Thursday, 17 March 2022

(10.00 am)

Presentation to the Inquiry about supply and demand for blood products in England and Wales by MR HILL

SIR BRIAN LANGSTAFF: Yes.

MR HILL: Sir, we finished yesterday at the end of the Stop-Gap programme, and as we have discussed, that was a precursor, in the mind of Dr Lane, to a full redevelopment of BPL, something that you have heard considerable evidence on, particularly from Dr Walford, Lord Clarke and Lord Fowler. I'm not going to repeat that evidence, and I'm not going to go through in any sort of detail the way in which the full redevelopment of BPL took place. There are a couple of points that I will make here because they will assist later when we are looking at some of th data.

The first is that the redevelopment of BPL, the full-scale redevelopment of BPL, was informed by th estimates that we looked at yesterday, particularly Dr Lane's estimates of 90 million international uni ts by the mid-1980s, and a ceiling figure of 120 milli on international units which he foresaw as the size of the redeveloped BPL in order to cater for an increa se in demand. He wasn't necessarily saying that deman

would get to 120 million international units.

From the documents that we went through with Dr Walford, Lord Fowler and Lord Clarke, we can see that in the planning stages of BPL, the size of the new development is usually expressed by reference t the amount of plasma per annum that it will fractionate. Treasury approval was originally give for a site fractionating 400,000 kilograms per annu m. Later, that is increased to 450,000 kilograms per annum, and that is a figure that we will pick u later in the tables. We understand that to have be en on the basis of the types of estimate that Dr Lane was making about usage.

There isn't a straight line to be drawn between the amount of international units to be created in, for example, 1989 and the amount of kilograms of plasma to be inputted as estimated in 1979, because there were a number of variables along the way, in particular a hope, an expectation, that yields woul improve as the plant developed and as techniques improved. As we will see, in fact, yields decrease because of the introduction of heat treatment.

Construction began on the redevelopment of BPL in May 1983. The original estimate for completion was July 1985. That slipped over the years to the summ er

of 1987, so approximately two years' slippage. The date --

SIR BRIAN LANGSTAFF: So it doubled, in effect? May '83 to July '85, two years. July '85 to summer '87, two years.

MR HILL: Yes. Yes. That's the construction period doubled, yes.

The estimates for achieving self-sufficiency, they shifted from 1986 to 1989. Now, the differenc between the completion of the plant and achieving self-sufficiency is explained by the fact that ther was an expectation that the plant would take some t ime to get up to full speed and up to full production, and that is borne out by the figures that we see later.

The cost of the project increased from £21.1 million in 1982 prices to a capital cost limi of £60 million as granted in 1987 -- sorry, 1986 at 1986 prices. I think that the ultimate price tag c ame in slightly under that, but that was the cost limit that was allowed.

There was an additional £7 million to be spent on what were considered to be essential extras in 1 986 prices. And we have seen from some of the document the contemporary views of ministers decrying the la ck of cost control.

Lord Fowler told this Inquiry, at paragraph 4.82 of his statement, that the overspend on the project reflected poorly on the Department. He suggested a number of factors contributed to the delays and t he expense, and the wider documents also suggest these kind of factors. They are: the underestimation of the initial project during the tender stage; the complexity of the plant and of the build; the vario us redesigns that took place during the project, in pa rt due to the new technology that was becoming availab le, and in part due to the design and build approach th at was taken. So there was an element of designing whilst the build was ongoing. There is also eviden ce to support poor management by the CBLA and a lack o oversight by the DHSS.

Lord Fowler did also point to three what lawyers might call points of mitigation about the project.

The first was that although, as you've said, sir, the length of time of the build of the project was longer than was anticipated, a submission from 29 December 1986, an internal DHSS submission, assessed that the building was still completed two or three years earlier than would have been the case w ith what were termed conventional methods. So I think that means instead of using the design and build

approach, a normal procurement approach had been taken, and the assessment from 1986 was that that would have taken even longer.

The second point is one which is taken from a minute from Baroness Trumpington, a minister in the DHSS, from 20 February 1987. She had been highly critical of the way that the project had been handled, but she said in her minutes -- the reference is WITN0771068 -- that it was, and I quote:

"Some small comfort that the new chief executive of the CBLA, who is not implicated in the project's history, has told officials that on the basis of a lifetime of experience in the pharmaceutical industry, he would say that the building represents value for money."

That is from 1987, at a time when the full cost of the project was known.

The third point that Lord Fowler made is a simple one, that he and his colleagues continued to sign the cheques. They continued to pay for the project. And £60 million worth of spending in 1987 would amount to about £180 million worth of spendin by 2021 prices, the date of Lord Fowler's statement He says, and I quote:

"It was a very considerable level of investment,

particularly given the financial pressures on healt spending."

It was met from the health budget, and it meant that that spending on BPL was given priority over other pressing areas as well. That is from paragraphs 4.81 and 4.83 of his statement and also the transcript of 21 September pages 116-118.

That is all I'm going to say about the redevelopment of BPL. We will come back shortly to look at how that redevelopment affected the amount of plasma that was fractionated and the amount of bloo products that were produced at BPL, at least in terms of Factor VIII.

I am going to turn briefly to heat treatment. I am touching upon it only briefly because I know that Ms Richards is going to be going through many of th documents with you in due course when looking at th evidence of Dr Smith and of Dr Lane, and I'm sure i is something that we will pick up with Dr Snape as well in a couple of weeks' time.

So what I'm going to try to do now is just provide a chronological framework that the later evidence is going to sit within, and it may be that the later evidence either throws into some doubt some of these dates; it may be that it qualifies them; i

may be that it supports everything that is said here. But what I am not trying to do is to supplant that later evidence; just to give an introduction, as it were, to it.

This is taken largely from the written presentation, and it's from paragraph 230 onwards. I won't be taking you to many of the documents. I'll leave that to Ms Richards in due course.

BPL and PFL had introduced RIA testing for hepatitis B antigen from 1976. Initially, they relied upon a commercial test, but over time, they developed and refined their own test. And we spoke yesterday about how a single-plasma pack was introduced. Par of the rationale for that was that it would be more amenable to sensitive testing for hepatitis B antigen.

In late 1980, according to Dr Lane in his fifth draft proof of evidence, he consulted with senior staff about the procedures that were available for viral inactivation. The context of that evidence suggests that the ongoing work of Dr John Craske an the Hepatitis Working Group was influential in shaping Dr Lane's thinking at that time.

On 13 February 1981, Dr Lane sent a memorandum to staff at BPL inviting them to set out projects for consideration for research and development. In

response to that memorandum, a proposal was put forward on 27 February 1981 which was entitled, and I quote, "The development of methods for production of coagulation factor concentrates with reduced risk o hepatitis transmission".

That proposal, from a more junior member of the BPL staff, noted the advances that were being made in hepatitis B testing, and reducing the risk of hepatitis B infection, and said that that highlighted the importance of the risks of non-A non-B hepatiti infection. To quote from the proposal, it argued that:

"The significance of a product free of hepatitis risk cannot be ignored and it is essential that BPL/PFL be well placed to take advantage of such developments. "

The reference for that proposal is CBLA0001291.

Dr Lane subsequently wrote in his fifth draft proof of evidence that this proposal marked the start of a move towards a viral inactivation programme at BPL and PFL.

On 4 March 1981, so the following month, Dr Lane put forward that proposal as one of six projects that he considered to be appropriate for central funding He put that forward to the Scientific and Technical

Committee of the Joint Management Committee, the body that we were looking at yesterday.

Something that Dr Lane says in his statement is that throughout 1981 there is an issue about trying to get research projects funded, in essence trying to get central funding from the DHSS to support such projects.

On 27 July 1981, Dr Smith produced a memorandum setting out various measures that could be used for reducing hepatitis infectivity in blood products.

It is important to note at this stage, sir, that heat treatment is one of several options. It's always tempting, when we are looking back, to pick out the one that eventually comes to fruition, but it was one of several at the time.

Interestingly, in that memorandum, on 27 July 1981, Dr Smith referred to the Behringwerke claims about their heat-treated product. There was no reference to that in the memorandum of 27 February, but there is in Dr Smith's memorandum on 27 July, although Dr Smith was at pains to point out that there was no reputable evidence for the claims made by Behringwerke at that time.

Dr Smith said in his memorandum that he had, and I quote, "a few ideas on how to start, but this might

more probably be an R&D project". My interpretation of that -- and I stress it is my interpretation -- is that that might be, again, going back to this issue of trying to get central funding for this type of work

The reference for that is CBLA0001414.

Dr Lane returned to the Scientific and Technical Committee on 24 November 1981, and a discussion took place on the inactivation of hepatitis and BPL products which drew heavily on Dr Smith's work. It may even have been Dr Smith who was giving that presentation.

The summary of the various methods that were thought to diminish the risk of hepatitis at that time included screening, limiting the size of plasma pools for certain products, neutralising or absorbing virus with an excess of hepatitis antibody, vaccination, virus removal through precipitation with polyethylene glycol, and viral inactivation through various methods including but not limited to heat treatment. So those are the types of areas being discussed.

In his fifth draft proof of evidence, Dr Lane said that no time was spent researching viral inactivation of viruses by heat treatment in 1981, and that such work only began in 1982. The exact nature of that work in 1982 isn't clear to us, or at least

isn't clear to me from the documents that I have seen.

In his draft proof of evidence Dr Smith stated that from November 1982 he was engaged in liaising with the protein Fractionation Centre on discussion about how to stabilise Factor IX for heating.

BPL was also involved, during 1981 and 1982, in a collaboration with Speywood on polyelectrolyte fractionation, and that is something we looked at during the pharmaceutical section of the hearings and the evidence of Sarah Middleton.

You'll recall, sir, that that collaboration was at points a little fractious.

Actual experimental work on the pasteurisation of Factor IX began in January 1983. We take that from both Dr Lane's draft proof of evidence and Dr Smith's.

That work was on wet heating, as it's sometimes called, genuine pasteurisation. Heating the solution at 60 degrees Celsius for 10 hours was the heat treatment regime that was being used. Dr Smith sai in his statement -- his draft proof of evidence, sorry, that, and I quote:

"The results were far from exciting but promising enough to continue as resources permitted."

I will, if I may, just take you briefly to one document, which comes from February 1983.

CBLA0001781, please, Paul.

This is a document that I think Ms Richards might be taking you to later so I won't go through it in depth. But we can see on page 1 it is entitled "Proposal to develop a 'hepatitis-safe' Factor VIII concentrate", and we know from the draft proofs of evidence given by Dr Smith that this is his document.

If we could just go and look at the first page, what is written is this:

"Factor VIII concentrates, in common with many other coagulation factors, are implicated in the transmission of at least three diseases:

"Hepatitis B; transmitted by a virus with well documented marker antigens and antibodies.

"Non-A, non-B hepatitis, (NANBH); thought to be transmitted by a blood-borne virus, but for which there are still no reliable markers.

"Acquired immune deficiency syndrome (AIDS); not yet proven to be of viral origin, but this is strongly presumed."

This is from February 1983.

I pause there to note that the previous discussions about viral inactivation have been about hepatitis and the focus has been on hepatitis. As is said there, there is a presumption that AIDS is

a virus which can be spread by blood as well, but that has not yet been proved.

SIR BRIAN LANGSTAFF: Well, actually, it says a strong presumption.

MR HILL: Strong presumption, yes.

SIR BRIAN LANGSTAFF: If there's a strong presumption, that's equivalent, I would suppose, to probability, is it?

MR HILL: I think you would have to ask --

SIR BRIAN LANGSTAFF: I'll leave that for others to comment on.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: It's a question mark at the end of that. Thank you.

MR HILL: The next paragraph says this:

"The incidence of hepatitis B is diminishing, possibly because haemophiliacs receiving many batches of large-pool concentrates become immune, and partl because of improved screening of the plasma used fo fractionation. The incidence of NANBH, especially on first treatment of mildly affected patients, remain very high and screening cannot yet be applied for want of markers. NANBH causes increasing concern, less on account of its acute effects (although deaths have been reported) than because of its association with

chronic active hepatitis in later life."

So that is what is informing his consideration of the various options for viral inactivation. He goes on to say that:

"Factor VIII coagulation activity has always been regarded as exceptionally labile ..."

That is something that we heard from [Sarah] Middleton and will no doubt be discussed in the coming days and weeks.

"... it is only recently that serious attempts have been made to apply to factor VIII concentrates some physical and chemical processes designed to inactivate hepatitis viruses. As with other concentrates, the options open to fractionators (excluding screening and vaccination) are:

"(1) Immunological neutralisation or immunoadsorption on solid phase antibody."

I pause to note that was the type of work that was going on with Speywood.

"(2) Physical removal of infective agents by eg semi-specific adsorbents or precipitants.

"(3) Inactivation by heat or virucides."

He then goes through -- and I won't go through in detail the paper, but he goes through -- if we could go on to page 2, please, Paul -- first,

a consideration of immunological methods; second, physical removal, which includes PEG precipitation. That's on the next page.

Then, on to page 4, inactivation: viricides and then heating.

And if we just pick up the bottom of that page, Dr Smith wrote this:

"Heating is considered the most promising approach to virus inactivation because:

"(1) It is likely to be of broad application, ie conditions which inactivate the exceptionally robust [hepatitis B] are likely to inactivate other blood-borne viruses.

"(2) The treatment is cheap, relatively easily controlled, recorded and scaled up with precision.

"(3) Extensive experience with other successful pasteurised proteins such as albumin offers readier regulatory and clinical acceptance than the use of a novel or unfamiliar chemical virucide."

So that last point is talking about how you persuade clinicians to actually use the product you're making.

The first point, sir, you might feel is relevant to the discussion on the first page about the stron presumption that AIDS was a virus.

The next page sees Dr Smith talk about irradiation, then fractionation of plasma from smal panels of "accredited" donors. Then if we go to point 3, there is a more detailed development of Option 2.3.2, inactivation of virus via heat. I won't go through that, but you can see that there is -- Dr Smith in essence proposing that that is, out of the various options that he has surveyed, the one that he would recommend proceeding with.

It is also notable from that paper that Dr Smith considered that the use of accredited donor panels was something that was worthy of further thought as well.

That paper was from February 1983, and with Ms Richards you will hear about meetings that took place in April 1983 in BPL as a response to growing concerns about AIDS and addressing the question of the role that BPL might play in that.

That paper from Dr Smith may be of some significance when considering that further evidence I won't take you to it now.

On 23 June 1983, so following that paper and following the meeting that I have just referred to, Dr Smith sent a memorandum to Mrs Winkelman of BPL and PFL giving the viral inactivation programme A1 priority. As the name suggests, this was, and

I quote:

"... most important to BPL's/PFL's immediate product strategy."

And Dr Lane subsequently confirmed that he approved that authority.

By July 1983, experiments on dry heating the intermediate purity Factor VIII concentrate that wa manufactured at PFL showed that heating at 60 degre es did not affect recovery or solubility at 60 degrees , but noticeable deterioration began at 80 degrees fo 10 hours, and at 75 degrees for 20 hours. These ar all degrees centigrade. So heating, through dry heating, the existing intermediate purity product from PFL, a product called 8CRV, at 60 degrees centigrad doesn't seem to affect recovery or solubility. But at 80 degrees centigrade for 10 hours, those measures are being affected, and at 75 degrees centigrade for 24 hours, those measures are being affected.

Dr Snape in his evidence to this Inquiry said that over the coming months, three types of heat treatment at BPL and PFL are developed. The first, HT1, is 60 degrees centigrade for 72 hours. And he says, Dr Snape says, that that degree of heat treatment was tolerated fairly well by all batches.

HT2 involved heating at 70 degrees centigrade

for 24 hours. Dr Snape said that this was tolerate by most batches but with some penalty in terms of yield and the resolution time, the time that it tak es to turn your freeze-dried concentrate back into a liquid.

HT3 involved heating at 80 degrees centigrade for 72 hours. And this only became possible follow ing the experimental work that Ms Richards will discuss with you in the coming days.

The second of those regimes, HT2, will be used to heat the initial heat treated Factor VIII that w as sent out by BPL on an interim basis in late 1984 an early 1985. We will come on to see why that was do ne.

The third regime, the 80 degrees regime, is the regime that was used to heat the product called 8Y, which was issued from later in 1985 and was a produ ct which inactivated both AIDS and non-A, non-B hepatitis.

BPL heated Factor IX, which was a product called 9A, was also treated with the HT3, 80-degree regime

On 15 July, Dr Smith produced a memorandum explaining the work that PFL was doing on heat treatment and also comparing it to the work that wa being done at that time by commercial manufacturers He set out the findings that had been done on the

yield effect of heat treating 8CRV, that's the prod uct from PFL. He said that they were encouraging, positive, and showed a loss of no more than about 5 of factor activity. I note that that is about the PFL product. When heat treatment is applied to the product which is being produced at BPL, there is a greater effect on yield, and we'll come to that shortly.

Ms Richards will take you to these documents, so I won't, but I will just read a short quotation fro Dr Smith from July 1983 where he says, and I quote:

"Provided we make no immodest and unsupportable claims about evidence of hepatitis safety or overst ate our confidence in this as a long-term solution, I believe that many clinicians would be happier to use a dry heated product than the existing one, and it might respectively be offered on that basis."

So what Dr Smith is saying here, and it is echoed in what he says in other papers, is that commercial companies are producing dry heated products, sometimes with claims that Dr Smith does not feel are borne out about hepatitis inactivation. The product that has been produced at PFL at that time he says is equivalent to those commercial products, bu it shouldn't be supported by, in his words, "immode st

and unsupportable claims about evidence of hepatiti safety". I pause here to note that at the time, th ere was no test for non-A, non-B hepatitis. So it was hard to establish that your product had inactivated non-A, non-B hepatitis. The only way that you coul examine that was through clinical studies which obviously would take some time.

So Dr Smith is saying that the product can be offered to clinicians. He expected clinicians migh be interested in taking up the NHS heat-treated product, but he is not claiming that it is hepatiti free.

It is also interesting, and this is developed in the written presentation, that it is again the presence of commercial products on the market which is helping to drive forward the research that is being done at BPL and PFL on heat treatment. There is a sense that an equivalent NHS product should be provided.

Dr Lane produced a paper entitled, and I quote, *AIDS: progress with heat treatment of human plasma products* on 26 July 1973. He again wrote that heat treatment was one of only several methods of viral inactivation, but it was the one that was most favoured at the present time. And again, he, like

Dr Smith, refers to or makes a comparison between the product which is coming out of PFL and might be expanded to BPL and the commercial products that were on the market at the time, and says, in effect, that the NHS can produce an equivalent product.

