

Wednesday, 23 March 2022

(9.59 am)

**Presentation to the Inquiry on domestic production of blood products in Scotland and for Northern Ireland by MR BOUKRAA**

**SIR BRIAN LANGSTAFF:** Yes?

**MR BOUKRAA:** Good morning, sir. We are turning now to demand estimates. For those who are following in the written note that I referred to yesterday, we should be in section 4. We are going to start by going back in time, compared with the documents that we were looking at yesterday afternoon, to the early 1970s.

The focus is going to be on Factor VIII because that was understood to pose the greatest challenge. Before I move the chronology, sir, I should say we've used the word "demand" in the written note and I'll be using it during this part of the presentation because that reflects the terminology in the documents from the time.

I think this may have been picked up last week during England and Wales but "demand" is a word that might need a bit of unpacking. It brings with it some questions, whose demand? What information was that demand based on? All sorts of other questions no doubt, but we've used it because it was in some of the

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his counterpart in Scotland, was not.

The meeting and that group was attended, I believe, by Dr McDonald on behalf of the Scottish Home and Health Department but not Mr Watt. It's just something to bear in mind when we look at some estimates that were being made in Scotland.

We turn now to a document which was prepared by Mr Watt around that same time as that expert group was considering demand for Factor VIII and, Sully, it's PRSE0003153.

So you can see from the date of this document at the bottom, 12 June 1973, prepared by Mr Watt, title "Plasma Fractionation in the United Kingdom. A Personal Appraisal". You'll see in the top right-hand corner, this is said to be a draft. We haven't been able to find an updated or more finalised version. Compared to the other document from Mr Watt that we looked at yesterday, this one is easier to follow. It seems to be more of a finalised document.

In terms of its timing and what it was prepared for, it's not completely clear from the chronology. It comes about eight days before that 20 June meeting of the joint steering committee that we looked at yesterday.

If we go over to page 3, and I'm just going to

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documents. When we get to look at some of the annexes that accompany the written note, in which we've set out the use of Factor VIII and IX, we've used the word "consumption" rather than the word "demand" but I just thought I'd flag that at the start to explain why I'll be using that word in this portion in this presentation.

**SIR BRIAN LANGSTAFF:** The two are, I suppose, different in that consumption is what is used, demand is what is asked in order to be used.

**MR BOUKRAA:** Yes. Yes. That's right, sir. They can sometimes be used almost interchangeably. We can sometimes see when demand has been estimated, what it seems to refer to is how much Factor VIII is going to be used, but it's quite right, sir, they are two different words. We've tried to use them in different ways in the presentation.

**SIR BRIAN LANGSTAFF:** Thank you.

**MR BOUKRAA:** So last week with the England and Wales presentation you looked at the meeting and the report which came about in March 1973 with the Expert Group on the Treatment of Haemophilia. I'm not going to go back to that. A couple of points I would note about it relate to attendees. It's worth just noting, sir, that Dr Maycock was a member of that group. Mr Watt,

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highlight a few passages in this document, but it is quite an important one. If you start with the introduction, you can see that Mr Watt introduces this paper by referring to communications that he has had with a number of different people, including counterparts in Europe, America, Australasia. If we look at the second paragraph in this introductory passage, Mr Watt says:

"The population in the United Kingdom is estimated at 60 million. Of this, for purposes of discussion, the Scottish population is estimated at 5 million."

The estimated number of haemophiliac patients, ie patients with haemophilia A, is 3,000.

Now, I know that figures for population of the UK came up last week. My understanding is that, in fact, the population of the UK around this time was closer to 56 million, I think about 50 million in England and Wales, 5 million in Scotland, about 1.5 million in Northern Ireland. It may be that population estimates were not quite as clear at the time. It may be that when different figures are talking about UK population, they've got different numbers in mind. It's not always clear from all the documents but at least Mr Watt here sets out what he

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understands the UK population to be at this time.

If we could have the whole page or rather the second half of the page, this is really just to note, sir, because we'll come back to it later, the third paragraph in this page refers to a policy on the use of cellular components, which I understand to be a reference to the use of red cell concentrates. We'll come back to that when we look at supply from PFC a little later.

At the bottom of this page, Mr Watt gets on to AHG, and he says:

"The official estimate of the need for fresh frozen plasma for AHG preparation is given as 10 donations [per] 1000 population."

Now, it's not totally clear to me which official estimate Mr Watt is referring to there. It's worth noting nonetheless. Then we're going to continue with the rest of this passage. It says:

"On this basis the Scottish plasma availability is correct. It is my personal belief that this figure [ie 10 donations per 1,000] is probably 30% too low since it presupposes an overall process yield of 40%. These calculations do not allow for:

"Increased use in domestic therapy."

I pause there, sir, to draw a contrast perhaps

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Now, there are number of figures that are set out there that will be worth noting and bearing in mind. It is also worth picking up from this passage, and this is something we will come back to as we look at the other documents. Demand estimates were quite often expressed using number of different metrics at this time, they are sometimes expressed in terms of the number of donations that are needed, they are sometimes expressed as the amount of Factor VIII in terms of units, that's all kinds of Factor VIII per head of population. They're sometimes expressed as the amount of Factor VIII that's needed per haemophiliac patient.

I've, at least, found it easy to not always be totally clear which is being referred to. I point that out because it's something that we'll see also in some later documents.

If we go on to the next page, please, Sully, page 5.

**SIR BRIAN LANGSTAFF:** The unit is used in the second -- in the paragraph in the middle of the page --

**MR BOUKRAA:** Yes.

**SIR BRIAN LANGSTAFF:** -- here is 1 million pu per million population. That's "plasma units", presumably?

**MR BOUKRAA:** Yes.

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with some of the work from Dr Biggs that was referred to last week and we'll come back to, which suggested that domestic therapy was not likely to lead to increased use.

Next:

"The need for a proportion of the production as low yielding, high purity fractions.

"A probable drop in yield, of Intermediate concentrate, to 30% when made on a realistic scale", ie when you start making more of the product, when you scale it up, it is likely that yield is going to drop from what it is when you're making smaller amounts.

He then says:

"Allowing that this argument is correct, Scottish need for [fresh frozen plasma] becomes 15,000 donations [per] million rather than the 10,000 donations now becoming available. This would provide (at 30% yield) about 4.8 million plasma units of AHG per annum for the country's need; approximately one million [units per] million population or 20,000 [units per haemophiliac per annum].

"It is my belief that a production of 15,000 litres of fresh frozen plasma is well within the capacity of the Scottish [RTCs] without [needing to use] plasmapheresis."

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**SIR BRIAN LANGSTAFF:** What is a plasma unit?

**MR BOUKRAA:** My understanding is that it is a unit of Factor VIII. That seems to me to make the most sense, and that equates to about a unit of Factor VIII.

**SIR BRIAN LANGSTAFF:** I'm not sure that can be right, can it? Oh, I see. Plasma units of AHG. Right. I now see it. Yes. He defines it himself, doesn't he, in the second-last line.

**MR BOUKRAA:** I think that's right.

**SIR BRIAN LANGSTAFF:** So a "pu" there is a plasma unit of antihaemophilic globulin.

**MR BOUKRAA:** Exactly, yes, and he refers to that both in terms of million population.

**SIR BRIAN LANGSTAFF:** Yes.

**MR BOUKRAA:** So that's one per million, ie one per person, because the Scottish population at this time was around 5 million, that leads to 4.8 million units for the whole of Scotland.

**SIR BRIAN LANGSTAFF:** Yes.

**MR BOUKRAA:** If we go over the page to the top, he refers here to, at the top passage, to the number of litres of plasma that he thinks are going to be necessary, suggesting that the figures may have to increase to reflect his estimate of need AHG.

If we go down to the middle of the page, we have

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1 it here actually, "Estimate of English Need", Mr Watt  
2 moves away from just looking at Scotland to apply his  
3 estimates to England, I presume that means England and  
4 Wales, perhaps also Northern Ireland, and he says  
5 this:

6 "Since there should be little difference between  
7 the community need of England and Scotland on  
8 a proportional basis it would appear that the Scottish  
9 figures should be applicable to England; especially  
10 since these figures are in close agreement with those  
11 established in other countries."

12 That leads him to a figure for England, or  
13 probably England and Wales at least, of 48 million  
14 plasma units of AHG, 48 million units of Factor VIII,  
15 split probably across all different types of  
16 Factor VIII.

17 He then applies that -- if we can go down,  
18 please, Sully, to the last part of the page -- to UK  
19 figures and his estimate is that the total UK  
20 requirement for the two plasma fractions, one of which  
21 is an albumin product and the second one is AHG, is  
22 53 million plasma units. At the bottom of the page,  
23 he suggests how many litres of plasma per annum are  
24 going to be necessary to obtain in order to meet those  
25 requirements.

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1 "BPL and PFC are each specified for  
2 70-80,000 litres of plasma per year. It is my opinion  
3 that BPL production could be increased to about  
4 150,000 litres, but further increase would appear  
5 impossible on the present site and could hardly be  
6 justified."

7 He then refers to a difference of more than  
8 250,000 litres that need to be accounted for.

9 At the bottom of this page, he says:

10 "Assuming that Scotland's resources will not be  
11 misused to subsidise England, a dual standard of  
12 clinical availability could come to exist."

13 If we go over the page, he sets out another  
14 comment:

15 "In my opinion, this intolerable situation could  
16 not be maintained, enough plasma to meet real need  
17 will be collected in England and, unless prompt action  
18 is taken, UK fractionation and finishing capacity will  
19 be inadequate to meet demand."

20 Before we go on to the next passages, worth just  
21 remembering the timing and context of this document.  
22 It's June 1973, so it's when the planning for the PFC  
23 that we looked at yesterday has already taken place in  
24 the late 1960s, and the facility is in the process of  
25 being built. It's getting towards the end of its

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1 If we could go over the page, please, Sully to  
2 page 6, and then about the middle of the page, 5.20,  
3 "Summary of Need for Plasma". Now these  
4 two paragraphs aren't -- might not be thought to be  
5 all that clear. They're worth looking at alongside  
6 each other, particularly the first sentence. He says:

7 "The amount of plasma (200,000 litres or  
8 1 million donations) required for AHG preparation is  
9 of no account in consideration of overall need."

10 I think that that sentence can be understood in  
11 light of the next paragraph, where he says:

12 "The critical figure of 400,000 litres required  
13 for PPS [ie albumin production] should ... be  
14 available from when existing [productions] ..."

15 Sir, maybe you can assist on this more than  
16 I can. I think what he's saying is that as long as  
17 you are getting enough to meet the albumin  
18 requirement, you should also be getting enough to meet  
19 the Factor VIII requirement. That's my understanding  
20 of these two passages read together.

21 And if we go down, then, to the paragraph we can  
22 see at the bottom here, Mr Watt then starts applying  
23 these figures to fractionation capacity, both within  
24 Scotland and also England and Wales. And he says, and  
25 this links back to what we were looking at yesterday:

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1 construction. He appears to be, Mr Watt, considering  
2 the possibility that there might still need to be  
3 a change of plans which might include further  
4 expansion to PFC.

5 He starts by ruling out, in paragraph 6.10,  
6 a third centre in the UK. He then says in 6.20, that:

7 "The PFC at Liberton has process potential to  
8 handle up to 300,000 litres of plasma per year but is  
9 unable to finish PPS at equivalent rates. However,  
10 the construction of premises equal to this task on the  
11 Liberton site would appear to be the most economic and  
12 most rapid means of achieving adequate fractionation  
13 capacity in the UK."

14 If we go down, please, Sully, to the bottom of  
15 the page. I'm moving a bit beyond demand estimates,  
16 sir, but I think these passages are worth looking at  
17 together. He says this:

18 "If, as seems certain, the additional facilities  
19 should be available as soon as the specified capacity  
20 of Liberton is exceeded (ie by the end of 1974).  
21 Planning would be required to start immediately,  
22 despite the fact that some technical questions remain  
23 unresolved. Obviously, this timescale is impossible,  
24 but it would seem feasible that, provided planning  
25 detail started at once, the increased facilities could

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1 be available on the Liberton site by the end of 1975.  
 2 Such a programme could be costly since it would  
 3 involve persuading existing contractors to accept a  
 4 new contract ..."  
 5 But he thinks that should be possible.  
 6 And if we then just get -- I'll just pick up the  
 7 last part of the last sentence here:  
 8 "However, in comparison with the global sums  
 9 involved, this additional expenditure could be  
 10 recouped in a period of months since each month  
 11 'saved' has a current financial implication of  
 12 approximately £1 million."  
 13 I think what he's referring to there is the cost  
 14 of having to buy commercial concentrates if you're not  
 15 able to produce enough of them in the UK. So what we  
 16 seem to have from this document, sir, is Mr Watt  
 17 coming at his own estimate for how much Factor VIII is  
 18 likely to be needed both in Scotland and in the whole  
 19 of the UK, and suggesting that, despite the fact that  
 20 PFC is coming close to the end of its construction  
 21 period, the PFC and the English facilities are not  
 22 going to be enough to meet demand, and he has some  
 23 suggestions for what might be done in response.  
 24 So, soon after this meeting, the joint steering  
 25 committee on blood products production met on 20 June.

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1 context of the letter is that the official is  
 2 concerned that another meeting of this joint steering  
 3 committee that had last taken place in June 1973 was  
 4 being postponed, and it seemed because there was  
 5 a divergence of view between Scotland and DHSS about  
 6 how to estimate needs, in particular for albumin. But  
 7 the official sets out some views that are more  
 8 generally applicable which illustrate the different  
 9 approaches. One of the things she says, and this is  
 10 covered also in the written note, she says this:  
 11 "The situation has been changed fundamentally  
 12 within the past year by the commencement of importing  
 13 blood products, beginning with Factor VIII."  
 14 She then outlines two alternative approaches.  
 15 The first is for the Blood Transfusion Service to  
 16 attempt to meet the reasonable demands of clinicians.  
 17 The second is:  
 18 "... to accept that we must depend upon  
 19 a significant level of imports over which we will have  
 20 no direct control because purchases will be made at  
 21 hospital level."  
 22 Alongside these meetings and this  
 23 correspondence -- so you'll be aware that Dr Biggs and  
 24 her colleagues were undertaking further work on demand  
 25 estimates for Factor VIII. You were taken last week

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1 We've already looked at the minutes of that meeting  
 2 last week -- I think you were also taken to it  
 3 yesterday, sorry, and you were also taken to it last  
 4 week, so I'm not going to return. The meeting  
 5 referred to Dr Biggs' estimate at that time of a need  
 6 for 400 to 700,000 donations.  
 7 We then enter into a period, sir, towards the  
 8 end of 1973 and into 1974 where there appears to be  
 9 some disagreement between the Scottish Home and Health  
 10 Department and their counterparts in England and  
 11 Wales, the DHSS, about how to approach estimating need  
 12 for blood products. We've got a number of documents  
 13 which are summarised in the written note. It's  
 14 important to be aware that the meetings that took  
 15 place and the correspondence that happened between the  
 16 two Departments often related to blood products other  
 17 than factor concentrates, in particular to albumin  
 18 products. Nonetheless, some of them do provide some  
 19 insight into how the different departments were  
 20 approaching these questions.  
 21 There's a document that I'm not going to bring  
 22 up on the screen, sir. I'm just going to give you the  
 23 reference for it because you may wish to return to it.  
 24 It's the 14 November 1973 letter from the SHHD to the  
 25 DHSS. The reference for it is SCGV0000074\_033. The

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1 to the paper which was presented at a January 1974  
 2 meeting of Haemophilia Centre Directors. I'm not  
 3 going to return to that paper, sir. It recorded  
 4 a suggestion that 500 to 700,000 donations annually  
 5 were going to be necessary.  
 6 I will pick things up in Scotland in the  
 7 mid-1970s by reference to a meeting of SNBTS and  
 8 Haemophilia Centre Directors which took place on  
 9 11 June 1975. We are going to look at a paper which  
 10 was prepared for that meeting.  
 11 Sully, it is at SCGV0000065\_117. Now, this was  
 12 a paper which I believe was prepared by Professor Cash  
 13 who at that time was the director of the Edinburgh and  
 14 Southeast Regional Transfusion Centre. It was an  
 15 annex to a paper prepared by Major General Jeffrey,  
 16 who was National Medical Director of the SNBTS,  
 17 Professor Cash's predecessor in that role.  
 18 And if we can just have the passage at the top  
 19 of the page, Professor Cash sets out suggested figures  
 20 for donations for fresh plasma. So you can see the  
 21 title is "Fresh plasma processing for Factor VIII".  
 22 He says:  
 23 "In order to facilitate the detailed planning,  
 24 at Regional Transfusion Centre ... of targets for the  
 25 production of fresh plasma destined for the management

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of haemophilia A, it is suggested that we should aim at a basic maintenance figure of 12,000 donations per [million] population per annum."

He says that this figure is the upper limit of the MRC estimate and is close to the current usage in some regions.

I won't take you to the minutes of the meeting, sir, but the SNBTS Directors and Haemophilia Centre Directors who were present at that meeting in June 1975 appeared to accept this figure as an appropriate target for donations for fresh frozen plasma.

There is a document that was prepared in 1976 by Major General Jeffrey, National Medical Director of the SNBTS, which is referred to in the written note, sir. I'm not going to take you to it. The title is "Problems of supply and demand". The reference is RCPE0000314\_002. It covers a whole range of different blood products. It does provide some useful insight into issues such as the use of red cell concentrates at the time.

It suggests a planning figure for Factor VIII and, by that, I mean all types of Factor VIII, so concentrate as well as cryoprecipitate. Then Major General Jeffrey suggests a figure of 10,000 units of

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target of an average of 15 000 units of factor VIII/patient/year with a total UK annual requirement of around 50 million units. Regionally [Regional Transfusion Centres] should aim to process at least 12 000 fresh donations/million people/year."

He then refers to the differences that might exist between regions and he picks up an important point -- or I should say they, because this paper was prepared with Mary Spencely, I presume Dr Spencely.

"These calculations are based on the assumption that 70% of the concentrate used is cryoprecipitate, which is by most standards a high yielding product. Any movement towards completely replacing cryoprecipitate by AHF [ie concentrate], unless counterbalanced by reducing the dose of factor VIII at treatment, will, because of diminishing yields, necessitate a substantial increase in donations. A more appropriate figure in these circumstances would be 20 000 donations/million population/year. This figure would rise further if the volume of fresh plasma obtained from each donation was reduced ..."

That's something that's already happening with the use of red cell concentrates.

Then the conclusion and comment:

"It is difficult not to conclude that

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Factor VIII per patient per year, and we'll contrast that figure with some of the others that we're about to look at.

And I'm going to start with a paper prepared at a similar time in September 1976 by Professor Cash and a colleague. If we can turn to that. It's PRSE0003425.

I'm not going to go into the detail of this because there's quite a lot of detail. I pick it up partly because it was prepared by Professor Cash within just a few years by 1979, who becomes director. So his views on these issues are particularly noteworthy.

If we look at the summary box in the introduction, you can see that the estimates that are in this paper are based on use in south-east Scotland in the 1961 to 1975 period. There's then, in fact, a more helpful summary, I think, of the figures that are suggested two pages ahead on page 3.

If we can then have in the left-hand column, about halfway down, the passage that begins "Hence". That's it, thank you.

Conclusions here are set out, sir:

"Hence we have concluded that the blood transfusion services should consider a production

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a programme designed to switch completely from cryoprecipitate to AHF will prove to be too costly and wasteful of raw material for the next decade. Consideration should instead be given to striking a balance between both products and perhaps even rethinking the cost-effectiveness of freeze-dried cryoprecipitate."

So we can immediately see, in terms of the number of Factor VIII units that are suggested per patient per year, 15,000, compared to the 10,000, in the Major General Jeffrey paper I referred to, contrasted with the 20,000 figure in Mr Watt's paper, and also the suggestion that, if we're going to be providing more concentrate than cryoprecipitate, the number of donations that will be necessary is going to go up.

That's it for that document, thank you, Sully.

One of the elements in these estimates of demand that you can see in some of the documents we have from the time is about the purpose of haemophilia treatment. There's one document which we referred to in the written note, which I won't take you to, which sets out an apparent view of the purpose of haemophilia treatment. It's a letter written by Mr Watt in February 1977 to a colleague at the York

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Hill Children's Hospital.

For your note, sir, it's PRSE0000659 and Mr Watt's suggests that the number of units required for both Factor VIII and Factor IX could only be calculated by the number of units required to maintain the patient in a reasonable state of health and he suggests there was general agreement that this could be defined as health that would allow the patient to maintain a normal sedentary existence.

We get to the end of 1977, the Working Group on Trends in Demand for Blood Products, which was a UK working group, which you were taken to last week during the England and Wales presentation, publishes its findings. I'm not going to go back to that document or repeat all of them. I'd ask you, again, sir, to note the membership, Dr Maycock was a member of that working group. Dr Cash was as well, and Dr McIntyre of the Scottish Home and Health Department. Mr Watt wasn't a member.

The estimate of the need for Factor VIII that's reached by that working group at the end of 1977 is 1,000 units per thousand population, in other words 10,000 units, using the metric we've been using so far.

I'll pick things up now at the end of December

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extent.

The next document is an important one from January 1981, it's a report prepared by Professor Cash and it's at CBLA0001252. So we can see that it's Professor Cash's document, partly from the initials in the bottom right-hand corner. You can see the date, January 1981. This is note or report prepared for a meeting of Haemophilia Centre Directors and Transfusion Directors.

If we go through to page 3, I'm going to pick up a few different parts of this report, sir, because it's an important one.

The introductory passage is worth just noting. Professor Cash there sets out what he considers the role of the SNBTS to be:

"... to eliminate the necessity for the purchase of factor VIII concentrates for commercial concerns."

He says that there's a need for close collaboration with Haemophilia Centre Directors.

If we could go over the page, please, Sully to page 4, and the passage that begins "Future Developments in Demand", and if we could go down a bit, thank you. This is Professor Cash introducing the section of this report in which he is estimating the future demands. He says:

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or rather the end of 1979, December 1979. I believe, by this point, Professor Cash has taken over as director of the SNBTS. We can see a changing and, again, increasing estimate of how much Factor VIII is thought to be needed.

Sully, the document is SBTS0000089\_120.

You can just see the description of the meeting; attendees, Mr Watt, Dr Cash was in the chair -- I presume he has taken over as director by then.

Then if we just go through to page 4, at the top of the page, section 5(ii):

"Dr Cash confirmed that the Directors should, in their calculations, now assume a target of 1,800 units of factor VIII per thousand population per annum."

So that figure has increased again. The figures that we've seen so far have tended to be 1,000 to 1,500, 1,800, there was also Mr Watt's earlier higher figure. So that's the position as of December 1979, at least in Scotland.

You'll recall, sir, from what we looked at yesterday, by the time we get to the late 1970s, the position as regards UK production, things had started to diverge. So we'd moved from a strong focus on UK planning at the start of the 1970s to, by the end of the 1970s, things had diverged to some significant

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"This is a particularly difficult problem at the present time, primarily because the practice of Home Therapy is still evolving, the appropriate method of managing patients with inhibitors is unresolved and the unequivocal evidence that haemophilia patients are living longer, thus increasing the overall population and becoming subject to similar disease processes of older age-groups in the non-haemophilia population which are amenable to surgical intervention.

"Despite these difficulties efforts are now required which will enable the SNBTS to formulate long term plans which can, if necessary, be adjusted at a later date."

He then makes reference to conversations that he has had with colleagues within the UK and internationally and, if we go down, please, to the rest of this page, he starts to set out the basis of his reasoning for the figure that he gets to, and he starts with home therapy or severe haemophilia A patients, which forms the bulk of the estimate for demand.

You'll see, sir, that Professor Cash sets out use figures from the time, from different settings, a figure from Oxford, from Newcastle, the USA, Treloar's, and West Germany. We'll come on to see

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1 that he suggests that the figure for Newcastle is  
2 an -- forms an appropriate basis for planning demand  
3 for home therapy patients, and we can see that, if we  
4 go to page 6, please. At the top of the page, there's  
5 a summary. Professor Cash says:

6 "I believe it would be appropriate, for planning  
7 purposes, to accept the figures from Newcastle for the  
8 single largest contributor (Home Therapy).

9 "It is probable that this figure has  
10 a sufficient margin of clinical flexibility to make it  
11 realistic for the next 10 years."

12 We'll come back later in the paper to the time  
13 period in which the demand has been estimated, but he  
14 suggests it would be realistic for the next 10 years,  
15 and he sets out the different elements of the figure  
16 for demand that he believes is appropriate with home  
17 therapy as the biggest element in setting out the  
18 others, as we can see on that page there.

19 That gives Professor Cash a figure of 2.75, and  
20 that's per million population. If we translate that  
21 into the metric we've been seeing in other documents,  
22 2,750, as opposed to 1,800. That was the figure in  
23 1979.

24 If we go through to page 9, please, we can see  
25 in the second half on the page heading "Specific

25

1 target.

2 There's one more document I wanted to come to in  
3 this section. It's another report from  
4 Professor Cash, it's from the following year there he  
5 revisits these figures and provides a little bit of  
6 comment that allows us to compare them with the  
7 figures for England and Wales.

8 Sully, it's SBTS0000613\_003.

9 **SIR BRIAN LANGSTAFF:** Can I just pause there for a moment.

10 **MR BOUKRAA:** Yes.

11 **SIR BRIAN LANGSTAFF:** Can I just understand how the  
12 figures play out and see if I am understanding what  
13 you've been telling me. You say that the paper which  
14 Cash produced was discussed at the end of  
15 January 1981, and a figure of 2.75 million, that's  
16 million units per million population.

17 **MR BOUKRAA:** Yes.

