Wednesday, 10 November 2021

(10.00 am)

MS RICHARDS: Sir, before I start with today's business, an issue came up yesterday afternoon during Ms Fraser Butlin's presentation in relation to the concept of non-specific testing.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: And I'm being provided with some further information about that and it's something I may come back to tomorrow.

Presentation by Counsel to the Inquiry on Professor John Cash

MS RICHARDS: In terms of the business for the rest of this week, we are looking first at Professor John Cash and his role and decisions and actions and then the role of Dr Harold Gunson. They occupied broadly equivalent positions in, respectively, Scotland and England and Wales, and we thought that talking about their views, often expressed in quite trenchant terms, and their decisions, roles and actions and responsibilities would be a useful introduction to a number of issues which will then be exploring over the coming weeks with witnesses who are giving evidence orally.

It won't surprise you to know there's a vast amount of documentation in relation to each of them and so the written presentations are inevitably selective. The oral presentation will inevitably be more selective still and no particular significance should be attached to the selection of documents.

There are really three purposes in drawing attention to material relating to Professor Cash. The first is to show you and those listening his views on a number of issues relevant to the Inquiry's terms of reference, and it's important to emphasise that by showing you his views, we are not to be taken to be suggesting that those views are either correct or incorrect. Those are matters which may be appropriate for submissions at a later stage on behalf of Core Participants. That's the first purpose.

The second is to help understand what his role was and the part he played in certain important decisions and actions relevant to the blood services.

Then the third is, as I've already indicated, to serve as an introduction to some of the key issues that we'll be exploring over the coming weeks. For example, either this afternoon or tomorrow morning we'll look at a number of documents relevant to the question of the introduction of screening or testing for hepatitis C, which we know was not introduced until the autumn of 1991, save in one Regional Transfusion Centre area, and we'll look at what Professor Cash said about that, his role in the decision-making process. But that will very much be as an introduction to the issue which we'll explore with a number of key players such as Professor Contreras and others when they give their oral evidence.

Just to start then with a brief overview of Professor Cash and his employment responsibilities, he was a consultant at the Edinburgh and South East Scotland Blood Transfusion Service from 1971 to 1979, and he was appointed as director of that service in 1974.

In 1979, he became the National Medical Director for the Scottish National Blood Transfusion Service and his role changed, in terms of its description at least, to National Medical and Scientific Director in, I think, 1988. According to his CV, which we have amongst the papers that we've disclosed, he retired in 1997.

We'll obviously be hearing a lot, not least from oral witnesses over the coming hearings, about the Scottish National Blood Transfusion Service, but there's a useful snapshot of it as at 1988 if we look at NHBT0002934. It's the annual report for 1988 to 1989. If we go to the next page we'll see a number of the leading individuals within the Scottish National Blood Transfusion Service. There we have "National Medical Director, Professor ... Cash", and then we have there listed the directors of the various transfusion centres within Scotland set out, and then towards the bottom we see "Director, Protein Fractionation Centre, Dr Perry".

I will obviously be touching on the activities of the Protein Fractionation Centre today and tomorrow morning, but that, again, is an issue that we'll be coming back to in substantially more detail when we look at both PFC and BPL in our hearings in March of next year.

Then if we go to the next page, just to see what the service was that Professor Cash was director of, if we look at the third paragraph we can see there the description of the seven operational units making up the SNBTS, the five Regional Transfusion Centres (Aberdeen, Dundee, Edinburgh, Glasgow Inverness), the Protein Fractionation Centre and the Headquarters Unit in Edinburgh.

Then if we look at the bottom paragraph we see:

"The responsibility for the operational

1 management of those aspects of the service which are
2 national in character primarily rests with the Centre
3 Directors who meet with the National Medical Director
4 [so that's Professor Cash] at regular intervals to
5 plan future strategies and monitor performance."
6 You can take that down, thank you.
7 So Professor Cash was a member of multiple
8 committees, working groups, societies and
9 organisations during his career with the Scottish
10 National Blood Transfusion Service. I'm just going to
11 mention some of them which are of more importance than
12 others to the Inquiry's investigative work. He was
13 appointed to the Medical Research Council Subcommittee
14 on Hepatitis in 1970.
15 From 1980 to 1982 he was a member of the Medical
16 Research Council's Committee on Blood Transfusion. If
17 we just look at PRSE0002836, this is one of the many
18 statements that Professor Cash gave to the Penrose
19 Inquiry. I think at my last count there are
20 16 witness statements, because of the way in which the
21 Penrose Inquiry took its statements, which was to ask
22 for statements on specific issues or sub-issues rather
23 than one overarching statement.
24 I will refer to a handful of those in the course
25 of the presentation, and also to some of his oral

1 evidence to the Penrose Inquiry, which we'll probably
2 get to tomorrow, but this is one of his statements to
3 the Penrose Inquiry.
4 If we just go to the bottom of the second page,
5 he makes an observation about the committee I've just
6 referred to at the bottom of the page. He says:
7 "I ... recall that SHHD [Scottish Home and
8 Health Department] officials showed little interest in
9 this work ..."
10 And then he says this:
11 "... and how dismayed, astonished and alarmed we
12 were ..."
13 Just go to the top of the next page:
14 "... when, without any consultation of the UK
15 Blood Transfusion Services, the MRC disbanded its
16 blood transfusion research committee in July 1982."
17 We can take that down thank you.
18 Professor Cash was a member of the DHSS's expert
19 advisory group on AIDS from 1985 to 1987, and he was
20 a member of the UK Advisory Committee on Transfusion
21 Transmitted Diseases, which was set up in 1989.
22 Again, if we look at the minutes of the first
23 meeting of that committee we'll get a flavour of that
24 work.
25 NHBT0000043_002, please, Soumik.

1 So you will see:
2 "National Directorate of the NBTS.
3 "UK Advisory Committee on Transfusion
4 Transmitted Diseases."
5 This was its first meeting, February 1989.
6 If we go to the next page, we'll see those
7 present and we see there Professor Cash identified
8 and, indeed, Dr Gunson. You see Dr Contreras and we
9 will be hearing oral evidence from Professor Contreras
10 at a later stage.
11 Then if we go a little further down, thank you,
12 paragraph 2, second paragraph, says:
13 "This present committee had been formed to
14 discuss transfusion transmitted diseases and to
15 provide advice to the Departments of Health."
16 If we go on to page 5 we'll see the heading at
17 point 7 "Non A, non B Hepatitis". One of the issues
18 being discussed by this committee in 1989 was the
19 question of testing for non-A, non-B hepatitis.
20 Again, that's a theme we'll come back to not just this
21 week but on multiple occasions, I think, over the
22 coming weeks. You will see there, there was
23 a discussion in relation to ALT testing, with
24 Professor Cash reporting at paragraph 7.3 and then 7.5
25 a discussion there about the screening or testing for

1 hepatitis C, which again I will be coming back to in
2 some more detail.
3 Professor Cash attended the meetings of this
4 committee on a regular basis.
5 We've referred to, on a number of occasions, the
6 Advisory Committee on the Virological Safety of Blood
7 and if we look at NHBT0000192_058, this is a letter
8 from Dr Gunson to Professor Cash, May 1991. If we
9 look at the second paragraph of the letter, you will
10 see Dr Gunson saying this:
11 "I well recall your efforts of a year or two ago
12 to establish a ministerial group to control the
13 introduction of additional donor testing. This led to
14 the formation of the ACVSB [the Advisory Committee on
15 the Virological Safety of Blood]."
16 Professor Cash himself did not sit on that
17 committee but you will see that letter suggests his
18 actions were instrumental or played a part at least in
19 its establishment.
20 If we look -- just sticking with this particular
21 committee, if we look at another of Professor Cash's
22 statements to the Penrose Inquiry, PRSE0002529, we'll
23 see some observations in this statement that Professor
24 Cash makes about both the ACVSB and the advisory
25 committee on transfusion-transmitted diseases. So if

1 we pick it up on the bottom half of the page, the
2 passage which is underlined:
3 "I was advised in 1991 [and this may be,
4 I think, a reference to the letter we have just looked
5 at] that the ACVSB [the Advisory Committee on the
6 Virological Safety of Blood] had been conceived by
7 DHSS officials partly in response to criticisms I had
8 made of the way officials had managed the HIV/BTS
9 interface. My concern in 1984/85 had been a lack of
10 involvement of UK [Blood Transfusion Service]
11 professionals; a lack of urgency; an absence of
12 transparency; and an uncertainty, (in my mind)
13 regarding accountability, with respect to SHHD and
14 Scottish Ministers. The response of DHSS in 1989 --
15 the creation of the ACVSB -- was, I recall, welcomed
16 but proved not to be entirely satisfactory. This
17 committee was again short of donation screening
18 virology expertise; there was no mechanism for the
19 SNBTS management team to have an input on the
20 construction of the ACVSB agendas, submit briefing
21 papers or have access to Meeting Minutes. A strict
22 code of secrecy, supported by SHHD, was imposed, so
23 that on many occasions the SNBTS general manager, the
24 medical scientific director and the CSA's [that's
25 Common Services Agency, Ms Scott referred to that

1 yesterday] general manager had no knowledge of what
2 was going on. There was no evidence of any urgency
3 with regard to the timely resolution of important
4 operational issues. Finally, the role of Scottish
5 Ministers in the process seemed unclear."
6 Then if we go over the page, he then turns to
7 consider the Advisory Committee on Transfusion
8 Transmitted Diseases:
9 "The ACTTD was the 'brain-child' of Dr Gunson.
10 Dr Gunson, believed it would assist him to take to the
11 ACVSB the views of a wider group of UK BTS experts.
12 He also wished to encourage the ACVSB academic
13 virologists to dialogue with UK BTS virologists. This
14 development enjoyed by full support, though in due
15 course, it generated serious problems for Dr Gunson.
16 "On a number of occasions considerable tension
17 arose between the two committees. The academic
18 virologists were at times uncomfortable working with
19 some other members of the ACTTD. Senior DHSS
20 officials became alarmed that they had no control of
21 ACTTD and at one time took extra-ordinary action to
22 prevent attempts to establish formal links between the
23 two committees. Dr Gunson was on occasions to find
24 himself in a difficult position when he knew that the
25 advice generated by the ACTTD would not be acceptable

1 to DHSS. On one occasion this led Dr Gunson to offer
2 his resignation as ACTTD Chairman. The deliberations
3 of the ACTTD also provided the first ever opportunity
4 for some members of wider UK BTS management teams to
5 scrutinise closely the operational differences between
6 the blood transfusion services in England and Wales
7 and Scotland. At times, this was a cause of some
8 distress and unhappiness."
9 Then if we just look a little further down to
10 the next underlined answer, he was asked a question
11 about how membership of the bodies were determined and
12 he says:
13 "ACVSB members were selected by DHSS after,
14 I presume, consultation with other Departments. ACTTD
15 members were selected by Dr Gunson in consultation
16 (for SNBTS members) with myself."
17 So that's a flavour of Professor Cash's views on
18 those committees. In terms of the reference to
19 a degree of secrecy, we can see that issue teased out
20 in correspondence between Professor Cash and David
21 McIntosh of SNBTS. So if we look at PRSE0000615, this
22 was a letter from Professor Cash to Mr McIntosh,
23 29 August 1991, in which he says:
24 "I have recently had access to Minutes of the
25 Advisory Committee on the Virological Safety of

1 Blood ..."
2 Then he notes what's said in those minutes about
3 the policy for a uniform starting date, and that's for
4 hepatitis C testing of blood donations.
5 That letter triggered an interesting response
6 from David McIntosh at NHBT0000077_071,
7 30 August 1991. He thanks Professor Cash for the
8 letter and then says this:
9 "Isn't it interesting that this, the first
10 alleged record of a clear UK policy in this regard,
11 should come to our hands
12 "indirectly.
13 "unofficially.
14 "and too late!?"
15 Then if we skip down a couple of further
16 paragraphs, he says:
17 "It will be of some considerable interest to see
18 if we can stimulate more clarity about:
19 "to whom the Advisory Committee on the
20 Virological Safety of Blood provides advice and what
21 status that advice has
22 "who is thereafter responsible for turning that
23 advice (or amended versions of it) into actual policy,
24 with authority to instruct action and/or inaction [and
25 then, thirdly]

"who is responsible for communicating relevant and authoritative instructions clearly and timeously to the relevant punters at the coal face."

Then if we go over the page -- actually no, I'm sorry, could we just continue where I left off from that previous section. It's probably easier to look at the whole letter. So Mr McIntosh continues by saying:

"There is for instance as yet no sign whatever that UK Health Ministers' alleged collective endorsement of the idea of a uniform starting date - having failed to achieve any such thing - has even gone as far as achieving a mild admonishment of the culprit who broke ranks."

That's a reference to Dr Lloyd's introduction of hepatitis C testing earlier than the national date, and that's an issue I will come back to.

Mr McIntosh continues:

"I remain uncomfortable that we are all most probably in a potentially compromised position with which Dr Metters' unpublished minutes do nothing to assist us."

Dr Metters was DHSS I think Deputy Chief Medical Officer. I will double-check I'm right about that.

Then he says:

"We are however, as often before (thank goodness) now taking important steps to help ourselves ..."

Then if we go over the page, pick it up in the second paragraph:

"As you know it is my belief that thereafter whatever policy decisions are ultimately taken, about what developments are to be progressed and when, should be conveyed to us very formally and very clearly by the relevant authorities in the NHS in Scotland. Where we are and where we are not free to do our own thing should also be made clear. That way we shall all knew exactly where we stand.

"Clearly it may only be possible to achieve part of what I am looking for here. A certain amount of inherent ambiguity will always be required by civil servants -- partly to protect Ministers and partly to protect themselves. I remain convinced however that we can do a lot better next time than we managed, collectively (UK wide) to achieve over HCV."

The theme that arises from that letter, a theme of tension between Scotland, on the one hand, and England and Wales, tension with the Scottish Home and Health Department, tension with the Department of Health and, indeed, tension between the Scottish

National Blood Transfusion Service and the Blood Transfusion Service for England and Wales, those are all themes which emerge at different times and in different ways but, nonetheless, very clearly, from a number of interactions that Professor Cash has or records.

Then if we go back to the question of committees that Professor Cash belonged to, he was a member also of the SNBTS and National Blood Transfusion Service Liaison Committee.

If we go to NHBT0000189_173, these are the minutes of the first meeting of the National Blood Transfusion Service/SNBTS Liaison Committee. So an attempt to have better communication, better dialogue between the Scottish and English and Welsh National Blood Transfusion Services.

The first meeting was 27 June 1990. We'll see present Dr Gunson, Professor Cash, Mr McIntosh, whose letter I just referred to, and RJ Moore. That, I think, was reference to Roger Moore, who was Deputy Director -- I think I'm right -- of the National Blood Transfusion Service.

We can see 1.2 says:

"Communications between SNBTS and NBTS, whilst generally good, would be improved by more prior to

consultation on appropriate issues. Awareness of each others activities should avoid needless duplication of effort."

Other meetings which Professor Cash attended, he attended meetings of Scottish Regional Transfusion Directors; he was a member of the SNBTS Ethics Committee Clinical Research Investigation, set up in 1984; he attended a number of meetings of the English and Welsh Regional Transfusion Directors as a representative of SNBTS; he attended some meetings between Regional Transfusion Directors and Haemophilia Centre Directors.

If we look at DHSC0002189_014, we'll see here he was a member of the Working Group on Trends in the Demand for Blood Products. This was their report, and paragraph 1 explains that this was a group established in January 1977 by the DHSS in consultation with the Scottish Home and Health Department and the Welsh Office:

"... decided that it would help in planning the future development of blood transfusion services if the likely trends in the demands or blood and blood products were known."

Then we can see the membership there set out, and number 1 is:

1 "Dr JD Cash, Director, Edinburgh and
2 [South East] Scotland Blood Transfusion Service."
3 The terms of reference of this particular
4 working group at the bottom of the page:
5 "To consider the likely trends in the demand for
6 blood products over the next 5 to 10 years, taking
7 into account the practicalities of supply."
8 Then if we look at CBLA0000473, again this is
9 just to give a flavour of the range of committees that
10 Professor Cash belonged to, this is described as an
11 "Exploratory Meeting of Blood Transfusion Directors
12 and Haemophilia Reference Centre Directors", held in
13 October 1976. The list of attendees is over the page,
14 and I won't go through all the names but I can assure
15 you Dr Cash is there on the right-hand side, about
16 halfway down the list of attendees.
17 If we go back to the first page, we'll just get
18 a flavour of the range of issues that were discussed
19 and to which Professor Cash contributed.
20 So paragraph 3 was a discussion of estimates for
21 usage of freeze-dried Factor VIII concentrates.
22 Item 4 was about plasma supply, and Dr Cash was
23 recorded there as being someone contributing to that
24 issue. Then reference made to making the case for
25 increased funding.

1 Then item 5 was raising questions about space,
2 staff and equipment to deal with the increased plasma
3 supply and, paragraph 6, methods of distribution in
4 England and Wales and in Scotland.
5 Sir, I should just say the vast majority of the
6 documents I've just referred to, and indeed the
7 documents we'll look at today and tomorrow, will refer
8 to Scotland, they will refer to England or to England
9 and Wales. There is very little reference in the
10 materials to Northern Ireland and there is very little
11 reference to attendance of Northern Ireland
12 representatives. That's not always the case, and we
13 do see -- I'm unlikely to explore it particularly this
14 week but we do see the relationship between the
15 Northern Ireland Blood Transfusion Centre and the
16 plasma being sent to from Belfast to the PFC in
17 Edinburgh, and we'll pick that up at future hearings
18 when we'll be looking at the position in Northern
19 Ireland. But it is quite a striking feature of the
20 documents I've looked at that whilst we see a lot of
21 discussion about the position in Scotland, the
22 position in England, to some extent the position in
23 England and Wales, Northern Ireland is rarely
24 mentioned in the materials that we'll be looking at
25 this week.

1 Just to complete the picture in terms of
2 committees, and this is not an exhaustive list, he
3 attended other groups, organisations, working parties
4 and so on, but Professor Cash was on the Medicines
5 Inspectorate's *ad hoc* project steering group in 1982
6 to co-ordinate matters relating to the Medicines
7 Inspectorate; he attended meetings of the Advisory
8 Committee on the National Blood Transfusion Service as
9 an observer from Scotland; he attended some meetings
10 of the Scottish and Northern Ireland coagulation
11 Factor VIII Working Party; and attended a liaison
12 committee between NIBSC and the UK Blood Transfusion
13 Service in 1987.
14 So, putting it colloquially, a finger in many
15 pies in terms of development in relation to blood and
16 blood safety.
17 Professor Cash also had the role of consultant
18 adviser on blood transfusion to the Scottish Home and
19 Health Department. So he was the equivalent in
20 Scotland to Dr Tovey and then Dr Gunson in England,
21 and he occupied that role from 1979 to 1986.
22 If we look at PRSC0001514, we'll see the terms
23 in which he stood down from that role. This is
24 a letter of 24 March 1986 to the Scottish Home and
25 Health Department:

1 "It has been my privilege to act as Consultant
2 Adviser in Blood Transfusion to the Scottish Home and
3 Health Department since 1979.
4 "I take the view that it is no longer
5 appropriate for me to hold this formal position, which
6 has attached to it a modest honorarium. I would
7 therefore wish to resign as of 1st May, 1986."
8 There were a number of tensions between
9 Professor Cash and the SHHD, which emerge when one
10 looks at the contemporaneous documentation. We can
11 get a flavour of that from PRSE0002563. This is
12 a letter from Professor Cash, 18 January 1986 -- so
13 a couple of months before he stepped down from his
14 role as consultant adviser -- addressed to
15 Dr Archie McIntyre at the SHHD, and he says in the
16 first paragraph:
17 "I write to express my grave concern at the way
18 colleagues in SHHD have been put in a position (and
19 appear to have accepted this position) in which they
20 are prepared to challenge the professional competence
21 of my senior scientific and medical staff. I refer to
22 the matter of our plans to validate the safety of our
23 heat treatment processes with respect to AIDS viruses.
24 "The good professional relationships we have
25 enjoyed over many years with colleagues in SHHD are

1 too precious a commodity to the SNBTS for me to do
2 anything that would cause unnecessary harm. On the
3 issue in question therefore I would wish only to
4 conclude that we have agreed that the plan is not
5 an overkill reaction, that it was never our intention
6 to validate spiking experiments in patients nor
7 undertake spiking activity within the production
8 facility at PFC."
9 Then he says this:
10 "Whilst I acknowledge that those of us who work
11 within the public sector must accept the ultimate
12 dominance of 'political' considerations, I would, at
13 this time, make a plea that those of your colleagues
14 who could continue to express concern at 'spiking'
15 procedures being done in PFC come to PFC, look at the
16 relevant facilities and discuss the problems with
17 Dr Perry and his staff."
18 So a specific issue which gave rise to that
19 letter but a hint of a broader issue in terms of the
20 relationship between SNBTS and SHHD.
21 If we look at another of Professor Cash's
22 multiple statements to the Penrose Inquiry,
23 PRSE0004020, Professor Cash talks about the
24 relationship between the SHHD and SNBTS and, indeed,
25 the relationship between SHHD and the DHSS in London.