That memorandum was tabled at the CBLA meeting of 27 July 1983, and the CBLA said that it would be kept informed of progress on this form of product treatment which, it was hoped, would become routine by late summer 1983. That didn't take place. It's not entirely sure what "routine" meant, whether or not that was a reference to an output of product, or a reference to the process of heating could become routine within the laboratories by late summer.

Either way, it is in October 1983 that experiments began on dry heating at BPL and heating the BPL product which was a product called HL. That distinction is important, as we have discussed before. PFL is a much smaller laboratory. At this time, it is being used, at least in part, as an experimental laboratory. BPL is much larger, and so you have to scale everything up. It is also producing a different form of intermediate purity product which might react differently to the heat treatment.

On 7 November 1983, Dr Lane stated that BPL had

a dry heat-treated product available, and following discussions it was recommended that this should be subjected to clinical trials as soon as possible. That position was endorsed by the CBLA at its meeting on 23 November 1983. Despite this recommendation -

SIR BRIAN LANGSTAFF: Just pause there.

Yes, so 7 November 1983, BPL could produce, was producing, had produced heat-treated product which it did not know would be effective against AIDS but reasonably supposed it might be.

MR HILL: I can't take you to Dr Lane or Dr Smith's thinking at that time. I'll leave that to Ms Richards.

SIR BRIAN LANGSTAFF: Does that follow from what you've just been telling me?

MR HILL: Not necessarily. There is a feeling that -- there is a strong presumption by that stage that AIDS is a virus or is caused by a virus. There is an assessment by Dr Smith that we saw in that earlier paper that if you can heat treat a product effectively so that it will get rid of hepatitis viruses, then it will get rid of a lot of other viruses as well, because hepatitis is known to be a particularly tough virus to inactivate. What BPL have produced by November 1983 is a heat-treated product that they

think works as a Factor VIII treatment. So they've heat treated something without removing the Factor VIII activity to such an extent that it wouldn't work.

What they don't know is whether or not that heat treatment has inactivated hepatitis, and what they also don't know is whether that heat treatment will have inactivated other blood-borne viruses, including the putative --

SIR BRIAN LANGSTAFF: Well, that brings me back to the way I formulated my question. They didn't know that it would work, but there was a chance it might. Was that the position? It seems to be, from what you've just told me.

MR HILL: It's a possibility, yes, but they don't --

SIR BRIAN LANGSTAFF: So the possibility is there is a chance it might work, and there's no such chance if the product is not heated, presumably?

MR HILL: It depends whether or not other techniques have been applied to it, heat treatment not being the only one.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: There is a process which has gone on which has designed virus inactivation, but it is not known whether or not that process has effectively achieve

virus inactivation.

SIR BRIAN LANGSTAFF: And what they need to check is whether it causes any other damage as a consequence

MR HILL: That's right.

SIR BRIAN LANGSTAFF: Yes, I see.

MR HILL: The heat treatment that was applied at this stage, it's not always clear from the paper, and it's perhaps something that we will pick up with Dr Snap and with others. It seems that it was probably that first level of heat treatment, 60 degrees centigrade for 72 hours, dry heated.

SIR BRIAN LANGSTAFF: So it was HT1, not HT2?

MR HILL: I think so at this stage, but I caveat that by saying that I'm -- I can't be absolutely sure, and that is something that we need to explore further in the evidence.

Despite the fact that this has been endorsed by the CBLA, clinicians appeared to show little interest in the dry heat-treated product, according to both Dr Lane and Dr Smith. In his draft proof of evidence -- perhaps actually we can -- no, we won't I'll simply read it to you. Dr Lane said at paragraph 932, and I quote:

"A trial protocol was subsequently developed for discussion and agreement with the Haemophilia Centr

Directors, but this took a long time, and in the meantime, those Haemophilia Centre Directors I had already approached showed no immediate enthusiasm t use the new BPL product on a trial basis. Our effo rt in this regard culminated in our securing three patients only on which to try out our new heat-trea ted product. The trial in actual fact never got off th ground. These three patients were recipient of hea ted 8CRV, the PFL product in 1984."

SIR BRIAN LANGSTAFF: That sounds like HT2, if it's 8CRV, does it?

MR HILL: No, not necessarily. 8CRV could be heated by any one of those. And, in fact, there is an extrac from Dr Smith's draft proof of evidence at paragraph 63 where he says that that concentrate wa heated at 60 degrees for 72 hours.

SIR BRIAN LANGSTAFF: So that's HT1.

MR HILL: That's HT1.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: He said that the patients suffered no ill effects, that in his comment there were, and I quot e:

"... no further takers."

Dr Smith's evidence was that after those October and November experiments, dry heating was then virtually shelved at BPL and PFL as a promising opt ion

to which they could return while they went on with their work on pasteurisation, which was thought wou ld be a more secure way of inactivating non-A, non-B hepatitis.

So the focus shifts over to pasteurisation. As we heard in the November presentations on pharmaceutical companies, there are different ways of heat treating. Pasteurisation, heating in a soluti on, true pasteurisation, was considered to be a more effective way of heating because you get a more uniform heat throughout the product. The compariso that I think it was Dr Kingdon made was it's like heating something in a bath rather than heating something in an oven. That's why it's considered t be more effective. The work that was being done at PFC at this time, as well, was focusing on pasteurisation rather than dry heat.

Now, the evidence from Dr Smith and Dr Lane about limited take-up from clinicians echoes that o Dr Kingdon, the sometime vice-president of Hyland division of Baxter Healthcare Corporation. We looked at his evidence, which is also in the form o a draft proof of evidence for the HIV Litigation. We looked at that in November.

His company had heat treated its Factor VIII

product Hemofil and, indeed, were the first to get a US licence for a heat treated Factor VIII product which they got in March 1983. Dr Kingdon, in his draft proof of evidence wrote this, and I quote:

"Initially, Hemofil T [that's the heat-treated product] was viewed with some suspicion by haemophi lia treaters who were slow to adopt and use the product There was much concern that the product was priced too high, but it did not prevent the transmission of hepatitis and that heating altered the Factor VIII in some subtle way which would lead to the development of antibodies in patients."

Turning to 1984 and 1985, as we have seen, the focus switches to pasteurisation. There are variou experiments done which Ms Richards will no doubt re fer to in her presentation on Dr Smith, including experiments on how to remove fibrinogen and fibronectin from Factor VIII during or before or af ter the heating process. And those experiments led to series of experiments known as the 8Y experiments which led to the development of that third level of heat treatment, the 80 degrees heat treatment. The story will be fleshed out in some detail by Ms Richards.

In November, Dr Smith attended the Groningen

Conference, and there he heard from representatives of the US Centers for Disease Control that experiments in the United States had shown that HIV was labile. A nd we have looked at that evidence in the pharmaceutic al section. I've used HIV as shorthand there. Of course, the terminology at the time was HTLV-III, t he virus having been discovered earlier in 1984, and then it was spiked, Factor VIII was subject to heat treatment and it was shown that that inactivated HTLV-III. There were then further experiments done on full-scale production of Factor VIII, and the effec of this is that by the autumn, there is robust evidence that HTLV-III is inactivated by heat treatment, and indeed is inactivated by heat treatm ent at a level which is not particularly high. It does n't have to get to the levels that one anticipated was needed for hepatitis.

On 12 October 1984, so before the Groningen Conference, Dr Lane had asked that Dr Smith, Dr Sna pe and Dr Wesley give, and I quote:

"... urgent consideration to the possibility of introducing as routine a dry heat treating step in the finishing of Factor VIII and Factor IX concentrates and this step would be aimed principally at the elimination of AIDS infectivity excepting the dubio us

effectiveness of dry heating in the prevention of non-A, non-B hepatitis transmission."

The reference for that is CBLA0001908. The date is 12 October 1984. We will explore in evidence th reasons for that date, but effectively, that is Dr Lane saying, "Let's focus on a heat treatment method which is directly aimed at eliminating AIDS, and we will accept that it may well not work for hepatitis."

The heat treatment on the BPL product, HL, was more problematic than on the PFL product, 8CRV, in terms of its effect on yield. But a decision was taken that both BPL and PFL would heat stocks of HL and 8CRV at that second level of heat treatment, 70 degrees for 24 hours, as an interim measure.

At this time there was a growing sense of excitement about 8Y as a product that could be heat ed at 80 degrees Celsius for 72 hours. But in order t produce 8Y, you had to come up with a slightly different form of concentrate than the existing intermediate purity form of concentrate. So you couldn't simply -- it wasn't a case that you could simply take your existing stock and heat it at 80 degrees. That would have led to both a loss of yield and potentially a loss of Factor VIII activit y.

So you had to start from scratch, build your new concentrate and then heat it at 80 degrees.

So as an interim measure, a decision was taken that the existing stock of intermediate purity prod uct would be heated at that lesser level, at 70 degrees for 24 hours, and that was a response to AIDS, and it was accepted that heating at that level may well ha ve no effect or little effect on non-A, non-B hepatiti s.

That decision to take that interim step was agreed with the Haemophilia Reference Centre Direct ors at a meeting at Elstree on 10 November 1984.

On 14 December 1984, Norman Pettet of BPL wrote to the Regional Transfusion Directors in England an Wales setting out the origins of the BPL heat-treat ing programme and the approach that was to be taken to heat-treated products in the coming months. He sai that BPL would not issue supplies of non-heat-treat ed Factor VIII in December '84 or January '85, but the product would still be available "on request". So it is not going on general issue but clinicians who wanted non-heat-treated product could request it. And regions were asked to inform BPL about their propos ed policies.

The reference for that is CBLA0001955.

In a later letter, dated 24 January 1985,

Dr Snape informed Haemophilia Centre Directors that it was anticipated that the heat-treated product th at would be provided to them would be about 50-60% of the amount of unheat-treated product that had originall been planned to be provided to them. And that was as a consequence of the loss of yield in the process t hat was involved, you lost some of the product by heat treating it.

That figure is also used subsequently in a letter by Mr Pettet. The references are CBLA0001 998 and CBLA0002154.

We'll come back to the effect that that has in due course.

But we can see it, in an indicative sense only, on INQY0000336, page 42, please, Paul.

This is the bar chart -- and we can expand that, please -- that we discussed yesterday, the one that has been created by the Inquiry legal team by using a graph that came from the UK Haemophilia Centre Directors in 1990. I stress again that this is indicative, not precise, because we don't have the underlying figures, but we do have enough to be abl to draw up something which shows a trend.

We can see, if we look at the period from about 1980 and 1981, and we're looking at the blue blocks

the NHS Factor VIII, we can see an expansion betwee 1980 and 1983. That is a consequence of a Stop-Gap programme. And then a further expansion going up t 1984. Again, the Stop-Gap programme working its wa through. 1984 to 1985, you see a decline in the amount of NHS Factor VIII that is available.

It is our understanding that the principal reason for that decline is this loss of product as result of heat treating, heat treatment, and the 50-60% that Dr Snape referred to in his letter to t he Haemophilia Centre Directors. And we can see it pi cks up again a little in 1986 and 1987. We'll come bac to the later figures.

You will see that, as a consequence of that, in 1985 there is a small overall decline in the use of Factor VIII products. There is a large expansion i the use of commercial Factor VIII products, many of which would have been heat-treated at that time.

We can take that down now, Paul, thank you.

According to Dr Lane's fifth draft proof of evidence, after 1 February 1985 only heat-treated Factor VIII concentrate was issued from BPL, but that is an issue that may be explored later in some other evidence.

In the same month, February 1985, 8Y, the

80 degrees heat-treated product, was first issued a part of a stage 1 trial, that is a trial to test th safety and objective efficacy of product.

The focus of the research effort at BPL had been switched to 8Y. Heating at 70 degrees of HL and 8C RV is a production issue. The research is going into 8Y because that is seen as the most promising method o treatment.

February 1985 saw the stage 1 trial. From April 1985, 1 April 1985, 8Y became available on a named-patient basis.

There is a discrepancy in the evidence about when 8Y became the only Factor VIII product issued by BPL. According to Dr Lane, that is in August 1985. Dr Snape puts the date at 18 September 1985. A sma ll discrepancy.

It took longer for BPL to develop and release its heat-treated Factor IX product. It is called 9 A. That delay seems to have been largely because of concerns about thrombin generation, so a concern ab out the effect that the drug -- that the product might have on those who take it.

9A was heat treated at 80 degrees Celsius for 72 hours. It was not generally available until lat September or October 1985, according to the evidenc

we have from Dr Smith, Dr Lane and Dr Snape.

Before that time, BPL had continued to produce some unheated Factor IX, 9D, but it's unclear at th present time how much of that was actually being issued to Haemophilia Centre Directors, and whether or not they could request it on demand. But we can se from a graph from the UK Haemophilia Centre Directo rs, the effect on Factor IX.

If we could have, please, Paul, HSOC0000596.

Sir, these are the annual returns for 1990 from the UK Haemophilia Centre Directors.

If you could go, please, Paul, first of all to page 16.

This is the Factor VIII graph showing the amounts -- the total amount of Factor VIII used, th commercial Factor VIII, the NHS Factor VIII, cryo a nd plasma, for the period from the late 1960s to 1990. That is the graph upon which the bar chart that we have been looking at is based. I am going to take you to a, I hope, more user-friendly version of that in due course, but I'm just showing you now that that is what the bar chart is based upon.

If we could go to the next page, please. We'll come back to look at those -- the distribution of those figures in due course. If we could turn that

around please.

This is the equivalent graph for Factor IX.

We can see represented by the clear circles the total amount of Factor IX used, and we can see a fairly steady upward growth.

We can see, with the line with the Xs in it, the amount of NHS Factor IX.

For most of the period from the early 1970s until 1984, 1985, we can see that those two lines a re fairly close together, very close together, indicat ing that almost all of the Factor IX product in the UK was produced by the NHS. That is confirmed by the fact that the other line, right at the bottom, with a cl ear triangle, that's commercial Factor IX, we can see j ust a very slight entry of the line in 1973 and 1974, a nd then it may or may not be there in very small level or very, very low level, going into the early 1980s

The other product that was used for haemophilia B patients was plasma, and we can see t hat that was used almost -- in fact more than NHS Factor IX in the late '60s. And then there is a crossover between 1970 and 1971 where NHS Factor IX concentrates are used instead of plasma and plasma use declines through the rest of the 1970s, and becomes minimal and disappears in the early 1980s.

In 1984, we can see that the NHS Factor IX decreases sharply in terms of the number of units issued, from somewhere in the region of 12 million to somewhere in the region of 8 million. At the same time, we can see that the amount of commercial Factor IX increases, and for the first time becomes clearly visible on this graph. It goes up to approximately 3 million international units for the year 1984 to 1985.

Then between 1985 and 1986 the inverse happens, so NHS Factor IX goes back up again, not quite to i ts previous levels but towards them, and commercial Factor IX declines, not quite to nothing but toward nothing. And that trend continues into 1987, where the NHS is more or less self-sufficient in Factor I X.

So there is that period between 1984 and 1985 when patients in the United Kingdom who required Factor IX were using commercial products in significant amounts in a way that they hadn't done before. And we understand that, sir, to be a resul of the introduction of heat treatment. The greater difficulties that BPL and PFL found in heat treatin Factor IX, led to, I use the word neutrally, a dela in providing the Factor IX heat-treated product. A nd during that time, either BPL was not issuing unheat ed

Factor IX or had cut down on the amount of unheated Factor IX that it was issuing, or clinicians were not using that product and were instead turning to commercial Factor IX, some of which, by that stage, was heat treated.

Thank you, Paul. That is all I will say about that graph.

That, sir, takes us to the end of the chronological part of the presentation. The next stage is to look at some of the themes, and look at the data that we have on the amount of Factor VIII that was produced across this period at BPL and PFL; the amount of plasma that was supplied to BPL and PFL; the capacity at BPL and PFL, in theory, to produce blood products; and also to look at the estimates that were made of usage across that period.

I can begin that now, sir, or I can do it after a break. I'm entirely in your hands.

SIR BRIAN LANGSTAFF: Well, I think perhaps we'd better have the break and then come back to that. I see there's some nods. We'll have it in one go before lunch, presumably. So we'll take a break now and come back at, what, 11.40.

(11.07 pm)

(A short break)

(11.39 am)

SIR BRIAN LANGSTAFF: Yes.

MR HILL: Sir, we are turning to the data across this period. Before I do so, there are just a couple of things to pick up from yesterday.

We looked at the Trends Working Group from 1977 yesterday, and you will recall that I showed you the second draft and said that that was the latest document that I had found. I have helpfully been told by the Inquiry legal team that we do have the final report. If we could have, please, on screen DHSC0001318. This, as you will see, is the "Report of the working group on trends in the demand for blood products". Yesterday's document had in the top right-hand corner "Second draft", and I think the date was some time in October. If we could go to the last page of that document, please, Paul.

We can see at the bottom left "December 1977", so that is the final draft. I'm happy to say that, save for a couple of typographical changes, there's no difference in substance between that which -- those bits that I read out yesterday and this document.

SIR BRIAN LANGSTAFF: Thank you.

MR HILL: There's also a document that I'd like to take you to which is DHSC0103249_096. This is a documen

we can see at the bottom right-hand corner is written "August 1977". It says:

"The National Blood Transfusion Service.

"The relationship of demand and supply of the main blood products."

What I interpret this to be is a working document, possibly as part of a Trends Working Group, because we can see that figure next to albumin, 200 grams per 1,000 of population, which is the estimated level of demand over the next five to ten years. That's the type of work that the Trends Working Group were doing, and that is the figure that the Trends Working Group arrive at.

For Factor VIII, the figure is given of 50 million international units. Then on the right-hand side, and the reason that I'm taking you to this document, is current rate of supply, and it says 17.5 million international units, NHS freeze-dried concentrate. You said yesterday, sir, that you had seen the figure of 17.5 million international units somewhere. I wonder if it may be from this documen or from around this time, but it ties in with Dr Walford's report of Dr Lane's talk.

Now, the 17.5 million international units there is expressed as "NHS freeze-dried concentrate". Th

most logical way to interpret that is that that is 17.5 million international units from BPL, PFL and PFC together.

SIR BRIAN LANGSTAFF: Well, that's difficult because if you go to the left, we have 50 million internationa units. It's the National Blood Transfusion Service which isn't the National Blood Transfusion Service in terms of UK. It's the --

MR HILL: Yes.

