

Wednesday, 30 March 2022

(10.00 am)

DR TERENCE JOSEPH SNAPE (continued)

SIR BRIAN LANGSTAFF: Good morning, Dr Snape.

A. Good morning, sir.

SIR BRIAN LANGSTAFF: That means you can hear me. You can see me as well?

A. I can see you. I can hear you. Thank you very much.

SIR BRIAN LANGSTAFF: Good. Well, you now, I think, have the same opportunity with Mr Hill.

Questions by MR HILL

MR HILL: Dr Snape, we are going to start today by looking at non-A, non-B hepatitis. Could we have on screen, please, Sully, WITN3431001 page 52. This is from your witness statement, Dr Snape, paragraph 141. You wrote there, and I quote:

"I am neither a physician nor a clinical virologist, but I became aware by the mid to late 1970s (from Oxford Haemophilia Centre meetings, literature reviews and reports of non-A, non-B hepatitis from PFL's relatively small pool Factor VIII and Factor IX concentrates) of post-treatment reports of an apparently mild form of hepatitis with no apparent serious sequelae and for which hepatitis A hepatitis B and obstructive jaundice had been excluded

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Q. Did you take steps to do that, both at PFL and BPL?

A. I can't speak for BPL in that timeline. We certainly took steps to do it at PFL. Again, it was pre computer technology, but we set up a system of 7x5 cards and flagged reports of apparent non-A, non-B jaundice on those cards, and each card -- when a card reached four flags from patient reports, then that would be -- information would have been passed on to Jean Spooner who was secretary to the -- to John Craske working party.

Q. To the best of your knowledge, in the mid to late 1970s, do you recall discussion taking place about potential long-term sequelae to non-A, non-B hepatitis?

A. Not at that time, no. I became more aware of such discussions as we progressed into the early '80s -- '81 through '82.

Q. We will come back to those discussions in a second. I just want to quickly refer to paragraph 144 of your statement. I don't ask for it to be brought up, but you say there that there was some evidence at that time that voluntary unpaid donor sources may be a lower risk, but they were certainly not risk free. Is that a reflection of your position in the late 1970s?

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as possible causes."

That is then a reference to your awareness from the mid to late 1970s of non-A, non-B hepatitis; is that right?

A. That's correct.

Q. Why did you think at that time that it was an apparently mild form of hepatitis?

A. It would be wrong to talk about it being my thinking. I think my thinking reflected what I heard being reported to me from physicians. Not to say that they were dismissive of the apparently mild hepatitis, lack of sequelae, but that in comparison with the change that treatment with clotting factor concentrates brought about, these were, I believe, seen as acceptable side effects, short-term side effects.

Q. The physicians with whom you were having these discussions, were they principally from the Oxford Haemophilia Centre?

A. From the Haemophilia Centre. I also recall a fair stern lecture from Professor Arie Zuckerman at the time who was recommending that we didn't -- that we established follow-up in the sense of recording which batches reflected patient sequelae and that we reported those to John Craske, to the working party, when it was established.

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A. Yes. I think we had to regard them as clearly not risk free because there were the reports that we received of jaundice post-treatment. They couldn't be risk free.

Q. Later, what did the research show about the comparative safety of UK and US factor concentrates, in terms of non-A, non-B infections?

A. There was a --

SIR BRIAN LANGSTAFF: Just a moment. Isn't that really a question for me from the literature? I think it might be appropriate to ask Dr Snape what he knew at the time about it.

MR HILL: What did you know, come the, say, mid-1980s about the comparative risk of UK and US fractionate concentrate?

A. At the time, if I wasn't attending the Haemophilia Centre Directors meetings or the Hepatitis Working Party, I was certainly receiving information back from them. And, for me, there was an interesting volte-face over a very short period, about 11 months, from the Hepatitis Working Party in autumn 1981, when the position was still being held that NHS concentrates were less likely to transmit to previously unexposed donors. And 11, 12 months later at the Hepatitis Working Party in 1982, the position

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had changed, and the perspective then or the perception then was that there was pretty much equal likelihood of transmission from NHS concentrates and commercial concentrates. And that was then firmed up not much later by the paper from Peter Kernoff and this group, confirming 10 out of 12 transmissions to -- by NHS concentrates to previously untreated patients.

Q. I would like to take you to a memorandum that went in under the name of Dr Lane to the Social Services Committee of the House of Commons on 25 March 1987. It's at LDOW0000247.

If we could have the first page of that, first of all, please. We can see there that this is the formal report from the Committee. We can see that the minutes of evidence are from 25 March 1987. Those attending were Dr Harold Gunson from NBTS; and from BPL, Dr Lane, Mr Crowley, you and Dr Smith. And then Professor Ian Kennedy also gave evidence there.

Could we turn, please, to page 6 of these minutes. This is the first page of a memorandum submitted by Dr Lane entitled, "The manufacture of therapeutic products from human plasma."

Were you involved in producing this memorandum for the House of Commons?

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perspective of whether NHS concentrates were more or less likely than commercial concentrates to be responsible for transmission. But that doesn't mean that even in autumn '81 it wasn't being taken seriously.

Q. Do you know the reason why Dr Lane selected that date by 1981?

A. I would imagine that he would have been reflecting on the minutes, which I'm sure he had and referred to, of the Hepatitis Working Party, chaired by John Craske.

Q. Dr Lane says there that that was a view that was shared by clinicians and BPL scientific staff alike. Are you aware of any difference in view about the seriousness of non-A, non-B between fractionators and clinicians at that time?

A. The only difference I would point to is that it seemed to -- my impression was that although physicians treating haemophiliacs, and also reflecting the views of haemophiliacs themselves, saw that non-A, non-B hepatitis transmission as less of a threat than the consequences of not treating patients to deal with joint bleeds and other serious bleeds.

As fractionators, we had a different perspective. Our job was to try to reflect on potential risks in our products and to put in place

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A. No. Not Richard Lane's paper, no.

Q. Did you see it before it was submitted?

A. I'm sure I would have done. It wouldn't have been usual for Dr Lane to put me in the position of attending a hearing like that and not having prepared me. I don't remember seeing Dr Gunson's paper, but I am sure I must have seen Richard Lane's paper.

Q. Presumably, Dr Lane would have taken some care about the creation of a paper, given that it was going to be presented to Parliament?

A. I'm sure he did.

Q. Could we go, please, to page 8. If we could just look at the paragraph starting "By 1981" under the subheading "Focus on factor 8Y".

At the top of the screen, you can see that paragraph. It reads as follows:

"By 1981, awareness of the serious nature of non-A, non-B hepatitis in haemophiliacs was shared by clinicians and BPL scientific staff alike."

First of all, would you agree that, by 1981, awareness of the serious nature of non-A, non-B hepatitis was shared by BPL scientific staff?

A. I would agree that, certainly as fractionators, we took it seriously. My earlier comment about the shift from autumn '81 to autumn '82 was about the

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mechanisms to limit those risks or eliminate those risks. Now, virus transmission was clearly a risk, and it was presenting itself.

Whilst we may have been in the beginning of putting together thinking on virus inactivation and virus elimination, what we were doing is looking at issues like donor selection, like our working practices that would give us the basis for producing safe and effective products.

Q. We heard of Dr Smith's evidence last week, where he said that fractionators were much more concerned than clinicians about non-A, non-B in the early stages, partly because of earlier awareness of potential product liability cases. The reference for that is CBLA000016_014.

Is that a view which you would agree with?

A. I would agree with it. I would say that Dr Smith was especially sensitive to issues of hepatitis resulting from fractionation because of the outbreak in the Edinburgh Royal Infirmary whilst he was still there, before the building of the new PFC. He did not treat hepatitis of any form trivially.

Q. I would like to move on now to pool sizes.

If we could go, please, to WITN3431001, page 86.

This is back to your statement. Forgive me,

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Sully, I've given you the wrong page number. It's page 58.

I'm just going to read paragraph 161 from your statement to you:

"Since the 1970s ..."

It's the top of that page, please, Sully.

"160. Since the 1970s it has been argued (and largely accepted) that increased pool size and the use of paid donations carry greater risk of infection than the use of small pools from voluntary unpaid donations. The protection afforded by the use of unpaid donations is directly translated to recipients of single donor products (unless the recipient is unfortunate enough to be treated with the one, unrecognised infective donation) but greatly diminished when donations from many donors, even voluntary unpaid donors, are mixed and used in one pool to produce coagulation factors. In the absence of reliable screening tests (and there was none for the entity causing NANBH in the early/mid-1980s) the larger the donor pool size, the greater the risk of unwittingly including an infective donation. Since pools had to be above a certain size for cost-effective production of the amounts of concentrate demanded for treatment of affected

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was the failure at the time, of the paid donor system to exclude donors with life-style risk factors."

Do I take it correctly from what you have said there that there was a recognition that, as a general proposition, and all other things being equal, the greater the pool size, the greater the risk of it containing an infected donation?

A. I should qualify it, in the sense that once you exceed the pool size -- let me start again.

For donor plasma of the same quality, ie for a properly qualified donor, the pool size as a risk increases as -- risk increases as pool size increases. There comes a point when the -- if, for example, we are talking about one in 100 donors being infective for non-A, non-B hepatitis or, for that matter, hepatitis B, then once you exceed the 1 in 100, certainly once you exceed the 500 that we initially specified at PFL, the thousand donors that we moved on to after that, then there is a diminishing return in terms of the risk of infection.

I think what I was also trying to say, perhaps a little clumsily, is that if donor characteristics were not controlled, if the selection of donors didn't deliberately exclude high risk donors, then I wouldn't say that pool size is irrelevant, but if you have

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individuals, and to achieve the range of antibodies required for some immunoglobulin preparations (pool >1000 donations specified), the risk of NANBH infection was significant. Risks associated with increased donor pool size, or donor selection issue implicit in the use of paid donor plasma, were most significant for coagulation factor concentrates, which enjoyed neither the protection afforded by the presence of neutralising antibodies (intramuscular immunoglobulins), nor the benefit of in-process virus inactivation, either deliberate (albumin) or serendipitous (immunoglobulins).

"161. Prior to the advent of effective virus inactivation methods, there was therefore a significant risk of infectivity from all coagulation factor concentrates made from pooled plasma (including those products made by BPL). The incidence of infection would have been determined by the amount of virus in the product being administered. There was a consensus view (in the UK at least) that coagulation factor concentrates made from unpaid (UK) donors carried a lower virus burden than those made from donations from paid (US) donors. Certainly, US fractionation pools were much larger (up to 20,000 donations used in a plasma pool), but more important

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a significant number of donors who are contributing regularly, many times a year, to a pool, then that pool is more infective than a pool of well qualified donors who are included perhaps twice a year in a plasma pool.

Q. You mention in those paragraphs the balance that the fractionator has to strike between pool size and efficiency. I wonder if you can just expand on that a little for us, please.

A. Yes. I mean, as -- I'm not going to use the term "pool size" -- as batch size decreases then the process is less efficient. Less efficient because of the fractionation equipment that's used, because of losses in process. Also less efficient because of the proportion of samples. That doesn't diminish -- predictably -- that the sample that's taken for quality control testing, to approve a product for release. Including, as we saw yesterday, the submission of samples to the official control authority.

Q. Could I just ask you to explain why you have chosen the term "batch size" rather than "pool size"?

A. Because it is batch size that determines efficiency. It is more efficient -- you can achieve greater efficiency by manufacturing a 2,500 kg batch, kilos of

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1 plasma batch, than processing ten 250 kg batches.
 2 Those numbers have nothing to do with donor pool size.
 3 They are simply the mechanics of the fractionation
 4 process and the sampling and testing that follows from
 5 it.

6 Every one of those 250 batches carries a penalty
 7 of a -- an irreducible penalty of somewhere around 20
 8 to 25 vials of final product that has to be sacrificed
 9 for sterility testing, for pyrogen testing, for all of
 10 the potency testing that happens, and add to that then
 11 the vials going off to the official control authority.
 12 So it's -- that's batch size that's driving efficiency
 13 there.

14 **SIR BRIAN LANGSTAFF:** May I just ask a question?

15 What do you understand by "efficiency" in this
 16 context? Because efficiency can have many different
 17 meanings, perhaps depending upon the desired result.

18 **A.** You're quite right, sir. Efficiency in the context
 19 that we are talking about -- what I was referring to
 20 was what proportion of the product -- of the
 21 Factor VIII in the however many donations in the
 22 starting pool can be recovered into vials and
 23 presented to the patient for clinical use.

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

25 **MR HILL:** Does it follow from what you have just said that

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1 **A.** I am sure I would have been. I don't remember
 2 particular -- and I certainly can't quote you
 3 particular minutes of meetings where they were
 4 discussed.
 5 **Q.** You say the decision would have emerged from the
 6 meeting. Ultimately at a meeting somebody is going to
 7 have to say what they think the answer should be.
 8 Whose voice would carry the most weight at those
 9 meetings?

10 **A.** Obviously the chief executive's voice would carry most
 11 weight, but I think at the time our chief executive
 12 was listening very carefully to the guidance that he
 13 got from the production team, from R&D and from QA.
 14 You also have to remember that those discussions
 15 were going on not in advance of building the factor
 16 but while the factory was being built, and whilst the
 17 facility -- where -- for example, Factor VIII, when
 18 that facility was being created, there would have been
 19 influences in terms of what could be changed, what
 20 could be changed without delaying the availability of
 21 product from that factory.

22 **Q.** When you say the chief executive, do you mean the
 23 chief executive of CBLA?

24 **A.** The meetings that I'm thinking of, yes.

25 **Q.** So that would have been --

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1 if a system had been put in place for fractionating
 2 smaller pool sizes at BPL, then the result would have
 3 been less Factor VIII concentrate produced at BPL?

4 **A.** Yes. That's my opinion.

5 **Q.** It would then have been for the clinicians to decide
 6 what they were going to do to make up any shortfall
 7 is that right?

8 **A.** It would have been, but before that it would have been
 9 our job, the fractionators' job, to decide what
 10 represented the greatest risk: making product from
 11 large manufacturing batches, whether that created
 12 a situation in which the product was less safe than
 13 the lesser amount of product for small batches.

14 **Q.** That was a decision for the fractionators at BPL?

15 **A.** In discussion with the agencies. And, of course, one
 16 would have to involve the clinicians in that
 17 discussion, one would have to involve the control
 18 agents in that discussion, because we all had
 19 contributions to make.

20 **Q.** Ultimately whose decision was it to decide on the size
 21 of the pool sizes at BPL?

22 **A.** I believe that that decision came out of meetings in
 23 the executive committee and the R&D working party.

24 **Q.** Were you present at those meetings where pool sizes
 25 were discussed?

14

1 **A.** But not at CBLA meetings. The chief executive,
 2 Bernard Crowley, of CBLA would have been present at
 3 our meetings.

4 **Q.** The CBLA was created, I believe, in December 1982, so
 5 from that period on you have described the situation.

6 **A.** Yes.

7 **Q.** Are you able to assist with how those decisions were
 8 taken firstly at BPL, before the establishment of the
 9 CBLA in 1982?

10 **A.** Yes, before 1982, those discussions would have taken
 11 place in fora convened either by Richard Lane or for
 12 Richard Lane. And they would have included people
 13 like Dr Smith, myself, and the head of R&D, Mike
 14 Harvey.

15 **Q.** Who would be informed about the decision to increase
 16 the pool size?

17 **A.** From my perspective, the decision would always have
 18 been taken in discussion with Richard Lane, as both
 19 director and medical director, but if you're saying:
 20 who was the decision communicated to, once it was
 21 taken, the answer is: I'm not sure -- I don't think
 22 I can answer it quite so easily.

23 There was a -- for a long period, as you know,
 24 as you saw with the paper last week, we were putting
 25 pool size number of donations limit on the label.

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1 Whether that was a good idea or not, from my
 2 perspective it at least allowed physicians and
 3 patients to see what the pool size was. Did we
 4 consult with physicians and patients? No, we didn't,
 5 except through the Hepatitis Working Party once
 6 a year.

7 **Q.** Am I right in understanding, then, that the decisio
 8 would be taken within BPL, within those structures
 9 that you have said, that there would be no formal
 10 input from clinicians or patient groups about the
 11 decision for the pool sizes?

12 **A.** There would have been no formal input, but we were
 13 listening to them.

14 **Q.** I'm just going to take you to one document from
 15 a little bit later in the piece, DHSC0002303_027.
 16 This is from June 1986. And important to remember
 17 that it is from that period and not earlier, and it is
 18 a letter that you wrote to Dr Alison Smithies of th
 19 Medicines Divisions of the DHSS. What you wrote is
 20 this:

21 "Maximum donor pool size for coagulation factor
 22 concentrates.

23 "I am writing to advise you of a proposed change
 24 in donor pool size limitation for BPL (and PFL)
 25 coagulation factor concentrates. It is proposed to

17

1 "In taking this decision, we were mindful of the
 2 terminal heat treatment of coagulation factor
 3 concentrates from such pools ..."

4 So I believe -- we were certainly at the point
 5 when we were enacting whatever was necessary to bri ng
 6 about the label change, for example. So, yes, I guess
 7 it's polite language. Thank you, sir.

8 **Q.** Do you know if this form of -- this way of informin
 9 the DHSS, by writing to them, was a new practice, o
 10 had something like that been in existence before?

11 **A.** I'm not aware of all of the situations in which -- and
 12 it would have been typically Richard Lane who would
 13 have made communications like that. I can't remember
 14 whether Richard Lane asked me to communicate that
 15 information to Alison Smithies. It's unlikely that
 16 I would simply have taken it on myself to write. It's
 17 more likely that my writing followed up a discussio
 18 with Richard Lane in which he probably would have said
 19 something like: I think we should let Alison Smithies
 20 know --

21 **Q.** If we could --

22 **A.** -- but I don't think it was standard practice.

23 **Q.** Sorry, I cut across you there. You said -- I think
 24 you said:

25 "I don't know if it was a standard practice."

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1 increase the maximum number of donations to be pooled
 2 from 10,000 to 25,000 plasma donations. In taking
 3 this decision, we were mindful of the terminal heat
 4 treatment of coagulation factor concentrates made from
 5 such pools and the fact that any increase beyond th
 6 already large 10,000 donor limit is probably not
 7 significant.

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

10 First question following on from that: am
 11 I right to read this as BPL informing the Medicines
 12 Division of the proposed change, not asking for
 13 permission?

14 **A.** Yes, you are correct in that.

15 **SIR BRIAN LANGSTAFF:** It does --

16 **A.** The decision had already been taken.

17 **SIR BRIAN LANGSTAFF:** It does refer to it as a proposal
 18 and not as a decision. Is that just polite language?

19 **MR HILL:** It is the first line, "proposed change".

20 **A.** Yes --

21 **SIR BRIAN LANGSTAFF:** And "proposal" is the last word
 22 before the "best wishes".

23 **A.** Perhaps it's polite language. I believe we had
 24 already taken the decision. I mean, in the -- my
 25 third sentence:

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1 **A.** I don't know if it would have been -- I don't belie ve
 2 it would have been standard practice for the
 3 Department to be notified of every change. But thi
 4 is a fairly significant change, in the sense that i
 5 happened after a conscious decision to review risk,
 6 having introduced terminal heat treatment, but also
 7 taking into account the fact that we were already a
 8 10,000 donors, well beyond the limit when there wou ld
 9 have been -- even with good donor screening, there
 10 would have been infected donations in the pool. That
 11 was the purpose of the terminal heat treatment.

12 **Q.** And is that why you say that the already large 10,000
 13 donor limit is -- increased beyond the already larg
 14 10,000 donor limit is probably not significant?

15 **A.** Yes.

16 **Q.** Just so that we square this off. If we could have on
 17 screen, please --

18 **SIR BRIAN LANGSTAFF:** May I just ask: what would have
 19 happened if Dr Smithies had written back and said,
 20 "Well, I'm sorry. I'm not sure I agree with this
 21 proposal or this decision"?

22 **A.** We would have -- sorry, sir.

23 **SIR BRIAN LANGSTAFF:** Or this decision, whichever --
 24 however she read the letter.

25 **A.** We would have had to take it back to the drawing board

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1 and either explore ways of convincing the Department
2 that we were right and they were wrong, or, I presume,
3 comply and not increase the donor pool size.

4 **SIR BRIAN LANGSTAFF:** So the ultimate authority for
5 an increase in the pool size, once reported at least
6 to the Department, was the Department in your view.

7 **A.** From my perspective, I would not have proceeded in
8 contravention of the Department's wishes. It's quite
9 possible that Richard Lane and the CBLA would have
10 taken a stronger line. I can't comment on that. But
11 I'm sure they wouldn't have done it without further
12 discussion with the Department.

13 **Q.** Do you recall any incident where there was such
14 pushback from the Department?

15 **A.** Off the top of my head, no, but if it occurs to me
16 before the end of today, I'll let you know.

17 **Q.** Thank you. Just so that we are aware of some of the
18 background of your letter and to place it within
19 context, could we have on screen, please, CBLA0004791.
20 This is a minute from the same day, 20 June 1986, from
21 you to Mr Prince, Dr Smith and copied to a number of
22 other people. It states:

23 "Pool size limitation for heat-treated
24 concentrates.

25 "Dr Lane has agreed that the maximum pool size

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1 a longer time still before the process had happened
2 So this wasn't a -- it certainly wasn't a quick
3 decision. It was a decision that had been long in
4 discussion and thinking about.

5 But, yes, Richard Lane would have been the one
6 to underwrite changes like that.

7 **Q.** You've spoken in your evidence about how once
8 a certain limit was passed, then the protection
9 offered by small pools was lost, and you did that by
10 reference to knowledge of hepatitis viruses.

11 What thought, if any, was given to the risk
12 posed by unknown viruses, and how did that impact upon
13 decisions on pool size?

14 **A.** Well, I think you have it already. Non-A, non-B
15 hepatitis was an unknown virus. What we were seeing
16 was the consequences of the presence of an unknown,
17 unidentified, unmeasured, untested virus. So, you see
18 evidence of a risk, you respond to that evidence of
19 risk and set out to reduce the risk.

20 I've said before, and I know that Dr Smith took
21 the same view in papers that he produced that when we
22 were planning for heat treatment, we were thinking
23 about unknown viruses. Even when HTLV-III was
24 identified and, if you like, terminal dry heat
25 treatment came as a -- what should have been a timely

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1 may be extended to 25,000 donations for heat-treated
2 coagulation factor concentrates. The appropriate
3 label revisions will be made as soon as possible.
4 Please check that any manufacturing document is
5 revised before the increased limit is implemented."

6 This would seem to confirm that you weren't
7 going off on a frolic of your own. Dr Lane had been
8 informed and had agreed to the increase in the pool
9 size. Just --

10 **A.** That's correct. Sorry. I interrupted.

11 **Q.** I was just going to ask: the language there used in
12 this minute is that Dr Lane has agreed that the pool
13 size be extended which, taken on its own, might
14 indicate that it was Dr Lane who made those kinds of
15 decisions. Do you think that is a fair interpretation
16 or not?

17 **A.** It's fair to say that he would always have had a loud
18 voice in making the decision.