1 So this happens to be a response to a statement from
2 David McIntosh who was the general manager of the
3 SNBTS, but if we look at the bottom half of the page,
4 Professor Cash says this more broadly about the
5 various relationships:
6 "There was never any doubt in my mind, after
7 over a decade as the SNBTS's National Medical
8 Director, that Scottish Ministers and their officials
9 were ultimately legally responsible for the work of
10 the SNBTS. Indeed this was well discussed in
11 a meeting held in SHHD in September 1988 ..."
12 Then he says:
13 "That said, occasions arose when Scottish
14 Ministers and their officials deemed it appropriate
15 (sometimes because of perceived limited resources)
16 that DHSS took a lead position in the development
17 policy/strategy. I understood that this situation did
18 not make the Scots in any way operationally
19 subservient to the English, but I sensed that, when
20 DHSS had a lead position, SHHD was reluctant to
21 challenge their advice, not least because DHSS seemed
22 always to ensure that SHHD were in some way engaged in
23 their policy/strategy developing process."
24 Then top of the next page he says:
25 "I was satisfied that in theory SHHD could, at

1 any time, have 'gone its own way'."
2 Then he suggests and sets out various examples
3 of there being a separate Scottish policy approach.
4 In the next paragraph he talks about his own
5 record for challenging events in England and Wales in
6 defence of the SNBTS. Again, I'm not going to read
7 all those aloud but he sets out a number of issues
8 there.
9 Then if we go to the bottom of the page, we can
10 then see concern about the role of DHSS in SHHD's, as
11 it were, a degree subservience being described. So he
12 says:
13 "There was never any doubt in my mind, from my
14 many discussions with in Dr McIntyre (SHHD), that,
15 both with the introduction of HIV and HCV donation
16 screening, SHHD [so Scotland] had invited the DHSS to
17 take the lead. Of course I regret that these
18 decisions were taken without consultation with the
19 SNBTS management team or SHHD's Consultant Adviser
20 (for HIV) on Blood Transfusion and made these
21 disappointments known to Dr McIntyre. Had
22 consultation taken place then we would almost
23 certainly advised SHHD colleagues that both with
24 regard to HIV and HCV, SNBTS had enough scientific
25 expertise to generate sufficient quality data from

1 which Scottish Ministers could be appropriately
2 informed. On both occasions (HIV and HCV), when
3 I discussed this option with Dr McIntyre (SHHD), it
4 was clear that policy decision had already been taken
5 to devolve the lead to DHSS, and SHHD considered the
6 separate engagement of SNBTS at this stage might be
7 a distraction and a potential cause of difficulty."
8 Just pausing there, in relation to the
9 introduction of hepatitis C screening, what this
10 appears to suggest is a desire on the part of
11 Professor Cash for Scotland to formulate it own
12 position, rather than be led by the DHSS in England.
13 That's not necessarily completely consistent with the
14 contemporaneous documents and when I come to
15 hepatitis C screening we'll see what Professor Cash
16 position recorded at the time was.
17 But, in any event, that's what he was saying in
18 relation to the relationships between SNBTS, SHHD and
19 the DHSS. If we just go over to the next page and the
20 bottom of the page, the last paragraph is effectively
21 an expression of regret at not having a more
22 influential role for SNBTS. So he says this:
23 "I believed and still do that the safety of
24 blood supplied by unpaid donors in a country such as
25 ours is a national (UK), corporate and moral high

1 priority, and within this donation testing should be
2 paramount. What I failed to do, both with HIV and
3 HCV, despite considerable efforts, was to secure
4 a place for the SNBTS to influence the management of
5 the UK agenda for kit evaluation and thereafter be
6 engaged in discussions on implementation."
7 So, as I say, I'll pick up some of the more
8 concrete interventions of Professor Cash in relation
9 to those issues, but particularly in relation to the
10 introduction of hepatitis C screening, in due course.
11 Lastly, by way of introduction, if we go to
12 SBTS0000187_047, this is a letter written by
13 Professor Cash on 11 January 1990 to Mr Hamill at the
14 SHHD, and the context is the HIV haemophilia
15 litigation. There are some specific observations
16 Professor Cash makes in this letter but I really draw
17 attention to it for some of the overall themes. If we
18 pick it up in the third paragraph, he says this:
19 "... the lawyers have now advised that PFC was
20 originally briefed during its design phase (in the
21 late 1960s I presume) to fractionate plasma from
22 Scotland and the North of England (Newcastle, Leeds,
23 Sheffield, Manchester and Liverpool). I was a young
24 senior registrar at the time but do recall some heated
25 conversations when the message came from SHHD

1 (originating I understood from London) 'forget it:
2 design only for Scotland'. It's easy with hindsight
3 but there can be no doubt that this decision was
4 a grave error of judgement and I would advise that you
5 delve into the archives and see whether there are
6 records which at the very least ensure SHHD is 'all
7 clear'.
8 "I would advise that you look out for two other
9 topics ..."
10 Then (a) he refers to the shift experiment at
11 the Protein Fractionation Centre that's been referred
12 to, sir, in earlier hearings. His recollection is, as
13 set out here, that PFC had demonstrated they had very
14 substantial spare fractionation capacity, and if we
15 look at the last few lines on the page, he says:
16 "It was assumed by those of us on the shop floor
17 that this experiment would expedite arrangements to
18 give England assistance -- but nothing materialised."
19 Then over the page, he records, at the top of
20 the page:
21 "Aside from the [England and Wales] connection
22 PFC management are on record over many years of
23 repeated requests for shift working facilities. It is
24 my understanding -- and that of PFC management -- that
25 SHHD consistently rejected these proposals. It is

1 also the opinion of those of us involved in this
2 succession of requests that the SHHD response on this
3 issue was dictated by London and that this in turn was
4 influenced by the Union ASTMS which had a closed shop
5 at BPL and was opposed to shift working."
6 I'm not proposing, sir, in the course of the
7 presentation today or tomorrow to go into the detail
8 of that shift-working experiment at all. It may be
9 that is an issue that we pick up in the March hearings
10 and we've touched on it, I think, during the evidence
11 of Dr Diana Walford. The purpose of showing you this
12 letter now is just to provide a further example of
13 what is said to be, by Professor Cash, this perhaps
14 uneasy relationship between SHHD and the DHSS in
15 London.
16 Then he continues in the next paragraph, more
17 broadly, on that topic, as follows:
18 "Finally, I think you should be aware that
19 during the anticipated litigation efforts will be made
20 to demonstrate that there were serious defects in the
21 operational liaison between SHHD and DHSS with regard
22 to Blood Transfusion matters. I have to tell you that
23 in my view this is a correct interpretation and is no
24 better today than in late 1970 and throughout the
25 1980s. I attempted to persuade, on numerous

1 occasions, both the CSA and SHHD that there was
2 an urgent need for policy harmonisation and joint
3 programmes of work: I even went and saw Mr David Smart
4 (previous Chairman of CBLA) and pled with him to no
5 avail. I persuaded Sir Simpson Stevenson (Chairman of
6 CSA) to go down to visit Mr Smart and he subsequently
7 declined to brief me on what transpired. In all these
8 exercises I had kept the relevant SHHD Undersecretary
9 fully briefed and on every occasion I was advised that
10 the problem was in DHSS."
11 Then he concludes as follows:
12 "I sense the ineptitude of the past (1970s --
13 1980s) are about to catch up with us and am of the
14 opinion that this anticipated litigation should be
15 settled out-of-court, if possible."
16 Then he goes on to say we should be looking to
17 the future. Of course, it is important to bear in
18 mind this letter is January 1990 and there are still
19 important decisions relating to the safety of the
20 blood service still to be made, not least the
21 introduction of hepatitis C screening and issues in
22 relation to look-back.
23 So he continues in this letter:
24 "... we need also to be looking to the future."
25 Then he refers to personnel within, I think,

SHHD and says, picking it up a few lines down:
"... it will be our task to persuade him [that's the new figure in SHHD] to start building some North/South policy and operational bridges. I don't wish to launch once again into the EC problems ahead, but the challenges from Brussels makes the coming together of Blood Transfusion on some sort of UK basis imperative."
Now, there are also a number of documents which talk about Professor Cash's perspective on the relationship between PFC and BPL touched on in this letter but not in any great detail.
If we go to PRSE0002836, this is one of the statements of the Penrose Inquiry. We have already looked at a passage in it relating to the MRC's disbandment of its Blood Transfusion Research Committee.
If we turn now to page 4, we pick up Professor Cash's observations about relationships between BPL and PFC. So, bottom of the page at paragraph 10.2, picking it up three lines down he says:
"On appointment as NMD [that's National Medical Director] in 1979 I discovered that the relationship between Mr Watt (Director of PFC) and his counterpart

at BPL (Dr Lane) was greatly strained. Before and after Mr Watt left the SNBTS (December 1983) I made considerable efforts to repair the professional interface between SNBTS and BPL ... prior to Mr Watt's departure I attempted in 1980 to arrange a meeting between the PFC and BPL management teams with a view to exploring ways of getting the VIII concentrate production and associated research on a joint UK basis. BPL management refused to agree to such a meeting -- I was later to learn this had the support of DHSS."
Then he refers to the role of Dr Smith.
Then if we pick it up at the bottom of this page, please, he goes into a little more detail. He was asked about a particular meeting in December 1982, which was a meeting with BPL. He says:
"There is no doubt that the meeting on 15 December 1982 at BPL was a very difficult one! As I recall, my difficulties were several ..."
Then he elaborates upon the point that he has already made:
"Two years before this meeting ... I had attempted to seek BPL's management support for a meeting which would explore the issue of a joint BPL/PFC approach to the manufacture and associated

research of factor VIII concentrates for the whole of the UK. This proposition was rejected (no meeting took place) and by 1982 I had reason to believe (briefed by Dr Harold Gunson) that DHSS had been party to this rejection, and that SHHD (not known to me) were aware of this ... I recall I took the view that as at December 1982, the efforts at bridge building had, before and after 1979, all come from the SNBTS and had been comprehensively rejected by BPL and DHSS."
Then 12.2 he gives some further examples:
"On a number of occasions in 1980/81/82 I had sought the support of SHHD officials to use their influence to ensure the Committee on Safety of Medicines explored what could be done to enhance the safety of commercial coagulation factor concentrates imported in to the UK. These exhortations came to naught and by December 1982 I had reason to believe this proposition had also been blocked by DHSS and this was known by BPL management. I was also concerned to discover that John Holgate (MCA) and Joe Smith (NIBSC) seemed to be party to the proposition that UK clinical trials of commercial plasma products should be encouraged."
Then he talks about the December '82 meeting in

the next paragraph:
"As I recall, the main reason why we met at BPL on 15 December 1982 was for BPL and MCA/DHSS to ascertain whether the SNBTS would support the introduction of clinical trials on UK haemophilia patients of US sourced commercial VIII concentrates that had been subject to some form of viral inactivation. I had the feeling throughout this meeting that a decision in favour of this development would somehow be an advantage to BPL and DHSS.
"12.14. I totally opposed this development but later greatly regretted the way I conveyed my opposition. My initial problem was that I felt we had been ambushed and was distressed to see Professor Arthur Bloom (an old friend, a mentor of Dr Ludlam and the HCD in Cardiff) had been persuaded to Chair the meeting."
Then he refers to the reasons for his opposition to the proposal. I'm not going to go through all of it but we can just, I think, perhaps get a flavour of it from paragraph -- what is said to be paragraph 12.141. So this is his opposition to SNBTS involvement in clinical trials on early heat-treated commercial concentrates, and his reason here is:
"By 1982/83 there were a very limited number of

1 haemophilia A patients in the UK that had not been
2 exposed to commercial concentrates ..."
3 So very few previously untreated with commercial
4 concentrates.
5 "... (the highest percentage were in Scotland).
6 This small of group of patients (which included an
7 even smaller subgroup -- previously untransfused
8 patients (PUPs)) would be essential for the UK (NHS)
9 fractionators when they wished, notwithstanding the
10 disturbing issue of Crown immunity, to validate their
11 viral inactivated production. If these patients 'were
12 given away' to US commercial interests then
13 NHS fractionators would be in serious difficulties.
14 Whilst Scotland had the highest percent of patients
15 which had not been exposed to commercial concentrates,
16 in terms of total UK patients the majority would be in
17 England and Wales (E&W). It followed that we had
18 intentions to seek access to some of the E&W patients
19 for the SNBTS virus inactivated products -- and in due
20 course we did."
21 Then if we just pick it up at paragraph 12.143,
22 he talks about viewing the development in the UK as
23 a sophisticated marketing exercise by US commercial
24 fractionators rather than one directed to product
25 safety.

1 He continues in a similar vein and talks about
2 the issue in greater detail. I am not going to take
3 time now going through all of it but it's a statement
4 well worth reading and considering.
5 Of course, more generally, in relation to
6 Professor Cash's views about the National Blood
7 Transfusion Service in England and Wales, Ms Scott
8 referred you yesterday to Professor Cash's letter in
9 the BMJ in which he was heavily critical of the
10 organisation, labelling it a "fragmented and
11 disorganised shambles". I'm not going to go back to
12 that because you have looked at it only yesterday.
13 The reference for the benefit of the transcript is
14 PRSE000059 -- I think it is 8, but I can't read my
15 own handwriting. Yes, PRSE0000598.
16 It's right to note that there's a response by
17 Dr Gunson and, indeed, a response by some others to
18 Professor Cash's article, perhaps unsurprisingly not
19 agreeing with it. I think Ms Scott will take you to
20 that during the presentation later this week on
21 Dr Gunson. Again, for the benefit of the transcript,
22 the reference is WITN2050047 I think. I think that's
23 right. Again, it might be a handwriting issue there.
24 Then if we look at one other statement to the
25 Penrose Inquiry, PRSE0002223, the subject of this

1 statement was Professor Cash's resignation as
2 Consultant Adviser to the Scottish Home and Health
3 Department in March 1986, and again the purpose of
4 looking at this is really because of what it reveals
5 about the wider relationships, wider tensions. He
6 says:
7 "It might be helpful to the inquiry team [that's
8 the Penrose Inquiry] to know that March 1986 was the
9 second time I offered my resignation as SHHD
10 Consultant Adviser in Blood Transfusion."
11 Then he details in the next paragraph the first
12 occasion, which was in 1983. I'm not going to go
13 through the detail of that but, if we look at the last
14 paragraph on this page, it was essentially an
15 industrial dispute. He describes the dispute ending
16 abruptly when the SHHD withdrew from its position, but
17 then says this in terms of the impact upon broader
18 relationships:
19 "... in my view, both at the time and
20 thereafter, it was the cause of an almost complete
21 disruption in professional relations between some
22 important and senior members of SHHD's medical team
23 and me, which I suspect lasted for more than a decade.
24 I took the view in 1983 that my conduct in this
25 industrial dispute may not have been appropriate for

1 a consultant adviser to SHHD, that my professional
2 relationship with the responsible DCMO had been
3 irreparably damaged and that as we were about to
4 address the consequences of HIV in our donor panels
5 I should offer to step down and allow SHHD colleagues
6 to make a fresh start. Dr Reid did not agree with
7 this position and the persuaded me to withdraw my
8 resignation."
9 So that was the position as at 1983. Then he
10 talks in the next paragraph about his second and final
11 resignation from the position in 1986:
12 "Sometime in the first weeks of March 1986
13 I requested a meeting with Hugh Morrison (SHHD
14 Under-Secretary with responsibility for the SNBTS).
15 At this meeting I listed a series of events which
16 I believed demonstrated that the SNBTS was, to its
17 detriment, increasingly being caught up in the
18 politically controlled management chaos of the NBTS.
19 I advised Hugh that I believed it was time for someone
20 to stand up and speak out, and regrettably that had to
21 be me. I further advised how I intended to do this by
22 way of a publication in the British Medical Journal
23 (BMJ) ..."
24 That is presumably a reference to the article
25 that was subsequently published.

1 "... and that as I intended to begin drafting
2 this as soon as possible I felt obliged to tender my
3 resignation as consultant adviser to SHHD with
4 immediate effect."
5 So that's, as it were, an introduction, in terms
6 of relationships, difficulties in relationships and
7 Professor Cash's perception of the roles, in broad
8 terms, of the SHHD and of the DHSS. Of course those
9 are his views and they may well be challenged by
10 others.
11 I'm just going to turn now to a discrete and
12 separate topic which sets out Professor Cash's views
13 on issues relating to licensing and product liability.
14 Again, it's a theme which emerges really on a number
15 of occasions in Professor Cash's interactions and
16 writings.
17 We can perhaps pick it up in 1979 at
18 DHSC0002367_003. So it's a Regional Transfusion
19 Directors' meeting on 27 June '79.
20 If we look at the bottom of this first page, we
21 can see the last paragraph, third line, that Dr Cash
22 was "attending his first RTD meeting as National
23 Medical Director" of SNBTS. Then if we go to page 7
24 there's a heading, "Draft consultative paper on
25 product liability":

1 "Directors were worried that they, as producers
2 or blood products at the [Regional Transfusion
3 Centres], could be held personally responsible if the
4 product was eventually found to be defective.
5 "Mr Wormald [that's a DHSS representative]
6 pointed out that in some cases Directors might be
7 jointly responsible with the Health Authority if it
8 was found, for example, that the blood had been
9 handled incorrectly at the hospital. The question
10 whether blood ought to be excluded from the scope of
11 product liability still had to be debated; there might
12 be a defensible case for treating blood differently
13 from pharmaceuticals, but so far the case had not been
14 made."
15 Then Dr Cash's contribution:
16 "Dr Cash thought it was difficult to discuss
17 product liability until the Department decided whether
18 the [National Blood Transfusion Service] should be
19 covered by Crown privilege, and if there was to be no
20 Crown privilege then the Government would have to
21 provide financial support in the event of a mishap
22 leading to liability."
23 The issue of Crown privilege or Crown immunity
24 was one which Professor Cash, returned to on a number
25 of occasions over the years that followed.

1 I'm only going to give you a flavour of that
2 because there are a lot of documents.
3 PRSE0003850. So this moves forward now a number
4 of years, this is February 1987, and it's a letter
5 from Professor Cash to Mr Donald at the Common
6 Services Agency. The subject is "Product Licences"
7 and he refers to a meeting of SHHD in the first
8 paragraph, and then in the second paragraph he
9 explains:
10 "... that [the] Boards (and presumably the CSA)
11 had been advised several years ago that there was no
12 requirement for SHS manufacturers of pharmaceuticals
13 to obtain product licences. The reason for this was
14 the privilege of Crown Immunity."
15 Then if we go two paragraphs further down, we
16 see Professor Cash saying:
17 "... I ... strongly advise that you arrange an
18 urgent meeting with Mr Hugh Morrison with a view to
19 getting the matter clarified."
20 That's the question of whether product licences
21 were required.
22 Then he makes a number of observations.
23 "1. There are 15 haemophilia A patients in
24 Edinburgh who have been unequivocally infected with
25 HIV from PFC product which we believe is licensed

1 (thus we presume no Crown Immunity). You will be
2 aware of the pending legal actions with regard to the
3 Glasgow patients.
4 "2. We have several products we believe are
5 fully licensed. Is it the Agency desire that we
6 immediately seek to revoke these licences?
7 "3. Is it the Agency desire that all work
8 currently going on to licence PFC products should
9 stop -- we plan to amend our Factor VIII licence for
10 Z8 early in April."
11 So we see the issue there being raised in the
12 context of potential litigation from HIV infection.
13 There's then some various subsequent letters and
14 other documents in which it's said that Professor Cash
15 was wrong to believe that holding a product licence or
16 applying for a product licence would affect Crown
17 immunity. We've set out some of the details in our
18 written presentation and I'm not going to go through
19 all of them.
20 If we look next at PRSC0000712, so it was an
21 issue which seemed to give rise to a number of
22 discussions throughout the course of 1987, so there's
23 a Scottish Health Service Common Services Agency memo,
24 there's a meeting in October 1987 which Professor Cash
25 attends in which the issue is discussed, and then we

1 pick it up with another letter from -- this is from
2 Dr Perry but copied to Professor Cash, December 1987,
3 in which we see the anxiety being expressed, really
4 from the heading of the letter, "Product
5 Liability/Personal Liability", and the concern which
6 Professor Cash shared recorded towards the end of that
7 first paragraph was that those involved with SNBTS or
8 the PFC were exposed and vulnerable in an area of
9 product manufacture which attracts considerable public
10 attention.
11 Then there was a response from the Common
12 Services Agency to the effect that this was
13 a red herring, which then resulted in Professor Cash
14 writing PRSE0000462 in the following terms, and I'm
15 not going to go into the full detail of the extent to
16 which this issue was resolved but just want to get
17 a sense of what Professor Cash thought as at July '88
18 on it. These are his views about the PFC, second
19 paragraph, second line:
20 "... it is my professional view that PFC has and
21 is operating outwith the standards of the
22 pharmaceutical industry. The evidence for this can be
23 summarised as follows:
24 "PFC has manufactured product which has
25 unequivocally endangered the lives of patients."

1 He gives reference to two recorded occasions of
2 that.
3 At paragraph 2:
4 "There have been a number of occasions when
5 I have been called upon to authorise the issue of
6 products which failed to meet specifications. I have
7 on many occasions since 1979 ... given authorisation
8 ... in order to keep supplies in place for the SHS
9 [that's Scottish Health Service].
10 "3. Unlike our sister commercial organisations
11 we have received no instruction to clear all batches
12 of PFC products with the National Institute of
13 Biological Standards and Control -- before we issue
14 for clinical use.
15 "4. Notwithstanding the awaited formal report
16 of HM Medicines Inspectors both Bob Perry and myself
17 were party to a conversation which clearly indicated
18 that on the basis of breaches of GMP [that's good
19 manufacturing practice] PFC's continued function
20 rested on the provision of crown immunity."
21 His fifth point:
22 "It is important for us to remember that the
23 provision of a product licence in the pharmaceutical
24 industry will only take place if the manufacturer has
25 a manufacturing licence. This does not seem to have

1 applied to PFC ..."
2 **SIR BRIAN LANGSTAFF:** Just going back to the previous page
3 for a moment, what is said at the bottom of
4 paragraph 4, on the basis of breaches of good
5 manufacturing practice, the PFC's continued function
6 rested on the provision of Crown immunity, that's
7 looking I think to the future. It's -- paragraph 1
8 looks to the past.
9 **MS RICHARDS:** Yes.
10 **SIR BRIAN LANGSTAFF:** There he says in an interesting
11 expression, in relation to the two recorded occasions
12 when it would seem that products produced at the PFC
13 had led to the transmission, I think what it is
14 said -- is intended here of HIV to patients, his view
15 is that breaches of good manufacturing practice could
16 not be ruled out.
17 **MS RICHARDS:** Yes, that is right.
18 I'm really just alighting on a handful of
19 documents here which show particularly strong
20 expressions of view by Professor Cash. We will want
21 to return to the issue more thematically and look at
22 it in a little greater detail, not exhaustively, in
23 March when we look at PFC and BPL and we'll no doubt
24 wish to explore a little the issues of Crown immunity
25 as they did or did not apply for these organisations.

