1		Tuesday, 26 July 2022	1		Then before we look at any of those bullet points,
2	(10	.00 am)	2		we're, here, looking at middle of July 1999, so would it
3	(10	PROFESSOR AILEEN KEEL (continued)	3		be right to understand that we're now in a devolved
4		Questioned by MS RICHARDS (continued)	4		government, exercising healthcare powers?
5	CID	BRIAN LANGSTAFF: Good morning, professor.	5	Α.	Yes.
6		E WITNESS: Good morning.	6	Q.	Then we can see the first bullet point is:
7		BRIAN LANGSTAFF: Ms Richards.	7	ω.	"- the patients concerned received the best
, 8		RICHARDS: Professor Keel, I want to ask you next about	8		treatment available at the time"
9	WO.	the Scottish Executive Inquiry that was undertaken	9		That's the line which we discussed yesterday.
3 10		between 1999 and 2000. I want to start in the middle	10		" which was essential for their survival and,
11		of 1999, so before the decision had been taken to have	11		in the absence of negligence on the part of the NHS
12		,	12		
		the Inquiry, at SCGV0000176_118.			there was no basis for making payments."
13		This is from Mr Bell in the Health Care Policy	13		Now I wanted to ask you about the addition that we
14		Division, 15 July 1999, and we can see it is addressed	14		see in this document of those words "which was essential
15		to the minister and copied to, amongst others, you, and	15		for their survival".
16		the purpose of the briefing is to brief the minister on	16		That might lead the reader to believe that they
17		The Haemophilia Society's continuing campaign for	17		were being told that the treatment was invariably
18		compensation for haemophiliacs infected with hepatitis C	18		life-saving, and that every haemophiliac would have died
19		as a result of NHS treatment using blood or blood	19		without it. Would you agree?
20		products.	20	Α.	Well, all severe haemophiliacs are at increased risk of
21		And if we go over the page, having referred to	21		death without coagulation factor treatment. So I think
22		The Haemophilia Society's campaign, paragraph 4 explains	22		that's what this bullet point is referring to. It
23		that:	23		doesn't mean that all of them are going to die from
24		"The previous administration rejected claims for	24		their condition, but as I've said yesterday,
25		such a no-fault payment scheme on the grounds that"	25		life-threatening bleeds in severe haemophiliacs are by 2
		1			2
1		no means rare, and particularly intracranial haemorrhage	1		"The issue now comes within the remit of the
2		clearly is a severe threat to survival, but I don't	2		Scottish Parliament and it appears from the attached
3		think this implies that all of them were at substantial	3		correspondence, and a recent enquiry from James
4		risk of death all the time, but in the event of a bleed,	4		Douglas-Hamilton, that the Haemophilia Society is now
5		particularly an intracranial bleed, then they definitely	5		focusing its efforts on the Parliament."
6		would be, and they would need treatment to allow them to	6		Then the recommendation in paragraph 9:
7		come through that bleed.	7		"In light of the fact that the Department of
8	Q.	This is addressed to a minister who is unlikely	8		Health have rigorously examined this issue twice in
9		themselves, for the most part, to have medical	9		recent years and that the Haemophilia Society have not
10		qualifications or medical knowledge of their own. Might	10		produced fresh evidence to support their claim for
11		it not be said that this was putting it too strong, and	11		financial assistance, we advise that a further
12		an overstatement both in terms of an over-generalisation	12		examination of this issue would only draw the same
13		but also an overstatement of the necessity for	13		conclusions previously reached. We therefore recommend
14		concentrates?	14		that the Minister endorses the decision taken by her
15	A.	I don't really think it's an overstatement. I mean, it	15		predecessor and signs the attached reply."
16		is a generalisation, I agree with you, but I don't	16		If we just go back to the first page, there's some
17		believe it's an overstatement.	17		handwriting which says, "I would agree but need SD
18	Q.	If we go to the next page, we can see paragraph 7	18		decision". Do you know whose handwriting that is?
19		explains:	19	A.	No, I don't, but SD is clearly Susan Deacon.
20		"This issue has been treated as a UK-wide matter	20	Q.	The minister to whom this was addressed?
21		on which the four territorial Health Departments should	21	A.	Yes.
22		adopt a consistent line. Mr Dobson's announcement was	22	Q.	And you're the only medical officer oh no, there's
23		, therefore endorsed by Mr Galbraith, as Scottish Office	23		Dr Woods. Who was Dr Woods?
24		Minister for Health."	24	Α.	Dr Woods is not a medical doctor. He was chief exec of
25		And that's what we looked at yesterday.	25		the Department at that point.
		3			4

(1) Pages 1 - 4

1	Q.	So would it be fair to assume that, in terms of any	1		concentrate in a period between 1985 and 1987; is that
2		medical advice within this document, either you're the	2		broadly correct?
3		source of it or effectively you've agreed with it?	3	A.	
4	A.	Yes.	4	Q.	5
5	Q.	Now that's July 1999. What's your recollection of how	5		of the particular focus of The Haemophilia Society's
6		it came about that the minister decided to commission an	6 7	A.	lobbying, is that right? That's correct.
7 8	٨	internal investigation? Well, it's a long time ago, but my recollection is that,	8	А. Q.	
9	Α.	as the submission indicates, post-devolution there was	9	α.	example, at the position of those should been infected
10		intense lobbying of MSPs through the Parliamentary	3 10		through blood transfusion?
11		process, particularly by The Haemophilia Society, and	11	A.	0
12		that the new minister, obviously it was in receipt of	12	А.	haemophiliac community, understandably, and the remit of
13		all that lobbying, and that, I suspect I mean, you	13		the internal inquiry was framed absolutely around what
14		are interviewing her, I believe, later this week?	14		they wanted to be looked at, and was agreed by them.
15	Q.	Yes.	14	0	And was there any lobby group or other group
16	A.	She's better placed to answer than I. But my impression	16	α.	representing the interests or position of those who had
17	Λ.	was that post-devolution, increased lobbying, and she	10		been infected through transfusion at that point in time
18		was persuaded that we needed to drill down further into	18		in Scotland?
19		the allegations of The Haemophilia Society that Scottish	10	۵	l can't recall.
20		blood products, principally Factor VIII, were less safe	20	Q.	
20		than those coming from England at the time, and she was	20	α.	some of the chronology.
22		very keen to get to the bottom of that.	22		It's SBTS0000379_040, please, Lawrence.
23	Q.	And the ambit of the investigation essentially became	23		So this is a meeting held on 30 August 1999 to
24	<b>.</b>	the question over Scotland lagging behind England in	24		discuss the investigation. We can see that from the
25		terms of producing hepatitis-safe heat-treated	25		Scottish Executive there are four in attendance: you,
		5			6
1		Mrs Towers, Mrs Falconer and Mr Palmer. There is also	1		lines of the Inquiry and get preliminary feedback from
2		someone attending from the Central Legal Office and then	2		them on the issues that might arise.
3		three from SNBTS.	3	Q.	It was presumably never going to be very likely that
4		Then if we look at the first paragraph we can see	4		SNBTS would put their hands up and say, "Yes, we were
5		it references to the minister being due to meet The	5		negligent" or "Yes, we were at fault". To what extent
6		Haemophilia Society on 14 September:	6		in the course of the investigation was the submissions
7		" to hear their concerns about the infection of	7		made by, material provided by SNBTS subjected to any
8		haemophiliacs with HCV through treatment with SNBTS	8		kind of rigorous scrutiny?
9		products explained that the Minister had requested	9	Α.	My recollection is that what was sought from SNBTS was
10		a report analysing what had happened at that time with	10		a factual, chronological account of the measures that we
11		an assessment of whether SNBTS' position could be said	11		had taken in the mid-1980s to ensure that hepatitis C
12		to have been negligent. After the investigation the	12		Factor VIII <i>(sic</i> ) was available.
13		Minister would brief the Parliament's Health Committee	13	Q.	If we turn then so that was 30 August. If we turn to
14		on its findings."	14		a meeting on 1 September.
15		Now, bearing in mind that the focus of the	15		That's PRSE0000978.
16		investigation is to determine whether SNBTS had been	16		So this is the second meeting that we see being
17		negligent, is there any particular reason why the	17		held, and this is with Professor Ludlam and
18		investigation process seems to have commenced with	18		Professor Lowe, and again you're in attendance,
19		a meeting with representatives of SNBTS before even the	19		Mrs Falconer and Mr Palmer, also from the Scottish
20		minister has met with The Haemophilia Society?	20		Executive.
21	Α.	Well, the meeting was clearly to prepare for that	21		The purpose of the meeting in the first paragraph
22		ministerial meeting and make sure that the minister was	22		is explained by you as being to clarify the validated
23		briefed as accurately as possible in advance of	23		information that would be needed from each of the
24		14 September. So I don't find it surprising in any way	24		Haemophilia Centres for the planned ministerial briefing
25		that we would want to meet with SNBTS to discuss the 7	25		on 9 September. 8