18 **SIR BRIAN LANGSTAFF:** If that's so, then what does that  
19 translate into, in terms of the targets that were made  
20 for the production at BPL in England, which was in the  
21 region of 100-120 long term. This would suggest  
22 rather more than that.

23 **MR BOUKRAA:** It was, sir, and, in fact, I hope the  
24 document we're about to look at will help on that  
25 front because it compares the two figures.

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1 Proposals for Discussion". We can see the time period  
2 that Professor Cash is proposing. He suggests that  
3 there's discussion that a target for 2.75 per million  
4 population for units of Factor VIII per year be  
5 considered as the one to which the SNBTS should aim  
6 for the next 5 years, ie until 1986, "with an  
7 increment thereafter" of 1,000 units per year.

8 While we're on this document I would just note  
9 very briefly on page 11, there is reference to  
10 Factor IX. If we could have the passage just at the  
11 top of the page, it links back to a comment I made at  
12 the start. Professor Cash says:

13 "Fortunately, because of the much smaller number  
14 of haemophilia B patients than A, the supply of these  
15 products is always more than adequate", with an  
16 exception that, I think, links to that table.

17 That helps to explain why the focus of these  
18 documents is on Factor VIII more than it is on  
19 Factor IX.

20 Now, this paper was discussed at a meeting of  
21 Haemophilia Directors and SNBTS Directors at the end  
22 of January 1981. The minute records that the figure  
23 of 2.75 million per million population was accepted as  
24 a suitable basis for further consideration. It seems  
25 that it is then accepted and becomes the accepted

26

1 Professor Cash suggests that his figures, 2.75 and the  
2 figure of the NBTS is 2, so if we take a population of  
3 say 50 million, that gives you 100 million.

4 **SIR BRIAN LANGSTAFF:** Yes. 2.75 gives you 137,500.

5 **MR BOUKRAA:** Yes, so a higher --

6 **SIR BRIAN LANGSTAFF:** Yes, higher than any other estimate  
7 which was ever produced, south of the border.

8 **MR BOUKRAA:** Certainly as far as I'm aware, sir, and as  
9 far as I've seen, I'm sure that's right.

10 **SIR BRIAN LANGSTAFF:** Yes, I see. So I had understood it  
11 correctly?

12 **MR BOUKRAA:** You had sir, yes.

13 **SIR BRIAN LANGSTAFF:** So this was -- this particular  
14 meeting in 1981, signing up to a target which was half  
15 as much again, roughly, as the target which England  
16 thought was the maximum that they might need.

17 **MR BOUKRAA:** That's right, sir. It's a big figure. In  
18 fact, in the document that we're about to look at,  
19 Professor Cash himself describes it as a dramatic  
20 increase on his previous figure.

21 **SIR BRIAN LANGSTAFF:** Yes.

22 **MR BOUKRAA:** There is no doubt, it seems, that it was  
23 a higher target than the one that was produced in  
24 England and Wales.

25 **SIR BRIAN LANGSTAFF:** Yes, it certainly was. Thank you.

28



1 **MR BOUKRAA:** Thank you.  
 2 Sully, could we pan out to get the whole of this  
 3 page. We can see the date in the bottom left-hand  
 4 corner, 1 February 1982, this is again a figure,  
 5 a document prepared by JDC, Professor Cash. It's  
 6 titled "A proposal to Increase the Production of  
 7 Factor VIII Concentrate in order to Achieve  
 8 Self-Sufficiency in Scotland for the Next Decade".  
 9 Now, we don't need all of this document for  
 10 present purposes. If we could go to page 3, and the  
 11 second half of the page that starts "The Need".  
 12 Sir, I'll read this out and you'll see that it  
 13 picks up, I believe, some of the comments that you've  
 14 just made and reflects them:  
 15 "Less than 5 years ago a Committee, created by  
 16 the DHSS, advised that the basic needs of the  
 17 haemophilia A population in the UK would be met by the  
 18 production of [1 million units of Factor VIII per  
 19 million population per year]."  
 20 I believe that's a reference to the  
 21 December 1977 working group that I mentioned earlier:  
 22 "SNBTS representation on the Committee was of  
 23 the opinion that the figure advised was more closely  
 24 related to what was believed to be possible with  
 25 regard to plasma procurement and the fractionation

29

1 is believed that the proposed target may go some way  
 2 to meeting the potential needs for bleeding associated  
 3 with chronic liver disease, which is likely to appear  
 4 in this patient group within the next 10 years.  
 5 "It is significant that the use in Scotland in  
 6 the year ending 31st March, 1981 was of the order of  
 7 [1.5 million units per total population] and that is  
 8 likely to have risen further to 1.7 for the year  
 9 ending 31st March, 1982."  
 10 Now, sir, I may have mistakenly told you that  
 11 it's in this document that Professor Cash contrasts  
 12 his figure with the one for NBTS, and my apologies for  
 13 that. I will get to you --  
 14 **SIR BRIAN LANGSTAFF:** I think he has done, hasn't he? If  
 15 we just go back over the page, to talk about the DHSS  
 16 figure.  
 17 **MR BOUKRAA:** Yes, well, he's talking about the DHSS  
 18 figure --  
 19 **SIR BRIAN LANGSTAFF:** 5 years before?  
 20 **MR BOUKRAA:** -- 5 years before.  
 21 **SIR BRIAN LANGSTAFF:** So the contrast is there.  
 22 **MR BOUKRAA:** The contrast is there, sir. He does also  
 23 contrast the figure with a more up-to-date one.  
 24 I will make sure I get you the reference, sir, in that  
 25 document. I'm sure that it's there.

31

1 facilities of the NBTS, rather than a true estimate of  
 2 what was required."  
 3 Now, the reference there to SNBTS representation  
 4 on the Committee, that may be a reference to the fact  
 5 that Professor Cash himself was a member, of that  
 6 working group:  
 7 "In any event, it should be stressed that this  
 8 Committee referred itself to basic needs and did not  
 9 take into consideration the extensive production of  
 10 Home Therapy and in particular, the concept of  
 11 prophylaxis.  
 12 "Studies carried out in the last 6 months in  
 13 Scotland, in association with the Scottish Haemophilia  
 14 Centre Directors under the aegis of the SHHD, have  
 15 revealed, when examining world-wide trends, that it  
 16 would be more appropriate to plan towards the  
 17 production of [2.75 million units of Factor VIII per  
 18 million population per year]. This dramatic increase  
 19 takes cognisance [if we go over the page, please,  
 20 Sully to the top of the next one] of the introduction  
 21 of prophylactic therapy, the increased life expectancy  
 22 of the haemophilia A population with the concomitant  
 23 increase in surgery for cardiovascular disease,  
 24 orthopaedic surgery of the elderly and surgery  
 25 required to manage malignant disease. In addition it

30

1 **SIR BRIAN LANGSTAFF:** Just before you pass from this,  
 2 the -- it's not part of the presentation, really, on  
 3 self-sufficiency, but it may be worth noting that  
 4 Professor Cash says, in just the last sentence before  
 5 he turns to paragraph 2.03:  
 6 "... the potential needs for bleeding associated  
 7 with chronic liver disease, which is likely to appear  
 8 in this patient group within the next 10 years."  
 9 So he in February, 1 February 1982, foresaw  
 10 a significant impact of chronic liver disease arising  
 11 in that patient group, and that might, probably be  
 12 because of the treatment they were having.  
 13 **MR BOUKRAA:** That certainly seems to be an inference which  
 14 is available from that passage.  
 15 **SIR BRIAN LANGSTAFF:** And --  
 16 **MR BOUKRAA:** It would be difficult to explain otherwise  
 17 what Professor Cash was referring to there.  
 18 **SIR BRIAN LANGSTAFF:** Well, the question would be why  
 19 would that patient group itself, of those with severe  
 20 haemophilia A, or (inaudible) ^ haemophilia A, why  
 21 would they, rather than other people as group, suffer  
 22 from chronic liver disease?  
 23 **MR BOUKRAA:** That's right, sir.  
 24 **SIR BRIAN LANGSTAFF:** Yes, and he's stating it as though  
 25 it wasn't at all controversial.

32

1 **MR BOUKRAA:** That's certainly one reading of this  
 2 document, sir.  
 3 **SIR BRIAN LANGSTAFF:** That's how he's stating it.  
 4 **MR BOUKRAA:** That is how --  
 5 **SIR BRIAN LANGSTAFF:** It may be controversial but he's  
 6 certainly setting it forward as an assumption without  
 7 trying to justify it. Yes, thank you.  
 8 **MR BOUKRAA:** Sir, those are all the documents I wanted to  
 9 take you to for this part of the presentation. I will  
 10 get that contrast that Professor Cash made with the  
 11 NBTS figure.  
 12 In the written note we have, towards the end of  
 13 this section, set out some comments that were made  
 14 later on by a number of figures including, in  
 15 particular, Professor Cash looking back at these  
 16 estimates, in particular the estimate that he made in  
 17 early 1981 and commenting on whether or not it proved  
 18 to be a successful estimate of what was going to be  
 19 needed. There's more detail on that in the written  
 20 note.  
 21 So that deals with this section. We're now  
 22 going to be moving on to the section dealing with  
 23 production of concentrates at PFC, the question of  
 24 self-sufficiency, whether it was reached and, if so,  
 25 what that meant.

33

1 Dr Foster or authored by Dr Perry in advance of their  
 2 oral evidence.  
 3 So we're going back in time, again, from the  
 4 1980s to the early 1970s, sir. There are a couple of  
 5 documents, which are set out in the written note, from  
 6 1973, 1974, 1975, which I won't take you to. There's  
 7 one from December 1973 prepared by Mr Watt, which is  
 8 a report on the development of Factor VIII  
 9 concentrates at that time. The reference for it is  
 10 PRSE0000678. We don't need it up.  
 11 It's a useful document to look at to get a sense  
 12 of what sort of concentrates were being developed by  
 13 the PFC at that time, while it was still at the RIE,  
 14 so before it moved to the Liberton site. What Mr Watt  
 15 considered production capacity might be, and what sort  
 16 of concentrates PFC should be focusing on. Similarly,  
 17 there's a quarterly report for the end of  
 18 September 1974, which gives some insight into the  
 19 development of concentrates at that time.  
 20 There's a letter, sir, which it may be useful  
 21 for you to turn to -- I won't go to it now -- later  
 22 on, from January 1975. It's by Major General Jeffrey,  
 23 he's writing to administrative medical officers in  
 24 health boards. He sets out some of the recent history  
 25 of the development of PFC and the impact of its move

35

1 Now, in the written note we've divided up this  
 2 part of the presentation into three sub-areas and  
 3 three parts of the chronology. The first one deals  
 4 with the position in the 1970s up to the end of 1984,  
 5 when heat treatment, at least for Factor VIII  
 6 concentrates, is introduced in Scotland and for  
 7 Northern Ireland.

8 We then divided it into heat treatment and the  
 9 impact of heat treatment on self-sufficiency. That  
 10 broadly covers the years '85, '86 to '87, and then  
 11 we've looked more briefly at the period at the end of  
 12 the 1980s to see whether or not self-sufficiency was  
 13 maintained in Scotland, assuming it was reached  
 14 before.

15 Now, as I go through this part of the oral  
 16 presentation, I'm likely to spend some time, a good  
 17 deal of time, on the first of those subheadings. I'm  
 18 likely to spend less time on heat treatment. Now,  
 19 heat treatment is obviously a very important topic but  
 20 we are going to be hearing very shortly from Dr Foster  
 21 and then from Dr Perry who were directly involved in  
 22 a number of the issues. So I'm intending to set out  
 23 an overview of some of the key dates, look at some  
 24 important documents, but perhaps not go into as much  
 25 detail about documents which were authored by

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1 to Liberton on the production of blood products.

2 The reference for that, if you want to look at  
 3 it, sir, later is SCGV0000127\_062. We don't need it  
 4 up.

5 One of the points that's made in that letter,  
 6 which is January 1975, is about the impact of the move  
 7 from the RIE site to the new Liberton site, and what  
 8 the letter seems to suggest is that it was not going  
 9 to be possible to overlap production at those two  
 10 sites, as I understand it, because, in this new  
 11 system, there was a computer which had to be moved  
 12 from the old site to the new site and you couldn't  
 13 have production at the two happening at the same time.

14 That was thought likely to have an impact on the  
 15 supply of certain blood products but it was not  
 16 thought likely to have an impact on the supply of  
 17 factor concentrates, including Factor VIII, at the  
 18 levels that they were being produced at the time,  
 19 because a stock had been built up.

20 I highlight that point, partly because it's  
 21 an interesting one on the question of building up  
 22 stocks that we'll come back to as we look through  
 23 these documents, through the later 1970s and into the  
 24 1980s.

25 Now when we move into the second half of the

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1 1970s and the PFC is trying to increase its production  
2 of Factor VIII in particular, one of the themes, as  
3 with England and Wales, that comes up, is about plasma  
4 supply. Getting enough fresh plasma.

5 In this respect, it appears that, from this  
6 period, Scotland had something of an advantage over  
7 England and Wales, which is its use or the use in  
8 Regional Transfusion Centres, and perhaps hospitals,  
9 of red cell concentrates, rather than whole blood, was  
10 already at a more advanced stage. Now, those who were  
11 here last week and attending some other hearings will  
12 know what that means.

13 Effectively, what it means is that when a unit  
14 or a donation of blood is collected, rather than using  
15 that whole blood for a blood transfusion, it is  
16 separated out into different components, including red  
17 cell concentrates, which are used for the transfusion,  
18 including plasma which can be sent off to be  
19 fractionated. So what that means is you've got the  
20 same number of donations but if you divide them up  
21 into these different components, including red cell  
22 concentrates, you can get more plasma out of the same  
23 number of donations.

24 There's a meeting of SNBTS directors, sir, in  
25 June 1975 where this issue was picked up, some targets

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1 Now, we're going to turn to a document in which  
2 some of these supply issues were discussed in a good  
3 deal of detail. It's a meeting, again, of SNBTS  
4 directors and Haemophilia Directors, it took place in  
5 November 1975. The reference is PRSE0002823. If we  
6 start with the attendees at the meeting, we see number  
7 of individuals we've been looking at already:  
8 Professor Cash, Mr Watt, Major General Jeffrey. So  
9 this is 1975, at that time Cash is still at the  
10 Edinburgh Transfusion Centre.

11 Now, this meeting covered a number of different  
12 issues related to supply and we're going to look at  
13 those, starting over the page. Towards the bottom of  
14 this page, the last passage, section headed "Supplies  
15 of Factor VIII", and I'm going to pick out a few  
16 sentences in these various paragraphs that start here.  
17 So it's recorded that:

18 "At the May meeting of Directors it had been  
19 agreed to look again at the possibility of releasing  
20 material to Haemophilia Centres before the stock  
21 target of 1,000,000 units had been reached and as a  
22 result, Major General Jeffrey had agreed with Mr Watt  
23 that reserves could be held in Blood Transfusion  
24 Centres rather than the Protein Fractionation Centre."

25 I've highlighted on that -- I've alighted,

39

1 are mentioned, and it suggests that good progress has  
2 been made on continuing to increase the use of red  
3 cell concentrates in Scotland. I will give you the  
4 reference. Again, sir, I won't go to it. It's  
5 PRSE0003812.

6 It was noted at that meeting that targets of  
7 a 40 per cent minimum use of concentrated red cells by  
8 September 1975 and 50 per cent by March 1976, the  
9 following year, were in some cases already being  
10 reached or exceeded.

11 Now, the use of red cell concentrates varied  
12 regionally but what that meeting suggests is that good  
13 progress was being made in a number of regions.

14 Notwithstanding that, the greater use of red  
15 cell concentrates, plasma supply was still a concern  
16 from the perspective of the fractionators, who were  
17 trying to produce more concentrates. We can see that  
18 in a paper prepared by Major General Jeffrey for  
19 11 June 1975 meeting of SNBTS directors. Again, sir,  
20 just for your note, the reference is SBTS0000098\_031.

21 In that paper Major General Jeffrey said the  
22 main concern was the supply of fresh frozen plasma for  
23 Factor VIII, so that a stockpile can be built up  
24 before a changeover from cryoprecipitate to  
25 intermediate factor can be planned.

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1 rather, on that, sir, because it points to what  
2 becomes and appears to be already an important part of  
3 the supply policy of the SNBTS, which is to build up  
4 a stockpile of Factor VIII, which is held partly at  
5 the PFC, partly in Regional Transfusion Centres.

6 **SIR BRIAN LANGSTAFF:** Now, was the reason for that the  
7 move to Liberton, what you were telling me earlier  
8 about the need to build up stock to cover the drop-off  
9 in production there would be before Liberton became  
10 fully operational? But Liberton began to be  
11 operational in '74, didn't it?

12 **MR BOUKRAA:** It began to be operational from the point of  
13 view of producing blood products, I believe, in 1975,  
14 and really only gets going more in 1976.

15 **SIR BRIAN LANGSTAFF:** So the computer system, which was  
16 necessary to operate the system of continuous  
17 production which had been developed by Watt and was in  
18 operation at the Royal Infirmary in Edinburgh, there  
19 being only one computer that was able to control the  
20 process, that was moved. When it was moved you  
21 couldn't get any more continuous production in the  
22 Royal Infirmary, so whatever production there was, was  
23 in a different method and obviously would produce much  
24 less, so they wanted to build up the stocks in advance  
25 of that, so they could distribute it.

40



1 So this is dealing with that problem, is it? In  
2 other words, is this stockpile a stockpile for all  
3 time as a form of strategic reserve, as it were, or is  
4 it to cover particular period?

5 **MR BOUKRAA:** I believe that the two are probably linked,  
6 sir. It seems to me, from some of the documents that  
7 we'll look at, that this is at least part of a more  
8 entrenched policy of building up a strategic reserve,  
9 but I'm sure you're quite right that this policy may  
10 well have originated in this period when there was  
11 a move from RIE to the Liberton site.

12 So, before the move took place, it was  
13 understood to be important to build up stockpile, so  
14 there wouldn't be a gap in supply during the  
15 transitional period, but once the move has taken  
16 place, we see, from number of documents starting  
17 around this time, a repeated emphasis on the  
18 importance of building up a stockpile in case there  
19 are future gaps in production.

20 **SIR BRIAN LANGSTAFF:** So the reason for having the  
21 stockpile is to smooth peaks and troughs in  
22 production?

23 **MR BOUKRAA:** That's my understanding, sir. Well, I'm sure  
24 it would have had a number of elements. One of them,  
25 I am sure, would be smoothing peaks and troughs. One

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1 to provide to patients, but also that there's  
2 a stockpile which exists of a certain size, and it  
3 seems that there are points at which Factor VIII is  
4 not been sent on to Regional Transfusion Centres and  
5 Haemophilia Centres in order to build the stockpile  
6 back up. So I --

7 **SIR BRIAN LANGSTAFF:** So this is, what, a robbing Peter to  
8 pay Paul type policy? It's not providing the  
9 Factor VIII which a Centre might wish to have  
10 manufactured by the NHS at any rate because there may  
11 be a future occasion when there is even less to  
12 provide to the -- to that centre.

13 **MR BOUKRAA:** There would certainly --

14 **SIR BRIAN LANGSTAFF:** And we want to use what we've got to  
15 build up the stock, rather than give it to you?

16 **MR BOUKRAA:** There would certainly seem to be a period in  
17 time when those dynamics start to come to the fore,  
18 and there's a sense that --

19 **SIR BRIAN LANGSTAFF:** What period of time, roughly --

20 **MR BOUKRAA:** Certainly the early 1980s. It comes up in  
21 the documents at least then. It may well have been  
22 implicit in the policy the whole time, that we're not  
23 going to provide you with the concentrates that you  
24 say you want in order to build up the stockpile. But  
25 certainly from what's in the documents, that tension

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1 of them, I suppose, related to that is, if at some  
2 point there's a shutdown --

3 **SIR BRIAN LANGSTAFF:** Well, that's a trough.

4 **MR BOUKRAA:** That's a trough. Yes. A big trough. I was  
5 thinking of perhaps smaller peaks and troughs that  
6 might happen as plasma supply goes up and down month  
7 to month. But you're quite right, sir; that's another  
8 type of trough.

9 **SIR BRIAN LANGSTAFF:** It would have been, I suppose,  
10 standard manufacturing practice at the time to have  
11 stocks always available. The just-in-time process of  
12 manufacturing is fairly recent, isn't it?

13 **MR BOUKRAA:** I'm sure that's right, sir, but we do see  
14 this policy and this approach being picked up on  
15 a number of times in the documents. The size of the  
16 stockpile being seen to be important. The period of  
17 time that the stockpile covers also being seen to be  
18 important. We get to the later period, in to 1980s,  
19 and I believe it's understood that there's a need for  
20 about 12 months' supply of stock. We'll also see in  
21 some of the documents that when the SNBTS and the  
22 fractionators are assessing whether or not  
23 self-sufficiency has been achieved, self-sufficiency  
24 seems to be understood as: not only is Factor VIII  
25 being provided to meet demand, whatever that might be,

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1 starts to become clear at least in the material that  
2 we've got during that time period. I believe it's  
3 early 1980s, but I'll come on to it.

4 **SIR BRIAN LANGSTAFF:** So that particular reason for having  
5 a stockpile didn't apply in '75, or at least there's  
6 no evidence of it applying. Or is there?

7 **MR BOUKRAA:** Well, not that immediately comes to mind,  
8 sir. I'll come back to you if there is. In this  
9 period, it's also important to note that patients are  
10 being treated with cryoprecipitate as well as  
11 concentrate, and we'll come to the graphs later on  
12 which show what kinds of products were being used. I  
13 believe some -- a small amount of commercial  
14 concentrate was still being used. So it could be that  
15 this dynamic was in place also in the second half of  
16 the 1970s. I don't believe it's quite as clear from  
17 the documents as it becomes later on.

18 **SIR BRIAN LANGSTAFF:** Thank you.

19 **MR BOUKRAA:** If we move on now to a document in  
20 March 1976. We'll pick up on this question of plasma  
21 supply again. Sully, it's SCGV0000114\_023. Sir, you  
22 might consider this to be an interesting document  
23 because it links back to some of the issues in England  
24 and Wales as well as looking at Scotland. We can see  
25 from the top that it is a note of a meeting I believe

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prepared by a DHSS official that was called to consider Factor VIII production, 11 March 1976, attended by figures including Dr Maycock, Mr Watt, General Jeffrey.

If we look at the heading "Production capacity at present", in just the first sentence there it says:

"In both England and Wales and Scotland, the main factor is the availability of fresh plasma."

I understand that to mean the main factor holding back the production of more factor concentrates is the availability of fresh plasma.

The end of that first paragraph refers to production in England and Wales at that time. And we considered yesterday this figure of 17.5 million, 15 million, when it might have been achieved, whether it reflected capacity or actual production. This is another piece of the jigsaw perhaps.

At the present time, production in England and Wales is at 30,000 containers of 250 units a year. The target is 55,000 containers by June 1977, the equivalent to 14.5 million units a year. Yesterday we looked at a document which was based on -- well, which referred to a date in August 1977, appeared to suggest a figure of 17.5 million, though that related both to BPL and PFL. As I say, it might just be another piece

45

This was a document which referred to there being an emotive response to the issue of Factor VIII supply in the UK. I believe Mr Hill took you to those passages. I won't go to them again, but this is a document in which those passages appear.

If we could go to page 11, please. In fact, if we could go back a page, we'll just see the heading. At 14, you can see this is about the use of coagulation factors including subparagraph (b), Factor VIII, and this was a passage that I was mentioning an emotive response.

If we go over the page to the bottom, subparagraph 4. So this is 1975 to 1976:

"Requirements of Factor VIII are at present based on an estimated average use of 10,000 units per patient annually ... some 4 million units for the known haemophilia population in Scotland."

If we go over the page, please, Sully, to page 12, looking at the second half, the section that is subparagraph or paragraph 6, "Present supply and demand situation". I'm not going to read all of that out. I bring to your attention, sir, the final third of that paragraph which is about plasma supply:

"The crucial point which should be a main target in the future of the directors is that by increasing

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of the jigsaw, sir, when trying to disentangle those different figures.

If we look at the second passage on this page, just the first sentence:

"The amount of Factor VIII concentrate required in Scotland, based on the same 1973 expert committee report, is 4.5 million units. That's 10 to 12,000 units per year for each haemophilia A patient."

And then I'm just going to highlight the final sentence that we can see on the screen at the moment:

"The target in Scotland of 4.5 million units a year can easily be met, given sufficient fresh frozen plasma. There's ample manufacturing capacity."

So a suggestion in that meeting in 1976 that production manufacturing capacity at PFC should be ample to meet Scotland's needs, provided enough fresh frozen plasma is available.

I'm now going to look at a document which sets out a number of points relevant to the supply position in Scotland in the mid-1970s. It's, in fact, one I believe Mr Hill took you to last week, but we're going to look at some different passages.

It's PRSE0002133. Now it's an SNBTS annual report, covering 1975 to '76. Again, at this time, Major General Jeffrey was the director for the SNBTS.

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issues of concentrated red cells instead of whole blood and by releasing plasma which would be used for cryoprecipitate production to the PFC as concentrated Factor VIII becomes available in increasing quantities (which depends on these two major factors) [it says] at least half of the plasma sent to the PFC is in the form of fresh frozen plasma."

There's then some comments on self-sufficiency and what self-sufficiency might mean, which points to its different uses at different points of time by different individuals. The report says this:

"As regards self-sufficiency, Factor VIII is available to treat adequately the known haemophilia population in Scotland. The form in which it is available does not as yet meet the major demand for home therapy. Present policy is to issue intermediate factor to centres, with only a very small national reserve at the PFC; Directors of haemophilia and Regional Transfusion Centres are expected to maintain their own reserves, and patients should be introduced to home therapy only when an adequate reserve -- three months' anticipated use -- is available for each individual in case the PFC meets manufacturing difficulties."

