

20 A. Yes.

21 Q. -- there was a sort of policy alert, that SHHD wished
22 the SNBTS to develop a programme of self-sufficiency.

23 A. That's the letter from Hamish Hamill I referred to this
24 morning.

25 Q. I'm sorry, the letter from ...?

1 A. Hamish Hamill, who was the undersecretary.

2 Q. The other reference that you make to matters in the past
3 occurs later in the paper. It's actually page 9. You
4 say:

5 "Self-sufficiency was made our operational policy by
6 the SNBTS directors in isolation in 1980. We closed our
7 objective in 1984 without any targeted additional
8 resources, particularly staff resources."

9 So again it seems to me you are recording that, even
10 in the absence of formal policy statements in the 1980s,
11 it hadn't stopped you from getting on with matters on
12 the ground.

13 A. Absolutely, absolutely.

14 Q. Yes.

15 A. And there are a number of technical ways we did this
16 which I won't bore you with.

17 Q. You certainly had a very full explanation from Dr Foster
18 of a lot of technical contributions that were made to
19 achieving self-sufficiency, whatever quite that means.

20 A. Well, I would just briefly add -- because Peter probably
21 wouldn't be aware of it so much -- the pigtail blood bag
22 proved to be -- and it's published and so on -- proved
23 to be critically important in giving us the kick-start
24 which convinced the Scottish Office that we could do it.
25 This was in 1979, 1980, 1981.

1 Q. How did the pigtail blood bag help?

2 A. The pigtail blood bag was a single bag with a pigtail
3 sicking out that you could plug into a giant bag. You
4 just plugged them in, squeezed them and the plasma came
5 out. Without the pigtail system, you would have double
6 and treble bags, all linked together, that you
7 purchased. When you purchased these bags -- and they
8 were very expensive, the double bags and triple bags.
9 Vast amounts of these bags at very expensive cost were
10 cut and thrown away because they weren't used.

11 We in Edinburgh -- it was developed in Edinburgh
12 during the time I was a doctor there -- developed the
13 pigtail bag system initially with Baxter Travenol to do
14 this work and it meant we could have a single bag for
15 every donation and have the facility to say, "What do we
16 want to use this for?" "Plug it into there". "What do
17 we want to use this for?" "Plug it into there." It
18 really cut our costs. If it had been introduced into
19 England and Wales, everybody worked out it would have
20 saved them about ú1.5 million a year.

21 Q. Right. Can we go back to another joint meeting? This
22 is the one that took place in 1983. The minutes are
23 [\[SNB0015160\]](#). I don't think, Professor Cash, that we
24 can gain any illumination from the minutes of this
25 meeting on the topic we were discussing before lunch,

1 which is the pattern of usage at Yorkhill. It does
2 looks as though this is rather late in the narrative, as
3 far as Yorkhill is concerned anyway, because the use of
4 commercial concentrate seems to have peaked several
5 years before this --

6 A. Yes, that's true.

7 Q. -- and in fact have been declining at this point and in
8 the course of being overtaken by use of PFC product. We
9 also note that in fact there was no representation from
10 Yorkhill at this meeting. Dr Willoughby sent his
11 apologies but we know that that was just at the time of
12 the changeover from Dr Willoughby to Professor Hann.

13 A. I was going to say, yes.

14 Q. I wonder if we can juxtapose Professor Cash's statement
15 as well, please. Can we go back to the statement at
16 page 3?

17 (Pause)

18 Professor Cash, while we are waiting, I was going to
19 take you to the part that says that you were the one who
20 ensured that the topic of HIV/AIDS was discussed at the
21 joint meeting on 21 January 1983. Just to flesh that
22 out a little bit -- and if it helps, we can do this
23 without the actual minutes of the meeting,
24 Professor Cash. Can we go on through the minutes,
25 please, and look at the discussion of AIDS, which is on

1 page 7. You were drawing members' attention to recent
2 articles in the United States and also in the Observer
3 and the Lancet.

4 For reasons of economy and looking at documents one
5 at a time, perhaps we will finish looking at the minutes
6 before we look at something else and just note that in
7 these minutes there is also another mention of
8 cryoprecipitate. I mentioned this before lunch. This
9 is where you refer, on page 3, to the successful
10 clinical trial of freeze-dried cryo in the West but,
11 because of the closure of the plant at Law --

12 A. That's right.

13 Q. -- it was a project that wasn't going any further. Is
14 that right?

15 A. That's right. It would have needed massive investment.

16 Q. Yes. I think we can leave the set of minutes and look at
17 what is in Professor Cash's paper, [\[SNB0137601\]](#). Was it
18 your practice, Professor Cash, to do a paper before
19 a meeting of this nature?

20 A. This is the joint?

21 Q. Yes.

22 A. Yes. I should perhaps say that the joint meeting was
23 created by myself, in the sense that I felt very
24 strongly in -- I don't know, 1980/1981, I think it
25 was -- that there needed to be a forum whereby the

1 clinicians and ourselves could work closely together.
2 This was established and welcomed and in the event it
3 fell upon me to meet Bert Bell, who was the chairman
4 from the Scottish Office, to discuss what we would have
5 on the agenda and the content. I suggested initially to
6 him that I produced a document for everybody to look at
7 and, yes, to the best of my knowledge, every meeting
8 I produced a document. The meeting changed later but in
9 this critical period I think you will find there is
10 a document for each meeting.

11 Q. You mentioned AIDS in it. Could we go to 7607, please?
12 That must be page 7. You are drawing the attention of
13 the haemophilia directors to this problem and you say:
14 "The information contained in appendix 6 has been
15 sent to Professor Bloom."

16 I think it was actually in the context of looking at
17 Professor Prentice's statement we realised that --

18 A. I can't remember.

19 Q. Well, when we looked at it in the Inquiry, we hadn't
20 actually identified quite what was before everybody at
21 the meeting on 21 January 1983, when you were discussing
22 AIDS. The answer to that question comes with this
23 paper. In particular now, looking at appendix 6, which
24 begins on page 14, we can see that this is the July 1982
25 MMWR.