(2) Pages 5 - 8

1		Now, bearing in mind this was looking at or
2		this was an investigation which was to look at SNBTS's
3		actions, why had it seemed particularly important to
4		speak to Professor Ludlam and Professor Lowe at the
5		outset, of the investigation?
6	Α.	Well, they, each of them, headed up the two biggest
7		Haemophilia Centres in Scotland, so therefore they were
8		the two main prescribers of Factor VIII, so clearly
9		their recollection of events in the mid-1980s was
10		material to the internal investigation.
11	Q.	Can you assist us in understanding why the focus of the
12		investigation was negligence, which would ordinarily be
13		a matter determined by the courts, rather than perhaps
14		a broader question of whether there was fault or things
15		that could or should have been done differently or
16		better?
17	Α.	As I said earlier, the remit was that requested by
18		The Haemophilia Society. I imagine that that word
19		the use of that word emanated from them.
20	Q.	If we go towards the bottom of the page, please,
21		paragraph 4, this records a further contribution from
22		you:
23		"Dr Keel pointed out that it would be necessary to
24		fully investigate the circumstances and events during
25		that time and to cost, based on a range of scenarios, 9
1		least one plant coming up with a breakthrough. PFC did
2		so for HIV and BPL then did so (in retrospect
2 3		so for HIV and BPL then did so (in retrospect unwittingly) for HCV."
2 3 4		so for HIV and BPL then did so (in retrospect unwittingly) for HCV." Was it your understanding, therefore, that the
2 3 4 5		so for HIV and BPL then did so (in retrospect unwittingly) for HCV." Was it your understanding, therefore, that the different heat treatment strategies adopted by BPL and
2 3 4 5 6		so for HIV and BPL then did so (in retrospect unwittingly) for HCV." Was it your understanding, therefore, that the different heat treatment strategies adopted by BPL and PFC were in some way coordinated so as to be
2 3 4 5 6 7		so for HIV and BPL then did so (in retrospect unwittingly) for HCV." Was it your understanding, therefore, that the different heat treatment strategies adopted by BPL and PFC were in some way coordinated so as to be complementary?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23		so for HIV and BPL then did so (in retrospect unwittingly) for HCV." Was it your understanding, therefore, that the different heat treatment strategies adopted by BPL and PFC were in some way coordinated so as to be complementary? I think there was a degree of complementarity. Whether it was serendipitous or there definitely was a degree of complementarity, whether that was deliberate or serendipitous evades me at this time. It's so long ago. We can see, if we then pick it up at paragraph 6, this: "Professor Lowe and Professor Ludlam confirmed that it was normal practice within their centres to inform patients of the result of a test if they were found to be HCV positive. Dr Keel would confirm that this was the procedure within the other Haemophilia Centres. In particular, she was concerned about the case of a Dundee patient highlighted in the press coverage, who had claimed not to have been informed of his infection for a year after he was tested." Now, why was it that this issue about informing patients or the failure to inform patients of test

1		the different types of assistance which might be
2		awarded."
3		Just pausing there, does that reflect the fact
4		that one of the underlying purposes of the investigation
5		was to inform a decision about whether or not to provide
6		financial support?
7	Α.	Not directly. The purpose of the investigation was to
8		understand, as I said earlier, the facts and the
9		chronology of events during the period in question. But
10		it would have been remiss of any Government department
11		not to be anticipating that The Haemophilia Society,
12		which was already lobbying hard for financial redress,
13		would increase those efforts during and after the
14		production of the report.
15	Q.	Then continuing on with paragraph 4:
16		"It was therefore essential to estimate how many
17		people would be eligible. Any follow-up action taken by
18		the Department would be in consultation with the other
19		territorial departments on a UK-wide basis."
20		Then this:
21		"She advised that the chronologies of events
22		provided by BPL and SNBTS were revealing. PFC and BPL
23		had deliberately chosen to pursue different paths in the
24		development of heat treatment methods, in order to cover
25		more than one option and increase the likelihood of at
20		10
1		focusing upon the '85-'87 period and SNBTS?
1 2	A.	focusing upon the '85-'87 period and SNBTS? The remit of the investigation also covered, at
	A.	
2	A.	The remit of the investigation also covered, at
2 3	A.	The remit of the investigation also covered, at The Haemophilia Society's request, the information
2 3 4	A. Q.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was
2 3 4 5		The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material.
2 3 4 5 6		The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said,
2 3 4 5 6 7		The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply
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2 3 4 5 6 7 8 9	Q.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"?
2 3 4 5 6 7 8 9 10	Q.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation
2 3 4 5 6 7 8 9 10 11	Q.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said
2 3 4 5 6 7 8 9 10 11 12	Q.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But
2 3 4 5 6 7 8 9 10 11 12 13	Q.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. A.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was different in Edinburgh.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was different in Edinburgh. In relation to Glasgow, you were there between 1983 and
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q. A.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was different in Edinburgh. In relation to Glasgow, you were there between 1983 and 1986 and, of course, hepatitis C was not known at that point in time, and there was no test available. So you couldn't, I think, have been familiar with
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. A.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was different in Edinburgh. In relation to Glasgow, you were there between 1983 and 1986 and, of course, hepatitis C was not known at that point in time, and there was no test available. So you couldn't, I think, have been familiar with Professor Lowe's practices in relation to hepatitis C,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. A.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was different in Edinburgh. In relation to Glasgow, you were there between 1983 and 1986 and, of course, hepatitis C was not known at that point in time, and there was no test available. So you couldn't, I think, have been familiar with Professor Lowe's practices in relation to hepatitis C, could you?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q. A.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was different in Edinburgh. In relation to Glasgow, you were there between 1983 and 1986 and, of course, hepatitis C was not known at that point in time, and there was no test available. So you couldn't, I think, have been familiar with Professor Lowe's practices in relation to hepatitis C, could you? Only insofar as liver enzymes were taken at every visit
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. A.	The remit of the investigation also covered, at The Haemophilia Society's request, the information provided to patients. So that's why this discussion was material. Was what Professor Lowe and Professor Ludlam there said, and the use of the word "confirmed", was that simply accepted as face value, "That's what they've told us so that must be correct"? Well, I am struggling to know what other investigation we could have undertaken to confirm that what they said was correct. So yes. It was taken at face value. But I also knew from my own clinical practice in Glasgow, which we touched on yesterday, doing clinics with Professor Lowe and others, that that was the practice in Glasgow. I had no reason to believe that it was different in Edinburgh. In relation to Glasgow, you were there between 1983 and 1986 and, of course, hepatitis C was not known at that point in time, and there was no test available. So you couldn't, I think, have been familiar with Professor Lowe's practices in relation to hepatitis C, could you?