19 You need to be aware as well, though, that the
20 last sentence means exactly what it says. The
21 manufacturing documentation, the batch record is what
22 drives the process. It would have been probably
23 a month from the time of that decision to the point
24 where even the manufacturing documentation could have
25 been prepared for the increased pool size, and

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1 correction of the presence of HTLV-III, but our focus,
2 the driver, certainly from a fractionator's point of
3 view at Elstree and at PFL was this beast, non-A,
4 non-B hepatitis, that we've been aware of.

5 **Q.** I'd like to turn now to some of the evidence about
6 what the pool sizes were and how they increased.

7 You gave some evidence about that yesterday when
8 you said that, in terms of routine production, the
9 smallest size that you can remember at PFL from early
10 in your career was, I think you said, around
11 65 litres, about five of the -- sorry, 12 of the
12 5-litre bags being used in fractionation. Is that
13 a fair summary of what you said yesterday?

14 **A.** I think I said 13. I would normally say 13 bags. So
15 probably around -- somewhere between 325 and 350
16 donations, yes.

17 **Q.** In your written statement at page 76, paragraph 214
18 if we could have that on screen, Sully. WITN343100 1,
19 page 76, paragraph 214.

20 I stress that yesterday we were talking about
21 your direct experience of having worked at PFL from
22 1970 onwards. In this paragraph of your witness
23 statement, you go back a little further in time. You
24 wrote, and I quote:

25 "Between 1967 and 1975, the plasma pool size for

24

1 BPL and PFL Factor VIII batches ranged from 50 to
2 100 litres. (250 to 500 donations.)"
3 Can I just ask about that figure of 50 litres
4 and 250 donors? Do you know where that comes from?

5 **A.** If you are asking me: can I pin it down to a piece of
6 paper, no, I can't. But in discussion when I first
7 joined PFL, I was aware from discussions with
8 Ethel Bidwell, with Ross Dike, of the pool sizes
9 they'd been working with when I visited Elstree ver
10 early on in my career in discussions with
11 Drummond Ellis.

12 It was obvious that there had been smaller pools
13 being fractionated at the scale that PFL would have
14 then almost carried on with under my guise as
15 scientist I/C production. I can't give you dates.

16 **Q.** Thank you. If we could --

17 **SIR BRIAN LANGSTAFF:** May I just ask, if you just have
18 a look at -- you have given a range here of 50 to 100,
19 and yesterday you told us about the figure of 70. Can
20 I just remind you of what was said, paragraph 86 of
21 your witness statement, it is page 31. It is where
22 you say:

23 "Initially, the process used for factor VIII
24 manufacture at PFL and BPL was a method developed i
25 Sweden by Blomback ..."

25

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

2 **MR HILL:** If we could turn to BPLL0009120, the first page
3 of that, please.

4 This is a document that was introduced in the
5 presentations a couple of weeks ago. We can see from
6 the first page that it is a memorandum from Dr Lane to
7 you, dated 29 January 1990. So at the time of the
8 HIV litigation.

9 Dr Lane wrote:

10 "A number of matters are arising out of the
11 reading of files for the litigation. I attach a list
12 below and should appreciate answers as soon as
13 possible from the individuals best able to provide the
14 information.

15 "1. Approximate pool size in kg of factor VIII
16 pools from 1975 onwards at Oxford and Elstree with
17 dates of change."

18 So that was the task set out by Dr Lane.

19 If we could turn to page 2.

20 We can see here a table is set out of PFL
21 products. Now, in our presentation we referred to
22 these as your estimates because the memorandum had
23 been sent to you. But is that accurate? Were the
24 estimates that you came to or was there some other
25 individual who was better placed to provide this

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1 You later on describe going on to the Johnson
2 process. That was, what, 1974 onwards, was it, the
3 Johnson process?

4 **A.** That's correct.

5 **SIR BRIAN LANGSTAFF:** So before 1974 you had been using
6 the Blomback method. And you see here:

7 "We worked with plasma batch sizes of up to
8 70 litres ..."

9 That's a slightly different figure from 100. So
10 were you giving the range of 50 to 100 just to make
11 sure you didn't miss anything that might be a bit
12 larger?

13 **A.** Well, I'll comment on paragraph 86 --

14 **SIR BRIAN LANGSTAFF:** How does that fit with the 50 to
15 100? That's what I'm really asking.

16 **A.** The 50 to 100 I think related to the process at PFL
17 and BPL. I think I'm probably being careless in
18 paragraph 86.

19 We worked with plasma batch sizes of up to
20 70 litres from -- I was talking about myself and PF
21 in that sentence. It -- that wasn't intended to
22 embrace BPL as well. But certainly from 1970 through
23 to the end of our processing by Blomback, we would
24 have been using batches of approximately 65-70 litres
25 from thirteen 5-litre packs of plasma.

26

1 information for Dr Lane?

2 **A.** Almost certainly at the time that I received
3 Richard Lane's memo I would have asked members of
4 staff in the control unit, headed up at that time b
5 David Donald -- but David wouldn't have done the
6 data mining himself; it would have been one of the
7 technical staff in the control unit who would have
8 gone through batch records to pull those batch size
9 out.

10 We did not have -- even in 1990, and
11 certainly -- we are talking about data here -- back to
12 the 1970s, this was not on any database. Someone
13 would have gone through in a stack of archived batc
14 records, pulling out batch sizes, to give those
15 figures there.

16 And that would have included, in the case of
17 Factor IX, for example, the pooling of supernatants
18 from two batches of Factor VIII to make Factor IX
19 concentrate.

20 **Q.** I'm going to come back and ask you about that pooling
21 in a second but let's just, for the transcript, go
22 through the figures that are given here for PFL
23 products.

24 From 1975 to 1979, for Factor VIII the
25 approximate batch size in plasma weight is given as

28

1 100kg, and for Factor IX, 100-200kg.
 2 1980, Factor VIII, the figure is given as
 3 300-500kg. Factor IX the same, 300-500kg.
 4 Then 1983, Factor VIII only, and the figure is
 5 given:
 6 "300kg and multiples of 300kg."
 7 And a note says:
 8 "1980 Onwards an increase in Haemonetics plasma
 9 usage therefore reducing donor exposure per batch."
 10 Just to deal with that last point first.
 11 Haemonetics plasma, is that plasma obtained from
 12 plasmapheresis?
 13 A. It is, yes.
 14 Q. Therefore more plasma can be obtained, and thus
 15 a 300kg batch will have fewer donations in it?
 16 A. That is correct.
 17 Q. The figure for Factor IX in 1975 to 1979, 100-200kg
 18 does that reflect what you have just said? That th
 19 supernatant that resulted from the fractionation
 20 Factor VIII was mixed together in order to make the
 21 Factor IX?
 22 A. It may not have been quite as you described it. It
 23 may not have been that the supernatants were pooled
 24 but rather the Factor IX concentrate, the bulk
 25 Factor IX concentrates from two column extractions

29

1 300kg, do you understand what was meant by that?
 2 A. I would have interpreted it -- I mean, I do interpret
 3 that as meaning the cryoprecipitate from more than one
 4 batch, from more than one processed batch would hav
 5 been frozen and then pooled for finishing manufacture.
 6 Q. If we can just jump back in time a little to
 7 a memorandum that was brought up during our
 8 presentations a couple of weeks ago.
 9 It is CBLA0000253. It is sent from Dr Bidwell,
 10 head of lab at PFL, to Dr Maycock. It is dated
 11 22 January 1975.
 12 I'm afraid, so far as we are able to discover at
 13 the moment, it is on its own, so we don't have any
 14 other papers that we can show you to give you conte xt.
 15 What it states is this:
 16 "When we talked about labels at Elstree in
 17 November we agreed to have printed on the label for
 18 factor VIII that it was derived from 'not more than
 19 500 donations' and that we would cease putting on the
 20 precise number of donors whose plasma had gone to make
 21 up the pool. Mr Snape has pointed out to me that the
 22 batches of factor IX prepared from the Elstree
 23 material correspond to much higher than 500 donations
 24 and that the exact number is not known to us. If w
 25 pool the smaller batches here we know the number bu

31

1 might well have been pooled to achieve the 200kg.
 2 But I think -- I need to just repeat that what
 3 the person doing the data mining was doing, was using
 4 actual numbers recorded for how many kilos of plasma.
 5 Working with plasma products, it is not like making
 6 paracetamol where you put a predefined amount of th
 7 material into a batch. The batch size is what appe ars
 8 on the scale of the floor balance when the pooled
 9 plasma is in the tank and measured. And so it woul
 10 be very -- it would be different for every batch. It
 11 could be 5 or 10 kilos different for each batch. But
 12 I am sure that what the technician who did that dat
 13 mining was doing was simply recording the number of
 14 kilos in each batch and then calculating an average
 15 Q. In terms of the number of donations that went into
 16 each kilo, before 1980 is our rough rule of thumb o
 17 about 5 per litre, 5 per kilo still a reasonable
 18 guide?
 19 A. Before 1980 and the introduction of plasmapheresis
 20 plasma and before the introduction of SAG-M, then,
 21 yes, the rule of thumb 5 is fine.
 22 Q. After 1980 it's more complicated and harder to come up
 23 with a precise metric?
 24 A. Because of pheresis plasma, because of SAG-M plasma.
 25 Q. In 1983, the reference there to 300kg and multiples of

30

1 again it is more than 500. I have told Mr Snape to
 2 have printed on the small labels 'not more than 100
 3 donations' but the whole subject of having anything at
 4 all on the label seems difficult. It is certainly not
 5 much of a guide to the clinicians any longer. Can we
 6 discuss this, please?"
 7 I'm afraid a rather lazy question, but can you
 8 explain to us what is behind this minute?
 9 A. The 500 or the 1,000-donor limit, you're asking what's
 10 behind that?
 11 Q. What is behind the concern you have raised with
 12 Ms Bidwell that she is now raising with Dr Maycock?
 13 A. Okay. Simply that we wouldn't necessarily -- when we
 14 received supernatant from Elstree, we wouldn't have
 15 had the precise batch size available to us. We
 16 certainly wouldn't have had the number of donations
 17 available to us. And I am sure it was me simply being
 18 cautious and not wanting to be caught out at a late
 19 date.
 20 Q. Do you know how this matter was resolved following the
 21 minute?
 22 A. Well, I do know that we increased the label stateme nt
 23 to 1,000 donations. I also know that that -- that
 24 the practice of putting a donation limit on labels
 25 persisted for a very long time. Probably longer than

32

1 was useful. I think Ethel Bidwell's comment that the
2 number of donations stated on the label wasn't much of
3 a guide to clinicians anymore was quite true.

4 I don't know what discussions Dr Maycock and
5 Dr Bidwell had as a result but clearly we persisted
6 with a label statement, but increased to
7 1,000 donations.

8 **Q.** Do you know of any incidents or any period of time
9 when vials of Factor VIII or Factor IX were sent out
10 to either BPL or PFL with inaccurate labels as to how
11 many donations they had within them?

12 **A.** No, I don't. I'll just qualify something that you
13 say. For a long time all Factor IX was being issued
14 from PFL, whether it had been manufactured at PFL or
15 sourced at BPL. But, no, I don't know of any such
16 event, and if I had known at the time there would have
17 been a correction made.

18 **Q.** Could we go back, please, Sully, to the previous
19 document that we were looking at, the estimates of
20 pool size, BPLL0009120, and this time to page 3.

21 We looked at the figures for the PFL products.
22 We are now going to turn to the products from Elstrée
23 and BPL. We can see the table produced there. The
24 first row doesn't have a batch number but has:

25 "Date Released: 1975.

33

1 would reflect more SAG-M use.

2 **Q.** "FHC", what does that stand for, please?

3 **A.** I hoped you weren't going to ask me that! I can't
4 remember. It is 30-something years ago. And
5 I wouldn't have generated the acronym myself. I don't
6 remember.

7 **Q.** Was it a fundamentally different product from 8Y?

8 **A.** No.

9 **Q.** It is still a heat-treated product done approximately
10 in the same way as 8Y?

11 **A.** Yes.

12 **Q.** I won't test you any further then on the acronyms.

13 I won't go through all of these figures because we
14 have them both on this document and in the earlier
15 presentation, but what we can see from them is
16 an increase. Just using the approximate number of
17 donors figure: from 1975 it is 750; it has risen to
18 2,250 in September 1977; then to 3,000 for
19 August 1980; 4,500 from March 1981; then 6,000 in
20 July 1982, April 1985, July 1985; rises to 7,000 in
21 November 1986; 10,000 in February 1988; 13,500 in
22 June 1988; and then, finally, 14,500 in December 1988
23 and July 1989.

24 Firstly, those figures are the figures for what
25 actually went into those batches rather than the

35

1 "Plasma [Weight]: [around] 150 [kilos].

2 "No. of donations: [around] 750 [kilos]."

3 That is the first figure that is entered there.

4 Asking the impossible, but do you know why no batch
5 number is given?

6 **A.** No.

7 **Q.** Thereafter, for the other figures in the table, we
8 have specific batch numbers given. Does that mean
9 that whoever compiled these figures would have gone to
10 the documents for that batch and found out what the
11 weight of the plasma was?

12 **A.** That's exactly what they would have done. But the
13 donation, the number in the "No. of donations" column,
14 would, I am sure, have been a conversion from the
15 plasma weight.

16 **Q.** Having done the maths, until November 1986, the
17 conversion is simply plasma weight x 5 to give
18 donation weight, and after February -- from
19 February 1988 onwards the conversion is around about
20 4.2 x the plasma weight to get to the donation figure.

21 Is that, presumably, to reflect the greater use
22 of SAG-M?

23 **A.** I mean, that would have been one factor certainly. It
24 doesn't surprise me that the shift occurs at --
25 between 8Y 3429 and the FHC batch 001. It certainly

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1 maximum donor figure which appears on some of the
2 labels, is that right?

3 **A.** That's correct. Can I also comment that if you look
4 at the -- rather than the number of donations column,
5 if you look at the plasma weight column, apart from
6 the batch with no name, you can see that the
7 progression -- I mean, we have the -- HL 1350 with
8 450 kilos, but after that you are seeing increased --
9 multiples increasing on units of 300 or units of 150,
10 if you like, all the way through. And some of that
11 would reflect pooling of frozen cryoprecipitates to
12 make a batch. But still subject to a calculated to total
13 donation limit that would have appeared on the label.

14 **Q.** If I could just highlight the period from August 1980
15 to July 1982. We see a doubling in the size of the
16 batch: 600kg to 1,200kg, approximately 3,000 donors to
17 approximately 6,000 donors. We can see from the final
18 column that that is a period when the product was not
19 heat-treated.

20 We know from your earlier evidence that this is
21 a period by which time the fractionators were aware
22 and taking seriously the long-term risks of non-A,
23 non-B hepatitis.

24 There was no test for non-A, non-B hepatitis at
25 that time, was there?

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1 **A.** There was no test for non-A, non-B hepatitis at that
 2 time, but there were controlling elements in terms of
 3 donor selection and the questionnaire that would have
 4 been administered at the donor collection centre
 5 inquiring about donor perception of risk.
 6 **Q.** That was the only mechanism to try to control the risk
 7 of non-A, non-B that was being used at that time; is
 8 that fair?
 9 **A.** It's the only mechanism that was available to us. We
 10 could test for hepatitis B. We certainly couldn't
 11 test for an entity that hadn't been identified and
 12 associated with a particular virus.
 13 **Q.** But by that time, in light of those figures that we
 14 have looked at, BPL wasn't using pool size as a for
 15 of protection against non-A, non-B hepatitis. Is that
 16 a fair comment?
 17 **A.** Subject to the maximum number of donations that at any
 18 one time was agreed and specified on the label.
 19 **Q.** Just to finish this section on pool sizes. If I could
 20 just ask a couple of hypothetical questions.
 21 If a decision had been taken to retain pool
 22 sizes or to have made pool sizes at BPL of, say,
 23 maximum 250/300 donors, what would have been the
 24 result of that decision, in terms of the amount of
 25 product that was produced?

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1 but I cannot think of a conjunction of rooms that
 2 could have been used to achieve that. I would have to
 3 say that I think the only way it could have been done
 4 would have been to reconfigure the rooms that were at
 5 that time being used to manufacture Factor VIII and
 6 Factor IX, which would have meant downtime while the
 7 reconfiguration happened, and possibly different
 8 equipment. You really are pushing me to limits of
 9 memory now.

10 **Q.** I will leave it there, in that case.

11 We know from your statement, and it's
 12 paragraph 104 at page 37, and also from the evidence
 13 of Dr Smith that we presented a couple of weeks ago
 14 that consideration was given to -- including an area
 15 for very small pool concentrates during the design of
 16 Building 27, the new BPL --

17 **SIR BRIAN LANGSTAFF:** I think just "small pool
 18 concentrates", rather than "very small". Both
 19 expressions are used in paragraph 104, but the
 20 designated area is, in quotes, "small pool products",
 21 so you may be right to say "very small" -- the word
 22 are there -- but the designation is small -- what the
 23 difference is, is simply one of emphasis and whether
 24 the word belongs or not.

25 **MR HILL:** Perhaps -- I can see that Dr Snape is looking

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1 **A.** The -- it's unlikely that it would have constrained
 2 the equipment that was in use, but what it would have
 3 done is increased the number of vials per batch that
 4 had to be sacrificed for testing and submission for
 5 control authority review. So the number of vials that
 6 would have been issued to the patient would have been
 7 smaller.
 8 **Q.** Once we get into the early 1980s, knowing what we did
 9 about the way that BPL had developed, was it possible
 10 to reconfigure Building 25, or any other building on
 11 the site, to arrange for fractionation through small
 12 pools of, say, 200/250/300 donors, without affecting
 13 the amount of product that was produced?
 14 **A.** In Building 25?
 15 **Q.** Yes.
 16 **A.** In the old BPL?
 17 **Q.** Yes.
 18 **A.** No. No, it couldn't have been done. Well, in my
 19 opinion.
 20 **Q.** So if a decision had been taken in, say, 1980, 1981
 21 that BPL should no longer fractionate with donation
 22 measured in the thousands but should fractionate with
 23 donations measured in the low hundreds, how would that
 24 have been achieved?
 25 **A.** Okay. You're taxing my physical memory of BPL now,

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1 for it now. Perhaps we'll bring it up on screen so
 2 that he has it in front of him WITN3431001. It's
 3 page 37, paragraph 104.

4 **SIR BRIAN LANGSTAFF:** And you were asking him about the
 5 design of BPL, the new design, and it's the second
 6 sentence, I think, there that relates to that. As
 7 I read it anyway.

8 **MR HILL:** We can see, I quote from it:

9 "BPL gave serious consideration to the
 10 preparation of very small pool (less than 10 plasma
 11 donations) concentrates of both factor VIII and
 12 prothrombin complex factors (II, IX & X) during the
 13 early years of design and construction of the new
 14 factory (Building 27). My memory is that in the 1982
 15 design and two years into facility construction,
 16 c.1984, a substantial area was designated 'small pool
 17 products'. Never commissioned for small pool product
 18 manufacture as such, this area would be seized on
 19 shortly before factory completion, c.1986, for use for
 20 the virus safe processing steps of 8Y and 9A."

21 First of all, Dr Snape, I'm conscious that you
 22 have told us that you weren't involved in the
 23 redesigning of B27. Are you able to assist with
 24 whether these are two separate entities, the "very
 25 small pool" plan in the first sentence, and then the

40

1 "small pool" plan in the second sentence?
 2 **A.** I believe they referred to the same concept, and th
 3 very small pool, as referred to in the first senten ce,
 4 was what was intended to be processed in the
 5 designated small pool products area in sentence two.
 6 **Q.** But, ultimately, that didn't go ahead, and the area
 7 was used for something else; is that right?
 8 **A.** That's correct. When the factory was in advanced
 9 design phase, we still hadn't settled on a -- on virus
 10 safe processing for Factor VIII and Factor IX. The re
 11 was no area in the factory -- on any drawing in 1984,
 12 for example, that would have said: virus inactivation
 13 for 8Y, or virus inactivation 9A, because that process
 14 had not been established, had not been defined.
 15 Come 1986, it was necessary to start to think
 16 about the flow of products through the factory to
 17 a virus safe processing step. A lot of the
 18 interaction -- There was a lot of interaction betwe en
 19 manufacturers and the regulatory agencies at that time
 20 around what kind of separation had to be introduced
 21 between pre- and post-virus inactivation.
 22 Now, 8Y and 9A had the excellent characteristic
 23 that the virus inactivation happened in the final vial
 24 by heat treatment after the product had been dried.
 25 But there were other products that we were

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1 the other. Then you go on -- there are two questi ons
 2 which arise out of this. One is how that figure,
 3 7,500 donations, which -- if you are using
 4 a conversion factor of 5, would give you what? It
 5 would give you 1,500, I think.
 6 **A.** 1,500.
 7 **SIR BRIAN LANGSTAFF:** And how that fits, if you go down to
 8 the bottom of the paragraph.
 9 Stop there, thank you, Sully.
 10 You see the sentence beginning:
 11 "In each case, the cost to the service was the
 12 cost of a 2,500kg plasma pool ..."
 13 So in each case the cost of the service was the
 14 cost of a 2,500kg plasma pool.
 15 The way it is written, it sounds as though each
 16 pool that was disposed of, which would have had no
 17 more than a maximum of 7,500 donations, that is
 18 1,500kg, was in fact 2,500kg. I just want to
 19 understand what the mathematics is there.
 20 **A.** I don't know when the mathematics went wrong but th
 21 mathematics clearly did go wrong. You are quite
 22 right. I mean, the pool -- even allowing for some
 23 variability, we are still talking about -- with
 24 a 7,500-donation pool, we are talking about
 25 a 1,500kg pool, so that -- I'm fairly sure that whe

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1 manufacturing that couldn't be handled in that way,
 2 where we had to demonstrate consistently steps from
 3 one part of the factory that we would have designat ed
 4 pre-virus inactivation, and another part that we would
 5 have designated post-virus inactivation. And so it
 6 was necessary -- I use the term "seized on", and
 7 that's, in a sense, what we were doing. We were -- or
 8 the factory design at that stage was taking advanta ge
 9 of some space that wasn't going to be otherwise use d.
 10 **MR HILL:** Sir, I wonder if that might be an opportune
 11 moment. I'm about to move on --
 12 **SIR BRIAN LANGSTAFF:** It would be, subject to a couple of
 13 questions if I may?
 14 Can we just go in your statement to the next
 15 couple of pages, two pages further on, page 39. Th is
 16 is a paragraph you were taken to yesterday. If you
 17 look about ten lines down, you see the sentence at the
 18 end of the line beginning:
 19 "Both of these events occurred in 1982, when the
 20 donor pool size had just been increased to
 21 7500 donations."
 22 You are talking here about the two occasions in
 23 which batches had to be disposed of because they
 24 proved to be infective because of errors in the Isl
 25 of Man, in one case, and there was some other error in

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1 I wrote the witness statement, I was reflecting on
 2 donation pool size. I'm afraid that's my error and
 3 I can't explain how it occurred.
 4 **SIR BRIAN LANGSTAFF:** I mean, one explanation that
 5 occurred to me, it might be that you meant to say i
 6 cost in total 2,500kg, which might be the result of
 7 both batches put together. But the way it is writt en
 8 it suggests it is two batches of 2,500kg.
 9 **A.** No, I think my phraseology is saying in each case -
 10 my phraseology was meaning each being the same, and it
 11 is the number that's wrong. It wasn't 2,500kg. It
 12 should be -- if I was going to say anything, it sho uld
 13 have been 1,500kg.
 14 **SIR BRIAN LANGSTAFF:** Okay. Now, bear in mind the figures
 15 there, the pool size has just been increased to
 16 7,500 donations, and then you were taken by Mr Hill to
 17 the memo, where we had that debate about whether
 18 proposal meant decision or not. That was 20 June 1986
 19 when Dr Smithies of the Department of Health was to ld
 20 of the proposed increase from a pool size -- a maxi mum
 21 pool size -- of 10,000 to 25,000 donations.
 22 Now that's in relation to BPL, Elstree. Can you
 23 help with how that fits with the document that you
 24 were taken to just shortly ago, BPLL0009120?
 25 **A.** Sorry, sir, I would have to see the document.