1 A. Yes.

2 Q. We are now quite familiar with that. If we go on to
3 page 15, this is the December MMWR. So the answer to
4 which MMWRs were circulated before the meeting on
5 21 January 1983 is that it was both of these ones from
6 1982.

7 A. I noticed they are my copies. I don't know who
8 circulated them.

9 Q. So could we go back to the statement then, please, and
10 read what Professor Cash is saying in his statement?
11 This is paragraph 3 at the top of the page.

12 A. Yes.

13 Q. The question we tried to focus on when we asked for
14 statements was whether there had been discussion of any
15 possible connection between AIDS and blood products at
16 that meeting and you don't think that the minutes
17 reflect the extent of the discussion that took place.
18 Do you actually remember that meeting?

19 A. No, to be honest, absolutely not.

20 Q. Right. Okay.

21 A. But I think I said, when I was here before, that minutes
22 don't always well reflect the quantity or the quality of
23 discussions.

24 Q. Yes.

25 A. I reported a sense of dark foreboding, I see. That to

1 me would mean at least it was fairly extensively
2 discussed.

3 Q. I don't think we need to go into paragraphs 4 and 5 but
4 paragraph 6 of your statement on that page.

5 A. Oh, yes.

6 Q. You say that around this time you had asked Dr Bell:

7 " ... whether the CMO ... might ... issue a letter
8 to Health Boards, prescribing physicians and patient
9 interest groups, drawing attention to the increased risk
10 of virus infections in patients receiving commercial
11 plasma products and advising that whenever possible the
12 safer SNBTS products should be preferred."

13 I think we can just take that paragraph as read and
14 the next paragraph also. Read paragraphs 8 and 9 on the
15 following page. (Pause)

16 Professor Cash, we did ask whether there was any
17 record that we could look at about these discussions,
18 and that was the other paragraph that was covered in the
19 letter from the Scottish executive. Perhaps we can just
20 go back and look at that. That's [\[PEN0150100\]](#). It's
21 paragraph 2.

22 A. Hm-mm.

23 Q. It's 28 years ago and it has, I think, been difficult to
24 find any documentation of this but it's plainly
25 something you remember quite clearly, is it?

1 A. Very clearly actually, yes.

2 Q. Are you thinking particularly of when you spoke to the
3 CMO directly?

4 A. Yes, absolutely.

5 Q. Right.

6 A. Yes.

7 Q. Can we go back then, please, to the statement at
8 paragraph 9. What was your understanding as to
9 Dr Reid's thinking?

10 A. Well, it's difficult. Years have gone by and this was
11 a fairly seminal moment, and all I can say is that in
12 the process by which I was appointed national medical
13 director I had a whole series of conversations with
14 Dr Graham Scott, who was then the deputy chief medical
15 officer.

16 My problem was that I had a superb job as director
17 of the Edinburgh centre and I was not at all anxious to
18 leave that, and when the post was advertised after the
19 death of Hugh Jeffrey, I didn't apply, and it was
20 readvertised and I didn't apply. And at that point
21 I was summoned to the department to talk to Graham Scott
22 and this I did, and he prevailed upon me to give it
23 careful consideration, and I did. And slowly but surely
24 I decided: okay, but there will be certain conditions.
25 And there was a number of conditions.

1 One of the conditions was that the Scottish Office
2 would back us in terms of national self-sufficiency.
3 I discovered in these discussions -- and these
4 discussions were in 1979 -- that this was a problem for
5 Graham, and I had the distinct impression, no more than
6 that, that there was certain pressure from London in
7 which the interpretation of self-sufficiency -- we
8 talked about this this morning -- was different from
9 ourselves. And Graham was initially very uncomfortable
10 that he could guarantee this to me and so on and so
11 forth.

12 But we met again and he had obviously had further
13 chats with some of his colleagues and he gave me an
14 assurance -- it wasn't policy -- he gave me a personal
15 assurance that they would do their damndest, and I was
16 delighted and so I took the job on. This was the second
17 moment, after I had taken the job on, that I had serious
18 doubts that I had made the right decision and switched
19 from coming out of Edinburgh. What was behind my
20 concern was, I began to feel -- not for the first time,
21 I have to say -- that behind the department in
22 Scotland -- and this is pre-devolution, don't forget --
23 was a powerful Secretary of State for Health down in
24 London. I look at it now and I sometimes think I was
25 very naive to go and see the chief medical officer,

1 "Could you write a letter to all the chaps in Scotland".
2 And I now, more than ever -- I didn't appreciate it
3 sufficiently then -- understand the position that he
4 said he wasn't able to do that.

5 I should point out, I have since learned that
6 John Reid came from London, the DHSS, to the big job up
7 here. So he knew his colleagues very well down there.

8 Q. So you are saying that really the possibility of taking
9 a different line from the DHSS was not open?

10 A. It didn't seem to me open. And when you say what proof
11 did I have that London were -- it was just a feeling, it
12 was just conversations. There were other conversations
13 with Harold Gunson -- but not related to this topic;
14 they are occurred on other occasions.

15 Q. What you were looking for was something of that sort,
16 a letter from the CMO --

17 A. It is really quite common in the health service, in
18 which the CMO writes a "Dear Doctor" letter, copies it
19 to health boards and whatever it is. Yes, it was just
20 a "Dear Doctor" letter in which he was pointing out
21 these things. What they would have signaled, I argued,
22 perhaps naively, that this was the Department of Health
23 in Scotland putting its shoulder behind what we were
24 doing in the SNBTS.

25 Q. Right. Professor Cash, in a different context, it does

1 looks as though you were quite grateful that SHHD
2 weren't too closely involved. If we look at
3 [\[SNB0125017\]](#), the context of this is leaflets. This is
4 a letter from you in December 1990 to the then
5 Dr K Calman, and you are saying that you have always
6 advised SHHD of what you were doing but you had had no
7 requirement for SHHD clearance:

8 "... the issue being regarded as a professional
9 matter, the significant advantage of this approach is
10 the speed at which the SNBTS can introduce change."