(3) Pages 9 - 12

1		non-A, non-B context was discussed in those clinics.	1	Α.	Well, it wasn't that element of the investigation
2	Q.	You have, I think, said in response to my question about	2		wasn't limited to what clinicians had told patients; it
3		whether this information was essentially taken at face	was also related to information provided in the form of		
4		value and I'm paraphrasing your answer,	4		leaflets, et cetera, and I think we laid hands on
5		Professor Keel what else could be done? The	5		a number of those publications in the course of the
6		Executive could have asked The Haemophilia Society to	6		Inquiry. So it was more of a holistic approach to
7		provide details of patients who claimed otherwise, could	7		information provided rather than just practices around
8		it not? It could have asked to see patient records?	8		informing patients of results.
9	Α.	Well, it The Haemophilia Society and many patients'	9	Q.	If we pick matters up next in September, about a week or
10		views were taken into account. Patients wrote in to the	10		so later, at SCGV0000043_047. So this is a briefing
11		Department in the process of the Inquiry, and aired	11		provided by Mr Palmer, who we saw in attendance at those
12		their views. So they were given that opportunity. I'm	12		two meetings, to the Minister, 8 September 1999, copied
13		not sure that going through patients' notes well, it	13		to you, amongst obviously a number of others. The
14		would have been a very lengthy and laborious process,	14		purpose is described in paragraph 1 as:
15		particularly going back so far, over 15 years by this	15		"To provide initial briefing to the Minister prior
16		point, to try to I don't think looking at the notes	16		to her meeting with the Haemophilia Society on
17		would have been a very fruitful exercise in trying to	17		14 September"
18		determine what the practice was around informing	18		If we go over the page, we can see paragraph 5
19		patients of their results.	19		sets out what the Government's position has been,
20	Q.	It might be said, professor, that if you have	20		essentially if there's no fault there should be no
21		an investigation, one aspect of which is to look at what	21		compensation and the assertion is made there again that
22		patients were told, but if all you're going to do is	22		patients received the best treatment available given the
23		accept a doctor's assurance that they did tell patients,	23		state of knowledge at the time.
24		that's not much of an investigation. If that submission	24		Then paragraph 6 says this
25		were to be made, what would be your comment?	25	SIR	R BRIAN LANGSTAFF: That's a slightly different
		13			14
1		formulation from the previous one. Previously, there	1		damaged but no negligence has been proved on the part of
2		was no reference to the state of knowledge at the time,	2		the NHS, then for the Government to embark on
3		but the words were, "which was essential for their	3		an open-ended no-fault compensation scheme would be
4		survival".	4		a very major change in policy with major implications
5	MS	RICHARDS: Yes, this picks up more the wording of the	5		further down the route on the amount of money to be
6		briefing we looked at yesterday afternoon.	6		spent and, therefore, by definition, the amount of money
7	SIF	RIAN LANGSTAFF: Yes, which was, as is set out here.	7		then available for direct patient care.
8	MS	RICHARDS: Yes. Then paragraph 6 says:	8		I think that's probably what he's trying to get
9		"Agreeing no-fault compensation for haemophiliacs	9		at. Of course, it's his words, as you said, not mine.
10		with HCV would have major policy implications in that it	10	Q.	Then under the heading "Recent developments" paragraph 7
11		would promote the elastic concept of 'a moral liability'	11		sets out the background in terms of the Society's
12		on government to compensate individuals who have been	12		campaigning, and then says:
13		damaged, however inadvertently, by its actions"	13		"Their key concerns seemed to be that"
14		Now, this is Mr Palmer's briefing, professor, not	14		And then there were a number, or three
15		yours, but do you recall what your thoughts were at the	15		subparagraphs. (a) is concerned with the issue that
16		time about the concept of a moral liability or moral	16		we've already touched on, the difference between
17		responsibility?	17		Scotland and England in terms of an HCV-safe product.
18	Α.	Well, at the time, my view was that there had been	18		Then (b) and (c), (b) is:
19		no fault attributed to SNBTS or the NHS and that that	19		"assurances were given at the time that the SNBTS
20		was the justification there had been for many, many	20		product was safe from infection, when in fact it was
21		years of the Government's position, with the exception	21		known that it was not safe from hepatitis C;
22		of the precedent we discussed yesterday for HIV.	22		"(c) some patients who were tested HCV-positive in
23		So my view was I mean, Mike Palmer's language	23		the early 1990s were not told that they were
24		is slightly difficult to interpret, but I suppose what	24		infected until long after the test results were known,
25		he's trying to say is that, where patients had been	25		during which time they ran a higher risk of infecting
		15			16

(4) Pages 13 - 16

1		close family members because their ignorance."	1		Then if we go to the heading "Draft agenda for the
2		So I just draw attention to that so we can make	2		meeting on 14 September", reference is made to an
3		sense of what we see a couple of pages further on. So	3		attached draft agenda at Annex C.
4		that's paragraph 7(b) and (c) of the briefing.	4		Then paragraph 20 says this:
5		If we go to the next page, the bottom of the page	5		"With regard to Section 3 of the agenda we will
6		has the heading "Current investigations", and	6		wish to probe the basis for the statements made at the
7		paragraph 14 refers to the Department being:	7		second and third indents of that section."
8		" engaged in an investigation of events and	8		Now, to understand that, I want to look at the
9		circumstances surrounding the introduction of	9		draft agenda with you. So if we could go, please, to
10		heat-treated Factor VIII blood products in the	10		page 11. This is the draft agenda, and if we look at
11		mid-1980s."	11		paragraph 3, which is the paragraph being referred to in
12		Then paragraph 15 refers to paragraph 7(a), so	12		Mr Palmer's briefing:
13		that's the issue about the heat-treated product, and	13		"Why were Scottish people with haemophilia exposed
14		says:	14		to the risk of HCV for longer than those treated with
15		" we have prepared an initial overview of the	15		English product?"
16		events in the mid-1980s, arising from our enquiries so	16		The second and third indents are:
17		far."	17		"Little or no information provided to patients at
18		If we go over the page, paragraphs 16 and 17 deal	18		the time about HCV risks although evidence of
19		with the charge at paragraph 7(b), so that's the	19		non-A, non-B hepatitis transmitted through blood
20		question of the extent to which information about	20		products was being accumulated through the 70s and early
21		infectivity of the product was provided to patients.	21		80s."
22		Paragraph 18 refers to the charge at	22		And:
23		paragraph 7(c), and it's said to be a claim currently	23		"By 1985 risks of HIV were very well documented
24		investigating, and that's the issue of people not being	24		and research well advanced into heat treatment."
25		told of their positive test results. 17	25		So those are the second and third indents. If we 18
1		go back to page 4, please, and paragraph 20 of the	1		of the page, and then paragraph 8 says this:
2		briefing. Again, I'm conscious this is not a document	2		"Our consultations suggest that from the late
3		authored by you, Professor Keel, but the suggestion	3		1970s (when NANBH first surfaced) to the mid-1980s,
4		there, wanting to "probe the basis" for	4		there was very little evidence that NANBH produced
5		The Haemophilia Society's statement in relation to the	5		adverse symptoms, and that it was generally regarded as
6		second indent, which is about little or no information	6		mild and non-progressive. For example, as late as
7		being provided to patients about HCV, it might be said	7		February 1987 Dr Forrester (Medical Adviser at the
8		that the Scottish Executive Health Department was taking	8		Scottish Office) reported that: 'Non-A, non-B Hepatitis
9		an approach towards The Haemophilia Society's	9		would appear to be relatively benign, despite some risk
10		assertions, wanting to probe the basis for them, that it	10		of cirrhosis of the liver in the long term, unless the
11		wasn't taking towards the Haemophilia Centre Directors,	11		recipient is pregnant when the effects can be very
12		accepting at face value what they told the Health	12		serious'."
13		Department.	13		Now, again, I appreciate that this is some time
14		Do you have any comment on that?	14		ago, but are you able to assist in understanding what's
15	A.	I think what we were looking for from The Haemophilia	15		referred to as "our consultations" there? In other
16		Society was as much intelligence to inform the Inquiry	16		words, what was the evidence-gathering exercise that led
17		that ultimately took place as possible. I think it was	17		to the conclusions that are being recorded in
18		a genuine desire to know what lay behind their	18		paragraph 8? Do you know?
19		allegations rather than subjecting them to a grilling	19	A.	No, I don't, but I infer from the mention of
20		that we weren't subjecting the Haemophilia Directors to.	20		Dr Forrester that at least part of that consultation was
21	Q.	And then Annex B of the briefing, which Mr Palmer had	21		looking through the files to see to gather references
22		described as an overview an "initial overview arising	22		to non-A, non-B hepatitis which had been collected by
23		from our enquiries so far", that starts on page 7.	23		Government. But I don't know what else it means, in
24		And if we go over the page to page 8, we've got	24		terms of consulting.
25		the heading "Protection from Hepatitis" towards the top	25	Q.	Was there any form of review of the medical literature
		19			20

(5) Pages 17 - 20

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than month.