SIR BRIAN LANGSTAFF: It's England and Wales, which we know. And 50 million approximates, I think, roughly -- "approximately", "roughly" I suppose are the same words, but it's pretty much one unit per person in the country.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: And that was the observation I made yesterday.

MR HILL: For England and Wales, yes.

SIR BRIAN LANGSTAFF: For England and Wales.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: But not for the country as a whole, if the country is the UK.

MR HILL: That's right. That's right. There is therefore a difficulty in trying to interpret all of this.

SIR BRIAN LANGSTAFF: You may be right, but you may not

be.
MR HILL: Exactly. Exactly. It may or may not then be related to the 17 million that Dr Walford noted Dr Lane saying was the BPL maximum production.
SIR BRIAN LANGSTAFF: It would be odd if it were the total UK production because what you were telling me yesterday was that it was thought that there was 15 million available capacity-wise from BPL, and 15 million capacity-wise at least from PFC. Did yo not tell me that?
MR HILL: I think that was 15 million of factor concentrates. I think the reference is 15 million factor concentrates, 15 million cryoprecipitate acr oss the UK. I don't know -- I'm afraid I can't assist with PFC values. Mr Boukraa next week may be able to. I'll just turn to Mr Terry.
(Pause)
Very approximately -- and this will be something picked up next week -- the figure for PFC at around this time is somewhere in the region of between 1.7 and 2 million. So if you added that --
SIR BRIAN LANGSTAFF: Between what?
MR HILL: 1.7 and 2 million of international units. If that were added to the 15 million from BPL --
SIR BRIAN LANGSTAFF: What, in 1977? After PFC has got up

and running? PFL I can understand, but PFC?
MR HILL: I may be confusing PFL and PFC there. I think I will have to stop, sir, and we'll have to look at those figures, and you'll get the figures from Scotland next week.
SIR BRIAN LANGSTAFF: Yes. Just looking back at my quick notes of what you were saying ... yes, well, I shal have to check back the actual words, I think. You may well be right.
MR HILL: If it's a reference to what Mr Moyle, the Secretary of State, said in Parliament in 1978, he said there that BPL and PFL produced approximately 15 million international units of concentrate. The total usage of Factor VIII in England and Wales was estimated to be approximately 45 million internationa units, suggesting a shortfall of 15 million, becaus 15 million was produced by cryoprecipitate. But he was careful to give the figures only for England an Wales, and he referred questions about Scotland to the Secretary of State for Scotland.
SIR BRIAN LANGSTAFF: Yes. I have a note that you told me that in 1976 -- the reference is CBLA0000391 at page 14.
MR HILL: Could you bring that up, please, Paul.
SIR BRIAN LANGSTAFF: Sorry, I may have got the wrong

reference. No, I think it is page 14. CBLA0000391 Obviously that's wrong. We'll come back to it.
MR HILL: I can check and we'll look into that. But there will be discussion next week about how much PFC was able to produce at this time.
SIR BRIAN LANGSTAFF: Yes, thanks.
MR HILL: The wider point, which I think that helpfully takes us to, is that the figure from the Trends Working Group, as you said, sir, it's expressed by head of population, and that will mean different things if you're looking at the UK than if you're looking at England and Wales. And it will also mea different things as the population changes over time. And the Trends Working Group was expressly invited to consider usage over five to 10 years.
So while Dr Lane put that figure of 60 million on it, and Dr Walford put the figure of 74 million on the amount that would be achieved if the full amoun of albumin was achieved, I think it is fair to say that, in both instances, those are figures for the UK based upon assumptions made about the size of the population, and Dr Lane's assumption is 60 million and, from the maths, I think that Dr Walford's is somewhere of a region of 56-57 million. So there isn't one single figure that can be used there.

And with that in mind, I should point out that in appendix 1 of the written presentation, the figu re that is used for the Trends Working Group estimate is 50 million international units, because that paper is predominantly concerned with England and Wales. An d, as you say, sir, 50 million is the approximate population size of England and Wales at that time.
As we've discussed, different figures can be drawn from it, depending upon whether or not you ar measuring the UK or just England and Wales. So it should be treated as an approximation of what they were saying, but that 50 million figure is a figure which crops up in other estimates at the time and t hat is all explored in appendix 1.
I'm going to begin our look across this period with estimates. And I'm not going to go through th detail that is contained in appendix 1, but there a re many other papers and meetings that are cited in appendix 1 where estimates for future usage are mad and one can look at those in greater detail at leisure.
But for the purposes of today, I have drawn up a table, and it's at INQY0000342, which is a selection of some of the estimates that are made. And it com es with the caveats that are written out at the top

there, the same caveats that we have discussed acro ss the board: that firstly it involves a degree of selection of which estimates one chooses, and this is my selection, and others may have others, but these seem to me to be some of the central estimates that were made over the relevant times.

It needs to be remembered that not all of these estimates are necessarily attempts to come to the same -- or an attempt to come to a figure for the s ame thing as the next estimate. So somebody is thinkin about an estimate for the UK as a whole, in the mid-70s, somebody else is thinking about an estimat for England in the mid-80s. So it's not comparing like with like across the board.

There is also a degree of translation, such as we've just discussed, about how you get to the figu re, 50 or 60 million, for example, for the Trends Worki ng Group. So is this is an approximation.

But we can see that there is an upward trend in the estimates that are being made. In March 1973, Dr Biggs's paper to the expert group, the estimate expressed in donations is 400,000 to 750,000 donations, and we have discussed what that is an estimate of, which is treatment on demand, major surgery and dental extractions.

Similar metric for the MRC paper from January 1974. That estimate is 38 million to 53 million international units, or expressed as 547,540 donations.

Dr Bidwell's paper from January 1976 gives an estimate which is not that far off the MRC estimate for usage, 36-45 million international units, but i a significant increase when expressed as donations. And that's the point that we were discussing yesterday, that Dr Bidwell made different assumptio ns about yield. And Dr Lane thought that Dr Bidwell's assumptions were more realistic. So even though sh is thinking in the same ballpark as the MRC, she thinks that there have to be more donations in orde to get there.

Then there is the Expert Group on the Treatment of Haemophilia from May 1976, and we looked at that meeting yesterday, agreed that the previous so-call ed "target" of the DHSS, the expansion to about 275,000 donations, then up to 340,000 donations, th ey decided that that was outmoded, but they didn't set a new target but the figures of 35-40 million international units were mentioned in discussion. So, again, within the same broad ballpark as Dr Bidwell and the MRC. And you'll remember that Dr Biggs at

that meeting expressed herself forcefully, in that and other meetings, but she had always said that the target was around there and she didn't really understand where a 50 million international unit target had come from.

We move on to the meeting in October 1977 between representatives of the DHSS and BPL, the beginnings of the Stop-Gap programme. That meeting referred to a target figure of 50 million international units. Now, it wasn't expressly said at that meeting that that would result in self-sufficiency, that is talking about a target fo redevelopment, which may or may not be related to t he next figure, which is the Trends Working Group, and that is the 50-60 million figure, so one per unit o population, for Factor VIII assessed need. And the 74 million figure is the figure that is reached by Dr Walford by saying: well, if they'd achieved the targets that they had set for albumin, that is how much Factor VIII would have been produced. But tha is not the assessed need by the Trends Working Grou at that time.

That's December 1977. We can see in the table that there is a significant upgrade of the estimate by March 1979. That is a reference to the Scientific and

Technical Committee discussion that we looked at yesterday, where the figure of 100 million is identified. I think it was expressed in the terms of, "If clinicians had free rein to prescribe what they wished to prescribe, then the figure could reach around 100 million international units."

Dr Lane went away, wrote a paper on the redevelopment of BPL following that meeting, and th figures that he used were 90 million international units by the mid-1980s and 120 million internationa units as the ceiling figure of BPL, as we discussed earlier. Not necessarily a statement that it will reach that level of demand, but that's where he thi nks the planning of the plant should be. So by 1979 we are in the region of about 100 million internationa units.

Again, there is a lack of clarity about whether or not those of the Scientific and Technical Commit tee were discussing just England and Wales or whether o not they were talking about the UK as a whole. The remit of the Scientific and Technical Committee wer the Central Blood Laboratories, which were the Engl ish and Welsh Central Blood Laboratories, so it may be that that was the focus of their attention. Certai nly Dr Lane's paper is about what BPL needs to produce for

England and Wales, not the UK as a whole.

So the broad trend that we can see there is from the period circa 1974 to circa 1977. The estimates are in the region of 40-50 million international units, perhaps going as high as 60 million for the Trends Working Group if one looks at the UK as a whole with a slight population growth going through the '70s and '80s. Then a significant increase in the estimates in 1979 going up to the region of 100 million international units and trying to project forward demand in the '80s.

With that in mind, could we go, please, to INQY0000336. Page 41, please. This is appendix 1 of the Inquiry legal team's presentation. If we could expand that graph, please.

Earlier today, sir, I showed you the black and white graph that was part of the UK Haemophilia Centre Directors returns from 1990. This is simply a transposition of that graph into a form that we think is perhaps a little more helpful for us here. We can see the different lines that are shown on it This is actual consumption of Factor VIII, accordin to those annual returns from the late '60s to 1990. We can see the different lines that are on this graph.

The yellow line is the total consumption of

Factor VIII products, and that includes concentrate and cryoprecipitate. It probably also includes plasma but is such a small figure it wouldn't make that much of a difference. But that is concentrate plus cryo essentially.

The green line is the total consumption without cryoprecipitate, so essentially concentrates.

The red line is the amount of commercial Factor VIII that is being consumed.

And the blue line is the amount of NHS Factor VIII.

And it is a UK-based table, not just England and Wales. Important to stress that the conversation that I'm about to have with you is about England and Wales, and Scotland is separate and distinct and will be referred to next week. This table, which is, we think, the best single guide to consumption, is for the UK as a whole, so one must bear in mind that it doesn't precisely tally with England and Wales.

What we can see from that table, just as a general point, is that in the period up until 197 and then going on into '76, '77, and '78, there is a significant gap between the total including cryoprecipitate and the total without cryoprecipitate, so the yellow and the green lines. So we can see that

cryoprecipitate is making up a significant proportion of the amount of Factor VIII treatment in that time

Those lines close and get closer together during the late '70s, and the amount of cryoprecipitate thereafter is minimal. And the lines gradually converge in the later '80s, showing that cryoprecipitate is no longer making up a significan contribution to Factor VIII treatment in the UK.

The commercial Factor VIII line starts low in the late '60s and early 1970s -- barely featuring a all -- picks up from the period after 1973 after th product licences are issued to Hemofil and Kryobulin, and then rises significantly in the '70s and into the '80s, falls back a little in '83 and '84. Part of the reason for that would appear to be that NHS product has increased at that time. Part of the reason may also be to do with concerns about AIDS.

Then commercial product picks up again in the period '84 to '85. What is not shown on the graph is the fact that this is the period in which heat treated commercial product becomes available. And then it continues at a significantly higher rate of usage for NHS Factor VIII until about 1987, where the two cross over, and there is a sharp increase in NHS Factor VIII. We'll come back to that in a second.

And because of the increase in NHS Factor VIII --

SIR BRIAN LANGSTAFF: That's not '87, is it? It's '88.

MR HILL: Sorry. '88. You're right, sir. Yes. '88.

A sharp increase in NHS production in '88, and a linked decline in commercial Factor VIII usage at that time.

Sir, I said "NHS production". I should have said "NHS usage". Obviously linked to NHS production.

On that bottom line, the NHS Factor VIII, we can see again a small contribution in the early '70s. A rise between 1975 and 1978. That was a rise that was associated with the investment of the £500,000 of direct central funding.

Then there is a plateauing effect from 1978, 1979 and 1980. And then a rise from 1981, about stable in '82, and then a rise '83 and '84. And that, in our assessment, is linked with the investment in the Stop-Gap programme.

SIR BRIAN LANGSTAFF: I think what's confusing a little bit about the graph, possibly, is the way in which the dots -- which, presumably, the dots correspond to years --

MR HILL: Yes.

SIR BRIAN LANGSTAFF: -- don'tentirely fit within the boxes, because the boxes are -- between '80 and '85,

for instance, there are three boxes but there are five years.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: So you really have to look at each dot and say that's a year.

MR HILL: Yes, that's right. The dots are years. There are a number of caveats which I'm going to come to in a second, but one of them is that although we have sought to enter those data points as years, the sources from which we have obtained the data aren't consistent. So it doesn't always say between what we would have liked is a single data set which said "between 1 January 1983 and 31 December 1983, 50 million international units were used. From 1 January 1984 to 31 January 1984, 55 million ..." That would have made it easier to plot.

Unfortunately, what we have is a series of different data points for England and Wales which w have to try to put together. And even in the 1980s when they become more standardised in BPL annual reports, to the intense frustration of your legal team, even those reports don't cover the same perio d. So the first BPL annual report is done for a financ ial year, then there is a report which covers a 21-mont period, presumably to tie in with the CBLA taking o ver

BPL.

So when those investments are made, usage of NHS factor products increases, and the association that the Inquiry legal team have made is that that is connected with the increases in production that result from that investment.

SIR BRIAN LANGSTAFF: What is interesting, in the light of what you were telling me earlier about the yield of Factor VIII once it was heat treated, being less th an the yield that it had been, and the letter which we nt around to Haemophilia Centre Directors saying, "You can expect 50-60% only of what you had before becau se we're now heat treating it," is that although there is the drop you might expect on this indicative chart in 1985, it doesn't seem to affect the overall consumption measured in terms of actual units delivered.

MR HILL: Perhaps that might be, in terms of commercial and --

SIR BRIAN LANGSTAFF: In terms of just the NHS.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: So looking at the blue line, one way or the other, there has been a production effort -- presumably, because you can't, obviously, consume w hat hasn't been produced -- which produces enough by wa

responsibility. Then there is a report which cover a calendar year, and then there is a report which g oes back to a financial year.

So although we have plotted these as best we can year by year, they don't necessarily show precisely how much was done in that year.

So it is a graph which is indicative and can show a general trend, but I don't think that one ca go to a point and say, "Right, that means that that is precisely how much was provided in that year."

The trend that we can discern is that rise between about '75 and '78 which is associated with the investment of the £500,000; the rise in the early '80s, which is associated with the Stop-Gap program me and the investment that was made then; and then, as we can see from the late -- in the later 1980s, 1987, 1988 and onwards, there is a significant rise in production, and that is connected with the investme nt that was made in redeveloping BPL.

SIR BRIAN LANGSTAFF: Well, you say "significant rise of production". This is a consumption chart.

MR HILL: Quite, sir. My mistake. Significant rise in NHS -- the usage of NHS Factor VIII, which we interpret as being linked to the significant rise i production that is a result of the redevelopment of

of international units despite the loss of yield, whatever the loss of yield is, involved in heat treatment?

MR HILL: There is, as you said, certainly the decline between '84 and '85, as shown on the graph, althoug with all the caveats I've just said, and then a mod est recovery, but still below the levels before.

There is an increase in commercial at the same time, and then the redevelopment of BPL.

I wonder, actually, if we go to the following page, the bar chart may assist on that as well.

SIR BRIAN LANGSTAFF: I mean, it may reflect -- what I am saying is this may reflect a difference of producti on, the increase of production over that period of time despite the difficulties of yield.

MR HILL: We are going to come to some actual figures in a little bit. Actually perhaps I'll leave it until then and we can pick up the conversation when we ha ve the actual --

SIR BRIAN LANGSTAFF: Yes, certainly.

MR HILL: I think that may be a little easier.

If we could go back, Paul, to the previous graph then, please, on page 41, thank you.

Tying this in with estimates, and again with caveats about the dangers of trying to draw too

precise a figure from a particular data point, the lower end of Dr Biggs's estimate from the early 1970s was 32 million international units, if one translates donations in that way, or the MRC paper puts it at 38 million international units.

If we look at where 40 million international units is on the graph and then we travel across, we can see that that is surpassed, in terms of total usage, including cryoprecipitate, the yellow line, by 1976, 1977 --

SIR BRIAN LANGSTAFF: '77.

MR HILL: Yes, somewhere around there.

Prior to 1979, the highest of the estimates that we looked at there was the region of 50-60 million, and if we go across, if we take the higher end of that, the 60 million, and we work across, we can see that that figure of 60 million is surpassed in 1980 1981, somewhere around there. The early '80s. Remember the Trends Working Group was there to try to calculate trends for the next five to ten years. If one takes the figure to be 50 million, then obviously it's surpassed slightly earlier.

The third set of figures that we looked at was that -- or range of estimates -- was that range of around 90 million to 100 million. If we take the line

up to 100 million, we can see that in 1990, total usage is around 100 million. But during that period of the 1980s it is below 100 million. And Dr Lane's 90 million estimate, we don't have a precise line across, but we can see he was talking about 90 million by the mid-1980s, and that seems to be a fairly robust estimate, in terms of how things panned out.

So we can take from that that the estimates prepared in the mid-1970s may have established immediate and short-term usage, with reasonable estimates of immediate and short-term usage, but were not as robust in terms of longer term usage.

From 1979, however, you have estimates that are more robust in terms of longer term usage. I don't make any judgment on that; that is merely an observation based on the data. Obviously there are a wide range of matters that you will need to consider about why that was so, the change in treatments, the greater use of prophylaxis, and so forth, but that is the conclusion that we draw from the data, and we leave all other matters to submissions for others and to your judgment.

That's all I will say about estimates at the moment.

In terms of plasma supply and concentrate

production, we've discussed many of the caveats that are involved over the last two days, and I won't repeat all of that discussion. The central issue is the one that I've just raised, that there isn't a single data set for each of the measures that we are looking at. There are a range of figures that could be selected and there is a need to exercise judgment in choosing which one. A different selection to that one that we have made could reasonably be made by others. We don't dispute that for a moment.

Even when figures are selected, there must sometimes be assumptions made by the Inquiry legal team in order to get to a usable figure. So, for example, if you are given a weekly figure for how much plasma BPL was fractioning per week, that needs to be translated to an annual figure in order to fit within our graph.

And the assumption there is a 48-week year.

Similarly, sometimes output is expressed as "10,000 vials of Factor VIII were sent out". The assumption that the Inquiry legal team have made is that unless it is otherwise stated, it is assumed that each vial had 250 international units within it. The reason for those assumptions are because those are the figures that we find elsewhere in the documents, and

so there is a reason why we have adopted them when making our calculations. But they are nonetheless assumptions, and so that is a warning which attaches to much of this data.