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1 **SIR BRIAN LANGSTAFF:** That's why I'm quoting it, so that
2 Sully gets it up. It is the document we were looking
3 at with the list of donations from the average -- the
4 pool sizes that you pulled out for him. Thank you.

5 Now, these appear to be looking at individual
6 batches and the plasma weight and the number of
7 donations. But how does the number of donations there
8 fit with what you remembered from 1982, the 7,500, and
9 the memo saying, "We are increasing the pool size from
10 10,000 to 25,000 donations", when at no time in the
11 table do you ever reach the 25,000? You don't get to
12 the 10,000 until February '88. Yet this memo was in
13 June '86. How does it all fit together?

14 I know that there weren't records kept as
15 a formal record of average pool size but can you help
16 to just give me some understanding of how -- what
17 I should take from all this.

18 **A.** I think my suggestion would be that the focus should
19 be on the plasma weight, in the first instance, and
20 the plasma weight would have been what the technician
21 who was pulling out that data was -- could be relied
22 on to be quoting, so around July '82 we were seeing
23 plasma weights of 1,200 kilos, which would translate
24 by a simple calculation to 6,000 donations. But that
25 wasn't the limit at the time. I think we have to

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1 records. What I'm having trouble doing in my head at
2 the moment is relating it to the batch size -- the
3 donation pool size that was being requested at date
4 along this table for inclusion on the label.

5 **SIR BRIAN LANGSTAFF:** If you have any thoughts about how
6 the two might fit together, please do let me know
7 because I would be very grateful. You are the one
8 person who might be able to help explain it.

9 **A.** I shall, sir, thank you.

10 **SIR BRIAN LANGSTAFF:** We will take a break now until
11 12.00.

12 (11.32 am)

(A short break)

14 (12.03 pm)

15 **SIR BRIAN LANGSTAFF:** Yes, Mr Hill.

16 **MR HILL:** Dr Snape, I just want to pick up on the
17 discussion that we were having before the break about
18 the interaction between the actual pool sizes and the
19 maximum pool sizes permitted, as per the labels in the
20 regulatory documentation.

21 If we could have on screen, Sully, please. On
22 the left-hand side is the document that we looked at
23 before the break, BPLL0009120, page 3, which is the
24 data taken from the batch numbers showing the plasma
25 weight at various points between 1975 and 1989.

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1 separate what was actually happening, which is what's
2 reflected in this table, from the limit that would
3 have been placed on the label at the time.

4 **SIR BRIAN LANGSTAFF:** So what was the -- I understand that
5 and this may reflect either individual batches or it
6 may reflect the average of what was being done, but
7 what would the purpose have been in seeking
8 an increase from 10,000 donations to 25,000 donations
9 if what was actually happening was that for a -- three
10 years and -- no more than 10,000 were being used?

11 **A.** I can't answer at this remove, sir. All I can do is
12 look at the data that I see there, which I am sure is
13 the recorded batch size, then a conversion to
14 donations. I'm finding it hard to then imagine the
15 dates on which the proposals for batch size change
16 took place alongside this table.

17 **SIR BRIAN LANGSTAFF:** You appreciate that I'm not asking
18 to challenge your evidence in any sense except to try
19 to understand it and what I take from these various
20 figures. And at the moment I'm not entirely sure --
21 just as you are not, I think, entirely sure -- from
22 these figures, how it all fits together.

23 **A.** I am sure that the data in the table here would have
24 been an accurate reflection of what the technician
25 found when he went through the individual batch

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1 And on the right-hand side is a table from the
2 Inquiry -- Counsel to the Inquiry's presentation on
3 pool sizes at the Blood Products Laboratory which was
4 given last week. For record, the reference is
5 INQ0000345, page 7.

6 Now, the second of those documents is not one
7 that you have seen or been provided with, and if you
8 would like to look at it, and if you have any comments
9 on it, then please do take your time to read it in due
10 course and provide us with any comments, either in
11 your oral evidence or in writing afterwards.

12 But because it has arisen now, I'm going to
13 bring it to your attention to see where we can go to
14 with it. And I stress that any errors that are
15 contained in that document are the errors of Counsel
16 to the Inquiry and not your errors.

17 **SIR BRIAN LANGSTAFF:** If you want to have a look at the
18 underlying documents, then Mr Hill may be able to
19 arrange that perhaps.

20 **MR HILL:** We certainly can, sir, yes. Yes.

21 **A.** Thank you, Mr Hill. Can I -- if I could just continue
22 or try to help with the discussion that we closed with
23 just before the break.

24 The tranche of documents that you sent me a week
25 or so ago, which included BPLL0009120, the table,

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1 number of donations in Factor VIII produced at
2 Elstree. There was a second document in that tranche
3 which is CBLA0004791. I don't know if it's possible
4 to display that document, and I may be able -- I hope
5 to explain some of my stumbling before the break.

6 **Q.** Just before we do, could I just ask you a couple of
7 questions about the documents that we have on screen.
8 But I will take you back to --

9 **A.** Yes, please.

10 **Q.** -- 4791 and, indeed, an additional document as well

11 **A.** Please.

12 **Q.** The table on the right-hand side shows the maximum
13 pool size; the table on the left-hand side, the actual
14 pool size for each of those batches that have been
15 fractionated. The maximum pool sizes, the dates given
16 for them are not dates necessarily on which they
17 changed, it's just that we have data from that date
18 which says that that was what the maximum pool size
19 was. The first of those is 27 October 1980, and the
20 maximum pool size then is said to be 5,000 donations.

21 If we go across to the table on the left-hand
22 side, we can see that in August 1980, the number of
23 donations was approximately 3,000, and in March 1981,
24 it was approximately 4,500, so underneath that 5,000
25 donations but with some headroom, as it were, between

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1 that there was a decision taken that the maximum pool
2 size should be set somewhere above the actual
3 fractionation number in order to allow for some
4 leeway. Is that a fair interpretation?

5 **A.** It's a fair interpretation, and it's an interpretation
6 that I wanted to go on and evoke with the later
7 document I was going to ask to be viewed.

8 **Q.** Let's come to that via this route, because the next
9 step up is to 10,000 donations in June 1985. We can
10 see on the table on the left-hand side that in
11 July 1985 it was still 6,000 donations approximately,
12 and it increases to about 7,000 by November 1986, and
13 not until February 1988 do we get to the 10,000. By
14 1988, as we go back to the table on the right-hand
15 side, we can see that the donor limit has been raised
16 to 25,000 donations.

17 The reference for the data about 10,000
18 donations is a document at CBLA0002190, which you have
19 been provided with, and I'd like to go to that first
20 before coming to the second document which is
21 CBLA0004791, which is the one that you have just
22 raised with me.

23 This is CBLA0002190 on screen now. It is
24 a memorandum from you on 10 June 1985, sent to
25 Mr Prince and copied to Dr Lane and Dr Smith. You

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1 the actual amount of donations and the maximum number
2 of donations.

3 The next piece of data that we have is from
4 25 January 1982, and we can see that the maximum pool
5 size at that stage has gone up to 7,500 donations. If
6 we correlate that to the table on the left-hand side,
7 we can see that by July 1982 the number of donation
8 has gone up to approximately 6,000, so, again,
9 underneath the maximum pool size and, again, some
10 headroom.

11 Now, we have heard in evidence about the work
12 done on the Stop-Gap redevelopment of Building 25
13 within BPL and how that increased the capacity to
14 fractionate plasma at the old BPL. Is it likely that
15 that increase in the maximum pool size from 1980 to
16 1982 reflects the fact that more plasma is being
17 processed at BPL as a result of the Stop-Gap
18 redevelopment?

19 **A.** Yes. And, of course, that was only possible with the
20 increased amount of plasma being supplied at that
21 time, so it's a combination of factors. But, yes, the
22 answer to your question is: that's certainly a factor.

23 **Q.** Now, I appreciate this is before your time at BPL.
24 You were still at PFL at this time.

25 One interpretation of the two sets of figures is

50

1 wrote the following:

2 "Coagulation factor batch sizes.

3 "Further to your memo of 25 April 1985. I have
4 assumed that a limit of 10,000 donations maximum will
5 not restrict operations in the present building, but
6 that an extension to 20,000 donations maximum will be
7 required for the new facility. The higher figure will
8 be used in any product licence applications."

9 So that's 10 June 1985. Then if we turn over to
10 CBLA0004791 -- finally, I'm afraid, getting to the
11 document that you asked me to take you to. This is
12 20 June 1986, so a year later, from you to Mr Prince
13 and Dr Smith, copied to a number of others. And this
14 is a document that we looked at a little earlier today
15 as well which says:

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

22 So having brought those documents up on screen,
23 what is it that you take from those?

24 **A.** Thank you very much. If we could go back to
25 CBLA0002190, the previous memo.

52

1 Yes. In thinking about the discussion before
2 the break, I knew that there was a piece of paper that
3 made sense of -- at least I thought it made sense -
4 this is my -- a classic example of attempting to
5 future-proof, and when one relates it to the table in
6 BPLL0009120, you have just yourself pointed out that
7 the 10,000 donations maximum that was in place was
8 comfortably above the process that was actually being
9 operated by Peter Prince up to April '85.

10 When we looked at the -- we looked forward to
11 the new facility, I had to assume that we would want
12 to extend or to increase process pool size -- not
13 necessarily individual processing batch size, but the
14 pool size -- and that's the origin of my
15 20,000 donations maximum to be used in the new
16 facility.

17 The last sentence is important because product
18 licence applications don't happen overnight, and I had
19 to assume that we needed to anticipate probably
20 a six months-plus delay while we phrased
21 an appropriate product licence application with
22 a larger pool size, and that that had to be in place
23 before we needed to use it.

24 So, the shift to 20,000 donations that was
25 requested made sense, anticipating the batch sizes

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1 is thawed on day 1, that batch might be in final -- as
2 final product, in vials, heated, and ready for
3 inspection, labelling and packing, possibly three
4 weeks later. After that, then, the sampling takes
5 place. And the sampling is -- includes samples taken
6 for BPL QC to do testing and for samples and protocols
7 to go to NIBSC, for testing and release.

8 So, some of those tests would take longer than
9 others and hence my 10 weeks from thawing the plasma
10 to the product being available.

11 **SIR BRIAN LANGSTAFF:** So the dates of release are the
12 dates which are quoted in the document, the date of
13 manufacture, which would therefore involve the maximum
14 pool size of the time, presumably, would be two or
15 three months earlier?

16 **A.** Yes, but it's the date of release that would dictate
17 the statement -- the label to be used for a particular
18 batch.

19 **SIR BRIAN LANGSTAFF:** I see. So there's not very much
20 likelihood, though there may be some, of the
21 maximum limit changing between the manufacture, in
22 terms of the processing, and the date of release?

23 **A.** I think you are right, sir.

24 **SIR BRIAN LANGSTAFF:** Yes. That's resolved that for me.
25 Thank you very much.

55

1 that were going to be manufactured in Building 27,
2 once that facility was operating. And, of course, the
3 last four batches in the table in BPLL0009120 are all
4 batches -- the FHC batches that are manufactured in
5 the new facility. They are all heat-treated
6 concentrates, manufactured in Building 27.

7 So, I was a little slow, I think, recognising
8 that particular connection, but I hope that assists
9 the Chair in understanding at least the data that's
10 available.

11 **SIR BRIAN LANGSTAFF:** It certainly is very helpful. There
12 may be a further point, if I may.

13 Can we just have a look on screen at BPLL0009120
14 again?

15 Can I ask, is there a gap between the date of
16 manufacture and the date of release?

17 **A.** Yes.

18 **SIR BRIAN LANGSTAFF:** Roughly how long a gap was there?
19 It may have varied, I take it, from time to time, but
20 roughly how long?

21 **A.** It would be somewhere between 6 and -- date of
22 manufacture, being when the plasma is thawed, would --
23 to date of release could be as much as 10 weeks. That
24 would be conditioned -- obviously, there's the ongoing
25 processing. A batch where the pool -- the plasma pool

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1 **MR HILL:** Just two very quick follow-ups on that.

2 Before the break, the chair took you to
3 paragraph 109 of your statement. I don't ask that it
4 is brought up, but that's where you used the figure
5 of 7,500, saying that the donor pool size had just
6 been increased in 1982 to 7,500.

7 From the table of what we are looking at here,
8 we can see that the actual number of donations was
9 around 6,000 in July 1982, and the table that we were
10 looking at a little earlier shows that the maximum
11 pool size went up to 7,500 donations by January 1982.

12 So should we read the figure in paragraph 109 to
13 be a reference to the maximum pool size rather than
14 the actual pool sizes?

15 **A.** Do you mind if I just look at the page itself?

16 **Q.** Of course. It is page 39 of your statement.

17 **A.** Yes. Yes, we should.

18 **Q.** For future reference, for Core Participants and for
19 the chair, if one wants to understand how much plasma
20 is actually being processed at BPL in various pools in
21 this period, which is the best source of data of the
22 two that we have just been looking at, so far as you
23 are concerned?

24 **A.** The plasma weight as -- in table 1B there would be
25 what I would use and would suggest should be used.

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1 Q. That is at BPLL0001920, page 3, for the record.
 2 Final question, I promise, on pool size, at
 3 least from me. From July 1982, in this table, until
 4 July 1985, we see that the same plasma weight is given
 5 for the three batches that are fractionated 1,200kg
 6 Was that the function of the size of a plant, of the
 7 amount that B25 could process at that time, or was
 8 that a function of a deliberate decision to hold the
 9 batch weight at that level, or was it both?
 10 A. No, I think it was the former. It was -- the batch
 11 manufacturing record would have defined and recorded
 12 the amount of plasma processed. There would have been
 13 no reason to feel constrained by the donor pool --
 14 the licensed donor pool limit that went on the label.
 15 It was simply what was practically achievable during
 16 that period in the factory.
 17 Q. I'm going to turn, then, to the labels themselves -
 18 sorry, I think you were about to say something?
 19 A. Yes, if I may. I was a little slow when you asked me
 20 earlier about what was the defence, why -- how did BPL
 21 see patients being protected if -- in the absence of
 22 a test or screening test for non-A, non-B hepatitis
 23 what did we have that we were relying on other than
 24 pool size? And of course what I should have pointed
 25 out is that the plasma that we were processing was, at

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1 We are going to come back to the plasma hold
 2 period in due course. I am conscious that some of the
 3 evidence you have given there is given in your
 4 statement and there is a helpful document as well.
 5 I will dig up those references at lunchtime so that we
 6 can place them on the transcript.
 7 A. Thank you.
 8 Q. For now, I would like to turn to labels. Could
 9 I begin by asking what role you played in the
 10 production of the labels that were placed on the
 11 products produced by PFL and BPL.
 12 A. Yes. First of all, it changed over time. At PFL,
 13 even up to 1982, we adopted the practice that product
 14 labels were generated or overprinted, if we were
 15 using, you know, commercially produced labels -- we re
 16 generated or overprinted by QC. And that's quite
 17 unusual. And I recall inspection comments when it was
 18 pointed out that this was unusual, that that was
 19 a production activity, and surely this was QC crossing
 20 the boundary between their QC role and the production
 21 role. But when we -- when I explained that what we
 22 were doing was making sure that, given the nature of
 23 production activities in PFL and the people involved,
 24 that, in fact, the individuals better placed to do it
 25 were the people in the control laboratory, in fact,

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1 that time, certainly, typically plasma recovered from
 2 individual plasma donations, and our plasma was, even
 3 by then, being subjected to, if not a quarantine
 4 period, at least an inventory hold of the frozen
 5 plasma before it was processed.

6 The significance of that with recovered plasma
 7 is the inventory hold allows a period during which any
 8 post-transfusion sequelae of patients who had received
 9 the cells from which that plasma had been recovered
 10 could be recorded and notified to BPL, so that
 11 we could interdict individual plasma donations if they
 12 were associated with post-transfusion hepatitis. And
 13 we regularly did.

14 My own experience and my memory of that
 15 experience was that hardly a month went by when we
 16 were not interdicting individual plasma donations and
 17 preventing them from being processed after we had had
 18 post-transfusion sequelae reported from centres.

19 And in fact a comment, certainly, from one quite
 20 senior Medicines Inspector visiting BPL, and when we
 21 were talking about the way that allowed us to retrieve
 22 plasma, was, "Well, you know, you hardly need to mimic
 23 that situation, you are doing it often enough that
 24 I can see that the process works."

25 Q. Thank you for that, Dr Snape.

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1 the clerks who were managing data for me, the
 2 Inspector accepted that this was a case of getting the
 3 right people to do the job rather than slavishly
 4 following guidance.

5 At BPL it was properly different. We had
 6 an inspection, labelling and packing department, and
 7 the labels were -- certainly for licensed products --
 8 the labels were prepared by a commercial company,
 9 a commercial press, and the role of -- my role, the
 10 role of QC, was to review copy for the labels before
 11 they were sent to the press and approve sample labels
 12 from the roll when they came back from printing. But
 13 from that point on, the labels were managed and
 14 administered in the inspection, label and packing
 15 department, and the role of QC was to ensure, by
 16 regular audit, that the labels were being stored
 17 appropriately and selected appropriately for use.

18 Q. Who would have had -- made the final decision on the
 19 wording that would be used, particularly in terms of
 20 warnings about viral risk?

21 A. Label copy was reviewed by a group. We operated what
 22 we loosely called a starburst mechanism, whereby copy
 23 went at the same time to as many contributing
 24 individuals as possible, typically electronically, by
 25 email, and then comments came back into that group.

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1 The final decision on what was stated on it would have
 2 been probably my role as the person chairing that
 3 group.
 4 **Q.** You mentioned email there. So, obviously, that's
 5 a little later in time. If we think about the
 6 mid-1980s, who would have had the final say at that
 7 time?
 8 **A.** It would have been a discussion between myself and the
 9 production manager, and we would always have drawn in
 10 Dr Lane if we felt that there was a change that needed
 11 a medical review, but that was often not necessary.
 12 There would be mechanical changes rather than in
 13 principle changes that made a difference.
 14 **Q.** Would you consult external agencies, the Medicines
 15 Agency, NIBSC, the DHSS about the wording of the
 16 warnings that were contained on the labels in the
 17 mid-1980s?
 18 **A.** Not NIBSC, but certainly the MCA, as was, would have
 19 been involved in those discussions, and once we had
 20 a European Medicines Agency, I would have also
 21 consulted with them.
 22 **Q.** You say the MCA. Would its predecessor, the Medicines
 23 Division of the DHSS, also have been involved at the
 24 earlier stage?
 25 **A.** In the same way. For me, that transition from

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1 the preparation of this batch."
 2 We have spoken about that, and I won't ask you
 3 any more questions.
 4 We can see that the label which has been
 5 attached to this by somebody, and we don't know who,
 6 suggests that this is an HL product, so the BPL
 7 product. It is stated to be dried Factor VIII
 8 fraction of intermediate specific activity which, a
 9 I understand it, would fit with it being an HL
 10 product.
 11 The warning, which is highlighted in blue on the
 12 package, reads as follows, and I quote:
 13 "The preparation is of human origin and cannot
 14 be assumed to be free of hepatitis virus."
 15 First of all, can you see that?
 16 **A.** Yes, I can see it. I can also see just below it on
 17 the right-hand of the centre panel the designation
 18 "HL5", so the nature of the label is defined there.
 19 **Q.** That is H--
 20 **A.** The line that says:
 21 "Store in the dark below +6 degrees C."
 22 To the right of that, there is a designation,
 23 HL5, and that's where the typescript above derives.
 24 **Q.** The warning about hepatitis?
 25 **A.** Yes.

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1 Medicines Division of DHSS to MCA was a fairly
 2 seamless transition.
 3 **Q.** Who were the labels intended for? Was it for the
 4 clinician, or for the patient?
 5 **A.** Sorry, who --
 6 **Q.** Who were the labels intended for? Were they intended
 7 for the clinician, or for the patient, or for both?
 8 **A.** When we were considering the content of the labels, we
 9 considered both. It's important to remember that
 10 a lot of the product that we issued was distributed --
 11 the product in the case of Factor VIII was distributed
 12 from transfusion centres to the Haemophilia Centres,
 13 and then a lot of that material was issued for home
 14 therapy. So the product would have been -- the
 15 Factor VIII product would have been in patients'
 16 fridges.
 17 **Q.** I'm going to bring up a sheet which shows three
 18 labels, and the dates are given on the sheet, though
 19 we cannot verify them ourselves. It is BPLL0002039,
 20 please, Sully.
 21 If we could expand the top label, please. This
 22 is stated to be pre-June 1985. I don't know how
 23 clearly you will be able to see it. On the left-hand
 24 side, we can see the wording:
 25 "Less than 7,500 plasma donations were used in

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1 **Q.** First of all, do you think that the date given there,
 2 pre-June 1985, is likely to be accurate?
 3 **A.** Yes.
 4 **Q.** Why is it that that warning contains no reference to
 5 AIDS?
 6 **A.** I guess -- well, the simple answer is that that
 7 warning would have been found, I'm sure, on previous
 8 sequences of labels, and we did not add the --
 9 a specific reference to AIDS virus at that stage.
 10 I'm sure you're right, that by the end of 1984,
 11 we could have added "and HTLV-III" or "HIV" as
 12 a statement. I can't tell you now why we didn't.
 13 **Q.** Do you know if there was any discussion about adding
 14 a warning about HTLV-III or HIV?
 15 **A.** I don't recall such a discussion. I think I would
 16 have recalled it, had it occurred.
 17 **Q.** How often were the words for the label reviewed at BPL
 18 at that time?
 19 **A.** Probably not more than twice a year, unless there was
 20 a specific -- and the most specific reason for doing
 21 so would have been the donation limit.
 22 **Q.** We have seen that the donation limit did increase to
 23 7,500 in 1982. It still appears to have been 7,500 by
 24 1985, but notwithstanding that you think that there
 25 would have been some form of review of the labels

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1 a couple of times a year; is that right?

2 **A.** In that particular case, I suspect probably not. The

3 only reason for changing would have been if it was

4 considered to be deficient. It's -- the label would

5 be part of the product licence application -- the P

6 numbers there at the bottom left-hand corner of the

7 centre panel -- and we would not have set about making

8 changes without a very good reason.