1		from the '70s and '80s undertaken?
2	Α.	That was part of the internal report, yes.
3	Q.	Who would have undertaken that review of the medical
4		literature? Was that you or was that somebody else?
5	Α.	Christine Dora was the administrator in the lead
6		drafting the report, so it was principally down to her.
7		But I would I can't remember but probably have drawn
8		attention, her attention, to key articles that had
9		appeared in the medical press around about this time.
10	Q.	Do you know whether any consideration was given, whether
11		by Ms Dora or you or by other colleagues within the
12		Health Department, to making any contact with the civil
13		servants in the Scottish Office who'd been dealing with
14		this issue in the course of the 1980s?
15	A.	I've no recollection of that happening.
16	Q.	If we go just then to page 10, paragraph 18 is headed
17		"Initial conclusions", and says:
18		"Our initial impressions from this outline of
19		events, which has been gathered from our preliminary
20		investigations, are:
21		"that SNBTS did all they could at the time to
22		develop a Factor VIII product which was safe from HCV,
23		given the state of knowledge at the time and the key
24		objective of combatting HIV."
25		Then, secondly:
		21
1		"In line with our discussions with the Minister
2		yesterday, we recommend that she closes the meeting on
3		14 September by outlining the following way forward:
4		"a) The Department have commenced investigations
5		into Scotland's efforts to make blood products HCV-safe
6		in the mid-1980s, and the concerns articulated by the
7		Society today will be followed up in carrying those
8		investigations forward. I want to emphasise that the
9		Department is at the arm's length from SNBTS and is
10		engaged in an impartial and objective analysis of the
11		events and circumstances surrounding this issue."
12		Do you consider it's right to say that the
13		Department is at arm's length from SNBTS? Obviously,

8		investigations forward. I want to emphasise that the
9		Department is at the arm's length from SNBTS and is
10		engaged in an impartial and objective analysis of the
11		events and circumstances surrounding this issue."
12		Do you consider it's right to say that the
13		Department is at arm's length from SNBTS? Obviously,
14		they are different bodies but we've seen that there was
15		a close perfectly understandably working
16		relationship between the Department and SNBTS, and there
17		had been regular meetings over the years with SNBTS
18		representatives, again for perfectly proper reasons.
19		Was the Department really in a position to engage
20		in an impartial and objective analysis of SNBTS's
21		actions?
22	Α.	I believe that it was. We had no direct involvement in
23		directing SNBTS's operations, so I think that the
24		Department was in a perfectly reasonable position to
25		conduct this investigation of events that had happened 23

1		"there is no evidence that SNBTS lagged without
2		good reason behind England"
3		Now, those are described as initial impressions
4		and initial conclusions and preliminary investigations,
5		but they're expressed in fairly strong and decided terms
6		at a point in time in which The Haemophilia Society
7		meeting hasn't even taken place yet. It may be
8		submitted to the Inquiry in due course that this was
9		an investigation undertaken essentially with a closed
10		mind or pre-determined position. Do you have any
11		observations in relation to that submission if it were
12		made?
13	A.	I disagree. I think it's absolutely consistent with
14		providing ministers with all the facts that were known
15		at the time and, indeed, the preliminary conclusions
16		that were being drawn from those facts in preparation
17		for a meeting with The Haemophilia Society.
18	Q.	If we turn to SCGV0000170_164, this is a further
19		briefing from Mr Palmer, 10 September 1999, to the
20		Minister, the purpose is said:
21		"To outline a way forward which the Minister can
22		offer the Haemophilia Society at her meeting with them
23		on 14 September."
24		Then if we just go down the page, the
25		"Recommendation" is:
		22
1		many years before, based on evidence gathering from
2		SNBTS but also from Haemophilia Directors, as well as
3	~	The Haemophilia Society.
4	Q.	If we turn to the next page, we can see in paragraph (b)
5		the link being made with the possibility of
6		compensation. Then on paragraph (c) says this:
7		"The Department aims to report on its
8		investigations within a month"
9		Now, as it happened, it took over a year, it's
10		late October 2000, I think, when the report was
11		published. What's your understanding of why it took
12	,	that length of time?
13	Α.	Well, my recollection of this is hazy, but at least part
14		of it, I think, relates to the fact that I was trying
15		to, from the UKHCDO registry, get accurate figures on

period in question and that proved a very difficult

task, and I can't remember now whether we ever finally

got that data that we were seeking. That, at least, was

part of the reason that the report took a year rather

Dr Colvin, chair of UKHCDO, I don't think the date of

Q. I haven't gone to it but I will give a reference for the

transcript. It's right to note that you wrote to

24

1		the letter is clear, but it's LOTH0000011_007, and then	1		wouldn't have been shared.
2		we will I think see some further documents in early 2000	2	Q.	The reason I ask that, professor, in particular is the
3		which report that you've not had a response or that	3		document I asked to be taken down, I'm just going to
4		you're chasing for a response.	4		read a sentence from it. It's paragraph 10 of that note
5		Can we then just go to SCGV0000170_232. Can we	5		of the meeting on 14 September and it records the
6		just go to the bottom of the page, please.	6		Minister pointing out that she wished the examination to
7		I'm sorry, can we take that down. There's	7		be carried out in an open and transparent manner, and it
8		something which hasn't been redacted, which I think	8		might be said, again, that conducting the investigation
9		possibly ought to have been redacted.	9		in an open and transparent manner might include
10		I'll come back to that document at a later stage	10		providing your initial findings when I say "your",
11		if we need to. That is the note of the meeting. Yes,	11		the Department's initial findings or impressions to
12		we do have another version of that document but not at	12		the Society for it to be able to respond on an informed
13		present. My apologies Professor Keel.	13		basis.
14		In any event, there was a meeting on 14 September	14	Α.	Well, again, I beg to differ. I think that when it came
15		with representatives of The Haemophilia Society. The	15		to the report, that final report being produced, it was
16		document that we looked at a few minutes ago that was	16		issued in draft form to the main stakeholders, if you
17		appended to Mr Palmer's briefing that Annex B which set	17		like, including The Haemophilia Society, so that they
18		out the initial investigations and initial impressions,	18		could comment on the more refined conclusions that we'd
19		do you know whether that document was provided to	19		arrived at, at that point. I don't think that not
20		The Haemophilia Society in the course of the	20		sharing the ministerial briefing with
21		investigation, so that they could see the Department's	21		The Haemophilia Society means that the Inquiry wasn't
22		thinking and comment on and respond to it?	22		conducted in an open and transparent way.
23	Α.	I don't remember but I think it's highly unlikely it	23	Q.	Yes, I should say, for the sake of clarity, I wasn't
24		would have been provided to them. It was internal	24		suggesting that the briefing itself was something that
25		briefing for ministers, so I think we can conclude it	25		ought to be shared with the Haemophilia Society. It was
		25			26
1		the annex to the briefing, Annex B, which set out what	1		1988". Can you help us in understanding why and whether
2		it was the Department had obtained by way of information	2		you were aware that there was evidence that the BPL
3		and evidence so far.	3		product didn't transmit hepatitis C, that was available
4	Α.	Well, I don't know whether it was shared but, as I said	4		in '85/'86?
5		earlier, I think it's highly unlikely.	5	Α.	Well, I think having a basis for optimism is not the
6	Q.	Can we then just pick up on a point of detail in your	6		same as proof that the product was HCV safe and that
7		witness statement, please. WITN5736003. If we go to	7		only emerged in 1988. So that's what I was trying to
8		page 47, in paragraph (d), if we just thank you.	8		reflect. There were preliminary, of course, findings
9		I just want to pick up on a point that's made in	9		along the way, but the nature of hepatitis C is that you
10		the second half of the paragraph. So you're talking	10		have to, in the absence of a test, which was not in
11		here about the different approaches taken by BPL and PFC	11		existence at that point, you have to let some time
12		to viral inactivation and, halfway down the paragraph,	12		elapse to determine whether patients had indeed been
13		you say this:	13		infected with non-A, non-B hepatitis.
14		"In the event, the PFC was ahead of BPL with an	14	Q.	Do you recall whether you were aware of the preliminary
15		HIV-safe product"	15		evidence that was available before 1988, which indicated
16		Then:	16		or pointed to the likelihood of this being safe, in
17		"BPL was ahead of the PFC in developing an	17		terms of transmission of non-A, non-B hepatitis?
18		HCV-safe product in 1985"	18	Α.	I don't recall whether I was aware or not. To me, the
19		Then it's this phrase:	19		material point is that it wasn't definitively proved
20		" (although this was not proven until 1988)."	20		until three years later.
21		Now, the Inquiry has seen documents from 1985 and	21	SIF	<b>R BRIAN LANGSTAFF:</b> May I just ask a question here? By
22		1986, which suggest that there was a basis for optimism	22		1988, there wasn't, as yet, a test for the actual virus
23		about the BPL product: the initial results and findings	23		itself because one hadn't yet been developed; that
24		were good. That's not something which is referred to	24		didn't take place until 1989. So what one is looking
25		here. You use the phrase "although not proven until	25		for here is a product being administered to recipients
		27			28
					(7) Pages 25 - 2