11 Then you return to that in the third paragraph. You
12 say:

13 "Scotland consistently introduces change many months
14 ahead of England and Wales."

15 How should we understand this, Professor Cash? Is
16 it that there were some issues where it was better not
17 to have SHHD involvement and some issues where it was
18 better to have such involvement?

19 A. Yes, but I would simply say, where we were looking for
20 SHHD involvement is the whole area of self-sufficiency.
21 That's a big, big -- as we discussed this morning --
22 policy issue, impacting on a lot of other doctors, you
23 know, on the health service in general.

24 The topic with Ken Calman is about an internal
25 functional bit of business within the SNBTS, ie the

1 whole business of developing donor self-exclusion
2 leaflets; in the AIDS era that was hugely important.

3 All I'm saying is that what happened there is -- and
4 I don't know whether we are going to come to this -- we
5 became very dismayed at the speed in which the London
6 department -- this has nothing to do with what we have
7 just been talking about -- the speed the London
8 department was in fact responding to the AIDS crisis in
9 the context of blood transfusion.

10 Q. I --

11 A. And this was an area where we took off on our own and
12 the Scottish Office very kindly said, "That's fine,
13 guys". Because traditionally, donor exclusion leaflets
14 were the work of the DHSS. If you ask: did they say,
15 "Carry on chaps" in terms of donation testing; no they
16 didn't. Donation testing in the HIV and HCV remained
17 unequivocally -- and Archie McIntyre referred in some of
18 his letters -- the area for DHSS. This was an area in
19 which we were allowed to get on ourselves.

20 Ken Calman didn't appreciate it but I was asked to
21 write this letter by Harold Gunson because they were
22 getting increasingly concerned at the difference between
23 the donor self-exclusion programmes north and south of
24 the border because of delays.

25 So, yes, there would be things that were internal

1 that we were managing. I was delighted if we didn't
2 have to touch base with our colleagues in the
3 Scottish Office. There are other things that we felt
4 would be very helpful.

5 Q. Right. We certainly see you using the expression in
6 this letter, "a professional matter". So as
7 a professional matter this was something that you felt
8 was appropriately left to you to get on with.

9 A. Yes. Yes.

10 Q. But you wouldn't say the same about trying to increase
11 the production of blood product concentrates,
12 Factor VIII concentrate; to you there was a wider policy
13 context --

14 A. I would have thought wider policy, managerial, pigtail
15 bags -- there was nothing medical about pigtail bags for
16 instance -- and things like that. This was what we
17 eventually called "Jack Gillon's country". Although at
18 that time, HIV, Brian McClelland did all the work.
19 Wonderful.

20 Q. Thank you. Just to ask you some questions about the
21 actual supply of concentrates.

22 I think the position we have reached so far in our
23 evidence is that, to start with Edinburgh, commercial
24 concentrates, if they were needed, when Dr Ludlam
25 arrived, the system that applied -- and that continued

1 to apply for another couple of years -- was that all the
2 commercial products were ordered via the regional
3 transfusion service.

4 Can we just have [\[PEN0150480\]](#) please? This is the
5 letter from Dr Ludlam in April 1983, where there is
6 a change taking place. But you see he says that in
7 relation to the ordering and storing of non-NHS produced
8 therapeutic materials, to date this has been arranged by
9 the Blood Transfusion Service. He was taking that over.
10 So that seems to be the piece of the jigsaw that relates
11 to commercial products in Edinburgh.

12 In April 1983 Dr Ludlam was cutting out the
13 involvement of the regional transfusion centre and
14 ordering material directly via the pharmacy. We
15 understand from his evidence that the products, once
16 obtained, would be stored in the SNBTS blood bank,
17 I think until 1983. And then from this change in 1983
18 they were stored in and issued from the pharmacy.

19 Commercial products in Glasgow, if we think about
20 firstly the situation that a specific product was needed
21 for a specific patient, which we have heard happened
22 from time to time, it's a little more difficult to work
23 out whether that was obtained by a doctor ordering
24 through the hospital pharmacy or by the doctor ordering
25 through the Blood Transfusion Service at Law. Do you

1 have any recollection of what would happen there?

2 A. I have no detailed recollection but I do know -- I mean,
3 I have written odd papers that are in the main database,
4 in which I have said I have reason to believe that in
5 Edinburgh and Glasgow, the West of Scotland, the
6 purchases are done by the pharmacy. I can't date those
7 documents, I am afraid, at the moment, out of my head.
8 Whereas I had the view -- and I may be quite wrong but
9 I said it -- that Aberdeen, Dundee and Inverness, any
10 orders were done through the
11 regional transfusion centre.

12 Q. Yes. You do say in your statement that SNBTS had no
13 involvement in any part of the purchasing process for
14 commercial products for the two big centres, Glasgow and
15 Edinburgh.

16 A. Yes.

17 Q. But I'm just saying that from this letter of
18 Dr Ludlam's, it does look as though they did until
19 1983.

20 A. Oh, yes. Can I say, the issue, which is what we have
21 just seen, of Chris Ludlam moving out, we were all very
22 unhappy with. The only reason that we were unhappy is
23 that, from moment on we became very uncertain that the
24 data we had on commercial purchases was accurate.
25 I think looking back, we exaggerated all that because it

1 remained very small, but we were very worried that
2 perhaps behind all this -- in which we had now been
3 excluded from seeing the data as it was being purchased
4 and so on -- there may be something bigger than we had
5 imagined. I think that wasn't so but from a planning
6 point of view, we became very anxious.

7 Q. Right. As far as commercial products at Yorkhill were
8 concerned, Dr Pettigrew thought, in her evidence, that
9 the material would be ordered by a technician at
10 Yorkhill. In fact she named an individual, a Mr Jewel,
11 a senior chief technician. But I don't suppose you are
12 in a position to offer --

13 A. That will be the local haematology and it will be the
14 blood bank section, I imagine. And he probably did it
15 through the hospital pharmacy.