Now, there we're looking at the different

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1 aspects of reserves and stockpiles and the reasons why  
2 they might be necessary. We've looked at some of the  
3 big picture strategic ones: if there's a drop in  
4 production, it's important to have stockpile.  
5 I believe the three months period there is referring  
6 to patients who will be on home therapy who will be  
7 using concentrate in order to avoid the possibility  
8 that they'll have to come off that programme. You  
9 want to have at least three months available for each  
10 patient who you've put on home therapy.

11 If we can just pick up briefly on page 18 and  
12 the bottom of this page, "Summary concerning the state  
13 of self-sufficiency". Now, this table is not laid out  
14 perhaps in the most immediately clear way, but it's  
15 useful looking at it to see at the top what the  
16 symbols mean:

17 "(+ = attained; - = not yet achieved; NA = not  
18 applicable ...)"

19 The table then deals with different products  
20 and, if we go over the page, we'll see Factor VIII as  
21 well as Factor IX. Thank you.

22 So towards the bottom of the table at the top,  
23 you can see I-Factor VIII -- I believe that's  
24 a reference to intermediate Factor VIII which is  
25 a product -- the target, and then two aspects to

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1 it's envisaged that at least 90 per cent of  
2 cryoprecipitate is replaced by concentrated  
3 Factor VIII.

4 That's all I wanted to take you to in that  
5 document. I'm going to be moving on now into the  
6 1980s. I note the time. I wonder if this would be  
7 a convenient moment.

8 **SIR BRIAN LANGSTAFF:** Yes, well, let's take a break then  
9 until 11.45. 11.45.

10 (11.13 am)

(A short break)

12 (11.45 am)

13 **SIR BRIAN LANGSTAFF:** Yes?

14 **MR BOUKRAA:** Sir, before we move on to the 1980s, I wonder  
15 if we might very briefly return to the table we were  
16 just looking at, a representative for one of the Core  
17 Participant groups has helpfully pointed out couple of  
18 features of that table I think I should draw to your  
19 attention.

20 Sir, we are back at the table, at the bottom of  
21 the page, the first point to note is that  
22 cryoprecipitate is included in the list of products.  
23 You may have already picked up on this, sir, 10 per  
24 cent present use. More importantly, over the page,  
25 and we look again at those entries for Factor VIII and

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1 self-sufficiency on the right-hand side: day-to-day,  
2 and one year's reserve and, for Factor VIII, the  
3 target was achieved at this time for neither. Neither  
4 was there enough day-to-day Factor VIII concentrates,  
5 nor was there a year's reserve.

6 And what I mentioned earlier, sir, this question  
7 of how self-sufficiency was defined by different  
8 people, this is one of the ways in which it's  
9 approached by the SNBTS, at least in the mid-1970s,  
10 and we can see that there are two forms of concentrate  
11 containing Factor IX. I believe the relevant one for  
12 our purposes is the top one, Factor II, IX and X.  
13 There, there is enough being produced for day-to-day  
14 self-sufficiency but not enough to meet the  
15 requirement for a year's reserve.

16 Then, finally, over the page, a couple of last  
17 points to pick out. Actually, it should be the  
18 previous, page 19, please. Sorry, it was the same  
19 page. The second half of this page, "Targets for  
20 1977-78", I just draw your attention, sir, to  
21 subparagraph (a) there, there's a target for red cell  
22 concentrates, "CRC" is concentrated red cells.  
23 A suggestion that they need to get to 60 per cent use  
24 of concentrated red cells.

25 Then subparagraph (b), again, this is a target,

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1 Factor IX, I wanted to highlight the asterisk that  
2 appears next to the minus symbol.

3 **SIR BRIAN LANGSTAFF:** Yes.

4 **MR BOUKRAA:** So for Factor VIII, no asterisk appears. For  
5 Factor IX, an asterisk appears next to the "One year's  
6 reserve", and if we look below in parenthesis, it says  
7 that the asterisk means "capable of achievement with  
8 present PFC stocks". Now, it's not entirely clear to  
9 me what those two symbols mean together. On the one  
10 hand, there's one year's reserve is not achieved, on  
11 the other hand, a year's reserve can be achieved with  
12 present stocks.

13 There's a little more explanation in the passage  
14 which follows, sir, but I thought I'd highlight that  
15 for anyone who is watching and perhaps for you to note  
16 this is another feature of that table.

17 **SIR BRIAN LANGSTAFF:** Yes, it's -- as a matter of literal  
18 reading, it's inconsistent but that's probably not  
19 what it means.

20 **MR BOUKRAA:** That's right, sir. Yes. I agree. It must  
21 mean something. It's not altogether clear what it  
22 does mean. Thank you.

23 So we move into the 1980s. It's important to  
24 note that when we get to the 1980s, and I'm not going  
25 to take you, sir, to any documents about this -- that

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1 there has been, in the late 1970s to about 1980, 1981,  
 2 significant changes in developments in manufacturing  
 3 processes at the PFC. We pointed to, in the written  
 4 notes, some documents which set some of those out.  
 5 They cover things like continuous thawing.  
 6 Dr Foster in his statement suggests that,  
 7 between 1976 and 1981, Factor VIII yields increased by  
 8 about 50 per cent. Now I'm not going to go into any  
 9 more detail about that issue but it's an important  
 10 part of the picture as we move into the late 1970s and  
 11 early 1980s, that we trying to understand changes to  
 12 supply of concentrates.  
 13 **SIR BRIAN LANGSTAFF:** It increased by about 50 per cent?  
 14 **MR BOUKRAA:** That's the suggestion, I believe, in  
 15 Dr Foster's statement, sir, between '76 and '81 --  
 16 50 per cent by '81.  
 17 I am going to take you to a couple of documents  
 18 from 1980, which go to this issue of PFC's  
 19 distribution arrangements. They seem to relate to the  
 20 introduction of a pro rata arrangement some time in  
 21 the early 1980s but they also link back to this  
 22 stockpile question.  
 23 The first one is PRSE0004005. This is letter  
 24 from Mr Watt to Dr Boulton in Edinburgh and Southeast  
 25 Transfusion Centre. We don't need to go to all of it,

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1 **MR BOUKRAA:** I hope it is.  
 2 **SIR BRIAN LANGSTAFF:** This is not looking at the right  
 3 one.  
 4 **MR BOUKRAA:** I might have given the wrong reference.  
 5 **SIR BRIAN LANGSTAFF:** You gave the same reference as you  
 6 had before.  
 7 **MR BOUKRAA:** I've got the right one here. PRSE0002207.  
 8 Thank you.  
 9 Sir, this is December 1980, later on in the same  
 10 year. Again, Mr Watt, a letter to Professor Cash.  
 11 I'm going to look at the introductory passages of the  
 12 letter. Mr Watt says:  
 13 "After our discussion ... I made the following  
 14 arrangements for the distribution of Factor VIII  
 15 concentrates, to be effective from 1 January 1981.  
 16 "Each month when we prepare the total issue from  
 17 production we shall allocate as follows:  
 18 "The first 15% of the total product will be  
 19 placed in the National Reserve."  
 20 That contrasts with the 10 per cent figure that  
 21 we just looked at. There is a special arrangement for  
 22 Inverness as there was in the previous letter. Then  
 23 there is a summary of the proportions that will be  
 24 provided to the remaining regions in Scotland.  
 25 At the bottom of this page, Mr Watt outlines

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1 I think the context of this letter is that  
 2 Professor Ludlam is trying to obtain more Factor VIII  
 3 for his patients in Edinburgh, I believe, in order to  
 4 place more patients on the home treatment programme.  
 5 If I can just highlight the second paragraph  
 6 here, where Mr Watt summarises what the distribution  
 7 arrangements are at that time for PFC product, and he  
 8 says:  
 9 "The present situation regarding the  
 10 distribution of Factor VIII to regional centres from  
 11 the [PFC] is that each pool comes to be ready for  
 12 issue we place 10% in the national stockpile to be  
 13 available for emergency purposes and the remainder is  
 14 distributed to regional centres in a proportion which  
 15 has been agreed by the Directors. This is roughly  
 16 according to the distribution of population in the  
 17 various regions but with a slight bias in favour of  
 18 Inverness where the geography of the region makes  
 19 a more widespread utilisation of home therapy a rather  
 20 necessary fact of life."  
 21 That's the position as of February 1980. We can  
 22 pick things up later in the year, December 1980, with  
 23 PRSE0004005. This is another letter from Mr Watt,  
 24 this time to Professor Cash.  
 25 **SIR BRIAN LANGSTAFF:** It probably is.

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1 some ways in which the proportions might be adjusted,  
 2 month to month, and refers to a league table which  
 3 exists at PFC.  
 4 That's the position at the end of 1980. As we  
 5 get into 1981, one of the issues that becomes  
 6 significant at PFC is a Medicines Inspectorate report.  
 7 I'm not going to go to the detail of that report, sir,  
 8 some of it is set out in the written note. I believe  
 9 it is also covered by Dr Foster in his statement, but  
 10 it's an important part of the chronology and trying to  
 11 understand what's happening around this time.  
 12 I believe the visits start from the inspectors  
 13 in 1979. They produce some initial comments. There's  
 14 an updated report that they produce in October 1981,  
 15 and that timing, what's set out in that October 1981  
 16 report, is relevant both for what's going to happen at  
 17 PFC in the years that follow. It's also relevant to  
 18 those discussions we were looking at yesterday between  
 19 Scotland and England. This figure of £6 to £7 million  
 20 appears, which is linked to changes that are going to  
 21 be necessary to be made at PFC.  
 22 **SIR BRIAN LANGSTAFF:** Well, half of them, I think, we  
 23 decided or roughly?  
 24 **MR BOUKRAA:** That's the suggestion in one of the letters.  
 25 I believe -- I don't have the reference immediately to

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1 hand -- that that number is divided up differently in  
 2 different documents.  
 3 **SIR BRIAN LANGSTAFF:** I think you mentioned that  
 4 yesterday.  
 5 **MR BOUKRAA:** Yes.  
 6 **SIR BRIAN LANGSTAFF:** So it's somewhere between nought and  
 7 six or seven, but it's probably around about half.  
 8 **MR BOUKRAA:** It might be around about half. It's  
 9 certainly a proportion of that figure.  
 10 I'm going to turn now, sir, to a document from  
 11 December 1981. It's PRSE0003364. It's one which  
 12 relates both to where PFC had got to in terms of its  
 13 supply but also this question of stockpile. I'm also  
 14 going to pick up in this document a reference to that  
 15 contrast between the NBTS and the SNBTS that I  
 16 couldn't find earlier. It appears a bit later in  
 17 time. This is when it appears.  
 18 So this is an 8 December 1981 meeting of SNBTS  
 19 directors. If we could go through, please, to page 3,  
 20 and the passage in section 4, "National Stocks of  
 21 Blood Products".  
 22 In the first paragraph there there's a reference  
 23 to a table, PFC products which had been issued. Then  
 24 in the second paragraph there's a reference to what  
 25 self-sufficiency was understood to mean by SNBTS

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1 note that plasma supply is increasing very  
 2 significantly to PFC. A problem that begins to emerge  
 3 relates to the amount of plasma that's been sent and  
 4 whether or not PFC could fractionate it all quickly  
 5 enough.  
 6 There's a memo which is in the note,  
 7 20 August 1981, where reference is made to an  
 8 estimated 25 per cent growth in supply of fresh frozen  
 9 plasma in six months.  
 10 We can see some of those issues reflected in  
 11 a document we'll go to now, another letter from  
 12 Mr Watt. It's PRSE0002316. This is a letter which  
 13 gives us some insight into that particular difficulty  
 14 that I was just describing but also more generally  
 15 into PFC's production capacity around this time.  
 16 So it's dated February 1982, it's from Mr Watt  
 17 to Mr Cash. If we go down to the first couple of  
 18 paragraphs, Mr Watt said that:  
 19 "By the time of the March issue of Factor VIII  
 20 under the 'Pro Rata' scheme the PFC will be  
 21 substantially in debt to the regions."  
 22 He then refers to a "slowly gathering difficulty  
 23 because of freeze-dryer limitation at PFC. At present  
 24 we are getting 700 [kilos] of fresh plasma weekly and  
 25 can process up to 720 [kilos] in a full capacity week.

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1 directors at the time. So:  
 2 "It was agreed that the concept of  
 3 self-sufficiency implied uninterrupted supply and  
 4 that, generally, the national stock should consist of  
 5 12 months' usage of products, labelled and ready for  
 6 issue."  
 7 It was also mentioned that there would be  
 8 an evaluation of a pro rata distribution of product,  
 9 which I think ties in with that document from late  
 10 1980 that we just looked at.  
 11 If we go to page 5, please, and the second  
 12 paragraph that appears on that page, you can see the  
 13 contrast between the Scottish figures and those  
 14 England and Wales:  
 15 "There had also been discussion on the current  
 16 target of 2.75 million [units of] Factor VIII [per]  
 17 million [per] population per annum, in view of the  
 18 fact that the current NBTS target was 2.0 million  
 19 [units per] million population per annum."  
 20 So it has been decided and was decided then to  
 21 retain the target of 2.75. So a significantly higher  
 22 target for the production of Factor VIII in Scotland  
 23 than in England and Wales at that time.  
 24 Now, as we're moving through 1981, sir, we can  
 25 see from the documents that are set out in the written

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1 If a lot is missed, for whatever reason, the net  
 2 effect is to increase plasma stock, which cannot be  
 3 cleared."  
 4 He also makes reference to the shift-working  
 5 trial we looked at yesterday and its effect on stocks  
 6 of plasma.  
 7 If we go down, actually, we've still got it up  
 8 here but if we look towards the bottom of the screen,  
 9 Mr Watt says:  
 10 "In summary, with the new shelf in the dryer  
 11 [which he outlines elsewhere in the letter] and  
 12 a reduction of cycle time by correction of the dryer  
 13 tray fault we expect to increase plasma process  
 14 capacity for [fresh frozen plasma] to about  
 15 2000 [kilos] per full two week period ..."  
 16 In other words about 1,000 kilos a week. It is  
 17 suggested:  
 18 "... this will help to make in road in the  
 19 stockpile and also keep up with input."  
 20 **SIR BRIAN LANGSTAFF:** So the new shelf in the dryer, is  
 21 that something which occurred because there's just the  
 22 dryer, it has to be utilised? There's a little bit of  
 23 space in it, but the bottles are too tall, and so the  
 24 size of the bottles is reduced or they get smaller  
 25 bottles; is that the -- is there is the -- where they

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1 found space for the new shelf in the dryer? Do you  
2 remember?

3 **MR BOUKRAA:** It's a good question, sir. I'm not sure is  
4 the answer. I don't know if it relates to the size of  
5 the bottles. It may well.

6 **SIR BRIAN LANGSTAFF:** I think it may be Dr Foster who  
7 talks about that but I can't remember where I recently  
8 read that, but I'm just wondering if this was the  
9 extra shelf.

10 **MR BOUKRAA:** You could well be right, sir. I'm sorry  
11 I can't assist by confirming that particular point.  
12 It could well be that we could check it by checking  
13 Dr Foster's statement or confirming with him when he's  
14 giving evidence. That sounds right. That sounds  
15 right. That sounds like what a new shelf in a dryer  
16 would help to achieve.

17 **SIR BRIAN LANGSTAFF:** There's a lesson in it for people  
18 packing their fridges, really.

19 **MR BOUKRAA:** Yes, exactly.  
20 I'm going to pick things up, sir, later in 1982,  
21 30 September 1982, and I'm going to go to a letter  
22 sent from Mr Watt to the Glasgow and West of Scotland  
23 RTC because it picks up on that issue that you were --  
24 we were discussing earlier about the national  
25 stockpile and the effect that that might have on

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1 that part, that effect of the arrangement, from these  
2 documents but it does provide some further insight  
3 into how this policy of having a significant national  
4 stock, national reserve at PFC could play out during  
5 these years in the early 1980s.

6 At this point in the written note, sir, we've  
7 got a few documents summarised and a few paragraphs  
8 relating to freeze-dried cryoprecipitate. I'm not  
9 intending to take you through any of those. It's  
10 an important issue at this time.

11 The broad brush headline picture is that there  
12 were proposals to investigate the production of  
13 freeze-dried cryoprecipitate, particularly in the West  
14 of Scotland. There was a trial that was agreed. This  
15 all takes place between about 1980 and 1983. The  
16 PFC's input, so far as we can see, were a number of  
17 letters from Mr Watt, in which Mr Watt sets out his  
18 pretty firmly expressed opposition to any sort of move  
19 to producing freeze-dried cryoprecipitate.

20 He has some opinions expressed both on  
21 freeze-dried cryoprecipitate as a product, and also  
22 suggests that, if there's going to be any move towards  
23 making it, it could not be produced at PFC or at least  
24 he would strongly oppose it being produced at the PFC.  
25 Now, that's gets us, sir, to 1983 to 1984.

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1 products being sent to particular RTCs. It's  
2 PRSE0000408, a letter from Mr Watt to the Glasgow and  
3 the West of Scotland RTC.

4 In the first paragraph, Mr Watt referred to the  
5 perilous state of Factor VIII supply. He then,  
6 actually still in that first paragraph -- I'm sorry,  
7 in the first sentence he refers to an arrangement  
8 between the Glasgow RTC and the PFC, and he thanks  
9 Dr Hopkins for the:

10 "... generous decision to return 2 000 vials of  
11 Factor VIII Concentrate to the national stock."

12 What that appears to be referring to is  
13 a request from Mr Watt at the PFC to an RTC to get  
14 some Factor VIII concentrate back in order to build up  
15 the national stock, rather than it remaining at the  
16 RTC and then being sent to patients.

17 Now, the implications of this sort of  
18 arrangement aren't immediately clear from this letter  
19 or from some of the other documents we have. From  
20 a patient's perspective, it's not entirely clear what  
21 the effects might be because it's not clear from these  
22 documents whether returning or keeping back more PFC  
23 concentrate in the national stock would mean for  
24 a patient that they're treated with cryoprecipitate or  
25 treated with commercial concentrates. So we can't get

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1 I will pick matters up with a meeting of SNBTS  
2 directors and I think Haemophilia Directors in  
3 January 1983. That's PRSE0001736. Now, this -- as we  
4 can see, it's a meeting of SNBTS and Haemophilia  
5 Directors. It's got a few passages that I'll take you  
6 to, sir, which provide both a summary of what's been  
7 happening in recent years and also set out the  
8 position as it was at that time.

9 If we could go over the page, please, the second  
10 half of that page (a), "Trends in supply and demand".  
11 I won't read all this out, but what you'll see and  
12 what will be apparent from this summary of the  
13 five-year period from 1978 to 1982 is that there have  
14 been very significant increases in PFC's production of  
15 Factor VIII concentrate. Alongside that, a decrease  
16 in the amount of cryoprecipitate had been issued from  
17 RTCs.

18 If we go over the next page, please, page 3, and  
19 there's a discussion starting at paragraph two about  
20 continued purchases of commercial products in Scotland  
21 at this time in, 1983:

22 "Concern again was expressed about the amount of  
23 commercially produced Factor VIII which was still  
24 being purchased and members went on to discuss the  
25 regional breakdown of usage of cryoprecipitate, PFC

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1 concentrate, and commercially produced Factor VIII.  
 2 It was noted that while purchases of commercial  
 3 [Factor] VIII had declined in Glasgow, purchases in  
 4 Edinburgh had increased. Dr Ludlam explained that the  
 5 reasons for the use of commercial material in  
 6 Edinburgh were partially clinical and partially  
 7 a policy of conserving a cushion of an NHS Factor VIII  
 8 against an anticipated shortage when production at the  
 9 PFC would be suspended to carry out alterations  
 10 required by the Medicines Inspectorate."

11 So that's a link back to that report produced by  
 12 the inspectorate, suggestion that there's going to be  
 13 a need to undertake some works and a slowdown in  
 14 production.

15 In the second paragraph, if we can -- I'll just  
 16 highlight the second part of that. This is in  
 17 response to fears of future shortage of Factor VIII  
 18 supply. It said that:

19 "Fears of a shortage were remote, and he  
 20 [Mr Watt] was confident that in co-operation between  
 21 regions, difficulties could be overcome. Dr Cash  
 22 emphasised that the pro rata scheme was not intended  
 23 to be applied inflexibly ... products could be  
 24 transferred between regions in the event of a local  
 25 shortage."

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1 articles in the United States and also in the Observer  
 2 and The Lancet about this problem. An MMWI extract  
 3 (CDC Atlanta) had been circulated with his paper.  
 4 Dr Ludlam informed members that in the UK a letter and  
 5 questionnaire had been sent out to Haemophilia  
 6 Directors."

7 Now, the arrangements between Edinburgh and  
 8 Northern Ireland is one that I'll summarise briefly.  
 9 It's set out with as much detail as we've been able to  
 10 provide in the written note, although there's not much  
 11 in the way of documentation about it. The arrangement  
 12 appears to have been that around the start of 1983,  
 13 Dr Ludlam agreed with Dr Mayne that Scotland would  
 14 send commercial product to Northern Ireland, and in  
 15 exchange, Dr Mayne would return some of the PFC  
 16 product that had been sent to Northern Ireland to  
 17 Edinburgh and Scotland.

18 We have got a letter that I'll briefly take you  
 19 to about that arrangement from the end of  
 20 December 1983. It's LOTH0000005\_071. Thank you. So  
 21 this a letter from Dr Brian McClelland to Dr Ludlam,  
 22 end of December 1983, by which point, as we'll see,  
 23 the arrangement has been in existence for some time.

24 This is essentially Dr McClelland asking  
 25 Dr Ludlam whether this arrangement was intended to

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1 And in the next paragraph, I'm just going to  
 2 note a sentence in the middle of that:

3 "Dr Ludlam also expressed some misgiving that  
 4 Edinburgh perhaps did not receive as much PFC  
 5 factor VIII concentrate as it should pro rata."

6 The reason for highlighting that is that I'm  
 7 going to briefly describe an arrangement that came to  
 8 be agreed between Dr Ludlam in Edinburgh and Dr Mayne  
 9 in Northern Ireland around this time, there to be an  
 10 exchange of commercial and PFC concentrate between the  
 11 two centres.

12 If we go to page 5, this is really just briefly  
 13 to note the position on Factor IX, subparagraph (f).  
 14 All it's said is:

15 "The supply position of DEFIX over the last  
 16 five years had remained strong ... demand reasonably  
 17 stable."

18 So no issues it seems with the supply of  
 19 Factor IX.

20 And just finally on page 7, this is not so much  
 21 on the supply issue, sir, but this is more to note  
 22 that this issue was discussed at this meeting. In the  
 23 middle of the page, there's a reference to AIDS.

24 So this is 21 January 1983:

25 "Dr Cash drew members' attention to recent

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1 continue. He says it has just been pointed out to  
 2 him:

3 "... that we are continuing to receive  
 4 substantial deliveries of PFC Factor VIII from  
 5 Belfast. I was indeed aware that you had on one  
 6 occasion made an exchange with Dr Mayne for some  
 7 commercial Factor VIII which you had previously  
 8 purchased, but I did not know that the process was  
 9 continuing."

10 The next paragraph, sir, I don't know if I'm  
 11 misreading it, or perhaps if a word is missing, it  
 12 reads:

13 "So far as I know, our stock level is low, and  
 14 indeed the total stock situation within the SNBTS is  
 15 at present very healthy, and I wonder if there is some  
 16 specific reason why the exchange ... [is] still  
 17 necessary ..."

18 I don't know if that should read: "As far as  
 19 I know, our stock level is not low and indeed the  
 20 stock level in the SNBTS is very healthy." In other  
 21 words: "We've got lots of stock. Why do you need to  
 22 keep receiving it from Belfast?"

23 And I'll take you very briefly to the response  
 24 from Dr Ludlam. That's LOTH0000005\_085. Have I taken  
 25 you to the wrong ... there you are. Thank you.

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1 Sir, this is January 1984. Dr Ludlam responding  
2 to Dr McClelland:

3 "Thank you for your letter ... about exchanges  
4 of commercial factor VIII with Belfast. The exchange  
5 was agreed early in 1983 because at that time SNBTS  
6 factor VIII was in very short supply. The first part  
7 of the exchange arrived shortly after the  
8 negotiations, and at the time, SNBTS material markedly  
9 improved. The material that has arrived recently just  
10 completes the exchange. As I understand it, we are  
11 now quits with Belfast."

12 So it seems to be an exchange that lasts  
13 effectively for a year, 1983, early 1983 to the start  
14 of 1984.

15 I won't take you to it, sir, but in the written  
16 note it's worth being aware that Professor Cash  
17 doesn't seem to have been aware of this arrangement.  
18 He writes a letter in January 1984 to Dr Mayne saying  
19 that he's just been made aware that there was this  
20 arrangement for this exchange, asking to be filled in  
21 effectively with the details, highlights some  
22 concerns. I'll just read out what he says in his  
23 final paragraph. He says:

24 "Am I right that this arrangement exists? If  
25 so, could you illuminate. On the face of it, this

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1 The second point about the international  
2 context, I'm afraid I'm not able to assist the Inquiry  
3 much further with that at this stage, suffice to say  
4 it may be that it's necessary to investigate that  
5 claim further before accepting that it's accurate.

6 Towards the end of November -- towards the end  
7 of 1983, November 1983, the supply situation at PFC is  
8 getting to a point where there's concern that so much  
9 Factor VIII is being produced and added to the  
10 national stockpile that some of it is in danger of  
11 becoming out of date. Factor VIII obviously has  
12 a limited shelf life.