We discussed yesterday, as well, using 1 litre for 1 kilogram. That is not an exact conversion but it is one that has been adopted because it is adopted elsewhere in the papers we have seen.

When looking at the figures, the Inquiry legal team have tried to use primary sources wherever they can. So the documents from the time. That hasn't always been possible, and sometimes there are gaps in the data. At other points, secondary sources have been used, and there's one in particular that I would refer you to, which is appendix 4 of Dr Lane's draft proof of evidence.

And if we could go, please, to CBLA0000007_023, we gain some understanding about how this was put together. These are instructions to counsel in the HIV Haemophilia Litigation. They're actually sent to Richard Price by Clifford Chance, the solicitors who were acting for the CBLA.

If we could turn, please, to page 3, and to paragraph 4. what is written by Clifford Chance to Mr Price is this:

"Counsel is referred to Bundle H which contains the appendices to Dr Lane's Proof."

This is Dr Lane's fourth draft proof of evidence.

"The information in the appendices has been compiled from the documentation comprising the CBLA's discovery."

I pause there to translate from legalese. The CBLA have gone through their papers as part of the litigation, preparing for them to be disclosed wher appropriate to the other parties. And while they have been doing that, they've pulled together the figure which go into appendix 4, and those are figures which cover things like the plasma provided to BPL in a given year, the amount of product that BPL is issuing in a given year, the amount of plasma that BPL is fractionating in a given year, and the nominal capacity for BPL in a given year.

When I say BPL there, sir, I'm afraid I'm using it slightly lazily, meaning BPL and PFL usually.

Going back to instructions, they say this:

"The figures have been obtained from a variety of sources and in a number of cases the figures for a particular year are inconsistent. Definitive figures for plasma production, concentrate produced by

BPL and PFL, and concentrate consumed in England an Wales have been obtained from a combination of BPL/ PFL records, and Haemophilia Centre Directors' returns. The other figures, however, are included because they illustrate the considerable difficulties which appeared to exist in the 1970s in producing and agreeing reliable statistics and estimates. At par one of appendix 4 relates to Factor VIII and part 2 applies to Factor IX. Counsel may consider that th figures for Factor IX are not helpful as self-sufficiency in Factor IX is not in issue. Instructing Solicitors have it in mind to produce a column chart to present these various figures in a way which is logical and helpful, but would welcome Counsel's comments on this exercise."

So this is from 1990. They faced the same problems that we have faced. They put together appendix 4 trying to draw on the information that they had available to them at that time, not all of whic we have necessarily been able to identify, and that is why the figures are given in the way that they are in appendix 4, but they come with the health warning that is issued there and which we repeat today as well.

We think it's a useful source but of course it

comes with caveats.

Even where we do have figures or figures from primary sources, it's not always clear what those figures are referring to, do they refer to both BPL and PFL or just BPL? Are they England and Wales or they are the UK? A reference to plasma being provided to BPL, is that a reference to plasma generally or to fresh frozen plasma for fractionation into Factor VIII? It's not always easy to discern what those figures are, and sometimes assumptions have had to be made.

Perhaps unsurprisingly, in light of all of those caveats, the figures don't always correlate. There are sometimes discrepancies, and we have tried to work out if there is a reason for the discrepancy that i substantive. In other words, is there something that was happening at BPL which explains why its total capacity was higher or was increasing while the plasma fractionation capacity remained the same? Was ther something going on that explains that, or is this just a quirk of the data that we have? And, again, we'l look at that in a few examples in a second. It's not always clear.

I mentioned the difficulties about the BPL annual reports and the periods that they cover. So we

can't be quite sure, particularly in the period between about 1982 and 1984, whether what has been referred to is for a 12-month period or for the longer or shorter period of that report.

The short point from all of this is the one that I have made. These figures helped to discern general trends, but we should be careful not to read a fals precision into them.

With all of those caveats, could we go, please, to INQ0000337, page 38. This is from appendix 2, which is the appendix on BPL/PFL capacity, production and plasma supply. And this is the annex to the appendix which shows a table setting out different measures.

The first column is the year that that row is concerned with, starting in 1973 and going up to 1988 to 1989.

The second column is FFP received. Fresh frozen plasma received. And that is a figure for the amount of fresh frozen plasma received at both BPL and PFL collectively.

SIR BRIAN LANGSTAFF: Can I just ask, and this may be yet another uncertainty, so far as the year is concerned, is that -- does that coincide with the chronologica year or the financial year or the year for returns to

UKHCDO, or what?
MR HILL: It is -- for the first part, it is, as best we can understand, a calendar year. But later, you will see in the table that we -- there is reference to '86 to '87, and that is the financial year because we are using the BPL records there as our best source. But, as you say, sir, it is an uncertainty. We cannot be sure all of the time that that is referring to the calendar year, and there are inevitably gaps, particularly between 1984. We see the BPL report i for a calendar year for 1984, and then the financia year 1985 to 1986. So, in essence, we were not sur what happened in the first quarter of 1985 because that's not necessarily captured by either report.
It's the kind of thing that, had an Inquiry been held in the early 1990s, one could ask questions of the witnesses who put together the reports, and we might be able to bottom this out, but at this perio in time, it's not possible to do so.
So the first column is fresh frozen plasma received by the two fractionation plants.
The second column is the fresh frozen plasma that was fractionated by those two different plants
The third column is the annual plasma capacity.
The fourth column is the annual capacity

measured in international units.
So two different ways of measuring how much the plants are capable of producing. One is by measuring how much plasma it can fractionate --
SIR BRIAN LANGSTAFF: Well, it is -- the capacity is dealing with -- I mean, I just want to understand the word "capacity", really, because from what we understand from various sources, the question is no just how much the production bit of the production premises can make; it also has to bring in, into th warehouse, the plasma in the first place and keep i in a warehouse before it's distributed at the end. So you've got the freezer area, presumably, if it's fresh frozen plasma, at the start. You have to then do whatever you do to make it, which is -- that's that process. Then at the end, you've got the product which, presumably, so far as Factor VIII is concerned, is going to be a freeze-dried product.
But two questions: when it deals with annual plasma capacity, is it dealing with the whole amoun of plasma bought in for all purposes, such as albumin et cetera, immunoglobulins, as well as Factor VIII; and is it referring to the capacity of the plant overall to handle this much in a year, which would involve all three elements that I've just mentioned --

warehousing, the raw material, warehousing the finished material, and the production in the middle Or does it mean something different when you come t international units, when you may be talking -- because, plainly, international units relates to a product, you're relating it specifically to Factor VIII.
MR HILL: Yes. Well, to deal with the last point first, the fourth column is annual plasma capacity, so how much is being fractionated. The fifth column --
SIR BRIAN LANGSTAFF: That's fractionated for all purposes, or just for Factor VIII?
MR HILL: I'll come back to that in a moment, sir.
The fifth column is annual capacity as measured by international units, and that is how much of the Factor VIII is going out, as measured by internatio nal units. So that is a fairly clear metric, and we know that relates to Factor VIII, and we are able to say that is, in effect, what the factory or the factories are putting out.
The fourth column, as you've said, sir, that's less certain because that is about how much plasma is being fractionated, but that doesn't necessarily mean that all of that is going to go out of the gate for the reasons that you have given.

Our best understanding is that these figures relate to fresh frozen plasma that is being fractionated for the purposes of producing Factor VIII, but we cannot always be sure that that is right. The attempt is to try to present a table that is relevant to Factor VIII rather than to the other blood products. But, as you've implied, sir, we can't always be sure.
SIR BRIAN LANGSTAFF: It may be that there's no real difference except for plasma which is time-expired, in terms of annual plasma capacity, because the fractionation process would start off, would it not with Factor VIII and then move on to Factor IX and then --
MR HILL: Yes.
SIR BRIAN LANGSTAFF: -- work through the various steps and end up with albumin and immunoglobulin?
MR HILL: That's right, sir.
SIR BRIAN LANGSTAFF: From the same litre of plasma.
MR HILL: Yes. But the time-expired plasma is the problem.
SIR BRIAN LANGSTAFF: Yes.
MR HILL: That's the grit in the oyster. And we have sought to identify the figures for fresh frozen plasma. We can't always be sure that the figure th at

we have got is just fresh frozen plasma.

It becomes clearer as time progresses that the figures from the early '70s are difficult. And you will see there actually that there are gaps in that table because we just haven't been able to identify that table, that figure.

But the second point that you made, sir, is, again, another important caveat, that just because you have fractionated the plasma, it doesn't mean that you have necessarily issued the Factor VIII. It could be sitting in a warehouse somewhere.

If we look at, firstly, the period 1973 to 1977 -- I should say that there are footnotes there and for each of these figures there is a source which is referred to, and can be looked at and checked, and I stress that there are other sources available as well.

If we go back to the table, please, Paul.

If we look first at the plasma supply, so the "FFP received", in 1973, 4,628 litres.

If we could go over to the next page, please.

We have two years where we don't have data. And then: 1976, 46,500 kilograms; '77, around 64,000 kilograms; '78, 76,000 kilograms; and '79, 77,000 kilograms.

We can see, therefore, the plasma supply increasing in that period between 1973 and 1978. The increase lessens between 1977 and 1978, and we hear a little about that yesterday, and I'll come back to that in a moment, but the increase is related, in our assessment, to the £500,000 of special allocation funding.

We can also see if we go back, please, Paul, that -- if we could go back to the previous page, and the column for the amount of Factor VIII issued. So the last column. In 1973, 2.6 million international units; 1974, 2.7; 1975, it drops down to 2.1. But then, over the page, on to 1976, 1977 and 1978, we can see that it increases to 6.1 million international units, then 11.5 million international units, then 14 million international units by 1978, which is approaching the capacity of the plant as then expressed in international units, which is 15 million international units.

Again --

SIR BRIAN LANGSTAFF: Just coming back to the point about the differential use of the word "capacity", if we -- if capacity means the ability to handle, how much can you take before you start overflowing, if you like, then I can understand that's exactly why you've got

15 million international units in the second from right column. But the third from right is the capacity, plasma capacity, and that's the amount of plasma you can handle. Why should that differ at all from the maximum?

In other words, if you start off with -- putting it in simple terms, if you've got a litre jug, once you've filled it to more than a litre you're overflowing, if you're less than a litre you've still got that bit left. So this -- the capacity is being used in a different sense, I think, in this, is it? Am I right or not?

MR HILL: They are two different measures. Yes.

SIR BRIAN LANGSTAFF: So what is the actual meaning of "capacity" in that fourth line or third from the right?

MR HILL: The meaning is the amount of plasma that can be fractionated.

SIR BRIAN LANGSTAFF: Can be fractionated?

MR HILL: Can be fractionated.

SIR BRIAN LANGSTAFF: So that differs each year?

MR HILL: Well, the --

SIR BRIAN LANGSTAFF: It's still -- is that not the example of the litre jug which that's the amount you can deal with?

MR HILL: I'm not sure that that is an analogy which fits because the capacity of a litre jug is defined. It's simple. It is one litre.

SIR BRIAN LANGSTAFF: Yes, but then the question arises: if that varies, the capacity for plasma, why does the capacity in the sense of the maximum you can make not differ with it in terms of international units? Because if something is -- if, for instance, the machinery breaks down, then obviously you can't the make material from the plasma that you have got, and your capacity measured across the year has dropped. So I can see there's space for capacity, meaning the maximum you can do -- if it means that -- varying. But those two columns seem to be saying rather different things.

MR HILL: There are a couple of points to make there, sir. The first is that they are different measures. If all things were equal, one would expect that the amount that PFL -- BPL and PFL could send out in terms of international units would correlate very closely with the amount that it could fractionate.

SIR BRIAN LANGSTAFF: No, because the amount it could send out depends on how much goes in. The amount it can fractionate depends on what you can actually make if you're at full tilt.

MR HILL: I think that's what I was trying to say, sir.

One would expect a correlation between the fourth and fifth columns because, all other things being equal, if a plant can handle more plasma, the it should be able to handle the production of more Factor VIII, so one would expect that correlation.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: There are points when there is a divergence that we can explain. And perhaps, actually, I'll take you to an example of that, which is -- if we could go, please, Paul, to page 41. This is to do with heat treatment.

If we look at that fourth column along, so that is the amount of plasma that in theory, or in actuality, BPL and PFL can fractionate, the capacity. That is 150,000 kilograms across these three years.

The next column is the capacity as measured by output of the international units, and that starts at 30 million, and that's the figure that we get to at the end of the Stop-Gap programme, but it drops in 1985 and 1986 to 24 million. And the reason for that is that there is a decline in yield from each kilogram of plasma that is provided to BPL and PFL because of the heat treatment programme. So you fractionate the same amount of plasma, but you get

less product at the end of it. That is why you get the drop down.

So that is an example of where the two differ, and we can explain it, or at least we think we can explain it.

The harder question is in the '70s and in particular in the 1980s, there is a divergence. If we go to page 39, please. It's particularly pronounce between 1978 and 1979. And there we can see that the figure given for the capacity as measured by international units is static -- it's 15 million -- based upon what Dr Maycock said and what various other people said at meetings; this is how much BPL and PFL can produce at this time. Whereas the figures that we have obtained for the data for the plasma capacity increase in that time.

Now, that is an example of a lack of correlation that we cannot readily explain. It may be that it is simply a quirk of the data, and in the '70s in particular, the data points are tricky. It may be that if we look at our source for the figure for 1978, that is -- or actually both sources are -- from 197 and 1979, both are taken from Dr Lane's draft proof of evidence, appendix 4. But, as we saw in the instructions to counsel, there's a reference to the

fact that figures can be inconsistent and that they're taken from a variety of sources.

So it may just be a reflection of the fact that we have poor quality data at that time.

An alternative is that there is something going on within the production plant that is causing this differential. And we cannot identify what that is in 1978 to 1979. A little later there is certainly -- and possibly even as early as 1979 there's certainl some disruption, which we picked up from the evidence, and we can -- is set out in appendix 1, where we can see that there is disruption to supply which result from some of the works that the Stop-Gap programme are involving. So there is a reduction of the efficiency of the plant, if one puts it in those terms.

But I cannot tell you why those figures in '78 and '79 diverge so dramatically from the international unit figures. Our best understanding in this period in terms of how much BPL and PFL could produce is, I think, reflected in the penultimate column, the international units, which is the production capacity in this period was fairly static. And we say that because there has been an increase after the £500,000 investment and the new equipment that BPL got after that, but we are not aware of

anything else that is done from that period, '75 to '79, which would increase the capacity of the plant significantly. It's not until Stop-Gap that you ge the further increase.

SIR BRIAN LANGSTAFF: Can I try to summarise this? I'm just trying to understand, really, what the documents are saying to me, and I hope the discussion is helpful to those who may be listening, who may also have some questions about it.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: I think the starting point for me is, first of all, the data is uncertain, and has to be approached with not only caution but probably a very great degree of caution.

Secondly, from what you've just said, it may be that what -- if we think of the manufacturing process in the terms of warehousing in advance, on the one hand, and the ability of the production facility to make as a stage 2, then the ability of the production machinery to make remains exactly the same every year, 1976 to 1979. But there may be a problem, as you've identified, with something going on at the plant, a you've put it, with the end which warehouses -- the refrigeration equipment or whatever it is that warehouses the fresh frozen plasma when it comes in.

Because if you haven't got the freezer working, you can't take stuff into it. You can still make just as much if you had the stuff, but you don't have the stuff.

So I can see that that might be a way of looking at it which would make -- could reconcile the figures, but we don't know if it does. Is that a fair --

MR HILL: That's right.

SIR BRIAN LANGSTAFF: -- summary of what this discussion has led to?

MR HILL: Yes, I think it is, sir.

The one point that I would add for your consideration as well is that the annual data point that we have selected lead to a rather kind of jagged line.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: '78 to '79 to '80. Actually, in reality, at some point between 1979 and 1982 various improvements were made to BPL, which led to an increase which is perhaps not reflected by those simple annual figures, and it may be that at some point in 1979, as part of the Stop-Gap programme, something was done which allowed for a greater capacity to fractionate plasma, which is reflected in that increase there, but we haven't carried that over in the next column becaus

our assessment of the output in terms of international units is that it increased to 30 million as of November 1982, when Stop-Gap finished.

So there's a degree of artificiality in terms of the points that we have chosen, and that may also have an impact. But I'm afraid that we can't be certain of any of those points.

SIR BRIAN LANGSTAFF: Well, that's very helpful. Thank you very much.

MR HILL: If we could go, please, to page 7. This is a graphical representation of those figures that we have just looked at for 1973 to 1977. And here you can see the straight lines are very pronounced, but they shouldn't mislead us into thinking that there is linear growth in this time. It's just the nature of the data means that those crude lines will be drawn. Particularly if one looks at annual capacity in the right-hand graph, graph 1b, we have a figure at 1973; we have a figure at 1976. They are joined by a straight line, but, in reality, it wouldn't have been a perfect, straight linear growth in capacity during that time.

But what the graphs can helpfully show is that if one looks at graph 1b, the green line showing total Factor VIII issued between 1973 and 1977 is below the

yellow line showing annual capacity after 1973. An although we must be careful about that yellow line, the general trend that we can discern is that BPL and PFL are not operating to their capacity at that time, and the likely reason for that is a lack of plasma supply.

We can see that on graph 1a, that the annual fractionation capacity, the yellow line, is above the red line which is showing the fresh frozen plasma received. And the fresh frozen plasma fractionated lags behind that as well.

The lines get closer as we move into 1977, and then if we go over, please, to ... if we could just quickly go to page 13, and we'll just take the stor up to 1978.

On the right-hand graph, you can see there that the lines have closed in 1978 and 1979. That is because, in our assessment, the plasma supply has increased as a result of that £500,000 investment o special allocation, and it is meant that although the capacity of BPL has also increased, BPL and PFL are able to operate at capacity of around 15 million international units in the late '70s.

If we go back now to the figures and page 39, please. And this the period where we have this

strange quirk between the capacity figures as measured by capacity of fractionation of plasma and annual output of international units, so I won't go into that again.

But we can see that the figures for fresh frozen plasma received begin to plateau between 1977, 1978 and 1979. Then over on to page -- the next page, please, page 40. The figure there is 85,940 kilograms, so about 86,000, up from 77,000.

The next figure is 116,000 kilograms, and then the next figure, 148,000 kilograms. So the plasma supply, having levelled off, then picks up again in the early 1980s, and that may well be associated with the pro rata distribution scheme and the single-plasma packs that were introduced at around those times.