16 Q. As far as general stock goes, if we think of Edinburgh,
17 thinking of material coming from PFC, we have heard
18 Dr Perry describing -- it is not a van, Professor Ludlam
19 called it a van. Dr Perry says it is more of a lorry,
20 it's a vehicle. It came to the Royal Infirmary very
21 conveniently delivering and uplifting.

22 A. Yes.

23 Q. It was refrigerated, a refrigerated truck.

24 A. Sure, sure.

25 Q. So I think we understand that. The stock from PFC in

1 the Royal Infirmary, once it had arrived at the Royal
2 Infirmary, Professor Ludlam said that Drs Boulton and
3 McClelland held it in a cupboard for him. No doubt he
4 means something cold, but they stored it in the blood
5 transfusion centre in the Royal Infirmary. Then general
6 stock for Glasgow, as we understand it, the same truck
7 would take that to Law and deliver it to Law.

8 A. I think that's right.

9 Q. Then it becomes slightly more mysterious because the
10 material has to get from Law to either the Royal
11 Infirmary in Glasgow or Yorkhill, and there is some
12 reference to daily ordering from the Royal Infirmary to
13 Law. Then presumably, once Yorkhill start to use PFC
14 material they must have had some kind of ordering system
15 too.

16 A. Yes.

17 Q. Do you have any recollection of the personnel in the
18 West, who were helping to make self-sufficiency
19 a practical reality, people who were assisting the users
20 in the West of Scotland to get the product they needed
21 from PFC, making things easier for them perhaps, taking
22 any comments or compliments/complaints back to PFC?

23 A. Yes.

24 Q. Who was involved in that?

25 A. There is no doubt Ruthven Mitchell, the director, was

1 very hands-on in that region. But I would imagine the
2 two guys who were doing the sort of thing you are really
3 interested in in terms of doctors would be Bob Crawford
4 and -- for goodness sake, I have just forgotten --

5 Q. Was it Dr Hopkins?

6 A. Thank you. The irascible Dr Hopkins, who I saw
7 a brilliant quote in one of the transcripts.

8 Q. Right.

9 A. Yes.

10 Q. Is this prompted by what you have read in the
11 transcripts?

12 A. No, Bob Hopkins was --

13 Q. I don't means his irascibility, I mean his involvement.

14 A. Oh, I see, yes. He was involved. And I think if the
15 late John Davidson was with us, who was the
16 haematologist operating on behalf of George McDonald in
17 the blood bank area in the Royal Infirmary, he would
18 confirm he had quite a lot of fun with Dr Hopkins. Yes,
19 that would be the pathway.

20 Q. Can we go back to the statement from Professor Cash,
21 please, on to page 5. Thank you.

22 There isn't very much else that we need to cover,
23 Professor Cash, because we have discussed most of it
24 already.

25 We clarified -- and this is evident from the

1 handwritten question that we can see on page 5 -- that
2 there seems to have been a bit of debate about Glasgow
3 and Edinburgh becoming reference centres; that being
4 rather different from ordinary membership of UKHCDO.

5 A. I apologise. I initially got it quite wrong.

6 Q. No. I should also explain, sir, that the reason for the
7 handwritten questions is because originally we only had
8 the statement as a PDF and it seemed like the best way
9 to put some questions on the statement to
10 Professor Cash.

11 A. It was very helpful.

12 Q. I'm glad it worked as a solution.

13 A. Oh, yes.

14 THE CHAIRMAN: I have seen a later reference, which I'll no
15 doubt in due course draw Ms Dunlop's reference to, in
16 a letter from the DHSS, saying that Glasgow and
17 Edinburgh were perhaps not strictly reference centres
18 but were rather centres of excellence. Do you remember
19 that coming into the --

20 A. Yes, I do. I saw Dr Ludlam -- because Ludlam's comments
21 about it -- and I thought he was pretty laid back with
22 you the other day -- it was quite tetchy, quite tetchy,
23 and we supported Chris and the Glasgow boys strongly.

24 MS DUNLOP: I'm certainly happy to look at that. It is
25 [\[DHF0017665\]](#). Is it pejorative?

1 A. I honestly don't know. Professor James may have a view
2 on this. Senior civil servants in London regarded
3 Scotland as a place like the northeast and Newcastle and
4 the notion of having two of these people on the UK was
5 too much. They had no idea of not only the
6 sensitivities and rivalries, but -- I was reading
7 a letter this morning about a superregional centre at
8 the Royal Free hospital, and the notion of having two
9 from Scotland was really irksome, and the arrival, for
10 instance, of five Scottish regional transfusion
11 directors down into England was regarded as just
12 outrageous. We just needed one. "You will do, John,"
13 was the comment.

14 Q. Certainly --

15 A. And that's another culture. It's all about the culture.

16 Q. Of course, Professor Cash. I'm not saying the Inquiry
17 team doesn't notice these things too but the chairman
18 has reminded us of this letter. There is another letter
19 which says words to the effect, "Of course, they have to
20 have two," meaning there has to be one in Glasgow and
21 one in Edinburgh?

22 A. Absolutely.

23 Q. And that's a whole different topic, which I don't think
24 we should even think about opening up.

25 THE CHAIRMAN: Certainly not at this time on a Friday

1 afternoon.

2 A. Thank you, sir.

3 MS DUNLOP: No. But just the reference to Scotland having
4 two haemophilia centres, which perhaps are regarded more
5 as centres of excellence than reference centres, one
6 wouldn't want to be oversensitive. Perhaps it wasn't
7 meant to be pejorative at all. I daresay we will never
8 know.

9 Can we just look at the heading please? I don't
10 think we know who said it.

11 A. I'm pretty sure it wouldn't be Arthur Bloom.

12 Q. No, it's a DHSS letter.

13 A. Yes, very gentle.

14 Q. We have enough information that I can tell you who
15 occupied that room in 1983, but that really would be
16 speculating to say that the same person was in that room
17 in 1985.

18 Can we just look at the end of the letter, please?
19 There we are. Absolutely no illumination there.

20 Now, we were in the statement. Can we go back to
21 the statement, please? There really isn't much else
22 I need to put to you at all. You don't think that at
23 the time you knew about Dr Galbraith's proposals.
24 That's at the bottom of page 5.