13 You can see that in the November 1983 memo from  
14 Dr Perry, an internal PFC memo. He notes that the  
15 previous year, the stockpile was 5 million units.  
16 It's grown to 7 million units. He starts to question  
17 whether some steps should be taken to reduce that  
18 stockpile.

19 There's a series of statements and claims that  
20 are made from September 1983 to quite a bit later  
21 in -- for example, from the DHSS, the Scottish office,  
22 suggesting that by this point Scotland had become  
23 either self-sufficient or virtually self-sufficient in  
24 blood products, as set out in the note that we're  
25 picking up from a chronological perspective.

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1 development looks a little worrying, AIDS, etc, and  
2 I'm anxious to help as much as possible."

3 Now, that gets us to later in 1983 and into 1984  
4 and it appears, when we get to this period, that  
5 Scotland is at least on one measure, depending on how  
6 you define it, getting close to self-sufficiency in  
7 Factor VIII. A number of claims begin to be made that  
8 Scotland is now self-sufficient in Factor VIII.  
9 I won't take you to it, but there's a letter from  
10 July 1983 from Mr Watt in which he is informing  
11 Professor Cash of his resignation from the PFC, so he  
12 announces the resignation in 1983. He stays on for  
13 a few more months before Dr Perry takes over.

14 In that letter, Mr Watt says that Scotland has  
15 become the first country in the world to be truly  
16 self-sufficient in plasma fractions. Now, I'm not  
17 going to comment any further on that claim, sir, aside  
18 from highlighting two points. The first is the  
19 suggestion that Scotland itself was self-sufficient at  
20 this point, July 1983, will have to be considered in  
21 the light of some of the figures that we're about to  
22 look at from 1983, and indeed 1984, on product usage  
23 in Scotland. They seem to suggest that in 198 -- both  
24 in 1983 and in 1984, commercial products, commercial  
25 Factor VIII were still being used.

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1 The next document I'm going to turn to, which  
2 examines this issue of self-sufficiency, is a paper  
3 prepared by Professor Cash. It's at PRSE0001556.  
4 Sorry, I think this is actually the minutes of the  
5 meeting, rather than Professor Cash's paper.

6 So Professor Cash prepared a paper in advance of  
7 this meeting. It's another meeting of Haemophilia  
8 Directors and SNBTS directors, February 1984. If we  
9 turn over the page and we focus on the section 5,  
10 "Review paper from SNBTS", this section of the minutes  
11 is -- reflects a discussion of a paper produced by  
12 Professor Cash.

13 The first point, sir, is worth noting:

14 "Details of the amount of fresh plasma  
15 [produced] for Factor VIII concentrates and the issues  
16 of concentrates indicated that the production level  
17 was about right. However, trends over the last  
18 five years indicated that the SNBTS production of  
19 Factor VIII concentrates may be exceeding clinical  
20 demand, and the current stocks at RTCs appear to be  
21 increasing."

22 I'll pick up subparagraph (ii), there's  
23 a discussion about the continuing use of  
24 cryoprecipitate at this time, February 1984:

25 "Members discussed the suggestion that the

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production of cryoprecipitate could now be reduced. Dr Ludlam said that cryoprecipitate was preferred in the treatment of children at present, because of the new danger of AIDS. Dr Hann concurred. A policy seemed to be emerging however to use less cryo for haemophilia A patients. It was agreed that a certain minimal amount of cryo was required and Dr Cash pointed out that [Transfusion Directors] could produce it in emergencies."

If we go down the page, point (iv), I won't go into the detail of this now but it's just worth noting that Dr Cash, during the course of this meeting, suggests that the time might be right to introduce a batch dedication system. The reason for that is to reduce the number of batch exposures per patient per year, so this is early 1984. I'll come on a bit later to when batch dedication was introduced by the PFC but it appears to be the case that it wasn't introduced until sometime later, end of 1984, early 1985.

I'll then pick up point (v):

"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."

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meeting took place. I won't take you to those documents. What they concerned was a proposal for Scotland, in view of its supply position, to send more of its Factor VIII products to Northern Ireland and to England and Wales. There's a paper by Professor Cash from May 1984, the title of it is "Proposal for the Decanting of Excess Factor VIII Concentrate to Northern Ireland and England and Wales".

He sets out in some detail the background to that proposal in the paper. He makes a number of proposals at the end of it. He suggested the first priority in the disposal exercise should be Northern Ireland, and that's disposal of Factor VIII concentrates which are surplus to Scottish needs, and suggests that the residual surplus be offered to the CBLA, ie England and Wales. He also suggests that some consideration should be given to charging for the arrangement.

There's a meeting which Professor Cash's proposals are accepted. That takes place on 23 May 1984.

We can then see what I believe is that proposal and agreement reflected in a letter between Dr Morris McClelland in Northern Ireland and Dr Mayne, and we'll just go to that document. It's NIBS0001718.

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I take the reference to a "superior product" being available to mean, as an example, a higher purity product for certain kinds of patients.

If we go over the page, we can see recorded a discussion involving the Haemophilia Directors about their preferences and approach to commercial versus PFC concentrates, so it's the top of the page:

"Dr McDonald said that the adult centre in the West was totally satisfied with the NHS product and that it was no longer necessary to purchase commercially. Dr Hann however found himself in the position of having inherited 30,000 [units] of commercial factor VIII which was rapidly going out of date and which he was prepared to dispose of.

"Dr Ludlam said that he required to have a small stock of high purity commercial material ...

"Dr Bell [who is there on behalf of the Scottish Home and Health Department] emphasised that the aim of the SNBTS and the 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."

In May 1984, sir, a document was prepared by Professor Cash and a blood transfusion subcommittee

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It's not very easy to read because of the quality of the copy. You can see the date at the top, 21 May 1984, and if we go down, please -- thank you -- I'll pick up the first paragraph where the issue is introduced.

"Some changes have recently taken place in the arrangements for the supply of blood products from Scotland and I thought it would be appropriate to update you."

Thank you. "Factor VIII concentrate", Dr Morris McClelland says:

"This has been produced in considerable excess of demand in Scotland during the past year or two with the result that the present pro-rata arrangement for supplies (in proportion to input of fresh frozen plasma from Transfusion Centres), this has been abandoned at least for the present.

"On a pro-rata basis we would now be entitled to receive Factor VIII at the rate of about 1.8 million units per year. (The increase has resulted partly from increased plasma supply and partly from increased yields during fractionation). With this new, more flexible arrangement we could certainly obtain more than this -- at least 2.5 million units per year."

Then the next paragraph:

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1 "I am aware from conversations with you that you  
2 are not at present planning to use this amount but you  
3 may find this information useful for future planning."

4 Now, it's not clear from the documents we've  
5 looked at, in the context at least of this  
6 presentation, why Dr Mayne might not have been  
7 proposing to use that amount of NHS product. We'll go  
8 on to look in a moment at some tables showing  
9 consumption figures in Northern Ireland, as well as  
10 Scotland, which show that a significant amount of  
11 commercial product is still in use at that time. But  
12 this is a reflection, at least, I believe, of  
13 Professor Cash's proposals to change arrangement --  
14 those arrangements with Northern Ireland.

15 As for England and Wales, in October 1984,  
16 Dr Perry, who by this point had become acting director  
17 at PFC, wrote to Dr Lane at BPL to offer around 2,000  
18 vials of Factor VIII, equating to about 460,000 units.  
19 In the letter, Dr Perry said that these vials of  
20 Factor VIII had failed to meet certain product  
21 specifications, things like solubility time, in other  
22 words these products were taking longer to dissolve,  
23 certain other technical specials.

24 Dr Perry says in the letter that, if there was  
25 any shortfall in Scotland of PFC product, then they

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1 period. I made some references already to Factor IX.  
2 For completeness, I'm going to pick up just a few  
3 other parts of the chronology briefly. The written  
4 note during this section separates out Factor VIII and  
5 Factor IX. That is because the stories become  
6 different in important respects. The chronology of  
7 products that are introduced at different times become  
8 different, and that's the reason why we've separated  
9 them out.

10 I'll highlight just a few points, sir. On the  
11 early history of product used to treat haemophilia B  
12 patients in Scotland, we've referred in the note to  
13 a 1973 article, journal article, which sets out some  
14 of that history. It suggests that, until 1967, fresh  
15 frozen plasma was the only product available to treat  
16 haemophilia B patients.

17 In 1967, the PFC, which was then known as the  
18 BPU, began producing a concentrate which contained  
19 Factor IX, known as PPSB. But then in 1971, and the  
20 article was concerned with the development of this  
21 product, a new concentrate is developed, which also  
22 contains Factor IX, and this is the product which  
23 becomes known as DEFIX, and it seems to be introduced  
24 routinely from around 1971.

25 Most of the documents I've covered in relation

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1 would be sending this product to RTCs. Because their  
2 supply position is strong, they don't need it, they're  
3 therefore offering it to England and Wales.

4 We can go to Dr Lane's response to that proposal  
5 just very quickly, CBLA0001912. I should say that in  
6 Dr Perry's letter making the offer, he made reference  
7 to tentative evidence in relation to the AIDS  
8 infectivity of commercial products. In other words,  
9 question marks around AIDS infectivity of commercial  
10 products, so would you therefore like to have this  
11 Scottish product? Dr Lane's response that we have  
12 here, November 1984, says:

13 "Thank you for your letter about those batches  
14 of factor VIII which are outside your defined finished  
15 product specifications. Whilst I entirely take the  
16 point you are making, I do not feel that it is in  
17 order to step outside normal regulatory practices,  
18 even in our current complicated situation with AIDS.  
19 In the same way that we would not release material  
20 which failed our quality control, regardless, I do not  
21 think that we would wish to circulate material in  
22 a similar category."

23 That's Dr Lane there refusing that offer to take  
24 product from Scotland.

25 Now, that addresses Factor VIII during this

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1 to Factor VIII for the 1970s and 1980s suggest that  
2 the supply position in relation to a Factor IX  
3 concentrate DEFIX was strong. There generally weren't  
4 issues with supplying and producing enough of it.

5 I've already picked up in Professor Cash's  
6 January 1981 paper the comment where he says:

7 "Because of the much smaller number of  
8 haemophilia B patients than A, the supply of these  
9 products [ie Factor IX concentrates] is always more  
10 than adequate."

11 He makes reference to an exception, I believe,  
12 that's one year, in 1979, where the supply drop.

13 In January 1983 Professor Cash suggested that  
14 the supply position with regards to DEFIX remains  
15 strong. The issue from PFC to RTCs is reasonably  
16 stable. At a January 1983 meeting of SNBTS and  
17 Haemophilia Directors, it was noted that the supply  
18 position of DEFIX over the last five years, so  
19 five years to 1983, have remained strong and the  
20 demand reasonably stable.

21 There's a reference in the documents to a supply  
22 difficulty that seems to arise around the middle of  
23 1983. It appears to be related to the use of DEFIX  
24 for haemophilia A patients with inhibitors. So,  
25 around this time, clinicians start to try to treat

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1 haemophilia A patients with inhibitors with DEFIX,  
2 that has a knock-on effect on the supply of DEFIX, and  
3 there are difficulties with keeping up with demand.

4 We set out in the note how that issue plays out.  
5 It continues into February 1985.

6 Now, sir, that completes the chronological part  
7 of this section of the presentation. At this point,  
8 I was intending to turn to some of the annexes and  
9 figures that the Inquiry has produced. We've got  
10 a bit of time still, I believe before the lunch break,  
11 so I don't know if you want to break now or if I can  
12 continue on. I've got some time left.

13 **SIR BRIAN LANGSTAFF:** Let's use the time, shall we?

14 **MR BOUKRAA:** Thank you.

15 So if we can get that the annexes up, Sully, you  
16 should have them at INQY0000344, thank you.

17 Now, before we go in to the detail of the  
18 figures in the tables, there are a few points I should  
19 explain. This is a set -- a document which contains  
20 all the annexes accompanying the presentation.  
21 Annex A, which we have the first page of here, sets  
22 out consumption of Factor VIII and then Factor IX  
23 concentrates in Scotland and Annex B does the same for  
24 Northern Ireland. Both Annex A and Annex B and both  
25 the Factor VIII and Factor IX figures are based on

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1 table.

2 In fact, that wasn't quite lastly. One more  
3 introductory point to note, these are consumption  
4 figures, rather than production figures. That may be  
5 an obvious distinction but it is an important one to  
6 bear in mind because, in some of the documents,  
7 there's reference to production, ie how much the PFC  
8 was producing each year. Figures for consumption are,  
9 of course, different.

10 So we can turn, please, to page 2. So this is  
11 the table setting out -- actually, can we have --  
12 yeah, that's fine. That'll do for now. Thank you.

13 These are the figures recording in Scotland  
14 consumption of Factor VIII products, going from 1976  
15 to 1990. You'll be able to see that there are  
16 footnotes which appear next to some of the entries,  
17 for example 1981, 1982. In fact, also, at the heading  
18 at the top, next to "Cryoprecipitate", there are  
19 footnotes.

20 If we pan back out, please, Sully, and go into  
21 the footnotes -- I wouldn't ordinarily go to  
22 footnotes, sir, but we've highlighted them here and  
23 I think they're important to bear in mind -- they  
24 suggest some caveats.

25 One of the caveats relates to figures for

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1 annual returns from haemophilia centres.

2 You can see at this page, we can set out the  
3 annual returns that apply to Scotland with the URNs in  
4 footnotes at the bottom. So as we go through the  
5 figures in the tables if any Core Participants, legal  
6 representatives at any point want to interrogate any  
7 of the figures, check whether we've got them right, if  
8 they want to look into particular issues, all of the  
9 sources for the data should be set out in those  
10 footnotes.

11 One effect of using the returns as the source of  
12 data means that the narrative and the figures only  
13 start in 1976. That's the earliest date for which we  
14 have returns.

15 Those returns are probably the most accurate  
16 guide to the consumption of these different factor  
17 concentrates during this time period that we have.  
18 But there are also, in some of them, gaps, issues with  
19 how the data is recorded, and it's important to be  
20 aware of them. What we've done in the tables is tried  
21 to flag any of those issues so that readers can be  
22 aware of them as they're looking at the tables and at  
23 the figures.

24 Lastly, sir, I've already said that we'd use the  
25 word "consumption" here rather than "demand" for this

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1 cryoprecipitate. In some of the annual returns, as  
2 we've seen during the Haemophilia Centre presentations  
3 and hearings, cryoprecipitate was sometimes recorded  
4 in a number of bags or packs. Generally speaking,  
5 we've translated that into 70 units per pack, which  
6 correlates with some explanations which are sometimes  
7 given in the returns. Obviously, all cryoprecipitate  
8 figures are estimates, even when there's a number  
9 recorded in the return. That's based on an estimate  
10 of units per pack, and of course a point to bear in  
11 mind.

12 When we've set out the figures for  
13 cryoprecipitate consumption, that also -- they include  
14 the figures for patients with von Willebrand's. For  
15 much of this period patients with von Willebrand's  
16 were treated with cryoprecipitate. Now, what that  
17 means is that the comparison, at least for some of the  
18 period, between cryoprecipitate and factor  
19 concentrates becomes less direct because  
20 von Willebrand's patients generally weren't treated  
21 with factor concentrates, so far as I understand it.  
22 But we thought that these were an important part of  
23 the overall picture, in terms of cryoprecipitate  
24 consumption at the time, so we've included that.

25 In terms of data for individual returns, gaps in

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the data, some of them make more difference than others. There's one I wanted to pick up here because it does make a material difference to the tables we're going to go on to look at the figures -- the charts we're going to look at. It's the Edinburgh data for 1981.

Now, the annual return for Edinburgh in 1981 is only very faintly legible. We can just about make out the figures for cryoprecipitate. Unfortunately, it's not possible to make out what the figures were for NHS or commercial concentrates. That's an important caveat to bear in mind when we go on to look at the tables.

Now, the data here has been used to create, first of all, a graph and then a set of bar charts. So if we can go on to the next page, I'm going to spend less time on this one. We can see how the figures have translated. The blue line is NHS PFC Factor VIII concentrate. The orange line is cryoprecipitate. The red line is commercial concentrate.

We can see that commercial concentrate is at a low level in the early period, increases a little up to about 1980, starts to decrease again to reach very low periods in 1984, and low figures in 1984 and, in

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different definitions of that term, sir, but one way of defining the term might be: were patients treated with domestic product only or were they also treated with imported product?

We can see that Scottish patients are treated with some commercial concentrate, which is the red block, relatively small amounts at the end of the 1970s, a larger amount in 1980. There's the figures for 1981, although they come with that same health warning because of the Edinburgh gap. Relatively small amounts of commercial concentrate, there's still some being used in '82, '83, a very small amount in '84 and then no commercial concentrate recorded used in '85, '86, '87, which coincides with the introduction of heat treated Factor VIII in Scotland.

If we look at the figures for cryo, we can see, starting in 1976, relatively steady levels, small increase in 1981, then the figures start to drop off. Then PFC Factor VIII, reasonably steady levels in the second half of the 1970s, a significant increase in use in 1980. I'll ignore 1981 for the reason I've given before. Then from '82 onwards, we can see that PFC Factor VIII becomes, by some distance, the greatest -- represents the greatest proportion in use of these products from '82, '83, '84 onwards.

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fact, when we get to 1984 onwards, we'll see just how far the figures drop.

Cryoprecipitate, relatively steady until 1980, and then starts to decrease. The use of PFC concentrate increases slowly in the 1976 to 1979 period. There's a significant jump in 1980.

I haven't interrogated, sir, the exact reasons for that jump. It may be related to Professor Ludlam's arrival in Edinburgh. As I understand it, he changed the treatment policies in Edinburgh to have more of a focus on the use of concentrate, rather than cryo.

I should say the dots represent years. On the blue line, after 1980, here there's a suggestion of a drop in 1981. That is likely to be a somewhat artificial figure because, in 1981, we don't have the return data for Edinburgh for its use of concentrate. Then we can see the figures increasing from '82 up to '84, dropping down and then increasing again as we move through the second half of the 1980s.

If we go on to the next page, please, Sully, again this is the same data that's recorded in the tables, this time translated into a bar chart. This might be a helpful chart for trying to assess whether or not self-sufficiency was achieved, when it was achieved. Now, I'm not going to go into all the

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I haven't yet covered heat treatment. I'll do that very briefly, but we can see that when we get to '88, by which time all factor concentrates, at least, are heat treated, commercial products make a reappearance, '88, '89, '90.

So, sir, that's the picture for Factor VIII in Scotland that we've been able to establish from the data. I'll look more briefly at Factor IX. If we go over the page, please, Sully. So we started again with a table of figures. I won't go through it in as much detail. A few caveats to note in -- a few caveats to note in footnotes that people can come back to. It's a bit easier to see from this table what the position is, because we can see, in the right-hand column, "Commercial Factor IX". Most years, no use of commercial Factor IX recorded, other than 1980, 1981.

If we go on to the -- in fact, can we go straight to the chart, so I think it'll be the bar chart two pages on -- you can see these figures translated into this bar chart. They are mostly blue, so it's mostly NHS Factor IX concentrate that's being used. Small amounts of commercial Factor IX in 1980 and 1981.

In contrast to Factor VIII, commercial Factor IX makes a reappearance in 1985. I'll come on to explain

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very briefly the reasons why that happened. In short, it's related to the introduction of a PFC heat treated Factor IX, during the course of 1985, being later than the commercial heat treated Factor IX product then available.

In other words, clinicians got to 1985, PFC wasn't yet able to provide heat treated Factor IX, so they started buying some commercial heat treated Factor IX.

We'll turn briefly to Northern Ireland. If we go to the next page, please. So this is the introduction to Annex B, which covers Northern Ireland. Again, similar points and caveats are summarised at the top. We'll start with Factor VIII on the next page, please.

A similar table is set out. We'll see this when we go on to the graphs and the charts but, as we've covered during the course of this presentation, it's important to be aware that there was a change in the arrangements for Northern Ireland, BPL -- or BPL/PFL generally providing Factor VIII concentrates up to 1982, PFC taking over in 1982.

In fact, if we just look at this table for a moment, and if you see the column for NHS Factor VIII, and we move down the figures from the late 1970s to

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concentrate don't increase immediately, my understanding is that because the Northern Ireland arrangement was a pro rata one in PFC, it took some time for Northern Ireland to increase the amount of fresh frozen plasma that it was collecting and was able to supply to PFC, so it took some time to increase the amount of PFC Factor VIII that it was receiving in return.

And the last -- the next page, please, Sully.

Factor IX. I'm not going to go through the figures in this table. If we could go through two pages on to the bar chart for Northern Ireland. So this is the position for Factor IX in Northern Ireland, and we can see some commercial Factor IX had been used in 1976/77, almost as much commercial Factor IX used as NHS Factor IX in 1978, and then no commercial Factor IX used again before 1990, by which time it will have been heat treated.

Sir, that takes me to the end of this section of the presentation. I was intending next to turn much more briefly to the arrival of heat treatment in Scotland and in Northern Ireland. I will finish that portion of the presentation and the presentation overall in time for Mr Hill to take over to cover pool sizes. I wonder if it might be a convenient moment to

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the early 1980s, we'll get to 1981, 122,000 units, then we see a very significant drop to 12,000 units in 1982. That's the changeover year.

I took you, sir, yesterday afternoon, to the Northern Ireland return for 1982, which records that NHS Factor VIII was only available in November and December of that year.

If we can go over the page, please, Sully. We can see here a different picture in Northern Ireland than in Scotland. So, again, the red line is commercial concentrate, the blue line is NHS Factor VIII. Up to 1982, that comes from BPL, and then comes from PFC. The orange line is cryoprecipitate.

If we go on to the bar chart, please, on the next page. Thank you. We can again see a different picture emerging from the one we just looked at in Scotland. In short, much more red, which means much more in the way of commercial concentrates, particularly in the period up to 1982. Still significant amount of -- amounts of commercial concentrate being used in '83 and '84. Still commercial concentrate being used in 1985, though by that stage it may have been heat treated. One of the reasons for explaining why the figures for NHS PFC

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break for lunch now. I then anticipate that I'll be able to try and finish things in the early part of the afternoon.

**SIR BRIAN LANGSTAFF:** Yes. Well, shall we break then now until 1.50? 1.50.

**(12.52 pm)**

**(The Luncheon Adjournment)**

**(1.49pm)**

**SIR BRIAN LANGSTAFF:** Yes?

**MR BOUKRAA:** Sir, I'm going to continue much more briefly now with an overview of the introduction of heat treatment of PFC products. I'm going to start by returning to the annex that we looked at earlier, a different part of it.

Sully, it's that document INQY. If you could go through, please, to page 15. Now, this is a table of products, PFC concentrates, that we've prepared in the Inquiry team. This table contains PFC concentrates -- products that were routinely issued. It doesn't contain all of the various products that were being developed, were sometimes issued for trial but were not issued routinely.

It provides a helpful route map and an overview of where we're going to go. As you can see, it's divided into Factor VIII and Factor IX and I'll just

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pick up a few dates in the middle column for Factor VIII. We can see the very early introduction of Factor VIII concentrate, Cohn Fraction I in 1956, then the next date, 1974, that's PFC's standard intermediate Factor VIII concentrate, sometimes known as NY and the NY prefix refers to a link between PFC and colleagues at New York University.

Then, you can see, we go from 1974 to December 1984, when PFC's first heat-treated product is introduced. There's then a series of other heat-treated products. The first one that's introduced is dry heat treated for two hours at 68 degrees. The next one is introduced around September/October 1985. It's a similar product again, 8Y, with some stabilisers added. Dry heat treated at the same temperature, 68 degrees, but this time for 24 hours. Then the next date, it's half cut off at the bottom, it's April to May 1987. It's a product which becomes known as Z8, April/May 1987.

If you go on to the next page, Sully, you'll just be able to see -- that's perfect, thank you.

That's a product which is dry heat treated again for 72 hours, initially at 75 degrees and, eventually, for 80 degrees.

We can contrast -- I won't pick up the 1991

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took place in Germany, in Bonn, in October 1980 that was attended by Professor Cash. During that conference the German company, Behringwerke -- I'm sure I pronounced that wrong -- report that they have been able to heat treat a Factor VIII product using pasteurisation, pasteurisation as opposed to dry heat treatment. Pasteurisation, I think, like Mr Hill said, is more like a water bath, dry heat treatment is more like an oven.

You can get a sense of the reaction to that claim from a letter that Professor Cash wrote to Mr Watt on 27 October 1980. He briefly described what was -- what the company was saying, this German company was saying and he ends with:

"Sounds unbelievable. Thought you might be interested."

As we're looking at heat treatment in this very early period, the focus is on trying to inactivate hepatitis, hepatitis B, and then also non-A, non-B hepatitis in Factor VIII concentrates.

I'll pick matters up in late 1981, the following year, when the SNBTS, through Professor Cash, establishes the Factor VIII study group. Now, the Factor VIII study group looks at a whole series of different issues and problems relating to Factor VIII.

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product which changes approach. We can contrast that Factor VIII timeline with the Factor IX timeline, which is in the right-hand column. So the story starts in 1967, I've covered already, PPSB, 1971, the haemophilia B patients, that's replaced by DEFIX. We can then see that the next key date for Factor IX is August 1985 when a heat treated Factor IX product, DEFIX, was introduced.

Two points to note about that introduction. First of all, as you can see from this table, it's later than the heat-treated Factor VIII product. The second point is that it is heat treated for longer at a higher temperature from the first iteration, and that remains the same product through the rest of the time period that we're looking at.

Sir, that's just to provide an overview of where we'll be going with some of these heat-treated products and I'm going to turn to a very brief chronology that goes back in time to the early 1980s, and I'm really just going to pick out a few key dates, focusing on Factor VIII first.