In terms of product issued, '78 and '79 -- if we could go back a page, please, Paul. The figure there is -- thank you. Sorry, no, the previous page, page 39. That's it, yes. The figure goes from 11.5 million to just over 14 million, and then a little higher, but still in the range of 14 million between 1977 and 1979.

So BPL is approaching capacity in that period. It's unlikely that a plant is ever going to operate exactly at capacity, so it is pretty much at capacity

in the late '70s.

And if we could go over, please, to 1980. Then 1981 and 1982. So the first figure is for 1980, th second figure is 1981 to '82, and the third figure is 1982 to '83. And we can see there the difference between the measures of the annual reports. So a slight concern about whether or not we are measuring like with like, whether each one of those is a 12-month period. So, wary of that point, I think it is still valid to say that there is a significant increase in the amount of product issued from 11.8 million international units in 1980 to a figur of 21.5 million international units in the year '81 to '82, and a similar figure, 22.6 million international units, in '82 to '83. That increase is one that is associated with Stop-Gap and the completion of Stop-Gap at the end of November 1982.

If we just go on to the next page, please, we can see 1984. BPL and PFL again approaching capacity in 1984, getting close to that 30 million international unit mark. So Stop-Gap allows for an increase and there it allow -- the Stop-Gap programme is completed in November 1982. By the year of 1984 capacity is again being reached.

I won't take you to the graphs there. If we go

over, please, to page -- actually stay on this page on 41. This is the point that we have just been discussing, sir, the decrease in capacity, as measured by international units, is a consequence of the hea treatment, and that is why the amount of product issued also declines, whereas the capacity in terms of how much the plant can fractionate of plasma remain the same, it's 150,000 kilograms. That is in the old BPL plant. The new one is being built alongside.

If we go over the page, please, to page 42.

We can see there the effect of the new BPL. So the capacity to fractionate plasma has gone up to 450,000 kilograms per year, which is the figure tha I mentioned earlier today. As measured as output o international units per year, it's up to 60 million That's from 1987 to 1988. The actual amount issued that year is about 25 million international units, and that is, as I indicated earlier, sir, because there is a period where it takes BPL to get up to full speed and we can see 1988/1989, it is pretty much at capacity, at 57 million international units for tha year.

If we could just go to page 25, the graphs associated with that last period. If we could have Graph 3a. You can see there that between about 198

and 1987 to 1988, more fresh frozen plasma is being received at BPL than the plant is able to fractionate. That excess is being stockpiled at BPL in order to be fractionated later, once the redevelopment is completed.

SIR BRIAN LANGSTAFF: I suppose that also may be a reason, going back to the earlier discussion we were having about the difference between the ability to take in plasma, assuming that it's the warehousing end at the start, the refrigeration end, if a lot of plasma ha come in, more than is actually being fractionated, or more than can be fractionated, then it'll stack up.

MR HILL: Yes.

SIR BRIAN LANGSTAFF: And that will give less space for what's due to come in.

So that might be a simpler reason still --

MR HILL: Yes.

SIR BRIAN LANGSTAFF: -- for explaining why it is that the capacity to handle plasma may be -- ie to receive it, assuming that's what capacity means for these purposes, if it does, then that would be an explanation too.

MR HILL: It could well be, sir, yes.

One point that I would make from one -- one further point I would make from Graph a as well is

that we can see that during this period from 1983, there is an increase in the amount of fresh frozen plasma which has been provided to BPL in these years. And that -- and it is a significant increase as well. I'll read the figures rather than take you back to them, but from that first column in the tables, in 1984, about 175,000 kilograms of fresh frozen plasm are provided to the BPL and PFL. In 1985 to 1986, it is up to 250,000 kilograms. In 1986 to 1987, it is a little over 300,000 kilograms. In 1987 to 1988, it's up to 375,000 kilograms.

This was part of a wider programme to increase plasma supply to BPL and PFL in this period. It wa a source of concern, and I think that you have seen some of the documents about that in the Blood Services hearings, where essentially the DHSS were saying: We're building this new plant. We must make sure that we've got enough plasma to actually use it.

There were concerns that that wasn't going to be achieved, but we can see from those figures that, actually, there is a significant increase in plasma supply, and one of the key reasons for that is the introduction of SAG-M, the additive solution which is discussed in appendix 6. I am not going to go through that in detail.

The short point is that SAG-M is an additive which can be added to red cell concentrates to make them less viscous and to improve their flow. And that in turn makes those red cell concentrates more attractive to clinicians, and it allows for more plasma to be obtained from a whole blood donation.

The figure -- various figures are given for how much can be taken using SAG-M, and the sources are set out in appendix 6. One figure given by Dr Lane and Mr Pettet of BPL is 290 millilitres; Dr Gunson give a figure of 275 millilitres. Whichever one is more accurate, it is well above the 190 millilitres that could be obtained which formed the basis of previou planning assumptions.

SAG-M begins to be used in England and Wales in about 1984. There is considerable regional variation. Funding is an issue, as ever. There is also an issue about the different approaches of different clinicians to the red cell concentrates with SAG-M in them. Some regions enthusiastically adopt SAG-M, especially because it's a cheaper way of increasing plasma supply than plasmapheresis.

I will take you briefly to two graphs. One is INQY0000335, page 14. And this is from annex 6, an it shows the percentage of plasma arriving at BPL,

Wales using three-monthly statistics from 1983 to 1985. The SAG-M line is the one with the solid dot and we can see, as with the previous graph that we have looked at, that that rises dramatically from 1985.

The top line at the start of this period, in 1983, with the dot which isn't coloured in in the middle, that is the single-plasma pack that we were discussing yesterday. And you will see that as SAG-M increases, the use of the single-plasma pack decreases significantly. The reason for that is that the single-plasma pack that we were discussing yesterda wasn't big enough to hold the increased amount of plasma that SAG-M allowed for, so it is not used so much, its usage falls away, and instead SAG-M becomes the dominant means of providing blood to BPL.

It shouldn't be thought, though, that SAG-M is different in the sense of being a pooled product. It's still a single donor product. It's just reached in a different way.

The next line down from the start are the 5-litre plasma packs, the old plasma product packs that Dr Lane was keen on getting rid of, and you ca see that there is a fairly stubborn line which remains. There's a slight decline but not a great

having been separated using SAG-M. And we can see it's zero in 1982, a small increase in 1984, and then a dramatic increase in 1985, and then a more modest increase from '85 onwards.

The relevant figures from the table -- if we leave the graph up there, I'll just read out the figures from the table. In 1984, it was about 8% o the plasma arriving at BPL had been the result of SAG-M usage. By 1985, that's up to 55%; 1987, 60%; 1988, 68%; and 1989, 75%. I should add there was never an intention to reach 100%. There was always an acceptance that there was going to be a need for some whole blood, but there are significant increases in the amount of plasma received at BPL to which SAG-M had contributed.

Then if we could go, please, to NHBT0017097. This is an article from the November 1986 edition o *Health Trends*, and it is, if we go over to the next page, please, an article written by Dr Gunson about trends in blood transfusion practice in England and Wales.

If we could go to page 4, please. If we could expand the graph on the right-hand side. This is Dr Gunson's graph showing the changing pattern of methods for fresh plasma collection in England and

decline.

And at the bottom, interestingly, is plasmapheresis. And we can see that in this period, 1983 to 1985, there is a slight increase in the amount of fresh plasma collected with plasmapheresis, but it is not a particularly marked increase, and it is a method of collection which is still far below SAG-M, and indeed the other methods of collection as well.

And the success of SAG-M in increasing plasma supply helps to explain why it is that plasmapheresis is not more used in England and Wales in this period.

One final point on this, and it's in appendix 6, paragraph 28. Dr Lane told a meeting of the CBLA o 25 March 1986 that the blood -- the plasma supply, sorry, to BPL was satisfactory, and he commented in particular, and I quote:

"The effectiveness of the SAG programme was particularly relevant."

So Dr Lane clearly seeing SAG-M as a reason why the plasma supply, which had been a source of such concern for everybody earlier in the '80s, was not as much of a concern by 1986.

I would briefly bring up the bar charts. I'm conscious of the time, but I have just a few minute left and I think it may be easier to finish now and

allow the transfer of the databases before Ms Richards' presentation.

INQY0000336, page 42, please.

This is the bar chart again, and, as I've said, indicative rather than precise. But we can see in that late '80s period the decline of NHS Factor VII between '84 and '85 as a result of heat treatment, and then the expansion as a result of the redevelopment of BPL, and, from 1989, a reduction in the amount of commercial concentrate product that is provided. The reduction may have started between '87 to '88 but it becomes more pronounced '88 to '89, cryoprecipitate by this time making up very little of the usage in the United Kingdom.

So that is the overall picture. Those last two bar charts, though, do still show the use of the commercial concentrate within the United Kingdom.

If we could go, please, to NHBT0103463_009.

This is a press release from 2 December 1988, dealing with the production at the Blood Products Laboratory reaching record levels. So a DHSS press release. And it refers to an answer given to a written Parliamentary question by Edwina Currie, then the Parliamentary Under-Secretary of State for Health. And it quotes the answer that she gave tha

day. And it says, and I quote:

"'The £60 million Blood Products Laboratory is now producing Factor VIII at record levels, but it is not yet possible to predict when we shall no longer need to import Factor VIII. Yields so far are lowe than expected though higher than the commercial producers', and a reappraisal of the buffer stock o plasma has shown it to be less than previously thought'."

I pause there to say I think that is a reference to a miscalculation that was made in the 1980s abou how much plasma had been stockpiled.

Back to the quotation:

"'Action is being taken by the Central Blood Laboratories Authority to increase yields and by th Blood Transfusion Service to increase the collectio of plasma which will lead to higher output over the next three years.'

"Mrs Currie later said:

"'The Government's aim is to meet the needs of haemophiliacs in England and Wales from home-produced Factor VIII. To this end the Government have invested nearly £60 million in a new plasma fractionation plant at Elstree. This new Blood Products Laboratory (BPL) is now producing Factor VIII at record levels.

"Over the year 1989/90 as a whole BPL expect to make a record 65 million international units of Factor VIII. This represents around 70% of our present requirement. The balance will be imported as now under very stringent quality controls. It is necessary to stress that all imported products are licensed under the Medicines Act, and the need to use imported products does not put haemophiliacs at any greater risk."

I think that is the end of the document. Oh no, sorry, over to the next page:

"We will, contrary to earlier expectations, still need to import Factor VIII for the time being We are disappointed that our previous hopes for self-sufficiency will not be realised. The new BPL represents a massive exercise in scaling up from production in the old plant. Yields at this stage are lower than those previously achieved and on which earlier forecasts of production were based."

I pause there to note, sir, that the impact of heat treatment is notable on the yield:

"Because yields are lower, we need to process more plasma to achieve the same level of output. Plasma collection is already at record levels. However, the newly created National Directorate for

the Blood Transfusion Service are making achievemen of even higher levels of plasma collection a priority task and are discussing with Regional Transfusion Directors how this can be achieved. By taking concerted action on both production yields and plasma supply, we expect significantly to increase production of Factor VIII over the next three years, and in th meantime, haemophiliacs can be reassured that the supply of Factor VIII to them will be maintained."

That's the end of the press release from Ms Currie -- Mrs Currie, I think it was.

One final document, DHSC00046936_009. This is from 25 October 1990, so slightly later. And it is a briefing sheet for the Secretary of State in anticipation of a Parliamentary question. The titl is "Self Sufficiency -- Factor VIII, Line to Take":

"Estimates made in the mid 70s of the amount of Factor VIII required to achieve self sufficiency di not anticipate the increased demand for this treatment. It was this administration's commitment to redevelop the Blood Products Laboratory in 1981 which enabled us to meet the clinical demand for our product."

That is the line that is being advised.

The "Background note" says this:

"1. Dr David Owen made a commitment in January 1975 to NHS self sufficiency in the production of Factor VIII, a target expected to be reached in mid 1977, and funded with an extra £0.5 million.

"2. Between 1975 and 1977, NHS production increased from 3.2 million units per annum to 12.8 million in 1977, but total demand increased from 8.2 to 27.4 million units in the same period, so that the proportion of commercial product remained the same.

"3. Between 1980 and 1982 Ministers approved spending of £2 million on upgrading the original plant at Elstree [that's the Stop-Gap]. In 1981 Minister agreed to the redevelopment of BPL. The design capacity for this was around 100 million international units of factor VIII.

"Current position on self sufficiency

"4. BPL are now meeting 75% of the total requirement for Factor VIII of about 110 [million international units] per year. Clearly BPL want to maximise use of their products, but the decision on which product is best for the patient rests with th clinician. Absolute self sufficiency is likely to be unattainable given the clinician's freedom to prescribe. The policy now is one of meeting the

clinical demand for home produced Factor VIII. (BP are able to meet such demand). The recent EC directive on blood products promotes the idea of community self sufficiency. This too is a factor which points away from being able to achieve sole use of the BPL product."

That, sir, is where the policy had reached by 1990. I take that to mean that the policy has changed from being one where NHS products would completely replace commercial products to one where the goal i that whenever a clinician in the United Kingdom seeks to use a domestically produced product, then that product would be available to the clinician. But i doesn't prohibit the clinician from using imported products if the clinician chose to do so.

And that, sir, is where we take our leave of domestic production and self-sufficiency, in terms of the chronological presentation, and we move to the individual presentations for Dr Smith first, and then Dr Lane, which will be given by Ms Richards.

SIR BRIAN LANGSTAFF: Yes. So Dr Smith at 2.15. The presentation about Dr Smith, 2.15.

(1.20 pm)

(The Luncheon Adjournment)

(2.15 pm)

(Proceedings delayed)

(2.59 pm)

Presentation to the Inquiry about the work and evidence of Dr James Smith (responsible for product development at the Plasma Fractionation Laboratory 1975-1992 and Blood Products Laboratory 1979-1982 and formerly of the Protein Fractionation Centre, Edinburgh) by MS RICHARDS

SIR BRIAN LANGSTAFF: Let me just start by apologising to those of you who are here, and those of you who are at home, for the delay that has been this afternoon in starting up again. The reason for that, so that yo know, is that there was a problem with being able t display the documents to you, to which Ms Richards will refer during the course of her presentation, and maybe you wouldn't have wanted to listen to the presentation without having the documents that went with it and having to identify them by numbers and letters and tracing them afterwards.

But we are, I gather, now in a position to begin, and what we'll do, so that you know, is we'l run straight through without having the usual afternoon break, and we'll save, therefore, about half an hour in the process, so we won't lose too much time, I hope. But I'm -- once again, I'm sorry.

MS RICHARDS: Sir, this afternoon's presentation, which

I anticipate will probably continue over until tomorrow morning, focuses on the evidence of Dr James Kemp Smith, usually referred to in contemporaneous documents as Dr Jim Smith. Dr Smith was not a clinician; he was a chemist working in the field of fractionation, and he worked in Edinburgh, in Oxford and in Elstree.

The presentation itself, I won't ask Paul to put it on the screen, but the reference for anyone who wants it is INQY0000329, and it's also available on the Inquiry's website.

It draws on, in particular, the following documents, and, again, I'm going to read a handful of URNs but we don't need to display them at present.

So there is a witness statement that Dr Smith provided to this Inquiry in 2020. The reference fo that is WITN3433001.

There is then a draft proof of evidence which Dr Smith produced or was produced for or with the involvement of Dr Smith during the HIV haemophilia litigation. The URN for that is CBLA0000016_034.

There is also a transcript of evidence Dr Smith gave to the Lindsay Tribunal, for which the reference is LIND0000318.

Then Dr Smith gave evidence both in writing and

orally to the Penrose Inquiry. The references to his two written statements are PRSE0004045 and PRSE0004368. And then the references for his oral evidence to the Penrose Inquiry are PRSE0006059 and PRSE0006060.

I'll come to some aspects of that material in much more detail shortly.

We're not able to hear oral evidence from Dr Smith, and so the purpose of this presentation is really to draw out the key elements of the evidence that he has provided previously, and, indeed, the written statement he provided to the Inquiry in 2020, and to explore a range of themes which emerge in his evidence. There are, I think, seven themes or issues that I'm going to address through his evidence: self-sufficiency; knowledge of risk of viral transmission; resources at PFL and BPL; the relationship between the fractionation centres in England and the fractionation centre in Scotland; some matters relating to pool sizes, and in particular restricted pool trials; heat treatment, which I anticipate will be probably the longest part of the presentation; and then Dr Smith's observations on the possibility of reversion to cryoprecipitate as a response to the AIDS crisis.

Those are the particular themes that I'll aim to pick up by reference to Dr Smith's statements and also by reference to some of the contemporaneous documents.

In terms of his background, Dr Smith studied chemistry, graduating in 1962 from the University of Edinburgh. He then studied for a PhD, and then undertook post-doctoral studies, again based at the University of Edinburgh, through to 1968.

Then, between 1968 and 1975 he was based at the Protein Fractionation Centre in Edinburgh. He was a senior biochemist then chief chemist responsible, his evidence tells us, at overlapping times for product management, product development and quality control of plasma protein concentrates.

A little more detail about some aspects of his work is set out in a CV which I think was prepared for the purposes of the Penrose Inquiry. We don't need to put it up on screen, but it's PRSE0001136.

After those seven or so years working at the PFC in Edinburgh, Dr Smith moved to England and took up a post in 1975 at the Plasma Fractionation Laboratory in Oxford. He remained there until 1992. He worked as a scientist in charge of fractionation, responsible for product development and manufacturing, closely involved in research and development, and from

January 1983, his job title was chief project scientist. And he described in his evidence in various stages a close relationship between the PFL in Oxford and the Oxford Haemophilia Centre.

For some three or so years during that time, he was seconded to BPL. So from 1979 to the end of 1982, as well as holding down his job at PFL, Dr Smith took up additional duties as head of coagulation factor production with some research and development responsibilities at BPL. And, according to his evidence, he would attend both laboratories for part of every day. So he travelled in-between Elstree and Oxford.

He planned and oversaw remedial action at the BPL facility and was involved in the initiation at BPL of systems of batch documentation.

In 1992, he ceased to work for PFL and became an independent consultant advisor on fractionation and coagulation until his retirement in 2015.

So he had what may have been a unique experience as a fractionator of working at PFC, PFL, and BPL, and we will draw on some aspects of comparison that he offers or offered in his evidence in due course.

If I can then turn to some of the evidence that he gave in writing at earlier stages in the

chronological order in which that evidence was prepared. We start with the draft proof of evidence in the HIV Litigation.