1 **SIR BRIAN LANGSTAFF:** I appreciate what you are taking me
2 to here is his views on Crown immunity and what I was
3 raising with you is really a comment on evidential
4 value, in another context, which is the question of
5 whether there was something wrong with the product and
6 it has to be noted, for anyone who is following this
7 and thinks that it is necessarily to be understood
8 that Mr Cash was saying that that was why they
9 transmitted HIV, he doesn't actually draw any
10 causative link directly.
11 **MS RICHARDS:** No, he doesn't in this letter. The earlier
12 letter we looked at, the 1987 letter, is the one which
13 uses that term of patients having been unequivocally
14 infected with HIV from PFC products, in circumstances
15 where he believed there was no Crown immunity.
16 **SIR BRIAN LANGSTAFF:** Yes. But he's not saying that the
17 good manufacturing practice led to that, necessarily.
18 **MS RICHARDS:** Not necessarily, no. Again, issues of
19 compliance with good manufacturing practice was,
20 again, something of a matter of concern for Professor
21 Cash over a number of years and that, I am sure, is
22 an issue we'll explore with PFC evidence in March.
23 **SIR BRIAN LANGSTAFF:** Yes.
24 **MS RICHARDS:** Sir, I want to turn next to Professor Cash's
25 views on issues relating to self-sufficiency and

1 plasma supply. I'm going to start with an interview
2 Professor Cash gave in 1990. That interview
3 encompasses a broader range of issues and, to avoid
4 the need to go back to it, what I propose to do is to
5 look at the interview in full, the transcript of the
6 interview in full, and then that will be probably the
7 appropriate moment for a morning break and then I can
8 return to some of the more specific details about
9 self-sufficiency and plasma supply.
10 So if we look at SBTS0000053_055, this is
11 described as "Edited notes of interview with
12 Professor John D Cash, Medical & Scientific Director
13 of Scottish Blood Transfusion Service, Edinburgh --
14 30 May 1990". We have the date of the interview.
15 We're told the notes are edited notes. If we go to
16 the last page, the signature's been redacted but it is
17 the signature of Dr Cash so it would appear that he
18 had approved this document and the contents of it,
19 that he signs it and dates it 29 November 1990.
20 It's not clear who's taken the notes or who the
21 interview is with but, as we'll see when we look at
22 the transcript or the notes, it refers to
23 a conversation that Professor Cash had with Graham
24 Ross so it looks as though this is an interview taking
25 place with Professor Cash for the purposes of and in

1 the context of the HIV haemophilia litigation.
2 So I'm not going to read the whole thing but
3 there are some interesting and important opinions
4 expressed by Professor Cash. So if we go to the
5 bottom of this first page, he's asked about an article
6 in the BMJ in September 1976. I'm going to look at
7 that article later in the presentation. It's
8 an article co-authored by Professor Cash and Mary
9 Spensley. For the benefit of the transcript and those
10 following, the reference for that BMJ article,
11 although we don't need to turn to it now, is
12 PRSE0003425.
13 Then the question is at the bottom of the page:
14 "In that article, you drew attention to the
15 respective benefits and disadvantages attaching to the
16 tree then methods of treating haemophilia which
17 were -- first, fresh frozen plasma, second, cryo and
18 third, AHF [anti-haemophilic factor]. Is it accurate
19 to use AHF as another term for what I call Factor VIII
20 concentrate?"
21 Over the page:
22 "Yes."
23 Then the question is put, by reference to the
24 article, that what the paper was saying was the
25 advantages of concentrate over cryo. The answer then

1 given by Professor Cash is:
2 "Cryoprecipitate was very unpopular with some
3 patients: for some of the reasons you have given but
4 also the higher incidence of allergic reactions when
5 compared to AHF."
6 Then there's an exploration of what might be
7 said to be the advantages of cryoprecipitate and then
8 the question is put:
9 "Insofar as there was an argument to be made for
10 cryo in 1976, it was essentially a logistic argument
11 and a financial argument -- is that a fair summary?"
12 Then this was Professor Cash's answer:
13 "Yes, but one of the main burdens of the paper
14 was not suggest that we should not abandon
15 cryoprecipitate until we were certain we have enough
16 plasma to withstand the anticipated drop in yield for
17 what clearly is a better product. If we moved in
18 an unplanned way from cryo to AHF, it might mean we
19 would have to buyer factor VIII from commercial
20 companies.
21 "Q. And that was the worry?
22 "A. Yes.
23 "Q. Was the worry directed at economics or safety
24 or a combination of both?
25 "A. For us, safety was paramount: we wished to

1 minimise exposure of patients to commercial
2 concentrates.
3 "Q. Does the article bring that out?
4 "A. Probably not as clearly as it could, although
5 I should say we were writing against the background of
6 the [World Health Organisation] recommendations of
7 1975. This is a very important document which
8 I suggest you read."
9 Then he sets out the WHO declaration and then
10 continues:
11 "The article to which you refer picks up from that
12 point and attempts to address some of the consequences
13 of these WHO recommendations in the context of
14 factor VIII concentrate.
15 "Q. What was the reaction from within the
16 profession to that article?
17 "A. I cannot honestly say. As far as I am aware
18 -- virtually zero, at least outside the Scottish
19 Health Service.
20 "Q. A voice in the wilderness?
21 "A. Perhaps, but at that time there wasn't
22 a satisfactory forum in which a corporate reaction
23 could be generated."
24 Then the question is put about self-sufficiency in
25 Scotland:

1 "... was Scotland self-sufficient in AHF?
2 "A. No. One of the reasons I wrote the article
3 was to galvanise my colleagues in Scotland to take
4 advantage of the major investment the Scottish Office
5 had made in building a new Fractionation Centre which
6 was opened in 1975. It was built on the basis that
7 'we are going to go for self-sufficiency'. The
8 published paper was, in fact, part of an invited
9 lecture I had delivered to an international meeting in
10 Helsinki some months before. So, in a sense, at
11 a local level, the BMJ article was a clarion call --
12 let's go."
13 Then there's a discussion of the date of opening
14 of the PFC and where the funding came from. If we go
15 towards the bottom of the page, the last question is:
16 "So Scotland had accepted the concept of self
17 sufficiency many years earlier?"
18 That's a reference to the fact that planning for
19 the PFC had begun in the late 1960s:
20 "A. Yes, I conclude that it had. However,
21 I should point out that I was not a Director at that
22 time, and thus was not party to these discussions and
23 certainly cannot take any credit. Moreover, it was
24 never, as far as I can remember, expressed in those
25 terms. It was always assumed in Scotland, ever since

1 I joined the service in 1962/3, that our job was to
2 provide all blood and blood products required for
3 Scotland. The concept of self sufficiency more
4 clearly emerged in 1975, against the background of the
5 WHO report. My (personal) interpretation of self
6 sufficiency from the WHO recommendations was that we
7 must develop a programme which led us to advise the
8 commercial providers of plasma products that they were
9 no longer required. Such sentiments, of course, had
10 political connotations and, in those days, one sensed
11 we didn't have overt Scottish Office support for the
12 concept of 'Commercial companies go home' but we did
13 sense strong Scottish Office support for the idea that
14 we should get going and make as much as the Scottish
15 Health Service patients needed."
16 The question then:
17 "It would take some time for the Fractionation
18 Centre to get into full production. By what date was
19 the Fractionation Centre able to meet all of
20 Scotland's demands for self sufficiency?
21 "A. Some time in 1983/84. It wasn't the
22 Fractionation Centre that was rate limiting. It was
23 the availability of plasma. In fact, we didn't have
24 any firm policy decisions in Scotland until we had
25 completed a major planning review, in 1979, from which

1 emerged our incremental targets up to the year 2006.
2 "Q. Insofar as you were not self sufficient
3 between 1975 and 1983, where were you buying your
4 commercial factor VIII concentrate?
5 "A. Yes, but this purchasing exercise was, as in
6 England and Wales, the responsibility of local Health
7 Authorities, [Haemophiliac] Centres, hospital
8 pharmacists, et cetera. We (the SNBTS) were not
9 directly involved.
10 "Q. Would you know where they bought from?
11 "A. They would buy from the identical sources our
12 friends in England and Wales -- primarily the [USA],
13 because, to the best of my knowledge, this was the
14 primary source in those days."
15 Then you see a reference, sir, to the conversation
16 with Ross, that's Graham Ross.
17 **SIR BRIAN LANGSTAFF:** If this is an interview with Graham
18 Ross --
19 **MS RICHARDS:** It's not, no. As it refers to an interview
20 Graham Ross.
21 **SIR BRIAN LANGSTAFF:** I see.
22 **MS RICHARDS:** It's clear it's not itself being conducted
23 by Mr Ross because the questions would have been
24 phrased differently but whoever is conducting it has
25 a note of Graham Ross's discussion, which is what

1 leads me to think it was probably an interview with
2 solicitors during the course of the HIV haemophilia
3 litigation.
4 We can pick that up at the top of page 6,
5 please:
6 "Q. Can I read to you part of Graham Ross's
7 note arising out of your telephone conversation with
8 him on 28 November 1989 and ask you to say whether or
9 not it accurately reflects your views ..."
10 Then the quote is:
11 "Appointed Medical Director of [SNBTS] in 1979.
12 At no time during the period he held that position did
13 he make any offer to Elstree to process English or
14 Welsh plasma nor was he involved, to his knowledge, in
15 any discussions on that matter."
16 Then the question is posed:
17 "Is that right?
18 "A. Yes and no. As we began to develop our own
19 self sufficiency programme in Scotland, some time in
20 the early 1980s it became clear to us that our friends
21 South of the Border were in serious difficulties and
22 this had arisen because they had accepted that their
23 laboratory at Elstree would be inspected. We
24 understood it had been inspected and found to be in
25 some difficulty. It became clear to us that, if we

1 operated our facility 24 hours a day, 7 days a week
2 [so this returns to the shift work at PFC], we could
3 take some pressure off our friends in England. There
4 would be two requirements: first, a modest expenditure
5 on increased accommodation for what we call
6 'finishing' ... Secondly, we required permission from
7 the Government to allow us to introduce a shift
8 working system. We had been anxious to introduce such
9 a system since our Centre had been commissioned in
10 1975 because the technology we had installed was quite
11 unique. It had been designed to run 24 hours a day,
12 7 days a week with a computer looking after it."
13 Then he provides a little more detail about
14 that, and then the last sentence of the paragraph on
15 the screen:
16 "My predecessors had been very distressed when
17 the final message came through that we would not
18 required to fractionate for the north of England but
19 for Scotland only."
20 So that's going back to the earlier period in
21 the 1970s. Then he says:
22 "I can well remember the resultant
23 disappointment of my then senior colleagues because it
24 was thought sensible to have two major fractionation
25 centres in the UK -- primarily for strategic supply

1 reasons and co-ordinated research and development. My
2 predecessors decided they would not change the
3 engineering system as such and so that potential
4 capacity remained in place but all the associated
5 'downstream' facilities -- packaging [et cetera] were
6 scaled down very substantially. When we came to the
7 1980s and were looking at our plans for self
8 sufficiency and, as our staff had gained confidence in
9 running the CVSM system, we were keen to introduce
10 a shift system. One way we thought we could get it
11 was to offer our English friends some help because, at
12 that time, they were in some difficulty. We did not
13 offer to sell products -- we hadn't enough plasma in
14 1981 for Scotland. What we offered was our
15 fractionation capacity. I don't think we should
16 delude ourselves that if it had come to pass it would
17 have solved all the problems in England and Wales.
18 Moreover, we didn't do the final sums and, at least
19 initially, the assistance would have been directed
20 towards albumin production only. We communicated our
21 thinking to our employing authority, the Common
22 Services Agency in Scotland. I was not, as far as
23 I can recall, involved in direct communications with
24 Elstree."
25 Then he is asked:

1 "And we are talking about 1981?
2 "A. Yes, 1980/81. To the best of my knowledge
3 our employing authority reported this to the Scottish
4 Office and they reported it to the DHSS in London.
5 I do not recall receiving any other response than one
6 which suggested our albumin was below the standard
7 required in England and Wales."
8 Then he refers to a Parliamentary commission
9 visiting PFC. Further down, we pick it up with the
10 paragraph saying:
11 "We assumed at the time, but nothing was said,
12 that this visit indicated that the Union was deeply
13 concerned that might be a movement of English plasma
14 to Scotland into an environment which was not a closed
15 shop. We assumed there was also understandable
16 anxiety about jobs at Elstree and local union leaders
17 had contacted that ASTMS sponsored MPs requesting them
18 to advise the Minister not to accept this Scottish
19 offer. This is all assumption. All I can tell you is
20 they came, they were very courteous, they had
21 afternoon tea and went, but we got no subsequent
22 feedback."
23 Of course I should say, and again we haven't
24 explored this issue fully by any stretch of the
25 imagination so far, and we'll come back to it in

1 March, but we have seen some of the DHSS materials
2 which suggest that perhaps a different way of thinking
3 and issues of the costs that might be involved playing
4 some part in the decision making.
5 Then the question is:
6 "Did you try to take it up again with your
7 employing authority?
8 "A. Yes, on several occasions, but, as
9 I recall, they had no clear response other than the
10 comment made about the quality of the albumin product
11 we produced, although this product has since been used
12 in England on many occasions without ail effect. The
13 issue seemed to simply run into the sand, for whatever
14 reasons, we got the distinct impression there was no
15 enthusiasm from those colleagues responsible south of
16 the Border."
17 Then a question is asked a couple of paragraphs
18 further down:
19 "If the English authorities had taken up your
20 offer to initiate a 24 hour shift working, would you
21 have needed corresponding increase in your finishing
22 facilities?
23 "A. Yes."
24 Then if we go to the next page, there's then
25 a discussion -- I'm not going to go through in full

1 detail but there's a discussion in the first paragraph
2 from Professor Cash about Crown immunity and the
3 Medicines Inspectorate not having gone into Elstree
4 until a point in time, and then he says this:
5 "We [so that's SNBTS PFC], on the other hand,
6 had always taken a different view. Despite having
7 Crown Immunity, we had welcomed the Inspectorate on
8 the grounds that we would learn an immense amount
9 about good manufacturing practice."
10 Then the discussion turns to Dr David Owen's
11 announcement of £500,000 towards the concept of
12 self-sufficiency and, if we go towards the bottom of
13 the page, you will see about four lines up from the
14 bottom, the view of Professor Cash:
15 "The managerial infrastructure that could
16 respond to Dr Owen's proposed investment was not in
17 place in England."
18 That's obviously just Professor Cash's opinion
19 but that is his recorded opinion here. The question
20 is:
21 "Q. A total lack of meaningful infrastructure?
22 "A. Yes."
23 Then if we just go over the page, a couple of
24 final passages in this, the second paragraph down is
25 a question about importing American concentrates and

1 what is said is this:
2 "It has been said to us by a virologist that
3 this was dirty blood -- a sewer of viruses. Was that
4 a preception [I think that must mean perception] of
5 American concentrate in the Scottish Transfusion
6 Service over that period?
7 "A. Yes, but this description is ..."
8 Oh.
9 **SIR BRIAN LANGSTAFF:** I think it is telling us it may be
10 time for a break.
11 **MS RICHARDS:** I've very nearly finished. I promise tea and
12 coffee will come soon.
13 So the answer is:
14 "I think we would simply say that, if you use
15 paid donors as your source material and you are
16 operating in any community in which that payment is
17 important to the donor, then, when you come to ask
18 serious questions about the donor's health and habits,
19 the payment is an incentive to lie. This sort of
20 incentive does not apply to the voluntary, unpaid
21 donor. This danger was clearly seen by the [World
22 Health Organisation] in 1975 in the context of the
23 transmission of viruses in large pool plasma
24 products."
25 Then he talks about hepatitis in the next

1 paragraph, concluding with this observation:
2 "Even in America today if you compare the unpaid
3 [versus] the paid, it is still higher and this also
4 applies to HIV and HCV detection."
5 Then next page, towards the bottom of the notes,
6 the question is put in these terms:
7 "It has been suggested that blood originating in
8 most Third World countries or from paid donors is
9 always at higher risk of transmitting viral infection,
10 no matter what the nature of the screening process; is
11 that something you would agree with or not?
12 "A. Yes.
13 "Q. And this risk had long been recognised?
14 "A. Yes."
15 So there Professor Cash's views recorded in
16 1990, touching on both issues of risk and on matters
17 of self-sufficiency in both Scotland and England.
18 With apologies to everyone for depriving them of their
19 tea and coffee for ten minutes, perhaps we could take
20 the break now.
21 **SIR BRIAN LANGSTAFF:** We will take a break then until
22 11.55. 11.55.
23 **(11.26 am)**
24 **(A short break)**
25 **(11.56 am)**

1 **SIR BRIAN LANGSTAFF:** Yes.
2 **MS RICHARDS:** Sir, picking up issues relating to
3 self-sufficiency, if we look at PRSE0001612, this is
4 a meeting of the Scottish National Blood Transfusion
5 Service September 1975, and we can see that Dr Cash
6 was present. He wasn't at this stage the National
7 Medical Director.
8 If we go to page 3 and pick it up halfway down
9 the page under the heading "The supply of
10 Factor VIII", we can see a discussion here about
11 matters relating to plasma supply.
12 There's a discussion in the first paragraph
13 about a letter that had been issued by
14 General Jeffrey.
15 Then the next paragraph says:
16 "There was discussion on the level of usage on
17 which issues had been based, in particular Dr Lewis
18 drew attention to the fact that projected issues were
19 some three times his yearly preparation of
20 Cryoprecipitate. General Jeffrey explained that the
21 figures used had been derived from returns received
22 from Haemophilia Directors."
23 Then the next paragraph says this:
24 "To improve the supply position ..."
25 So that's the supply of plasma.

1 "... General Jeffrey asked Directors to reduce
2 their production of cryoprecipitate as stocks of
3 intermediate factor were built up and send the
4 equivalent in FFP to PFL."
5 So that's a request made as at 1975.
6 If we then pick broader national discussions
7 about self-sufficiency up at DHSC0000064, these are
8 the:
9 "Minutes of a meeting on 1 December 1980 to
10 discuss self-sufficiency in blood and blood products."
11 If we turn to the next page, we can see it's
12 a meeting -- described as:
13 "... a meeting ... with the Scottish Home and
14 Health Department, Department of Health and Social
15 Services, Northern Ireland [so one of the relatively
16 few meetings that we'll be looking at in which there's
17 a Northern Ireland representation], and the
18 Welsh Office to discuss UK self-sufficiency in blood
19 and blood products."
20 We can see that Dr Cash, who by now was National
21 Medical Director of SNBTS, was present.
22 Then we can pick up the discussion under the
23 heading "Total need for blood products in the UK and
24 how these needs could be met". There's a discussion
25 there about what future requirements might be. We

1 pick it up halfway down that paragraph. It says:
2 "Scotland was almost self-sufficient ..."
3 So this is December 1980:
4 "... but Northern Ireland's needs would have to
5 be considered."
6 Then there's a reference to the PFC in Edinburgh
7 playing a role in helping to meet total UK needs, and
8 that's essentially by the fractionation of Northern
9 Ireland plasma.
10 Then the next paragraph records:
11 "Dr Cash's view was that in order to meet the
12 rising UK demand for blood products the target for
13 plasma collection would have to be in the region of
14 1 million litres per annum. Experience in Belgium,
15 which also had a voluntary donor system, had shown
16 that this could be possible if a major plasmapheresis
17 programme was set up."
18 There's a discussion about the short-term
19 ability of PFC to:
20 "... fractionate an extra 500 litres of fresh
21 frozen plasma (ffp) per week to produced Factor VIII
22 and albumin ..."
23 Then, paragraph 5, what was said could be done
24 in the longer term provided more funds were made
25 available and agreements could be reached on shift

1 working.
2 Top of the next page:
3 "6. There was a possibility that ultimately PFC
4 might be able to meet up to half the UK's requirements
5 for blood products.
6 "7. It was agreed that the question of how
7 future UK fractionation might be divided between BPL
8 and PFC would be to be discussed in detail once total
9 requirements had been defined. One possibility might
10 be that PFC would fractionate plasma from the 4
11 Northern English Regions and from Northern Ireland."
12 We know that was what happened in relation to
13 Northern Ireland.
14 So that's the position as at 1980 in terms of
15 Scotland, it being recorded that Scotland was at that
16 point almost self-sufficient.
17 If we then look at PRSE0000144, these are the
18 minutes of a meeting in January of 1981 and it's
19 a meeting of SNBTS representatives and Scottish
20 haemophilia directors, and again we see Dr Cash's
21 attendance.
22 Paragraph 2 records Dr Bell, who was from the
23 SHHD, saying that:
24 "... for a number of reasons the Department
25 thought that the time was right to reconvene the

1 group, which had not met since 1977."
2 Then there is a heading "Trends in plasma
3 procurement and production of factors VIII and IX
4 concentrate", and there's a reference there to Dr Cash
5 introducing:
6 "... a paper he had provided to assist
7 discussion of SNBTS planning for the future
8 availability of Factor VIII and 9 concentrates ..."
9 I'm not going to go to the paper itself but for
10 the benefit of those who would wish to look at it, and
11 for the transcript, the reference for the paper is
12 CBLA0001252.
13 Then if we look at the minutes we can see in any
14 event in broad terms what the paper encompassed.
15 So paragraph (b):
16 "Supply and demand
17 "Section 1 of the paper dealt with the
18 supply/demand from 1975-1980 and gave details of ..."
19 What had processed. Then the bottom of the page
20 records that:
21 "The data provided for 1979 and 1980 showed that
22 a significant and apparently increasing quantity of
23 commercially produced Factor VIII was being used, and
24 that the reasons for this were discussed. It was
25 stated by haemophilia directors that sometimes only

a commercial product was available; there were also occasions when, for clinical reasons, a high purity product was required."

There's a further discussion in relation to that.

Then if we go towards the bottom of the page we can see a heading "Cryoprecipitate yields and use", and we record here Dr Cash speaking about the role of cryoprecipitate:

"... Dr Cash emphasised the important part cryoprecipitate could play in haemophilia treatment. The increase in home therapy would place such a strain on resources that all options had to be studied, including serious consideration of the use of cryoprecipitate for this form of treatment."

So for home treatment. So that's a proposal advanced by Professor Cash.

"Haemophilia directors were generally not in favour of using cryoprecipitate in this way, as in their view the risks of side effects were too great. They were however prepared to use cryoprecipitate in hospitals."

Then, top of the next page, we'll just see there's a discussion then that in relation to Factor IX, because of lower demand it did not present

problems similar to those in relation to Factor VIII.

Picking matters up a little later, in 1981, at SBTS0000382_008, this is a meeting on 4 March 1981 of the Haemophilia and Blood Transfusion Working Group. Again, we can see Dr Cash is in attendance.

Paragraph 2 explains this is the:

"... first meeting of the Working Group established by the haemophilia/Blood Transfusion Directors to consider specific proposals in Dr Cash's paper and certain other issues."

There's then a discussion about production targets. I'm not going to go through the detail of that but you'll see from paragraph 4 Dr Cash presented information about target figures in Denmark and Belgium and the States, and was essentially looking forward -- as in looking to the future -- as to the prospect of prophylactic home therapy programmes being practised.