So far as the Inquiry has been able to identify, PFC and the wider SNBTS first begin to look into the possibility of heat treating Factor VIII concentrates in late 1980. That seems to follow a conference that

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It establishes a subgroup, the Safety Action Group, which focuses on viral inactivation.

Now, that group meets in January 1982, prepares a first report around March 1982. At least in that early period, it's made up of a Dr Cuthbertson from the PFC, two other members, Drs Pepper and Sommerville, so includes non-PFC members as well from the wider SNBTS. A report is prepared by that Safety Action Group on possible viral inactivation of Factor VIII, considering different methods, considering the possibility of inactivating hepatitis.

By the time of a March 1982 meeting of the Factor VIII study group there was a discussion of the proposals. At that time, the suggestion of the Safety Action Group was that proposals to achieve a hepatitis reduced Factor VIII product -- and that was how it was phrased at the time, "hepatitis reduced product" -- would take time and considerable investment. It was thought that this could not be achieved in less than two years. So in March 1982, the suggestion to produce a hepatitis reduced product, Factor VIII product, would be around two years.

The group continues investigating viral inactivation through the remainder of 1982, there are various important parts of the chronology that are

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1 picked up here in the written note, including meetings  
2 internationally that Dr Foster attends, and various  
3 other meetings and reports that are prepared, but  
4 I won't go into the detail of those now.

5 By the time we get to October 1982, the  
6 Factor VIII Study Group is suggesting that it's first  
7 option, preferred option for viral inactivation, is  
8 heat treatment. Now, the context for that is that, in  
9 this early period, various other possible viral  
10 inactivation methods have been considered:  
11 irradiation, for example; treatment with detergents;  
12 there's more of a focus at this point in heat  
13 treatment. The kind of heat treatment that the group  
14 is focusing on is pasteurisation.

15 Alongside that focus on pasteurisation, what we  
16 can see in these documents from this early period is  
17 a belief that part of the key to producing  
18 a successfully virally inactivated Factor VIII is to  
19 have a higher purity concentrate, so there  
20 investigation into producing high purity concentrates,  
21 alongside investigations into pasteurisation.

22 That gets us to around January 1983. This work  
23 is ongoing. There's some discussion on the  
24 relationship between this work on heat treatment and  
25 self-sufficiency. There's a meeting of SNBTS and

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1 months of 1983, reference begins to be made to AIDS.  
2 In the first references that we can see that are set  
3 out in the written note, there's not always a direct  
4 link between AIDS and PFC's heat treatment strategy,  
5 but a direct link is made soon thereafter in May 1983  
6 and it's a document I'm going to bring up.

7 Sully, it's PRSE0001111. I'll just check I've  
8 got the right --

9 Sir, all I'm going to do with this document is  
10 highlight the context and read out some of the  
11 passages. It's an important document. As you'll see,  
12 it's drafted by Dr Foster, so I'm not going to suggest  
13 any inferences or meaning that might be drawn from it  
14 beyond what's set out in the document. Before we go  
15 to that, it might just be worth noting the date,  
16 3 May 1983. Now, the direct reliance of this  
17 document, for present purposes, is to try to work out  
18 what the impact was for reports of AIDS on PFC's heat  
19 treatment strategy. It also has a place in the  
20 Inquiry's wider investigation into knowledge and  
21 understanding of the risk of AIDS and how that was  
22 communicated to patients.

23 I've mentioned the date, 3 May 1983, because it  
24 is almost exactly of the same date as the message  
25 which went out from Professor Bloom through

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1 Haemophilia Directors on 21 January 1983, during which  
2 Mr Watt explains or sets out, rather, this link  
3 explicitly. I'll just read out a couple of -- part of  
4 the passage that's recorded in the minutes. It's said  
5 that:

6 "Mr Watt explained the problems which had to be  
7 overcome in preserving acceptable yields and providing  
8 a product which was not too expensive, considerations  
9 that were of less importance with the commercial  
10 product."

11 Around this time, early 1983, commercial  
12 producers of early factor concentrates were also  
13 trying to market virally inactivated products. He  
14 said:

15 "During the meeting, Directors were made aware  
16 of fierce competition facing the PFC from commercial  
17 concerns and were asked to bear in mind the state of  
18 policy for the Scottish Health Service to be  
19 self-supporting in blood products. The PFC would have  
20 limited amounts of heat-treated Factor VIII available  
21 for trials in the near future, and the Haemophilia  
22 Directors agreed to support the PFC as much as  
23 possible in the development and clinical trials of the  
24 NHS product."

25 So that gets us to early 1983. In the first few

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1 The Haemophilia Society to patients about AIDS and  
2 what the reaction should be to AIDS. Now, I'm not  
3 suggesting there's any direct link between Dr Foster,  
4 the PFC and Professor Bloom, but when we're looking at  
5 how the AIDS risk is set out in this document and how  
6 the AIDS risk was set out in that Professor Bloom  
7 communication to patients, it's worth just noting that  
8 timing.

9 **SIR BRIAN LANGSTAFF:** Well, the two days before was 1 May,  
10 it was a Sunday, and that's when the Sunday papers  
11 carried articles concerning the risk of AIDS. So talk  
12 of "killer blood". So that may well have something in  
13 the mind of anyone who was concerned with producing  
14 something which might transmit the cause of AIDS.

15 **MR BOUKRAA:** It may well have been, sir. I'll obviously  
16 leave that Dr Foster, who is giving evidence.

17 **SIR BRIAN LANGSTAFF:** Yes.

18 **MR BOUKRAA:** But you're quite right, sir: those articles  
19 appeared and, in fact, they prompted the message from  
20 Professor Bloom. A request went out to him from  
21 The Haemophilia Society in response to those articles,  
22 saying "Please can you prepare a message for patients  
23 as a result of what's been said". I think he drafts  
24 it around 3 May, it goes out the following day.

25 If we can scroll down, please, Sully, just to

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1 get the first few passages.  
 2 We can see at the top -- actually, sorry, can we  
 3 get the top half of that, that's great -- "Until very  
 4 recently" -- and this summarises the background to  
 5 PFC's heat treatment programme at the time. Dr Foster  
 6 says:  
 7 "Until very recently the objective of our heat  
 8 treatment programme was to cope with the hepatitis  
 9 problem in haemophiliacs.  
 10 "Because severe haemophiliacs have already been  
 11 heavily exposed to untreated products then only mild  
 12 and moderate haemophiliacs could benefit from  
 13 a treated product (in the foreseeable future). It was  
 14 estimated that the mild/moderate group could use up to  
 15 30% of the total [Factor VIII]. This estimate, plus  
 16 the fact that these patients are presently likely to  
 17 be treated with single donor cryoprecipitate have  
 18 determined our present strategy ie that we will.  
 19 "Plan for 4-6 pilot-scale lots during 1983.  
 20 "Design a full-scale plant to handle 30%  
 21 production for 1984/85 at the earliest.  
 22 "Mild and moderate haemophiliacs can continue to  
 23 receive single donor cryo meanwhile."  
 24 He then goes on to say -- and if we can scroll  
 25 down, Sully, I'll pick up the impact of AIDS:

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1 that's Mr Watt, the last sentence, expressing a view  
 2 that people will err on the safe side.  
 3 **MR BOUKRAA:** It looks like that, sir. I should clarify  
 4 this is Dr Foster --  
 5 **SIR BRIAN LANGSTAFF:** The word "err" is simply adopting  
 6 a colloquial expression. It's not a suggestion that  
 7 they will be in error to do so.  
 8 **MR BOUKRAA:** No, sir. Just for the transcript rather than  
 9 you, sir, this is a Dr Foster memo rather than  
 10 Mr Watt's.  
 11 **SIR BRIAN LANGSTAFF:** I'm sorry. He can explain what he  
 12 had in mind.  
 13 **MR BOUKRAA:** Yes, quite.  
 14 **SIR BRIAN LANGSTAFF:** Thank you.  
 15 **MR BOUKRAA:** I'm not going to comment too much on what all  
 16 of this might mean. Dr Foster is meant to be here --  
 17 **SIR BRIAN LANGSTAFF:** Ultimately, it's for me having  
 18 listened to submissions.  
 19 **MR BOUKRAA:** Yes. Then the final passage on this page:  
 20 "ii) There are some who would find a move back  
 21 to cryo attractive, and if this gathers momentum (it  
 22 would only need one suspected case from NHS  
 23 Factor VIII), we can see our fresh frozen plasma  
 24 disappear overnight."  
 25 If we go over to the next page, please, at the

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1 "The possibility that another more serious  
 2 infectious agent (AIDS) is now involved suggests that  
 3 we may need to review this strategy. In the new  
 4 scenario:-  
 5 "i) The haemophiliacs most at risk are the  
 6 severes rather than the mild and moderates.  
 7 "ii) There is already evidence of a panic  
 8 recourse to cryoprecipitate.  
 9 "In the absence of any hard data, heat treatment  
 10 (of everything) looks at the moment to be the most  
 11 likely possibility that we have to face up to. If  
 12 this is so, then we will have to plan to pasteurise  
 13 all of the Factor VIII (rather than 30%) and we may  
 14 also want to review the timescales noted above."  
 15 If we could go down a bit further, please:  
 16 "Timing may become crucial for a number of  
 17 reasons:-  
 18 "i) The publicised view that FVIII is  
 19 infectious and that there may be a long incubation  
 20 period (ie 3 years). We may argue that this has not  
 21 been proven but hard data (one way or the other) could  
 22 take years to achieve. Meanwhile, decisions will  
 23 probably be taken according to the 'worst case'  
 24 hypothesis."  
 25 **SIR BRIAN LANGSTAFF:** Just pause there for a moment. Yes,

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1 top, Dr Foster says:  
 2 "There may therefore be a case for accelerating  
 3 our heat treatment programme. While I do not disagree  
 4 with point (2) above [I believe point (2) is about  
 5 plans for building a full-scale plant], it may be  
 6 possible to introduce an intermediate stage still  
 7 using the pasteurisation cabinets. We probably have  
 8 most of the equipment to allow us to do this already."  
 9 He then sets out some detail of the technical  
 10 process that would be involved in the rest of this  
 11 memo.  
 12 Sir, that's all I wanted to take from this  
 13 document for now.  
 14 In the written note, we've recorded that it  
 15 appears that a change of approach was agreed at the  
 16 PFC as following this memo in a meeting which may have  
 17 followed it. I believe that that involved scaling up  
 18 the pasteurisation product, but I'll allow Dr Foster  
 19 and Dr Perry perhaps to explain that further.  
 20 The Safety Action Group was still continuing its  
 21 work during this period. It met again on  
 22 15 June 1983, and I just want to take you to a record  
 23 of its meeting very briefly. It's PRSE0003460.  
 24 I just want to highlight two passages. If we  
 25 can have the top of this page where we can see the

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date and those who were present. These are the members of the Safety Action Group, so there's Dr Cuthbertson of the PFC, and then there's two other members, reflecting -- who are not from the PFC, reflecting that this is part of a wider SNBTS initiative.

If we go down to the bottom of this page, there's a summary there of the approach of PFC to heat treatment at this time. It says:

"Considerable progress had been made at PFC in producing heat treated Factor VIII, and clinical trials should start towards the end of the summer in Glasgow and Edinburgh. No infectious model for non-A, non-B has been produced yet. The putative 'AIDS' virus must be considered as a potential hazard in Factor VIII concentrates."

A lot of this document involves technical issues relating to viral inactivation. There's one more passage I wanted to draw out that links into the wider context, and that's at page 5, please, under the heading "AIDS". It's just the first two or three sentences:

"Although not proven to be a virus, this apparently infectious agent had been found in haemophiliacs in the UK. It would seem wise to try

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might, during 1983, during the summer or later 1983, that they in fact started towards the start of 1984, January to March.

An important date in the chronology to note is January 1984, Professor Ludlam reports an adverse reaction in one of his patients who has been treated with this pasteurised Factor VIII. He reports symptoms like chest pain, retching.

Dr Forbes provides some -- a report of these early observations of the product in March 1984, with no adverse reactions. Now, during the remainder of the first half of 1984 and the beginning of the second, it appears that the focus of the PFC continues to be on producing a pasteurised Factor VIII product, and that's not to say that there weren't some -- wasn't some consideration given to dry heat treatment, I believe starting during 1983. I won't go into the details of that but, in terms of the overall focus, it seems that continued to be pasteurisation until later in 1984.

There's then a major shift that occurs in PFC's strategy. It appears to be linked to two events around the same time. The first is the discovery in October 1984 that a cohort of patients in Edinburgh who had been treated with PFC Factor VIII had

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somehow to encompass AIDS inactivation along with hepatitis B and non-A, non-B inactivation schemes."

There's then a discussion of the impact of that on viral inactivation methods.

June 1983, sir, we've previously had a presentation on the first patient, of which the Inquiry is aware, in the UK with haemophilia, to exhibit symptoms of AIDS, one of Professor Bloom's patients.

**SIR BRIAN LANGSTAFF:** Well, he probably, it was said. That's how it was reported to the NIBSC, that he probably had AIDS.

**MR BOUKRAA:** That's right, sir. There was a report on 6 May 1983 to the CDSC about this patient. It may be that that's the patient who was being referred to here. There was another patient in Bristol, I'm not quite so familiar with the chronology of that patient but my understanding is that it may not have become common knowledge until later in 1983 that there was a Bristol patient with AIDS too.

I'm going to move forward to the beginning of 1984. Now, Drs Foster and Perry will be able to correct me if I'm wrong, but my understanding is that the trials of PFC's first heat-treated Factor VIII products didn't take place, as it was thought they

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developed antibodies to HIV -- HTLV-III, as it was then.

Now, the Inquiry has explored the timing related to that discovery and other evidence, no doubt it can be picked up with the witnesses we'll be hearing from so I won't go into it any further. Alongside that discovery, on the 1 to 2 November 1984, a plasma fractionation conference took place in the Netherlands, somewhere called Groningen. It was attended by Dr Foster, Dr Perry, and Dr McIntosh as well, of the PFC. During that conference it was reported that dry heat treatment appeared to successfully inactivate HIV.

Those attendees come back from the conference, there is a major change in the PFC's approach during the course of November and December 1983 to dry heating the existing PFC Factor VIII concentrate. What appears to have taken place is that the stocks which existed of PFC NY, normal intermediate unheated product were heat treated from December -- a point in December 1984. That product begins to be sent out to RTCs in Scotland and also Haemophilia Centres, and the PFC and the wider SNBTS introduce or appear to introduce a policy of seeking to re-call unheated products that was at RTCs and was also in blood banks

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1 and possibly stocks of home treated product as well,  
2 although it may be that there's more to explore on  
3 those details.

4 So we get into 1985 and this first heat-treated  
5 product is being introduced. The type of treatment,  
6 as I said, was dry heat treatment, it was heated at  
7 68 degrees for two hours.

8 Now, that gets us into 1985. I'm going to say  
9 very little about what happened with Factor IX during  
10 the period we've just looked at, the '83 to  
11 '84 period, other than to say that there was some  
12 early investigation into heat treating Factor IX  
13 during that period. Heat-treated products, Factor IX,  
14 is not introduced as we've seen also in December 1984.  
15 It comes a little later.

16 So we're into 1985. PFC is continuing to  
17 explore further the heat treatment of its Factor VIII  
18 product and, in particular, to explore different heat  
19 treatment viral inactivation regimes being applied to  
20 its product, not just 68 degrees for two hours. We've  
21 set out the detail of some of those attempts in the  
22 written note. What appears to take place is that,  
23 from around January to September 1985, the first  
24 heat-treated product, the first generation product,  
25 the 68 degrees for two hours is issued. From around

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1 a batch dedication system.

2 It then comes in around March 1985, and I'm just  
3 going to go to a document which briefly explains it.  
4 It's PRSE0004101.

5 This is, we can see from the title, a PFC report  
6 that was prepared for a meeting in March 1985.

7 If we go through to page 5, please, there are  
8 other parts of this document that are certainly worth  
9 considering. It has an update on heat treatment. If  
10 we go down to the second half of the page, there's  
11 an explanation of the approach to batch dedication.  
12 It says:

13 "The ability to prospectively dedicate whole  
14 batches of product to individual patients or groups of  
15 patients depends, for success, on substantial reserves  
16 of product. Such reserves are now available and it is  
17 now possible to implement a system of limited batch  
18 exposure.

19 "Briefly, such a system would operate by  
20 dividing patients into groups (on a regional basis)  
21 with each group receiving product from a designate  
22 batch held at the RTC. RTCs would also carry reserve  
23 batches for replacement of 'active' batches where  
24 these became exhausted."

25 Then it sets out how groups of patients might be

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1 September 1985, it's replaced by a second generation  
2 product which is heated at 68 degrees for 24 hours.

3 Now, as part of that policy of introducing the  
4 second generation of product, there appears to have  
5 been a PFC policy of exhausting existing stocks of  
6 heat-treated product before bringing in the second --  
7 the new generation one. So, in other words, it may be  
8 that a product treated for 24 hours at 68 degrees was  
9 available earlier but, before it was introduced to  
10 RTCs and the patients, they would exhaust the first  
11 generation product, all of that would be used up.

12 The new product would be introduced through  
13 a batch dedication scheme that had, by then, been  
14 introduced at the PFC. I mentioned this briefly  
15 earlier. I'm going to go into very little detail  
16 about it, sir, save to note that, in the written  
17 presentation, we've picked up a suggestion from  
18 Professor Cash in 1983, November 1983, that the SNBTS  
19 and PFC might need to be considering some sort of  
20 batch dedication arrangement.

21 He raises it again, Professor Cash, at the  
22 2 February 1984 meeting that we looked at earlier.  
23 There's then a period between February 1984 and early  
24 1985 where it's not quite clear, at least from the  
25 documents, what happens to this proposal to introduce

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1 divided up and then, at the bottom of this section of  
2 the report, it says:

3 "Present estimates indicate that such a system  
4 can be in place by the end of March 1985 with existing  
5 product which will sustain supply until Autumn 1985."

6 Now, it appears that a batch dedication system  
7 was introduced around this time, and that it remains  
8 in place until at least some time in 1987. The exact  
9 end date isn't completely clear from the documents.

10 So we're now into -- late in 1985, PFC's second  
11 generation heat treated Factor VIII, heated for  
12 24 hours, is being issued. Research is being  
13 undertaken into a third generation of product and, so  
14 far as it appears from the documents, that appears to  
15 be because it was understood, at the time, that heat  
16 treating -- dry heat treating at 68 degrees for  
17 24 hours should be successful in inactivating  
18 HIV/HTLV-III but was thought unlikely to inactivate  
19 non-A, non-B hepatitis. In other words, this 68  
20 degrees, 24-hour product could still transmit non-A,  
21 non-B hepatitis.

22 We're done with that document now, thanks,  
23 Sully.

24 So there then begins focused or more research,  
25 rather, on this new product which becomes to be known

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as Z8.

There's -- it seems that there's a change of direction which happens towards the end of December 1985, with the focus on this Z8 product, which will involve heating for 72 hours at 80 degrees, ie the same amount of time, the same temperature, as the BPL 8Y product, which we heard about last week during the hearings on England and Wales.

I'm not going to go into all of the detail around the development of Z8. What would appear to happen is that the product has been developed. Around August 1986, there is some difficulties encountered in manufacturing it at a large scale, scaling it up from the initial small test batches. There's a reference in a 29 August 1986 letter from Dr Perry to an 11th hour problem with freeze drying.

We get to late 1986, around December 1986, and it appears that Z8, this new product, which it is hoped will be effective against non-A, non-B hepatitis as well as HIV, is ready for clinical trial.

Now, while this product development was taking place, there had been a number of letters and some discussions around what's termed in the documents "compensation arrangements for patients". Now, what this relates to is the arrangements for compensating

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existing policies might be subject to a caveat for certain patients, in particular patients who had been -- not been treated previously with factor concentrates, or treated very little with factor concentrates, on the basis that they were understood to be the highest priority for a new product which was hoped to be effective against non-A, non-B hepatitis as well as other viruses.

Now, that's a brief overview of the position on heat treatment of Factor VIII products.

Factor IX we've covered in a reasonable amount of detail in the written note.

As we get into 1985, with a heat treated Factor VIII product in existence but no heat treated Factor IX, Haemophilia Centre Directors start to ask PFC what might be happening and when they might expect a heat-treated Factor IX. Around that time, and in fact even before from some years previously, there's an explanation that in order to introduce a Factor IX heat-treated product, there might be additional complexities because of the need to ensure that the product is not going to result in -- I always pronounce this wrong -- thrombo --

**SIR BRIAN LANGSTAFF:** Thrombogenicity.

**MR BOUKRAA:** Thrombogenicity. Sir, thank you.

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patients who participate in clinical trials in the case of an adverse reaction. Dr Ludlam had raised this issue some time earlier. It had not been resolved. Resolving it required the involvement of the Scottish Home and Health Department and others.

We get to the beginning of 1987. Dr Ludlam raises his concern again, and effectively appears to say, "I'm not prepared to enter my patients into the clinical trials of Z8 until this issue has been resolved."

There's some evidence that Haemophilia Centre Directors in other parts of Scotland adopt a similar position. There's correspondence back and forth with a number of individuals, including at the Scottish Home and Health Department. It appears around February 1987 some form of compensation arrangement is agreed, at least with the clinical trial aspect. Trials appear to begin around February 1987 for Z8.

We then get to April, and it seems that the SNBTS and PFC, following those clinical trials, are ready to start issuing Z8 on more of a routine basis. It seems, generally speaking, to be fed into that batch dedication system that we discussed and to reflect the policy of exhausting stocks. At least from the documents, there's a suggestion that those

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I understand that to be -- might cause blood clots in patients. That required an additional amount of testing involving animal studies. That is one of the explanations provided for why heat treated Factor IX was going to be introduced later.

In the meantime, during the course of 1985, some Haemophilia Centre Directors appeared to decide that while they're waiting for the PFC to introduce its product, they'll start buying some commercial heat treated Factor IX, and that will explain why, in the graphs that we looked at earlier, there is an appearance of commercial Factor IX concentrate in 1985 when there hadn't been before that.

The reasons why the Factor IX heat-treated product that is introduced around August 1985 by the PFC is immediately at the higher end of the heat treatment regimes that we've been considering -- 80 degrees for 72 hours -- is related to the nature of the Factor IX molecule as against a Factor VIII molecule. I won't try to provide any more explanation for that issue.

That gets us, sir, to the end of 1987 and more or less to the end of this presentation. In the written note we've covered the 1988 period to 1991. I don't propose to go through any of the details now.

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For those who'd like to review that portion of the written note again, what will become apparent is that, in the later 1980s, Scottish Haemophilia Centre Directors start to purchase heat-treated product, including heat-treated Factor VIII products, again, rather than just relying on Z8. The reasons for that are set out in the written note. There is also, during this period, another arrangement between Professor Ludlam and Dr Mayne in Northern Ireland to exchange PFC products for commercial products, and we set out the chronology of that agreement and some correspondence which points to the reasoning and the rationale behind it.

Sir, that was all I was intending to say in the oral presentation for Scotland and Northern Ireland. As I've said many times, there's more detail in the written note. I'm going to be handing over now to Mr Hill, who is going to be dealing with pool sizes, sir, but I wonder if before that, it might be appropriate to take a short break.

**SIR BRIAN LANGSTAFF:** Well, let's take an early break in that case, and come back at 2.50.

2.50.

(2.32 pm)

(A short break)

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of different data sets, different figures, some correlation, more correlation perhaps here than in other cases. But there is, I'm afraid, a little bit of leaping from one set of material to another.

I will go through what those sources show in terms of figures and present that in tables and in some graphs. Then we will go back and look at some of the underlying documents to see what they can tell us about the reasons behind the increases, and about the processes involved, although, as a spoiler warning, there is only a limited amount of material that the Inquiry legal team has been able to discover on that.

I'm also conscious that you will hear evidence in the coming days from Dr Snape, for England and Wales, and Drs Perry and Foster covering Scotland. As ever, we do not seek to pre-empt that evidence. They may be able to shed some more light on this.

Before turning to what is covered in the presentation, there is, as ever, a pre-history to the growth of plasma pools in the 1970s. We don't have a great deal of evidence about plasma pool sizes in the '60s and '70s at the moment but more work can be done on that area in due course.

What we do have, are little fragments, which may help to set the scene before we pick up the story

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(2.49 pm)

**Presentation to the Inquiry on the size of pools of plasma used in domestic production of blood products by MR HILL**

**SIR BRIAN LANGSTAFF:** Yes, Mr Hill?

**MR HILL:** Sir, we are turning now to two presentations on pool sizes used in fractionation, firstly in England and Wales and then in Scotland.

All of the qualifications that usually apply to presentations given by counsel to the Inquiry apply to these as well, and I won't repeat those here. The focus is going to be on Factor VIII, in terms of the pool sizes. We have some data for Factor IX but it is much less satisfactory, unfortunately.

I'll start with the England and Wales presentation. There is a written presentation that goes alongside this, and similarly for the Scottish presentation as well. It may be that people find it easier to read the written presentation than to reflect back on the transcript today because there are a lot of figures which are going to be given and I'm afraid it might be quite hard to follow at points but we'll do our best.

In England and Wales, the focus of the presentation is on BPL. There are various sources that we will look at. I'm afraid it's the same story

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again in the mid-'70s, from where we have much more data, not least because that is the area which the HIV Litigation focused on.

If we could go first, please, Sully, to HCDO0000581, page 1, please. This is an article that has been introduced before the Inquiry and I'm certainly not going to go through it in any detail. It is an article from the British Journal of Haematology in 1974, Volume 26, page 313 by Dr Rosemary Biggs, entitled "Jaundice and Antibodies Directed Against Factors VIII and IX in Patients Treated for Haemophilia or Christmas Disease in the United Kingdom."