Paul, could we have up on screen, please, CBLA0000016_034. You will see this is a document for Dr JK Smith, headed "Draft/proof of evidence". The top right-hand corner describes it as "Draft 3", and there is a date of 1 November 1990. It's important, therefore, to understand the context within which this document was produced. It was produced as part of the HIV haemophilia litigation. It was produced, as I understand it, at the request of or at the behest of the solicitors representing the CBLA, Clifford Chance, and it was never finalised. And if we go to the very last page, it should be page 70, we can see that it was not signed or dated.

Before we look, however, a little more at what was in that statement, if we can just look at Dr Smith's later observations on the accuracy of the statement and the procedure by which it was put together. That's in his statement to this Inquiry from 2020. WITN3433001. Sir, this is statement 27 July 2020 to this Inquiry. If we go to page 4, he was asked about the draft proof of evidence that we've looked at and, indeed, about an earlier draft which is

referred to in this document as draft 1. And I'm just going to read what he says about. Starting with paragraph 12, he says:

"The Inquiry has provided me with a document headed with my name and entitled 'Draft proof of evidence, draft 1' and has suggested that this is a draft proof of evidence from the HIV haemophilia litigation. It is unsigned and undated. I do not today recall ever seeing draft 1, although the existence of draft 3 suggests that I must have. My only recollection of the apparent context is a single visit to the offices of Clifford Chance who I believe were organising the defence for BPL and possibly others."

Skipping over a sentence:

"The style of some elements of the draft, particularly the last section, suggests that I've been asked for notes on various topics, probably in advance of this interview or conceivably just later, but I have no positive recollection of having been asked for or having provided notes."

Then he has some other observations in relation to draft 1 which I don't think I need trouble with.

The next paragraph, he explains that:

"Draft 3 [and that's the draft that we'll be

looking at today] is more recognisably in my words, but some of the wording in the commentaries is not mine, and there's evidence of dictation to a typist not the PFL secretary. The context appears to be that responding to the unidentified draft as interpolations in draft 1, I provided small adjustments and explanations to draft 1. The main text of draft 3 continues to follow draft 1 and continues the narrative to the end of 1984. I would have thought that a full text might have continued until 1990, ie, the time of the draft. Draft 3 continues with my commentaries attempting to explain to the lawyers the significance of mainly BPL internal memoranda."

And I'll show shortly what he meant by that.

Then if we go to paragraph 14, Dr Smith said:

"Draft 3 not an ideal source of evidence, but it has the merit of being closer in time to the events described than were, eg my submissions to the Penrose Inquiry in 2011. I found nothing in the narrative or the explanatory section which is contrary to my recollections, but there is much information here [that] I have not retained over 30 years and must simply take at face value."

Then paragraph 15, he says:

"Since the Draft does not include any statement

of its intended scope, I cannot judge whether it should have included other material. Although it does not continue to 1990, it does cover the most crucial years in BPL's development of safer concentrates. I get no impression of it attempting to hide or omit anything inconvenient and have no reason to think that this has occurred."

That, in 2020, was Dr Smith's recollection of the process by which the draft proof of evidence in 1990 was obtained, and those were his comments on it.

If we go back, then, to the 1990 draft proof, draft 3, CBLA0000016_034, we'll see it's in five principal sections.

If we turn to page 3, the first principal section is a history of the Plasma Fractionation Laboratory, and I'll just go through that. Although much of it pre-dates Dr Smith's employment there, he does explain the source of his knowledge. And we've seen I think a similar account in relation to BPL elsewhere.

So he says:

"The events described below, to the extent they pre-date my joining PFL in 1975, are based upon the recollections of Mr GRW Dike ..."

And then you'll see in brackets, sir, the words

"still to confirm this information", and that, we anticipate, is probably a comment from the solicitors who were involved in the drafting of the document.

"... who is a Technical Officer working in PFL and who was first employed by the then head of PFL, Dr Ethel Bidwell, in the early 1950s. Mr Dike worked closely with Dr Bidwell throughout the 1950s and 1960s and, by the time I joined PFL in 1975, worked on research and development."

Then you'll see that he was still employed -- Mr Dike was still employed at PFL at the time of this statement.

If we go over the page, we then have what's essentially is Dr Smith describing what Mr Dike had said to him about the history of PFL:

"His recollection is that in about 1937/38, the MRC [Medical Research Council] were charged by the Government with responsibility for developing therapeutic concentrates utilising blood and plasma It is believed that the MRC really quickly sub-contracted this work at least to the extent that it applied to freeze-dried plasma, to the Lister Institute which was then based in Chelsea Bridge Road in London.

"7. In 1951, Dr RG Macfarlane and Dr Biggs

started research on thrombosis and coagulation disorders in the Radcliffe Infirmary's Pathology Laboratory funded by Oxford University (at least partly through the Nuffield Haemophilia Research Fund) and the United Oxford Hospitals. In fact Mr Dike was first employed the Radford Infirmary.

"8. In 1952, Dr Ethel Bidwell was employed to investigate the possibility of making therapeutic Factor VIII concentrates, at this time in the form of AHG (anti haemophilic globulin) from animal plasma.

"9. In 1956 bovine AHG was used for the first time in a major operation. Porcine AHG was also used for the first time in 1958 and other species such a sheep and horse were investigated during this period.

"10. Up to this point, any 'policy' on manufacture and use of the therapeutic products rested with Oxford University, the physicians of the Unite Oxford Hospitals and the Wingfield-Morris Orthopaedic Centre.

"11. In 1958 the MRC formed the MRC Blood Coagulation Research Unit under the directorship of Dr Macfarlane at the Churchill Hospital in Oxford. Th policy of the Unit and its funding became the responsibility of the MRC. There were three divisions in the Unit; research, clinical and fractionation (the

latter included biochemical research work). At the time it was formed, the MRC central workshops were already on the Churchill Hospital site. In 1962 th Blood Transfusion Service moved to the Churchill Hospital site as well and as a consequence, more significant volumes of human plasma became availabl for fractionation in 5 litre batches."

"12. In 1962, co-operation between the MRC Unit Biochemical Section under Dr Ethel Bidwell, and the Lister Institute under the direction of Dr, later Sir, William Maycock, took place with regard to the provision of crude plasma residue for Factor IX concentrate (C9 as it was then called), from the ether fractionation process from the production of Factor VIII at Elstree. Concurrent with the preparation of Factor IX, immunological and biochemical research was carried out into the natur of Factor VIII, including its separation from fibrinogen. Bovine and porcine Factor VIII was still in use and much work was carried out into the natur of, and avoidance of development of inhibitors to Factor VIII caused by the infusion of heterologous Factor VIII.

"13. In 1968, Dr Macfarlane retired and the MRC dictated that the Unit should close. MRC policy at

the time was to funding only front-line as opposed to applied research; research once established and in a position to be applied was passed to the Health Authority. Dr Ethel Bidwell gave consideration to whether the fractionation laboratory might be taken over by the Health Authority or by the Lister Institute and it was eventually agreed that the latter style of management would be more appropriate. The BCRU has split into three sections:

"(i) Haemophilia Centre, operated by NHS but with a continuing MRC role;

"(ii) Plasma Fractionation Laboratory, under [and then blank] ..."

And then, over the page:

"(iii) Research under the MRC only.

"Protein Fractionation Centre performed as a research pilot plant on an intermediate scale for the preparation of a number of human blood plasma fractions, principally Factor VIII, II, VII IX and X, immunoglobulins and albumin. All PFL staff except Mr Dike were employed by the Lister Institute."

Then he says Dr Bidwell became responsible to Dr Maycock of BPL.

And then finally, and for current purposes, paragraph 14:

"By 1972, almost all the Factor VIII preparations produced by PFL were used by the Oxfor Haemophilia Centre and the clinical trials of the 'DE' Factor IX preparation were underway in Oxford. DE Factor IX was being developed to replace the then current Factor IX concentrate, C9. However C9 continued in production alongside DE9 until 1975 as DE9 did not contain Factor VII which was needed by a few patients. In 1976 a Factor VII preparation was developed and underwent clinical trials in Oxford, Spain and Italy, thereafter production of C9 was stopped. During this period and until 1978 the Factor VIII concentrate produced by PFL was a low-potency intermediate purity product, 8IP. In 1978 8CRV ..."

And we've heard that referred to by Mr Hill in the course of the presentation this week, the CRV standing for:

"... (cooled, reduced volume) and HL, higher-potency intermediate purity products were pu into production."

Just pausing there, 8CRV from 1978 was the Factor VIII concentrate produced at PFL until it wa replaced by 8Y in 1985. HL was the Factor VIII concentrate produced by BPL, again until it was

replaced by 8Y in 1985.

By the time we get to the early 1980s, the Factor IX product is more commonly referred to as 9 D.

So there's a plotted history from Dr Smith in relation to the establishment in Oxford.

The second part of this draft proof starts on the next page, and you will see it contains an explanation from Dr Smith of various terms associat ed with the process of fractionation. I'm not going t go through them in detail, but just point out what we have.

So he explains pasteurisation, referred to elsewhere, as Mr Hill has already referred, sometim es as "wet heating". He then describes the process of dry heating. And then, over the page, I don't thin we need to worry about precipitation for present purposes, but if we go to the next page he describe two further concepts: recovery/yield and purity, bo th of which will become of some relevance when we look at the experimental work in relation to heat treatment

And then over the page, we see there the reference at paragraph 27 to solvent detergent. Again, that's one of the possible areas that were explored by PFL.

And then on the next page, we see, in

paragraph 29, he deals with the problem of thrombogenicity in relation to Factor IX concentrat es, and I'll come back to that when we look at the heat-treatment process in relation to Factor IX.

The next part of Dr Smith's draft proof starts over the page, page 12. And here he set out an account of the work that was undertaken principally at PFL in relation to the development of the heat-treatment process. I'm going to come back to that in some detail at a later stage of the presentation, but that runs from page 12 to page 34 of this draft proof.

If we move on then to page 39 of the draft proof -- sorry, 35 of the draft proof, my apologies

Previous page, Paul, sorry, page 34.

You'll see there, sir, a heading "'Restricted pool' Factor VIII trials, 1983/1984". Again, I'll come back to that but Dr Smith essentially set out in the draft proof here a particular component of the work at PFL, in particular in relation to -- or response to hepatitis, in the period 1983 to '84, i relation to what is sometimes called "limited pool" or "restricted pool" or sometimes referred to as "smal panel trials". And I'll explain what was meant by that in due course.

If we then turn to page 39, we have the last section of Dr Smith's draft proof, and this is a commentary on various documents. They're documen ts from, as we can see from the heading, the CBLA's discovery, so documents it was disclosing as part o the HIV Haemophilia Litigation. And for the remain der of the statement, if we just go over the page for example, we see on the bottom half of the page a number and then a description by Dr Smith of the document.

For the most part, this final section of the draft proof really does little more than summarise the document, but from time to time Dr Smith did add so me commentary or some context to the document.

It's not clear, and the same will be true when we look at Dr Lane's draft proof of evidence someti me tomorrow, it's not clear who made the selection of documents. In other words, on what basis were particular documents put before Dr Smith or put bef ore Dr Lane? And whether it was a selection into which they contributed or whether it was a selection on t he part of the legal representatives.

That's the draft proof of evidence in the HIV haemophilia litigation. As I say, I'll come back t what he said in this draft proof in relation to hea

treatment and the restricted pool trials in due course.

So that was 1990, obviously closer in time to the events in question than any of the later eviden ce.

The next occasion upon which Dr Smith gave evidence --

SIR BRIAN LANGSTAFF: You did say, I think, there were five sections to that, and you've told me about fou r.

MS RICHARDS: So the history of PFC.

SIR BRIAN LANGSTAFF: The first was the history of PFL.

MS RICHARDS: The terminology.

SIR BRIAN LANGSTAFF: Ah, the terminology. Right, that's it. Thank you.

MS RICHARDS: Yes. Heat treatment, restricted pool, and then the commentary.

SIR BRIAN LANGSTAFF: Thank you. Got it.

MS RICHARDS: Chronologically, the next piece of evidence from Dr Smith was his evidence to the Lindsay Tribunal. He gave oral evidence to the Lindsay Tribunal on 18 July 2001.

Paul, can we have, please, LIND0000318. Sir, you'll see here the first page of the transcript of the oral evidence, and we see the date at the top, and then Dr Smith was questioned.

We don't, I'm afraid, have a copy of the written

report or statement that Dr Smith provided to the Lindsay Tribunal. There is reference in the course of the oral evidence to there having been a written document, but we don't have it, and when Dr Smith provided this Inquiry with his statement in 2020, h no longer had it either.

Unsurprisingly, the oral evidence that Dr Smith gave to the Lindsay Tribunal largely covered issues of particular relevance to Ireland, so it covered the extent to which the PFC in Edinburgh could have fractionated Irish plasma and produced factor concentrates for Ireland. In other words, the arrangement that we know was subsequently set in pl ace in relation to Northern Ireland, a question was explored with Dr Smith as to whether that could hav been undertaken in relation to Ireland.

He was asked about the extent of his contact with fractionators and clinicians in Ireland. He w as asked about a particular element of work undertaken at PFL on something called the Gail Rock method of attempting to increase the yield of Factor VIII. B ut he was also asked about PFL's work on exploring pasteurisation and dry heating. And for your note, sir, and for anyone else who wants to look at that, that's covered largely from page 10 onwards of the

oral transcript.

I will just, whilst we're looking at this, show you the question and answer session in relation to could Scotland have fractionated Irish plasma, beca use that has some relevance to an issue you may need to consider, sir, as to whether the PFC could have bee used as a resource for the fractionation of plasma from England and Wales.

So if we pick that up at page 3 of this transcript. You'll see, however, it's apparent fro Dr Smith's answers that he can only really assist w ith the position relating to PFC up to 1975. So it's about halfway down the page. There is the question :

"I see. Now, if I can go back to the situation with Scotland, and again you were only there up to 1975, was there or could the Scottish centre have fractionated Irish plasma and produced Factor VIII and Factor IX for Ireland at that time?"

Then this was Dr Smith's answer:

"In the technical sense, I think that could have been done and was quite an attractive option for th Scottish centre. There would have been -- there ma have been certain difficulties in that. However, i another case what you might call contract fractionation would have been done. There was

pressure from the regulatory authorities in Ireland the donor or the fractionating nation, to ensure th at the streams of the two plasmas were kept separate, and that would have raised difficulties even in the new centre in Edinburgh."

Question: "Perhaps we'll break it down into pieces. If the country which was sending the plasm insisted on separate streams in the sense of keepin their plasma separate from other plasma in the Scottish centre, would that have caused some difficulty?"

Answer: "It would have made it -- increased the difficulty of Factor VIII and Factor IX production quite a bit, but it would have been very, very difficult with the larger fractions, IGG and albumin, with the system that Scotland was running at the time."

Question: "If we just deal with the Factor VIII and Factor IX, while it would have rendered it perh aps more difficult, would it have been an impossible situation?"

Answer: "Not impossible."

Question: "I see. Now, the other possibility is what I might describe as a shared system which I presume means that the Irish plasma would have go ne

in with other plasma and that the product would hav been produced at the end which represented a shared source."

Just pausing there. That's what Dr Morris McClelland told us what happened in relation to the Northern Irish plasma. It was pooled with Scottish plasma.

Answer: "Yes."

Over the page:

Question: "Was that a possibility?"

Answer: "That would have been more practical I believe from the Scottish point of view."

Question: "I see. I think you said that this would have had some attractions from the Scottish point of view. Why do you say that?"

Answer: "The Scottish centre was built with an eye on fractionating more plasma than was currently available from Scotland, although Scotland was one of the most prolific countries in getting plasma out o the Transfusion Service. Part of the idea at the t ime was that the English centre was becoming more elder ly and that we might receive -- there were certainly proposals to receive English plasma from the north of England, more naturally, more nearly going into the Scottish centre. Nothing came of that. Another

possibility might have been to seek plasma from other countries of a similar size to Scotland."

Question: "In other words, did you in Scotland have capacity to deal with more plasma and were looking -- were sort of looking around the place to see was there a possibility of getting plasma from other places?"

Answer: "Yes. It improves the economies of fractionation if you utilise your capacity to the fullest."

He's then asked specifically a question about whether there were discussions in relation to Irish plasma, and he says:

"I can't recall."

The next question is:

"Were there arrangements with any other countries or any other areas in regard to contract fractionation by the Centre in Edinburgh?"

And Dr Smith said if there were, he didn't know of them.

And then he's asked if he knew why discussions with Ireland never came to any actual arrangements, and he answers he did not, and then he left in 1975

So that's some contextual evidence in relation to his understanding of the position as at the PFC in

Edinburgh in the first half of the 1970s when Dr Smith was there.

So that was Dr Smith's evidence to the Lindsay Tribunal. He then provided two written statements to the Penrose Inquiry. The first is at PRSE0004045. This is a statement dated 22 June 2011, and it addressed the Penrose Inquiry's topic B3, which was viral inactivation in the period to 1985. And you will see from this that Dr Smith gave a statement in what he described as three parts. The first, "Snapshots and landmarks". That's a reference to a document produced by the Penrose Inquiry to which - or on which Dr Smith provided comments. And then the second part of his statement was what he referred to as "notes", "JKS", that's his initials, "Notes 1-5". Then the third part of his evidence were some comments on specific paragraphs of the Penrose preliminary report.

I'm not going to go through this in detail, although we'll come back to some parts of it, but in we can just look over the page, we'll see what he meant by this.

So this document contains in ordinary print the observations and questions posed by the Penrose Inquiry, and then that which you see in bold italic

are Dr Smith's observations in response.

If we then go on to page 17, please, we will see the supplemental notes which Dr Smith produced. For present purposes, I want to come back to one or two of them later. I'm just going to show you what the subject of each of those notes was.

So his first note was headed "Impediments to the development of heat treatment against non-A, non-B hepatitis". We'll come back to this, but he listed a whole range of factors which he suggested were impediments to any earlier heat treatment work.

If we go over the page, his second note is headed "Pasteurisation of albumin is not directly transferable to Factor VIII". So, essentially, in a nutshell, explaining there why it's not simply a question of saying, "Well, we do this albumin; let's do it with Factor VIII," and he explained why in the note.

The next note on page 19, so the next page, note 3, is headed "The clinical trial of PFC's first pasteurised Factor VIII and its impact on the pasteurisation programme". Obviously, by this time, Dr Smith was firmly based in Oxford and Elstree; no longer involved in work in the PFC in Edinburgh. So this was Dr Smith's comments and observations from his

external perspective on aspects of the work being undertaken in Edinburgh.