9 **Q.** Do you remember anyone raising the lack of an AIDS

10 warning on the label with you? Clinicians, patients,

11 the DHSS, anybody?

12 **A.** No.

13 **Q.** You say that you wouldn't have made changes without

14 a very good reason. The developing knowledge of HI

15 and AIDS, a life-threatening disease, would have been

16 a good reason, wouldn't it, to have included

17 a warning?

18 **A.** It would have been a good reason if it could be

19 expected to result in a change in clinical practice

20 I'm not sure -- I struggle to see that clinical

21 practice would have changed as a result of drawing

22 a specific attention to HIV, HTLV-III. I would have

23 favoured, if we were going to change that at all, to

24 change it to something like "cannot be assumed to be

25 free of viruses transmissible by blood". But I'm not

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1 There would have been an information sheet

2 provided with the vials as well. We saw that in the

3 video being packed in the same package. Are you able

4 to say whether further detail was given about

5 hepatitis and/or AIDS in the information sheet in the

6 mid-1980s?

7 **A.** I haven't had access to the package insert leaflets

8 during the time that I've have been preparing my

9 witness statement, and I simply don't remember back

10 35 years to what was in a PIL at that time. It would

11 have been subjected to exactly the same review as the

12 label at the time, so it would have been consistent

13 with the label.

14 **Q.** If we could turn then to the next label, please. This

15 is a label which is clearly for 8Y. We can see that's

16 mentioned there. The date's given of June 1985 to

17 February 1987. The warning section states this:

18 "The preparation is of human origin (less than

19 10,000 plasma donations used per batch). It has been

20 subjected to heat treatment in the vial to reduce

21 the risk of infection by viral agents, including

22 hepatitis and AIDS viruses, but cannot be assumed to

23 be free of the risk of infection."

24 First of all, do you have any recollection of

25 how the change came to be made and the discussions

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1 convinced that it would -- that adding "HTLV-III" or

2 "HIV" to that would have changed the way people

3 thought about the product.

4 **Q.** The way in which people thought about the product, in

5 clinical practice, is something that is outside of

6 your control. What is inside your control at BPL is

7 the label that you put on a product that BPL produces.

8 Looking back, do you think that that label

9 should have had a warning that at least allowed

10 sufficient space for the AIDS and HIV to be included

11 within the warning?

12 **A.** You're asking me to indulge in 20/20 hindsight. The

13 answer is: at the moment, I'm not convinced.

14 **Q.** You're not convinced that it was necessary for BPL in

15 the mid-1980s to have included a warning about HIV and

16 AIDS on the label of its product?

17 **A.** Because pre-June 19 -- we are at the cusp, aren't we,

18 there of when individuals were -- individual

19 physicians were convinced of the aetiology of AIDS

20 transmission. Should we -- I would need to reflect

21 I'm sorry.

22 **Q.** We'll come on a little bit later to the date of

23 knowledge about AIDS, and perhaps we'll return to that

24 conversation when we have done so, but you've given

25 your answers for now.

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1 that went into the change of label?

2 **A.** Do I have a recollection? No. But what I would have

3 expected to happen is that the print copy group would

4 have taken into account the nature of 8Y, and I'm sure

5 that I would have discussed with Dr Smith the

6 phraseology because -- particularly because of the

7 nature of 8Y and the extent to which we could make

8 a claim for virus inactivation resulting from the HT3

9 treatment.

10 **Q.** Finally, if we could turn to the last label. This is

11 dated from February 1987 onward. It is said to be for

12 product FHC1. It is -- the warning states this:

13 "The preparation is of human origin. It has

14 been heat treated in the vial to reduce the risk of

15 infection by viral agents (including hepatitis and

16 AIDS viruses) but it cannot be assumed to be free from

17 the risk of transmission of viral infections."

18 Firstly on this, do you know why the reference

19 to donor numbers has been removed from the label?

20 **A.** I do know that a decision was taken, and I think it's

21 picked up in the tranche of papers that you sent me

22 last week. So, it was a conscious decision, it wasn't

23 an omission, to eliminate the donation limit. But

24 beyond that, no. I am sure we felt that it had

25 reached the stage that, by then, the donation limit

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1 had no -- contributed nothing. Either to physician's
2 awareness or patient awareness of risk.
3 If I can make the comment?
4 **Q.** Of course.
5 **A.** I think probably that donation limit could have been
6 removed from the label even before this. Certainly
7 once we reached the 10,000-donation limit, it was
8 hardly relevant or hardly helpful to physicians or
9 patients.
10 **Q.** The other addition to this label is that of a barcode.
11 I think we saw on the video that there was a scanning
12 system. Is that part of the automation and
13 computerisation of the new BPL?
14 **A.** Part of that, but it's also a -- was part of our
15 arrangement with the print company that generated
16 them. The barcode gave an extra level of security in
17 terms of identifying roll labels.
18 **Q.** If we could take that down, please, Sully, and turn
19 from the labels to the question of knowledge of HIV
20 and AIDS, and, of course, HTLV-III, as the terminology
21 was at the time.
22 If we could go, please, to WITN3431001.
23 Page 63. This is from your statement. At
24 paragraph 176 you wrote:
25 "In July 1982 the first report of AIDS related

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1 neutral way. You are talking about yourself there.
2 What about colleagues at BPL? Do you think that they
3 had a similar journey or did they arrive at that
4 destination sooner or later than you?
5 **A.** I don't think colleagues at BPL would necessarily
6 have -- I don't think they would have arrived there
7 sooner than me. I think I would, in turn, have relied
8 on discussions with Dr Smith, Dr Rizza and feedback
9 from John Craske's working party to give me
10 confidence. But I think, like many fractionators,
11 I would have been sceptical about the coincidence of
12 the number of transmissions to haemophilic patients as
13 being just dismissible as being a coincidence.
14 **Q.** I was just going to say, I think in your Lindsay
15 evidence -- I won't take you to it, but the reference
16 is LIND0000311, and it is page 14 -- I think you refer
17 to fractionators taking a pessimistic view, as it
18 were, that there may well be a link, is that right?
19 **A.** Yes. And I think we did. And it was proper that we
20 did.
21 **Q.** I'm going to take you now to a document that the
22 Inquiry has seen before and you have been provided
23 with; it is CBLA0001691.
24 **A.** Whilst that document is being found, can I just
25 qualify what I have just said?

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1 symptoms associated with a haemophiliac [patient] was
2 published and fractionators, like haemophilia
3 treaters, were very concerned about whether the
4 causative agent of AIDS could be transmitted through
5 clotting factor concentrates. Of course, until the
6 causative agent had been identified and characterised,
7 it was not possible to conclude that heat treatment of
8 concentrates would help to prevent transmission of
9 AIDS to haemophiliacs."
10 Are you able to say now when you first became
11 aware of that July 1982 report, which I think was from
12 MMWR, the publication from the Centres for Disease
13 Control of the United States?
14 **A.** Probably within several months. But what I would say
15 was that I was also conscious of the fact that, first
16 of all, in the US, at the time, there was
17 a considerable agnosticism about whether the AIDS
18 syndrome was a result of virus transmission, or
19 whether it was something associated with the practices
20 of homosexuals like use of nitrites or whatever. So
21 I think it was not -- certainly my consciousness, my
22 awareness of confirmed relationship between AIDS
23 and -- as an agent transmissible by blood didn't come
24 until well into 1983.
25 **Q.** Do you think that -- sorry, I will ask it in a more

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1 **Q.** Please do.
2 **A.** I interpret "pessimistic" as meaning we had to assume
3 that there was a likelihood that AIDS was the result
4 of a virus transmissible by blood. That kind of
5 pessimism.
6 **Q.** That is how I had understood your evidence but thank
7 you.

8 This document is a memo from 24 March 1983,
9 dictated by Dr Lane and signed in his absence, sent to
10 Mr Mallory and to a number of other people, including
11 you and Dr Smith. It says this:

12 "AIDS.
13 "Professor Bloom drew to the attention of the
14 CBLA at their meeting on Wednesday, 23 March, the
15 problems that are becoming associated with blood
16 transfusion and blood product administration with the
17 increasing incidence of reported AIDS cases which
18 continues to gain momentum in the United States on
19 a monthly basis. The high mortality in reported cases
20 is a cause for concern and is a primary factor behind
21 what is described as the American over-reaction to the
22 problem. The aetiological factor or factors remain
23 unknown."

24 If we go a little further down the document to
25 the fourth paragraph, Dr Lane describes what

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Professor Bloom and Gunson had been doing, and refers to patients at risk in the United Kingdom, notably people with haemophilia. He then goes on to say this:

"It is necessary for this laboratory to develop a policy, which may only be implemented on a short-term basis, which will allow for the presentation of a large proportion of NHS factor VIII as cryoprecipitate. Staff will be aware that many Regional Transfusion Centres have not made wet cryoprecipitate for some time and would now be both out of practice and in some cases without the facilities to recommence large-scale production. The implications for BPL source material are very real.

"A meeting involving those circulated with this memorandum should be set up at the earliest convenient opportunity" --

SIR BRIAN LANGSTAFF: I think we are missing that on the screen.

MR HILL: Sorry, Sully, if we could go on to the following paragraph. Forgive me, I have read ahead.

"A meeting involving those circulated with this memorandum should be set up at the earliest convenient opportunity to discuss the strategic alternatives a BPL for manufacturing small pool freeze dried cryoprecipitate to offset the requirement for

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met not just in respect of AIDS but other things to -- and discussed what should be done. And that committee was stout in its objection to change in guidance, for example, for -- to plasma donor centres, exclusion of individuals whose sexual behaviour put them at risk of transmission. That committee was opposed to anything that might reduce the production of plasma for fractionation without proper evidence that this was a transmissible virus.

Q. Does it --

A. That's probably -- I have actually -- I think I have referred to it in parts in my witness statement but I would need time to pull it up and point you to it.

Q. Should we read, then, that sentence not as meaning that Dr Lane considered there to have been an American over-reaction but that he was referring to the fact that others, including those clinicians that you have mentioned, considered it to be an over-reaction?

A. That's the way I read it, yes.

Q. In the third paragraph, the final sentence, Dr Lane wrote this:

"Equally, there is a likelihood that a return to cryoprecipitate as a desirable form of treatment may become irresistible, whether logical or not."

Can you assist with what he meant by those last

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manufacturing at BTS level. Considerable adjustments to resources should be envisaged and taken account of. Equally, a (temporary) fractionation programme commencing with cryoprecipitate supernatant from the BTCs should also be taken into consideration. The implications concerning factor IX production will need to be examined and the potential benefits of pasteurisation of factor IX given some priority."

So that is Dr Lane's memorandum, and we can see what has prompted it.

Are you able to assist with who was describing the "American over-reaction to the problem"?

A. A group of physicians in the US whose names -- the names that come to mind would be Professor Harold Roberts, from North Carolina, and two or three others, who were really -- and when I referred earlier to agnosticism about AIDS as a transmissible -- a blood-transmissible virus, I was thinking of that group. And I'd even include, certainly at the time, for example, of this memo, in March '83, I recall that David Aronson, at the behest of the Bureau of Biologics at Bethesda, was still not convinced that AIDS was a transmissible virus.

And I presume that the "American over-reaction to the problem" referred to the -- a committee that

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words "whether logical or not"?

A. I think so. It -- my view and I think others who have been addressing on that list would have taken the view that, practically, BPL would have found it very difficult to assist the transfusion service in creating a supply of freeze-dried cryoprecipitate for treatment as an alternative to freeze-dried concentrates. And I think that's the kind of logic that he was referring to, that it might be attractive but would be extremely difficult. And I'm not saying expensive; I'm just saying extremely difficult to do.

Q. That is a practical consideration. Is it possible that "logical" was hinting at something else, that Dr Lane was suggesting that a return to cryoprecipitate wouldn't do much good, in terms of reducing the exposure to a potential virus?

A. Well, I think if that's what he was thinking, I think he was right on that as well because it became quite clear, as time passed, that the virus had become part of our donor population just in the same way that non-A, non-B hepatitis had. And certainly the recall that I've referred to separately in another part of my witness statement indicated -- was an example of an England and Wales blood donor who donated blood, presumably convinced that he wasn't a source of risk.

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1 And he wouldn't have been the only one.

2 **Q.** We will come on to that later, the HL1386 incident.

3 But if we take that as an example, that donor

4 gave his blood donations, and one of those came into

5 BPL and was fractionated into many hundreds of vials

6 of Factor VIII concentrate which went out to patients.

7 If that plasma had been used in the form of

8 cryoprecipitate, it would have been a single donor

9 use, would it not? Would that not have reduced

10 the risk?

11 **A.** If we're talking about single donor cryoprecipitate

12 of course. It would only have infected the one

13 patient who was unfortunate enough to receive it.

14 **Q.** But you think this may also be reflecting on

15 freeze-dried cryoprecipitate which would not be single

16 donor; is that correct?

17 **A.** It didn't have to be single donors. It might have

18 provided one way of providing a supply -- a reduced

19 risk supply based on smaller donors (audio distortion)

20 in the pool.

21 **Q.** Obviously we haven't got Dr Lane to ask him those

22 questions, which is why I explore it a little with you

23 but recognise, of course, that you cannot speak for

24 him.

25 The memorandum as a whole reads as if it is

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1 Regional Transfusion Centres to be provided to BPL?

2 **A.** It would have -- if that had transpired, it would have

3 been possible to receive cryoprecipitate supernatant

4 from transfusion centres, and that could have been

5 used for recovery of Factor IX and Factor VII and, of

6 course, for albumins and immunoglobulins. But

7 a change in practice that would have needed -- that

8 BPL would have needed to adjust to and would almost

9 certainly have taken us back to receipt of that

10 cryoprecipitate supernatant in 5-litre bags with the

11 pooling of -- that the supernatant into those bags

12 being undertaken at the transfusion centres which

13 would be -- some better placed to do so under GMP

14 conditions.

15 **Q.** GMP is good manufacturing practice?

16 **A.** Yes, sorry.

17 **Q.** Some Regional Transfusion Centres would have been in

18 a better position to have done that, according to the

19 best standards at the time, than others?

20 **A.** Yes, indeed, but then in 1983, BPL was hardly best

21 placed to talk about processed GMP, given the facility

22 in Building 25.

23 **Q.** We'll come on to the meeting perhaps after lunch.

24 But just one final question from me on this

25 document. Is this, to the best of your memory, the

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1 inviting thought and discussion to be given to the

2 question of what BPL should do if there is this

3 departure in course and a reversion to

4 cryoprecipitate. Some of the issues that Dr Lane

5 raises for consideration are the use of

6 cryoprecipitate supernatants from the BTCs, at the

7 Blood Transfusion Centres. Am I right in reading that

8 as meaning that if the --

9 **SIR BRIAN LANGSTAFF:** Could we just have the document back

10 on the screen, please?

11 **MR HILL:** CBLA0001691.

12 **SIR BRIAN LANGSTAFF:** Thank you. You were asking about

13 particular wording on this document.

14 **MR HILL:** Penultimate paragraph, please. We can see

15 towards the end of that paragraph, he speaks about

16 the -- sorry, I have lost my place:

17 "Equally, a (temporary) fractionation programme

18 commencing with cryoprecipitate supernatant from BTCs

19 should also be taken into consideration."

20 Am I right in understanding that to mean that if

21 the Regional Transfusion Centres were producing their

22 own cryoprecipitate for Factor VIII patients, BPL was

23 still going to be asked to produce other blood

24 products, and in order to produce those blood

25 products, they would require the supernatant from the

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1 first time that you can recall a discussion or

2 a structured discussion taking place about the

3 reversion -- the possibility of a reversion to

4 cryoprecipitate and the effect that that would have on

5 BPL?

6 **A.** It's the first document, and if you look at -- I mean,

7 you've already addressed the first two paragraphs.

8 It's clear that there wasn't a consensus in the UK

9 that AIDS was a transmissible virus, so not surprising

10 that it was the first document of its kind.

11 **MR HILL:** Sir, I have reached the end of that document.

12 **SIR BRIAN LANGSTAFF:** Yes. Now would be a good time for

13 a break, I think. Shall we take a break until 2.10

14 2.10.

15 **(1.09 pm)**

16 **(The short adjournment)**

17 **(2.14 pm)**

18 **SIR BRIAN LANGSTAFF:** Yes.

19 **MR HILL:** Dr Snape, before we go back to the documents,

20 I've been asked to clarify something with you.

21 In response to my questions earlier, when I was

22 asking about non-A, non-B hepatitis, you gave

23 an answer saying that:

24 "I would agree that certainly, as fractionators,

25 we took it seriously."

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1 Then a little later when asked about AIDS, you
2 said, and I quote:

3 "... I think, like many fractionators, I would
4 have been sceptical about the coincidence of the
5 number of transmissions to haemophilic patients as
6 being [admissible] as being a mere coincidence."

7 In those answers when you were talking about
8 fractionators, are you talking about you and your
9 colleagues at BPL, or the wider community of
10 fractionators in the United Kingdom, or a more general
11 community of fractionators internationally?

12 **A.** I was certainly talking about fractionators in the
13 United Kingdom. I think in the context of developm ent
14 of understanding about AIDS as a risk, it was clear
15 that US fractionators were also responding, at the
16 very least, in terms of introducing or attempting t
17 introduce heat treatment processes for virus
18 inactivation.

19 Now, I'm not going to comment because I don't
20 have the knowledge, but I -- that could be simply
21 because they were commercially savvy and were looking
22 to create opportunity, but it could also be that, I like
23 UK fractionators, they felt it was necessary to tak
24 the warning that was coming across, particularly from
25 the CDC, about AIDS as a virus transmissible diseas e.

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1 **A.** No.

2 **Q.** Is it right that it is an internal BPL meeting? Al
3 of those people are employees of BPL?

4 **A.** That's correct.

5 **Q.** Reading from the minute, the first item is headed
6 "Acquired Immune Deficiency Syndrome", and I quote:
7 "The Director advised the meeting that
8 Professor Bloom had raised the subject of AIDS at t he
9 last CBLA meeting, and at the next CBLA meeting, he
10 wished to respond to any questions raised on AIDS. In
11 particular, what the BPL response would be to any
12 likely problem with AIDS and raw material input.

13 "Letters on AIDS have been circulated to
14 Haemophilia Directors by the supra-regional
15 directors -- BPL has to decide now whether to chang
16 course if a move away from concentrates (F.VIII and
17 F.IX) is requested.

18 "Mr Vallet had brought back recommendations from
19 the USA that outlined ways of reducing AIDS in sour ce
20 plasma, eg, by further screening of donors, taking
21 account of their history and background and sexual
22 activities.

23 "Plasma from high-risk donors (including their
24 sexual partners) was recommended by the B.O.B. [whi ch
25 I take to be the Bureau of Biologics] to be used fo

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1 My earlier comment about non-A, non-B hepatitis
2 I think probably was more applicable to -- from my
3 knowledge to UK fractionators.

4 **Q.** Thank you for that clarification.

5 I would like to move to the meeting that took
6 place following the memorandum that Dr Lane sent in
7 1983. Could we have on screen, please, BPLL0008758
8 This document is headed "Notes of a meeting held on
9 18 April 1983". It's a relatively lengthy minute; it
10 runs to 6 pages. The minute was taken by Mr Pettet
11 I'm not going to read all of it, but I am going to
12 read the first couple of pages.

13 We can see who was present: Dr Lane in the
14 Chair, Dr Harvey, Mr Mallory, Mr Pettet, Dr Smith,
15 you, Mr Vallet and Mr Wesley. Is it fair to descri be
16 those people as the senior management team at BPL a
17 that time?

18 **A.** Certainly everyone except Norman Pettet would have
19 been seen as senior management by that time. Norma n's
20 role as assistant to the director was invaluable, but
21 I don't think he would have described himself and
22 wouldn't have been described as part of the senior
23 management team.

24 **Q.** Is there anybody missing from that meeting who you
25 would have expected to be there?

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1 the preparation of Ig, PPF and diagnostic reagents.

2 "No directive has been issued with regard to
3 F.VIII. Discussions with Dr Aronstam indicated tha
4 the relationship of AIDS to haemophiliacs had not been
5 established nor the extent of the risk."

6 **A.** May I make a comment at that point, Mr Hill?

7 **Q.** Yes, please do.

8 **A.** That's not Dr Aronstam, although I accept that that 's
9 what the minute says. It was actually Dr Aronson,
10 Dr David Aronson, who was Bureau of Biologics in th
11 US.

12 **Q.** Thank you. That's very helpful:

13 "The producers of concentrates are concerned and
14 expect the B.O.B. to make a statement that no furth er
15 clinical trials be carried out on materials that ha
16 not been rendered safe from the risks of transmitta ble
17 disease.

18 "Another view from the USA was that the
19 commercial producers may withdraw from the market,
20 leaving only the state financed operations producin
21 F.VIII.

22 "Dr Snape stated that the B.O.B. reaction was
23 predictable and that an association was now being
24 formed between heat-treated concentrates in reducin
25 the risk from AIDS."