25 A. Yes.

1 Q. And then on to the next page. We have discussed this,
2 the different considerations that applied to supply in
3 England.

4 A. I don't want to delay the weekend for you but the
5 Galbraith thing is hugely important --

6 Q. Quite.

7 A. -- in my view. First of all, I was absolutely dismayed
8 and quite angry that I knew nothing about it until
9 I read the papers of this Inquiry. What I can tell you
10 is that I discovered quite by chance that John Watt was
11 on the Committee on the Safety of Medicines biological
12 subcommittee -- quite by chance -- by going over to see
13 him in 1980 and falling over these sacks of documents
14 that these chaps get with all evidence. He told me he
15 was on this committee. I said "Excellent," because what
16 we want to do with that committee is persuade them to up
17 the ante in terms of safety of the commercial products
18 coming into the United Kingdom.

19 John asked me to produce an A4 list of suggestions
20 that they might do to improve the safety and when I took
21 it back, he was now of a different mind, that (a) he was
22 working under state secrets (inaudible) and couldn't
23 divulge to me or anybody else the business of this
24 particular committee and furthermore he was very anxious
25 that he might be accused of conflicts of interest, ie he

1 was the public sector and he was making comments about
2 the private sector.

3 I do not know, to be absolutely honest, because he
4 never came back to me, whether John in fact took these
5 proposals, but they were really quite important
6 proposals, that I had hoped -- you know, when the
7 Galbraith thing finally arrived in 1983, I would have
8 hoped that committee, which John was on, would have
9 said, "Okay, we can't abandon the American stuff, but
10 can we make it any safer?" And there is no doubt that
11 they could have, and they took no action at all, and
12 I was pretty concerned about that, I must say, when
13 I read the Galbraith story here.

14 Q. Can we just look at page 3 of Professor Cash's
15 statement? In the paragraph which has the number 4 you
16 have made a reference to -- actually this is UKHCDO and
17 their conclusions being difficult to challenge, where
18 almost 60 per cent of the concentrate used was sourced
19 commercially. Certainly, the meeting on 13 July 1983,
20 that considered Dr Galbraith's papers, appears to have
21 been strongly influenced by considerations of supply.
22 You say that yourself on page 6.

23 You have obviously thought about this recently. One
24 question that one could pose about that debate on
25 13 July 1983 is: if one has a little of a product or

1 a lot of a product -- so the product is either scarce or
2 plentiful -- how does that affect a judgment as to
3 whether or not it's safe?

4 A. I'm sorry, I am not quite with you. I think it's the
5 nature of, not the amount.

6 Q. It's perhaps a slightly tongue in cheek question,
7 Professor Cash. It does seem that the discussion very
8 much centred on the supply: is this scarce or plentiful?
9 And the answer was it was scarce, but the topic for the
10 meeting looks to have been the safety of the product,
11 and I'm wondering if you can see how the fact that
12 something was scarce or plentiful would impact on
13 whether or not it was safe.

14 A. No, I can't but the dead hand of the DHSS, whether it's
15 their supplies division or in other departments, on the
16 work of the Committee on the Safety of Medicines -- if
17 you look at the Medicines Act and what's around it, the
18 CSM is supposed to be totally independent and so on, and
19 there is absolutely no doubt that the chairman of that
20 committee on the day, I knew very well -- and Joe was
21 not independent, he was very influenced by policy-makers
22 and DHSS, and it would not surprise me, I mean,
23 I wouldn't criticise this, that in fact that committee
24 met and the chairman already had been given the steer as
25 to where he was to take the thing and it was about

1 supply. Forgive me but it was about supply in the end
2 and I'm absolutely certain that ministers would have
3 been extremely concerned if a bunch of experts had said,
4 "It's dangerous, take it out, just walk away from it,"
5 which is what Dr Galbraith in fact was recommending.

6 Some people -- and I would have to share that
7 view -- would have regarded that view as irresponsible.
8 But there was a middle way and it was not even
9 considered and that's the thing that distressed me. It
10 might in my view -- and it sounds outrageous -- have
11 saved a lot of lives.

12 Q. Professor Cash, much of what's in the rest of your
13 statement is either material that we have already
14 covered or that you say is more relevant for haemophilia
15 clinicians to answer.

16 I think the only section that we should look at --
17 you can perhaps take the intervening pages as read and
18 look at page 9, just to look in particular at the views
19 express in the paragraph numbered 2.

20 The question that is being asked is in relation to
21 the early part of 1984 but how should we understand the
22 timeframe to which you are referring in paragraph 2,
23 particularly your comment that:

24 "NHS product were viewed by many haemophilia centre
25 directors as intrinsically unreliable, both in terms of

1 supply and quality of product."

2 What timeframe are you speaking of?

3 A. Oh, as best recollected, it would be pre-high purity.

4 Q. So up until when?

5 A. That would be 1988-ish.

6 Q. Right.

7 A. If you ask me were these views justified, I would
8 unequivocally say no but I think there was great anxiety
9 by the prescribing clinicians throughout the
10 United Kingdom that if we let the public sector, which
11 is run by civil servants and politicians -- "Not by you,
12 Cash," they would tell me, and rightly so -- we may get
13 into trouble in the future.

14 I think I have said it somewhere in one of my
15 witness statements: in Scotland we eventually fell
16 from -- I call it fell from grace. By 1988 we had run
17 short of plasma. We had signalled the need and the
18 funding had not come. There were a lot of clinicians
19 who were very keen to have NHS stuff but they
20 regarded -- for reliability and indeed quality. We had
21 problems with research, we had problems with optimising
22 yield so that we remained self-sufficient, whereas all
23 our commercial mates didn't have these problems, they
24 just charged the money or whatever costs. So it was
25 a difficult task to manage.

1 Q. Yes. But there are some positive comments --

2 A. Oh, yes.

3 Q. -- really throughout the minutes of meetings in the
4 early 1980s too, for example 21 January 1983. I don't
5 want to go back to it but Dr George McDonald was
6 complimenting the SNBTS directors and PFC on the
7 quantity and quality of Factor VIII concentrate.