Over the page, his fourth note is headed "Why did fractionators in Scotland and England take different decisions on heat treatment of Factor VIII?" Obviously, we'll be hearing from Dr Foster directly next week about the Scottish decision-making in that regard, and we'll look in more detail this afternoon or tomorrow morning about the direction taken by English fractionators. That's Dr Smith's account, in any event, of his understanding of why there was a different course taken.

And then his fifth note at page 23, towards the bottom of the page, is headed "Clinical trials of 8Y". Self-explanatory. That's a short narrative account by Dr Smith.

And then the final part of this first statement to the Penrose Inquiry starts on page 26. You'll see it's headed "Some remarks on specific sections of the preliminary report". And then the paragraph number that are there listed are the paragraph numbers in the preliminary Penrose report, and Dr Smith sets out some elements of agreement, disagreement, or additional observation. There are a couple of passages in that I might come back to at a later stage.

The second statement which Dr Smith provided to the Penrose Inquiry is at PRSE0004368. This was a statement dated 29 August 2011, and this addresse the Penrose Inquiry's topic C3, which was hepatitis C and viral inactivation in the period 1985 to 1987. And you'll see, again, he set out on this first pag that his contribution was in three parts. The firs was responses to the Inquiry's specific questions, the second was a further note authored by Dr Smith, his note 6, and then the third were annotations on a chronology that had been produced by the Penrose Inquiry. And if I just show you what they are because, again, we might need to come back to some of this. If we go to the next page, you'll see there the first part of Dr Smith's response to the Penrose Inquiry. And if we go to the bottom of the page, you'll see this time it's in slightly fainter print but italicised, that we have Dr Smith's answers to observations on the matters being raised by the Penrose Inquiry. It's a bit clearer if we go to th next page. So the italics represents what Dr Smith was saying by way of response.

If we go over to page 8, we see there Dr Smith's sixth supplemental note. The topic of this note wa "Collaboration between PFC and PFL/BPL in the perio

1981-1987", and I'll be coming back to some aspects of that.

Then the third part of his response on this occasion to the Penrose Inquiry is a separate document. It's at PRSE0002057. You'll see it's headed "Dr Smith's comments on C3, viral inactivati on chronology", so it's a chronology compiled by the Penrose Inquiry. Dr Smith's comments on some items in the chronology are shown in italics. And there wil be a couple of those, his specific comments, that I 'll want to come back to in the course of presentation.

As I indicated at the outset, Dr Smith also gave oral evidence to the Penrose Inquiry. I'm not proposing to go to the transcripts of his oral evidence, but the dates of his oral evidence were 1 and 2 November 2011. I've already given the refere nce numbers. For the most part, his oral testimony doe not add significantly to what he had already told t he Penrose Inquiry in writing, although obviously ther were aspects of his written statements that were expanded.

And then, finally, in terms of his written material, we have the statement to this Inquiry. W don't need to put it up on screen for present purposes, but the principal issues addressed in his

statement to this Inquiry are as follows, and I'll be looking at all of them in the course of the presentation: knowledge of risk of viral transmissi on, which is pages 9 to 20 on his Inquiry witness statement; heat treatment, pages 20-40 of the Inqui ry statement; issues relating to pools and restricted pool trials, pages 41-55 of his Inquiry statement; and self-sufficiency, which he addresses in pages 55 to 61 of his Inquiry statement. So we'll look at some aspects of those -- of his evidence in the course o the afternoon or tomorrow morning.

So against that introduction, which I hope will enable both you, sir, and those who are listening a nd in particular perhaps recognised legal representatives, to navigate their way around the various different forms in which we have evidence f rom Dr Smith.

I'm going to turn to the first theme that I wanted to address, which is that of self-sufficienc and what Dr Smith had to say about self-sufficiency in his various statements.

Now, as a chemist and scientist, the achievement of self-sufficiency for England and Wales was not t he principal focus of Dr Smith's work. Nonetheless, a a fractionator who worked in both Scotland and

England, he had a perspective to offer, and it's ri ght to note he was also a member of a working party on self-sufficiency in blood products set up by Dr Gunson. And we can see that if we look, first o all, at CBLA0000016_034. This is back in the 1990 draft proof of evidence. If we go to paragraph 110 , page 50. This was in the context of the section of his statement in which he comments on particular documents.

Dr Smith said this:

"At the time I sent this memorandum, Dr Gunson was about to become a ministerial advisor on blood transfusion, and he set up a working party for self-sufficiency in blood products. One of its tas ks was to consider how to increase the amount of plasm available to the fractionation centre. The idea wa that blood was taken from more donors, and a higher percentage could be used as components. That committee, of which I was a member, took a year or so to report. One of our tasks was trying to predict the amounts of plasma that would be required in order t achieve self-sufficiency in Factor VIII. There was some disparity between the plasma needed for Factor VIII production and other blood products, such as albumin on the one hand and the need for red cells on

the other."

Then he talked about the process of plasmapheresis. He said:

"At the time I wrote this memorandum, Dr Gunson was setting up trials on plasmapheresis and made a number of visits to Europe to see what the Europeans were doing. Although at the time plasmapheresis seemed a very expensive way of obtaining plasma, the memorandum does show that the NHS and DHSS were determined to set realistic goals for Factor VIII and to adopt measures which would achieve those goals. Drs Gunson and Robinson were the more energetic of the Haemophilia Centre Directors at that time ..."

And that's obviously an error because they're Regional Transfusion Directors, not Haemophilia Centre Directors.

"... and not all of the Directors were enthusiastic about introducing plasmapheresis simply in order to collect plasma for FVIII."

So that's an observation from the 1990s statement.

In terms of Dr Smith's own involvement with this working party, there are two documents just to show you.

The first is CBLA0001313.

This is a memo from Dr Smith to Dr Lane, March 1981. We see the heading there "working party for self-sufficiency in blood products". And Dr Smith is observing that Dr Gunson has put Dr Smith down to address problems relating to albumin and anti-D as well as coagulation factors.

If we just go over the page, we get a sense of what Dr Smith's involvement in the working party may have been. The heading on the document is "Information Required by Working Party", and then we can see, in relation to the information that Dr Smith is being asked to provide, paragraph 4.1.3, "Volume of plasma required for fractionation". That's against Dr Smith's name.

If we go further down the page to 4.1.5:

"Production aspects:

"(a) Types of Factor VIII preparation ...

"(b) Presentation of raw material ...

"(c) Capacity for preparation of albumin products after 1982 ..."

Again, Dr Smith is being asked to provide information in relation to that.

Then if we go to the next page, we can see he's down to provide information -- at the top of the page -- on agreed standards for starting material and

finished products.

And then, towards the bottom of the page, "Phasing of increase in plasma supplies", paragraph 4.1.8, Dr Smith has been asked to provide information relating to:

"Stocks required for introducing increased development."

And then I don't think I need to show you over the page because that's concerned with specific immunoglobulins.

Then just one further document, CBLA0001377.

So you'll see there this is -- again refers to the working party established by Dr Gunson. This is a preliminary report, and we can see Dr Smith is down as a member of the working party.

If we just look at the very bottom of the page we can see the date of the preliminary report, June 1981. And then over the page there's a summary which continues to the next page. I'm not proposing to go through it. The purpose of introducing this document, apart from so that you, sir, and others, can see that the document exists, is just to suggest that Dr Smith did have some contemporaneous involvement in deliberations relating to self-sufficiency.

If we then go to what Dr Smith said about

self-sufficiency in his statement to this Inquiry.

So if we can go back, please, Paul to WITN3433001.

If we pick it up at page 57, start at the bottom of the page, you will see that the Inquiry asked Dr Smith his views about reasons why the UK did not become self-sufficient, and this was his response:

"The concept of 'UK [underlined] self-sufficiency' is an empty one. Although national self-sufficiency in blood products was strongly endorsed by WHO [and the reference he gives there is the WHO's May 1975 resolution], no-one could claim that the principle, and its consequent responsibilities, were embraced as energetically in England as in Scotland. I believe that, at some decision-making levels, 'illegal Governmental assistance' and 'restraint of trade' were adduced as serious impediments, despite EU's adoption of the WHO position."

The reference there, sir, for your note, is to the Council of Europe Committee of Ministers' recommendation of April 1980.

"At the clinical level, where the other important decisions were made, an influential group of [Haemophilia Centre Directors] saw it as limiting

a clinician's choice of the best product available for his patient; Scottish clinicians, no less fervent for their patients' welfare, seemed to cope with that challenge."

Then he continues again, drawing on his experience of being both in Scotland and in England, and says this:

"Coming from Edinburgh to Oxford in 1975, I was shocked by this lack of appetite for self-sufficiency at a national level. The situation I found in Oxford already provided a worked example of commitment and co-ordination which might have been adopted, with local adjustment, in any of the English Regions. The Oxford [Haemophilia Centre] in Churchill Hospital treated many more patients than average, partly because families with haemophilia migrated to the Centre which, under Dr Macfarlane and Dr Biggs, had always offered more generous treatment from the beginning. Partly, too, because it attracted some of the hardest cases, often from farther afield, including those needing innovative surgery -- also carried out in Churchill Hospital, by Professor Duthie. About 50m from the [Haemophilia Centre], and working under the most trying conditions, Dr Grant and later Dr Gunson at

Oxford [Regional Transfusion Centre] made heroic efforts to provide the fresh plasma for PFL's production of FVIII, all of which went next door to the [Haemophilia Centre]. I was never given a convincing technical reason why, with BPL playing the role of PFL in the Virtuous Triangle [I'll come back to that phrase in a moment], the same could no have been done in every Region, long before the surge in about 1982. Some pointed ... to the possible merits of establishing a National [Blood Transfusio Service] in more than namely."

The references there are to Dr Cash's article in the BMJ in 1987 about the state of the Blood Transfusion Service in England and Wales and some o the responses that followed.

The phrase "Virtuous Triangle" is not one that we've encountered elsewhere. What I have understoo it to be describing is a description of a triangula relationship, an equal relationship between three bodies: the Oxford Regional Transfusion Centre, the PFL in Oxford and the Oxford Haemophilia Centre.

And he is suggesting that that is, as I understand it, a worked example of local self-sufficiency, and he is saying he can see no good reason why that could not have been something

replicated on a wider stage in England and Wales. That's how I read the statement. It's obviously a matter for you, sir, in due course to consider.

SIR BRIAN LANGSTAFF: Yes, the question then is BPL -- he plainly envisages BPL as a national -- that is English and Welsh national -- body, playing the role of PFL So it's giving as much plasma as you can to BPL, BP making the stuff and passing it back.

What's the particular feature about Oxford that makes it successful, in his view, which didn't appl to the arrangements as they were?

MS RICHARDS: This is in one sense speculation on my part, but it picks up upon some of the things that Dr Smith said elsewhere in parts of his evidence.

There was -- he describes this on a number of occasions -- a very close practical working relationship between the three corners of the triangle in Oxford. So Dr Smith described elsewhere weekly, sometimes more frequent, encounters with Dr Rizza. He describes having a much more vivid understanding of the realities of haemophilia treatment than may hav been the case at the BPL or indeed in Regional Transfusion Centres. So it's the closeness of the relationship, the symbiotic relationship between th three, which I think he may be referring to.

Hence possibly the relevance of that last sentence, which is referring back then to the criticisms that we have explored on a number of occasions, sir, about the lack of a cohesive Blood Transfusion Service, the 14 fiefdoms as they've sometimes been described, or the autonomous centres The absence of the overarching national structure or, as Mr Hill was talking about earlier in the week, some form of executive body.

Elsewhere in his evidence, Dr Smith made a point -- I think it's in one of his commentaries in his Penrose evidence -- he made a point of saying, well, the CBLA had no relationship with the Regiona Transfusion Centres and no authority over them.

So it may well be that those are the kinds of matters that he had in mind when he wrote this paragraph. That would certainly be consistent with observations he made elsewhere.

SIR BRIAN LANGSTAFF: And that might go back, I suppose, to the second sentence in that paragraph, after his expression of being shocked, Oxford was a "worked example of commitment and co-ordination".

MS RICHARDS: Yes.

SIR BRIAN LANGSTAFF: So he's looking for commitment and co-ordination which he sees as being absent

nationally. It looks as though that's because he thinks, well, people aren't really -- the heart's not in it, is what he seems to be saying.

MS RICHARDS: Possibly, sir. Certainly -- he's certainly drawing a distinction, on any view, between Scotland on the one hand --

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: -- of which he had obviously some personal experience, and England and Wales. And then he's drawing a distinction between what he sees in Oxford, this "Virtuous Triangle", to use that somewhat curious phrase, and the rest of England and Wales. And those are the words he uses. You're right, sir, "commitment and co-ordination".

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: He then goes on in the next paragraph to say:

"PFC was virtually [so, again, talking about the Edinburgh fractionation plant] always able to meet the core Scottish demand for their F.VIII and F.IX ..."

The reference there, sir, is to a report from Dr Foster to the Penrose Inquiry. We'll be looking at that with Dr Foster next week no doubt.

"England could make the heavily-nuanced claim in 1985 only because so many clinicians were choosing to

buy imported products. The BPL claim ... became progressively more realistic after 1987, due to a better balance between the [Regional Transfusion Centres] and BPL's efforts, and BPL's development of more 'attractive' F.VIII products -- only to see them pre-empted by the UKHCDs' recommendation in 1997 that the UK HC's should use only recombinant coagulation factors, in which BPL had not invested. The vCJD disaster of the late 1990s dealt the killing blow to the regrettably brief co-operation between the RTCs and BPL ..."

SIR BRIAN LANGSTAFF: So, again, you're coming back to the theme of a lack of co-operation?

MS RICHARDS: Yes, absolutely. And then if we go over the page, there are three more paragraphs in his statement which are -- four more paragraphs in the statement on this topic, which it is instructive to read. So paragraph 167:

"From about 1982, the [Regional Transfusion Centres] did all that was asked of them and were no the limiting factor in the provision of F.VIII to [England and Wales]."

So contrasting the position before 1982 with what he perceived around 1982.

Then this:

"Given a suspended death sentence in 1979 [that's no doubt a reference to the Medicines Inspection] BPL had to push the capacity of the old Coagulation Factor plant to its creaky limits until 1987, then began to catch up with demand fairly quickly in the new B.27. Although calculations of demand had varied rather widely, the design capacit of the new Coagulation Factor plant was adequate, and even accommodated several challenging changes of product and processes until BPL ceased to be a national asset. Throughout the 1970s, the [Haemophilia Centre Directors], often with Dr Biggs or Dr Rizza of Oxford as their spokesperson, faithfully kept their projections of demand up to date and ever more emphatic. The upward trajectory of demand, accelerated at times by new concepts such a prophylaxis and home therapy, could at any time hav been extrapolated to the likely date of commissioning a new building, and therefore a decision-making process. We were constantly being reminded that it was not DH practice to spend large sums on 'speculations'. The design of the new BPL Coagulation Factor plant had to take appropriate cognisance of this."

SIR BRIAN LANGSTAFF: Can you just help me with that?

What is he seeing, what does he mean, what practical effect does he see in the sentence:

"The upward trajectory of demand, accelerated at times by new concepts such as prophylaxis and home therapy, could at any time have been extrapolated ..."

That's extrapolating the upward trajectory of demand.

"... to the likely date of commissioning a new building, and therefore a decision-making process."

Is he saying that you can plot where demand is going to go? We know when -- assume you know when you're going to commission a new building, you can plan for the in between and what you use in the in between period, or what's he saying?

MS RICHARDS: He may be saying that. He may be saying that -- he may be saying it could and should have been predicted and therefore reflected in an appropriate decision-making process on the part of the Department of Health, that self-sufficiency was only going to be achieved with an earlier decision to --

SIR BRIAN LANGSTAFF: -- (overspeaking) -- earlier.

MS RICHARDS: -- BPL.

SIR BRIAN LANGSTAFF: Yes.

MS RICHARDS: In broad terms, that is how I had read this

paragraph.
SIR BRIAN LANGSTAFF: I think you may well be right. I mean, there are different ways of reading it.
MS RICHARDS: There are.
SIR BRIAN LANGSTAFF: But I think that interpretation sounds the better. Yours, that is.
MS RICHARDS: Yes. And obviously we can't, I'm afraid, ask Dr Smith --
SIR BRIAN LANGSTAFF: And this is obviously open to submission in due course if anyone wants to submit about it.
MS RICHARDS: Yes, absolutely.
And then paragraph 169, and this I think perhaps may reinforce the understanding of the previous paragraph, he says this:
"The political climate at the turn of the 1980s was not naturally favourable to expenditure in the public service. Once convinced that in fact a modern fractionation service could be a sound investment even in cash terms, considering the high market prices o imported plasma products and the huge advantages of an unpaid donor source, the Government of the day accepted the necessity to make provision. The initial proposal was for private industry to take over the task. BPL was only just kept in public ownership b

"I contend elsewhere that, to prevent infections with HIV and at least staunch the surge of new HCV infections in the next generation, we would have to have had safe products before 1983. Even if heatin had been more than a gleam in the eye in 1982, a 5-year programme of re-building BPL would have to have started in about 1978, not in 1982 as actually happened. The projections of UK need, made about 1975-78 on the basis of Scottish demand, notably by Dr Cash, were not taken seriously in England, excep perhaps by some [Haemophilia Centre Directors]. Th one-off bounty in 1975 by the then Minister for Hea lth ... was spread far too thinly. Very little reached BPL and it did not simulate even ground studies for a building commensurate with the task."
SIR BRIAN LANGSTAFF: So he appears to be saying: well, if they'd listened to what was being said, before 1978 it could have been done by 1983 and might have made a difference?
MS RICHARDS: I think, again, that's a respectable interpretation of what Dr Smith said in these paragraphs in his statement.
So that's Dr Smith on self-sufficiency in his statement to this Inquiry in 2020. If we can then just pick up just one very brief comment in one of the

an alliance of disparate arguments. Time had been lost, but by the end of 1982 the client brief had been fixed and costed, a 'design-and-build' contract - reputed to be the faster track - had been awarded, and detailed plans had been thrashed out with the contractors. I had no further input into the programme thereafter."
SIR BRIAN LANGSTAFF: So he is saying this is far too -- the word "far" is wrong -- this is too late?
MS RICHARDS: That is, I think, a respectable reading of what he's saying. Absolutely. And then essentiall saying: by the time we get to 1982, then, as it were, it's on track.
SIR BRIAN LANGSTAFF: So if you put the two paragraphs together, he's saying: there's Dr Biggs and Dr Rizza, they're constantly updating their projections. If we'd thought about that at the time, we'd have realised much more needed to be done much sooner.
MS RICHARDS: Yes. And it's important to read the next paragraph as well, it's important --
SIR BRIAN LANGSTAFF: And we might have had money to do it?
MS RICHARDS: Yes.
And if we go over the page to paragraph 170 he says this:

Penrose documents.
So it's at PRSE0002057.
We looked very briefly at this document so that we could see what it was earlier, "Dr Smith's comments on [the Penrose Inquiry] C3, viral inactivation chronology".
For present purposes, if we can just look at the bottom of the second page, the entry in the chronology at the bottom of the page for 24 November 1982 refers to a note for a meeting of the CSA -- so Common Services Agency -- Blood Transfusion Service subcommittee, and the Penrose Inquiry has set out i its chronology an extract from that document.
If we go over the page it's just a very brief comment by Dr Smith that may be instructive. So to of the page, it's the written italics:
"It may not have been clear to Dr Cash and others in Scotland at that time that CBLA had only peripheral interest in blood transfusion in England and Wales, and no formal links to the RTCs. CBLA administered only BPL and BGRL."
So it picks up again on some of the hints and suggestions in the Inquiry statement about the organisation and structure in England and Wales.
We'll see, when we look at Dr Lane's draft proof

of evidence at some point tomorrow, Dr Lane deals with the question of self-sufficiency in considerably more detail in his 1990 HIV haemophilia litigation proof

Sir, the second topic, then, is the question of knowledge of risks of hepatitis and AIDS.