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1 If we go over the page, please:
 2 "The Director commented on the price increase
 3 now being seen for commercial concentrates, and the
 4 emphasis on marketing hepatitis-reduced risk material.
 5 "Dr Smith remarked that at the present time
 6 there was little firm knowledge on how effective heat
 7 treatment is on non-A, non-B or AIDS, nor what the
 8 effect on yields would be.
 9 "Several other comments were raised:
 10 "1) Do the UK haemophiliacs perceive the threat
 11 as serious as do the USA?
 12 "2) Is large pool material worse than small
 13 pool? Very little evidence in this area.
 14 "3) What would be the effect if BPL only able
 15 to produce one half of the UK requirement for F.VII I,
 16 if heat-treated yields were much lower than those seen
 17 currently for normal material.
 18 "4) The arguments for non-A, non-B and AIDS
 19 were separate and different with respect to risk, e.g.,
 20 the risk of non-A, non-B was seen in low and medium
 21 users, whereas AIDS would be of greater risk to heavy
 22 users.
 23 "The Director asked the meeting to consider
 24 a situation where AIDS was established in the UK, and
 25 some haemophiliacs had evidence of an altered immun

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1 to be large to reduce this present risk by any
 2 significant extent.
 3 "The answer to the AIDS question was therefore
 4 to consider what was feasible and what was not. Thus,
 5 if BPL was to be involved in the preparation of small
 6 pool concentrates, free of AIDS, there would have to
 7 be an extensive pool of accredited donors (or at least
 8 a high follow-up procedure for donors)."
 9 There is then some discussion about the
 10 differences between the UK and the US.
 11 Picking it up after that:
 12 "The Director asked Dr Smith whether BPL should
 13 promote the collection of small pool material into
 14 a working programme, eg, by the use of ...
 15 Leeds Haemonetics material (currently 100kg/week).
 16 "Dr Smith felt that Dr Robinson (Leeds) would be
 17 unwilling (for reasons associated with the present
 18 programme) or unable to provide significant increases
 19 in Haemonetics plasma.
 20 "Dr Smith suggested that the meeting
 21 differentiate between small pool (ie small volume
 22 pools) and small panel (ie large volume pools with few
 23 donors) and asked whether BPL should not be making
 24 a small panel F.VIII and F.IX in addition to the
 25 normal concentrate. If the answer was yes, a careful

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1 state (AIDS related or not). What is the ability of
 2 BPL to respond to a request to make small pool
 3 material, or that only heat-treated product was
 4 required by the Haemophilia Directors.
 5 "The general feeling was that a response to
 6 these requests would be difficult.
 7 "It was noted that US plasma was of two main
 8 types:
 9 "1) Recovered plasma pools (large unsecured
 10 donor pools)
 11 "2) Source plasma pools (small panel secured
 12 policies)
 13 "The UK is different in that only large donor
 14 pools are used, ie, there is still no major use of
 15 small panel plasmapheresis plasma, and that plans are
 16 in progress to increase plasma collection primarily by
 17 the use of SAG-M with secondary use of plasmapheresis.
 18 "It would be difficult to change the philosophy
 19 once major progress has been achieved in the SAG-M
 20 programme. In addition, the use of small panel
 21 accredited donors would be very expensive."
 22 Going over the page:
 23 "Mr Vallet suggested that if the present risk of
 24 using a large pool was small, the effect of
 25 an expensive screening programme of donors would have

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1 costing exercise would need to be carried out. The
 2 general feeling of the meeting was that BPL should go
 3 for both small panel and heat-treated products.
 4 "The overriding concern was that in trying to
 5 provide full UK demand with a secure product, BPL may
 6 end up not being able to supply the demand.
 7 "The Director also asked whether the current
 8 problems posed by AIDS could be used to obtain
 9 financial support for more work in this area.
 10 "Several views were expressed -- notably the
 11 lack of space and staff, and the doubts on which
 12 programme of direction to follow. The overriding view
 13 was one of wait and see."
 14 The minute does go on but I will leave it there.
 15 If we could go back to the first page of that
 16 minute, please, Sully.
 17 I would like to ask about that section where
 18 there is a record of what you are said to have said:
 19 "Dr Snape stated that the BOB [Bureau of
 20 Biologics] reaction was predictable ..."
 21 What did you mean by that?
 22 A. Predictable in the sense that BOB were cautious
 23 regulators and, in that sense -- going back up four
 24 paragraphs:
 25 "Discussions with Dr Aronson indicated that the

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relationship of AIDS to haemophiliacs had not been established nor the extent of the risk."

David Aronson was, in that sense, behaving as a BOB regulator would and saying, "Look, we don't know yet, and we are about to make -- or, to consider some big decisions based on incomplete evidence."

Q. The second part of what you are recorded as saying is that:

"... an association was now being formed between heat treated concentrates in reducing the risk from AIDS."

Do you know, now, what the basis of that statement was?

A. Yes. One US fractionator in particular, Baxter Hyland, had produced a moderately heated freeze-dried product, and it wasn't -- it didn't take long for the three other big fractionators to follow down that route.

In practice, what actually happened was that whilst those heat treatment programmes practically delivered a lot of reduction in the AIDS virus in the concentrates, they had relatively little impact on the hepatitis component of risk, and that was to be borne out by transmission of non-A, non-B hepatitis by those concentrates.

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raised, a number of questions are asked there, including:

"Is large pool material worse than small pool? - very little evidence in this area."

Are you able to assist now with what that discussion was at the time of that meeting or is it just too far in the past to be able to do so reliably?

A. Given the -- I'm assuming that that point is targeted at UK. Is large pool-material worse than small-pool? I would say it was accurate at the time. There was no evidence. If we'd been thinking about the US, then because of -- I think this was January '83 --

SIR BRIAN LANGSTAFF: It is April '83.

A. April '83, sorry. In the US, the population of plasma donors contributing to most of the big four US concentrate manufacturers was significantly threatened by high-risk individuals, and in that sense large-pool materials simply captured all of that risk.

MR HILL: I'm not going to go through all of the other points that are raised in the meeting, because I am going to take you to the paper that Dr Lane produced as a result of it, summing up his interpretation of the discussion.

If we can go to CBLA0001697. This is a document dated 22 April 1983. We can see from its heading that

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Having -- sorry, at the very top of that page:

"The Director commented on the price increase now being seen for commercial concentrates ..."

There was a profound increase in price of concentrates in the US on the back of introducing the so-called hepatitis reduced risk material and Jim Smith's remark in the next paragraph was just drawing us back to the fact that, look, we don't know how effective the heat treatment they are putting in place is going to be on AIDS or non-A, non-B hepatitis.

Q. I was about to take you to that paragraph from Dr Smith. Is there any dispute or contradiction between your views of an association now being formed and Dr Smith pointing out that there was very little firm knowledge? Were they in contradiction or were you in agreement on this point?

A. I think we were in agreement.

Q. There was some indication that there might be an association between heat treatment and reduction of risk but very little in the way of firm evidence. Is that a fair summary?

A. That is a fair summary. And the evidence that was to come would indicate that our caution was wise.

Q. The four paragraphs that followed, the comments being

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it is intended for the CBLA. The reference, the internal reference is CBLA83/23. The paper is entitled "Acquired Immune Deficiency Syndrome (AIDS)".

What Dr Lane wrote is this:

"Progress with AIDS is being kept under regular survey.

"A senior management meeting at BPL was called on the 18th April to review the laboratory policy as it might be affected by increasing reports of AIDS in the United Kingdom or by mounting pressure from the United States and Europe via popular press, haemophilia association, etc.

"Whilst AIDS continues to concern Federal and State authorities in the USA, a current review in the UK indicates that the disorder is limited to some 14 cases in known active homosexuals, but CDR reports give no evidence of AIDS in haemophiliacs. Haemophilia directors have been alerted to maintain heightened levels of surveillance so that the disorder, if proven, can be reported at the earliest opportunity.

"The production policy at BPL will adopt a 'wait and see' basis with continued manufacture of factor VIII concentrates and with continued attention to research and development programmes designed to

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inactivate transmissible viruses by heat pasteurisation and other methods. The potential of the laboratory to manufacture small pool freeze-dried cryoprecipitate in significant amounts, as an alternative to large pool intermediate factor VIII concentrate, has been ruled out on logistic production considerations.

"Whilst the situation in the UK appears to be under control, it is recognised that a first genuine report of AIDS in a haemophiliac could well bring about a sudden and significant general request for single unit wet cryoprecipitate for a large number of haemophiliacs. Whether this demand could be suppressed is unknown, but it would seriously reduce the efficiency of the current plasma procurement programme to satisfy BPL targets for factor VIII concentrate. An elaborate programme of pooled capture under sterile conditions of regional cryoprecipitate supernatant would have to be introduced to provide starting material for factor IX immunoglobulin and albumin products.

"The situation brought about by AIDS in the USA accentuates the requirement, always recognised at BPL, for there to be considerable flexibility within production and for the importance of having a properly

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plasma for Factor VIII production and, secondly, as we were discussing previously, a need to obtain the supernatant from the Regional Centres to produce the other blood products. Is that a fair summary?

A. Yes, that is a fair summary. Practically what, of course, it doesn't address, and didn't need to from Richard's point of view, is whether it was practically possible at enough Regional Transfusion Centres to make the switch to cryo. But, you know, that wasn't for him, at that stage, to seek to flag up.

Q. The paragraph about the need for flexibility and the properly supported vigorous programme of research and development; on one reading that could be read as Dr Lane giving a push to those who might be reading this document that those are areas that are needed and that may not have been sufficiently provided for in the past. Is that a fair reading of those paragraphs?

A. It is a fair reading and it builds on previous similar concerns expressed about lack of R&D and lack of flexibility as a result.

Q. And was that in part a consequence of the state of Building 25 and the lack of redevelopment before this time?

A. Partly that, but largely lack of investment in R&D personnel on the Elstree site and lack of R&D

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supported vigorous programme of research and development by in key areas.

"The possible impact of AIDS and the high incidence of non-A non-B hepatitis has caused the Director to review the current level of resources set aside for virus inactivation, and further proposals will be put to the Authority if it is felt that expansion of this programme is needed."

That is the end of the paper. The first point to pick up from that is that the paper states that small pool production at BPL has been ruled out at BPL on logistical grounds.

Am I right in reading that as meaning that if there was a decision taken by others to go for small pool production for the use of cryoprecipitate, then that, for logistical reasons, couldn't be done at BPL, but it is not saying that it should not be done?

A. That's a fair statement. It could not be done at BPL in Building 25, but in April 1983 Building 25 was all we had.

Q. So if a decision is taken to revert to cryo, to use a convenient shorthand, then that cryoprecipitate would be made at Regional Transfusion Centres and BPL then had to consider the consequences of that for its own production, and that would mean, firstly, less

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facilities.

But one of the things that doesn't really come out, I suspect, certainly not in my witness statement, is that because -- we didn't just not have R&D facilities, we didn't have virology testing facilities, we did not have a properly designed laboratory in which to carry out simulation studies where we could actually carry out virus inactivation steps or develop virus inactivation steps using spiked virus. It would have been improper on that site, with the facilities that we had. And yet it is what you really need if you want to develop virus-safe materials, is to be able to prove that you have done so.

Q. The reason that it would have been improper to carry it out on the site, is that because you were producing on that site Factor VIII for patient use and it would have been dangerous to introduce into that environment material that you knew to be infected with HIV or whichever virus you were looking at?

A. Certainly impossible in any building, even the new building, Building 27, to undertake that kind of experimentation. In a -- perhaps on the same site but in a specifically designed facility, fine. But we didn't have that and it was a long way in the future.

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1 Q. As of 1983, Dr Lane stated that the need for that kind
2 of research and development facility had always been
3 recognised at BPL. But it was not present at BPL
4 because of the way in which BPL had been funded and
5 developed. Was this an case of chickens coming home
6 to roost as of April 1983?

7 A. I suspect, I mean, if Dr Lane could answer for
8 himself, he would say it is not a case of chickens
9 coming home to roost, it is just a case of his
10 warnings not having been heeded. But that was where
11 we were.

12 Q. Just to summarise, then, the paper. We know that this
13 paper went to the CBLA and it was noted by the CBLA
14 and formed part of their discussion. I won't take you
15 to that document.

16 But am I right in summarising it as a meeting
17 and a paper with BPL, as it were, trying to get ahead
18 of the game, to think about how it would react if
19 there was a call for a reversion to cryoprecipitate?
20 But then there was no such call that followed?

21 A. Yes, that is a good statement.

22 Q. Do you know if Dr Lane, or BPL more generally, sought
23 to advocate one way or another for a reversion to
24 cryoprecipitate, or was this paper part of a wider
25 preparation for what BPL would have to do if that

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1 summary I have ever seen of the development of the
2 AIDS situation in the US. And there are some lessons
3 there that, had we had that paper back in 1983, we
4 could have learned from. But it is a good document to
5 go back to, to see how the situation developed. And
6 at the end of the day, what happened in the US was
7 what happened to us 6-12 months later anyway.

8 Q. I think the reference is CVHB0000042. It is
9 Dr Evatt's *Tragic History*, is that right?

10 A. That's the one.

11 Q. Just so that you are aware, Dr Snape, in November when
12 we were looking at the pharmaceutical companies, that
13 document was, in a way, the bedrock of the
14 presentation that was put forward about the response
15 to risk of AIDS in the United States, so it is
16 a document that the Inquiry has seen and has studied
17 in some detail, but thank you for referring to it, and
18 it's helpful to know your views on it.

19 I will come back briefly to the question of heat
20 treatment and response to risk. The reason that I'm
21 moving on to product recall is my understanding of
22 your statement and your evidence is that while you
23 have very helpfully set out a history of the
24 development of heat treatment at BPL, in terms of the
25 research and development that was principally a matter

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1 reversion was made?
2 Sorry, I haven't expressed that very clearly.
3 Was Dr Lane actively part of the lobbying for
4 one decision or another?

5 A. Bearing in mind that he had several years' experience
6 of working in a blood transfusion centre, and he knew
7 what the pressures in a busy centre were, and the
8 limited facilities in the centre were, I am sure he
9 was being very cautious but trying to be even-handed
10 and say, "This may be one approach, but, on the other
11 hand, there are problems."

12 Q. I'm going to move on from that document and that to pick
13 to the question of product recall. I will come back
14 a little later to discuss -- sorry, just before I do,
15 what I should say as part of the summaries, the two
16 points that Dr Lane raises in his paper as something
17 that BPL are going to take forward is work on,
18 firstly, heat treatment and, secondly, work on small
19 panel fractionation. Is that right?

20 A. That's correct. Before moving on, can I just flag up
21 something that may be useful?

22 Q. Yes, please do.

23 A. It is a document that I referenced in my witness
24 statement. You have got it as CVHB0000042. It is
25 a paper by Bruce Evatt. It is probably the best

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1 for Dr Smith and his team, something, obviously, that
2 you were aware of and worked with but it's -- I think
3 you, in a way, defer to Dr Smith's evidence on that
4 point. Is that right?

5 A. It is.

6 Q. For that reason, I'm going to turn to product recall
7 which was an area in which you were more directly
8 involved yourself.

9 You touched upon this earlier when we were
10 talking about the way in which the hepatitis risk was
11 monitored and communicated to Dr Craske, and I'll take
12 you to the section of your witness statement where you
13 deal with it. It's page 147, paragraphs 91 and 92.
14 WITN3431001. If I just read through your statement
15 What you wrote is this:

16 "There was no formal documented procedure for
17 recall, but, in my opinion, the system ..."

18 Sorry, I should have given the context. The
19 question is about the period 1970s to 1980s. A more
20 formalised process does come into play in the late
21 1980s, but you were answering about the slightly
22 earlier period where you said:

23 "There was no formal documented procedure for
24 recall, but, in my opinion, the system in place worked
25 effectively. Plasma (and product, but mostly plasma)

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incidents were tracked using an arrangement of brown Manila envelope wallets, with incident correspondence stored within the wallet, and with an overview of the progress of the incident in a pro forma sheet on the outside front cover which prompted actions (including batch 'hold' or 'recall'). The system was managed by a clerk reporting to me as scientist in charge of quality control. We did not have a computer database at the time, and the incident file tracking system was simple but effective, avoiding any consideration of dependence on an electronic backup. The pro forma sheet on the outside front cover set out a decision flow for actions to be taken, including withholding of release of product or recall of product. Each incident was closed out with a formal incident report -- the report INCREP02 is an example of such a report."

I will say we're going to come on to that report in a second:

"In the absence of a computer database, we used a 7"x5" card index system, one card per PFL batch, to record reports of patient events -- no patient names, just a yellow flag per hepatitis report. Results were notified to Miss Rosemary Jean Spooner, secretary to the OHC Directors Hepatitis Working Party, chaired by

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Dr John Craske. Batches that accrued four or more yellow flags were identified for HWP attention. I recall that on transfer to Elstree in 1982, I was granted a full time clerk and a full time technician staffing the BPL control unit. The same brown wallet incident file tracking system was established and managed by the technician who reported directly to me. Again, as at PFL, there was no computer database, but the paper-based system continued to be simple and effective."

So that is what is in your written statement.

You go on in paragraph 93 to refer to a statement that was provided by David Donald, somebody who you've mentioned at various points in your evidence over the last couple of days. I won't go to the document, but what Dr Donald said was that the first formal complaints procedure and product recall document was authorised for use at BPL on 3 November 1988, and from my understanding of your evidence, you don't dispute Dr Donald's recollection in that regard.

A. No, I don't.

Q. So, before 1988, you had a system in place, but it was not a system that was committed to writing; is that correct?

A. Sorry. Not a system that was committed --

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Q. To writing.

A. To writing. It was not a recall procedure; it was a review mechanism that, in our experience and my lack of experience in terms of pharmaceutical manufacturing, served the purpose and was seen by successive medicines inspectors and, in that sense, not criticised. That's not to say I would seek to defend it as fulfilling the recall procedure requirements that were first stated in the orange - the 1977 Orange Guide, in chapter 9 of that guide.

Q. I won't go to that document in light of what you've said, but so that we have the reference for it, it is PRSE0002339 and page 35 of that document. That's the 1977 Orange Guide which said there should be a recall system which is written down. Is that a fair summary?

A. Yes.

Q. And BPL did not comply with that until 1988, but it did have a system that was unwritten.

A. Yes. We had a mechanism that worked, and it was written only in the sense of the pro forma on the Manila envelope data capture system.

Q. I would like now to turn to the report that you referred to in paragraph 91 of your statement, which is -- INCREP02 is the internal reference for it. I is WITN3431014.

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This concerns an incident which is sometimes referred to as the "Wessex donor incident". I'm going to read through the entirety of the report and then ask you a few questions about it.

We can see at the top that it is a report prepared by you. The reference is INCREP02. It is distributed to Dr Lane, Mr Mallory and Mr Vallet, but I understand that it may have been sent on to other as well in due course. And the title is "Summary report on the recall of Factor VIII batch HL3186 occasioned by probable diagnosis of AIDS in a contributing donor."

What the report says in full is this:

"1. Donor condition and products affected.

"1.1. A donor was admitted to Boumemouth Hospital with a skin rash consistent with Kaposi's sarcoma, leukopenia and anaemia. Biopsy results awaited. Donor admits to homosexual activity but was VDRL negative when he donated blood on 25.9.84 (this donation was separated at Wessex RTC but plasma was not dispatched to BPL)."

I pause there, sir, to note that I should have said that the report is dated 23 October 1984, an important point of context, and forgive me for not raising it before:

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1 "The original report of this incident,
2 telephoned by Dr D Smith on 2.10.84, was confirmed in
3 writing by Dr M Barnes (letter of 4.10.84 attached)
4 "Dr Barnes confirmed the following circumstances
5 concerning the donor (telephone 12.10.84):
6 "(i) Biopsy confirmed early Kaposi's sarcoma;
7 "(ii) Plasma samples tested by Dr Tedder were
8 positive for HTLV-III;
9 "(iii) The donor was now been diagnosed as
10 suffering from pneumocystis pneumonia.
11 "1.2. Plasma donation number ... [and the
12 number is been given but has been redacted by our
13 team] was collected into an IPP on 27.3.84 and
14 dispatched to BPL on 6.4.84 in box number SF4333.
15 This pack was used in the manufacture of batch HL31 86.
16 "No Factor IX was recovered from the
17 cryosupernatant.
18 "No fraction II was recovered from the A + I
19 precipitate.
20 "Fraction V was recovered and is presently held
21 as L938 and L939.
22 "Factor VIII batch HL3186 was distributed as
23 follows:
24 "Wessex RTC - 485 vials (sent 10 August)
25 "Cardiff RTC - 400 vials (sent 15 August)

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1 implication of HL3186 (telephone 2.10.84, TS)."
2 Presumably those are your initials?
3 A. That's correct.
4 Q. "... and was asked to recall all vials, including any
5 held by patients for home therapy.
6 "Dr Napier (Cardiff) was unavailable, but
7 Mr Booth (Sen.Ch.MLSO, Cardiff) was informed
8 (telephone 3.10.84, TS) and was asked to recall all
9 vials of HL3186, including home therapy issues.
10 "Both telephone conversations were confirmed in
11 writing (3.10.84, copies attached).
12 "2.2. Fraction V concentrate L938 and L939 were
13 secured and labelled 'HELD' -- although PPF might b
14 argued safe in respect of viral transmission, it is
15 not considered that the risks possibly associated with
16 further processing can be justified. These fractions
17 will be held against the possibility of development of
18 suitable test methods.
19 "2.3. PPF batch AD1305 will be held pending
20 results of investigations to determine process
21 efficacy of heat in relation to HTLV-III inactivation.
22 Provided it can be demonstrated that wet-heat
23 pasteurisation inactivates the virus, the product may
24 be considered for release.
25 "PPF batch AD1315 will also be held; the

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1 "1.3. Time-expired plasma from the donation of
2 21.11.82 was received at BPL as pool number C31621E
3 (ie from Leeds RTC). This was subsequently
4 fractionated, yielding fraction V concentrate L825.
5 Two batches of PPF were manufactured from this
6 concentrate:
7 "AD1305 - labelled but not released for issue;
8 held at Bullens.
9 "AD1315 - finished but QC incomplete; held on
10 site.
11 "No fraction II was recovered from the A + I
12 precipitate."
13 Going over to the next page, please. That is
14 just some marginalia on it. I won't bother with it
15 "1.4. The donor also gave blood in the West
16 Midlands region on 14.2.83. This donation was used as
17 whole blood; no components were sent to BPL.
18 "1.5. There is no indication from records
19 maintained at Wessex RTC that any other plasma from
20 this donor has been received at BPL during the last
21 five years (but see the penultimate paragraph of
22 Dr Barnes' letter).
23 "2. Actions to secure/recall implicated
24 products.
25 "2.1. Dr Smith (Wessex) was informed of

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1 situation here is more complex in that completion o
2 finished product QC would require that further
3 analytical work be carried out on unheated samples.
4 "2.4. All samples of intermediate and finished
5 products held in house have been secured, and will be
6 held pending development of appropriate test methods."
7 Over the page please.
8 "3. Results of factor VIII recall.
9 "3.1. The 400 vials of batch HL3186 dispatched
10 to Cardiff break down thus:
11 "Stock held at RTC - 150 vials
12 "Heath Park, Cardiff - recovered 101 out of 150
13 vials (6 patients),
14 "Morriston - recovered 51 out of 60 vials
15 (2 patients),
16 "Carmarthen - recovered 36 out of 40 vials
17 (1 patient).
18 "A total of 338 vials were recovered; 9 patients
19 received the batch.
20 "3.2. The 485 vials of batch HL3186 dispatched
21 to Wessex break down thus:
22 "Alton (LMT College) - recovered 105 out of
23 200 vials,
24 "Dorchester County - recovered 5 out of 25
25 vials,

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"Salisbury - all 70 vials used,
 "Winchester - all 10 vials used,
 "Bournemouth - recovered 60 out of 60 vials,
 "Southampton - recovered 1 out of 60 vials,
 "Portsmouth - recovered 6 out of 50 vials,
 "Newport, IOW - recovered 10 out of 10 vials.
 "A total of 187 vials was recovered; the number
 of patients involved was not reported."

"4. Follow-up actions.

"4.1. Dr Smith (Wessex) was asked to report any
 plasma from this donor despatched to BPL (or PFL)
 within the last 5 years. Dr Smith was also asked to
 determine whether the donor had a history of
 attendance at local special clinics for venereal
 disease. (Dr Barnes subsequently confirmed that this
 was the case.)"

"4.2. Dr Tedder (Middlesex) was consulted but
 indicated that he did not wish at the moment to
 receive samples of plasma fractions since he did not
 feel test methods presently in use were appropriate.
 He did however ask to receive a sample from the most
 recent donation (September, 1984) and this was
 arranged with Dr Smith (Wessex)."

"4.3. Dr Craske (PHLS Manchester and Chairman
 of the Haemophilia Centre Directors' working party on

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"Enforcement of a three month quarantine period
 would not in this instance have avoided the loss of
 resource resulting from the plasma pool being
 compromised by a single donation; it would almost
 certainly have avoided patient exposure to the product
 however.

"Enforcement of a six month quarantine period
 would have been prevented release of the batch for
 clinical use; it would also have allowed the donation
 to be excluded before pooling, thus avoiding a very
 expensive reject situation.