8 A. George was not a clinician and I don't think, if you
9 read -- I'm sure you have -- Charles Forbes' comments,
10 they would necessarily mirror that. So there was an
11 area of difficulty and we were aware of it.

12 Q. Yes but even if he wasn't a clinician, Dr McDonald was
13 presumably going on what people were telling you at that
14 time?

15 A. I can't tell you. He was a dear friend.

16 Q. Right. Not a big point. We did suggest to you there
17 was a word missing in paragraph 4. It's not a big point
18 at all. I think we just wondered if the phrase at the
19 end, "rather to retain some sort of the marketplace",
20 means just to retain some sort of involvement in the
21 marketplace.

22 A. "Some sort of." There's a "the", I think, that probably
23 shouldn't be there.

24 Q. Okay, it is not a word missing, it is a word too many?

25 A. Yes.

1 Q. Right. Just, in conclusion, look at your supplementary
2 comments. I think again we have covered most of these.
3 [\[PEN0150362\]](#). I think we have covered everything on the
4 first page.

5 Then the second page. Apart from one or two textual
6 corrections, the biggest point, obviously, on the
7 second page is in relation to exactly that issue; that's
8 the question 6 in the statement, the paragraph we have
9 just looked at about the views of haemophilia centre
10 directors. You have said you basically are adhering to
11 the views expressed in your statement. I think we
12 should just read for ourselves what you say about your
13 doubts as to whether the haemophilia centre directors or
14 SHHD were fully committed. (Pause)

15 Some at least of this, Professor Cash, does relate
16 to a period beyond the period we are examining at the
17 moment, which is primarily the use of concentrates in
18 the early 1980s.

19 A. I think the big change came in 1988/1989 with the EU
20 Directive 381, with the now Lord Forsyth coming into my
21 office and having chats and walking out leaving a cheque
22 for ú4 million in effect. That produced a huge change,
23 that allowed us -- and we abandoned Crown immunity, we
24 invested very heavily and so on, and for certainly the
25 period that I was there, until I retired in 1997, there

1 was a complete change. I was conscious -- and the
2 attitude of my mate and colleagues in the
3 Scottish Office -- for whatever reason we seemed to
4 have, I thought, detached ourself from London.

5 Q. Well, Professor Cash, a speaker should, I gather, leave
6 his audience always wanting more. So perhaps with your
7 reference of having been left a cheque for ú4 million,
8 we can conclude for today.

9 A. Thank you very, very much.

10 THE CHAIRMAN: Mr Di Rollo?

11 Questions by MR DI ROLLO

12 MR DI ROLLO: Professor Cash, there was one document which
13 I would like to put to you. It's [\[SNF0010178\]](#). Can it
14 just be put up on to the screen? I think this is in the
15 context of certain remarks you made about Yorkhill this
16 morning. If you go to page 3 of the document, under
17 (e), "Purchase of commercial blood products", we will
18 see that there is a paragraph there:

19 "During a full discussion, in which it was
20 acknowledged that the Glasgow West Infirmary Royal
21 Hospital for Sick Children appeared to be the last
22 remaining hospital to use substantial quantities of
23 commercial Factor VIII in the West of Scotland, it was
24 agreed that Dr Mitchell should write to the consultants
25 concerned to enquire why they needed commercial

1 products. In addition, Dr Cash would include the matter
2 in a document which he was preparing concerning planning
3 for self-sufficiency in clinically safe products."

4 It does appear from that that there was obviously
5 some involvement by you and some knowledge on your part
6 in respect of the situation at Yorkhill and
7 Glasgow West Infirmary and their use of commercial
8 products at the time. Do you agree with that?

9 A. I have not checked the dates but I take your point and
10 apologise for misleading this morning. I do not
11 remember that.

12 Q. Just dealing with the point generally, my learned friend
13 was asking you about the use of commercial material at
14 Yorkhill, and it does appear that that was something
15 that was going on. You said today that you didn't ever
16 meet Dr Willoughby and you are not really able to tell
17 us why it was that he may have been using commercial
18 product to the extent that he was and certainly seems to
19 have been doing more or less to the exclusion of NHS
20 product. You can't really help us with that?

21 A. No, forgive me. I did make some suggestions as to why
22 he might.

23 Q. Yes, but you do not know?

24 A. I don't know.

25 Q. It was never discussed with you at the time?

1 A. No, no.

2 Q. You would assume, I suppose, that it was for good
3 clinical reasons.

4 A. Of course, yes.

5 Q. There wouldn't be any other reason to choose commercial
6 over NHS, something to do with marketing or a better
7 relationship with the company they were dealing with
8 rather than with PFC Limited or anything of that nature?
9 You are assuming that it's a clinical reason rather than
10 anything else?

11 A. No, no, it's a clinical reason, yes. As I said this
12 morning, it might be he had strong views about
13 solubility, about the volume that he could get compared
14 to the volume he could get our doses. There were all
15 sorts of potential reasons that I could see a
16 paediatrician ...

17 Q. As I understand it, you think that it's important that
18 the clinicians should have a choice. Is that what you
19 are saying?

20 A. Oh, yes. Forgive me, yes.

21 Q. So if, for example, government had dictated to you that
22 you will only use NHS product, would you have said, "No,
23 no, we can't have that because the clinician must have
24 a choice"?

25 A. No, I'm simply saying that clinical freedom has got some

1 very significant advantages. Situations may arise when
2 clinical freedom has to take second place and we see
3 this today, we have seen it for decades, ie the
4 financial manager in the Royal Infirmary in Edinburgh
5 tells the doctor there is no money for that patient with
6 cancer: Good night and good bye, and he has to
7 accept -- that's the only point.

8 Q. At what point in the self-sufficiency drive do you say
9 that the physician gives up his clinical freedom?
10 That's what I'm trying to get to. Obviously, you can't
11 have self-sufficiency if the clinicians are free to
12 choose commercial products.