Now, obviously we have heard a lot of evidence from clinicians about that. We've looked at a lot of contemporaneous material. Dr Smith's evidence offers the fractionator's perspective.

If we start with hepatitis and go to, again, a 1990 draft proof, so CBLA0000016_034, if we pick it up at page 14, we can see a heading "The target viruses", and this was what Dr Smith said in 1990, looking back, as I read the statement, to the early 1980s:

"Hepatitis B was at the time diminishing in importance because of much better screening (i.e. testing of donations); the impending introduction of vaccination against hepatitis B, and the immunity of haemophiliacs who had already been treated with concentrate and had as a consequence already caught hepatitis B and recovered, leaving them with antibodies against further infection. Most severe haemophiliacs had received substantial amounts of Factor VIII by this time and, having been infected,

would have been immune from future hepatitis B infection. However, fractionators cannot rely on donor screening since one failure through insensitivity of a test or an error might infect 10 haemophiliacs from a single batch. Most Haemophili Centre Directors probably recognised that hepatitis non-A, non-B was by this time a more frequent cause of hepatitis than hepatitis B, but the near 100% infection of first-time recipients with hepatitis non-A, non-B was realised only in 1983 after prospective ALT studies. At that time, the only wa we could test for hepatitis non-A, non-B was throug prospective tests which involved taking serum samples every two to three weeks and testing the level of the transaminase enzyme. If the level was consistently higher than normal, it tended to mean the haemophiliac had hepatitis. Most Haemophilia Centre Directors, Dr Preston, Sheffield, a notable exception, seemed to think that hepatitis non-A, non-B was not a very serious disease ..."

Top of the next page:

"... rarely causing death, hardly ever giving clinical jaundice, and without the late sequelae of liver cancer or cirrhosis seen after hepatitis B."

Pausing there. That's Dr Smith setting out his

understanding of what the clinicians in the field thought about non-A, non-B hepatitis and its seriousness.

He then says, in the next paragraph:

"Fractionators were much more concerned, partly because of earlier awareness of potential product liability cases."

If we then just look at paragraph 37, under the heading "Virus Inactivation" we get more of a sense, then, of what Dr Smith was saying the view of fractionators was. He says:

"From the above, it would be true to infer that fractionators would want to be doing something about hepatitis transmission, but at the time it was not the top imperative and by no means negligent to produce life-saving concentrates which might have unfortunate side effects, but without which a significant proportion of haemophiliacs would otherwise die or suffer severe joint injury. In other words, the risk/benefit ratio in favour of using such concentrates was still perceived as very low."

Now, by whom he is suggesting that was perceived in that part of the paragraph is not clear, and obviously the perception of risk would be very different if you're the patient rather than the

clinician, and maybe different still if you're the scientist.

He then sets out some of the options for ameliorating hepatitis risk. I'm going to come up back to those, because he introduces ideas of pasteurisation and dry heating. But if we then just skip over that for present purposes, go to page 19, he says at paragraph 38:

"It was against this background in 1982 that thoughts were moving towards heat inactivation. As will see seen from the description above, this was only one of a number of potential routes."

Then this, and this is why I'm referring to it now, because it's about the understanding of non-A, non-B hepatitis, he says this:

"It must be remembered that the work was undertaken against the background of hepatitis C ceasing to be of much practical concern, and hepatitis non-A, non-B not yet being recognised for the serious condition it later emerged to be. In the circumstances, virus inactivation whilst desirable, was not an imperative."

So two particular thoughts from this part of Dr Smith's statement. Firstly, of course, it would be a matter for others to make submissions and for you to

make decisions in due course, sir, about whether this perception of non-A, non-B hepatitis at this time was right, even viewed at the time], leaving aside any question of hindsight. We know with hindsight, obviously, it was wrong. And secondly, looking at the extent to which that view of non-A, non-B hepatitis of being not something to worry about too much, even in the early 1980s, what impact that had on the pursuit of different methods of viral inactivation.

SIR BRIAN LANGSTAFF: Another way of putting the same point is to say that if people had thought or, should I say realised, depending which view we want to take, that hepatitis non-A, non-B was a really serious disease, there would have been urgent research, and viral inactivation would have been examined much more energetically than it was.

MS RICHARDS: Yes. And that's undoubtedly, I'm sure, a submission that will be made to you and which you will need to evaluate and look at Dr Smith's evidence as part of the material you look at.

Of course it's only right to observe that the work actually then involved in particular in identifying dry heating, and indeed in finding a method HT3, as Dr Snape describes them, which did inactivate non-A, non-B hepatitis, that is -- well,

Dr Smith, as we will see when we get on to heat treatment tomorrow, describes in some detail in his statements the amount of work that went into that. But obviously, sir, you're entitled to ask the question: if that had started significantly earlier would that have made a difference?

Still on the topic of understanding of hepatitis, if we then go to Dr Smith's statement to this Inquiry, WITN3433001. If we pick it up at page 9, we can see paragraph 29, Dr Smith's evidence.

"In the 1960s and 1970s, viral hepatitis was a threat to both those receiving multiple whole blood donations and to those receiving some products made from pooled plasma. Albumin did not transmit hepatitis following the discovery of protective agents which permitted virus inactivation by pasteurisation. Normal Immunoglobulin prepared by the Cohn cold-ethanol process appeared not to cause liver disease. Fibrinogen was withdrawn from the US market in the mid-1970s because its few indications for use were being replaced by alternative treatments and the risk of transmitting viral hepatitis (interpreted a hepatitis B) was too great.

"Single-donor cryoprecipitate was becoming part of the repertoire of Regional Transfusion Centres."

Again, he's talking about the '60s and early '70s here.

"Before the both of cryo, the fraction used to provide Factor VIII for haemophiliacs was essentially the same as Fibrinogen, except that is was commonly made from fresh-frozen plasma in pools of fewer tha 50 donations. However, the perceived of balance of risk was quite different."

Again, the question of who was doing the perceiving is obviously relevant here.

Dr Smith went on then to set out his own perception of the balance of risk as between treatments that might cause hepatitis and non-treatment, by saying this:

"In untreated, severe F.VIII deficiency, bleeds may be life-threatening or liable to lead to life-altering joint damage, as well as being extremely painful. Even before donation testing for HBV became feasible at the end of the 1980s [sic] physicians would almost always choose to treat haemophilia wit F.VIII, even if all that was available was FFP, rather than rely on palliative measures. They were aware that there was a finite risk of transmitting hepatitis, reflecting the incidence of infection in the donor population. The risk of HBV transmission

did not greatly deter the use of whole blood in general transfusion practice.

"Once screening tests on blood donations had largely eliminated HBV from the blood supply, it wa recognised that recipients of whole blood and of pooled plasma products, particularly first-time recipients, were still at risk of acute river dysfunction. With the advent of reliable testing for HAV in 1974 (following that for HBV in 1972), the agent responsible was judged to be another hepatiti virus, logically called non-A, non-B hepatitis (NANBH). As with HBV before donation testing, the risks of treatment were considered worth taking ...

Again, begs the question: considered by whom? Dr Smith is I think here talking about the perception of clinicians and not that of patients:

"... in both blood transfusion practice and the treatment of haemophilia."

Then this, which sets out his understanding of non-A, non-B:

"A crucial difference was that with the rare exception of acute fulminant disease, non-A, non-B hepatitis was universally considered to be an acute infection producing only relatively mild symptoms o none at all. Since symptoms were most commonly noted

in first time recipients, there was a suggestion that a first infection conferred a degree of immunity. There were few reports of serious chronic disease associated with non-A, non-B hepatitis until the 1980s. In interpreting the perceptions of physicians and patients in this period ..."

And again, the extent to which Dr Smith was in a position to interpret the perceptions of patients may be questionable. He may well have been better placed to have a sense of what physicians thought:

"... I do not wish to imply complacency, but a rational risk-benefit assessment based on contemporary knowledge."

He then in the next paragraph set out his own knowledge of the Edinburgh outbreak of viral hepatitis and the renal dialysis unit in 1969 which we've considered in other hearings.

Then over the page, he says:

"In the late 1970s, certain Factor IX concentrates were reported as carrying a high incidence of non-A, non-B in recipients."

The reference there, which is WITN3433003 -- perhaps we should just go to that. Have we got that, Paul? WITN3433003. If you haven't, don't worry. No. Okay, we don't have that.

What I can tell you, sir, is that in fact that's a publication in the Annals of Internal Medicine fo October 1970, I think, rather than the late 1970s. And there's a letter relating to hepatitis after Konyne. But we can check that.

In any event, going back to the statement:

"In the UK, the incidence of infection from Factor IX concentrates was considered to be less than from Factor VIII concentrates made from the same plasma pools of 500 to 1,000 donations. This comfortable assumption became untenable in 1978-79 when an alarming incidence of non-A, non-B hepatitis, including acute, fulminant fatal disease, was reported in patients receiving Factor IX concentrate for the first time for reasons other than haemophilia B. Such uses became less common, the risk-benefit being unacceptably higher in these situations than in haemophilia B."

He then in paragraph 35 talks about some proposals presented to Dr Lane which I'll come back to.

And then in paragraph 36, he talked about:

"The next blow to fractionators' confidence in their products came with the transmission of acute and sometimes fatal hepatitis, in a group of patients

taking part in the clinical trial of a new BPL intravenously administered immunoglobulin. We were left with the conclusion that our only product safe from hepatitis was pasteurised albumin. There was no reason to believe that other blood-borne viruses would not arrive in the blood supply to compound the problem. It would mean the end of our ambitions to provide a comprehensive array of plasma products fo all who clearly needed them, from the blood generously provided by the donors of our own country. It's very doubtful whether the production of albumin alone would justify the continuation of public-service fractionation. Inevitably, our failure to provide safe concentrates would invite the arrival of products from other countries and other donor populations whose viral status was almost certainly inferior to our own."

So the two events which Dr Smith described here as "Blows to fractionators' confidence" were not discoveries of hepatitis in haemophiliacs but in incidence of non-A, non-B hepatitis in those receiving Factor IX concentrates for other reasons, and then the transmission of hepatitis to a group of patients involved in a clinical trial of an immunoglobulin.

And then if we just go to the bottom of the

page, he was asked the question, perfectly understandably, says he wasn't sure what it meant. And then, just in terms of his answer, says this:

"Fractionators and clinicians were not withholding any knowledge from each other. They were receiving the same, sometimes conflicting messages, eg about long-term liver damage associated with chroni non-A, non-B infection at the same time, but the impact was different. Fractionators were saying, 'We know that it keeps getting harder to justify using large pool coagulation products, and we are working to make your decisions easier, but there are gaps in our basic knowledge which make it difficult to get a toehold on testing and inactivation of non-A, non-B hepatitis'. Meanwhile, clinicians had to make hard daily choices based on their own interpretation of the danger and make risk-benefit assessments on individual patients. Most would continue to recommend or use concentrates, aware of the risks. Fractionators have no place in telling clinicians how to make these choices."

And then you will see in the next question that was posed by the Inquiry to Dr Smith, reference was made to a description he gave in his Penrose evidence of Dr Preston and others as "Cassandras". That's

a reference to the figure from Greek mythology whos accurate prophecies were not believed. And he was asked the question:

"Do you have a view on why the opinions of Dr Preston and the other Cassandras were not given more weight in the 1970s and early 1980s?"

And he said:

"The term "Cassandras" was not intended to be pejorative. As I recall, Cassandra was ultimately right in her predictions but received scant thanks for it. Our Cassandras faced much opposition but their fate was harsh."

Then he said this:

"I recall lively debates in general and special conferences, as well as the medical journals, about the justification of liver biopsy in haemophiliacs and pathologists' differing interpretations of what these samples were claimed to show."

And then the reference there, sir, is to Dr Preston's 1978 study:

"Most clinicians treating haemophilia were not seeing unusual incidences of late symptomatic liver disease, perhaps because they had not been alerted to looking for it systematically. The ultimate consensus was that the majority of those infected with non-A,

non-B hepatitis developed chronic hepatitis, and about 15 to 20% of those went on to have cirrhosis and other serious liver disease, usually after a delay of many years. Statistically, however, the largest studies indicated that morbidity and mortality from liver disease and haemophilia did not diverge significantly from those of the general population until combined HIV/HCV infections later became common."

If we just go back to the previous page and the reference there to "lively debates and general and special conferences in the medical journals". I should note that Dr Smith was present at the Glasgow symposium that took place in the autumn of 1980. You'll recall, sir, we've looked at it with other witnesses. It was the symposium on unresolved problems in haemophilia in which there was -- and there's a record compiled by Dr Forbes and Dr Lowe of the contributions, both in terms of papers in the debate, and there was much discussion from Dr Preston, Dr Triger and others, about issues relating to hepatitis and liver disease. So Dr Smith was at that meeting.

It's also relevant to note that either Dr Lane or Dr Smith quite often attended meetings of either the Hepatitis Working Party or meetings of the UK

Haemophilia Centre Directors in the early part of the 1980s. So Dr Smith, for example, was present at the Haemophilia Centre Directors meeting in September 1980, October '81, and then again in 1984 autumn 1984, and February 1985.

Dr Lane was present at Hepatitis Working Party meetings and Haemophilia Centre Directors meetings for the period 1980 through to 1983. So both Dr Lane and Dr Smith would have been aware of and listening to some of the discussions and debates that went on amongst the Haemophilia Centre Directors and other clinicians.

So that's Dr Smith's evidence in relation to his understanding of hepatitis. Just perhaps two further references before we end for today.

In his evidence to the Penrose Inquiry, it may be more of the same but still, I think, relevant to note. If we go to PRSE0004045, this was the first statement, first written statement to the Penrose Inquiry. And if we go to page 4, the paragraph that's in bold print and italicised under the sentence "I could deduce two main threads" begins this:

"It is not sufficiently realised, even in the PR [the preliminary Penrose report] how little pressur there was from the haemophilia treaters and patient

to take non-A, non-B hepatitis seriously in this period before 1983."

Pausing there. Again, if we think of the position of patients, it's not clear to me the basi upon which Dr Smith would have been able to reach any views about the position of patients. And, of course, again, it begs the question of the pressure that might or might not be applied by patients who depend upon the information that their own clinicians are or ar not giving to them.

But in any event, Dr Smith was perhaps in a position to have a sense about what haemophilia treaters were saying. And he emphasises there:

"The absence of pressure to take non-A, non-B hepatitis seriously."

He goes on to say:

"Most clinicians would have assumed that NHS concentrates were much safer from non-A, non-B hepatitis than commercial concentrates because of the unpaid donor source. The view that non-A, non-B hepatitis could have serious long term sequelae was not widely held. Hepatitis B was thought to have been tamed by donation testing. There was a vaccine on the near horizon (1984). It really took AIDS in 1983-4 to get the attention of the majority on to blood-borne

viruses."

Then he contrasts that with fractionators. So that paragraph is dealing with clinicians:

"Fractionators were much more concerned about non-A, non-B hepatitis, but this was always a very recalcitrant viruses with no convincing markers unt il right at the end of the decade. We had very few to ols at our disposal, especially for proving whether any attempt at inactivation had succeeded. We were als misled by persistent claims that there might be mor than one non-A, non-B hepatitis virus."

Then he goes on to talk about some of the work done at PFC which we'll no doubt be exploring with Dr Foster next week.

And then if we go in this same document -- sorry, if we could have that back on screen -- to page 28, I think. Sorry, if we can start with page 17. So this is one of Dr Smith's supplemental notes. The first bullet point there is:

"Non-A, non-B hepatitis was widely perceived as a mild transient illness with only very rare seriou sequelae."

And that's his first bullet point in a note addressing impediment to the development of heat treatment against non-A, non-B hepatitis. In other

words, non-A, non-B hepatitis wasn't regarded as necessarily sufficiently serious to bring it higher up the agenda of the fractionators.

And then the reference to Cassandras is on page 28, just over halfway down the page, paragraph 11.95. This is Dr Smith's commentary on the Penrose report, and he refers to several Cassandras being already in the ring: Preston, Mannucci, ie, those saying, "No. Non-A, non-B hepatitis is more serious than you're giving credit for."

Sir, I think that's probably, given the time, a convenient point to finish. There are a handful of contemporaneous documents relevant to hepatitis that I want to look at before turning to AIDS, but it'll take more than couple of minutes, so perhaps we could pick that up in the morning.

SIR BRIAN LANGSTAFF: Okay. Well, let's do that and come back at 10.00. 10.00 tomorrow.

(4.31 pm)

(Adjourned until 10.00 am the following day)

I N D E X

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supply and demand for blood
products in England and Wales
by MR HILL

Presentation to the Inquiry about 95
the work and evidence of
Dr James Smith (responsible
for product development at the
Plasma Fractionation
Laboratory 1975-1992 and Blood
Products Laboratory 1979-1982
and formerly of the Protein
Fractionation Centre,
Edinburgh) by MS RICHARDS

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