"This incident must be an extremely cogent
 argument for the establishment of cold storage
 facilities capable of supporting a six-month
 quarantine of fresh frozen plasma.

"5.3. The appearance of this donor at three
 different Centres within two years clearly underlines
 a fundamental problem when carrying out follow-up on
 donor incidents of this sort. Surely central
 co-ordination of donor records is unavoidable."

That is the end of the report, and it is signed
 by you as head of quality control.

It is quite a lot to take in there so I'm just
 going to give a summary. This report concerns a donor
 who was later diagnosed with AIDS, who gave blood on

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viral transmission of disease) was consulted and asked
 to be supplied with a list of haemophilia centres
 supplied with HL3186, in order to initiate follow-up
 studies on patients treated with the batch. Dr Craaske
 will be asked to provide BPL with a list of
 haemophiliacs identified as having received batch
 HL3186.

"4.4. Medicines Division appraised of the
 situation (Dr K Fowler and also 'Defects Report'
 section)."

"5. Observations on the incident

"5.1. With an incubation period exceeding two
 years it is likely that a donor diagnosed as suffering
 from AIDS will compromise more than one pool of plasma
 fractionated at BPL."

"5.2. In this particular instance, the last
 (and most damaging) donation was received at BPL on
 6th April 1984, pooled for fractionation on
 17th May 1984 and issued for clinical use on
 10th August 1984. This timetable is consistent with
 the five week period of quarantine presently
 supportable for fresh frozen plasma and the
 irreducible six to eight week delay from pooling
 plasma to release of factor VIII concentrate for
 clinical use.

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21 November 1982 and on that occasion the time-expired
 plasma was received at BPL but no product was issued
 from BPL.

The donor also gave blood on 14 February 1983.
 That was a whole blood donation and no plasma was sent
 to BPL.

The donor gave blood on 27 March 1984. That was
 collected in an international plasma pack, single unit
 pack. It was received at BPL on 6 April 1984. It was
 subjected to the five-week quarantine period that was
 then in place and was fractionated a little after the
 end of that period, on 17 May 1984. It was issued for
 clinical use on 10 August 1984 with the code HL3186

The donor also donated on 25 November 1984. The
 plasma from that donation was separated but it was
 held at the Wessex Regional Transfusion Centre where
 the donation had taken place.

The report about the donor's suspected diagnosis
 was made on 2 October 1984, by telephone from
 Dr Smith. Dr Smith of the Wessex Regional Transfusion
 Centre was told of the implications that day,
 2 October, and asked to recall all of his vials,
 including those issued for home therapy.

As I understand it, that contact was made by you
 on 2 October, because we see your initials next to the

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1 note of the telephone call. Is that right?

2 **A.** Correct.

3 **Q.** Dr Napier of the Cardiff Regional Transfusion Centre

4 was not available that day, but Mr Booth was informed

5 the following day, 3 October, again by you; is that

6 correct?

7 **A.** Yes, I spoke to Tim on the following day.

8 **Q.** Mr Booth is listed there as "Sen.Ch.MLSO". Could you

9 assist with what that means?

10 **A.** Senior chief medical laboratory scientific officer.

11 **Q.** Thank you.

12 **A.** In Blood Transfusion Centre terms, a senior person.

13 **Q.** Do you know why Dr Napier was unavailable on the 2nd

14 or why it was you weren't able to get in contact with

15 him?

16 **A.** I do not think he was in the centre at the time.

17 I don't remember now. But I had no qualms about

18 giving the information to Tim Booth.

19 **Q.** Was there anybody in the centre on 2nd October to whom

20 you could have given the information, so far as you

21 recall?

22 **A.** I really don't recall, it is a long time ago.

23 **Q.** Also a function of it being a long time ago is we must

24 remember back to the technology that was in place at

25 the time. You had telephone as a way of getting in

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1 report at the time if that information had come in,

2 but I have no means of knowing now.

3 **Q.** Just to finish the summary, at section 4 there is

4 a list of the follow-up actions that were taken. Were

5 these presumably taken by a combination of BPL and by

6 the reporting doctor as well?

7 **A.** Sorry, would you mind just flipping -- can we just

8 display that -- the previous page, with the actions

9 **Q.** It is contacting Dr Tedder and Dr Craske, the

10 Medicines Division?

11 **A.** I know that Dr Craske followed up, and in fact I think

12 there is a separate letter relating -- there is,

13 I know, a separate letter relating to it on file.

14 Richard Tedder had the sample from Dr Smith at Wessex,

15 performed the testing and confirmed positivity. An

16 obviously, my comment there, Barnes followed up on the

17 attendance at local VD clinics.

18 **Q.** I would like to ask you about the quarantine period

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

20 From the report it appears that the donation

21 that was fractionated into HL3186 did go through the

22 appropriate quarantine period that was in place at

23 BPL, which was a five-week quarantine; is that right?

24 **A.** It did. If I can be pedantic, I used the word

25 "quarantine" there as the only word describing holding

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1 contact. Letter as well. And presumably -- were

2 there any fax machines?

3 **A.** In '82 I don't believe we had a fax. We didn't have

4 a fax machine in the control unit. I'm sure there was

5 a fax machine in Queensbury(?) Lodge, the

6 headquarters, but the -- it didn't seem to be untimely

7 to follow it up on the 3rd rather than the 2nd. If

8 I knew what precise times of day the calls were made

9 it might even have been that I was running out of time

10 on the 2nd. I don't know.

11 **Q.** In terms of the recall, 400 vials were despatched to

12 Cardiff, 338 were recovered and it is recorded that

13 9 patients received the batch.

14 485 vials were despatched to Wessex. 187 were

15 recovered. And as of 23 October, there was no report

16 of the number of patients involved.

17 Are you able to assist as to why it was possible

18 to recover more from Cardiff than it was from Wessex?

19 **A.** I'm sure it would have been rate of use of the

20 product, and the amount of product held in the centre

21 versus the amount of product out for home treatment

22 **Q.** Do you know whether it was ever possible to discover

23 the number of patients of the Wessex Regional

24 Transfusion Centre who were exposed to the product?

25 **A.** I don't know. I believe I would have updated the

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1 plasma before use. If I'd -- later, we would have

2 defined that as -- no, I'm sorry, I have forgotten the

3 term now. Not "quarantine" but --

4 **Q.** Inventory hold?

5 **A.** Inventory hold. The difference being, quarantine is

6 when plasma is put on hold and it is not released

7 until there is a test result allowing it to be

8 released. With inventory hold, it is the time that

9 determines whether the plasma will be released or not.

10 So I was using the term "quarantine" then, but that

11 would have been better described "inventory hold".

12 **Q.** How had the five-week period of inventory hold at that

13 time been arrived at?

14 **A.** By what we could do. We were conscious that if we

15 could extend it, we would. But five weeks was

16 a reasonable period at that time, given the stock of

17 plasma and the rate of use of plasma.

18 **Q.** We saw from the video that we looked at yesterday that

19 the inventory hold period requires for plasma to be

20 kept in minus 40 degree temperatures, or at least very

21 cold temperatures, and we saw it is a process that

22 requires a fair degree of space, given the physical

23 size of the plasma that is provided to BPL. So when

24 you say it was what we could do, is that a reflection

25 of the facilities that you had to hand as of 1984?

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1 BPL?

2 **A.** Yes, because it was a storage facility attached to

3 Building 25. It was -- we had to wait for Building 27

4 to be able to achieve the three-month quarantine

5 period. Six months would have been nice but

6 three months was certainly practical in Building 27

7 **Q.** The discussion that you include in your observation

8 about a three-month versus a six-month quarantine

9 period, is that with an eye to an ongoing debate at

10 the time about how things were going to be arranged

11 once Building 27 was in operation?

12 **A.** Yes, I was putting markers down, yes.

13 **Q.** Your preference expressed there appears to be for

14 a six-month quarantine period?

15 **A.** Oh, I didn't necessarily expect that my wishes would

16 be granted, but I certainly was pleased to have space

17 for three-month quarantine.

18 **Q.** Was that something that had to await the commissioning

19 of Building 27 sometime in 1987?

20 **A.** That is correct.

21 **Q.** Did the five-week quarantine period remain in place

22 until that point?

23 **A.** Yes, though, again, memory eludes me, but I doubt if

24 that quarantine -- I hate using this term

25 "quarantine" -- whether that inventory hold would have

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1 **A.** That's correct.

2 **Q.** The six-month inventory hold period would have allowed

3 for the donation to be excluded before pooling. Does

4 that mean that it would have involved that individual

5 plasma pack being taken out and discarded but the rest

6 of the plasma packs with which it was subsequently

7 pooled would have been saved and could have been used

8 to create product?

9 **A.** Yes, because every individual donor was barcode scanned

10 into the plasma pool and could then be cross-checked

11 against the donor list supplied from the centre.

12 **Q.** You say at paragraph 5.3, right at the bottom of that

13 page:

14 "The appearance of this donor at three

15 different Centres within two years clearly underlines

16 a fundamental problem when carrying out follow-up of

17 donor incidents of this sort. Surely central

18 co-ordination of donor records is unavoidable."

19 Could you just expand upon what you meant by

20 that?

21 **A.** On the assumption that a donor presents for blood

22 donation twice a year, then the idea that a blood

23 donor would go to three different transfusion centres

24 or donation halls in two years -- maybe what I should

25 have done also is to extend that by challenging

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1 been done at minus 40. It would have been done in the

2 cold room that was accessible to us at -- or

3 associated with Building 25, which memory says was

4 a minus 30 not a minus 40 cold room.

5 **Q.** Forgive me, it was my slipping back into "inventory"

6 which led you to do the same. I will try to be more

7 disciplined.

8 The difference that you identify in the report

9 between the three-month period and the six-month

10 period for inventory hold is that with the three-month

11 period, then, it wouldn't have avoided the loss of

12 resource but it would have avoided patient exposure

13 Am I right in understanding --

14 **A.** That is correct.

15 **Q.** So the product would have been fractionated but it

16 wouldn't have been used by patients; is that what you

17 were getting at?

18 **A.** It probably wouldn't even have been released.

19 **Q.** And that's just a function of the period of time

20 involved and the chronology that we have just been

21 through?

22 **A.** That is correct.

23 **Q.** Because there wasn't going to be any testing done

24 in 1984 because the test wasn't available to you at

25 BPL at that time?

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1 whether or not there was coordination of the record

2 between three different centres, and I don't believe

3 that there was at that time. But that's something you

4 would need to check with blood transfusion people at

5 the time.

6 **Q.** Looking back, knowing what you do now, do you think

7 that that donor recall could have been handled more

8 effectively from the point when BPL were informed on

9 2 October 1984?

10 **A.** I don't -- I think the one thing you flagged up that

11 left me trying to remember but failing to remember is

12 could I have followed up at Cardiff within the 24-hour

13 period or within the -- instead of making it the

14 following day, could I have sent out a police

15 motorcycle rider to get the information? I'm not

16 convinced that it would have -- that I could have

17 improved much on that system. And no one reading the

18 report at the time or since, apart from yourself, has

19 actually found deficiencies in it.

20 **Q.** I should stress, I make no findings, I'm merely asking

21 questions.

22 **A.** Good probing questions though.

23 **Q.** As I understand it, this report was sent to the

24 Department of Health and Social Security. To the best

25 of your memory is that correct?

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1 **A.** Yes, it was sent to Keith Fowler, and perhaps the more
 2 predictable target was the Defective Medicines
 3 Reporting Centre, where all such reports would have
 4 gone.
 5 **Q.** I'm just going to have a quick look at a couple of
 6 documents which followed on from this. Can we have
 7 CBLA0001997 on screen, please.
 8 This is a letter that you wrote on 24 January to
 9 a number of doctors. We can see from the following
 10 page the doctors to whom it was sent, and we will come
 11 to that in a second. It's a letter which is entitled
 12 "Follow up of patients treated with Factor VIII batch
 13 HL3186", so concerning, obviously, the same batch that
 14 we've just been looking at. In it, you wrote:
 15 "In October 1984, you were informed by
 16 Dr D.S Smith, director of Wessex RTC, of the need to
 17 recover and return to BPL all unused vials from batch
 18 HL3186, following confirmation of the inclusion, in
 19 the plasma pool from which the batch was manufactured,
 20 of plasma from a confirmed AIDS sufferer. With your
 21 assistance, this recall was completed promptly and
 22 effectively.
 23 "As you know, the follow up of patients treated
 24 with batch HL3186 is being coordinated by Dr John
 25 Craske, PHLS, Manchester. I understand from Dr Craske

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1 been crossed out, Dr Parry, Dr Chisholm, Dr Marbour
 2 Dr Alan Green at the Queen Alexander Hospital in
 3 Portsmouth, Dr McAndrews and Dr Aronstam. Copied to
 4 Dr Craske, Dr Lane, Dr Smith and Professor Bloom.
 5 That letter appears, if I may put it this way,
 6 to be giving those doctors a bit of a kick to
 7 co-operate with Dr Craske in his follow up. Is that
 8 (a) a fair summary, and (b) if it is, why was that
 9 kick necessary?
 10 **A.** Yes, it was meant to be a prompt. You could argue
 11 that I was exceeding my authority in the sense that
 12 I had no right to see patient names. With hindsight,
 13 what I possibly should have done would have been to
 14 push harder for the information -- for the patient
 15 names to be presented to Craske, but I couldn't see
 16 any other way of getting the information that Craske
 17 needed. And you asked me -- there was a second follow
 18 up --
 19 **Q.** Why was it necessary? Why weren't the doctors doing
 20 it already?
 21 **A.** They are busy people treating haemophiliac patients
 22 It was irritating but I felt that through -- by
 23 including Arthur Bloom in the copy list -- I mean, he
 24 is in two places, as a receiver of product but also as
 25 chairman of the Haemophilia Centre Directors -- I was

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1 that he has received very poor response to requests
 2 for details of patients treated with this batch, and
 3 even less satisfactory response to requests for
 4 samples of patients' sera. I would urge you to give
 5 Dr Craske your complete support in the identification
 6 of patients treated with this batch and in the
 7 clinical follow up outlined in Dr Craske's letter of
 8 20 November 1984.

9 "BPL has no direct role in clinical follow up,
 10 but I am required to furnish a report on the
 11 effectiveness of the recall procedure and the extent
 12 of treatment with this compromised batch. To this
 13 end, I would be grateful if you would supply me with
 14 a list of patients treated with batch HL3186 (with
 15 copy to Dr Craske if you have not already supplied
 16 this information to him)."

17 So that letter appears to be -- sorry, if we
 18 could just go over to the following page, please, to
 19 see the list of people to whom it was sent.

20 Professor Bloom -- was it sent to
 21 Professor Bloom in his capacity as Chairman of the
 22 Haemophilia Centre Directors, or was it sent to him as
 23 a doctor of the University Hospital of Wales?

24 **A.** The latter.

25 **Q.** We also have Dr Gilliver, Dr Hamblin, whose name has

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1 hoping to get some push from there as well.

2 **Q.** Was it effective to the best of your knowledge?

3 **A.** I don't believe so. I think Craske got a proportion
 4 of samples but not what he might reasonably have
 5 expected.

6 **Q.** I'm going to take you to one response to you.
 7 CBLA0000010_196. It is from 2 February 1985. It
 8 comes from Dr Green, from Portsmouth District
 9 Pathology Service at St Mary's Hospital in Portsmouth.
 10 He says this:

11 "Please address all further correspondence about
 12 haemophilia, factor VIII, AIDS etc, to me as I am the
 13 Director of the Haemophilia Centre for the Portsmouth
 14 District.

15 "I object to the tone of your letter. I intend
 16 to follow up the patients affected by the transfusion
 17 of HL3186 and I reserve the right to do this in my own
 18 time and in my own way. If you had taken the trouble
 19 to [en]quire from Dr Craske you would know that he is
 20 in possession of samples from some of my patients and
 21 in due time he will be in receipt of samples from all
 22 of them. It has taken him 7 weeks to supply me with
 23 the results of the tests he does and I only then go
 24 them by 'phoning him. Things I dare say will work out
 25 in their own time."

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1 Are you aware of why Dr Green took the stance
2 and the tone that he did in that letter?

3 **A.** No. It surprised me. I accept that as a physician he
4 has clinical care of the patients, not me, not
5 John Craske. But no, I don't know why it has taken
6 him so long. And I certainly had enquired from Cra ske
7 how well he was in receipt of samples. I wasn't to ld
8 that Dr Green had supplied a proportion of them.

9 **Q.** We know from your statement that Dr Green also seem
10 to have taken exception to a later request from BPL to
11 return unheated Factor IX. It is page 152,
12 paragraphs 100 to 101.

13 Was Dr Green typical of the way in which
14 clinicians were responding to such requests from BPL?

15 **A.** No, I don't recall getting that kind of fractious
16 response from other physicians. Just looking now a
17 the Dr Green, PJ Green -- if I really wrote to Dr A lan
18 Green in the initial communication -- it never
19 occurred to me before, but perhaps the letter was
20 misdirected. But I don't think so. I'm just tryin
21 to invent excuses for him.

22 **MR HILL:** That is all I wish to ask you about those
23 documents.

24 I have rather run over time, sir.

25 I only have a couple of questions left myself

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1 (3.31 pm)

(A short break)

3 (4.17 pm)

4 **SIR BRIAN LANGSTAFF:** Yes, Mr Hill.

5 **MR HILL:** Dr Snape, I have just one small topic to ask you
6 questions about. I'm conscious that I haven't take
7 you to the sections of your witness statement that
8 deal with viral inactivation and heat treatment. You
9 can be assured that the Chair and the Core
10 Participants have access to that statement and will be
11 able to go through it and look at it and take it in to
12 consideration later in the Inquiry.

13 I, however, am just going to take you to the
14 very end of your initial statement because I'm
15 conscious that you chose to end your written evidence
16 in this way, and I want to give you the opportunity of
17 ending this part of your oral evidence as well. It is
18 WITN3431001. Page 110, paragraph 332 of your
19 statement.

20 What you wrote there at the very end of your
21 initial statement to the Inquiry is this:

22 "Finally, I want to pay tribute to an individual
23 whose enthusiasm, vision and indefatigable commitment
24 made possible a new, state of the art BPL. The BPL
25 facility was already substandard in pharmaceutical

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1 for Dr Snape and I'm conscious that the Core
2 Participants and the representatives of the Core
3 Participants may be sending in questions as I speak
4 which I will consider over the break if I may.

5 **SIR BRIAN LANGSTAFF:** Yes. Let's take a break then.

6 Do you want any longer a break because of that
7 or not?

8 **MR HILL:** Can I -- I will aim for half an hour and
9 I hope --

10 **SIR BRIAN LANGSTAFF:** Right. Well, what I will say is not
11 before 4 o'clock. So not before 4 o'clock. It may be
12 a bit longer.

13 What happens now, Dr Snape, is that counsel has
14 virtually finished the questions he has, but of course
15 there are Core Participants who, through their lega
16 representatives, have the right to and do ask
17 questions through counsel of you and we have to giv
18 an opportunity for those questions to be formulated
19 and considered. So that's what will happen in the
20 next 30 minutes or so, but it won't be any shorter
21 than 4 o'clock.

22 So you have got until at least 4 o'clock, and if
23 you would be ready then, if there is a further dela
24 we will let you know.

25 **A.** Thank you, sir.

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1 manufacturing terms when it was built in 1954 as
2 a civil defence project for the preparation of
3 freeze-dried, large pool, UV irradiated plasma.
4 Manufacturing on site had been neglected and
5 under-resourced for a further 25 years and was
6 under-supplied with plasma even for the presumed
7 requirements of the late 1970s. From his arrival a
8 BPL in April 1977, Dr Richard Lane saw what was
9 missing and set about planning the concept, design and
10 build of the B27 manufacturing facility. Dr Lane's
11 persistence in identifying and securing the plasma
12 needs of B27 to meet demands considered necessary a
13 the time for self-sufficiency and his determination to
14 plan beyond that, for the future, were key. It is my
15 personal opinion that, without Richard Lane's
16 unstinting commitment of time, energy and enthusias m,
17 B27 would never have been built and the product needs
18 of England and Wales would forever have had to be met
19 by commercial imports. It is deeply unfortunate th at
20 ... [I won't say why] [Dr Lane] is unable to presen
21 his own views to the Inquiry; it falls to me to be
22 a poor substitute."

23 Does that remain your evidence?

24 **A.** Absolutely.

25 **Q.** That is --

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1 A. And thank you.

2 Q. That is all I have for you but there are questions

3 from the Core Participants that I will now take you

4 to.

5 As the chair said there will be a bit of leaping

6 around from one topic to another so please bear wit

7 me and if you need a moment to be reorientated as t

8 where you are then please do ask.

9 I begin with this question, you talked in your

10 evidence about economic fractionation being like

11 a milking stool and one of the -- the word "economic"

12 is one that I have been asked to pick up and ask yo

13 about. Does that term "economic" refer to cost

14 savings or to maximising the scarce resource of plasma

15 or to both?

16 A. For me the milking stool analogy was thinking about

17 the effective use of the donor's gift of plasma.

18 The fact is that in a real world, if we didn't utilise

19 it fully, down the three streams of clotting factors,

20 albumin and immunoglobulin, then the process would not

21 survive and we would not be serving the patients or

22 the donor.

23 Q. Sully, if we could have onscreen, please, WITN3431001.

24 A separate question. This relates to the

25 difficulties that Dr Maycock faced in the 1970s in

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1 "b. The capacity/capability of the NBTS in E&W

2 to meet those demands.

3 "c. The capacity/capability of the (then)

4 unlicensed facility at BPL, Elstree to meet those

5 demands (even with attention to its GMP limitations,

6 PFL in Oxford could only ever operate as a development

7 and GMP pilot scale facility).

8 "d. The yield achievable with the manufacturing

9 process, including any confounding effects such as:

10 "i. Patient/physician demands for desirable

11 product characteristics (presentation, storage

12 requirements, solubility, specific activity,

13 convenience in use).

14 "ii. The impact of any process modification(s)

15 required to take into account newly emerging risks, in

16 particular blood-borne infectious agents like

17 hepatitis viruses and HIV."

18 So those are, as I read it, some of the

19 complications and variables that were involved in the

20 1970s and indeed the 1980s in estimating demand.

21 Do you stand by that evidence?

22 A. I do, though obviously Sir William Maycock wasn't

23 faced at the time with HIV, but hepatitis viruses were

24 a challenge to us.

25 Q. And those challenges would have been faced not only by

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1 predicting plasma demand, and I have been asked to

2 draw your attention to this section of your witness

3 statement. It is page 112. What you wrote is this

4 "To be trustworthy, self-sufficiency

5 calculations would have required two parameters to be

6 known with a reasonable degree of accuracy:

7 "1) The amount of factor VIII required for

8 treatment, as determined by:

9 "a. The number of haemophiliac patients to be

10 treated and the severity of their factor VIII

11 deficiency.

12 "b. The treatment regimen to be followed:

13 "i. Treatment in response to bleeding.

14 "ii. Home therapy (as it developed over time).

15 "iii. Treatment by prophylaxis (as it developed

16 over time) to formalise life as far as possible.