13 A. Well, I'm not convinced by that. I can take you to
14 documents in which the clinicians are saying, "We want
15 NHS products of that quality and that amount and if you
16 deliver that, great stuff. That's all we want." To
17 deliver that -- and we have never got down to talking
18 about it yet -- is really quite complicated, it isn't
19 just about money. But I have always taken the view that
20 if we could have delivered, and our mates south of the
21 border could have delivered, quality compared to the
22 commercial, quantity and delivered on time, it would
23 have naturally meant that the clinician would have said,
24 "That's great, we will have it." Why? It's NHS, and as
25 Ms Dunlop has said, in Scotland -- not England, but in

1 Scotland it didn't cost them anything to their budgets,
2 the hospitals.

3 Q. Did you feel they did get there in Scotland at a certain
4 point, in your view?

5 A. No. We had surpluses of the product in 1983/1984 that
6 we produced, and we sent a lot of that surplus down to
7 England, but in my view, in discussion with clinical
8 colleagues -- and I was well aware of this when I worked
9 in the Edinburgh centre -- there was the odd patient,
10 haemophilia patient, you put in the NHS stuff and they
11 reacted to it.

12 Q. Yes, but --

13 A. And you had an odd patient for the commercial, same.

14 Q. -- leaving aside those kinds of cases. We are not
15 really talking about that; we are talking about the
16 sorts of situations where one is as good as the other in
17 terms of -- you do actually genuinely have a choice.
18 Then did they reach self-sufficiency in Scotland at any
19 point, leaving aside the reactions of patients or that
20 kind of thing?

21 A. Yes, I think the moment we were surplus and handing it
22 down to England we were self-sufficient. However, in
23 the real world, if the clinicians were not picking it
24 all up and were for some reason using alternatives
25 because ours in their view was not appropriate to give

1 ...

2 Q. It's a question of their view, though --

3 A. Yes, of course.

4 Q. -- it is a question of how you control or affect or

5 influence their view.

6 A. Yes.

7 Q. And what I'm saying to you is it can't presumably just

8 be a question of the government doing it because if it

9 was the government doing it, then the medical profession

10 would react against that and say, "You are not going to

11 tell us what we do in terms of prescribing material."

12 A. Well, we are getting into another area about

13 self-sufficiency. In my view, if you are going to be

14 really self-sufficient, you need the government, the

15 civil servant's team, you need the transfusion service

16 and you need the clinicians to be working very closely

17 together.

18 Q. Surely.

19 A. And if you have listened to half of today, as far as I'm

20 concerned, you will have realised that that didn't

21 happen quite as well as we had wanted. You can say that

22 was the clinicians but there were other people involved.

23 All of us have got motes in our eye. We didn't quite

24 get our act together. But I will tell you

25 internationally we did a hell of a lot better than any

1 other country I know actually.

2 Q. Can I just ask you about one more matter, again arising
3 from the questions you were asked earlier.

4 You referred in the context of Dr Galbraith's
5 intervention, the decision that had to be made by the
6 committee in relation to what to do at that point. You
7 said there was a middle way in relation to that. What's
8 the middle way that you are suggesting, I'm not entirely
9 sure?

10 A. There are a number of options and we haven't enough time
11 to go into this in detail but it is a recorded fact --
12 and I know Ms Dunlop doesn't want any more paper for
13 this Inquiry and I appreciate that, but if you are at
14 all interested, and if you are into Douglas Starr --
15 which I see you are and I'm delighted -- there is
16 another series of publications of all papers, the
17 Philadelphia Inquirer -- which you may laugh but it is
18 actually a very serious paper -- that ran a series of
19 major investigative articles on the bad blood business
20 in the US of A.

21 I became aware of these articles because, in 1969
22 when I visited the States, I made a great friend --
23 a number of them -- but one of them
24 was Lieutenant Colonel Tom Zuck of the US army, and in
25 1984/1985 he was seconded to the FDA. And the reason he

1 was seconded -- and I was very close to him and knew all
2 about this -- is that the FDA inspection area for blood
3 banks and plasma centres was a disaster area, and if you
4 want to see this in detail, read the
5 Philadelphia Inquirer. There was a major Douglas Starr
6 investigation of it. At the time we are talking about,
7 the regulation of the blood industry, in its broadest
8 sense, in the US just went out of the attic. Primarily
9 because, they say, Mr Reagan did what Mrs T did, had
10 a massive cut in the -- and the staff of the FDA were
11 halved overnight.

12 So at the crucial period, when the -- and my
13 argument was the Committee on the Safety On Medicines
14 should know -- I knew that, John Watt my old friend knew
15 that. The Committee of Medicines should be saying, "We
16 are importing these materials from the US of A; what's
17 going on in terms of regulation?" And almost
18 certainly -- because I asked them -- the inspectors from
19 London of the MCA, I thought they went and inspected
20 these -- they didn't, they didn't have the resources.

21 So we were importing stuff from the USA from set-ups
22 that were not being inspected at all. And if you want
23 the gory detail, I'll tell you. Have a look at the
24 Philadelphia Inquirer.

25 You say: what could we have done? First of all,

1 introduce some inspection. Secondly -- and I don't know
2 whether this is on -- there were certain companies, and
3 if you look at the World in Action, John Prothero, the
4 haemophiliac in the second disc, super guy, he actually
5 says, "I'm very amazed by this documentary" because he
6 says, "I know of some companies that claim they don't
7 use skid row at all". It's part of their marketing, and
8 certainly I did -- I'm not going to name the one -- and
9 they claimed, "If you get your stuff from us, we can
10 guarantee it is not coming from there. We can guarantee
11 it's of the highest quality in terms of plasma." One of
12 the companies claimed it would be just as safe as ours.

13 We could have actually then said to supplies
14 division in DHSS -- when I say "we", the Committee on
15 the Safety of Medicines -- then what we should be doing
16 is getting our contracts from these companies that have
17 approval. "That company, that company" -- the Committee
18 of Medicine -- "doesn't have our approval". Whether
19 that was politically on, I don't know, but it was
20 a middle way.