Then over the page, at paragraph 6, we see recorded:

"Concern was expressed at the level of are commercial material being purchased and it was agreed that the aim must be for the NHS in Scotland to be self sufficient."

So as at March 1981 it would appear that

self-sufficiency in Scotland had not yet been attainted. The note continues:

"This could be achieved with good planning, and steps had been taken to improve the input of plasma. Dr Cash suggested that self sufficiency included the provision of a reserve stock capable of meeting unexpected demands such a temporary failure at PFC."

Then, sir, I invite you to note the next heading, which is "Production of Freeze Dried Cryoprecipitate". Again, we've seen reference to this in earlier hearings. We see:

"The Chairman invited Dr Cash to comment on the proposal that freeze dried cryoprecipitate be produced with a view to study, on a multicentre basis, its role in home therapy ..."

Then paragraph 8 records Dr Cash saying that:

"... there were two factors in favour of cryoprecipitate (a) the increased yield and (b) the increased pool size, although there was a school of thought in the UK that the larger pool size may increase the risk of hepatitis. He urged members to think carefully before embarking on a full scale programme and to bear in mind the allergic reactions and side effects which could arise. The majority of home therapy patients had no problems when using

cryoprecipitate and in Belgium it was used extensively."

It's not an entirely easy passage to follow, but what I think Dr Cash is recorded as referring to at the beginning of the paragraph is freeze-dried cryoprecipitate as opposed to cryoprecipitate, and hence the reference to an increased pool size in relation to freeze-dried cryoprecipitate.

SIR BRIAN LANGSTAFF: And that being a factor in favour might suggest that what he had in mind there was that it was easier, because of the averaging process, to know how much factor activity there would be in a given volume.

MS RICHARDS: Yes. I think that's right. But interesting to note it appears to be his view that home therapy patients have no problems using cryoprecipitate, and you'll see there reference made to extensive use in Belgium.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Again, we'll pick up what happened to this proposal in relation to freeze-dried cryoprecipitate in future hearings.

Then if we move forward in time now to 1983, PRSE0001736. These are the minutes of a meeting of directors of SNBTS and haemophilia directors,

1 21 January 1983. We can see Dr Cash was present.
2 If we go over the page, paragraph 4 refers to
3 Dr Cash being invited to introduce a paper he prepared
4 to facilitate discussion with regard to future SNBTS
5 planning for the production of blood products.
6 We will look at that paper in a moment.
7 There's then a discussion about trends in supply
8 and demand for Factor VIII concentrate, and we'll see
9 what's said there is that for the period '78 to '82:
10 "Figures ... showed that:
11 "(i) there had been a sustained increase in the
12 total amount of fresh plasma processed, although it
13 was anticipated the increases would probably now level
14 out ...
15 "(ii) there had been a address in the amount of
16 cryoprecipitate issued from the RTCs; and
17 "(iii) there had been a substantial increase in
18 issues of the PFC intermediate factor VIII
19 concentrate."
20 So although we saw in that earlier meeting
21 Dr Cash, it would seem, extolling the virtues of
22 cryoprecipitate but that view not necessarily being
23 shared by others, the data, by the beginning of 1983,
24 indicates a decrease in terms of production of
25 cryoprecipitate within SNBTS.

1 If we go to the next page, and pick it up in the
2 second paragraph, we can see commercial Factor VIII
3 still use. So:
4 "Concern was again expressed about the amount of
5 commercially produced factor VIII which was still
6 being purchased and members went on to discuss the
7 regional breakdown of the usage of cryoprecipitate,
8 PFC concentrate and commercially produced
9 Factor VIII."
10 Reference is made to Dr Ludlam's use of
11 commercial material in Edinburgh. Then if we go two
12 paragraphs further down, we'll see it being:
13 "... stressed that the SNBTS had been set up to
14 have the capability to cope with all Scottish
15 requirements, other than those few therapeutic agents
16 the production of which might not be justified on
17 a very small scale, and that in terms of national
18 policy the purchase of commercial products should be
19 avoided so far as possible."
20 We then see picked up at the bottom of the page
21 reference to the trial of freeze-dried
22 cryoprecipitate. Dr Cash is recorded as expressing
23 thanks to those who undertook it but the minutes
24 record that:
25 "Notwithstanding this work, it had been decided

1 to abandon production of [freeze-dried
2 cryoprecipitate] meantime, having regard to the
3 closure of the plasma freeze drying plant at Law and
4 the cost of meeting the standards demanded by the
5 Medicines Inspectorate. The prospective availability
6 of a hepatitis risk reduced factor VIII concentrate
7 also cast uncertainty over the future of FDC at the
8 present time."
9 Then, just for completeness sake, the next page
10 records the position in relation to Factor IX
11 concentrate and records that the supply position of
12 DEFIX, which was the Factor IX concentrate, had
13 remained strong and demand reasonably stable.
14 So that we don't need to come back to this
15 document when we look at issues relating to AIDS, if
16 we go to page 7, bearing in mind this is a meeting in
17 January 1983, there is a heading at paragraph 6
18 "Acquired Immune Deficiency Syndrome":
19 "Dr Cash drew member attention to recent
20 articles in the United States, and also in The
21 Observer and The Lancet, about this problem."
22 So no room for doubt there, really, in terms of
23 Dr Cash being *au fait* with the most recent
24 publications in that regard. Then he records that:
25 "An MMWR extract ... had been circulated with

1 his paper. Dr Ludlam informed members that in the UK
2 a letter and questionnaire had been sent out to
3 haemophilia directors."
4 We can just look at the paper itself,
5 PRSE0001991. This is the paper produced by Dr Cash --
6 Professor Cash for this meeting, to which reference
7 was made in the minutes. If we go to page 3, not
8 proposing to go through the detail, but we can see
9 there the data being set out by Professor Cash in
10 relation to fresh plasma procurement, the provision of
11 Factor VIII concentrates and the purchase, further
12 down the page, of commercial Factor VIII.
13 If we go over the page, bottom of that page
14 refers to "Heat treated Factor VIII concentrate":
15 "It is common knowledge that this type of
16 product, which should have a reduced risk of
17 transmitting hepatitis, will be commercially available
18 in 1983 throughout the UK."
19 Then there's a reference to PFC's work on a heat
20 treated Factor VIII product.
21 Then if we turn to page 7, we can see reference
22 halfway down the page, under the heading
23 "Miscellaneous", to AIDS:
24 "The attention of the Haemophilia Directors is
25 drawn to this problem ..."

So this is Professor Cash drawing this issue to their attention:

"It is noted that in the US the National Hemophilia Foundation and CDC are already conducting a survey and intend to establish a permanent surveillance programme. The information contained in Appendix VI has been sent to Professor Bloom", presumably by Professor Cash, because he is the author of this paper.

The information in Appendix VI, if we go to the last two pages of this document is, in fact, the December 1982 MMWR report with an "Update on [AIDS] among Patients with Haemophilia A". We can see quite clearly Professor Cash, first of all, himself aware of this material, this information; secondly, it would appear Professor Cash drawing it to the attention of Professor Bloom, although evidence would suggest Professor Bloom may well have been aware of it in any event; and then, thirdly, Professor Cash drawing it to the attention of the Scottish Haemophilia Centre Directors in January 1983.

SIR BRIAN LANGSTAFF: This is the publication which refers, I think, to the San Francisco baby?

MS RICHARDS: Absolutely, sir, that's right, which a number of witnesses have described as being really

a seminal moment in terms of the appreciation of the risk from blood or blood products or the potential risk in relation to the transmission of AIDS.

Just returning then to the position in relation to self-sufficiency. So we saw, as at January 1983, it would appear self-sufficiency not completely attained in Scotland, although the suggestion is well on its way. If we look at PRSE0001556, please, we come forward here now to February 1984 and this is a meeting of directors of Scottish National Blood Transfusion Service and Haemophilia Directors.

If we turn to the second page, we can see, under the heading "Review Paper from SNBTS", there's reference to another paper produced by Professor Cash in terms of planning. (i) records:

"Details of the amount of fresh plasma processed for factor VIII concentrates and the issues of concentrates indicated that the production level was about right. However trends over the last 5 years indicated that the SNBTS production of factor VIII concentrates may be exceeding clinical demand in that current stocks at RTCs appear to be increasing."

So it would appear that, by this stage, sufficient domestic factor concentrates being produced to effectively meet all clinical demand. Then the

next paragraph says:

"Members were agreed that it was desirable to stick to the target production figure ... and that the existing stocks required to be held for sudden demands which could be made in the service, and to bridge the period when the PFC would be converting to a heat treated product. If a surplus of factor VIII became a reality other parts of the UK could be asked if they wished to make use of the product in preference to purchasing from other sources."

Then there's a discussion about production of cryoprecipitate and the views of Dr Ludlam and Dr Hann -- and we explored this, I think, with both of them in their oral evidence -- that cryoprecipitate was now to be preferred because of the new danger of AIDS for certain categories of patient.

Then towards the bottom -- sorry, at the bottom of this page, there's then reference to commercial concentrates, so:

"Dr Cash asked members to consider whether, given the present SNBTS production level of factor VIII concentrates, it was necessary to purchase commercially unless exceptionally a superior product was available."

Top of the next page, we see a number of

responses:

Dr McDonald, "no longer necessary to purchase commercially".

Dr Hann had "inherited [units] of commercial factor VIII ... rapidly going out of date which he was prepared to dispose of".

Dr Ludlam wanted to have "a small stock of high purity commercial material for a very few patients".

Then we see Dr Bell, so that's the SHHD representative, emphasising:

"... the aim of the SNBTS and of national policy was for Scotland to be self sufficient, and, although the Department would not wish to intervene in what clinicians prescribed, it was not sensible to purchase imported material when suitable NHS product was available."

Then, just under the heading "Factor IX Concentrates", we can see there the discussion now has moved to the potential of replacing Defix with Supernine, and discussions of development of a heat-treated Factor IX product.

Then if we turn to CGRA0000610, we looked at this document previously for other purposes. It was a meeting on 9 February 1984 at the National Institute for Biological Standards and Control, the subject

matter being the issue in relation to risk of AIDS. If we go to the bottom of the second page, we can see the last paragraph reads:

"During the discussion period Dr Cash noted that Scotland is now totally self-sufficient and thought there might be an opportunity to study these patients who have not been exposed to commercial blood products, also noting that the pool sizes are very different as well as the donor population."

So by the beginning of 1984 it would appear self-sufficiency in Scotland attained.

I'm not proposing to go to it but there is an interesting discussion of self-sufficiency in 1989 by Dr Cash. The reference, just for the transcript, is PRSE0004541, and it's a discussion paper which suggests that, as at 1989, self-sufficiency -- or there is no longer self-sufficiency in Scotland. There's a discussion of how it had been attained at an earlier period but was no longer met.

Then if we look, lastly on the topic of self-sufficiency, at SBTS0000603_027, this is a later document from the 1990s, and its topic is donor plasmapheresis. It's a presentation by Professor Cash.

I'm not going to go into the details of his

discussions about the role of plasmapheresis within Scotland but if we just look at this first page, we'll see his view as to how it was possible for Scotland to achieve self-sufficiency. So he says:

"Scotland is a small country within the [UK]. It has a population of only 5 million and well over 95% of our health care programmes are provided, free of charge to the population, by the Government. The national health care programme in Scotland includes a national blood transfusion service which is centrally co-ordinated and managed, which relies exclusively on voluntary unpaid donors and in the late 1970s was directed to develop a programme of self-sufficiency in blood and blood products. The opportunity to achieve self-sufficiency has been much enhanced by the blood transfusion service having its own in plasma fractionation centre. Thus a single organisation has managerial control over both plasma acquisition and its fractionation, the former represented by 5 regional centres and the latter by the protein fractionation centre."

So it would appear Professor Cash attributing Scotland's ability to achieve self-sufficiency in part to the fact that there was a unified Scottish National Service, of which the fractionation plant was

an integral part.

Professor Cash also expressed views on a number of occasions about the advantages of the use of red cell concentrates, as part of the strategy to achieve self-sufficiency. I am not proposing to go through the detail of his views in relation to that. We've set out a number of reference in the written presentation, but there is one particular document in which he not only discusses that issue but discusses, more broadly, safe transfusion practices and principles. I want to look next at that.

So it's PRSE0002637. It's a publication, if we look at the very top of the page the date is 1971/1972. The document is headed "Principles of Effective and Safe Transfusion". There are a number of passages I'm going to refer to in this. So picking it up, first of all, on this page in the second paragraph, under the heading "Effective Blood Transfusion", and I should say we can see that this is Professor Cash's address to a symposium that was taking place. It says:

"The product given to us in trust by our donors we call whole blood. It can best be described as a complex soup known as plasma, somewhat thinned by a volume of anticoagulant, in which are suspended red

cells, essential for the transport of oxygen; white cells, essential to combat foreign invasion; and platelets which play a fundamental role in haemostatic mechanism.

"Approximately 80 per cent of all the donations used in Scotland during 1971 were given in the form of whole blood. Did all patients require *whole blood*? The answer is no, for many recipients could have received red cell concentrates ... The implication of this statement must be that several thousand litres of plasma and billions of platelets were given along with red cells to patients who either had no need of them or could have been managed with simpler and safer alternatives. These thousands of litres were thus lost without trace. Why? Is this important? Is Scotland unique in this practice?"

Then he goes on to provide an answer to that question that he's posed.

If we then pick up the issue at the bottom of the page, he poses three questions:

"Are there some patients who require a constituent in whole in an amount which far exceeds that found in whole blood?

"Are there other patients whose requirements are so small, that one donation, suitably processed, is

1 capable of meeting the needs of several patients?"
2 Then 3:
3 "Is it possible to process plasma in some way
4 that in so doing a product is made available which has
5 equal clinical efficacy but is now safe from the
6 transmission of disease?"
7 He then goes on to talk about three forms of
8 plasma or plasma products. So he talks about
9 coagulation Factor VIII platelet therapy and purified
10 protein solution. I'm not going to go into the detail
11 of what he sets out in relation to those but it is
12 an article, I think, worth reading.
13 We pick it up towards the bottom of page 4 --
14 I'm sorry, top of page 5. No, I'm going to stick with
15 the bottom of page 4. There's just a sentence which
16 is quite revealing. He says:
17 "... in the interests of efficiency, in terms of
18 the optimal utilisation of raw material to facilitate
19 effective patient-care, Chaplain's (1969) declaration
20 that routine whole blood transfusions is
21 a 'thoughtless habit' may have to be considered much
22 more seriously by clinicians and Blood Transfusion
23 Services alike."
24 Then he goes on to talk, in the next section,
25 about safe blood transfusion, and says this:

1 "Although the medical profession has long
2 recognised the concept that there are no therapeutic
3 roses without thorns, there is no doubt that the
4 dangers of blood transfusion, in all its forms, have
5 yet to be fully defined. However, in the ardour of
6 therapeutic endeavour, we are frequently guilty of
7 forgetting those hazards which have already been well
8 documented. Moreover, compared to 20 years ago, new
9 types of patients, such as those on chronic renal
10 dialysis and marrow ablation for leukaemia are being
11 exposed repeatedly to the hazards of blood
12 transfusion."
13 Then, next paragraph, he talks about:
14 "Recent data ... would suggest that the number
15 of deaths attributable to blood transfusion are
16 comparable to those complicating general anaesthesia.
17 Almost 50 per cent of the post transfusion deaths were
18 due to hepatitis. While not intending to
19 underemphasise the importance of incompatible red
20 cell, white cell and platelet transfusions, allergic
21 reactions to plasma proteins, systemic effects of
22 bacterial pyrogens and heavily contaminated blood and
23 blood products, air embolism", et cetera, et cetera.
24 So not intending to under-emphasise all those.
25 He continues:

1 "... the magnitude of the hepatitis problem and
2 the recent explosion of highly productive research in
3 this area is so great that it seems appropriate on
4 this occasion to continue this particular feature of
5 safety in some detail."
6 He then goes on to record matters relating to
7 discovery and research in relation to the Australia
8 antigen and hepatitis B. We don't need to look at
9 those.
10 If we go over to the next page, he explained at
11 the top of the page:
12 "From the early beginnings of this work, debate
13 has gone on as to whether Australia antigen is
14 responsible for serum hepatitis alone or both
15 infectious hepatitis and the serum form of this
16 disease."
17 There is then a further discussion in relation
18 to that.
19 Then if we pick matters up under the heading
20 "Clinician's Contribution", he says this:
21 "It is sometimes forgotten that a much more
22 conservative approach in the use of blood transfusion
23 by our clinical colleagues could make a significant
24 impact on the incidence of post-transfusion hepatitis.
25 In a critical appraisal of transfusion practice in the

1 surgical units of a large hospital over an 8-month
2 period, Morton (1969) reported that the administration
3 of a significant proportion of blood was either
4 unnecessary or questionable. Rush and Stewart (1969)
5 have also shown that the introduction of a more
6 liberal use of safe plasma volume expanders in the
7 management of operative and traumatic blood loss, with
8 the transfusions given over when the haematocrit was
9 less than 30 per cent, reduced the amount of blood
10 used by 35 per cent. These findings are of great
11 interest for they underline the observations of
12 Gardiner and Dudley (1963) that with good anaesthesia,
13 accurate dissection and the avoidance of bloody
14 mobilisation of diseased structures then the loss of
15 blood in standard operations should rarely approach
16 half a litre. In most elective procedures this volume
17 will not require blood replacement. Thus, the
18 reduction of the use of blood by no transfusion at all
19 or using safe alternatives could have as great an
20 impact on the incidence of post-transfusion hepatitis
21 as current techniques for Australia antigen
22 testing ..."
23 Of course we will be picking up a number of
24 those themes and issues about use of transfusions in
25 later hearings, but interesting and instructive to

1 note the views of Professor Cash in that regard at the
2 very beginning of the 1970s.
3 Then if we go to the bottom of the next page,
4 I'm not going to read it out but there's
5 a discussion in the penultimate paragraph about
6 screening of blood donations for Australia antigen and
7 then, at the bottom of the page, he says:
8 "Although the recent introduction of total donor
9 screening throughout the length and breadth of
10 Scotland must be regarded as a major step forward,
11 there is still much to be done."
12 Then there's a further discussion in relation to
13 that. Again, I'm not going to go through the detail
14 of that but perhaps worth noting -- above the heading
15 "Miscellaneous Contributions", about seven or eight
16 lines above that -- he says, having set out a number
17 of matters:
18 "In short, the Blood Transfusion Service must be
19 up in front rather than behind, for we must not assume
20 that the elimination of all antigen-positive units
21 will solve the post-transfusion hepatitis dilemma."
22 Then under the heading "Miscellaneous
23 Contributions", Professor Cash says this:
24 "Although the use of immunoglobulin will be
25 discussed in detail elsewhere in this Symposium there

1 is one aspect of this topic which is of particular
2 relevance in the general context of safe blood
3 transfusion. The Blood Transfusion Service should be
4 concerned and involved ... in those measures which
5 seek to reduce the evidence of all forms of
6 transmissible hepatitis in the community at large, as
7 it is from this same community that we obtain our raw
8 material."
9 Then, again, further discussion in relation to
10 that. I'm not going to go through the detail.
11 If we go to the next page, he then, under the
12 heading "Conclusions", sets out some observations
13 about the role of the Blood Transfusion Service:
14 "The peculiar role of the Blood Transfusion
15 Service is to provide a link between the healthy
16 section of the community and its sick. In some
17 respects this is a delicate link for the manner in
18 which a professional body (ourselves) works in harmony
19 with a voluntary community organisation is quite
20 unique."
21 Then the next paragraph:
22 "As the future bores in upon us, the increase in
23 complexity and clinical demands on the Blood
24 Transfusion Service becomes disturbingly evident.
25 Thus the answers to some of these fundamental

1 questions are a matter of urgency."
2 He then sets out a number of questions in terms
3 of the organisation of the Blood Transfusion Service.
4 So a number of issues that provide food for
5 thought there in Professor Cash's symposium
6 presentation.
7 Can I then just draw your attention, sir, to
8 PRSE0002133. This is not a document I propose to go
9 through but I just wanted to flag up the existence of
10 it. It's the SNBTS annual report from 1975 to 1976.
11 What it does, if we go over the page, is, first of
12 all, identifying the very first sentence, top of the
13 page, the aim of the SNBTS, which is "the provision of
14 safe blood and blood products to meet patient needs".
15 So that's what's set out as the aim.
16 Then this document sets out details of donor
17 numbers, the rejection rate in terms of donors and
18 reasons for rejection, the different usages to which
19 donations were put, and the various products made
20 within the Regional Transfusion Centre and details of
21 transmission of products to PFC.
22 If we go to page 25 you will see that it
23 includes a range of statistical tables setting out
24 a whole range of pieces of information, including, as
25 I say: donor response, use of whole blood,

1 concentrated red cells, use of plasma,
2 cryoprecipitate, immunoglobulins, et cetera, and then
3 various forms of hard data are set out in the tables
4 themselves.
5 I draw attention to it because it's a useful --
6 very useful -- source of information giving the
7 picture in relation to supplies available to the SNBTS
8 in this particular year and the use made of them, and
9 we're trying to draw together the relevant references
10 for all of the successive annual reports, which
11 hopefully will enable you, sir, to build up a very
12 comprehensive picture of the materials available to
13 the SNBTS and the use that was made of them.
14 I'm going to turn now then to various matters
15 relating specifically to early knowledge of hepatitis.
16 We can start with a document at LOTH0000111_018.
17 This is a document relating to the hepatitis
18 outbreak at the Edinburgh Royal Infirmary which began
19 in 1969 and which others have made reference to. When
20 we look, probably tomorrow morning, at
21 Professor Cash's oral evidence to the Penrose Inquiry,
22 it's an issue that he made express reference to there.
23 You'll see, under the heading "Sequence of
24 events":
25 "Note of meeting held on ... 8th January 1970."

We see there recorded Dr Cash's presence at that meeting. There are then a series of meetings and discussions set out.

If we go to page 3 and we look at the bottom half of the page, there's then a reference to notes of meeting held on 18 February and there's a list of those present, who include, again, Dr Cash.

Then we see a number of recommendations set out arising out of this hepatitis outbreak, which at this point in time was still ongoing. It had begun in 1969 but the ramifications continued to be felt over quite a long period of time.

So we can see:

"After a lengthy discussion it was agreed that following recommendations be made.

"1. That the Scottish Home and Health Department be asked to provide guidance as to the procedure to be followed by persons exposed to the risk of infection.