As I say, I'm not going to go into the substance of that article. What I am going to take you to at page 6, please, Sully, is a table that Dr Biggs gives us that shows the material given to haemophiliac patients in Oxford from 1969 to 1971, to quote the words which she used in the article.

We can see three years are given, 1969, 1970, and 1971. The table includes information about the number of patients treated and then gives figures for the different types of material that those patients were treated with, plasma, cryoprecipitate and Factor VIII concentrate. If we look at the last of

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those for each of the years, Factor VIII concentrate, in the final column we can see the mean pool size given in terms of the number of donations that went into the pool. For 1969, that mean pool size is 160 donations. In 1970 it is 192 donations. In 1971 it is, again, 192 donations.

That is from the PFL in Oxford. We can see from the preceding column that for those years the number of pools fractionated were 83 in 1969, 72 in 1970 and 80 in 1971.

In the presentation, the general way of translating donations into the size of a pool or vice versa is to adopt an assumption that, at this time, about 180 millilitres of plasma was given per donation. Some sources have it at a little higher, some have it a little lower, but we've adopted 180 millilitres.

Using that figure, the pool sizes would be about 30 litres to 35 litres, expressed as volume, rather than donations, according to this table.

When comparing this to the later figures I'm going to give you, it is important to emphasise that these come from the PFL in Oxford and not BPL, which is where the later figures come from. Second, as Dr Lane put it, this was at the cottage industry stage

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of donors whose plasma had gone into that bottle.

The agreement that was reached in November 1974 was that, instead of doing it that way, the label would carry the words "Not more than 500 donations". We'll come on and look at some labels shortly.

**SIR BRIAN LANGSTAFF:** So it might mean -- well, it obviously means less, the 500 donations or less. It could be 500 donors at most, but it may be less if, for instance the donors had given more than one --

**MR HILL:** Yes.

**SIR BRIAN LANGSTAFF:** -- donation.

**MR HILL:** Again, in the presentation, we have assumed that one donation equals one donor. We're on safer ground doing that in England and Wales, and indeed in Scotland, than we are with commercial concentrates because plasmapheresis isn't generally being used. So a donor will be giving, at most, two donations a year. So it's unlikely they will end up in the same pool. The exception is the plasmapheresis donors, but they are a relatively small number in the UK at this time.

If we could take that down, please, Sully. The third document I will take you to is BPLL0003721. This is a memorandum from Dr Maycock to Dr Bidwell from 8 December 1975, so approximately 11 months later than the one that we have just looked at, and it is

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of plasma fractionation. Later, we're going to move on to the factory stage or the industrial stage, where far more factor concentrates are being produced. But that is a figure that we have for 1969 to 1971 in Oxford.

The next document we're going to take you to in terms of history is CBLA 0000253.

This is a memorandum from Dr Bidwell of the PFL to Dr Maycock, then director of BPL, dated 22 January 1975.

It is entitled "Number of donations in a batch of factor IX", and I'm going to come back to this document when we're talking about Factor IX specifically. But for now, I'm just going to take you to the first sentence. Dr Bidwell wrote, and I quote:

"When we talked about labels at Elstree in November we agreed to have printed on the label for factor VIII that it was derived from 'not more than 500 donations' and that we would cease putting on the precise number of donors whose plasma had gone to make up the pool."

That is where I will stop for now. What this appears to be saying is that, before this discussion in November 1974, the label on a bottle of BPL Factor VIII would have the exact number of the amount

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not in reply to the previous memorandum, but it does refer to donor pool numbers.

Dr Maycock wrote:

"Thank you for your memorandum of 3rd December, 1975.

"As we increase preparation of Factor VIII concentrate we propose to increase the size of pool as far as labelling is concerned in two steps during 1976 and 1977:

"Present 150 [litres] 830 donations

"1976 270 [litres] 1500 donations

"1977 360 [litres] 2000 donations

"[Numbers] of donations are based upon 180 [millilitres] of plasma per donation)

"The large pool size can be defended on the ground that starting plasma and concentrate are tested by RIA.

"I think PF Lab and BPL should keep in step.

"Therefore I would like you to introduce steps of 1500 and 2000 donations in the size of plasma pools for Factor IX concentrate.

"I think the number of donations should be shown on the Factor IX label as well as on the Factor VIII label."

We'll come back, again, to the question of

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1 Factor IX. For present purposes what I draw your  
2 attention to is this: firstly, as of 3 December 1975,  
3 the present pool, as expressed at least in terms of  
4 labelling, was 830 donations, being a plasma pool of  
5 about 150 litres, and you'll see that Dr Maycock uses  
6 that 180 millilitres figure as a way of translating  
7 from donations to litres.

8 You'll see that there is a plan to increase the  
9 size of the pool from 150 litres to 360 litres between  
10 December 1975 and December 1977, and that will be  
11 an increase from 830 donations to 2,000 donations.

12 I had brought you to that document because  
13 that is the first one that appears in the tables in  
14 the written presentation that I'm going to show you  
15 shortly. But, as we can see from the documents that  
16 proceed it, there has already been a growth in pool  
17 size by that time.

18 **SIR BRIAN LANGSTAFF:** Well, we've moved from Biggs's 160  
19 average number of donations in a pool through to  
20 180 -- to CBLA, not more than 500 donations, to 830,  
21 1,500, 2,000.

22 **MR HILL:** Yes, we had switched centre, at that time, as  
23 well, from Oxford to BPL, but yes.

24 **SIR BRIAN LANGSTAFF:** But if the -- yes, it's no longer  
25 the cottage industry we're looking at; it's the

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1 look at are some BPL product labels from the 1970s and  
2 the 1980s. I note that I'm not going to be going to  
3 product labels from Scotland because Ms Richards is  
4 going to be looking at those in due course with  
5 witnesses, so I won't pre-empt that.

6 If we could turn, please, Sully, to CBLA0009269.  
7 This is a label from a BPL Factor VIII bottle, which  
8 is dated, according to the date at the bottom of the  
9 document, March 1976. We don't have any reason to  
10 doubt that date, even though the label itself is not  
11 filled in.

12 If we look at the left-hand side, we can see  
13 that it says, the label says, "Prepared by Blood  
14 Products Laboratory, Lister Institute, Elstree,  
15 Herts."

16 That is BPL.

17 The label is entitled "Human anti-haemophilic  
18 fraction", and we can see the bottle contents are said  
19 to contain Factor VIII, and there is a gap left for  
20 saying how many international units are contained in  
21 the bottle. There are instructions about how to  
22 reconstitute the concentrate.

23 Then on the right-hand side, we can see on the  
24 label:

25 "Less than 1,500 plasma donations used in the

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1 production facility.

2 **MR HILL:** Yes. Yes. It's also relevant to note that in  
3 this memorandum, Dr Maycock says:

4 "I think PF lab and BPL should keep in step."

5 **SIR BRIAN LANGSTAFF:** Yes.

6 **MR HILL:** Now, the qualification to that is that the  
7 memorandum as a whole is talking about labelling, but  
8 whether or not that translates to actual donation  
9 sizes is not wholly clear, but he does say:

10 "I would like you to introduce steps of 1,500  
11 and 2,000 donations in the size of plasma pools for  
12 Factor IX concentrate."

13 I'm going to turn now to the two sets of  
14 contemporaneous documents that we have that help to  
15 set out the maximum limits on pool sizes in the 1970s  
16 and the 1980s at BPL. These are primary sources, in  
17 the sense that they come from the time that they are  
18 describing. It is important to note that they are  
19 about the maximum limits and, in terms of labels that  
20 are placed on bottles and correspondence about what  
21 the maximum limit could be, it doesn't necessarily  
22 follow that the maximum was being used at the time,  
23 but we will see in due course we have some other data  
24 on that which correlates relatively closely.

25 The first set of documents that we're going to

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1 production of this batch."

2 We're having a little difficulty spinning it  
3 around, but I hope people can see that on the  
4 right-hand side of the label, written bottom to top,  
5 as it were. Thank you, Sully.

6 **SIR BRIAN LANGSTAFF:** Ah, there we are.

7 **MR HILL:** So 1,500 donations -- that's it. Thank you --  
8 or less than 1,500 donations 1,500 plasma donations,  
9 used in the production of this batch. That is  
10 March 1976.

11 If we could now go, Sully, please, to  
12 BPLL0001692\_008. If we could go to the second of  
13 those labels, please. This is a label -- sorry, if we  
14 could just pull out for a second, Sully. Thank you.

15 This is a label that comes from a bottle that  
16 was fractionated, according to this sheet, on  
17 11 September 1980, and the Factor VIII assay date is  
18 3 October 1980. So we're in the autumn of 1980.

19 If we can now please expand it, please, Sully.

20 We can see again that this has been prepared by  
21 BPL in Elstree. It is said to contain Factor VIII,  
22 250 international units. It is an intermediate purity  
23 product. If we look on the left-hand side, first of  
24 all, we can see that less than 5,000 plasma donations  
25 were used in the preparation of this batch.

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1 If we could turn it back around, Sully, to its  
 2 original orientation, and expand the central part of  
 3 the label.  
 4 This label contains the warning:  
 5 "The preparation is of human origin and cannot  
 6 be assumed to be free of hepatitis virus."  
 7 That is a warning that was not on the previous  
 8 label from 1976.  
 9 Thank you, Sully.  
 10 The next label we will look at comes from  
 11 7 January 1983. It is BPLL001692\_009.  
 12 BPL0001692\_009. Apologies, Sully.  
 13 The top label is, if we could just pull out  
 14 a little, please, Sully, we can see a date at the top,  
 15 "Date effective", 7 January 1983. Then if we could  
 16 zoom in on the label, please. Again, the warning is  
 17 there:  
 18 "The preparation is of human origin and cannot  
 19 be assumed to be free of hepatitis virus."  
 20 We can see that the batch number is HL and then  
 21 the batch number is given. HL is the intermediate  
 22 purity product that was produced by BPL.  
 23 On the left-hand side, we have the words "Less  
 24 than 7500 plasma donations were used in the production  
 25 of this batch."

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1 second label is about a year later, isn't it?  
 2 **MR HILL:** The second label is March '85 and concerns 8Y.  
 3 There's a document which helpfully sets out a number  
 4 of different labels including labels for 8Y and gives  
 5 dates for them.  
 6 **SIR BRIAN LANGSTAFF:** Well, this one does actually have  
 7 a figure in it. If you look underneath "Dried  
 8 Factor VIII Fraction", and look at the wording  
 9 underneath that, underneath the warning:  
 10 "... the preparation is of human origin (less  
 11 than 10,000 plasma donations used per batch)."  
 12 **MR HILL:** Yes.  
 13 **SIR BRIAN LANGSTAFF:** So albeit that it's 8Y, it's heat  
 14 treated, we have moved from less than 7,500 in  
 15 January '83 to 10,000 or less -- sorry, less than  
 16 10,000 in 1985.  
 17 **MR HILL:** Yes, that's right. We can see that helpfully on  
 18 the document BPLL0002039. We have three labels set  
 19 out and before we go to any of them you can see on the  
 20 right-hand side, added to those labels, written next  
 21 to them by whoever has prepared this document, are the  
 22 words "Pre-June 1985", "June 1985 -- February 1987"  
 23 and "February 1987 onward".  
 24 Now, we don't go who put these dates there, we  
 25 can't say that we have found evidence that absolutely

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1 **SIR BRIAN LANGSTAFF:** I think that may be so small you can  
 2 hardly see it, but it's --  
 3 **MR HILL:** I have read it on the computer. I am confident  
 4 it's --  
 5 **SIR BRIAN LANGSTAFF:** I can read it but I'm just thinking  
 6 about those who are watching it at a distance or maybe  
 7 on a home screen.  
 8 **MR HILL:** Yes.  
 9 **SIR BRIAN LANGSTAFF:** So I think they can be assured that  
 10 it is there. If they need further assurance, they can  
 11 go into the actual document itself, those who are Core  
 12 Participants, and can do so into the Relativity or  
 13 catch it online.  
 14 **MR HILL:** All of these figures are set out at paragraph 12  
 15 of the written presentation. I'm going to bring up  
 16 that table in a second, and the references to the  
 17 underlying documents are there as well. So they can  
 18 be checked in that way.  
 19 **SIR BRIAN LANGSTAFF:** Thank you.  
 20 **MR HILL:** I'm now going to go to a document which  
 21 contains --  
 22 **SIR BRIAN LANGSTAFF:** Can we just go back to that page,  
 23 the original page?  
 24 **MR HILL:** BPLL0001692\_009.  
 25 **SIR BRIAN LANGSTAFF:** I'm looking to see if -- because the

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1 confirms those dates but we can say that we haven't  
 2 found evidence which disproves those dates given.  
 3 The first one, pre-June 1985, if we could expand  
 4 that, please, Sully. This is stated to be for  
 5 an intermediate purity product with no heat treatment  
 6 and that fits with what is on the label and fits with  
 7 those labels we have just seen.  
 8 On the left-hand side, a little bit more clearly  
 9 this time, you can see that it says, "Less than 7,500  
 10 plasma donations were used in the preparation of this  
 11 batch."  
 12 So that is in keeping with what we have just  
 13 been looking at. The warning there, "The preparation  
 14 is of human origin and cannot be assumed to be free of  
 15 hepatitis virus", is also consistent with the labels  
 16 we have just seen.  
 17 If we could go to the second of those labels,  
 18 please. This is stated to be from June 1985 to  
 19 February 1987. It is for a high purity HT3 product,  
 20 which is 8Y. We can confirm that it's 8Y because, in  
 21 the bottom right-hand corner of that label, you can  
 22 see the code "8Y1".  
 23 As with the label that you just went to, sir, it  
 24 says:  
 25 "Warning: the preparation is of human origin

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(less than 10,000 plasma donations used per batch). It has been subjected to heat treatment, in the vial, to reduce the risk of infection by viral agents (including hepatitis and AIDS viruses) but cannot be assumed to be free from risk of infection."

If we could then expand and go to the final of these three labels, it's stated to be from February 1987 onward and for FHC1. I have to say I'm not entirely sure what FHC1 stands for there. It is also stated to be barcoded, and we can indeed see a barcode in the bottom right-hand corner. It is also stated that there is no donation limit. That is confirmed by looking at the section on the warning, which now reads, and I quote:

"... the preparation is of human origin. It has been heat treated, in the vial, to reduce the risk of infection by viral agents (including hepatitis and AIDS viruses) but it cannot be assumed to be free of the risk of transmission of viral infections."

So the same warning as the previous label but with the reference to the product being derived from less than 10,000 donations removed. It is stated to be a dried Factor VIII fraction, high purity heat treated.

If we could just go to one further document,

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I have given you a duff reference. It's INQY0000345, not 375. Sorry, my mistake. This is the written presentation. The labels I've just taken you to and some others are included in this table, and we can see how the maximum pool size on those labels increases from 1,500 donations in the March 1976 label; up to 5,000 donations on the September 1980 label; then 7,500 donations on the January 1983 label; 10,000 donations on the March 1985 label; and then from June 1985, according to the document we saw.

Then no stated limit from February 1987 onwards, according to the document that we saw and according to our own research, as we've found that on a label from June 1988. It is important to note that we cannot say that the label changed on 11 September 1980 just that we have a label from that date which shows 5,000 donations, whereas the previous label we'd found from 1976 has 1,500.

The second source that we have from the time itself which helps us to understand the maximum limits on BPL pool sizes are references that are contained in correspondence, and particularly correspondence between people at BPL and people at PFL, about what the maximum pool sizes are. I'm not going to take you to the documents, but I will take you to the table

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which helps to bear out what I have said about the fact that we can't establish, from our own research, that those dates are correct, the material that we have seen is consistent with them. To make that point, could we go to BPLL0016009\_161.

If we could look at the top left-hand corner there is a date given for "Date effective", which is 15 February 1988. The batch number is FHC. The label below, which is stated to be a sample label, is headed "Dried Factor VIII Fraction, High Purity: Heat Treated". We can see on the left-hand side that "8Y" is stamped on it. A barcode in the bottom right-hand corner, and the warning is this:

"... the preparation is of human origin. It has been heat treated, in the vial, to reduce the risk of infection by viral agents (including hepatitis and AIDS viruses) but it cannot be assumed to be free of the risk of transmission of viral infections."

Again, no reference to the number of donors.

Thank you, Sully. If we could take that from the screen and if we could, instead, put up, please, INQ0000375, the tables on page 5 and 6, please.

Sorry, INQY0000375. The tables on pages 5 and 6. It's the presentation itself.

Just give me a moment, sir.

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which is at the same reference, Sully, at page 7.

We can see table 2 at paragraph 16 contains four references. The documents are given their unique IDs in the right-hand column. The information that we have obtained from those documents give maximum pool sizes of 5,000 donations in October 1980, 7,500 in January 1982, 10,000 in June 1985, and then 25,000 in June 1986. We will come back and look at that document a little later.

That correlates closely with the labels that we have looked at, the additional piece of information coming from the June 1986 data suggesting 25,000 donations at a time when there was no limit stated on the labels on the bottles themselves.

We also have some secondary sources which help us to check and to test the information that we have received from the primary sources.

The first is a series of estimates about pool size given by Dr Terry Snape during the course of the HIV Haemophilia Litigation. Dr Snape is going to be coming to give evidence next week, so this may be something that we pick up with him then. But for now, I will show you the table that is in the written presentation at paragraph 27 which records Dr Snape's estimates. These were given in response to a request

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1 from Dr Lane for information on the pool sizes used to  
 2 manufacture Factor VIII at BPL from 1975 onwards.  
 3 If we could go, please, to page 11. If we could  
 4 expand that table, table 3, please. Dr Snape's  
 5 estimates are that in 1975 the approximate weight of  
 6 the plasma pool used at BPL was 150 kilograms, and  
 7 that that came from around 750 donations.  
 8 **SIR BRIAN LANGSTAFF:** That is assuming, of course, that  
 9 each of the donations produces, what, how many? It's  
 10 20 -- 200, isn't it?  
 11 **MR HILL:** I think it is.  
 12 **SIR BRIAN LANGSTAFF:** Because on the assumption that five  
 13 times 200 millilitres equals 1 litre, 1 litre is  
 14 therefore 1 kilogram, assuming that that's the  
 15 equation, which is I think the equation that's broadly  
 16 within -- in line with the figures.  
 17 **MR HILL:** Yes.  
 18 **SIR BRIAN LANGSTAFF:** 150 -- that is 150 times that, so  
 19 it's on the assumption of 200 per -- which is rather  
 20 higher than the assumption which you've used.  
 21 **MR HILL:** Yes. It's also worth noting that later on -- if  
 22 we look down, for example, at February 1988, and the  
 23 batch is FHC, 2,400 kilograms; 10,000 donations. The  
 24 assumption there is 240 millilitres.  
 25 **SIR BRIAN LANGSTAFF:** Yes.

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1 **MR HILL:** Yes. Yes.  
 2 **SIR BRIAN LANGSTAFF:** Both going down possibly with the  
 3 start of heat treatment, but then up again with  
 4 the different processes.  
 5 **MR HILL:** Yes.  
 6 **SIR BRIAN LANGSTAFF:** Yes.  
 7 **MR HILL:** We can come back and we can ask Dr Snape more  
 8 about the assumptions that he made and how he drew  
 9 this data. For now, we simply include it as a further  
 10 data source for this presentation, and it is one,  
 11 I should say, that does correlate relatively closely  
 12 to other data sources, save towards the end of this  
 13 period.  
 14 The weight of the donor pools, approximated,  
 15 increases from 150 kilograms in 1975 to 450 kilograms  
 16 in 1977, which Dr Snape equates to an increase from  
 17 750 donors to 2,250.  
 18 **SIR BRIAN LANGSTAFF:** Yes.  
 19 **MR HILL:** Then up to 600 kilograms in August 1980. The  
 20 number of donors there is 3,000.  
 21 March 1981, it increases to 900 kilograms;  
 22 number of donations, 4,500.  
 23 July 1982, the approximate weight is up to  
 24 1,200 kilograms. The number of donations is 6,000.  
 25 The same figures are given for April 1985.

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1 **MR HILL:** Which may well reflect the growing use of SAG-M,  
 2 the additive which allowed for more plasma to be taken  
 3 from a single donation.  
 4 **SIR BRIAN LANGSTAFF:** Yes. It's between 86 and 88. It  
 5 goes up from 200 to a higher figure.  
 6 **MR HILL:** Yes, that's right.  
 7 **SIR BRIAN LANGSTAFF:** 240, as is obvious from the figures  
 8 there.  
 9 **MR HILL:** We have been using a different figure,  
 10 180 millilitres. That is not to say that we are right  
 11 and Dr Snape is wrong, just that we have used those  
 12 different figures.  
 13 **SIR BRIAN LANGSTAFF:** Yes.  
 14 **MR HILL:** Something that we recognise in the written  
 15 presentation is that the figure of 180 millilitres,  
 16 which we have stuck with all the way through for  
 17 consistency, becomes less reliable as we move through  
 18 the mid '80s into the late '80s because of the  
 19 increased use of SAG-M. There aren't that many  
 20 conversions that we do in the written presentation  
 21 from that time, but it is something to keep firmly in  
 22 mind.  
 23 **SIR BRIAN LANGSTAFF:** I suppose also there may be  
 24 developments in the amount of Factor VIII activity  
 25 that you can extract, known as ^check the yield.

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1 I pause there to note that the figures from  
 2 September '77, August 1980, March '81,  
 3 July '82 and April '85 are all given by reference to  
 4 specific batches of HL, the intermediate purity  
 5 non-heat-treated product. So presumably Dr Snape has  
 6 gone back to the records and checked those batches and  
 7 given those figures accordingly. But he refers to the  
 8 weight as an approximate weight, and obviously the  
 9 donations figure is derived from the calculations that  
 10 we have just been discussing.  
 11 July 1985 is the next figure in the table.  
 12 That is again said to come from an approximate weight  
 13 of 1,200 kilograms and 6,000 donations. That is for  
 14 8Y.  
 15 In November 1986, 8Y is again the batch code.  
 16 The donor pool has gone up to 1,400 kilograms; 7,000  
 17 donations by this time.  
 18 The next figure is for February 1988. The  
 19 weight has gone up to 2,400 kilograms; number of  
 20 donations, 10,000.  
 21 June 1988, 3,200 kilograms; number of donations  
 22 13,500.  
 23 December 1988, 3,400 kilograms; number of  
 24 donations 14,500.  
 25 Same figures for July 1989.

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So that is what we get from Dr Snape's estimate.

A further secondary source that we have, a set of documents which are entitled "Batch histories". If we could go, please, Sully, to CBLA0014475. If we stay on this page for a second, we can see that this is a document that is prepared during the HIV Haemophilia Litigation. As with other such documents, we don't have a final document because the litigation was settled. So these kind of working papers weren't finalised, but they do provide us with some information from those who had been working on the case, as of 1989 and 1990, putting the documents that they had to hand in order.

If we could go to page 168, please. These are the batch histories that we have. It is really a list of batch numbers, the year issued, and then a column saying, "Number of donors". Then columns about whether or not the product has been heat treated, whether it has been tested for HIV or the pool has been tested for HIV.

The column stating "Number of donors" is not explained further. So we don't know whether they are basing this on a precise figure or on a maximum label, or what the basis of the number of donors is.

Thank you, Sully. We can take that off.

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that figure of 6,000 donations remains constant. But at some point in 1986 the approximate number of donations increases to 7,000 and that is also the figure given going into 1987, and that is where the batch histories table stop. So an increase from 2,250 in 1978 to 1979, to 7,000 at some point in 1986.

Of note there, sir, I've pointed out here it's reflected in some of the other data as well, but it's perhaps easier to point it out on this table, that that period between some point in 1982 and some point in 1986 sees a plateauing of approximately 6,000 donations per batch, after a period of increase before, preceding a period of increase afterwards.

The final table that I will take you to, which is from paragraph 43 of the written presentation, is a table that is drawn from contemporary reports that we have from BPL. When I say reports, these are reports that are given in letters, in memoranda, in minutes, and indeed in more formal reports as well in publications.

If we could go, please, to page 16 of the same reference. The table goes over into page 17 as well, please, Sully.

These are figures that we have extracted from various pieces of information that we have got from

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Having looked at the batch history, we have produced a table which is at page 12 and just going over into page 13 of the written presentation. If we could have that, please, INQY0000345.

Thank you, Sully.

Something to note here is that the batch history sometimes shows changes in donation numbers but it doesn't give a specific date for when that change has occurred. In order to be able to present this in tabular form, we have used January and July of a given year to reflect a change during that year. But that does not mean that the change came in July 1980, it's just our way of showing that during the year it changed, and the table is set out this way so that it can feed into a later graph.

We can see that the approximate number of donations, according to the batch history figures, were 2,250 in 1978 and 1979. That figure went into 1980 but, during 1980, it increased to 3,000 donations. That figure again went into 1981 but, during 1981, it increased to 4,500 donations. That is also the figure that we have for 1982 -- at the start of 1982, sorry -- but during that year it increased to 6,000 donations.

From 1983 to 1985, and even going into 1986,

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the relevant periods. There are a series of caveats that go with them, which are set out from paragraph 36 of the written presentation. We have discussed those as we've been going along, sir. They are about the size of the -- sorry, the translation between volume and donation numbers, and weight and donation numbers, and weight and volume, and the one donor to one donation ratio that has been used.

It bears repeating that the figures that are contained in this table are, therefore, approximations. They show a trend, but they cannot always be relied upon to be precise at that particular moment.

The first entry is the one that we looked at, at the start of this presentation, which is the 830 donations that Dr Maycock said was the present figure on 8 December 1975.