(7) Pages 25 - 28

1		and seeing whether any of them then showed the signs	
2		which clinically indicated that they had non-A, non-B.	
3		Those signs would be what were repeated liver function	
4		tests on more than one occasion which showed elevation,	
5		and the absence of any positive test for hepatitis B and	
6		hepatitis A. It was really a diagnosis of exclusion,	
7		wasn't it?	
8	A.	Indeed, yes.	
9	SIR	R BRIAN LANGSTAFF: So the proof of the pudding is the	
10		absence of any infection demonstrated by those tests.	
11		You just need one person or two people to say, "Well,	
12		I had this product, I have this result, the result is	
13		positive, I've got non-A, non-B", and you'd be able to	
14		say, well, the product doesn't work.	
15		The proof of the negative is what you have to have	
16		to show that the English BPL product actually worked.	
17		It's not going to come quickly, but by 1988 you regard	
18		it as proven. In other words, there'd been sufficient	
19		product out there without any report of any infection.	
20		The steps along the way to that are seeing whether	
21		anyone checks at intervals and sees if there's any	
22		infection and, progressively, my impression would be	
23		with those tests nobody produces a positive result, that	
24		goes on, and the groundswell develops to an extent where	
25		you can say that yes, this is absolutely proven. Is	
		29	
1		other products.	
2	Q.	Now you observe, as I understand it correctly, that at	
3		this point in time, BPL wasn't producing sufficient	
4		quantities of product for everybody in England or	
5		England and Wales to be treated. Did the Department's	
6		investigation look at what might be thought to be the	
7		separate but important question of whether BPL might	
8		have sufficient quantities of 8Y in order to be able to	
9		spare some for that smaller cohort of patients in	
10		Scotland who were previously untreated or had been	
11		minimally treated? In other words, the very cohort most	
12		at risk? Was that something the investigation	
13		looked at?	
14	Α.	I think there is mention in the investigation report, or	
15		I've seen it in some document, that a small amount	
16		of 8Y, the BPL product, was indeed obtained, I think by	
17		Edinburgh, but that was obviously on the basis of	
18		clinician-to-clinician approach. I mean, I was working	

in London during this period in the mid-'80s and

I recall that at the Middlesex, where I worked for

I think it highly unlikely that, other than the small 31

a bit, that 8Y was often in short supply, even in that

So BPL were not hanging on to loads of that

product that could have been accessed by Scotland. So

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major Centre.

1		that a fair summary of the process?
2	Α.	That's absolutely what I was trying to convey but much
3	Λ.	more fluently, thank you.
4	SIR	BRIAN LANGSTAFF: Thank you.
5		<b>RICHARDS:</b> The penultimate sentence in that paragraph
6		makes the point that the BPL product was not produced in
7		sufficient quantities to make England self-sufficient.
8		Was it your understanding that the cohort of
9		patients who might be particularly at risk in this
10		period that you were looking at, that the Department was
11		looking at, '85 to '87, would be likely to be patients
12		who had been either previously untreated or minimally
13		treated? They were those who were most likely to be at
14		risk from treatment with a product that transmitted
15		hepatitis C; is that correct?
16	Α.	Yes, because we know, with hindsight, that prior to an
17		HCV-safe product being produced, that 100 per cent of
18		haemophilia patients would have contracted
19		non-A, non-B hepatitis. So the clinical trials and
20		of course this long pre-dates any involvement or any of
21		my involvement through the Government the clinical
22		trials that would have been conducted in the mid-1980s
23		would have, I think, exclusively been in previously
24		untreated patients, so that the effects could be
25		determined in them who had never been exposed to any
		30
		and the second second second second second
1		amount that came in, as I said, I think to Edinburgh,
2 3		there would have been excess product available for north of the border.
4	Q.	It's an issue that this Inquiry has been investigating.
5	ω.	Professor Keel, as to whether requests could and should
6		have been made earlier to BPL for a small supply but
7		sufficient to enable the smaller number of Scottish
, 8		patients most at risk to be treated.
9		If you don't recall, please say so, and we can
10		obviously look and will look with Mrs Deacon in due
11		course at the final Inquiry report, but do you recall
12		that coming up as an issue in the course of the
13		investigation, whether requests could and should have
14		been made to BPL for a supply earlier than they were?
15	A.	I don't remember that being a subject that was
16		discussed, but I as I said a minute ago, I think
17		there is reference in the document that a small amount
18		had found its way north. I imagine that it was
19		understood at the time that BPL were not able to produce
20		enough product to cover England, and therefore that the
21		prospect of them, even if they had been formally
22		approached of releasing any for Scotland were low.
23	Q.	If we go to SCGV0000170_152.
24		This is still in September 1999. If we look at
25		the top of the page, it's an email sent on behalf of the
		32

(8) Pages 29 - 32

	First Minister, 23 September. And again, it's copied to	1		There's a note on the right-hand side which I think says
	you, amongst others, and it says this:	2		this:
	"The First Minister has seen your minute of	3		"Ms Deacon's office advises that this is very much
	17 September to the Minister for Health outlining a way	4		a PR exercise and that there is unlikely to be any
	forward following the meeting with the	5		compensation paid."
	Haemophilia Society. He was a little concerned about	6		Now, this is nine days after the meeting with The
	the possible financial implications and fears that an	7		Haemophilia Society where the Minister has said to The
		8		Haemophilia Society "We're going to be open and
	open mind could be taken to mean an open cheque book. He would be grateful for information on the likely	9		transparent". Obviously, this is a matter that
	· ·	9 10		
	exposure if compensation were to be awarded."	10		Ms Deacon will no doubt be asked about in the course of
	Now, before we look at anything else on this	12		the week but do you maintain the answer you gave earlier
	document, do you have any recollection of your thoughts	12		that, from your perspective, this was an independent and
	when you saw this email, and the fear about an open			impartial investigation in light of, what's said to be
	mind?	14		here, the advice from the Minister that it was very much
Α.	No, I don't recall what I thought when I saw the email,	15		a PR exercise?
	but clearly, any administration would want to be able to		Α.	Well, as I said in my written statement, I certainly
	quantify the amount associated with the compensation if	17		don't agree with the use of the term "PR exercise".
	that were to be rewarded awarded. And as we've seen	18		Undoubtedly, ministers were under great pressure to
	from earlier documents, in preparation for this kind of	19		further investigate this area and The Haemophilia
	response from ministers, the Department had already	20		Society undoubtedly had in mind compensation at the end
	begun to try to scope the numbers, so that from who	21		of that period. However, I don't think that means that
	might be eligible from those numbers we could build	22		the investigation the internal investigation was not
	scenarios around the possible financial implications of	23		conducted in an entirely proper way, as I said, earlier,
~	such a scheme if it were adopted.	24		finding out the facts, detailing the chronology, so that
Q.	Could we look at the bottom part of the page, please. 33	25		we could really understand what The Haemophilia 34
				07
	Society whether what The Haemophilia Society were	1		a letter from you dated 17 January 2000, and we can see
	alleging was true or not. So the use of this term does	2		it's Scottish Haemophilia Directors. Paragraph 1 refers
	not tally with my recollection of that period around the	3		to the meeting that we just briefly looked at.
	investigation.	4		Paragraph 2 of the letter says this:
Q.	Moving on, then, through the course of the investigation	5		"You may recall that The Haemophilia Society are
	to November '99, WITN2287019, please.	6		also particularly interested in pursuing the issue of
	WITN2280719, we don't have it. Ah, okay, I'll	7		what patients were told at the time of Hepatitis C
	pick that up after the break, in that case.	8		testing, including the clinical implications of
	My apologies, professor, for the document issues	9		a positive diagnosis, in addition, the Society allege
	this morning.	10		that Scottish patients were often completely unaware of
	We'll come back to that, so I'll take the	11		possible adverse effects resulting from plasma derived
	investigation slightly out of chronological order.	12		blood products, and of other potential treatment
	If we then move to SCGV0000170_078, this	13		options."
	a meeting, 14 January 2000, and I draw attention to this	14		' So that's one of the issues that have been flagged
	just to see what's set out in paragraph 2, and this,	15		up by the Society, and then we can see that, in the
	I think, confirms the point you made earlier,	16		third paragraph, you want to discuss these important
	Professor Keel. It refers in paragraph 2 to the lack of	17		issues in more depth and so you're inviting the
	information received so far from the Haemophilia	18		Haemophilia Centre Directors to a meeting.
	Directors, and then it sets out that you had written in	19		We can see the meeting itself at ARCH0003312_020.
	September, written again in mid-December, and sent	20		So meeting on 10 February 2000, we can see again the
	another reminder in early January, and that the	21		attendees from the Scottish Executive and then on this
	information received didn't answer all the questions.	22		occasion we have Professor Ludlam and Professor Lowe
	So I think that reflects what you already told us and	23		again but we also have directors from Dundee, Aberdeen,
	put some dates on it.	24		Inverness and Yorkhill.
	Can we then pick up ARCH0003312_031. Now, this is	25		If we go towards the bottom of the page, we can
	35			36