"2. That the SERHB be asked to provide facilities for the treatment of major hepatic failure in Edinburgh as soon as possible."

Point 3 relates to what should be done in relation to the close contacts of a particular patient.

5 is then:

"That all cases of hepatitis occurring in the [Royal Infirmary of Edinburgh] group be notified to the Medical Superintendent."

So again, as I say, I will come back to this when we look at Professor Cash's oral evidence, but he was well aware of that outbreak at that Royal Edinburgh Infirmary, and indeed knew, I think, a number of those infected, including a friend and colleague who died.

Professor Cash's CV, which I'm not going to put onscreen, tells us that, again I think in 1970, Professor Cash was the recipient of a World Health Organisation travelling fellowship to visit the United States where he investigated problems of Australia antigen testing.

If we then pick up matters relating to hepatitis with a letter from Professor Cash in the BMJ, PRSE0004064.

This is 24 January 1976, so it's shortly after the broadcast of the World in Action documentary in December 1975, and Professor Cash's letter is written in response, in part, to that documentary.

So if we go further down the page, there's a heading in the middle column, "Commercial and NHS

factor VIII concentrates", and this is Professor Cash's letter:

"One of the inevitable dangers of a journalistic approach to medical problems is that limitations in time (radio or television) or space (newspapers or periodicals) may give rise to a selection of comments made by experts which, when taken out of context and put together for a programme or article, are misleading. This probably arose during the ITN television series 'World in Action' in which two consecutive programmes attempted to deal with the availability of factor VIII concentrates for haemophilia patients in the United Kingdom.

"There is no doubt that the import into the [UK] of factor VIII concentrates derived from external sources, however well screened for hepatitis viruses, represents an unequivocal pathway by which the level of a potentially lethal virus into the whole community is being deliberately increased. Although the absolute magnitude of this problem was exaggerated and overdramatised by the television programmes, nobody with direct or indirect responsibilities for this phenomenon would wish to belittle the serious nature of the moral and practical dilemmas which face us all.

"Perhaps the most important misleading feature

of the second television programme was the impression given that the recent and specific injection of £500,000 by the DHSS into the blood transfusion services will have worked it way through by mid-1977, and by that time the necessity to purchase further supplies of factor VIII concentrates will be eliminated. Our own experience indicates that this will not occur, not least because the present NHS production target for factor VIII concentrates is too low. What seems more certain, however, is that by mid-1977 we shall begin to understand that the problems are multifactorial, a good deal more complex than hitherto appreciated, and only partly related to the haemophiliac. In the meantime we would be well advised not to raise the expectations of the patients, their relatives and the staff of the regional haemophilia centres beyond the certainty that things will improve very slowly, and at the same time look at the problem once again."

Of course, whatever the merits or otherwise of his views about the television programme itself, this letter would seem to indicate, first of all, that it was a programme which Professor Cash either watched or very soon became aware of.

Secondly, sir, you will note the terms in which

he describes the unequivocal pathway by which the level of a potentially lethal virus into the whole community is being deliberately increased, and there I think identifying that the risk is not only the patients with haemophilia but a risk that may potentially affect the community much more widely.

The third point perhaps to draw from this is what you might think is the accuracy of his view that the £500,000 would not achieve self-sufficiency for the United Kingdom or for England and Wales.

SIR BRIAN LANGSTAFF: His views about the TV programme essentially are it's a bit overstated but it's making a very valid point, is what I think he's saying.

MS RICHARDS: Precisely.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: Professor Cash was then involved, as I indicated this morning, in a number of committees or working groups, working parties, which were considering matters relating to hepatitis and transmission of hepatitis by blood and by blood products.

By way of example, if we go to DHSC0002191_099, we can see that he was here part of and present at the first meeting of the reconvened advisory group on testing for the presence of hepatitis B surface

antigen and its antibody and the purpose of, or one purpose of, the group, and the fact of its being reconvened, was to advise the Department of Health on measures which should be introduced to offer greater safety to recipients of blood and blood products and to protect the interests of blood donors.

Sorry, I should have said, we see that from the top of page 2.

So it's the draft terms of reference which were agreed, and the point 2 is, as I have just read out:

"... [advising] the Department on measures which should be introduced to offer greater safety to recipients of blood and blood products ..."

There's then a discussion in relation to this particular meeting of a number of matters.

If we turn to page 5, you will see that there was discussion at the top of the page about the significance of elevated transaminase levels, and the agreement was that:

"... the matter required consideration but that too stringent a ruling to exclude donors on the basis of a single raised transaminase, which is a non-specific indicator of liver dysfunction, might lead to the rejection of an unacceptably high number of donors."

It's recorded that at this time the advisory group are opposed to the routine determination of transaminase levels.

Then we see the heading "Non-A, non-B hepatitis", reference to a publication in the Journal of Hygiene, and then it says:

"The Advisory Group after discussion, made a strong recommendation to the Department that research in 2 areas be undertaken ..." and the first of which is a retrospective study of chronic hepatitis.

Then the next heading down is "The position of donors with a history of hepatitis". It said:

"It was agreed to consider whether they should be re-examined with a view to re-admission to the donor panel, when the appropriate section of the Report was being revised."

That's a reference to the fact that part of this advisory group's role on being reconvened was to look at the second report of the previous advisory group and see whether there were aspects of it that needed to be revised, and one issue which was up for re-examination was whether those with a history of hepatitis should be permitted to donate blood.

There was then a second meeting at which

Professor Cash participated at CBLA000931 -- I'm sorry, CBLA0000931.

So this is April 1979, 2 April, it's a note of the second meeting of the reconvened advisory group. Dr Cash was in attendance and there's a discussion again of non-A, non-B hepatitis on page 3, to which he would therefore have been party:

"As previously reported [this is the top of the page] the Department was anxious to encourage research directed towards establishing the extent of the problem in the UK and the development of tests for the agent(s) of non-A, non-B hepatitis."

Then reference was made to a working party to be convened by the Medical Research Council, and then the minutes record that:

"The Chairman said it would be reasonable to await the outcome of the MRC research before the Group attempts to report on this problem."

There's then a discussion about notification of or reporting of post-transfusion hepatitis, again to which Dr Cash would have been party.

The report of this group, I'm not going to go through it in any great detail, but it is at DHSC0002211_007, so you will see it's the third report of the Advisory Group, it's dated 1981. If we go to

1 page 3, second paragraph, we'll see that the report
2 was being circulated, amongst other, to Regional
3 Transfusion Directors, Regional Medical Officers,
4 et cetera.
5 If we go to page 4, we'll see the issues which
6 were discussed by the group, which include, first of
7 all, the screening of blood donations for the
8 hepatitis B surface antigen and then chapter 3, "Other
9 Screening Tests", including there tests for non-A,
10 non-B hepatitis viruses and liver function tests.
11 If we go to page 5, we see there Dr Cash
12 identified as a participant in the group and then, I'm
13 not going to go through the detail of the report but
14 if we just go to page 13, we'll see the summary of the
15 principal recommendations. The first, I think, five
16 deal with hepatitis B screening, and then if we pick
17 it up at subparagraph vi:
18 "There should be no general screening of
19 donations for anti-HBc. Donors implicated in cases of
20 post transfusion hepatitis should be comprehensively
21 tested at reference centres."
22 Then vii:
23 "Liver function tests should not be used for
24 general screening of blood donors.
25 "viii. Hospitals should be encouraged to report

1 all cases of post-transfusion jaundice and where these
2 could be due to non-A, non-B hepatitis, the facts
3 should be reported to the appropriate Adviser in Blood
4 Transfusion at the DHSS or SHHD."
5 That would have been, in relation to SHHD,
6 Professor Cash.
7 "ix. Research should be undertaken in the UK to
8 determine the extent and severity of post-transfusion
9 hepatitis due to non-A, non-B hepatitis viruses.
10 "x. A committee of experts should be
11 established to assess the suitability of any new tests
12 for hepatitis markers."
13 So that was the outcome, as at 1981 of the
14 deliberations of this group, of which Professor Cash
15 was part.
16 I don't think I'll go to it but I will just give
17 the reference. There was, in June 1981, a meeting of
18 the Medical Research Council's blood transfusion
19 research committee, of which Dr Cash was a member.
20 The reference for the transcript is CBLA0001396, and
21 there's a further discussion there about non-A, non-B
22 hepatitis and concern expressed, not specifically
23 attributed to Professor Cash, but concern expressed
24 about how using transaminase testing to indicate liver
25 damage would reduce greatly the number of possible

1 donors.
2 So that's just an indication of some early
3 knowledge of Professor Cash in the 1970s and beginning
4 of the 1980s directly and closely involved with
5 discussions and deliberations about the risks of
6 hepatitis from blood and consideration of measures
7 that could be taken or would not be taken to address
8 those risks. I'm going to pick up questions in
9 relation to hepatitis C testing in much more detail at
10 a later stage.
11 If we just then turn to Professor Cash's
12 knowledge of and involvement in matters relating to
13 HIV, we've already looked at his attendance at the
14 meeting in January 1983, in which he drew attention to
15 articles concerning AIDS in The Observer, in The
16 Lancet and to the December 1982 MMWR, so I won't go
17 back to that.
18 If we pick matters up, there's then a meeting in
19 March 1983 at PRSE0000728. The date of this meeting
20 is 22 March. It's a meeting of haemophilia and blood
21 transfusion -- sorry of the Haemophilia and Blood
22 Transfusion Working Group, and we can see Dr Cash
23 there participating. If we go to the bottom of the
24 second page, we see the heading "AIDS":
25 "Members were reminded of the recent articles

1 both at home and abroad about AIDS. Dr Ludlam
2 reported that in the UK a letter and questionnaire had
3 been sent out to haemophilia directors. AIDS was
4 an emotive issue in the [US] and Canada, and was
5 causing a move away from factor VIII concentrate to
6 the use of cryoprecipitate, with resultant supply
7 problems."
8 We looked at this, I think, possibly during
9 Dr Ludlam's evidence but certainly at an earlier
10 stage.
11 "There was concern that AIDS might appear in the
12 UK, and the Haemophilia Society was attempting to
13 reassure its members and put fears of infection from
14 blood products into perspective."
15 Top of the next page then picks up the position
16 from the perspective of the Transfusion Service:
17 "The Transfusion Directors were loath to ask
18 questions to which exception could be taken by
19 potential donors but it was hoped that homosexuals and
20 others at risk might be discouraged from being blood
21 donors. In the meantime the Transfusion Directors
22 were considering how best to ensure the safety of the
23 plasma supply", and then reference to a study by
24 Dr Forbes of immunological status.
25 So that's the position as at March 1983. By then

1 we then just perhaps turn to Professor Cash's
2 statement on the issue of AIDS to the Penrose Inquiry,
3 which is PRSE0004252. PRSE0004252, no?
4 I want to spend some time on this so, having
5 regard to the time, perhaps we can sort that out over
6 lunch and then I can come back to it a 2 o'clock.
7 **SIR BRIAN LANGSTAFF:** Yes, we'll take a break until
8 2 o'clock. 2 o'clock.
9 **(12.57 pm)**
10 **(Luncheon Adjournment)**
11 **(2.00 pm)**
12 **(Proceedings delayed)**
13 **(2.14 pm)**
14 **MS RICHARDS:** Sir, with apologies for the delay, we needed
15 to try and sort out the availability of some documents
16 for display in the hearing room, and the first
17 document is PRSE0004252.
18 This is one of Professor Cash's statements to
19 the Penrose Inquiry, and this is concerned with
20 knowledge of and involvement in issues relating to
21 AIDS and HIV, in particular in 1983.
22 If we go to the second page, bottom of the page,
23 the passage in bold print, number (2), actually
24 pre-dates the issue of AIDS by a number of years but
25 is worth looking at, Professor Cash says:

1 "... as I recall, the first public warning in
2 the UK concerning the potential dangers of commercial
3 concentrates came from the SNBTS ..."
4 He refers to the BMJ Article in January 1976:
5 "I quote: 'There is no doubt that the import
6 into the UK of Factor VIII concentrates derived from
7 external sources, however well screened for viruses,
8 represents an unequivocal pathway by which the level
9 of a potential lethal virus into the whole community
10 is being deliberately increased'."
11 That's what we looked at earlier.
12 **SIR BRIAN LANGSTAFF:** So he is quoting himself?
13 **MS RICHARDS:** He is quoting himself, yes. He then refers
14 to what he says were "similar SNBTS exhortations" at
15 a later stage.
16 **SIR BRIAN LANGSTAFF:** He is claiming to be the first
17 public warning when one might have thought that just
18 a few days before there had been the public warning
19 given by Granada.
20 **MS RICHARDS:** Well, quite. Yes, sir.
21 **SIR BRIAN LANGSTAFF:** There we are.
22 **MS RICHARDS:** He then, top of the next page, deals with
23 the meeting in January 1983, which we've looked at,
24 and says this:
25 "I believe it may be relevant to emphasise that

1 it was myself, on behalf of the SNBTS Directors, who
2 ensured that the topic of HIV/AIDS was discussed at
3 the joint meeting with the SHS HCDs on
4 21 January 1983. I'm quite certain that the Minute
5 note of this item ... does not reflect the extent of
6 the discussions which took place nor the sense of dark
7 foreboding, which was further expressed in June 1983
8 at the SNBTS factor VIII safety sub-committee."
9 So there is, as it were, an amplification about
10 the mood of the meeting, which obviously one doesn't
11 get from the bare words of the minutes.
12 **SIR BRIAN LANGSTAFF:** Difficult to see actually how
13 a minute note on 21 January could reflect a sense of
14 dark foreboding six months later.
15 **MS RICHARDS:** Well, I think he is suggesting -- as I read
16 it, he was suggesting there was already a sense of
17 dark foreboding at that January 1983 meeting, in other
18 words --
19 **SIR BRIAN LANGSTAFF:** It must be what he means, because
20 otherwise it wouldn't make sense.
21 **MS RICHARDS:** Yes. In other words, a sense that there was
22 something very, very problematic, very serious, here
23 indeed, and that then found further expression at the
24 meeting later that year, is how I've read that
25 passage. But it is what it is.

1 **SIR BRIAN LANGSTAFF:** Was Dr Hann at that meeting by any
2 chance?
3 **MS RICHARDS:** The 21 January meeting?
4 **SIR BRIAN LANGSTAFF:** Yes.
5 **MS RICHARDS:** Let me double-check. It's PRSE0001736.
6 No, he was not.
7 **SIR BRIAN LANGSTAFF:** Yes, thanks.
8 **MS RICHARDS:** If we just go back and look briefly at those
9 minutes in light of Professor Cash's observations.
10 The attendees are there listed, so we have Dr Bell
11 from SHHD, we have Dr Cash, and then we have various
12 Haemophilia Centre Directors. So we've got, for
13 example, Dr Forbes and Dr Ludlam. We've got Regional
14 Transfusion Director representatives, for example,
15 Dr Brookes, Dr Mitchell, Dr McClelland. We've got
16 Mr Watt of the PFC. So not, at that stage, Dr Hann.
17 Then the passage that we looked at and which
18 Professor Cash is then commenting on is at page 7
19 where -- so it's 6(a), where it refers to drawing
20 attention to recent articles and Dr Ludlam referring
21 to what was being done in the UK.
22 So, as I read it, Professor Cash is saying that
23 doesn't capture, unsurprisingly perhaps in a set of
24 minutes, the real mood of the meeting.
25 **SIR BRIAN LANGSTAFF:** If you would just go back for

1 a moment to 4252, that's PRSE0004252.
2 **MS RICHARDS:** Page 3.
3 **SIR BRIAN LANGSTAFF:** I think we may find there the answer
4 to my own question in the opening words of
5 paragraph 4. Just as we left the screen I noticed
6 that.
7 **MS RICHARDS:** Yes.
8 **SIR BRIAN LANGSTAFF:** That makes it clear what he meant.
9 **MS RICHARDS:** It does. It does.
10 "It should also be added that this dark
11 foreboding in January 1983 must have been shared by
12 the UK HC clinical teams."
13 Then if we go further down this page to
14 paragraph 6, he says this:
15 "During the preparation for the joint meeting on
16 13 January 1983 ..."
17 I think that must be 21 January but I don't
18 think it matters one way or another.
19 "... I had asked Dr AE Bell (the meeting
20 Chairman) whether the CMO (Scotland) might be prepared
21 to issue a letter to Health Boards, prescribing
22 physicians and patient interests groups, drawing
23 attention to the increased risk of virus infections in
24 patients receiving commercial plasma products and
25 advising that whenever possible the safer SNBTS

1 products should be preferred. I should add that
2 I don't take much credit for generating this proposal;
3 it emerged as a consequence of my contact with
4 European colleagues who were advising their
5 governments in a consultation process by the Council
6 of Europe Committee of Ministers on the prevention of
7 the possible transmission of AIDS from affected blood
8 donors to patients received blood or blood products.
9 Dr Bell requested my proposal was not included in the
10 meeting briefing paper, but advised he would discuss
11 it with the CMO (Dr John Reid).
12 "(7. By the time the meeting took place on
13 13 January 1983 Dr Bell had not yet spoken to the CMO
14 but during the meeting he commented thus: 'The
15 Chairman stressed that .... in terms of
16 national policy the purchase of commercial products
17 should be avoided so far as possible'...
18 "(8. Some weeks later Dr Bell advised me that
19 he had spoken to the CMO and my proposal did not enjoy
20 the CMO's support."
21 So evidence there that at the outset of
22 January 1983 there was a specific proposal put forward
23 to the Scottish Chief Medical Officer for sending some
24 form of guidance or letter within Scotland which was
25 rejected. That's what Professor Cash is saying.

1 He then continues as follows:
2 "(9. In the early summer of 1983 I put my
3 proposal to the CMO in his office. By that time I was
4 able to remind the CMO that the Council of Europe
5 Committee of Ministers had adopted
6 recommendations ..."
7 Those are the recommendations we have looked at
8 now on multiple occasions, sir.
9 "... which included a recommendation of
10 governments to 'inform attending physicians and
11 selected recipients, such as haemophiliacs, of the
12 potential hazards of haemotherapy and the
13 possibilities of minimising these risks'. Dr Reid
14 advised that my proposal would not enjoy the support
15 of DHSS and was therefore unacceptable to him and his
16 administrative colleagues. I have to confess this was
17 one of the darkest days of my tenure as [National
18 Medical Director] and contributed greatly to
19 subsequent events, which included my resignation as
20 SHHD Adviser in blood transfusion. There followed
21 a number of acrimonious and distressing exchanges on
22 this topic which went on until 5 September 1987 on the
23 occasion of the Annual Scientific Meeting of the
24 British Blood Transfusion Society meeting in
25 Stirling."

1 I don't, sir, I am afraid, have details of what
2 happened at that latter meeting in 1987.
3 Those are Professor Cash's recollections of
4 interactions either directly with or the CMO or with
5 the CMO through the intervention of Dr Bell.
6 The other issue dealt with in this statement is
7 the question of Dr Spence Galbraith's 9 May 1983
8 letter. Professor Cash was asked about that. If we
9 go to the next page, we can see there's a reference in
10 the third paragraph. It says:
11 "Dr Galbraith of the [PHLS] specifically
12 recommended on 9 May 1983 that blood products from the
13 USA should cease to be used ..."
14 This is part of the question to Dr Cash, this is
15 not his answer. Then there's a quote from the letter,
16 and then the question continues:
17 "There must have been knowledge in Scotland of
18 this recommendation from Dr Galbraith. It was
19 referred to the English Directors meeting of
20 18 May 1983, which was attended by
21 Dr Ruthven Mitchell. He prepared a note of the
22 meeting ... which must have been circulated within
23 SNBTS."
24 That is an issue we will need to pick up on
25 later occasions.

"Presumably it was sent to Dr Cash whose apologies were tendered at the meeting?"

Then the question was posed:

"Was there every any thinking along these lines in Scotland?"

If we go further down the page to the bold and underlined answer, Professor Cash says this:

"I regret I am unable to recall whether we discussed Dr Galbraith's proposal (contained in a letter to DHSS, dated 9 May 1983) to ban the importation of all commercial factor concentrates from the USA. I have been advised that there is no evidence available (from records of SNBTS Directors' Meetings) which demonstrates that either I and/or the SNBTS Directors were ever briefed by either Dr Gunson or SHHD officials on Dr Galbraith's proposals. Dr Mitchell's note ... makes no mention of Dr Galbraith or the impending deliberations of the CSM subcommittee."

So that's Professor Cash's recollection in relation to the Galbraith letter and you will recall, sir, from the evidence we've heard from haemophilia clinicians that that's a recollection shared by the majority of haemophilia clinicians, that they too were unaware of this recommendation.

If we then just turn finally in this document to page 9, I think it is, Soumik, and -- sorry, let me pick it up at the bottom of the previous page, so we can see the question which Professor Cash is answering. So bottom of the page, the question is this:

"By the early part of 1984 there appears to have been caution in Scotland in relation to the use of commercial products from abroad. But 'small amounts' of commercial products were still purchased. Why was this necessary? We also need to ascertain what happened in practice re the use of heated concentrates in Scotland in 1984. When were physicians able to begin using heat treated commercial concentrate?"

That's the question. Professor Cash's first response is to suggest that the questions are also directed to the relevant clinicians. Then he says this:

"From an SNBTS perspective there appeared, at this time, to be a major concern throughout UK Haemophilia Centres that, despite all the political exhortations supporting clinical freedom, at some time in the future the Haemophilia Centre Directors might be forced by government to rely exclusively on NHS products. For those clinicians who had practised in

the early 1970s this perceived threat was a cause of considerable concern. NHS products were viewed by many HCDs as intrinsically unreliable, both in terms of supply and quality of product. Moreover, unlike their commercial counterparts, NHS products were manufactured under the aegis of Crown Immunity which was viewed in some clinical quarters as an opportunity for interior manufacturing practices.

"Hence, I believed that even in Scotland, there was a view that it was unwise, to rely too heavily on an NHS supply monopoly but rather to retain some sort of the market place."

Then paragraph 5:

"I had reason to believe that this view (*floreat res* market place) enjoyed the support of some Health Board officials in Edinburgh and Glasgow and officials in SHHD, notably the Chief Pharmaceutical Officer (Dr Graham Calder). It follows that the notion that the continued importation in to Scotland of commercial coagulation factor concentrates in the early 1980s was solely promoted by the SHS [so Scottish Health Service] Haemophilia Centre Directors under the guise of clinical freedom is, in my view, simplistic and misleading. It was part of what was viewed as an emerging government inspired NHS market place

culture."