17 "iv. Enhanced treatment in support of surgery."

18 That is the first parameters which would be

19 required to be known with a reasonable degree of

20 accuracy.

21 Second is the:

22 "The amount of factor VIII available for

23 treatment, as determined by.

24 "a. The quantity and type of plasma available

25 for factor VIII production.

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1 Dr Maycock but by others who were seeking to estimate

2 demands in the 1970s and 80s as well?

3 A. Including so, including the Department of Health and

4 Haemophilia Centre Directors and Transfusion Centre

5 Directors.

6 Q. Separate question. You said it would have been

7 extremely difficult for BPL to have assisted the

8 transfusion service in creating a supply of

9 cryoprecipitate as an alternative to concentrates.

10 Why did you say that?

11 A. Because at the time in question, in 1983, attempting

12 to -- I make no apologise for the term -- attempting

13 to shoehorn a new process into an already overcrowded

14 and improperly constructed, inappropriate facility

15 would have done more harm than good.

16 Q. Following on from that, are you able to summarise the

17 implications for BPL of a reversion to cryoprecipitate

18 in or around 1983/1984?

19 A. First of all, if BPL was to be involved, then, we

20 would have tried to assist the transfusion service in

21 turning the clock back, reintroducing some of the

22 issues associated with cryoprecipitate, and helping

23 them address those. They had moved on and they no

24 longer had that -- or they didn't necessarily have

25 that experience in house.

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In terms of what we received from the transfusion service, we would have received less plasma, assuming that the plasma was used to make cryoprecipitate centres. We would simply have had to deal with that and we would have produced less Factor VIII. And we would have had to look at a different starting material, cryoprecipitate supernatant -- different cryoprecipitate supernatant, produced at 14 different centres, to be used to recover other coagulation factors like Factor IX and albumin and immunoglobulin.

There were considerable difficulties involved.

Q. Am I right in understanding your answer then to mean that it could have been done but it would have been a very major undertaking?

A. It would have been a major undertaking. It wouldn't have produced for patients all of the product that they needed and in my opinion it wouldn't have produced them the kind of product that they needed.

Q. Why do you say it wouldn't have produced the kind of product that they needed?

A. Because cryoprecipitate had inherent problems in terms of cryoprecipitate produced as a single-donor product was not susceptible to quality control. My experience was that in order to give cryoprecipitate a dose

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would make the amount of product available to patients greater.

The losses would be largely the process losses of working with smaller batches and the quality control losses involved in taking more product, more vials for testing and making less product available to the patient.

Q. And is it right that there were certain blood products that had to be made through larger pools?

A. Immunoglobulin, certainly. It was essential. The pharmacopoeial monograph for intramuscular immunoglobulin, which I was part of the committee constructing, specified a minimum pool size of 1,000 donations in order to have the right profile of antibodies present.

Q. Would it have been possible to have continued to make immunoglobulin according to those pool sizes whilst making Factor VIII and other coagulation factors in lesser pool sizes?

A. Yes. By pooling the supernatants from Factor VIII to make immunoglobulins, yes, they could have been done like that, and, similarly, we could have used time-expired plasma. But, no, let's stay with the supernatants; that's the -- that would have been the practical option.

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calculated on the basis of one unit of cryo was typically administered as two units of cryo to be sure to get the amount of Factor VIII that the patient needed.

Q. Are you aware of any meeting or series of meetings or discussion papers where BPL, representatives of the Regional Transfusion Centres, representatives of the Haemophilia Centre Directors, representatives of the DHSS gathered together to try to come up with or at least to discuss the possibility of a coordinated response to AIDS, such as going through the pros and cons of a reversion to cryo?

A. If such a meeting occurred, I wasn't aware of it, and I wasn't present at it.

Q. If there had been a reversion to cryoprecipitate in 1983/1984, that kind of period, do you think there would have been knock-on effects for the redevelopment of Building 27 at BPL?

A. Of course. We would have needed a different BPL, i.e. we needed a BPL.

Q. I have been asked to ask if you could summarise the benefits that there were in fractionating through larger pools rather than smaller pools.

A. I will try. The benefits clearly are from 1kg of plasma, we would recover more Factor VIII, and that

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Q. Is it correct that commercial Factor VIII products were perceived to have advantages such as better solubility, higher potency in small volume, lower viscosity, which made for ease of administration for home treatment and prophylaxis?

A. It was perceived quite properly that that was the case before -- when we were still making Blomback fraction in the early '70s. Once we moved to the 8IB product, pre heat treatment, and to the 8CRV product, its extension, and certainly once we moved to 8Y, the FHC product, then I don't believe there was -- any criticism could be levelled at the BPL product compared with the available commercial products at the time.

Q. You mentioned the Blomback method there and the change to the Johnson method. Are you able to assist in any more detail about when that change took place at BPL, in terms of the year in which it took place. I think in your statement you referred to 1974 to 1975 as the point of change for PFL. Can you assist any further as to when it happened at BPL?

A. I can't give you an authoritative statement but I would have expected to be at the same time.

Q. Do you know why that change didn't take place at either BPL or PFL earlier than 1974 and 1975?

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1 **A.** At PFL we simply did not -- I did not have the
2 resource to investigate and establish the alternative
3 to the Johnson product any sooner than we did.
4 Effectively my work was capitalised on by Dr Smith
5 when he came to PFL in 1975.

6 Processes of that complexity don't happen
7 overnight. You can't simply import the paper
8 definition for a process and make it work quickly.
9 The freeze dryer, for example, that we had at PFL was
10 geared to freeze drying from bottles. It was not
11 geared to freeze drying from vials. And I am sure the
12 same was true at BPL.

13 **Q.** A further question about process but perhaps a little
14 later in time. The Inquiry heard from Dr Foster about
15 the continuous small volume mixing process that was
16 employed at the PFC.

17 Firstly, were you aware of that process and what
18 went into it?

19 **A.** I wasn't intimately involved in reviewing it. I know
20 that my colleague David Wesley was. But I also know
21 that that process was targeted at albumin and worked,
22 at least in PFC's hands, well for albumin. I'm not
23 aware of any evidence that it was extended or scaled
24 up to bigger molecules like immunoglobulin molecule
25 and Factor VIII molecules. But that's something I

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1 **Q.** In your evidence, you said that you gained the
2 impression that physicians treating people with
3 haemophilia considered that the use of factor
4 concentrates was the lesser risk than non-A, non-B
5 hepatitis transmission. You gave the impression that
6 that was the view of their patients as well.

7 First of all, is it right to say that you never
8 yourself undertook a kind of formal survey of patient
9 views?

10 **A.** I did not undertake such a survey, no.

11 **Q.** So your impression of the views of people with
12 haemophilia is one that is gained from seeing how the
13 products were used and talking to clinicians, rather
14 than taking the views of the people with haemophilia
15 themselves?

16 **A.** True, but not just the physicians at the Oxford
17 Haemophilia Centre; also the other physicians who
18 I met at scientific meetings and at the Haemophilia
19 Centre Directors meetings.

20 **Q.** You as a fractionator wouldn't have any knowledge of
21 what the patients were being told by their clinicians
22 about the balance of risk; is that fair?

23 **A.** That's fair.

24 **Q.** Also to do with the end users, as it were, of BPL's
25 product. The size of the pool was placed on the label

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1 sure Dr Perry may help with.

2 **Q.** Do you know if there was any discussion at BPL about
3 adopting a version of CVM -- CSVM in Building 25 or in
4 Building 27 when it was completed?

5 **A.** Taking Building 27 first, no, I don't believe there
6 was any discussion of the CSVM process being installed
7 in Building 27. I know that David Wesley visited PFC
8 and did an analysis of the CSVM process. His report
9 was not favourable in terms of its appropriateness -- a
10 being appropriate for BPL.

11 **Q.** In terms of Building 25 could it have been adapted
12 there and used there or is the building simply not
13 appropriate for it?

14 **A.** It could have been adopted for albumin manufacture or
15 for the recovery of Fraction V, but our deficiencies
16 in Building 25 weren't primarily associated with
17 albumin products. They were the challenge of
18 producing a product like Factor VIII in that facility.

19 **Q.** Turning to a different topic, which is to do with
20 knowledge of the views of people with haemophilia.
21 I think you said in your evidence while at Oxford you
22 had some interaction with haemophilia patients but
23 more with haemophilia clinicians. Is that a fair
24 summary?

25 **A.** Yes.

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1 of BPL product, and you said in your evidence that you
2 were conscious that that label would be seen not just
3 by clinicians but also by patients. What was your
4 understanding of how much use that would be to the
5 patients themselves about the nature of the product?

6 **SIR BRIAN LANGSTAFF:** I think that's really inviting
7 a comment which is for me.

8 **MR HILL:** I will move on from that, then, sir.

9 Did you and your team at BPL ever consider doing
10 some form of market research to understand what
11 information patients would find useful in the patient
12 information leaflets or on the label of a bottle
13 itself?

14 **A.** I certainly didn't. I wouldn't have seen it as being
15 appropriate for me to be involved in that. I don't
16 know whether BPL product services, as it was called in
17 the early days, or the marketing department, as it
18 became in 1990, I don't know if they did, but
19 I certainly didn't.

20 **Q.** On the related question of pool sizes, did you or
21 colleagues at BPL feel any discomfort at the fact that
22 the decisions that BPL were making on the size of
23 a pool involved weighing the risk of greater pool
24 sizes against the risk of greater infection against
25 non-A, non-B hepatitis?

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1 **A.** I don't think so because by the time we were making
2 pools of greater than 100 or certainly 500 kilos of
3 plasma, I personally was not convinced that increasing
4 further necessarily increased risk to patients.

5 **Q.** On a related theme, given what you have just said
6 about the level of risk involved with fractionation of
7 that size, I have been asked to put to you that the
8 label on the bottle shouldn't have said that there was
9 a possibility that the product -- the label shouldn't
10 have said "cannot be assumed to be free of hepatitis
11 virus". It should have said something along the lines
12 of: the user should assume that the contents do
13 contain hepatitis virus. How would you respond to
14 that?

15 **A.** I think all I could say is the phrase was never -- the
16 phraseology on our label was never criticised either
17 by physicians or the regulatory agencies or the
18 Department of Health, and it was a carefully
19 constructed phrase. I don't recall seeing anything
20 more aggressive, anything more explicit on any other
21 concentrates made by other organisations.

22 **Q.** The Chair has the wording of those labels, and I will
23 leave other questions on that for submissions to him.
24 Moving on to a different topic. In relation to
25 the failure to provide research and development

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1 **MR HILL:** Different topic. When you said yesterday that
2 some clinicians would have preferred BPL and PFL to
3 promote their services and products more actively,
4 what did you understand to be the aim of such
5 promotion?

6 **A.** I guess the impression that some people received was
7 BPL didn't have the confidence to present its role and
8 its products as positively as we should have done.
9 I can't believe for a minute that those individuals
10 would have wanted BPL to take on a very active
11 marketing role because we were not selling our
12 products. Certainly not at that time. But perhaps
13 they saw it as being a deficiency in terms of not
14 presenting a positive front to the people we were
15 supplying our products to.

16 **Q.** Different topic. Your audits of Regional Transfusion
17 Centres. Was anyone at BPL responsible for going back
18 to a transfusion centre and checking to see if the
19 changes which you had suggested had been made?

20 **A.** It would have been exactly the same individuals doing
21 the follow-up and -- at the next visit. But there's
22 no reason why one has to physically audit. It's
23 possible to -- even then, to pick up a telephone and
24 find out what had been done. And we saw the result
25 in the context of shipments of plasma to BPL.

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1 facilities at BPL, and virology testing and such -- so
2 forth, you said today that Dr Lane's warnings in that
3 respect were not heeded. Who or which body was
4 responsible for heeding such warnings?

5 **A.** I think it would have had to be upwards from
6 Richard Lane to CBLA and then via CBLA or NBA, whoever
7 was the managing authority at the time, to Department
8 of Health.

9 **SIR BRIAN LANGSTAFF:** What about the period before CBLA?
10 Dr Lane took over in 1977 or '78. There was a period
11 of time before CBLA was formed in December 1982. So
12 who would have responded then, would you expect?

13 **A.** I believe that it would have to be the Department of
14 Health. North West Thames were a different -- played
15 a different role. If Dr Lane was going to convince or
16 try to convince anyone, it would have been through his
17 links to the Department of Health and to groups like
18 ACVSB, the Advisory Committee on the [Viral] Safety of
19 Blood. Those would be the locations of power, in that
20 sense.

21 **SIR BRIAN LANGSTAFF:** I think probably the ACVSB didn't
22 exist at that time but there may have been other
23 committees which occupied a role which might have been
24 relevant, I can see that.

25 **A.** Yes.

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1 **Q.** So there would have been an eye kept on whether or not
2 a particular Regional Transfusion Centre had
3 implemented the types of changes that you had
4 suggested?

5 **A.** And whether the quality of plasma had improved as
6 a result.

7 **Q.** Moving on to some of the processes within BPL, you
8 referred yesterday to plasma compromise as being one
9 of the reasons to open up pallets of stored plasma
10 when the inventory hold was in place. What did you
11 mean by "plasma compromise" and can you give examples
12 of the type of compromise that you were talking about
13 there?

14 **A.** Yes. It came up again earlier today when, on
15 a frequent basis, we received notification from
16 a transfusion centre of a donation of blood which had
17 yielded plasma that had been sent to BPL being
18 involved in post-transfusion -- post-cellular
19 transfusion infection in a patient. Then, it was
20 necessary for BPL to enter a pallet and recover the
21 specific donation of plasma associated with that
22 recorded infection.

23 That system was core to our quality systems. We
24 had to be able to trace forward from the individual
25 donation of plasma to its pooled end product and, in

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1 the event of an event with a BPL product, to trace
2 back from the batch of product to the pool to the
3 donation.

4 **Q.** I won't go to it now, but I said earlier that I would
5 flag up parts of your witness statement that deal with
6 some of the processes that were in place, certainly in
7 the later '80s, in this respect, and I just put it on
8 the transcript that page 149 at paragraphs 96 and 9
9 and the references contained therein may be helpful to
10 Core Participants and the Chair in that respect.

11 Single plasma packs or international plasma
12 packs. I have been asked to ask why it wasn't
13 possible to introduce those at BPL earlier than the
14 were introduced, which I take to be in the very late
15 1970s and the early 1980s.

16 **A.** The international plasma pack was the specific
17 polyolefin pack that was designed for use with the
18 tear-down machine going into the factory.

19 Single donation packs, one of the
20 difficulties -- and I wouldn't know all of them
21 because I wasn't involved at BPL at the time -- was
22 that there wasn't just one single donation pack; there
23 were a number. And because the 5-litre Vallet pack
24 was serving us as well as it could, without going back
25 to transfusion centres and saying, "Okay, we'd like

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1 through the private pharmaceutical manufacturing
2 system?

3 **A.** When is probably the second half of 1981, when there
4 was consideration to the appointment of
5 a manufacturing manager, in the case of
6 Gilbert Mallory, a head of quality control, me, and
7 an engineer, Ian Ling. Before that, I'm not
8 convinced -- I didn't see any evidence that the
9 organisation was looking for people with manufacturing
10 experience. And before that, of course, we're talking
11 about the Lister Institute, and that was not their
12 focus.

13 **Q.** Was recruitment of people from the private sector easy
14 given the salaries involved and, indeed, given the
15 state of Building 25 at the time?

16 **A.** No on both counts. We could not afford to recruit
17 from the industry at NHS pay scales. I'll forbear
18 talking about my own situation, but with engineers we
19 were constrained to recruit on hospital engineers' pay
20 scales, and hospital engineers didn't have the
21 experience that we needed at BPL.

22 **Q.** Who imposed those constraints on the pay scales?

23 **A.** In the time of the Lister Institute, the
24 Lister Institute imposed those scales subsequently
25 between '78 and '82. Then it would have been through

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1 you tomorrow to stop sending 5-litre packs but send us
2 individual donors -- individual donations," that's the
3 only way it could have happened.

4 I can't -- I don't have enough familiarity with
5 what individual transfusion centre practices were or
6 how difficult they would have found it to switch to
7 SPPs.

8 At the time that I started at PFL, all of our
9 plasma was coming from the Oxford Transfusion Centre,
10 and blood was still collected in bottles at that time,
11 not plastic bags.

12 **Q.** Is this also another example of how BPL could come up
13 with ideas and could propose ideas and could seek to
14 persuade Regional Transfusion Centres, but they
15 couldn't direct them to switch to single plasma packs?

16 **A.** It would have needed a coordinated activity that
17 included BPL and the transfusion centres. Without
18 that coordination, no, it couldn't have.

19 **Q.** A question about the expertise of you and some of your
20 colleagues at BPL. You had grown up through the State
21 fractionation system, as had Dr Smith, save for the
22 caveat that you gave, and to an extent Dr Lane as
23 well, again with the caveat you gave.

24 What steps were taken, and when, to obtain
25 experience and expertise from those who had grown up

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1 the Department of Health and their agents at North
2 West Thames Health Authority.

3 **Q.** A couple of further questions on pool size and in
4 particular the later decision to increase the maximum
5 pool size from 10,000 donations to 25,000 donations.

6 What was the motivation for increasing the pool
7 size in that way?

8 **A.** To take advantage of the expected processing
9 capability of Building 27 and, again, to achieve more
10 vials of Factor VIII from a given quantity of plasma.

11 **Q.** Heat treatment would have been in place by that stage.
12 Did you consider that there was an appreciable
13 increase in risk in expanding the pool size in that
14 way?

15 **A.** By "you", I presume you mean BPL?

16 **Q.** Yes.

17 **A.** No, we did not.

18 **Q.** Why didn't you think there was an appreciable increase
19 in risk?

20 **A.** Because producing a 10,000 -- producing, say, a 20,000
21 donor pool in one week compared to two 10,000 donor
22 pools either the same week or the following week was
23 exposing patients to the same very large donation
24 risk.

25 **Q.** I have been asked to ask you whether you have a view

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1 on what the tipping point was, so to speak, between
 2 a pool size that would provide some measure of
 3 protection against non-A, non-B hepatitis and the pool
 4 size that would not provide a measure of protection
 5 against non-A, non-B hepatitis.

6 **A.** On the principle of 1 donation in 100 being infected,
 7 assuming that that continued throughout the period of
 8 time, I don't think it's possible -- well, I don't
 9 think it's possible for me to make that judgment. I'm
 10 not -- I wasn't an epidemiologist. I'm not
 11 an epidemiologist, and I would have gone to an expert
 12 for guidance.

13 **Q.** Discussions about AIDS. You referred in your evidence
 14 to discussing AIDS with colleagues, and obviously w
 15 have seen the minutes of the meeting at BPL. Did you
 16 also have such discussions with clinicians in the
 17 1982/1983/1984 period?

18 **A.** Clinicians in the UK, in terms of the Haemophilia
 19 Centre Directors' meetings and clinicians that I me
 20 at scientific meetings, yes, I did. And some of those
 21 discussions would also have extended to individuals at
 22 the Bureau of Biologics in the States and the Blood
 23 Products Committee in the States. So, yes, I had
 24 those discussions.

25 **Q.** Did you discuss the matter with Dr Rizza who you ha

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1 and would have been collected by clerks, or my cler
 2 in PFL, recovering the information without patient
 3 name from the Haemophilia Centre.

4 At BPL, it would have been reports of
 5 post-transfusion infection, but they would not have
 6 been systematic.

7 **Q.** What do you mean by saying "they wouldn't have been
 8 systematic"? There was no formal system in place?

9 **A.** No. If a batch or batches did not -- were not
 10 recorded at a treatment centre with a record of
 11 patient or patients becoming jaundiced, then we would
 12 not have had negative reports from -- in respect of
 13 batches. It would have been when there was something
 14 to report.

15 **Q.** Were you aware of what patients were being told abo ut
 16 the use of that information, that ultimately came from
 17 them and from their condition?

18 **A.** No.

19 **Q.** And looking at it from the other end, were you awar
 20 of what use Dr Zuckerman and Dr Craske put that
 21 information to?

22 **A.** Only from the reports of the Hepatitis Working Part
 23 to the Haemophilia Centre Directors' meetings, whic
 24 Richard Lane would typically have attended or which
 25 Dr Smith or I would also have attended.

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1 a relationship with?

2 **A.** Indeed, yes.

3 **Q.** Did the clinicians refer you to the number of their
 4 patients who had been found to have HTLV-III
 5 antibodies?

6 **A.** I don't -- I would doubt that the discussions took
 7 that line, but increasingly that data was available
 8 from publication, so we would have discussed the
 9 publications in which such reports were made.

10 **Q.** I have been asked to ask about a prefix for a batch,
 11 the prefix being "HLA", that being a prefix given t
 12 one batch, and another batch being labelled "LA". Are
 13 you able to explain the difference between those tw
 14 batches? I'm afraid I don't have a document that
 15 I can take you to.

16 **A.** No, not without some preparation. I do apologise.

17 **Q.** Please, no apologies necessary. We will think abou
 18 how we can take that forward in a different way, si r.
 19 Hepatitis, and in particular the system for
 20 monitoring hepatitis that you told us about, the card
 21 system. How did the information come to you about the
 22 possible association between batches and transmission
 23 of hepatitis?

24 **A.** It would have come from -- at PFL, the information
 25 would have come directly from the Haemophilia Centr

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1 **Q.** So, in effect, you would see the published work, as it
 2 were, or at least the work disclosed to those
 3 meetings, and that was the end result that you saw
 4 but, other than that, you didn't know the use to wh ich
 5 they were putting that information?

6 **A.** No.

7 **Q.** What was the reason for waiting until the fourth
 8 incident of hepatitis before contacting Dr Craske?

9 **A.** I can't -- there was no statistical reason. I mean,
 10 there's nothing magic about the number four but, to
 11 begin with, not every batch recorded even one flag.
 12 Increasingly, I think, it became obvious that more
 13 batches were being flagged, presumably reflecting
 14 a higher non-A, non-B hepatitis incidence in the donor
 15 pool.

16 **Q.** Were efforts made to recall a batch when four flags
 17 were reached?

18 **A.** No. And I don't think it would have been practical ly
 19 possible because by then -- I mean, bear in mind that
 20 PFL batches were quite small. By then the batch wo uld
 21 have been exhausted in any case.

22 **Q.** Were any steps taken, perhaps after one or two flag s,
 23 to seek to restrict the use of that batch, for
 24 example, saying, "Don't give it to patients who hav
 25 not previously been exposed to factor concentrates"?

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1 **A.** Not that I can remember. But that's not to say that
2 information wasn't being exchanged between PFL and the
3 Oxford Haemophilia Centre on a discussion basis.

4 **Q.** On AIDS we've looked at the exercise that was
5 undertaken in respect of batch HL3186. Were other
6 efforts made by BPL to try to identify their own
7 products that had caused HIV infection, as in some
8 form of look-back exercise?

9 **A.** I don't know. I don't believe so.

10 **Q.** Yield of factor concentrates. You have mentioned that
11 as one of the complicating factors for Dr Maycock in
12 estimating demand. Was the yield of Factor VIII from
13 plasma that was made into cryoprecipitate consistent?