(9) Pages 33 - 36

,			,
1		see and I'm not going to go through the detail of it	1
2		but we can see reference there to figures of HCV	2
3		positive patients said to be currently alive.	3
4		Then if we go over the page, there's further	4
5		information about the figures.	5
6		If we can pick it up at the bottom of the page,	6
7 8		please, paragraph 3: "Dr Keel reported that a major concern of	7 8
9		The Haemophilia Society was that members alleged they	9
9 10		were not given a clear explanation of the risks of	9 10
11		treatment or the therapeutic options. Patients were	10
12		tested without their knowledge and were not told of the	12
13		results for some time and that during that time their	13
14		partners were exposed to the unnecessary risk of	13
15		infection."	14
16		So you're there recording	16
17		The Haemophilia Society's complaint from members as to	10
18		what they were not being told and what was happening	18
19		without their knowledge.	10
20		Then Mrs Towers is then recorded as contributing.	20
20		Now, Mrs Towers was who?	20
22	A.	She was a legal adviser to Government.	21
23	Q.	What she then says is:	23
23	ч.	" explained that it was therefore necessary to	23
25		try to establish whether there was a general policy on	25
20		37	20
1		the medical literature? Do you know?	1
2	Α.	The latter.	2
3	Q.	Then if we go down to paragraph 7, we can see it said:	3
4		"Professor Lowe pointed out that there was an	4
5		awareness of Hepatitis at that time and every patient	5
6		was treated with great care because of the risks of	6
7		transmission. He explained that the policy was that	7
8		patients would be informed they were being tested	8
9		and that the results would be discussed at their next	9
10		appointment."	10
11		Then he refers to a publication in '85 and British	11
12		Liver Trust leaflets.	12
13		Was this information provided by Professor Lowe at	13
14		this meeting again essentially accepted at face value by	14
15		the investigation, as far as you can recall?	15
16	Α.	Yes, I think it was.	16
17	Q.	Then if we go over the page, paragraph 9 says this:	17
18		"Professor Lowe pointed out that most patients	18
19		would have been infected whilst their predecessors were	19
20		in post and asked whether it was necessary to contact	20
21		them to make them aware of the situation. Mrs Towers	21
22		explained that this was a factual information gathering	22
23		exercise but that it should be borne in mind that the	23
24		information might be used in future Court actions.	24
25		Professor Ludiam also sought advice on whether HDs 39	25

39

1		what patients were told and whether there [I think the
2		word 'was' is missing] an assessment of risk and if
3		patients were given a choice."
4		Now, it might be said that Mrs Towers is there
5		identifying a narrower issue so, rather than looking at
6		what, as a matter of fact, did or didn't happen, looking
7		to see whether there was a general policy about the
8		provision of information to patients. What, if any,
9		comment would you make in relation to that?
10	Α.	Not sure I have any comment. She was clearly probing
11		one aspect of this area of the Inquiry.
12	Q.	We can then see a response from Professor Ludlam
13		describing non-A, non-B hepatitis as a mild
14		non-progressive condition sorry, in terms of the
15		perceptions until the late 1980s, the first serious
16		study on liver biopsy having been undertaken in 1985.
17		Then this:
18		"Dr Keel confirmed that this was also her
19		understanding, and Dr Watson advised the only tests for
20		the virus at the time would have been via surrogate
21		markers."
22		Was your understanding of this important issue,
23		about what was known regarding non-A, non-B hepatitis,
24		essentially based upon what Dr Ludlam was saying to you,
25		or was it based upon your own knowledge and review of
		38
1		[Haemophilia Directors] should be looking back to try to
2		identify what had happened to patients whose whereabouts
3		and status were unknown. Mrs Towers confirmed that
4		Central Legal Office was representing the Trusts and
5		SNBTS and that the HDs should therefore follow CLO
6		advice on whether any further investigation or the
7		tracking down of patients was necessary."
8		Now obviously this paragraph doesn't record any
9		contribution or expression of view from you,
10		Professor Keel. But as a medical practitioner as well,
11		obviously, as medical advisor to the Government, do you
12		have any concerns about the discussion that's recorded
13		here? We have Professor Lowe asking about whether
14		contact should be made with patients who might have been
15		infected, and Mrs Towers saying, "Well, that information
16		might be used in future court actions and you should
17		take legal advice."
18	Α.	I don't recollect this part of the discussion. I mean,
	А.	
19 20		legal advice is clearly very important. SNBTS were already in touch with CLO, so I think it's probably
20 21		reasonable that Lynda Towers advised them to speak to
21		CLO before doing anything further.
22	Q.	As a matter I'm sorry.
23 24	Q. A.	If I may. I'm not quite sure what Professor Lowe had in
24 25	м.	mind in terms of tracking the patients down. I don't
20		40