So those are Professor Cash's reflections upon what he thought might have been some of the thinking of others both within haemophilia centres and within the Scottish Health Boards and Scottish Home and Health Department.

If we pick up then issues relating to developments on AIDS by reference to the contemporaneous documents, PRSE0003911, please. This was a letter from Professor Cash to Dr Bell of the Scottish Home and Health Department, 15 February 1984. It refers to a meeting of the SNBTS earlier that month, and he then says:

"I have been interested to convey to the Department the views of SNBTS Directors on this matter. They can be summarised as follows:

"1. That there should be formed a single UK group responsible to the Departments of Health for co-ordinating research in the area covering the interface between blood transfusion and AIDS. This group should have representatives of existing smaller groups already in existence -- haematologists and haemophilia centre directors and of the SNBTS Directors."

Then he identifies what he says are the major

areas requiring attention:
"Prospective study on homosexual males and a control blood donor population.
"Prospective clinical study to determine value of existing tests in transmitting AIDS. [And then]
"Studying on autotransfusion, small pool factor VIII and physically treated factor VIII."
Sir, that's the position being conveyed to Dr Bell as at February 1984.
The next key development in 1984, as regards developing knowledge of what was happening in relation to AIDS was, of course, the discovery that a number of patients had been infected or were testing positive for HTLV-III, having been treated with PFC product and, obviously, we've explored that issue with Professor Ludlam in the course of his oral evidence.
If we just pick up Professor Cash's own involvement, and I'm not going to go through the full history, but we can see his involvement at PRSE0000828. This is a memo from Dr McClelland of SNBTS to Dr Perry copied to Professor Cash. It's dated 20 November 1984 and it's concerned with events leading up to the recall of Factor VIII batch 023110090.
We can see paragraph 1 records Dr Ludlam

telephoning Dr McClelland to inform him that six of his patients had developed antibodies to HTLV-III. That was the evening of 26 October. We can then see that that was notified almost immediately to Professor Cash.
Paragraph 2 that tells us that Dr McClelland contacted Professor Cash on 27 October, the following morning, and discussed this information with him:
"We were both agreed [so that's McClelland and Cash] that the information was insufficient to require any recall of PFC products."
There's then reference to discussion between Dr Ludlam and Dr Boulton in paragraph 3, and we'll be hearing from Dr Boulton in the next few weeks when he gives oral evidence.
Then we can see from the end of paragraph 3 that it was again concluded that the data did not at this time justify a formal recall of any batch. There's then reference to further information being provided by Dr Ludlam to Dr McClelland on 2 November, 15 or 16 patients having received this particular batch, and then we can see the recall decision communicated and described in paragraph 5. The date of 3 October is obviously wrong -- 3 November:
"... Dr Boulton and I personally contacted all

the Scottish Transfusion Centres and the Northern Ireland Transfusion Centre and informed a senior member of staff that the above batch should be immediately recalled."
So Dr Cash had some involvement. Whether he had involvement in the subsequent discussions that are recorded is not clear but he appears to have been party to the initial decision not to recall the PFC products on 27 October.
I'm not proposing to go to it but there is a letter from Dr McClelland to Dr Cash on 15 November 1984. The reference for the transcript is LOTH0000005_052, which sets out the position as at that date.
There is then a meeting of the SNBTS on 11 December, chaired by Professor Cash, PRSE0001767. You will see the list of attendees there and that Professor Cash was in the chair. If we go, first of all, to page 4, we can pick up the narrative in relation to that particular batch in the third paragraph on the page, headed "Factor VIII batch ... 023110090":
"Dr Cash recalled the decision taken at the Co-ordinating Group meeting on 20 November to quarantine the plasma from subsequent donations by

donors who had contributed to the suspect pool and to discard the red cells, platelets et cetera. It had transpired that discarding cells would cause considerable shortage in some Regions, particularly over Christmas and New Year and it had therefore been relaxed: the final decision on the matter would lie with individual Directors."
So that would suggest a modification of the original decision which was to discard everything prepared from donations by donors who contributed to the suspect pool and that was modified in relation to red cells because of shortages or potential shortages in some regions, and it was said that that would be a matter for individual director discretion.
It then says:
"All the plasma had been identified and notified to the Transfusion Centres who would continue to keep the donor samples", and there is further discussion in relation to that.
This letter also records Dr Cash's view about the need for a co-ordinated UK approach to transfusion and AIDS and we can pick that up at the bottom of the previous page, bottom of page 3, last two paragraphs there's reference there to the advice of the advisory committee on dangerous pathogens, which again we've

1 looked at in earlier hearings. Then the last
2 paragraph reads:
3 "Dr Cash said he would make further
4 representations to the SHHD that there should be
5 a more effectively co-ordinated UK approach to
6 transfusion and AIDS. This had already been
7 recommended by the Scottish Directors. The Directors
8 noted with regret that a second meeting of this
9 Working Group on AIDS had not been arranged", and if
10 we go then to the top of the next page, it's not
11 entirely easy to read, but it looks like:
12 "... and ... there appeared to be no evidence of
13 co-ordination of the many splinter groups which
14 existed."
15 There is also discussion in this meeting of
16 circulation of the AIDS leaflet but I will come on to
17 the issue of the AIDS leaflet later in the course of
18 the afternoon.
19 So that's 11 December 1984. I can't recall
20 without checking whether Professor Cash had been
21 present at the meeting at BPL on 10 December 1984 but
22 he certainly contributed to the UKHCDO AIDS advisory
23 document that was pulled together after that meeting.
24 We can see that from HCDO0000270_007, again we've
25 looked at this on multiple occasions, "AIDS Advisory

1 Document":
2 "At a recent meeting of Reference Centre
3 Directors [that's 10 December meeting at Elstree] the
4 following observations were discussed and
5 recommendations made in consultation with Drs Richard
6 Lane, John Cash, Harold Gunson, Phillip Mortimer,
7 Richard Tedder, John Craske and others."
8 Just to pick up the picture in relation to
9 Scotland, over the page, top of the page records the
10 probability that:
11 "... HTLV III has been incorporated into at
12 least one BPL and one Scottish batch of factor VIII."
13 Then further down the page, just around halfway
14 down, there's a heading "Edinburgh", which records:
15 "From now on all Scottish factor VIII will be
16 dry heated to supply Scotland and [Northern] Ireland."
17 If we then just pick matters up in January 1984
18 with PRSE0004386, we see perhaps a characteristically
19 trenchant letter from Professor Cash to Dr Bell at the
20 Scottish Home and Health Department, 24 January. The
21 first paragraph:
22 "The inevitable delay in my discussion with the
23 Chief Medical Officer means that there may be the
24 occasional topic which I must draw to the attention of
25 Departmental colleagues earlier than I had

1 anticipated. The matter to which I refer below arises
2 as a result of recent meetings of both the SNBTS and
3 NBTS Directors."
4 Then he picks up on the issue of what was
5 happening in terms of introducing testing for
6 donations, blood donations, for HTLV-III.
7 So he says:
8 "I have been seriously concerned by reports I
9 have received from those who attended the meeting of
10 the Working Group on AIDS 'to consider the
11 implications for the National Blood Transfusion
12 Service of testing blood donations for antibody to
13 HTLV-III'. This meeting, from the stand-point of
14 those left with the actual responsibility of running
15 the UK Transfusion Services, was wholly inadequate.
16 None of the really important matters which will affect
17 policy were appropriately discussed and more
18 importantly no arrangements were made for the creation
19 of sub-groups to examine some of the many major
20 problems, nor even was a date set for any further
21 meeting. The SNBTS (Director) representative, the
22 Chairman of the NBTS Directors' meeting and the DHSS
23 Adviser on Blood Transfusion have all reported to me
24 that they 'remain completely in the dark'."
25 The next paragraph --

1 **SIR BRIAN LANGSTAFF:** That's a reference, is it, to
2 a meeting which took place in November 1984?
3 **MS RICHARDS:** Yes, I think that's right, sir. I don't
4 think it can be -- it's not a reference to the meeting
5 of the expert advisory group on AIDS, which was
6 January 1985 --
7 **SIR BRIAN LANGSTAFF:** I think it's --
8 **MS RICHARDS:** -- so I think it must be a reference to the
9 November '84 meeting, yes.
10 **SIR BRIAN LANGSTAFF:** That would be 20 November, is it, am
11 I right? Or 24th, I can't remember.
12 **MS RICHARDS:** That sounds right but I'm afraid, without
13 checking, I can't recall.
14 **SIR BRIAN LANGSTAFF:** Some time around then anyway. And
15 I think the note of the meeting begins with the fact
16 that there was unanimous view that testing should be
17 urgently introduced.
18 **MS RICHARDS:** Yes. I'm just -- I'm not sure whether we've
19 got the meeting available to display.
20 **SIR BRIAN LANGSTAFF:** I'm afraid I haven't got my notes of
21 references with me, so I can't simply give it to you.
22 **MS RICHARDS:** Sorry, let me just check, sir, whether we
23 have it available this afternoon. If not, I can check
24 overnight. There's a meeting on 8 November but
25 I don't think it's that. 27 November.

1 **SIR BRIAN LANGSTAFF:** 27th.
2 **MS RICHARDS:** But I -- according to the minutes of
3 a meeting that took place on 8 November. So the
4 advisory committee on the NBTS met on 8 November '84.
5 I have got that available today. But it says that
6 screening was one of the points to be considered by
7 the working group on 27 November.
8 **SIR BRIAN LANGSTAFF:** So that will be this meeting?
9 **MS RICHARDS:** I'm fairly sure that's right, sir. We'll
10 have it available for tomorrow so that we can
11 double-check.
12 So then Professor Cash continues by saying:
13 "At a meeting of the SNBTS directors on
14 7th February 1984 (11 months ago) the whole question
15 of AIDS and the Transfusion Services was discussed,
16 after the Directors had studied a report prepared by
17 Dr McClelland at their request. It was concluded that
18 it would be inappropriate for the SNBTS to
19 'go it alone' and there was an urgent need for this
20 topic to be taken up as a UK (Joint Departmental)
21 matter. I was asked to convey this conclusion to the
22 SHHD as soon as possible. I did so in a letter to you
23 dated 15th February, 1984. I know not whether these
24 views were transmitted to the DHSS.
25 "Some 9 months later a meeting was organised by

1 DHSS. It was not a Joint Departmental one -- the
2 Scots were there as observers (the SHHD representative
3 had no experience in transfusion matters) -- and there
4 seems little doubt that it was, as far as we can judge
5 at the present time, a waste of public money."
6 Over the page:
7 "Two months after this Working Group meeting the
8 DHSS Adviser in Blood Transfusion ..."
9 Which is presumably a reference to Dr Gunson.
10 "... found himself unable to answer vital
11 questions put to him by the NBTS Directors (meeting in
12 Manchester, 23rd January, 1985) and could say no more
13 than he believed the Chairman of the Working Group
14 would be reporting back at the next meeting of the
15 parent Committee (DHSS NBTS Advisory Committee) -- on
16 May 23rd, 1985. The DHSS Adviser was, however, able
17 to report that the DHSS was 'about to release' the new
18 AIDS leaflet for blood donors with recommendations on
19 the ways they should be distributed, which would not
20 be binding."
21 I'm not sure that that is actually a reference
22 to Dr Gunson. I will check the minutes again, sir.
23 Then it says:
24 "The NBTS Directors then moved on to the topic
25 of HTLV-III antibody testing. Richard Lane and

1 Harold Gunson described the fiasco which emerged at
2 DHSS on 27th November. Richard further described more
3 recent events and announced that the CBLA had now
4 written to the DHSS conveying its serious disquiet
5 that CBLA was deliberately excluded from a 'secret'
6 meeting between DHSS officials, Professor Weiss,
7 Dr Tedder and Wellcome Diagnostics. The assembled
8 Directors listened to this in dismay and bemusement.
9 The DHSS Adviser insisted that he had not been
10 involved in development!"
11 Then there is a reference to antibody testing
12 kits. So:
13 "Finally, news was brought to the NBTS Directors
14 that at least 3 foreign companies were actively
15 involved in establishing 'proving trials' for their
16 HTLV-III antibody kits in UK Transfusion Centres. The
17 purpose of these exercises is to provide data for FDA
18 licences. Once these licences are released the
19 floodgates would open. The American companies wished
20 to have the UK data by 31st March. Some present NBTS
21 Directors expressed the view, which Brian McClelland
22 and I share following information we have received
23 from the US, that licences will be granted despite
24 a possible 10-15% incidence of false positives. All
25 these would require sophisticated (Western Blot) check

1 tests and the problems created in the donor programmes
2 would be significant, to say the least."
3 He refers to a publication in The Lancet.
4 Then it goes back to some of the generic issues
5 about co-ordination or lack of it.
6 Three lines down into that paragraph:
7 "After all this time ... it is with dismay that
8 I must conclude that there are just no mechanisms in
9 the UK for these crucially important topics to be
10 discussed, openly and confidentially ..."
11 Not quite sure what is meant by "openly and
12 confidentially".
13 **SIR BRIAN LANGSTAFF:** I think he means the two separate
14 processes, part of it's open, part of it's
15 confidential.
16 **MS RICHARDS:** Maybe.
17 "... and for clear, co-ordinated policies to
18 emerge. The biggest anxiety of the NBTS Directors
19 with regard to this problem is the Scots: that they
20 will unilaterally move to come in line with the
21 American proposals. They're right: we are in detailed
22 discussion with commercial (kit) companies, our
23 technical staff are already looking at ways of
24 introducing the technology within existing staff
25 establishments, we have the Western Blot technique (HQ

1 and SE Labs), we are already liaising with local
2 (Communicable Disease) physicians with a view to
3 securing care for our positive donors and we are
4 currently arranging our financial planning
5 accordingly. I advised the NBTS Directors that we
6 would do everything possible to avoid such
7 a development. They were not impressed and cited our
8 unilateral introduction of RIA HBs-Ag testing; the
9 issue of heat treated factor VIII and our new AIDS
10 donor leaflet. I had much sympathy with them for I am
11 bound to reflect that 'everything possible' isn't much
12 when we're dealing with an non-existent management
13 structure of a fragmented organisation led by the
14 Department of Health which, as far as I can see, in
15 terms of this aspect of the NHS, is lost and
16 floundering in an increasingly high profile.
17 "I write, therefore, once again to request that
18 the SHHD pursues this matter into the UK arena. I'm
19 doing my best to contain matters with my professional
20 colleagues (the NBTS Directors have agreed to hold an
21 extra meeting on 18 February, 1985). Judging from the
22 discussions in Manchester there is very likely to be
23 a call to see the Minister, a view which I would, at
24 present time, support. The Minister is on record that
25 all the AIDS work in the UK is being funded and

1 directed by the MRC. When asked what direct
2 contribution the DHSS was making he directed the
3 interviewer's attention to the money being invested in
4 Elstree. I'm afraid that is just not good enough."
5 So a number of issues being traversed there,
6 a number of opinions being expressed, and they, of
7 course, Professor Cash's perspective, expressed, as
8 I said, in what appear to be quite characteristically
9 strong terms. We may need to unpick some of the
10 issues in relation in particular to meetings in due
11 course.
12 But instructive at least to see what
13 Professor Cash's concerns were about a lack of
14 strategy or co-ordination in relation to response to
15 the unfolding AIDS situation.
16 On 29 January, so a few days after this letter,
17 Professor Cash attended the first Expert Advisory
18 Group on AIDS meeting. I'm not proposing to go to
19 that. Again, we've looked at it before and we will no
20 doubt look at it again. PRSE0002734 for the
21 transcript.
22 Now, some of the issues in relation to HIV
23 testing I'll pick up shortly. I just want to turn to
24 what might be loosely termed responses to risk or
25 measures that might reduce risk, and deal with a range

1 of different topics here, which will include
2 HIV screening, include donor selection and the issue
3 of the AIDS leaflet.
4 Before I deal with those issues, I just want to
5 go back to an article I've referred to but not taken
6 you to, which was Professor Cash's article in the BMJ
7 in 1976, September of 1976, at PRSE0003425.
8 The relevance for present purposes of showing
9 you this article is obviously one of the measures for
10 responding to the unfolding AIDS crisis that might
11 have been greater use of cryoprecipitate. This is an
12 early article in which Professor Cash -- Dr Cash as he
13 then was -- together with Mary Spencely discuss
14 various matters relating to cryoprecipitate, and also
15 forewarn that there may be increased reliance upon
16 commercial products.
17 We can see that from the second paragraph in the
18 summary, on the left-hand side, where they say:
19 "Although cryoprecipitate is much harder to
20 store and administer than AHF its yield from plasma
21 maybe far greater and its cost far smaller. Unless
22 the blood transfusion services receive increased
23 amounts of money and reappraise their functions and
24 operation, it seems likely that they will have to rely
25 increasingly on commercial (and costly) sources for

1 the major plasma fractions."
2 There's then a discussion about production on
3 the right-hand side under the heading "Methods", where
4 they describe patients with haemophilia having been
5 managed with various products, including fresh frozen
6 plasma, cryoprecipitate and anti-haemophilic fraction.
7 The last sentence of that paragraph explains that the
8 fresh frozen plasma and cryoprecipitate are prepared
9 in the Regional Transfusion Centre, whereas AHF is
10 produced by the Protein Fractionation Centre in
11 Edinburgh.
12 Then if we go over the page, on the right-hand
13 side, under the heading "Concentrate Specifications",
14 there's a fairly detailed discussion about the
15 production of factor concentrates and the production
16 of cryoprecipitate. If we pick it up in the third
17 paragraph, he says:
18 "We recognise that the preparation of
19 cryoprecipitate with an average 60% yield may be
20 unusual ..."
21 He sets that out in more detail in the paragraph
22 above.
23 "... but this can be achieved providing the
24 centre's staff regard it as a high priority and
25 appreciate that it is extremely cost effective."

1 Then he refers to the average Factor VIII
2 concentrate of single-donation cryoprecipitate.
3 Then a few lines down he says this:
4 "We appreciate that many colleagues in
5 haemophilia centres consider that the modern
6 developments surrounding on-demand treatment, in
7 particular its implementation in the home, make the
8 ready availability of AHF essential. Although we
9 recognise that ideally such a policy is admirable,
10 enough evidence shows that cryoprecipitate can be used
11 successfully for home treatment. Should this be
12 wholly unacceptable for certain patients then recourse
13 to hospitals and health centres, peripheral to the
14 regional haemophilia centres, may prove satisfactory
15 temporary alternatives."
16 If we go to the next page and pick it up in the
17 top right-hand column, third line:
18 "In the meantime the blood transfusion services
19 ought to look towards improving the quality of
20 cryoprecipitate production and procedures for the
21 procuring of bulk fresh plasma."
22 Then if we could just look at the list of
23 references, the source references for the statement
24 that the evidence shows that cryoprecipitate can be
25 used successfully for home treatment are footnotes 9

1 to 12, and we'll ensure that we track down, if we
2 don't have already have them, each of those, sir.
3 Because obviously the potential use of cryoprecipitate
4 for home treatment's an important issue for the
5 Inquiry.
6 Sir, we've looked at a number of other
7 developments under the broad heading of
8 self-sufficiency in relation to what was actually
9 happening in terms of cryoprecipitate use in Scotland
10 so I won't go back to those, but there are some early
11 thoughts from Professor Cash in relation to use of
12 cryo.
13 I want to come next, then, under this broad
14 heading of measures to reduce or respond to risk, to
15 the question of high-risk donations and, in
16 particular, collection from prisons and borstals.
17 We can start by looking at PRSE0000193, minutes
18 of the directors' meeting in SNBTS headquarters,
19 29 March 1983. We see that Professor Cash was in the
20 chair.
21 If we turn to page 5, paragraph 7:
22 "Blood collection in prisons and borstals
23 "Dr Cash reported that the Medicines Inspector
24 had commented adversely on the practice of collecting
25 blood in prisons and borstal institutions, and he

1 invited Directors to comment on the practices in each
2 region and to give their views on the Medicine
3 Inspector's criticism.
4 "It was reported by all directors present that
5 sessions were held in penal institutions in all
6 regions, although Dr Brookes and Dr Urbaniak intended
7 to review the situation in their regions.
8 "It was not possible for the Directors to agree
9 on future policy, but it was agreed that Dr Brookes,
10 as the Scottish representative, should ask the Working
11 Party on the Selection and Care of Blood Donors to
12 consider this issue. In the meantime, Dr Cash agreed
13 to inform the Medicines Inspectorate of these SNBTS
14 discussions and conclusions."
15 So you will see there a snapshot of the picture
16 as at March 1983 -- by which time, of course, AIDS is
17 very much on the agenda, and hepatitis has been on the
18 agenda for many years by this point in time -- blood
19 still being collected from prisons and borstal
20 institutions.
21 If we can then look at Professor Cash's witness
22 statement to the Penrose Inquiry on this issue.
23 PRSE0004484, please, Soumik.
24 So you will see the heading there is
25 "Prison Donations". In fact, the issue is wider than

1 prison donations that he is being asked to address, so
2 if we just go a little further down the page:
3 "Issue in respect of which a statement is sought
4 "Hepatitis C
5 "The acceptance of blood from 'higher risk'
6 donors, in particular:
7 "a) prisoners; and
8 "b) donors who had a history of jaundice, and
9 who were negative for Hepatitis B when the existence
10 of Non-A Non-B Hepatitis was known and its presence
11 could not be excluded."
12 I am going to concentrate for present purposes
13 on prison collection.
14 If we go to the next page, we pick it up at
15 paragraph 3, which is the second paragraph down, he
16 was asked when the practice of collecting blood from
17 penal institutions stopped in each region in Scotland,
18 and then he sets out the information he had been
19 provided with by SNBTS in order to answer the Penrose
20 Inquiry's question, saying this:
21 "Dr Anne Welsh (SNBTS) has kindly advised me
22 that the following dates are the occasions of the last
23 prison donors sessions: Aberdeen: 28 [July] 1983,
24 Belfast: 26 [October] 1983, Dundee: 2 [August] 1983,
25 Edinburgh: 7 [April] 1980, Glasgow: 25 [March] 1984,

1 Inverness: 24 [February] 1983."
2 Then in response to the question "Why the
3 practice stopped", he says this:
4 "It may be helpful to swear information from
5 those Regional Centre Directors ... who are still
6 alive. But it can be assumed that it had much to do
7 with the comments of the MCA Inspectors [we saw
8 reference to that in the minutes of the meeting we
9 looked at] (though this issue was not raised at the
10 Glasgow, Inverness, Aberdeen or Northern Ireland
11 inspections); the lively/heated discussions of the
12 Directors at their meeting on 29 March 1983, [that's
13 what we were just looking at], when no consensus was
14 achieved; and subsequent regional reflections on ways
15 of sustaining supplies without prison sessions. What
16 is more certain, however, is that these dates do not
17 derive from a national (SNBTS Directors) management
18 decision because such decisions required consensus or
19 an instruction from SHHD; neither was forthcoming.
20 What we did do, as did the MCS Inspectors, was seek
21 guidance from DHSS. None came.
22 "My father was a prison chaplain and on several
23 occasions I visited HM Armley Prison. I judged the
24 health of many paid donors seen by me in 1969 in
25 plasma collection centres in Los Angeles was much

1 worse than that of inmates of Leeds HM prison in 1983.
2 As I recall the problem of drug addiction in UK
3 prisons in 1983 was not the problem it is now.
4 "Whilst arguably not relevant, it may be worth
5 pointing out that MCA Inspectors did not seek to
6 impose a ban on prison donors used by commercial
7 plasma collection agencies in the US which supplied
8 plasma for coagulation factor concentrates ... for the
9 UK. It is my understanding that prison donors were
10 not excluded in the US until 1990 ..."
11 Then in paragraph 5 he is asked about what
12 consideration was given between 1975 and 1984 by SNBTS
13 as to whether there was a higher risk of hepatitis and
14 whether the practice of collecting blood from penal
15 institutions should continue, and his answer is:
16 "As far as I can recall, this topic was not
17 discussed by the SNBTS Directors until the matter was
18 raised by the Medicines Inspector in 1982.
19 Furthermore, to the best of my recollection, the news
20 on 29 March 1983 that Edinburgh had abandoned prison
21 donor session in 1980 came as a complete surprise to
22 me and all other SNBTS Directors."
23 The cessation of prison donor sessions in
24 Edinburgh in 1980 isn't actually what is recorded in
25 the minutes but it is the information that was

1 supplied to Professor Cash by SNBTS for the purpose of
2 making this statement.
3 **SIR BRIAN LANGSTAFF:** Yes, it's doubly surprising,
4 possibly, that he wouldn't have heard of it, because
5 he had stopped being the director of the Edinburgh and
6 South East Scotland Blood Service in 1979.
7 **MS RICHARDS:** Yes.
8 **SIR BRIAN LANGSTAFF:** So you would have expected perhaps
9 that there may have been -- remained contact between
10 him and it.
11 **MS RICHARDS:** Yes, perhaps, and it may be that we'll be
12 able to obtain information about that from oral
13 witnesses or, indeed, from other documents but, in any
14 event, what he appears to be saying is that
15 an enhanced risk of hepatitis from prisons and
16 consequent suggestion that one might stop taking
17 prison donations, doesn't seem to have been on the
18 SNBTS agenda until the issue was expressly raised by
19 the Medicines Inspectorate with them, in the course of
20 inspections of some of the centres in 1982, which then
21 led to the meeting -- or, sorry, which led to the
22 discussion at the meeting in March 1983 that we've
23 looked at, following which, over the next few months,
24 the various centres appear then to have stopped prison
25 collections in Scotland.