The next entry for 11 January 1978 -- I'm not going to take you to the underlying documents, the next entry is 2,000-plus donations, 11 January 1978. At the 18 January 1978 the figure is 3,000 donations. Then other figures from 1978 are given by reference to volume, 400 litres, which translates at 2,200 donations if one takes 180 millilitres as the measure.

1979 and 1980, we can see an increase up to

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600 kilograms, about 3,330 donations. We understand that to be linked to the Stop-Gap programme and I will come back to that shortly.

1980, 5,000 donations, for 1 September. A different figure at 3 September 1980, 3,500 donations. Now, this is not to say that pools were necessarily fluctuating at this time. It may be that we just have these little snapshots of data which may refer to the maximum possible size, whereas the 3,500 donations refers to an individual pool that was fractionated at that level.

A figure for March 1981 is 2,504 donations; but April 1981, 5,000 donations; February 1982, more than 3,000 donations; April 1985, 1,200 kilograms, which equates to about 6,660 donations.

Later in March 1985, 7,200 donations; in June 1988, so a significant gap there, three years, a 2,000-litre pool which would be a little over 11,000 donations; and then April 1990, so again another gap of two years, 25,000 donations, going -- said to go into a plasma pool.

April 1991, 20,000 donors; and 17 May 1991, 13,000 donations.

So these are little snapshots from different times, and, again, I stress they're helpful to show

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later into the '90s, whereas the other data stops in the 1980s.

So that graph illustrates that the tables that we have been looking at tell broadly the same story.

Then if we could turn over, please, to page 19.

**SIR BRIAN LANGSTAFF:** Yes, well, if you put a -- try to just envisage a line of best fit between those various data sources, it might look pretty much like a straight, upward line without any great increase in its rising up. So it's not a bell-shaped curve, not the sort of curve we've been used to seeing in respect of coronavirus.

**MR HILL:** No. That's right. Until 1986, 1987, 1988, at the point where the new BPL opens. And, granted, that we have far fewer data points after that, there does seem to be a sharp increase --

**SIR BRIAN LANGSTAFF:** At that stage.

**MR HILL:** Yes.

Another point to note about this graph is that in order to capture that late surge in pool size, if that's what it was, it's been necessary to extend the vertical axis up to 25,000 donations. So, inevitably, if one does that, then the rises in donor size at the start of the period look more modest than they would look if the vertical access was a -- had a smaller

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a trend, and it shouldn't -- one shouldn't alight on a single figure and say that is what the pool size was for the entirety of that year.

Two graphs help to show this situation. First, same reference, please, Sully, page 18, please. The same caveat applies as I gave a few days ago, that data points on this graph are joined by a straight line but it shouldn't be assumed that there has been linear growth between those two data points. In fact, often you will see a step up when a pool size is increased.

There are three lines shown on this graph. The one in purple are -- is drawn from Dr Snape's estimates that we looked at earlier. The one in green is drawn from the batch history that we looked at earlier. The one in blue is drawn from the contemporary records table which is the table that we have just looked at.

The point that I take from these figures is that they correlate fairly closely up to January 1985. There is then less data in the later '80s, but again, there seems to be a correlation of a growth in pool size and steep growth after about 1986, 1987, so at the time of the redevelopment of BPL. Then the contemporary records go much higher, because they go

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figure in it, if that makes sense.

**SIR BRIAN LANGSTAFF:** Yes.

**MR HILL:** If we could go over, please, to page 19. The same three lines are shown on this graph and this is just to compare them to the data that we have about maximum limits of pool sizes from the product labels and from the correspondence.

The product labels are shown by the yellow line, and the correspondence is shown by the red line.

I think it is fair to say from that graph that the maximum limits are higher than the data points that we have from the other sources -- Dr Snape's estimates for batch history and the contemporary records -- with a couple of exceptions which are very close to the line and may just be quirks of the way that the data has been put together.

So it would appear from that graph that while the donation size of -- while the pool size has grown in the period, it has not exceeded the maximum pool sizes given, either on the labels which accompany the product or in the correspondence with it.

Thank you, Sully. That can be taken down now.

That was for Factor VIII. As I say, the Factor IX data is, I'm afraid, much less satisfactory.

If we could go to INQ0000345, page 20, please.

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I've given you the wrong reference again, sorry, sir.  
 INQY0000345. This is, at paragraph 52 in the table that is shown there, the best that we are able to do with the information that we have about the size of Factor IX pools at BPL from 1983 to 1987. We can see that the figures there contain the smallest batch, the largest batch, and the mode figure, which is the figure that appears most often. That is, we think, the better measure than an average figure at the time, given the data source that we've got.

These are taken from the batch history documents that were compiled as part of the HIV Litigation. As you will see, it's far less extensive than Factor VIII data. 1983 to 1985, the smallest batch, the largest batch and the mode are all 6,000 donations. In 1986, we see that the smallest batch and the mode are 6,000 donations, so the most common pool size in 1986, from the data that we have, was 6,000 donations. But the largest batch was 24,000 donations.

Now that may be explained by the fact that in 1986 your standard production was 6,000 donations, that there were experiments run or a batch run at 24,000 donations. Then in 1987, the smallest batch is 8,000 donations. The largest batch is 20,000 donations, and the mode, so the most common batch, is

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But I would like to take you to the document that we looked at earlier, sir, because it does raise a question that we will perhaps come back to in evidence in due course.

It is CBLA0000253, please, Sully.

This is the minute from Dr Bidwell to Dr Maycock, dated 22 January 1975. We looked at the first sentence earlier, which was about the conversation they had had about labels at Elstree, and it was agreed that they would now say not more than 500 donations.

What Dr Bidwell goes on to say is this, and I quote:

"Mr Snape has pointed out to me that the batches of factor IX prepared from the Elstree material correspond to much higher than 500 donations and that the exact number is not known to us. If we pool the smaller batches here we know the number but again it is more than 500. I have told Mr Snape to have printed on the new labels 'not more than 1000 donations' but the whole subject of having anything at all on the label seems difficult. It is certainly not much of a guide to the clinicians any longer. Can we discuss this, please?"

Now, frustratingly, we don't have a document

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18,000 donations.

If we could then, please, Sully, go to page 22 of the same document. This is a table that is drawn from the contemporary report that we have for BPL Factor IX so the same approach that we took to Factor VIII. Unfortunately, it's difficult sometimes to discern whether the references in the documents are specifically to Factor IX or whether there is an assumption that what applies to Factor VIII will also apply to Factor IX. That may not have been a safe assumption for the reasons that we'll come on to in a second.

But we can see there the figures obtained for January 1978 is over 2,000 donations; then a second figure a week later of 3,000 donations; July 1978, 400 litres, approximately 2,200 donations; April 1981, 5,000 donations; December 1984, 1,200 kilograms or 6,600 donations; June 1988, 2,000 litres, or a little over 11,000 donations; April 1990, 25,000 donations; April 1991, about 20,000 donors, which we equate to 20,000 donations.

Those are the figures that we have.

If we can have page 23, please, Sully. We can see a graph again showing similar rise to that which we've seen for Factor VIII.

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setting out Dr Maycock's reply, and it may be that there never was such a document; the discussion may have been an oral one.

I am conscious that Mr Snape, or Dr Snape as he now is, is going to come and give evidence, so I won't speculate about what this means. But I will raise one possibility, which is that there is evidence to suggest that Factor IX was sometimes fractionated from Factor VIII pools which had been used to produce Factor VIII and then were re-pooled in order to make Factor IX and, if that is right, then it may be that there is a -- potentially a larger donor pool which went into a Factor IX product than a Factor VIII product. But as I say, Dr Snape is giving evidence next week, and we may return to that in due course.

Those are the figures, then, that we have for BPL. I'm going to go to a couple of documents now, which may shed some light on why the pool sizes increased and the processes involved.

If we could start with CBLA0000149, please, Sully. If we expand the top half, please.

This is a memorandum which is entitled "Notes on an outlined scheme for preparation of Factor VIII concentrate from 1,000 litres of plasma per week".

This document doesn't have a date, but from the

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context of it, we know that it was before March 1974. I take that from paragraph 5 of the note, which I'm not going to take you to but refers to a timetable being achieved by March 1974, so we know that this document preceded March 1974.

What it says is that, and I quote:

"This scheme is intended to use, as far as possible, existing facilities in the lab.

"1. Pool sizes: 250 litres, 4 per week."

250 litres would equate to about 1,375 donors.

If we look just below where the handwriting is, we can see these words:

"The present working capacity of the large plant for 1,500 litres of plasma weekly includes 200 litres of supernatant from fresh plasma."

Now, it's hard to piece together what is contained in this document but what it appears to be is a proposal to move from fractionating plasma in pools of unknown quantity, but amounting to 200 litres per week, possibly one pool at 200 litres per week but we don't know that. Possibly that 200 litres could have been split into different pools. But what is proposed is a pool size, a new pool size of 250 litres and, as I say, that's about 1,375 donors.

The suggestion is to do that four times per

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500 litres, and he said that he was agreeing this "On the understanding that the final pool is prepared from two or three sub-pools, each of which has passed its safety tests, including RIA test for the presence of HBsAg."

So, again, a reference to the fact that testing is being linked to the increase in pool size.

I note from that memorandum that there is a reference to the Factor IX being prepared from two or three sub-pools, which may be that process that I was mentioning earlier, that once Factor VIII has been fractionated from the supernatant, the pools are then mixed to allow for Factor IX fractionation.

In the same month, March 1976, as we heard in the previous presentation, BPL made an application for a product licence for Factor VIII from Elstree, and that product licence said that the maximum pool size foreseen at Elstree is 450 litres. 2,500 donations are the figures that were given in the product licence application.

I note the word "foreseen" there, rather than the word being -- or words "being used" or "the present size".

The application also stated this, and I quote:

"Because of the large number of control tests

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week, and that will increase the amount of product that is produced at BPL.

There are then technical discussions about what will be needed in order to achieve that is.

Then, Sully, if we could go, please, to BPLL0003721. This is Dr Maycock's memorandum of the 8 December 1975, which we went to earlier.

I highlighted earlier that the present pool size was given as 830 donations 150 litres. The plan was to increase that pool size -- if we could go down, please, Sully -- to 270 litres and then 360 litres.

Then Dr Maycock said, and I quote:

"The large pool size can be defended on the ground that starting plasma and concentrates are tested by RIA."

That's radioimmunoassay. That is the test for hepatitis B surface antigen. So that is the "defence", to adopt the word used by Dr Maycock, that is being put forward for expanding the pool at that time.

Another memorandum from Dr Maycock, which I won't ask to be brought up on screen but is referred to at paragraph 63(b) of the written report, comes from 19 March 1976, where Dr Maycock agreed to the pool size of PFL Factor IX being increased to

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which have to be made, there is a trend towards larger pools, in order to lessen the amount of testing and reduce waste of valuable material."

The reference is given at paragraph 64 of the written presentation.

Moving toward 1977 and 1978, we get to the period of the Stop-Gap programme that we discussed before. And at that size, and as we heard, part of the Stop-Gap programme involved increasing the size of the plasma pools fractionated at BPL from 400 litres to 600 litres. That is approximately 2,200 donations to 3,300 donations.

That increase may shed light on something that we discussed before.

Sully, if we could have, please, INQY0000337, page 39.

Sir, is from Appendix 2 to the chronological presentation to England and Wales, and it's this confusing point that we discussed before about why it is that, in the fourth column there, the capacity of BPL, expressed in the amount of plasma that, in theory, could be fractionated, is given as increasing between 1977 and 1979, whereas the capacity, as expressed in the amount of product that could be provided, expressed in terms of international units,

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1 remains constant.  
 2 Now, I don't claim to have an answer, but one  
 3 possibility is that this increase in pool size helps  
 4 to increase the figures between 1978 and 1979, and  
 5 that is perhaps not reflected in conversations that  
 6 were taking place about what the output was in terms  
 7 of international units at the time, which is why we  
 8 have the figures for 15 million there. I still can't  
 9 resolve it, but I do note that the increase in pool  
 10 size at this time may have played its role in helping  
 11 to increase the capacity of fractionation as expressed  
 12 in the weight of plasma that is fractionated.  
 13 While we are on this document, sir, it was  
 14 pointed out to me by some of the Core Participants  
 15 whose mental arithmetic is far superior to mine, that  
 16 if you add the figure for 1977, 67,200 kilograms, to  
 17 the figure for 1978, 57,600 kilograms, you get the  
 18 figure --  
 19 **SIR BRIAN LANGSTAFF:** You do, yes.  
 20 **MR HILL:** I can see you nodding along. Again, your mental  
 21 arithmetic is --  
 22 **SIR BRIAN LANGSTAFF:** In 1979.  
 23 **MR HILL:** They raised this because, as was pointed out,  
 24 it's a very odd coincidence if it is indeed  
 25 a coincidence. We agreed, and sir, we have gone back

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1 that the international units actually produced at the  
 2 far right-hand side aren't additive.  
 3 **MR HILL:** It is, sir. It is a period of unsatisfactory  
 4 data --  
 5 **SIR BRIAN LANGSTAFF:** Yes.  
 6 **MR HILL:** -- if we put it that way. I'm afraid I don't  
 7 have an answer for why these figures behave in the way  
 8 that they do. The wider picture is that the Stop-Gap  
 9 programme does allow an expansion of production, and  
 10 it is taking place during this time, and, therefore,  
 11 it might not be a step change but a gradual change  
 12 which is reflected in some of these figures but not in  
 13 others.  
 14 **SIR BRIAN LANGSTAFF:** Yes.  
 15 **MR HILL:** Going back, then, to pool sizes. Ms Richards,  
 16 when presenting the work on Dr Lane, took you to two  
 17 documents, that I won't take you back to, in which  
 18 Dr Lane explained in September 1980 that he was  
 19 content to expand the pool sizes at Dr Smith's request  
 20 up to 900 kilograms on some days, as Dr Smith put it.  
 21 Dr Lane said that he was prepared to do this as,  
 22 and I quote:  
 23 "I'm sure that once one has exceeded 100 to  
 24 200 kilograms pool size, one has already exceeded any  
 25 possibility of small pool protection. I have

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1 and looked at the underlying documents to see whether  
 2 or not this is just a function of somebody adding 1977  
 3 to 1978, and coming up with a figure for 1979.  
 4 We don't think that that is what happened.  
 5 Having gone back to the original documents, the 1977  
 6 figure is based on a number given by Mr Watt of the  
 7 SNBTS in a meeting on 11 March 1977. I won't take you  
 8 to the reference, but for the record, it is  
 9 SCGV0000001\_172.  
 10 The 1978 figure is taken from a handwritten  
 11 memorandum to Dr Lane dated 28 February 1978. The  
 12 reference is CBLA0000738.  
 13 And the 1979 figure is derived from a document  
 14 prepared by Norman Pettet of BPL, dated  
 15 27 February 1979, and the reference to that is  
 16 CBLA0000916.  
 17 So three independent sources from at least two,  
 18 possibly three, different authors, written at  
 19 different times. So we are as satisfied as we can be  
 20 that the fact that the 1979 figure is the sum of the  
 21 1977 and the 1978 figures is a coincidence, rather  
 22 than indicating anything more substantive. It is,  
 23 however, a very strange coincidence, and we're  
 24 grateful for it being brought to our attention.  
 25 **SIR BRIAN LANGSTAFF:** It's curious, if it was additional,

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1 discussed this with John Craske, and he agrees exactly  
 2 on this point."  
 3 The document you saw yesterday, I won't go back  
 4 to it, but 100 to 200 kilograms pool size quoted by  
 5 Dr Lane would approximate to about 550 to 1,100  
 6 donations.  
 7 Moving on to January 1982. Again, I won't take  
 8 you to this document but it is at paragraph 76 of the  
 9 written presentation. Dr Smith wrote to Dr Lane  
 10 requesting permission to increase the pool size  
 11 from -- sorry, requesting permission to increase the  
 12 pool size to the equivalent of 1,200 kilograms or  
 13 7,500 donations, and he gave reasons for it, including  
 14 making the most effective use of the freeze drying  
 15 plant and helping to test new processes in preparation  
 16 for the expansion of BPL. Those are all set out at  
 17 paragraph 76 of the written presentation.  
 18 We then have that period where pool sizes appear  
 19 to remain broadly constant from about 1982/83 to about  
 20 1985.  
 21 Then three documents to finish with, that we may  
 22 come back to with Dr Snape. The first is CBLA0002190.  
 23 This is a memo from Dr Snape to Mr Prince, copying  
 24 Dr Smith and Dr Lane, dated 10 June 1985. It is  
 25 entitled "Coagulation Factor Batch Sizes". Dr Snape

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wrote this:

"Further to your memo of 25th April, 1985.

I have assumed that a limit of 10,000 donations maximum will not restrict operations in the present building, but that an extension to 20,000 donations maximum will be required for the new facility. The higher figure will be used in any product licence applications."

So it appears to be gearing up for the redeveloped BPL.

If we could then go to CBLA0004791. This is from June 1986, so a year later. Again, from Dr Snape to Mr Prince and Dr Smith, copied to Dr Lane and others, entitled "Pool Size Limitations for heat-treated concentrates". It's important to stress that concentrates are by this stage heat treated.

Dr Snape wrote this, and I quote:

"Dr Lane has agreed that the maximum pool size may be extended to 25,000 donations for heat treated coagulation factor concentrates. The appropriate label revisions will be made as soon as possible. Please check that any manufacturing documentation is revised before the increased limit is implemented."

On the same day, Dr Snape wrote to Dr Smithies at the DHSS and this is at DHSC0002303\_027.

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a more straightforward story.

Again, there is a written presentation that has been provided on Relativity and on the Internet. The reference is INQY0000346. Mr Boukraa over the last couple of days has taken you through developments in Scotland, and I won't repeat that.

There is a shift from the use of cryoprecipitate to the use of factor concentrates, and a concentration of the production of blood products at the PFC in Liberton, as opposed to occasional alternative suggestions of having fractionation sites locally. I won't take you to any of the documents there.

There was a hope expressed at a meeting of SNBTS directors and Haemophilia Directors on 8 May 1975 that cryoprecipitate should be completely replaced by concentrates, and it was suggested that cryoprecipitate could be, and I quote, "obsolete in 5 years." The reference is paragraph 6 of the written presentation.

That was 1975. That did not come to pass, but factor concentrates did increase in use, as you have heard. The figure from 1976 to 1982 is an increase in PFC Factor VIII from about 1.3 million international units to 4.75 million international units. There was a corresponding decrease in cryoprecipitate from

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Dr Smithies was the successor to Dr Walford as principal medical officer in the DHSS and the relevant division of the DHSS.

The document is dated 20 June 1986. It is entitled "Maximum donor pool size for coagulation factor concentrates", and what Dr Snape says or writes is this:

"I am writing to advise you of a proposed change in donor pool size limitation for BPL (and PFL) coagulation factor concentrates. It is proposed to increase the maximum number of donations to be pooled from 10,000 to 25,000 plasma donations. In taking this decision, we were mindful of the terminal heat-treatment of coagulation factor concentrates made from such pools and the fact that any increase beyond the already large 10,000 donor limit is probably not significant.

"I thought you should be aware of this proposal."

That is from Dr Snape. We will pick that up with him in due course. The terms of the memorandum you may feel, sir, are significant as to who was taking that decision and who was being informed of it.

That is where I will leave the BPL presentation and turn now to Scotland, which I'm happy to say is

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1.27 million international units in 1976 to 681,000 -- sorry, 682,000 international units in 1982.

That increase in the use of factor concentrates seems to have had an effect on the pool sizes used at PFC. It appears that the pool sizes were in part determined by a desire to reach the level of production that self-sufficiency in blood products required in Scotland.

If we could go, please, to SBTS000309\_023. This is a letter dated 16 March 1973, so very early on in this part of the story. It is a letter to Dr Macdonald of the Scottish Home and Health Department from Mr Watt, Scientific Director of the SNBTS.

At paragraph 1, we can see that Dr Watt wrote this:

"At present, we are between products in that one is being phased down whilst the other is being raised. As discussed yesterday, we are embarking on preparation of a 'high purity' fraction which we might, for convenience, call 'Supereight'. The planned production capacity for this product is one pool of 200 litres per week. This was deliberately chosen to meet a projected need to process 50,000 donations of plasma per annum to meet Scottish needs

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for this product. We do not expect to reach this rate before mid-May, and capability beyond that date would be dependent on plasma supply, completion of clinical acceptance trials, clinical demand et seq."

So that is from March 1973.

There are also documents set out at paragraph 14 of the written presentation that indicate that pool sizes at PFC also increased because of a sense that it was advantageous, in terms of yield and reduction of loss, to fractionate in a larger pool size. I won't take you to that document but it is, as I say, set out at paragraph 14.

As demand rose for factor concentrates going into the 1980s, there was an exploration by Dr Foster and others of ways of increasing supply from the PFC. In a memorandum dated 29 December 1980, again I won't take you to it but it is at paragraph 15 on the written presentation, Dr Foster explored the limiting factors on production at PFC at that time. He concluded that the key limiting factor, both on the pool size and the frequency of processing, was the freeze drying capability at PFC.

Two freeze dryers were available for use. One was limited to freeze drying plasma pool of 300 kilograms, the other was limited to freeze drying

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SBTS0000238\_009. This is a review report from April 1984 from Dr Foster and Ida Dickson of PFC, looking at a Factor VIII recovery at PFC from April 1980 to September 1983. So it is not a report about pool sizes but it does touch upon pool sizes. If we go to page 8, please.

This is a table that was compiled as part of that report which refers to Factor VIII batches that were still in process, and, question mark, pending rework. what I take that to mean is that these are batches that have not been dispatched from PFC for various reasons.

You can see the reason for holding in the right-hand column.

What this helpfully shows is the size of the plasma pool for each of these batches. We can see in the top row a batch from 1978 to 1979 had a plasma pool of 114 litres. Three batches are there from 1979 to 1980. They are stated to be 167 litres, 175 litres and 300 litres. 1981 to 1982, we can see a number of batches. There are three that are 255, 260 -- sorry, two that are 260 and 290 litres. One is expressed as 255 vials, and we're not quite sure if a vial equates to a litre. But you have two at 290 and 260 litres, and then the other three are 450, 479 and 535 litres.

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a plasma pool of 500 kilograms.

In that memorandum, Dr Foster suggests that one way of increasing production would be to increase the plasma pools by using smaller vials, which means that you could fit more into the larger freezer, and that would allow for a pool size of 700 kilograms.

The significance of this is borne out by Dr Perry's written statement to this Inquiry, in which he said, and I quote, that PFC pool sizes:

"... were designed and established to be aligned with anticipated process yields and the maximum capacity of freeze dryers used for the final stage of processing. At the time in question, PFC had two production scale freeze dryers of different capacities for this purpose."

That is paragraph 16 of the written presentation, Dr Perry and Dr Foster are both coming to give evidence, so I won't go into this any further, save to say that the data that we are about to look at seems to bear out the fact that pool sizes at PFC in the early 1980s were conditioned to an extent by the fact that the plasma from one pool had to fit into one dryer or the other.

Now, we have some data about the pool sizes at PFC at this time. If we could go, please, to

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So it would appear that you have those two freezers, one of which can cope with up to about 290 litres, possibly up to 300 litres, of plasma, the other of which can cope with up to, on these figures, 535 litres.

It is a similar story for 1982 to 1983, that you have a split between seven batches, three are just under 300 litres, and four are between 495 and 555 litres.

If we could just go over the page as well, please, Sully.

We have another table setting out further batches that failed quality assurance tests, and we can see the size of those batches. And, again, similar story, from 1980 to 1981 and 1981 to 1982, where you have some batches which hover between 250 and 300 litres, and other batches which are about 500 -- in this case 540 and 555 litres for 1983 to 1984.

That information correlates with other sources that the Inquiry has. These are set out at paragraph 19 of the written presentation. I don't think there's a need to go to the underlying documents. But we can see at paragraph 19 that in a letter from November 1990, Professor Cash said that

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pool sizes for Factor VIII at PFC were between 200 and 300 kilograms between 1978 and 1980.

Dr Perry in his written reason statement to the Inquiry says that the pool sizes increased during the early 1980s and varied between 300 and 550 kilograms.

Then Dr Perry's evidence is consistent with another report that we have for the period 1981 to June 1983 from the SNBTS Factor VIII Study Group which recorded pool sizes of either 320 or 550 kilograms.

If we could please put on screen, Sully, INQY0000346. Page 9. Table at the top of that page.

This is taken from the written presentation, and it draws together that information that we have just gone through. It is important to state that the table is comprised of limited data points, and it is possible there are other data points and other pool sizes that were used at the time, particularly in the early 1970s.

We have used in the final column the same measure of donations per litre, so 5.5 donations per litre, as we have used for England and Wales, although Dr Perry in his statement estimated that there were about 4 or 5 donations per litre, saying there is a degree of reasonable difference, depending on which translation one takes.

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and which you've heard evidence about before, the 16 people who were infected with HIV through the use of PFC products.

Dr Perry, in the third paragraph down, refers to the fact that all of the donors who contributed to this pool of Factor VIII had been identified or had sought to be identified, and he states that there were 4,000 such donors. So it appears that Dr Perry's conclusion is that the suspected pool was made up of 4,000 donors or donations. It is not entirely clear which metric is being referred to, but perhaps in this instance it doesn't matter.

That is a little higher than the figures that we have looked at in the table which took us up to 1983 and 1984.

You have heard from Mr Boukraa the steps that were taken in response to HIV and AIDS. They notably did not include steps to restrict the donor pool size at that time. There is a reference at paragraph 23 to a memorandum sent from Professor Cash to Dr Perry on 7 December 1984, in which he gave his view that any moves to restricting donor pools should be discussed by all directors. He said, and I quote:

"It is an exciting option that I suspect will have colossal cost and operational implications.

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But looking at that, we can see that from the data, the estimated donations for a pool size of 114 litres in 1978 to 1989, is 627. That is just one data point that we have from that year.