(10) Pages 37 - 40

1		know what was in his mind. I mean, was he going to ask	1		imp
2		them about what information they'd been given? They	2		the
3		would presumably be under the care of another	3		pro
4		Haemophilia Director or centre somewhere else, who was	4		imp
5		looking after them from a non-A, non-B infection point	5		and
6		of view, and monitoring them. So and in due course,	6	Α.	We
7		the report was going to be produced and indeed, as	7		hae
8		subsequently happened, there was publicity around	8		little
9 10		awareness raising. So I'm really a bit mystified as to	9		in tl
10 11	~	what was in Gordon Lowe's mind.	10		a h
	Q.	Yes. Whatever Professor Lowe had in mind, it's I think	11 12		effo in n
12 13		tolerably clear what Professor Ludlam had in mind, which was the question of whether Haemophilia Directors should			in r
13 14			13 14		for
14		be looking back to try to identify what had happened to	14	0	pro
15		patients whose whereabouts and status were unknown. The Inquiry has heard evidence, Professor Keel, in	16	Q.	Jus
10		particular in relation to mild haemophiliacs who may not	17		mo
18		be in contact with Haemophilia Centres from one year to	18		28
10		the next, and so there may be cohorts of patients not	10		the
20		attending regularly at their Haemophilia Centre who	20		
20 21		might have been infected and were unaware of their	20		em
21		infection.	21		nov
22		As a medical professional, whatever this	22		Mrs
23 24		particular paragraph does or doesn't mean, as a medical	23		IVIIC
24 25		professional, would it have been, in your view,	24		per
20		41	20		por
1		investigation, and it's her fact-finding exercise and	1		due
2		her conclusions that we see in the investigation report,	2		in te
3		is it not?	3		in tl
4	Α.	Yes.	4		lead
5	Q.	Then we see her saying this:	5		son
6		"Dr Keel, Mrs Towers	6		rela
7		"I have now waded through the papers you got from	7	Α.	We
8		Prof Cash, relating to SNBTS, and the only things I can	8		Pro
9		say are:	9		то
10		"a) I don't understand half of them!	10		the
11		"b) as far as I can make out, 'we' (in Scotland)	11		sur
					WOI
12		were only getting around to seriously thinking about	12		
12 13		ALT testing of donations in March 1988 after the	12 13		But
					But is w
13		ALT testing of donations in March 1988 after the	13		
13 14		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise	13 14		is w
13 14 15		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is	13 14 15		is w ma
13 14 15 16		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is a big dollop of hindsight."	13 14 15 16		is w ma
13 14 15 16 17		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is a big dollop of hindsight." "The Haemophilia Society are not going to let it	13 14 15 16 17		is w ma cov
13 14 15 16 17 18		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is a big dollop of hindsight." "The Haemophilia Society are not going to let it rest if we put nothing in about testing. Can you give	13 14 15 16 17 18		is w maj cov tha
13 14 15 16 17 18 19		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is a big dollop of hindsight." "The Haemophilia Society are not going to let it rest if we put nothing in about testing. Can you give me any advice in relation to the sequence of events as	13 14 15 16 17 18 19	Q.	is w may cov tha rela
13 14 15 16 17 18 19 20		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is a big dollop of hindsight." "The Haemophilia Society are not going to let it rest if we put nothing in about testing. Can you give me any advice in relation to the sequence of events as they might relate to our investigation? Even something demonstrating that by the time adequate testing of donations was available, heat treatment was already	13 14 15 16 17 18 19 20	Q.	is w may cov tha rela
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> </ol>		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is a big dollop of hindsight." "The Haemophilia Society are not going to let it rest if we put nothing in about testing. Can you give me any advice in relation to the sequence of events as they might relate to our investigation? Even something demonstrating that by the time adequate testing of	13 14 15 16 17 18 19 20 21	Q.	is w may cov that rela cros
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is a big dollop of hindsight." "The Haemophilia Society are not going to let it rest if we put nothing in about testing. Can you give me any advice in relation to the sequence of events as they might relate to our investigation? Even something demonstrating that by the time adequate testing of donations was available, heat treatment was already protecting people? Or something demonstrating that the testing available at the time was inadequate?"	13 14 15 16 17 18 19 20 21 22	Q.	is w may cov that rela cros Nov fror
<ol> <li>13</li> <li>14</li> <li>15</li> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> </ol>		ALT testing of donations in March 1988 after the period in question. I suppose we could try to emphasise about how unreliable it was but that in itself is a big dollop of hindsight." "The Haemophilia Society are not going to let it rest if we put nothing in about testing. Can you give me any advice in relation to the sequence of events as they might relate to our investigation? Even something demonstrating that by the time adequate testing of donations was available, heat treatment was already protecting people? Or something demonstrating that the	13 14 15 16 17 18 19 20 21 22 23	Q.	is w may cov that rela cros from from

1		important that bearing in mind we're now in 2000 and
2		there's a possibility of patients infected through blood
3		products not knowing of their infection, would it be
4		important for those patients to be identified and tested
5		and informed?
6	Α.	Well, it would be, but I suspect that even the mild
7		haemophiliacs who, as you say, would probably have
8		little contact with the Centre, would have been aware,
9		in the preceding decade, of the existence of
10		a hepatitis C test, and there certainly were great
11		efforts and we discussed some of these vesterday
12		in raising awareness of the availability of an HCV test
13		for anybody who'd received blood transfusion or blood
14		products.
15	Q.	Just one further document before we break, and this now
16		moves to March 2000. It's SCGV0000171_052.
17		This is an email from Christine Dora, dated
18		28 March 2000, and I'm looking not at the very top of
19		the page but at the which is I think forwarding the
20		email on but to the next thank you to what is
21		now on top of the screen.
22		So it's from Christine Dora to you and to
23		Mrs Towers, subject "help! haemophilia and hepatitis C".
24		Just to understand, Mrs Dora or Ms Dora was the
25		person who was primarily charged with undertaking the
20		42
1		due course that this is not a reassuring email to read,
1 2		due course that this is not a reassuring email to read, in terms of the reliability of the conclusions set out
2		in terms of the reliability of the conclusions set out
2 3		in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the
2 3 4		in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the lead fact finder is apparently struggling to understand
2 3 4 5		in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the lead fact finder is apparently struggling to understand some of the issues. Do you have any observations in
2 3 4 5 6		in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the lead fact finder is apparently struggling to understand some of the issues. Do you have any observations in relation to that?
2 3 4 5	A.	in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the lead fact finder is apparently struggling to understand some of the issues. Do you have any observations in
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22		in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the lead fact finder is apparently struggling to understand some of the issues. Do you have any observations in relation to that? Well, first of all, I don't think we know the content of Professor Cash's papers. In my experience of his <i>modus operandi</i> , many of them possibly didn't relate to the subject of the Inquiry, so I don't think it's surprising that Christine Dora and the administrator would not be able to understand medical communications. But what I think we do not know, as I said a minute ago, is what was in those papers from Professor Cash, they may not even have been about hepatitis C, they may have covered other areas. And the other element, of course, is that anything that Christine Dora was going to put in the report relating to the medical facts, then I was there to cross-check them. Now, we can see there being identified a concern arising from Professor Cash's papers about ALT testing, and that not having been considered, the inference may be,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24		in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the lead fact finder is apparently struggling to understand some of the issues. Do you have any observations in relation to that? Well, first of all, I don't think we know the content of Professor Cash's papers. In my experience of his <i>modus operandi</i> , many of them possibly didn't relate to the subject of the Inquiry, so I don't think it's surprising that Christine Dora and the administrator would not be able to understand medical communications. But what I think we do not know, as I said a minute ago, is what was in those papers from Professor Cash, they may not even have been about hepatitis C, they may have covered other areas. And the other element, of course, is that anything that Christine Dora was going to put in the report relating to the medical facts, then I was there to cross-check them. Now, we can see there being identified a concern arising from Professor Cash's papers about ALT testing, and that not having been considered, the inference may be, sufficiently timelessly. We see Ms Dora commenting
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23		in terms of the reliability of the conclusions set out in the investigation report, bearing in mind that the lead fact finder is apparently struggling to understand some of the issues. Do you have any observations in relation to that? Well, first of all, I don't think we know the content of Professor Cash's papers. In my experience of his <i>modus operandi</i> , many of them possibly didn't relate to the subject of the Inquiry, so I don't think it's surprising that Christine Dora and the administrator would not be able to understand medical communications. But what I think we do not know, as I said a minute ago, is what was in those papers from Professor Cash, they may not even have been about hepatitis C, they may have covered other areas. And the other element, of course, is that anything that Christine Dora was going to put in the report relating to the medical facts, then I was there to cross-check them. Now, we can see there being identified a concern arising from Professor Cash's papers about ALT testing, and that not having been considered, the inference may be,