1 He then is asked whether the cessation of the
2 practice of collecting blood from penal institutions
3 led to any difficulties in maintaining a sufficient
4 supply of blood in Scotland. He says:
5 "None that I recall but I would advise that each
6 former living Regional Centre Director should be
7 consulted. Certainly I am aware that on a number of
8 occasions after 1983 surgical procedures were
9 postponed due to blood shortages in the West of
10 Scotland. SNBTS has access to documents which will
11 confirm this. Whether these shortages had anything to
12 do with abandoning prison donor session is not known
13 to me, but it is worth pointing out that the annual
14 blood collection figures per million of population in
15 the West was significantly below all other regions in
16 Scotland throughout the 1980s."
17 Then he was asked, bottom of the page, whether
18 he was aware of evidence produced by the National
19 Blood Transfusion Service for England and Wales around
20 July 1974 that the incidence of hepatitis B in donors
21 from prisons was approximately five times greater than
22 the incidence in donations from the general public
23 and, if so, what, if anything, he did in response to
24 that. Top of the next page, he says:
25 "I cannot recall whether I was aware of this

1 evidence or the work published work from the West of
2 Scotland BTS [it doesn't entirely make grammatical
3 sense but I don't think it matters]. If it was
4 discussed by the SNBTS Directors then I would imagine
5 it ... would have been raised by Dr John Wallace (RTD
6 West of Scotland) in 1974/75 and by Dr Mitchell in
7 1981/82."
8 Then this:
9 "I must confess I do not recall having ever
10 given the matter on prison donors any consideration
11 until it was raised by the [Medicines Inspectorate] in
12 1982/3."
13 He is then asked if he:
14 "... was aware of the letter dated
15 6 January 1975 by J Garrott Allen ... to Dr William
16 Maycock ... warning of the increased risk of
17 hepatitis, including [non-A, non-B] Hepatitis, from
18 the blood of prisoners."
19 Answer:
20 "As far as I can recall, I was not aware of this
21 letter and first discovered its existence when reading
22 Douglas Starr's book in 2007."
23 The next question asks him if he was aware of
24 the letter of 1 May 1975 by Dr Yellowlees, Sir Henry
25 Yellowlees, the Chief Medical Officer for England and

1 Wales, and whether he, Professor Cash:
2 "... agreed with the advice contained in that
3 letter, ie that it was not necessary to discontinue
4 the collection of blood from prisons provided that all
5 donations were tested for hepatitis B using
6 a sensitive test."
7 His answer is:
8 "As far as I can recall, I was not aware of this
9 communication, but SNBTS may have access to copies of
10 Directors' Meetings which reveal the contrary."
11 Then bottom of the page, next question is:
12 "Why the SNBTS continued to collect blood from
13 penal institutions following the Medicines
14 Inspectorate's adverse comments on that practice in
15 March/May 1982."
16 Answer:
17 "As far as I recall there were 4 reasons: 1.
18 there was bemusement that no mention of this
19 difficulty had been in the MI reports for Aberdeen
20 Glasgow and Inverness. 2. There was a strong view
21 that this could have significant adverse effects on
22 red cell supplies at certain times of the year --
23 notably in the West. 3. Without SNBTS Directors'
24 consensus, there was no national management process
25 for considering issues related to the location of

1 blood collection sessions in the regions. Throughout
2 the UK: this issue were strictly left to the RTDs and
3 their teams and the priority was maintenance of
4 supply. This management practice and the operational
5 priorities enjoyed SHHD/DOH support. 4. There was
6 uncertainty, at the time, with regard to the *locus* of
7 the Medicines Inspectors regarding donor session
8 issues (a view shared by SHHD)."
9 Sir, should say I am proposing to look at some
10 aspects of Professor Cash's oral evidence to the
11 Penrose Inquiry but that will be tomorrow morning so
12 some of these issues are further teased out.
13 There is then a reference to, in the next
14 question, the meeting at the National Institute for
15 Biological Standards Controls on 9 February 1984,
16 where it said that Dr McClelland said that certain
17 policies had been adopted in Scotland to minimise the
18 risk of transmission of infection. Professor Cash
19 says:
20 "I have no recollection of this NIBSC meeting
21 and therefore unable to comment whether the Minute
22 accurately reflects what Dr McClelland said."
23 It may be we will be able to ask Dr McClelland
24 about this.
25 "Certainly there was no SNBTS policy in place in

1 February 1984, regarding prison blood donor sessions."
2 Then if we go to the bottom of the next page,
3 please, so bottom of page 6, this now picks up the
4 issue of donors with a history of jaundice or
5 hepatitis, and the question is posed as to:
6 "Whether the SNBTS accepted the recommendation
7 in the 2nd report of Dr Maycock's Advisory Group on
8 the Testing for the Presence of Hepatitis B Surface
9 Antigen ..."
10 You will recall from what we looked at this
11 morning that Dr Cash was part of the advisory group
12 which produced the third report but this pre-dated his
13 involvement.
14 If we go to the top of the next page, this is
15 Professor Cash's response:
16 "I do not recall this topic being discussed by
17 the SNBTS Directors in 1975 but I do recall, soon
18 after I was appointed [National Medical Director],
19 expressing my concern to Dr Ed Harris ([Deputy Chief
20 Medical Officer], London) that the criteria for the
21 selection of blood donors in the UK was left in the
22 hands of junior DHSS civil servants who had little
23 knowledge of blood transfusion practice nor were in
24 touch with international experts."
25 It's not clear precisely what Professor Cash's

point is there, I think, with all due respect. I will check whether that particular point is amplified in the oral evidence but why he forms the view that this has been left in the hands of junior DHSS civil servants is not immediately apparent.

He is asked a number of other questions which I think he's not able to give much by way of a substantive answer, so I don't think there's anything else in that statement which is likely to greatly assist you.

Just then picking up the issue then in relation to donor selection and exclusion of high-risk donors in the context of the risk of AIDS, this leads to the question of the production of the AIDS leaflet. Perhaps if we start by looking at PRSE0003620, these are the minutes of a meeting of the Blood Transfusion Service, that's the SNBTS's co-ordinating group, 24 May 1983, with Dr Cash in the chair. If we go to page 5, please, we can see the heading "AIDS" halfway down the page, the heading "Donor Selection and Communication of Donors":

"Dr Mitchell reported that he had introduced into the health questionnaire to donors a question inviting those who were worried about AIDS to consult the doctor at the session. It was understood that the

AABB's advice [that's the American Association of Blood Banks] to blood banks in the USA was that individual donors should sign a statement to the effect that they had read the literature and understood that certain groups of donors had been asked to refrain from donating."

Just pausing there, this is, as I said, May 1983. We know, in terms of what was happening with the production of an AIDS leaflet in England and Wales, was the various exchanges we've looked at with Dr Walford and the ministerial witnesses, which led to a leaflet being produced in September 1983. So just to get that sense of the parallel developments within the DHSS and the England and Wales National Blood Transfusion Service.

So we've got, as at May 1983, a different approach is being taken by regional transfusion services within Scotland, Dr Mitchell introducing the question into the health questionnaire. The next paragraph says:

"Dr Urbaniak had decided, after consideration, not to do anything locally, his view being that once a donor had entered the session it was too late to make an approach and the problem was minor in [north-east] Scotland.

"Dr McClelland had prepared a leaflet (which he tabled) which explained through questions and answers the background to the recent publicity and detailed those donors should refrain from donating blood. He intended to consult some of the organisations representing the 'gay' community through which his leaflet might be circulated. It might go also to VD clinics and possibly also to drug abuse centres."

The question of precisely what happened with the Scottish leaflets and the Scottish initiatives will be explored in more detail than I am going to attempt today with individual witnesses or through further presentations. But I just want to alight upon certain meetings and communications to which Professor Cash was party.

If we go to the bottom of the page, there's then a heading "SNBTS Publicity":

"Dr Cash sought his colleagues' agreement to the issue of a general statement to the media to the effect that until appropriate markers had been developed the SNBTS would not wish to have blood donations from certain individuals. It was reported that the Directors of England and Wales and discussed the problem at their most recent regular meeting and had decided that publicity should be both local and

national, the latter in the form of a press release plus nomination of a Press Officer from DHSS to maintain contact with the media. They had decided also to ask Dr John Barbara to draft a leaflet for the information of donors to be made available in Transfusion Centres. This leaflet was to be ready by 30 June.

"It was agreed, after discussion, that Dr Cash should contact Dr Barbara for information about the proposed leaflet after which he would arrange a meeting from colleagues from SHHD to discuss the possibility of a press statement for Scotland and the provision of information which the Transfusion Directors could use if they wished. Dr Mitchell's donor questionnaire and Dr McClelland's leaflet would be circulated and discussed at the meeting. In view of the time constraints the Directors agreed that Deputies could attend if they themselves were unavailable."

So that's how matters were discussed in May 1983. We know then that in the intervening period the leaflet produced, over which the DHSS had had some control or had some involvement, was published in September 1983. If we pick the matter up in December 1983 at PRSE0003679, we have a letter from

1 Dr McClelland to Professor Cash. As I say, in terms
2 of everything that happen in the intervening period
3 we're likely to want to explore that with individual
4 witnesses. But here is Dr McClelland writing to
5 Professor Cash in December 1983:
6 "Following our recent discussion at the
7 Directors Meeting, I thought you might like to look at
8 the enclosed."
9 Then he refers to three pieces of material. He
10 says:
11 "As you know, we haven't sent the existing AIDS
12 leaflet out to all donors until now, because we don't
13 have sufficient stock, and in any case, my own view is
14 that the wording needs to be changed a bit before we
15 send it out. As an interim measure, however, we have
16 added a specific reference to AIDS to all the donor
17 call-up letters, drawing attention to the leaflet and
18 the availability of information from the BTS.
19 "We have added specific questions and a specific
20 reference to AIDS and the availability of the leaflet
21 and further information to the questionnaire which is
22 filled in and signed by all new and repeat donors.
23 I enclose a copy of the new donor questionnaire."
24 Then, thirdly:
25 "Frank Boulton and I have personally briefed,

1 individually, all the donor medical staff on how to
2 respond to donor questions about AIDS, using the
3 enclosed briefing document. This document has also
4 been made available to all other session staff, and
5 has been written in such a way that it is also quite
6 suitable to be read by donors."
7 I'm not going to go to them now because I think
8 we probably will pick this up with Dr Boulton and/or
9 Dr McClelland in due course but the staff document,
10 for the transcript, is PRSE0001861. There is
11 a version of the questionnaire. I'm not yet confident
12 whether it is the version that is being referred to in
13 Dr McClelland's letter at PRSE0001302, and I don't, at
14 the moment, have a reference for the addition to the
15 donor call-up letters, but no doubt we can rectify
16 that between now and when these issues are explored
17 further with oral witnesses.
18 There was a further leaflet produced by SNBTS in
19 the course of 1984. Again, the precise timings and
20 changes to wording, I think, is probably best explored
21 with individual oral witnesses. We can then look at
22 a meeting on 20 November 1984 at SBTS0002210.
23 This is an SNBTS co-ordinating group meeting
24 20 November 1984, chaired by Professor Cash. If we go
25 to the next page, we see it said, under the heading

1 "AIDS: Decisions taken at co-ordinating group meeting
2 20 November 1984":
3 "Dr Cash tabled a confidential letter addressed
4 to each Director. The contents were discussed and the
5 following main points agreed:
6 "Declaration by blood donors.
7 "Each Transfusion Centre to incorporate into the
8 Health Questionnaire given to each donor at a session
9 the following words:
10 "'I have read the SNBTS AIDS leaflet (Important
11 Message to Blood Donors) and confirm that, to the best
12 of my knowledge, I am not in one of the defined
13 transfusion-related risk groups.'"
14 Then the second heading is "Distribution of
15 'Important Message to Blood Donors'", so this is the
16 distribution of the SNBTS leaflet:
17 "The text of the above must be distributed as
18 follows -- either as the leaflet which is available or
19 in another printed form:
20 "1. With call-up letter.
21 "2. At session to every donor who attends.
22 "3. To the organisers of work place and
23 college/university sessions.
24 "4. With the registration book to new donors.
25 "5. To the home address of donors who, not

1 having been called to a session, attend nevertheless.
2 This would be after donation.
3 "Overall aim of the above is that as many donors
4 possible should have seen the message before attending
5 a session. This practice would be continued until
6 further notice but would be reviewed in 12 months'
7 time or before."
8 Then "Supply of Leaflets":
9 "Each Director to find out within 24 hours how
10 many leaflets he/she needs and to contract
11 Miss Corrie.
12 "(It was subsequently established that a large
13 order could be obtained within one week)."
14 So we see that between May 1983, when the issue
15 was discussed at that meeting and matters were
16 effectively being left to the discretion of individual
17 directors as to what information they provided to
18 donors and how they approached the question of
19 high-risk donors, between then and November 1984,
20 there is a significant change in the sense that by
21 November 1984 there is a universal approach to be
22 applied to all that Scottish centres. As I say, we
23 will pick that up in more detail, no doubt with
24 individual Scottish centre directors who had some
25 involvement in this issue.

1 Sir, just two further documents, I think, on the
2 issue of AIDS donor leaflets. We have, in previous
3 hearings, focused very much and for obvious reasons on
4 the position in relation to 1983/84 through into 1985,
5 but it's interesting to note that the question of
6 whether the AIDS donor leaflet should be changed or
7 strengthened still further continued to be an issue in
8 the second half of the 1980s.
9 So we can see from CBLA0002345, and this is now
10 October 1986, and if we go to the bottom of the second
11 page we see the headings "AIDS donor leaflet" and
12 there is discussion there about whether specific risk
13 groups should be identified or not in those leaflets.
14 I am not going to read through the detail but, if we
15 go to the top of the next page, we can see there
16 discussion about what risk groups, perhaps in terms of
17 countries to which visits had been made, and so on,
18 should be referred to. Then six lines down:
19 "Dr Cash also expressed concern that the AIDS
20 leaflet was not being taken seriously and supported
21 this with evidence of his own experience as a donor
22 recently. He said that Directors in Scotland were
23 considering sending a health check letter with every
24 call-up which would incorporate the details in the
25 AIDS leaflet."

1 So that's the position in 1986 and even into
2 1989 and 1990 there are further discussions about
3 improvements or changes to either the health
4 questionnaire or to the information provided to
5 donors. I'm not going to look at those now but if
6 I just give the references, and then we can pick up
7 a new topic after that break.
8 So SBTS0000144_003 and SBTS0000189_081 are an
9 exchange of correspondence in December '89 between
10 Dr Thornton of SNBTS and Dr Cash about the SNBTS
11 health questionnaire.
12 Then NHBT0000190_063 is a letter in
13 December 1990 from Professor Cash to Dr Kenneth
14 Calman, Chief Medical Officer, about the issue of
15 whether donor self-exclusion leaflets did or did not
16 require departmental approval, Dr Cash's point being
17 that the approval of the Scottish Home and Health
18 Department had not been required for the production of
19 new leaflets, and he said that enabled SNBTS to
20 respond more flexibly, and he was contrasting that
21 with what he said was the position outside of Scotland
22 where matters could be held up by the need to seek
23 approval from the Department of Health.
24 Sir, is that a convenient moment at which to
25 take a break? I'm going to move to a different topic.

1 **SIR BRIAN LANGSTAFF:** Yes, it is. So we meet again at
2 3.55. 3.55.
3 **(3.25 pm)**
4 **(A short break)**
5 **(3.56 pm)**
6 **MS RICHARDS:** Sir, there are two further topics I am going
7 to endeavour to cover this afternoon, again all under
8 the umbrella heading of responses to risk.
9 The first is the issue of viral inactivations,
10 which I will be dealing with fairly briefly, because
11 we will pick that up in March when we look at PFC and
12 BPL in more detail.
13 The second is the issue of HIV screening of
14 blood donations.
15 I'm going to then, in the morning, deal with
16 three matters. The first will be the question of the
17 introduction of hepatitis C screening of blood
18 donations and Dr Cash's involvement in and views in
19 relation to that. That will be the last main topic in
20 relation to Professor Cash.
21 The second topic in the morning will be
22 look-back and his involvement in look-back exercises,
23 but that will be fairly short.
24 Then finally in relation to Professor Cash
25 tomorrow I am going to look at some of the transcripts

1 of his oral evidence to the Penrose Inquiry.
2 Sir, before I go to the two final topics for
3 today, there's a short extract or three separate
4 extracts in fact from the 2017 Panorama documentary
5 that we're going to play. They are three separate
6 extracts so they don't follow one after the other,
7 although it will appear on the screen as if they do,
8 and they show Professor Cash talking to camera.
9 I mention that in case there is anybody watching
10 on behalf of Professor Cash who would wish to know
11 that his image will shortly appear on camera.
12 **SIR BRIAN LANGSTAFF:** So what are we missing in the
13 in between?
14 **MS RICHARDS:** A range of matters. So there are interviews
15 with Dr David Owen, or Lord Owen. There's interviews
16 with Dr Brian Colvin. I think -- I can't remember if
17 we played the whole Panorama documentary in the
18 hearing. I don't think we have. But there's a debate
19 about self-sufficiency I think between the first and
20 second excerpt, and -- which will help you make sense
21 of the second excerpt.
22 I'm afraid I can't remember exactly what comes
23 between the second and third excerpts. There are
24 discussions about the Penrose Inquiry which then lead,
25 I think, to the final excerpt. They make sense on

1 their own.
2 Soumik, if we could play those, please.
3 *(Video extract played)*
4 Sir, those are the three short extracts from the
5 documentary which feature Professor Cash and his
6 observations.
7 So if I pick up the issue of viral inactivation
8 within Scotland as I say we will be exploring this in
9 far greater detail in March and hopefully hearing from
10 Dr Peter Foster.
11 If we can look, first of all, at PRSE0003349,
12 this was a statement that Dr Foster gave to the
13 Penrose Inquiry.
14 I just want to look at one very short passage at
15 page 10. This was about the work on pasteurisation of
16 Factor VIII being undertaken in Germany, and if we
17 look at the bottom half of the page you will see that
18 in paragraph -- sorry, just go up a tiny bit --
19 paragraph 5(a), Dr Foster refers to a symposium in
20 Bonn attended by Dr Cash, which Dr Foster's
21 understanding was that:
22 "... was the first public disclosure of the work
23 of Behring on the pasteurisation of factor VIII."
24 Next paragraph, second sentence, he says that:
25 "... Dr Cash and other attendees of the

1 symposium in Bonn in October 1980 would have been
2 first to learn of this development."
3 Then (c), he recalls being:
4 "... informed directly by Dr Cash that Behring
5 had claimed to be able to pasteurise factor VIII.
6 This [he says] was the first time I had heard of this
7 claim and was before I saw his letter of
8 27 October 1980 to Mr Watt. I am not aware that
9 anyone at the PFL knew of this work by Behring prior
10 to the information from Dr Cash."
11 Then if we just look at Dr Cash's letter of
12 27 October which Dr Foster refers to, that's
13 PRSE00003704, please.
14 You've not got that?
15 It is entirely possible I have written down the
16 reference incorrectly.
17 **SIR BRIAN LANGSTAFF:** We have an extra number in there.
18 Try three zeros.
19 **MS RICHARDS:** Did I say 0000? Yes, I'm sorry. 0003704.
20 Thank you, sir.
21 So we'll see this is the reference. The letter
22 that was being referred to, it's from Professor Cash
23 to John Watt at the PFC, 27 October 1980, and it says:
24 "Dear John
25 "During the meeting in Bonn I learnt, for the