21 Q. Thank you. Thank you very much, professor.

22 MR ANDERSON: I have no questions.

23 THE CHAIRMAN: Mr Sheldon?

24 MR SHELDON: Briefly, sir, please.

25 Questions by MR SHELDON

1 MR SHELDON: Professor Cash, I wanted to ask you about your
2 proposal to the Scottish CMO that a letter be issued.
3 I really just want to ask you this: why did you feel it
4 necessary to suggest or request that such a letter be
5 issued by the Scottish CMO?

6 A. Because I was not certain in my mind that our clinical
7 colleagues were at all impressed that the SNBTS had the
8 fullest support of the Scottish Home and Health
9 Department in that context.

10 The main evidence for that came, for them, when we
11 said, "Could we have full data on purchases of
12 Factor VIII, and therefore, if the best way of getting
13 that is if we issue it, you tell us what to buy, we will
14 buy it for you and we will issue it," the directors of
15 the haemophilia centres did not like that, the supplies
16 in England.

17 DHSS went to the UK haemophilia doctors making that
18 request and it was turned down, and after that I wanted
19 an assurance from the Scottish Office -- that was
20 communicated to hospital pharmacies, to regional
21 pharmacies -- that the purchases of commercial
22 Factor VIII in Scotland should be very carefully
23 considered.

24 Q. We looked this morning at a couple of minutes of joint
25 directors' meetings, one in January 1983 and one

1 in February 1984, where really that very point is made,
2 that purchases of commercial products should be kept to
3 a minimum. This is in the context of a discussion about
4 the risks associated with imported product. The
5 impression that was given really, from the minutes of
6 those meetings is that there was substantial consensus
7 among those present, ie the transfusion directors, the
8 haemophilia directors and representatives of SHHD, that
9 commercial purchases should be restricted and NHS
10 products preferred.

11 Is that a fair way of characterising it?

12 A. Yes, but I think the concern that we had, as I explained
13 an hour or so ago, is that we were not entirely certain
14 that the data we were getting on commercial purchases
15 was accurate.

16 Q. I'm not quite sure that I follow that. Is the concern
17 that there were purchases being made by haemophilia
18 directors, for example, which weren't being declared or
19 which weren't being talked about at these meetings?

20 A. Yes.

21 I'm not suggesting that -- they could have been
22 mistakes or whatever but until -- I think in the
23 preliminary report, comments have been made about the
24 work of Bob Stewart. And the great strength that
25 Bob Stewart had when he joined the organisation -- that

1 clearly the regional pharmacy people had been instructed
2 then, finally, in 1989/1989, to provide us with the
3 information, and they did and it was magnificent.

4 Q. Is it your recollection that your concern about the
5 amount of commercial concentrate being purchased in
6 Scotland was shared by officials within SHHD?

7 A. Yes, but I think there is a statement made by Bert Bell
8 at one point that the department does not wish to
9 interfere with the autonomy -- I think that's right,
10 sir -- the autonomy of the regional health authority.

11 Q. Perhaps we can just look at that, in fairness to
12 Dr Bell. We have already looked at it briefly. It's
13 [\[SNB0015252\]](#).

14 This is the minute of the meeting of
15 2 February 1984. Could we look, please, at page 2. If
16 we look to the bottom of that page, we can see the
17 context which is you asking members to consider whether
18 it's necessary to purchase commercially. If we look
19 over the page.

20 A. This is 1984, is it, this one?

21 Q. That's right, 2 February, 1984.

22 A. Thank you.

23 Q. Over the page, there is clearly some discussion:

24 Drs McDonald, Hann and Ludlam make contributions, and
25 Dr Bell emphasises that the aim of SNBTS and national

1 policy was for Scotland to be self-sufficient, and
2 although the department would not wish to intervene in
3 what physicians prescribed it was not sensible to
4 purchase imported material when suitable NHS product was
5 available.

6 So is Dr Bell really there trying to negotiate the
7 line, or walk the line between affording freedom to
8 clinicians but also saying that, "If possible, you
9 shouldn't be buying commercial product"?

10 A. Yes. I welcomed that and I welcomed also the statement
11 he made, I think, in the 1983 meeting. And all I was
12 doing was to get, in a sense, the CMO to say the same
13 thing.

14 I have to say to you -- and I'm sure you will
15 appreciate -- that a relatively junior medical
16 officer -- and he was not a junior in terms of
17 experience but in terms of position -- saying something
18 in a committee -- a very small group of a committee --
19 "That minute won't be seen by regional pharmacies", and
20 so on and so forth, "and chairmen of health boards,
21 whereas a CMO letter will". So I notched it up on --
22 I think I was pretty naive in doing that -- but that was
23 the purpose of it certainly.

24 Q. Thank you, sir. Nothing further.

25 THE CHAIRMAN: Yes, thank you.

1 Ms Dunlop, are you content to stop at that?
2 MS DUNLOP: Yes. I have no other witnesses for today, sir.
3 THE CHAIRMAN: Professor Cash, thank you very much once
4 more.
5 A. Thank you, sir.
6 THE CHAIRMAN: I think it's merely an instalment.
7 A. Oh, dear. Thank you very much.
8 THE CHAIRMAN: Yes?
9 MS DUNLOP: I wonder, sir, I think it's perhaps a good time
10 for a five minute break. I have been going for an hour
11 and 20 minutes. I think, in terms of discussing whether
12 we should do anything else today, it might be useful to
13 take a five minute break.

14 (3.19 pm)

(Short break)

17 (3.30 pm)

18 (The Inquiry adjourned until 9.30 am on Tuesday, 17 May
19 2011)

21 I N D E X

22
23 DR ROBERT PERRY (continued)1
24 Questions by MS DUNLOP (continued)1
25 Questions by MR DI ROLLO39

1 Questions by MR SHELDON52
2 Further Questions by MS DUNLOP66
3 PROFESSOR JOHN CASH (continued)72
4 Questions by MS DUNLOP (continued)72
5 Questions by MR DI ROLLO145
6 Questions by MR SHELDON153
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