14 **A.** No. If you mean cryoprecipitate made at transfusion
15 centres, no, it was not. But physicians using
16 cryoprecipitate wouldn't have known that, because
17 physicians using cryoprecipitate didn't typically have
18 access to assay facilities that would allow the
19 potency to be determined.

20 I worked quite closely with the Manchester
21 Transfusion Centre, with Richard Wensley, in a working
22 party studying cryoprecipitate, and it was clear from
23 that working party, which is one of the papers that
24 referenced in my witness statement -- and there was
25 significant variability in cryos. That was one of the

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1 one donation to another. When you pooled plasma to
2 make Factor VIII concentrate, you make a pool, you
3 fractionate that pool, and what you're able to do is
4 undertake testing on representative samples of all of
5 the vials recovered from the pool, and then you can
6 give a reliable statement about the yield. For any
7 individual cryo, you could never do that.

8 **Q.** Also on yield, you've said that there was a difference
9 of opinion about the yield achieved in Scotland
10 compared to the yield achieved in England.

11 First of all, was that just a difference of
12 opinion, or was there a different yield that was
13 achieved at PFC to BPL, and if there was, what was the
14 cause of that difference?

15 **A.** Sometimes the difference was a matter of statement.
16 A statement that says -- that plans for a Factor VIII
17 yield of 70 per cent simply doesn't bear thinking
18 about. It won't happen. It will never happen.

19 In terms of were there specific differences
20 between PFC and BPL/PFL, yes, the most obvious one is
21 the Factor VIII assay that we used. BPL/PFL used
22 a two stage Factor VIII assay. PFC used a stage
23 assay. And they were -- there's lots of evidence of
24 differences according to whether use of a one stage or
25 two stage assay. There were also differences

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1 reasons that Dr Gunson wanted that working party to be
2 assembled and to take place, so that we could provide
3 guidance on how to improve the quality of
4 cryoprecipitates.

5 **Q.** Does it follow from your answer that a clinician
6 couldn't be sure how much specific activity there was
7 going to be in a unit of cryoprecipitate? Does it
8 also follow from that, that if you look back at the
9 plasma that you have with which to work in the first
10 place, you cannot be sure of the type of yield that
11 you are going to get from that block of plasma?

12 **A.** Are you talking -- throughout all of that, are you
13 referring to the manufacture of cryoprecipitate?

14 **Q.** Yes, I am.

15 **A.** The -- I'm sorry, my head became full of cotton wool.
16 The --

17 **SIR BRIAN LANGSTAFF:** I think you are being asked, are
18 you, about single donor cryoprecipitate?

19 **MR HILL:** Yes.

20 **SIR BRIAN LANGSTAFF:** So the case of one single donor is
21 what you are considering?

22 **A.** Working with single-donor cryos, the variability in --
23 the variability in Factor VIII units that could be
24 recovered from it would vary -- did vary enormously
25 from one centre to another and within a centre from

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1 according to the standard, the reference preparation
2 that was used. But the difference between BPL/PFL and
3 PFC, I'm sorry, I would have to say that much of that
4 was down to exaggeration of yield, or exaggeration of
5 yield claim at a certain time by particular
6 individuals.

7 **SIR BRIAN LANGSTAFF:** Can I just ask you about that, the
8 answer you gave in respect of the reference standard.

9 The international unit presumably has an origin
10 rather like the yard in measurement in the UK or the
11 original pint, whenever that was identified, in some
12 central, as it were, library of the units, and then
13 you can copy that and send around the reference
14 standard. That's my mental picture of it. Is it the
15 same standard in that sort of way, or is it different?

16 **A.** It's -- the principle is the same. So every
17 international unit that was used was a concentrate.
18 BPL provided -- or PFL, rather, provided many batches
19 of concentrate to NIBSC for them to make their
20 international standard. The international standard
21 would then be released in very small quantity from
22 NIBSC, from a WHO laboratory, to a manufacturer who
23 would prepare their working standard, and the working
24 standard hopefully was also a concentrate that was
25 representative of the company's products, so had the

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1 same characteristic.

2 It was -- and that was fine when it was possible
3 to do it like that, but when organisations tried to
4 compare concentrates with plasma standards, which is
5 what was the initial situation in the late '60s, early
6 '70s, then that comparison of a concentrate test
7 sample with a plasma reference preparation is much
8 less reliable.

9 And the differences were not trivial. They
10 could be 20 or 30 per cent differences. And the
11 introduction of new reference preparations on more
12 than one occasion resulted in organisations suddenly
13 seeing the yield measured in-house either rising by 20
14 per cent or, occasionally, falling by 20 per cent.
15 And I can very clearly remember embarrassing
16 discussions with my chief executive as to why
17 suddenly, because of something happening in an assay,
18 our output of Factor VIII appeared to have dropped by
19 15 per cent. And it wasn't real at all; it was the
20 same process making the same product. It was just the
21 way the assay was seeing it.

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

23 **MR HILL:** Final topic from me. You used the phrase "batch
24 size" rather than "pool size". Could you just explain
25 the difference between those two terms.

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1 Then you describe those. I will come back to
2 that description in a moment.

3 What or who was putting you under pressure?

4 **A.** Remotely, of course, the pressure was from patient use
5 and physician demand. But locally the pressure was in
6 terms of a commitment to produce and to increase the
7 amount of Factor VIII that we could obtain from the
8 plasma supply available to us.

9 There was -- Mr Hill's referred to it certainly
10 yesterday and, I think, today -- there was a cap
11 imposed on that by the Medicines Inspectorate after
12 the 1979 inspection. Quite properly imposed. Which
13 we then respected until improvements of the
14 facility -- or rather improvements in some local
15 equipment became available under the Stop-Gap
16 programme.

17 **SIR BRIAN LANGSTAFF:** Now these are then pressures in
18 terms of quantity of product. How does that compare
19 with any pressures that there were on you -- "you"
20 meaning BPL or PFL, depending on the period -- in
21 respect of the quality, particularly the safety of the
22 product?

23 **A.** That would always be a balance in the manufacturing
24 process, especially for a manufacturing process
25 designed to produce products for intravenous

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1 **A.** For me the batch size is what, as a fractionator,
2 I begin my process with. It is what goes into a tank.
3 It reflects the characteristics of the equipment that
4 I'm using and the plasma that's available to me.

5 The pool -- the donor pool size, for me, only
6 had relevance insofar as we had, at any one time,
7 a commitment in our process description lodged with
8 the agency of what was our limiting pool size. And
9 that was what was reflected on the label.

10 **MR HILL:** Those are all the questions that I have for you
11 Dr Snape. I turn to the chair.

12 Questions from SIR BRIAN LANGSTAFF

13 **SIR BRIAN LANGSTAFF:** Yes, well I have got four questions
14 for you.

15 Can I begin by asking Sully, if you would, to go
16 to the witness statement, WITN3431001, and go to
17 page 34.

18 It is paragraph 94. And it is the last sentence
19 that you have there. The last sentence leads on, and
20 it happens, to the next question I'm going to ask you
21 about. But you say:

22 "The practical reality though, is that we were
23 under pressure to produce as much factor VIII as
24 possible, from a limited supply of plasma and in
25 deficient facilities ..."

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1 injection. So at the same time as making the process
2 more efficient in producing more Factor VIII, at the
3 time that's referenced in that particular sentence,
4 what we were also trying to do is to compensate for
5 the inadequate facilities within which manufacturing
6 was taking place.

7 So, the balance between process throughput and
8 quality was always real. And it was certainly one of
9 the roles of the qualified person to make sure that
10 people didn't forget that balance, and that things
11 were kept -- were really kept properly in balance.

12 **SIR BRIAN LANGSTAFF:** Now, the second question really
13 arises from -- hinted at in a theme you have come back
14 to a number of times in your evidence, which is the
15 inadequacy of the facilities at BPL throughout the
16 1970s, as you understand it, and into the early '80s.

17 And if we can just -- please can you leave it
18 up, Sully. Thank you.

19 If we see there:

20 "... the facilities of BPL ..."

21 "Deficient facilities" you say:

22 "... the facilities of BPL were built in the
23 mid-1950s, with little subsequent improvement, and few
24 concessions to the developing concepts of [good
25 manufacturing practice] ..."

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1 That's dealing, I think, largely with the
2 structure of the building.

3 "... see [paragraphs] 235 [and following],
4 'Limitations of the old facility Building 25 (B25) at
5 Elstree'."

6 Sully, can we go to that, 235, which you will
7 find at page 81.

8 You start by saying that the -- description:

9 "Limitations of the old facilities at Elstree,
10 including (Building 25 ...

11 "The title ... does not really do full justice
12 to the issues involved ..."

13 Do I take it from that that you feel quite
14 strongly about the inadequacy of what BPL was dealt or
15 had to deal with in the early 1970s and following?

16 **A.** Yes.

17 **SIR BRIAN LANGSTAFF:** And you say at 236:

18 "The basic infrastructure of BPL, inherited from
19 the Lister Institute, was more appropriate to
20 a laboratory engaged in research and relatively small
21 scale production."

22 You say how it was built really postwar as
23 a civil defence project for, really, something which
24 it was not now being used for. And little planning
25 for fractionation process.

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1 of having to say: this is too much. This is too far.

2 With the decision to build a new facility, then,
3 it was possible to see into the future to a building
4 that could deliver safe plasma products -- I won't
5 just say Factor VIII, but safe plasma products -- in
6 the quantity that patients deserved, but it wouldn't
7 have happened in Building 25.

8 **SIR BRIAN LANGSTAFF:** So you suggest it took too long.

9 I have been told in this Inquiry that in 1967,
10 Dr Rosemary Biggs was issuing, in effect, what might
11 be described as a clarion call for the increased and
12 improved production of Factor VIII concentrates or
13 treatments, looking into the future and seeing that
14 there would need to be manufactured and for the
15 investment necessary to do it.

16 Is it your view that that call should have been
17 answered sooner rather than when it was?

18 **A.** It is. Partly because prolonging the use of
19 Building 25 was inappropriate and potentially --
20 certainly put output at risk but potentially put
21 patients at risk. But also because by delaying the
22 decision to specify and build a new facility, we
23 created a situation where importation of commercial
24 Factor VIII concentrates was the only resort available
25 to haemophilia treaters, and that then created the

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1 "An extension to the building in 1962 did little
2 more than relieve immediate pressure by creating a new
3 bacteriology laboratory, and moving small pool plasma
4 processing into the vacated space. A further
5 extension in 1972 made space for immunoglobulin
6 production ... and allowed freeze-dried small pool
7 plasma to be replaced by very limited (inadequate)
8 space for albumin and factor VIII production."

9 You go on, really, to describe how it was almost
10 inevitable that the Medicines Inspectorate had the
11 visit that they did in 1979, and condemned the
12 building, or condemned the use of it. If it had been
13 a pharmaceutical facility, it might not have survived.

14 Do you think that perhaps far too long or too
15 long -- let's start with too long -- was taken to
16 renovate or replace the facilities for the purpose
17 that it was going to be used in the 1970s?

18 **A.** I think too long was taken, first of all, deciding
19 that it was not possible to renovate the facility and
20 that the only solution was a new facility. If we had
21 tried -- if the solution had imposed -- been imposed
22 upon us that we had to keep making do and mending in
23 the old BPL, we -- it would have been inevitable that,
24 at some point -- I, for example, as the QP, once
25 I moved to BPL might have found myself in the position

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1 situation in which having experienced concentrate a
2 a way of treating haemophilia, nothing else was going
3 to be enough. Cryoprecipitate wouldn't be enough.
4 The products from BPL were too -- we were not
5 producing enough. And in order to stop that event, we
6 would have had to be beginning the commissioning of
7 a new BPL facility probably by '78, by 1978 at the
8 latest, in order to have that facility producing safe,
9 effective product in adequate quantity by 1982.

10 **SIR BRIAN LANGSTAFF:** The difference between Factor VIII
11 which we have been talking about, treating haemophilia
12 A and Factor IX treating haemophilia B could be seen
13 in this way, and I just want to ask you about it. It
14 is the same topic. Because the supplies of Factor IX
15 produced by BPL and then at PFL were such that very
16 little commercial concentrate was used until there was
17 a problem over heat treatment; is that right?

18 **A.** Yes, that's correct.

19 **SIR BRIAN LANGSTAFF:** If that had been the case with
20 Factor VIII supplies, would you have seen any reason
21 why clinicians given sufficient supply would have
22 chosen to use commercial products?

23 **A.** No. The reason, of course, with Factor IX is there
24 were fewer -- Christmas disease patients, Factor IX
25 deficient patients, and the demand for Factor IX was

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1 lower. We were able to meet that demand initially
2 from PFL, as small as it was, and then from the joint
3 efforts of PFL and BPL.

4 **SIR BRIAN LANGSTAFF:** Yes. Thank you very much.

5 Third topic. In the early '90s I think, am
6 I right in thinking that BPL operated a shift system
7 in terms of their production?

8 **A.** Yes.

9 **SIR BRIAN LANGSTAFF:** And was that a two-shift or
10 a three-shift?

11 **A.** It was both. In different departments. Negotiating
12 that shift operation was challenging, initially in
13 terms of interactions with the union and then in terms
14 of making sure that we could provide the facilities
15 that operators needed overnight, to have food -- hot
16 food, hot drink. We're not talking about people
17 working in an office here, we're talking about people
18 working in cold rooms and working in extremely
19 uncomfortable situations. So, yes, we needed -- we
20 operated a shift system and it was managed carefully,
21 but it took a while to establish.

22 If I could make a comment there though, sir.
23 Building 27, the new facility, was designed with
24 multi-shift operation in mind. If someone had said to
25 me, "Oh, you can put three times as much product

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1 **SIR BRIAN LANGSTAFF:** Which in turn lead to
2 an impossibility or a great difficulty in introducing
3 a revised process which might in itself produce more
4 product.

5 **A.** And a process that at the time in -- when this was
6 being discussed in 1978/79, the process that we were
7 going to want to use it for hadn't even been
8 conceived. It was somewhere down the road.

9 **SIR BRIAN LANGSTAFF:** The last point I want to ask you
10 about is minor by comparison, but it's -- the topic is
11 dealing with identifying the batch which may have gone
12 wrong, might be a rogue batch, might be infected.

13 In the videos which we saw at the beginning of
14 your evidence, it was plain that a barcode was read
15 for each box that came in, and each individual plasma
16 donation had a barcode on it.

17 When the video itself showed the finished
18 product and described how everything was logged, there
19 is a sight -- the only thing I could see was the sight
20 of someone's hand writing in a ledger. Now, what
21 I have to ask you arising out of that is: was the
22 finished product also barcoded?

23 **A.** The batch number was recoverable as -- by barcode,
24 but -- I'm trying to picture what you saw in terms of
25 something being written by hand, and I can't think

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1 through Building 25 just by operating shifts", I would
2 have laughed -- no, I would have cried! -- because
3 what -- the single biggest problem with moving from
4 one shift to two shifts to three shifts is the impact
5 of putting more people into a room served with the
6 heating and ventilation, filtered air, that's designed
7 for a smaller number of people.

8 In my opinion, had the attempt been made to --
9 for example at PFC, to introduce two or three-shift
10 finishing activities in the clean rooms, fulfilling
11 Factor VIII or Factor IX or albumin, that would have
12 failed miserably because the environmental control
13 tests on the clean rooms would very quickly have
14 disclosed that the system was over-challenged by
15 particles and microorganisms shed by the number of
16 people. And the system never having 18 hours to rest
17 in between working periods.

18 **SIR BRIAN LANGSTAFF:** So, the answer, so far as BPL at
19 Elstree is concerned, is, as much as you might have
20 wanted to do it in order to increase production had
21 that been something you wanted to do to meet the
22 pressures that you have described upon you, you could
23 not have done it. So we come back, do we, to the
24 inadequacies of the facilities in Building 25?

25 **A.** Yes, exactly.

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1 what that was.

2 **SIR BRIAN LANGSTAFF:** I can't help you because I haven't
3 replayed the video to check, but it's my clear memory
4 of it, and it really just gives rise to -- it's the
5 introduction to a question which was: how were the
6 individual products recorded? Was it one system? Was
7 it more than one system? I can understand how it
8 might have been written in a book and barcoded, but
9 you can tell me.

10 **A.** The individual vials within a batch were not
11 recognisable by barcode, but the batch number was
12 identifiable by barcode, so it was possible to trace
13 back electronically from the batch number to the
14 plasma -- individual plasma donations that went into
15 that batch.

16 What you saw in the video when the boxes arrived
17 and the technician was scanning the barcode on the
18 outside of those cardboard boxes, that was
19 an identifier of the box of packs. But within that
20 pack -- within that box were individual donations
21 which were also barcode identified and related to the
22 shipment list from the transfusion centre. So it was
23 possible to electronically go from the batch number to
24 every individual donation in that batch by barcode,
25 and if a donation report came in after the batch had

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been pooled for manufacture, at that point, what we have is an index of a batch that's potentially compromised, but we can't do anything other than investigate the nature and severity of the problem and potentially interdict that particular batch.

SIR BRIAN LANGSTAFF: In terms of the individual patient receiving a bottle which doesn't have a barcode on it, they will have to trace that back through their own supplier, the Haemophilia Centre or maybe the hospital, and the hospital or Haemophilia Centre will have to attribute that donation to a particular batch and back, then, to you, and then you can trace it back.

Now, that's looking from the patient end back to where it all started and where there may have been an infected donation in the first place, or more than one.

A. Sadly -- certainly at the time that I had direct involvement, we did not have the equivalent of the German blood law which requires vein to vein recording of data. Everything depended, and, in my experience, fell down, on those many occasions I had to investigate it, when you got to the clinic and discovered that the treatment administered -- that the batch number wasn't necessarily available to you.

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treatment of patients with single donor cellular products. They can be traced and the follow-up is relatively simple. But for a haemophiliac who is receiving multiple batches of different products over a period of time, it would be quite difficult, and demonstrably difficult, to identify which product, which batch might have been responsible for the adverse event that occurred.

SIR BRIAN LANGSTAFF: Now of course I have been asking you questions really from the -- starting at the patient's end, with symptoms or an infection and working back to where it might have come from. But it might be much easier in a way to trace who might be infected by going in the other direction, from identifying when somebody who has given a donation to a pool has actually come down with an infection or shown signs of being infected.

You would rely, I suppose, upon there being reports from a donor's clinician coming through the National Blood Transfusion Service, of which you weren't part, to BPL or PFL to tell you that this had happened, would you?

A. Yes. And HL3186 was a classic example of what happens when such a report comes in a significant time after the batch has been processed, released and used to

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SIR BRIAN LANGSTAFF: Yes, I wondered if that might be the case, and you have just confirmed it. Thank you for that.

The next question, really, it is the same topic, the question of identifying when there has been a product failure. A lot of the evidence which we have heard in the Inquiry has described how patient with severe haemophilia A had quite a lot of different products. Rarely were they supplied with -- just with NHS, rarely perhaps with just one commercial product.

In those cases, it might be quite difficult, I suppose, to trace back the presence of an infection, particularly if the infection happens to be a virus such as non-A, non-B, which wasn't identifiable as a virus by genetic testing until 1989 and thereafter. You would have to rely upon clinicians reporting back. And you spoke in answer to Mr Hill describing how the clinician may send a report of someone who has got jaundiced.

In the case of someone who is regularly receiving the concentrate and jaundice which may take three or four months to develop, were there difficulties in getting any look-back, as you would see it?

A. Much more difficult than look-back in the case of

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treat patients.

You are starting, there, from an individual donation which we know went into HL3186, and that batch then went to two transfusion centres, and was dispatched from there to a number of treatment centres, including Lord Mayor Treloar at Alton, and that -- that follow-up then -- that's why it was so important to get the feedback from the treating physicians about which patients and to make sure that samples were made available to John Craske for follow-up.

SIR BRIAN LANGSTAFF: How often was it that you got a report from the Blood Transfusion Service, the Regional Transfusion Director, who himself or herself would have had a report in from the treating clinician of hepatitis non-A, non-B?

A. Probably one or two a month but usually in time for us to recover the plasma donation from the stock in our cauldron.

Next worse case, to identify a batch that we'd made from a donation.

Ultimate worse case, to identify a batch that had been released and therefore had to be considered for recall.

SIR BRIAN LANGSTAFF: So far as non-A, non-B is concerned

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1 that was chronic, of which there had been very few
2 symptoms during the first six months, so nothing much
3 in the acute phase to see, did you ever have any
4 reports of that?

5 **A.** Don't forget that the incidents that I'm talking about
6 are where plasma has been supplied to BPL but the
7 cellular components from that same donation had been
8 used to treat a sick person in hospital, and they
9 would be -- follow up would be much more effective in
10 that situation and, therefore, look-back much easier
11 to perform.

12 **SIR BRIAN LANGSTAFF:** Thank you very much. That's all
13 that I have to ask.

14 **MR HILL:** Dr Snape, as with all of our witnesses we turn
15 to you now and ask if there's anything else that you
16 would like to say at this Inquiry?

17 **A.** If I may, please, and it won't take long, but I feel
18 it is important that I say it.

19 It wouldn't have been possible to watch most of
20 the Inquiry interviews with the infected and affected,
21 as I did, without being moved, often to tears. When
22 I was preparing my witness statement, I tried to focus
23 on what BPL/PFL did from 1970 onwards and what we
24 achieved during that time and what stopped us doing
25 more. Much of that was summarised two weeks ago by

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1 So, I want to thank you for that but I want to
2 thank you for more than that. It is quite obvious, if
3 I may say so, that you have gone out of your way to
4 try to help in all aspects, not just those that
5 concerned you as quality control manager for much of
6 the time, but more generally, insofar as you could,
7 involving your own research and going back to
8 documents and always with the intention, as I see it,
9 of attempting to help, to answer the questions
10 properly and fairly, and I want to thank you very much
11 for that. Thank you.

12 **A.** Thank you, sir.

13 **MR HILL:** Tomorrow we have Dr Perry, sir.

14 **SIR BRIAN LANGSTAFF:** Yes. Dr Perry tomorrow at 10.00.
15 (5.54 pm)

16 (Adjourned until 10.00 am on Thursday, 31 March 2022)

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1 counsel to the Inquiry and, I felt, with fair and
2 proper focus on two key players for BPL,
3 Dr Richard Lane and Dr Jim Smith.

4 Now I know that my evidence is the only oral
5 testimony from BPL/PFL. If I had to summarise what we
6 achieved in just a few words, it would be too little,
7 too late.

8 I know that BPL/PFL staff worked tirelessly,
9 achieved a great deal, but that influences external to
10 BPL/PFL stopped us doing more and doing it sooner.
11 And for that I'm profoundly sorry.

12 Thank you.

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

14 I want to thank you in particular, I'm very
15 sorry that we have taken so much of your domestic time
16 away from you. I hope it hasn't been too much of
17 an inconvenience. But it is obvious from the number
18 of questions that Mr Hill has asked you from the
19 Core Participants, and I have to confess my own time
20 that I have taken of yours to answer my questions,
21 that you have evidence of great value to most of those
22 who are concerned with this Inquiry and it is obvious
23 why that should be. As you've said yourself, you are
24 the live witness that we have giving live evidence
25 about BPL and PFL.

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