1 first time, that Behringwerke were getting rather
2 excited -- following chimpanzee studies -- that their
3 preparations of factor VIII ... appear to be safe.
4 The reason given is that they are heat treating the
5 product for 10 hours at 60ºC in the presence of
6 glycine and sucrose. Apparently the glycine and
7 sucrose protect the VIII from denaturation.
8 "Sounds unbelievable: thought you might be
9 interested."
10 So that's an early contribution by
11 Professor Cash to the information available to PFC.
12 If we then pick matters up in 1983,
13 Professor Cash, by now of course fully aware of the
14 work that was being undertaken by PFC to develop its
15 own product, wrote in January 1983 to Dr Forbes at the
16 Glasgow Haemophilia Centre -- I'm not going to go to
17 the document but I will just give the reference for
18 the transcript: PRSE0004875 -- and he was inviting
19 Dr Forbes to collaborate with PFC and undertake
20 studies in relation to that concentrate.
21 He then wrote to Dr Ludlam in June of 1983,
22 and again, I don't propose to go to this, the
23 reference is PRSE0004875 I think. I'll check that
24 overnight.
25 That was providing information to Dr Ludlam

1 about the PFC's work on producing a heat-treated
2 product and inviting participation in studies in
3 relation to that.
4 There's further correspondence on that issue
5 which we've set out in the written presentation.
6 There are a number of issues canvassed with
7 Professor Cash in relation to the PFC's heat-treated
8 product in his testimony to the Penrose Inquiry.
9 Again, I'm not going to go to it now. The
10 reference for the transcript is PRSE0002836.
11 That's one of Professor Cash's multiple
12 statements to the Penrose Inquiry in which he deals
13 with the suggestion that the infection of the
14 Edinburgh cohort could have been prevented if PFC had
15 started its heat-treated work earlier. He says that
16 he regarded that as a non-starter because it wouldn't
17 have been possible to produce that in time to prevent
18 the infection.
19 He was also asked for the purposes of his
20 statements to the Penrose Inquiry about PFC's
21 intermediate Factor VIII product and the fact that it
22 wasn't made available then until 1987, in contrast
23 with the position in relation to the product produced
24 by BPL. Again I'm not going to go to that because we
25 will pick it up more directly in March. The reference

1 for his statement, again for the transcript, is
2 PRSE0000651, and he sets his understanding there of
3 a number of the technical challenges involved in
4 developing the product.
5 That brings me to the final topic for this
6 afternoon, which is the issue of the introduction of
7 testing or screening for HIV of blood donations.
8 Again, this was the subject of a statement to
9 the Penrose Inquiry, and this one I do want to put up
10 on the screen.
11 It's PRSE0003395.
12 If we go to the second page, we'll see the
13 heading "Donation Screening Test Kit Evaluations", and
14 he sets out a number of matters here which I think
15 merit consideration in some details.
16 "In February 1984 the SNBTS Directors advised
17 SHHD that there was an urgent need for the UK
18 Departments of Health to work together to ensure that
19 appropriate steps were taken to expedite effective
20 responses that would ensure, as much as possible, the
21 safety of blood/blood products in the face of the new
22 threat of HIV/AIDS.
23 "Some time later in early 1984 I found myself
24 visiting Professor Robin Weiss's laboratory at the
25 Chester Beatty Institute, London. The purpose of this

1 visit was to explore whether Weiss's team could supply
2 the SNBTS with aliquots of HIV to enable PFC to
3 undertake in vitro virus inactivation validation
4 studies. However, I also noted that the Weiss team
5 had developed a RIA to anti-HIV. At that time I was
6 only aware of the developing commercial ELISA
7 programmes in the US."
8 He continues:
9 "It seemed to me that the Chester Beatty
10 Institute's HIV cultures and assay were important
11 potential developments and I called Dr Gunson to brief
12 him and discuss how best the UK BTS might respond.
13 I discovered that Dr Gunson was already aware of the
14 Weiss team's assay and was strongly in favour of it
15 being commercially developed as a RIA and marketed
16 by BPL. In the face of the advanced position of the
17 more attractive ELISA technology in this field, I did
18 not share his enthusiasm for a RIA approach nor BPL's
19 involvement. Never the less we agreed that Dr Gunson
20 would forward a proposal to the DHSS that the UK
21 [Blood Transfusion Service] should establish an
22 assessment of the Chester Beatty Institute assay along
23 those ELISA assays being commercially developed.
24 I was to discover that, after consultation with
25 others, Dr Gunson wrote to DHSS in July 1984 advising

1 that a NBTS (not UK BTS) technical team ..."
2 So, inferentially excluding SNBTS.
3 "... should assess the Chester Beatty assay as
4 soon as possible. I was disappointed that Dr Gunson
5 did not mention including an assessment of available
6 US ELISA assays in the proposed evaluation programme,
7 excluded any SNBTS involvement and did not copy his
8 letter to me!
9 "2.04. Dr McClelland kindly sent me a copy of
10 Dr Gunson's July letter to DHSS and throughout the
11 late summer/autumn of 1984 I made repeated efforts to
12 ascertain whether he had received a response from
13 DHSS. It soon became apparent that there were
14 difficulties. It appeared that both his passion for
15 a RIA technical option that the kits be manufactured
16 in BPL had been challenged. Indeed, I had the
17 impression that much precious time had been wasted in
18 1984 with internal civil service wrangles on this
19 topic rather than pressing ahead with assessing
20 available commercial HIV donation screening kits which
21 were already under scrutiny by the FDA. As I recall,
22 by December 1984 we knew Dr Gunson had lost the
23 battle: the Chester Beatty assay project had been
24 handed by Ministers to Wellcome Diagnostics Ltd and
25 they (Wellcome) had (I believed wisely) rejected RIA

1 in favour of ELISA.
2 "2.05. By late December 1984 there was deep
3 concern among the SNBTS Directors. Almost 12 months
4 had gone by since they had advised SHHD to promote
5 urgent inter-Departmental action directed to ensuring
6 the safety (with regard to HIV) of the UK blood
7 supply. Moreover, we had evidence that the FDA was
8 now well advanced in its assessment of HIV donation
9 screening kits, which was later published. As far as
10 we could judge there was no evidence that our pleas
11 for interdepartmental collaboration was occurring. We
12 were also concerned that the official selected by SHHD
13 to liaise with DHSS in this area was a medical officer
14 with no knowledge of blood transfusion matters, no
15 operational contact with the SNBTS and, as far as we
16 were aware, no line management links with Dr Bert Bell
17 or Dr Archie McIntyre (SHHD).
18 "Finally, there was concern that the policy
19 development priority in this area for the next
20 6 months might not be the assessment of existing
21 commercial kits and expediting the introduction of
22 UK wide donation screening, but actions directed
23 towards enabling Wellcome Diagnostics to catch up.
24 The extent of the catch up required, as of
25 1 January 1985, seemed substantial.

"2.06. There was no doubt that in December 1984 a priority for the SNBTS was the evaluation of developed and developing commercial HIV donation screening kits. In this regard we believed this evaluation should be done by UK BTS technical staff who had extensive experience of large scale donation [testing *(sic)*] and that the key information urgently required was specificity. We also believed, for the sake of our donors and our donor support staff, more technical effort was needed in the area of confirmatory testing.

"An analysis of the state of play, as seen by the SNBTS Directors at January 1985, was conveyed to SHHD on 24 January. In the earlier weeks of January the Directors had met and decided to abandon the notion of a joint UK approach and instead mount an independent SNBTS evaluation of the commercial HIV donation screening kits as soon as possible. This decision was consolidated and conveyed to colleagues and SHHD on the 25 January. I recall we had made it clear to manufacturers that if they wished their kits and associated equipment to be evaluated by the SNBTS then they would have to be supplied free of charge. As I recall, this they readily agreed to. Thus the only significant cost for this evaluation would be

modest overtime payments for our technical staff. Once again our primary first duty of care at this time was to acquire local data on the specificity of the screening kits, as the current information (some verbal) from the US on this issue had been confused, with reports of screen positive rates in low risk blood donor like populations ranging from 1-10%."

Then it continues bottom of the page:

"Some days after 25 January I was invited to discuss the situation with Dr McIntyre (SHHD). Dr McIntyre made it clear that SHHD was strongly opposed to the prospect of SNBTS undertaking its own kit evaluation. He further advised that SHHD had given an assurance to DHSS that they were content with the proposition that HIV kit evaluations in the UK would be managed by DHSS, and that the commencement of routine HIV donation testing in Scotland would be determined by Ministers, on the advice of DHSS, and that this date would apply across the UK. I recall that Dr McIntyre also advised that these views would be transmitted to the CSA [Common Services Agency]. As I recall, I thereafter consulted with Dr Mitchell and Dr McClelland and we agreed that, in view of the hostile reaction of SHHD, this SNBTS initiative should be stood down. This proposal was later conveyed to

and supported by the SNBTS Directors. This position may have given rise to my letter to the CMO Scotland on 12 February 1985."

Then he sets out his understanding of what happened thereafter:

"Some time after January 1985 it emerged that DHSS were moving to establish an HIV donation screening test kit evaluation programme. In the subsequent months, largely through access to EAGA meetings [that's the Expert Advisory Group on AIDS], I came to the conclusion that this long delayed DHSS managed evaluation programme was less than satisfactory. My concerns can be summarised as following:

"(a) UK BTS scientific/technical experts, including the DHSS and SHHD consultant advisers in blood transfusion, were excluded from the design of the programme.

"(b) The design was undertaken by invited (by DHSS) virologists with no experience in, or responsibility for, large scale donation testing *[sic]*. (Of further concern was that one of these virologists was heading the Wellcome Diagnostics' HIV ELISA programme and that this was known to all planning team participants).

"(c) The expert virologists, with DHSS support, insisted that there was to be an independent (of UK BTS) preliminary scoping study, undertaken in PHLS laboratories and supervised by them. This phase 1 study had first to be completed before UK BTS teams could commence their evaluation. I believed that much of this preliminary study, which took nearly 6 months to complete, was unnecessary and those elements of interest to the UK BTS could have been done as well and in much less time by a UK BTS team and more certainly by a SNBTS team, as proposed in January 1985.

"(d) Because the DHSS invited virologists had no experience in large scale donation screening, the design of this early scoping work was less than satisfactory in terms of UK BTS requirements and some of the work had to be repeated, giving rise to further delays.

"(e) It was of interest that the preliminary scoping study (phase 1) took almost 6 months and the field evaluation (phase 2, done by UK BTS teams) 6 weeks.

"(f) We were later to discover that this whole programme appeared to be dogged by lack of financial support from certain DHSS budget holders. It was also

1 dogged by what seemed to be an extra-ordinary *laissez*
2 *faire* attitude among senior DHSS managers; one (the
3 Chairman at the May 1985 EAGA meeting) declared that
4 the preliminary evaluation study (which began in March
5 and involved only 220 blood donor sera) should 'not be
6 rushed'. Professor Arthur Bloom attended this meeting
7 and rightly conveyed both at the meeting and in
8 a letter to the Chairman (Dr EL Harris) his concern at
9 the lack of urgency in clearing obstacles to the
10 introduction of full routine HIV donation testing in
11 the UK. Professor Bloom subsequently joined forces
12 with the [Haemophilia Centre Directors] of Glasgow and
13 Oxford to put this view into the public domain. I am
14 not aware whether Professor Forbes discussed with his
15 SHS HCDs colleagues and conveyed these concerns to
16 SHHD. Certainly, I have no recollection of him
17 discussing his concerns with me.
18 "(g) Finally, there were no provisions in this
19 DHSS sponsored evaluation for studies on confirmation
20 testing.
21 "To the best of my recollection, the orderly and
22 leisurely progress of 1985 HIV kit evaluations in the
23 UK abruptly changed with the publication of concern at
24 its slow rate of progress. As a consequence
25 appropriate UK BTS evaluations were not undertaken.

1 Indeed the only evidence I have that some form of RTC
2 evaluation was done appears in a NBTS/RTD's Meeting
3 Minute of January 1986. It still is my view that HIV
4 donation screening was introduced in the UK without
5 the most appropriate consideration of the welfare of
6 blood donors."
7 Then finally, in this section of his statement:
8 "There were frequent occasions in late 1984 and
9 the whole of 1985 when it was embarrassingly clear
10 that DHSS had major problems in agreeing the funding
11 of both the evaluation and implementation of HIV blood
12 donation screening. It is not known whether SHHD were
13 required to make a financial contribution to the PHLS
14 phase 1 study. But there seemed no doubt that SHHD
15 had agreed in advance that ring fenced funding for
16 routine HIV donation screening in Scotland would be
17 available when required. That said SHHD used this
18 position to ensure that it retained ... control of the
19 start date. As far as I could judge, the main burden
20 of the financial difficulties south of the border
21 impacted most severely on confirmatory testing and the
22 quality of the donor counselling programme. They
23 commenced routine testing without an agreed strategy
24 for confirmatory testing."
25 Those are Professor Cash's recollections and

1 reflections when he gave his written statement to the
2 Penrose Inquiry of his impression of the position in
3 relation to HIV testing, which, as we know, was then
4 introduced in the autumn of 1985.
5 I'm not going to go through all of the rest of
6 this statement. It does merit reading in full and, of
7 course, it may well be that much of what Professor
8 Cash says would be disputed by others but there are
9 just two further pages that it I may be useful to look
10 at now.
11 Page 16, so this is in response to a number of
12 specific points that were put to him for him to answer
13 in writing. The first refers to a letter in The
14 Lancet which was co-authored by Dr Cash. You will see
15 the question is:
16 "On 21 February 1985, Dr Cash and others from
17 the SNBTS and NBTS sent a letter to The Lancet. The
18 letter stated 'we the undersigned believe that the
19 likely incidence of false positive HTLV-III antibody
20 tests using the current generation of commercial kits
21 in our voluntary blood donor populations will be
22 high'."
23 Can we just look at that letter in the Lancet
24 and then we will come back to the statement. It is at
25 PRSE0004824, and it's on the second page. There are

1 letters by others, and you will see the date. There
2 it is referred to 2 March 1985, which is not the same
3 as the date given in the Penrose questions. But, in
4 any event, if we look at the right-hand column, the
5 second letter down, you will see there it is authored
6 by a number of Regional Transfusion Directors, so we
7 have Dr Ala, Dr Contreras, Fraser, Lee, Smith,
8 Wagstaff, Collins, Entwistle, Harrison, Napier, Tovey,
9 Brookes, McClelland, Mitchell, Urbaniak, Whitrow,
10 Perry and then Professor Cash at the end. Some of
11 these are witnesses who will we'll be hearing from
12 orally.
13 Then if we just go up to the text of the letter
14 it said this:
15 "We believe that current commercial kits for
16 HTLV-III antibody tests are likely to give a high rate
17 of false-positive results. We would therefore
18 recommend that careful consideration be given before
19 they are introduced for the screening of all voluntary
20 blood donors, for the amount and degree of unnecessary
21 stress and hardship that a fair number of our donors
22 and their families would thus have to undergo is
23 unacceptable. This in turn could lead to a sizeable
24 drop in the supply of blood and blood products. Of no
25 less importance, for the safety of transfused

1 patients, is the need to ensure that the first
2 priority for the introduction of any HTLV-III antibody
3 tests into a community is given to patients attending
4 special (venereal disease) clinics and other members
5 of the general public who wish to have access to these
6 tests. If this is not done, many high-risk people,
7 from a blood transfusion point of view, may present
8 themselves at blood-donation sessions simply to find
9 their HTLV-III antibody status.
10 "We do support, strongly, the screening of all
11 blood donors for HTLV-III antibody testing, but we
12 would advise that this is delayed until test systems
13 have been appropriately evaluated and efforts have
14 been made to give all members of the public access to
15 HTLV-III antibody testing."
16 Now, whether that is entirely consistent with
17 everything that Professor Cash says in his statement
18 may be a matter to which further consideration will
19 need to be given. It's certainly not inconsistent
20 with everything that Professor Cash says because
21 obviously he is critical of what had been happening in
22 the evaluation process prior to this, the date of the
23 publication of this letter. But, nonetheless, here is
24 a letter to which his name is appended which is urging
25 a degree of caution and further work to be undertaken

1 before the testing is introduced.
2 If we then go back to his statement,
3 PRSE0003395, page 16, thank you, Soumik, his comment
4 is:
5 "After so many years, I'm reluctant to comment
6 on behalf of my SNBTS/NBTS colleagues. But there was
7 no doesn't in my mind, after consulting with several
8 US colleagues, that the position in February 1985 with
9 regard to the specificity of the available HIV
10 donation screening kits seemed a little uncertain and
11 somewhat confused. Whilst an early claim that some of
12 the kits had a high screen positive rate, I was
13 advised by US colleagues that there had been
14 significant improvements, such that by late 1984/early
15 1985 figures of less than 10% screen positives were
16 quoted. The US team reporting this figure, which was
17 based on the study of over 1000 donations, claimed it
18 would be acceptable provided the donors who were
19 screen positive but confirmatory test negative were
20 reinstated and not excluded from future donating. As
21 I recall this false positive re-instatement approach
22 was considered and rejected by UK BTS as there was at
23 that time lack of confidence with regard to the
24 efficacy of the confirmatory tests. It followed that
25 we might be faced with a loss of up to 10% of our

1 donor panel. On the other hand, I recall from
2 contacts with FDA colleagues, I think in late 1984
3 that the kits they had recently looked at had screen
4 positive rates of only 1% in a low risk population
5 which would have much in common with our donors."
6 Then a final point is the bottom of the page,
7 reference is made in the question to the letter from
8 Professor Bloom and, again, we have looked at that
9 I think on more than one occasion, that one of the
10 kits should be introduced immediately, and Professor
11 Bloom, Dr Rizza and Dr Forbes wrote to the BMJ to that
12 effect, if we see the top of the next page.
13 Professor Cash's reflection on that is as
14 follows:
15 "I must confess to being a little surprised that
16 Professor Bloom's concerns (which I strongly
17 supported) were later put into the public domain.
18 That said, I recall believing that had not Professor
19 Bloom and his colleagues 'gone public' then the UK HIV
20 donations screening programme might have commenced
21 even later than 14 October 1985."
22 So that's Professor Cash's comment on the
23 intervention of Bloom, Rizza and Forbes.
24 There are, I think, two or three other
25 documents -- two other documents I just want to look

1 at to complete this topic, and it's an exchange of
2 correspondence in March 1985.
3 The first is NHBT0007985.
4 I am not going to read the whole of this letter.
5 If we go to the second page. It's a long letter from
6 Professor Cash dated 14 March 1985 to Dr Abrams in the
7 DHSS, and it follows a meeting that had taken place on
8 13 March, and he sets out a number of concerns about
9 what was and was not discussed at that meeting.
10 You will see at paragraph (a) he looks at the
11 evaluation exercise in relation to the screening kits
12 and says it must include the Western Blot technique.
13 If we go to it's paragraph (c), he says:
14 "I was interested and pleased to note at the
15 13 March meeting that the EAGA [Expert Advisory Group
16 on AIDS] agreed that HTLV-III antibody testing should
17 be introduced simultaneously in the UK Transfusion
18 Services ..." and then asks the question of how that
19 will be implemented without additional central
20 funding.
21 So his view in this letter was, it would appear,
22 firmly in favour of a simultaneous across the UK
23 introduction of testing.
24 Then if we go to the next page, again I'm not
25 going to go through the detail, paragraph (g) refers

to the question of false positive donors and donations and how that will need to be addressed.

(h) deals with issues relating to the question of counselling donors who were not false positive but found to be truly HTLV-III positive.

If we go over the page, there are then discussions, for example, at (k) about how information about donor testing and donor results should be handled.

Then if we go to the last page he just makes one last point:

"If it's been decided that the UK Transfusion Services will introduce HTLV-III antibody testing simultaneously, then we will soon need to have an approximate expected date for the completion of the kit evaluation and thus D-Day. This will in turn sharpen our thoughts with regard to the planning of when donor counselling systems will have to be up and ready to receive their first donors. The sooner this detailed planning commences the better for, based on the experience of Dr Pinching's group, there will be a requirement for training."

He copied that letter to -- or sent a copy to Dr Gunson.

The final document to consider is NHBT0007984.

This is Dr Gunson's response to Dr Abrams, and you will see, in the first paragraph, Dr Gunson characterised Professor Cash's letter as rather aggressive and then he deals with each of the points in turn.

I'm not going to take time now going through that, but it is no doubt a letter that you will wish to consider in more detail in due course.

There was further discussion about the AIDS screening tests and the consideration of the various tests under evaluation at the fifth meeting of the expert advisory group on AIDS in July of '85. That was attended by Professor Cash but the minutes don't record his particular contributions to the discussion on that issue, so I'll just give the reference, which is PRSE0002628.

As we know, HIV donation testing was then implemented across SNBTS and England, Wales and Northern Ireland in October 1985.

There is one final letter from Professor Cash several years later which touches on it, SBTS0000061_033.

This is a letter from Professor Cash to the Central Legal Office, 1 August 1990, and the context is the HIV haemophilia litigation, so it's commenting

on a chronology document that we don't have as a comparison for the purposes of following every point he makes here, but he's clearly, in the main paragraph, talking about the development of the HIV donation screening, and he says this in the second line:

"I am bound to say that the SNBTS was excluded from the key discussions which took place on 28 June 1984. I emphasise 'key' because they provide the first evidence of a development (HIV donation screening) which was not implemented until October 1985."

He then refers to issues about funding and suggests that:

"... that decision in November 1984 may have had a crucial bearing on the delays of the results of the initial evaluation of HIV tests and perhaps the subsequent field evaluations. You will recall that mass HIV-1 donation testing was commenced in the USA in March 1985 and not until October 1985 in the UK."

So there appears to be, implicitly at least, a suggestion that there was unnecessary delay in the introduction of testing but you will need, sir, to evaluate again that as against what Dr Cash himself was saying, amongst other things, in that letter to

The Lancet in March.

SIR BRIAN LANGSTAFF: Yes, when he was saying that delay was desirable.

MS RICHARDS: Yes.

Sir, that completes this topic. I say "completes"; there's a huge amount more that will need to be examined in relation to that topic but not through the perspective of Professor Cash. So I propose then tomorrow to deal with the three topics I referred to earlier. The main focus will be on the issue about hepatitis C screening but I will also deal with questions of surrogate testing as well.

SIR BRIAN LANGSTAFF: Thank you. Very well, 10.00 tomorrow.

(4.34 pm)

(Adjourned until 10.00 am the following day)

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