1979 to 1980, we have a range of between 167 to 300 litres. That's a range of donors from about 900 to about 1,650.

1980 to '81, the pool size in litres is 144 to 290 litres; the range in donors, 792 to 1,595. That's 792 is a precise figure given but, of course, it is an approximation.

1981 to 1982, the plasma pool size in litres ranges from 260 to 540 litres. The estimated donations, 1,430 to 2,970.

1982-83, 283 litres to 555 litres, or 1,557 donors to 3,053 donors. That figure of 3,053 donors is also used for the single data point for 1983 to '84.

We have only limited data for pool sizes thereafter. One interesting point of data is -- I think we could have this on screen, please, Sully, it's PRSE0000965. This is a memorandum from Dr Perry to all staff, subject line "AIDS", date 31 January 1985. So this is just after the discovery of the Edinburgh cohort that Mr Boukraa referred to

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There is much to be done before we need consider this option."

The final piece of data that we have is an article from 1985 written by Dr Foster, and Alan Dickson of PFC. That recorded -- I needn't take you to it -- that at the time of writing, the pool sizes for continuous flooring ^wd were between 600 kilograms and 1,000 kilograms, adopting the 5.5 donations per kilogram conversion figure, that equates to 3,300 to 5,500 donations.

That is from 1985. The reference is at paragraph 24 of the written presentation.

There is a graph, sir, at page 12 of the written presentation. So that, Sully, is INQY0000346. I think perhaps we could try page 13.

Page 11? Found it in the end. If we could expand that, please, at the bottom. The same caveats apply to this graph as to the previous ones about the lines between the data points. There are two lines which show the lowest range and the highest range of the pool sizes at PFC. There is also a dotted line which shows the average pool size at PFC, but I'd suggest that perhaps isn't as useful because it does seem to be that the plasma pools are either one size or another depending on which of the freeze dryers was

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1 being used.  
 2 But we can see that both of the lines do show an  
 3 increase in the early '80s and then a further increase  
 4 between 1984 and 1985. But I stress that the start  
 5 and the end dates are based on very limited data  
 6 points and so obviously come with a degree of caution  
 7 as a result.  
 8 That is all I intend to say at this stage about  
 9 pool sizes at PFC as well and you will, of course, be  
 10 hearing further evidence in the coming days from  
 11 Dr Foster about production at PFC among other matters.  
 12 That, sir, is all I have for you today.  
 13 **SIR BRIAN LANGSTAFF:** Well, thank you very much indeed,  
 14 Mr Hill.  
 15 So tomorrow we have Dr Foster, don't we?  
 16 **MR HILL:** Yes.  
 17 **SIR BRIAN LANGSTAFF:** 10.00. 10.00 tomorrow.  
 18 (4.37 pm)  
 19 (Adjourned until 10.00 am the following day)  
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103/17 106/10 115/24 117/21 118/4 123/6 123/11 125/18 125/24 126/5 128/6 130/1 130/5 130/9 130/19 130/22 130/25 131/6 131/13 137/8 137/12 137/18 137/25 138/4 138/7 138/13 138/23 139/2	139/6 139/18 147/6 147/17 148/2 157/19 157/22 158/25 159/5 159/14 173/13 173/17  <b>'60s [1]</b> 119/22 <b>'70s [2]</b> 119/22 120/1 <b>'74 [1]</b> 40/11 <b>'75 [1]</b> 44/5 <b>'76 [2]</b> 46/24 53/15 <b>'77 [1]</b> 140/2 <b>'80s [4]</b> 138/18 138/18 146/21 173/3 <b>'81 [4]</b> 53/15 53/16 140/2 170/8 <b>'82 [5]</b> 86/17 87/12 87/22 87/25 140/3 <b>'82 onwards [1]</b> 87/22 <b>'82 up [1]</b> 86/17 <b>'83 [5]</b> 87/12 87/25 90/22 109/10 131/15 <b>'83 and [1]</b> 90/22 <b>'83 to [1]</b> 109/10 <b>'84 [6]</b> 86/18 87/13 87/25 90/22 109/11 170/18 <b>'84 onwards [1]</b> 87/25 <b>'84 period [1]</b> 109/11 <b>'85 [4]</b> 34/10 87/14 131/2 140/3 <b>'86 [2]</b> 34/10 87/14 <b>'87 [2]</b> 34/10 87/14 <b>'88 [2]</b> 88/3 88/5 <b>'89 [1]</b> 88/5 <b>'90 [1]</b> 88/5 <b>'90s [1]</b> 147/1 <b>'active' [1]</b> 111/23 <b>'AIDS' [1]</b> 105/15 <b>'high [1]</b> 164/20 <b>'not [2]</b> 122/18 151/20 <b>'Pro [1]</b> 59/20 <b>'Pro Rata' [1]</b> 59/20 <b>'saved' [1]</b> 13/11 <b>'Supereight' [1]</b> 164/21 <b>'worst [1]</b> 102/23  <b>0</b> <b>000 [4]</b> 19/1 19/5 19/19 62/10 <b>0000253 [1]</b> 122/7 <b>002 [1]</b> 17/18 <b>003 [1]</b> 27/8 <b>008 [1]</b> 128/12 <b>009 [4]</b> 129/11 129/12 130/24 167/1 <b>023 [2]</b> 44/21 164/9 <b>027 [1]</b> 161/25 <b>031 [1]</b> 38/20 <b>033 [1]</b> 14/25 <b>062 [1]</b> 36/3	<b>071 [1]</b> 67/20 <b>085 [1]</b> 68/24  <b>1</b> <b>1 February 1982 [2]</b> 29/4 32/9 <b>1 January 1981 [1]</b> 55/15 <b>1 May [1]</b> 100/9 <b>1 million [4]</b> 7/23 10/8 13/12 29/18 <b>1 September [1]</b> 145/4 <b>1,000 [4]</b> 5/21 21/22 22/16 26/7 <b>1,000 kilograms [1]</b> 172/8 <b>1,000 kilos [1]</b> 60/16 <b>1,000 litres [1]</b> 152/24 <b>1,000,000 [1]</b> 39/21 <b>1,100 [1]</b> 160/5 <b>1,200 [1]</b> 145/14 <b>1,200 kilograms [4]</b> 139/24 140/13 150/17 160/12 <b>1,375 [2]</b> 153/10 153/24 <b>1,400 kilograms [1]</b> 140/16 <b>1,430 [1]</b> 170/14 <b>1,500 [9]</b> 22/17 125/21 126/10 127/25 128/7 128/8 128/8 135/6 135/18 <b>1,500 litres [1]</b> 153/14 <b>1,557 [1]</b> 170/15 <b>1,595 [1]</b> 170/9 <b>1,650 [1]</b> 170/7 <b>1,800 [3]</b> 22/13 22/17 25/22 <b>1.27 million [1]</b> 164/1 <b>1.3 million [1]</b> 163/23 <b>1.49pm [1]</b> 92/8 <b>1.5 million [2]</b> 4/20 31/7 <b>1.50 [2]</b> 92/5 92/5 <b>1.7 [1]</b> 31/8 <b>1.8 million [1]</b> 76/19 <b>10 [5]</b> 5/13 5/21 46/7 51/23 54/12 <b>10 June 1985 [1]</b> 160/24 <b>10 per cent [1]</b> 55/20 <b>10 years [4]</b> 25/11 25/14 31/4 32/8 <b>10,000 [17]</b> 6/16 17/25 20/10 21/23 47/15 131/11 131/15 131/16 133/1 133/22 135/9 136/7 137/23 140/20 161/3 162/12 162/16 <b>10.00 [3]</b> 173/17	173/17 173/19 <b>100 [2]</b> 159/23 160/4 <b>100 million [1]</b> 28/3 <b>100-120 [1]</b> 27/21 <b>1000 [2]</b> 5/14 151/20 <b>11 [5]</b> 26/9 47/6 123/24 137/3 172/16 <b>11 January 1978 [2]</b> 144/18 144/20 <b>11 June 1975 [2]</b> 16/9 38/19 <b>11 March 1976 [1]</b> 45/2 <b>11 March 1977 [1]</b> 158/7 <b>11 September 1980</b> <b>[2]</b> 128/17 135/15 <b>11,000 [2]</b> 145/18 150/19 <b>11.13 [1]</b> 51/10 <b>11.45 [3]</b> 51/9 51/9 51/12 <b>114 litres [2]</b> 167/18 170/3 <b>117 [1]</b> 16/11 <b>11th hour [1]</b> 113/16 <b>12 [5]</b> 19/4 47/19 130/14 142/2 172/13 <b>12 June 1973 [1]</b> 3/12 <b>12 months' [2]</b> 42/20 58/5 <b>12,000 [3]</b> 17/2 46/7 90/2 <b>12.52 [1]</b> 92/6 <b>120 [2]</b> 22/6 27/21 <b>122,000 [1]</b> 90/1 <b>13 [2]</b> 142/3 172/15 <b>13,000 [1]</b> 145/23 <b>13,500 [1]</b> 140/22 <b>137,500 [1]</b> 28/4 <b>14 [3]</b> 47/8 165/6 165/12 <b>14 November 1973 [1]</b> 14/24 <b>14,500 [1]</b> 140/24 <b>14.5 million [1]</b> 45/21 <b>144 [1]</b> 170/8 <b>15 [4]</b> 19/1 55/18 92/16 165/17 <b>15 February 1988 [1]</b> 134/8 <b>15 June 1983 [1]</b> 104/22 <b>15 million [2]</b> 45/15 157/8 <b>15,000 [2]</b> 6/15 20/10 <b>15,000 litres [1]</b> 6/23 <b>150 [3]</b> 124/10 137/18 137/18 <b>150 kilograms [2]</b> 137/6 139/15 <b>150 litres [3]</b> 125/5	125/9 154/9 <b>150,000 litres [1]</b> 11/4 <b>1500 [2]</b> 124/11 124/20 <b>16 [4]</b> 136/2 143/21 166/16 171/1 <b>16 March 1973 [1]</b> 164/10 <b>160 [2]</b> 121/4 125/18 <b>161 [1]</b> 134/5 <b>167 [1]</b> 170/5 <b>167 litres [1]</b> 167/19 <b>168 [1]</b> 141/14 <b>17 [1]</b> 143/22 <b>17 May 1991 [1]</b> 145/22 <b>17.5 million [2]</b> 45/14 45/24 <b>172 [1]</b> 158/9 <b>175 litres [1]</b> 167/19 <b>18 [2]</b> 49/11 146/5 <b>18 January 1978 [1]</b> 144/21 <b>18,000 [1]</b> 150/1 <b>180 [2]</b> 124/14 125/20 <b>180 millilitres [6]</b> 121/14 121/17 125/6 138/10 138/15 144/24 <b>19 [5]</b> 50/18 147/5 148/3 168/22 168/24 <b>19 March 1976 [1]</b> 154/24 <b>192 [2]</b> 121/5 121/6 <b>1956 [1]</b> 93/3 <b>1960s [1]</b> 11/24 <b>1961 [1]</b> 18/17 <b>1967 [3]</b> 79/14 79/17 94/4 <b>1969 [5]</b> 120/18 120/20 121/4 121/9 122/4 <b>1970 [3]</b> 120/20 121/5 121/9 <b>1970s [22]</b> 1/12 16/7 22/21 22/24 22/25 34/4 35/4 36/23 37/1 44/16 46/20 50/9 53/1 53/10 80/1 87/8 87/20 89/25 119/20 126/15 127/1 169/18 <b>1971 [8]</b> 79/19 79/24 94/4 120/18 120/21 121/5 121/10 122/4 <b>1973 [12]</b> 2/21 3/12 11/22 14/8 14/24 15/3 35/6 35/7 46/6 79/13 164/10 165/5 <b>1974 [13]</b> 12/20 14/8 16/1 35/6 35/18 93/4 93/8 120/9 122/24 123/2 153/1 153/4 153/5	<b>1975 [28]</b> 13/1 16/9 17/10 18/17 35/6 35/22 36/6 37/25 38/8 38/19 39/5 39/9 40/13 46/24 47/13 122/10 123/24 124/5 125/2 125/10 137/2 137/5 139/15 144/17 151/7 154/7 163/14 163/20 <b>1976 [24]</b> 17/13 18/5 38/8 40/14 44/20 45/2 46/14 47/13 53/7 82/13 83/14 86/5 87/17 124/8 124/11 127/9 128/10 129/8 135/6 135/18 154/24 155/14 163/22 164/1 <b>1976/77 [1]</b> 91/15 <b>1977 [21]</b> 20/25 21/10 21/21 29/21 45/20 45/23 124/9 124/12 125/10 139/16 156/6 156/23 157/16 158/2 158/5 158/7 158/21 <b>1977-78 [1]</b> 50/20 <b>1978 [20]</b> 64/13 91/16 142/18 143/6 144/18 144/20 144/21 144/22 150/14 150/15 156/6 157/4 157/17 158/3 158/10 158/11 158/21 167/17 169/2 170/3 <b>1979 [21]</b> 18/11 22/1 22/1 22/18 25/23 56/13 80/12 86/5 142/18 143/6 144/25 156/23 157/4 157/22 158/3 158/13 158/15 158/20 167/17 167/18 170/5 <b>198 [1]</b> 70/23 <b>1980 [41]</b> 53/1 53/18 54/21 54/22 55/9 56/4 58/10 63/15 85/24 86/3 86/6 86/13 87/8 87/21 88/16 88/22 94/25 95/1 95/12 128/17 128/18 128/18 135/7 135/15 136/6 139/19 140/2 142/12 142/19 142/19 144/25 145/4 145/5 159/18 165/16 167/4 167/19 168/15 169/2 170/5 170/8 <b>1980s [24]</b> 34/12 35/4 36/24 42/18 43/20 44/3 51/6 51/14 52/23 52/24 53/11 53/21 63/5 80/1 86/19 90/1 94/19 117/3 126/16 127/2 147/2 165/14
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<b>1</b>	<b>1985 [46]</b> 73/19 81/5 88/25 89/3 89/6 90/23 93/14 94/7 109/4 109/8 109/16 109/23 110/1 110/24 111/2 111/6 112/4 112/5 112/10 113/4 115/13 116/6 116/12 116/15 131/16 131/22 131/22 132/3 132/18 135/9 135/10 136/7 139/25 140/11 142/25 145/14 145/16 146/20 149/14 160/20 160/24 161/2 170/24 172/4 172/11 173/4 <b>1986 [19]</b> 26/6 113/12 113/15 113/17 113/17 136/8 136/12 140/15 142/25 143/2 143/6 143/11 146/23 147/13 149/15 149/17 149/21 161/12 162/4 <b>1987 [17]</b> 93/18 93/19 112/8 114/6 114/16 114/18 116/22 131/22 131/23 132/19 133/8 135/11 143/4 146/23 147/13 149/5 149/23 <b>1988 [10]</b> 116/24 134/8 135/14 137/22 140/18 140/21 140/23 145/17 147/13 150/18 <b>1989 [3]</b> 140/25 141/12 170/3 <b>1990 [6]</b> 83/15 91/17 141/12 145/19 150/19 168/25 <b>1991 [5]</b> 93/25 116/24 145/22 145/22 150/20	<b>2.32 [1]</b> 117/24 <b>2.49 [1]</b> 118/1 <b>2.5 million [1]</b> 76/24 <b>2.50 [2]</b> 117/22 117/23 <b>2.75 [5]</b> 25/19 26/3 28/1 28/4 58/21 <b>2.75 million [4]</b> 26/23 27/15 30/17 58/16 <b>20 [3]</b> 19/19 137/10 148/25 <b>20 August 1981 [1]</b> 59/7 <b>20 June [2]</b> 3/22 13/25 <b>20 June 1986 [1]</b> 162/4 <b>20,000 [7]</b> 6/20 20/12 145/22 149/24 150/20 150/21 161/5 <b>200 [4]</b> 137/10 137/19 138/5 169/1 <b>200 kilograms [2]</b> 159/24 160/4 <b>200 litres [5]</b> 153/14 153/19 153/20 153/21 164/23 <b>200 millilitres [1]</b> 137/13 <b>200,000 litres [1]</b> 10/7 <b>2000 [3]</b> 60/15 124/12 124/20 <b>2022 [1]</b> 1/1 <b>21 January 1983 [2]</b> 66/24 98/1 <b>21 May 1984 [1]</b> 76/3 <b>22 [1]</b> 150/2 <b>22 January 1975 [2]</b> 122/10 151/7 <b>23 [2]</b> 150/23 171/19 <b>23 March 2022 [1]</b> 1/1 <b>23 May 1984 [1]</b> 75/21 <b>24 [1]</b> 172/12 <b>24 hours [5]</b> 93/17 110/2 110/8 112/12 112/17 <b>24,000 [2]</b> 149/19 149/23 <b>24-hour [1]</b> 112/20 <b>240 [1]</b> 138/7 <b>240 millilitres [1]</b> 137/24 <b>25 per cent [1]</b> 59/8 <b>25,000 [7]</b> 136/7 136/12 145/20 147/22 150/19 161/19 162/12 <b>250 [3]</b> 45/19 128/22 168/16 <b>250 litres [3]</b> 153/9 153/10 153/23 <b>250,000 litres [1]</b> 11/8 <b>255 [2]</b> 167/21 167/23 <b>25th April [1]</b> 161/2	<b>26 [1]</b> 120/9 <b>260 [3]</b> 167/21 167/22 170/13 <b>260 litres [1]</b> 167/24 <b>27 [1]</b> 136/24 <b>27 February 1979 [1]</b> 158/15 <b>27 October 1980 [1]</b> 95/12 <b>270 [1]</b> 124/11 <b>270 litres [1]</b> 154/11 <b>28 February 1978 [1]</b> 158/11 <b>283 litres [1]</b> 170/15 <b>29 August 1986 [1]</b> 113/15 <b>29 December 1980 [1]</b> 165/16 <b>290 [1]</b> 167/24 <b>290 litres [3]</b> 167/22 168/2 170/9	<b>3</b> <b>3 December 1975 [1]</b> 125/2 <b>3 May [1]</b> 100/24 <b>3 May 1983 [2]</b> 99/16 99/23 <b>3 October 1980 [1]</b> 128/18 <b>3 September 1980 [1]</b> 145/5 <b>3,000 [6]</b> 4/14 139/20 142/19 144/21 145/14 150/15 <b>3,053 [2]</b> 170/16 170/16 <b>3,200 kilograms [1]</b> 140/21 <b>3,300 [2]</b> 156/12 172/10 <b>3,330 [1]</b> 145/1 <b>3,400 kilograms [1]</b> 140/23 <b>3,500 [2]</b> 145/5 145/9 <b>30 [6]</b> 5/21 6/9 6/18 101/15 101/20 102/13 <b>30 litres [1]</b> 121/19 <b>30 September 1982</b> <b>[1]</b> 61/21 <b>30,000 [2]</b> 45/19 74/12 <b>300 [1]</b> 169/5 <b>300 kilograms [2]</b> 165/25 169/2 <b>300 litres [5]</b> 167/20 168/3 168/8 168/17 170/6 <b>300,000 [1]</b> 12/8 <b>31 January 1985 [1]</b> 170/24 <b>313 [1]</b> 120/9 <b>31st [1]</b> 31/6	<b>31st March [1]</b> 31/9 <b>320 [1]</b> 169/9 <b>35 litres [1]</b> 121/19 <b>36 [1]</b> 144/2 <b>360 [1]</b> 124/12 <b>360 litres [2]</b> 125/9 154/11 <b>375 [1]</b> 135/2 <b>39 [1]</b> 156/16 <b>3rd December [1]</b> 124/4	<b>4</b> <b>4 million [1]</b> 47/16 <b>4,000 [2]</b> 171/8 171/10 <b>4,500 [2]</b> 139/22 142/21 <b>4.6 [1]</b> 101/19 <b>4.37 [1]</b> 173/18 <b>4.5 million [2]</b> 46/7 46/11 <b>4.75 million [1]</b> 163/24 <b>4.8 million [2]</b> 6/18 8/17 <b>40 [1]</b> 5/22 <b>400 [1]</b> 14/6 <b>400 litres [3]</b> 144/23 150/16 156/10 <b>400,000 litres [1]</b> 10/12 <b>43 [1]</b> 143/15 <b>450 [1]</b> 167/25 <b>450 kilograms [1]</b> 139/15 <b>450 litres [1]</b> 155/18 <b>460,000 [1]</b> 77/18 <b>479 [1]</b> 167/25 <b>48 million [2]</b> 9/13 9/14 <b>495 [1]</b> 168/8	<b>5</b> <b>5 million [4]</b> 4/12 4/19 8/17 71/15 <b>5 years [5]</b> 26/6 29/15 31/19 31/20 163/18 <b>5,000 [7]</b> 128/24 135/7 135/16 136/6 145/4 145/13 150/17 <b>5,500 [1]</b> 172/10 <b>5.20 [1]</b> 10/2 <b>5.5 [2]</b> 169/20 172/8 <b>50 [2]</b> 38/8 53/13 <b>50 million [3]</b> 4/18 19/3 28/3 <b>50 per cent [2]</b> 53/8 53/16 <b>50,000 [1]</b> 164/24 <b>500 [10]</b> 16/4 122/19 123/4 123/7 123/8 125/20 151/11 151/16	151/19 168/18 <b>500 kilograms [1]</b> 166/1 <b>500 litres [1]</b> 155/1 <b>52 [1]</b> 149/2 <b>53 million [1]</b> 9/22 <b>535 litres [2]</b> 167/25 168/5 <b>540 [1]</b> 168/18 <b>540 litres [1]</b> 170/13 <b>55,000 [1]</b> 45/20 <b>550 [1]</b> 160/5 <b>550 kilograms [2]</b> 169/5 169/9 <b>555 litres [3]</b> 168/9 168/18 170/15 <b>56 million [1]</b> 4/18 <b>57,600 kilograms [1]</b> 157/17
	<b>2</b> <b>2 February 1984 [1]</b> 110/22 <b>2 November 1984 [1]</b> 108/7 <b>2,000 [5]</b> 77/17 125/11 125/21 126/11 150/14 <b>2,000 litres [1]</b> 150/18 <b>2,000-plus [1]</b> 144/20 <b>2,200 [3]</b> 144/23 150/16 156/11 <b>2,250 [3]</b> 139/17 142/18 143/5 <b>2,400 kilograms [2]</b> 137/23 140/19 <b>2,500 [1]</b> 155/18 <b>2,504 [1]</b> 145/12 <b>2,750 [1]</b> 25/22 <b>2,970 [1]</b> 170/14 <b>2.0 million [1]</b> 58/18 <b>2.03 [1]</b> 32/5					<b>6</b> <b>6 May 1983 [1]</b> 106/14 <b>6,000 [9]</b> 139/24 140/13 142/24 143/1 143/11 149/15 149/16 149/18 149/21 <b>6,600 [1]</b> 150/18 <b>6,660 [1]</b> 145/15 <b>6.10 [1]</b> 12/5 <b>6.20 [1]</b> 12/6 <b>60 [1]</b> 50/23 <b>60 million [1]</b> 4/10 <b>600 kilograms [3]</b> 139/19 145/1 172/8 <b>600 litres [1]</b> 156/11 <b>627 [1]</b> 170/3 <b>63 [1]</b> 154/23 <b>64 [1]</b> 156/4 <b>67,200 kilograms [1]</b> 157/16 <b>68 [2]</b> 93/16 112/19 <b>68 degrees [7]</b> 93/13 109/7 109/20 109/25 110/2 110/8 112/16 <b>681,000 [1]</b> 164/1 <b>682,000 [1]</b> 164/2		
						<b>7</b> <b>7 December 1984 [1]</b> 171/21 <b>7 January 1983 [2]</b> 129/11 129/15 <b>7 million [2]</b> 56/19 71/16 <b>7,000 [3]</b> 140/16 143/3 143/6 <b>7,200 [1]</b> 145/16 <b>7,500 [5]</b> 131/14 132/9 135/8 136/6 160/13 <b>70 [2]</b> 19/11 84/5 <b>70-80,000 litres [1]</b> 11/2		

(46) 1980s... - 70-80,000 litres



<b>7</b> 700 [1] 59/24 700 kilograms [1] 166/6 700,000 [2] 14/6 16/4 72 [1] 121/9 72 hours [3] 93/23 113/5 116/18 720 [1] 59/25 75 degrees [1] 93/23 750 [2] 137/7 139/17 7500 [1] 129/24 76 [2] 160/8 160/17 77 [1] 91/15 78 [1] 50/20 792 [2] 170/9 170/10	20/20 27/24 28/18 31/15 31/17 34/25 36/6 37/3 40/8 42/20 47/8 47/23 52/25 53/1 53/8 53/9 53/13 57/7 57/8 60/14 60/16 61/7 61/24 63/15 64/19 64/22 67/2 67/11 67/19 69/3 70/21 71/1 72/17 72/23 74/5 76/19 77/18 78/13 85/8 85/24 94/9 100/1 104/4 106/14 109/9 110/16 113/7 119/9 119/9 119/21 120/21 121/14 121/18 122/13 122/16 125/5 126/7 126/19 126/20 127/21 130/6 131/1 134/1 135/23 136/18 139/8 141/17 144/4 145/1 145/15 146/23 147/19 148/5 149/4 150/20 151/8 151/9 152/6 153/10 153/24 154/3 156/19 157/6 160/5 160/19 160/19 163/23 166/19 166/24 167/5 168/2 168/17 169/23 170/6 170/7 171/1 172/18 173/8 173/11 above [2] 102/14 104/4 absence [1] 102/9 absolutely [1] 131/25 accelerating [1] 104/2 accept [4] 13/3 15/18 17/10 25/7 acceptable [1] 98/7 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