(11) Pages 41 - 44

1		"The Haemophilia Society are not going to rest	1	context of tying to understand what efforts were made by
2		if we put nothing in about testing."	2	SNBTS to produce a non-A, non-B safe product in the
3		Then if we can just go to the top of the page	3	mid-1980s.
4		there's a handwritten note, is that your handwriting,	4	MS RICHARDS: Sir, I trespassed into break territory, so
5	-	where it says, "X is a balance between"?	5	perhaps we could take our morning break now.
6	Α.	I can't actually be sure. It may be, but I don't think	6	SIR BRIAN LANGSTAFF: Yes, well, we'll take a break until
7	-	it is.	7	11.50. 11.50.
8	Q.	In any event, it says:	8	(11.19 am)
9		"X [and that's the paragraph about The Haemophilia	9	(A short break)
10		Society not resting 'if we put nothing in about	10	(11.50 am)
11		testing'] is a balance between sticking to what we were	11	MS RICHARDS: Professor Keel, I'm going to go back to
12		asked to do & anticipating further demands. I am still	12	a document which I had wanted to look at earlier, and we
13		inclined not to cover testing in the body of the	13	didn't have it and it's entirely my fault because I gave
14		report."	14	the wrong reference. So the correct reference is
15		Regardless of what the remit of the report was,	15	WITN2287021.
16		and whether testing fell within the existing remit or	16	And if we go to the second page, top half of the
17		not, was the concern about what Scotland had or hadn't	17	page, we can see these are the notes of a meeting
18		done in relation to ALT testing, something that was	18	between The Haemophilia Society and the Scottish
19		identified and flagged up as an issue for the minister	19	National Blood Transfusion Service, 25 November 1999,
20		to consider, as far as you can recall?	20	and then we can see a number of attendees on behalf of
21	Α.	I can't recall, and we spent some time on ALT testing	21	The Haemophilia Society, and then on behalf of SNBTS,
22		yesterday, and I gave you my views on its lack of	22	and then you and Thea Teale there on behalf of the
23		sensitivity and specificity, in particular, in terms of	23	Scottish Office.
24		picking up non-A, non-B hepatitis. So I think we	24	This was taking place in the course of the
25		probably regarded ALT testing as an irrelevance in the 45	25	investigation and, as I understand it, the suggestion of 46
1		a meeting between SNBTS and the Haemophilia Society was	1	There's a response from BMcC [that's
2		something which arose out of one of the earlier meetings	2	Brian McClelland] and then you're recorded as saying:
3		as an idea that this might be a good thing to do.	3	"AK advice that the ACVSB had considered this
4	Α.	Yes.	4	issue over a number of years. On each occasion, they
5	Q.	If we go to the third page, there's just a couple of	5	agreed that ALT testing should not be introduced because
6	-4.	points I wanted to pick up. So the bottom half of the	6	of the poor specificity of this test."
7		page refers to a presentation by PF, so that's	7	Now, Professor Keel, the ACVSB only met for the
8		Peter Foster, and then paragraph 3.1 we see PD, that's	8	first time in 1989, in April 1989. So it would appear
9		Philip Dolan, for The Haemophilia Society, raising the	9	that what you're setting out at the bottom of that page
10		question of who determined the operating policies for	10	may not be correct. What was the basis of your
11		haemophilia provision.	11	understanding that the issue of ALT testing had been
12		l just wanted to ask you about what you say here	12	considered over a number of years by ACVSB?
13		and on the following page. In the third bullet point	13	A. Well, if they met for the first time in 1989, then 1999
14		iťs:	14	we're talking about ten years later. So I think my
15		"AK [that's you] also advised that national policy	15	statement could be considered accurate.
16		in matters relating to donor testing were the	16	Q. Do you know or did you know in 1999 what consideration
17		responsibility of UK ministers. They took advice from	17	had been given and by whom to the question of surrogate
18		a UK advisory committee the Advisory Committee for the	18	testing in Scotland in the 1980s? It wasn't the ACVSB
19		Virological Safety of Blood, ACVSB."	19	in the '80s, because it unless you're just talking
20		Then there's reference to the membership of ACVSB.	20	about 1989. Did you have any knowledge of what other
21		Then if we go over the page, if we look again at	21	bodies or organisations or individuals had considered
22		the bottom half of the page, about halfway through the	22	that issue?
23		paragraph that's on the screen it says:	23	A. No, I can't recall having any knowledge of them.
24		"Several questions were asked on why ALT testing	24	<b>Q.</b> And this deals with ALT testing, and of course that may
25		was not introduced in the UK."	25	be the specific issue that had been raised by those
		47		48

(12) Pages 45 - 48

1		present. But another aspect of surrogate testing is HBc	1
2		testing. Was that something which was thought about in	2
3		the course of the investigation at all as far as you can	3
4		recall?	4 5
5 6	Α.	Well, it had been the remit of the investigation agreed by The Haemophilia Society didn't cover surrogate	6
7		testing. So I think the answer to your question is no.	7
, 8	Q.	I don't know what independent recollection you have of	, 8
9	ч.	this meeting at this distance of time, Professor Keel,	9
10		but if we go back to the second page	1(
11	SIR	BRIAN LANGSTAFF: Just before we do, can we come back to	1
12		that, the page we were on, please? And let me ask you	12
13		just a couple of questions, Professor, about the last	1:
14		bullet point on the page.	14
15		ACVSB, having met for the first time in 1989, by	15
16		which time a test was being promoted by the Chiron	16
17		Corporation in the United States, and rapidly was	17
18		becoming available in the UK, albeit a second	18
19		generation, ultimately, can you help at all with why the	19
20		ACVSB might have been considering ALT testing in the	20
21		first place? After all, if there was a specific	2'
22		a test specific to the virus in question, why would you	22
23		want a surrogate test?	23
24		That's the first question.	24
25	Α.	Yes, well, you'll forgive me because, of course, this 49	25
1		consider it a false positive. It's elevated for other	1
2		reasons, and I've already referred to them on a number	2
3		of occasions, you know, other hepatitis viruses, other	3
4		affections, alcohol, obesity, et cetera.	4
5		So that would be considered a false positive in	5
6		the context of a screening test aimed at identifying	6
7		non-A, non-B hepatitis.	7
8	SIR	BRIAN LANGSTAFF: I understand. So what you are	8
9		summarising here, or at least it's a minute, of	9
10		course, so may not represent everything that you said,	1(
11		but what you are summarising here was the problem of	1
12		confirming, as it were, a positive test, of eliminating	12
13		false positives	1:
14	Α.	Yes.	14
15	SIR	BRIAN LANGSTAFF: albeit they'd been screened out,	15
16		the you're left with the donor who is told they're	16
17		positive when they're not, and that may cause problems.	17
18		I understand. Right, thank you very much.	18
19 20	МS	RICHARDS: If we go back to the second page, please, and	19
20 21		the list of attendees. You'll see, Professor Keel, that	20
21 22		the list of attendees for the Haemophilia Society includes B Wright, Bill Wright, and Mr Wright has told	2* 22
22		the Inquiry of his recollection of this meeting, of	23
23 24		surprise being expressed by SNBTS representatives that	24
25		someone could be infected as late as 1986, and with the	25
		51	_`

1		comment, and ACVSB's first meeting of course pre-date my
2		Government employment, so I have no direct knowledge of
3		what exactly discussions were in ACVSB. You're
4		absolutely right, there must have been other bodies.
5		There would have been other bodies in the departments of
6		health which preceded ACVSB who considered issues of
7		surrogate testing, and I guess that my comment here was
8		not as precise as it might have been. I should have
9		said ACVSB and predecessor committees, have considered
10		this issue over a number of years.
11	SIR	BRIAN LANGSTAFF: I see. That explains that, thank you.
12		The second question is that what is being
13		envisaged for ALT testing here, I think, is use as
14		a form of screening test. That would be right, would
15		it?
16	Α.	Yes.
17	SIR	BRIAN LANGSTAFF: If one's having a screening test, the
18		object of the test is to screen out anything which might
19		be the infection in question, am I right about that?
20	Α.	You are.
21	SIR	BRIAN LANGSTAFF: So why does the poor specificity of
22		the test, rather than the poor sensitivity, matter
23		directly?
24	A.	Well, if the test is positive, not because of non-A,
25		non-B hepatitis or whatever organism, then you could
		50
,		
1		response being, "Well, he's sitting here". Because that
2		was Mr Wright's own situation.
2 3		was Mr Wright's own situation. Do you have any recollection of that, or of being
2 3 4		was Mr Wright's own situation. Do you have any recollection of that, or of being aware that somebody infected in the very period that you
2 3 4 5		was Mr Wright's own situation. Do you have any recollection of that, or of being aware that somebody infected in the very period that you were investigating was there?
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(13) Pages 49 - 52

		development".	1		preparation for that, should it be an eventuality.
1 2		I'll come back to that in a moment but if we just	2	o	If we turn to the draft report, it starts on page 3., we
3		go over the page, you then say this:	3	•••	can see that there are and this continues through the
4		"Finally, as far as financial help is concerned,	4		draft a number of if we go to the bottom of the
5		you will need no reminding that DH are very nervous	5		page, please, Lawrence a number of handwritten
6		about this. Mike McGovern made a point of bringing the	6		comments and then there are deletions and additions that
7		issue up with me during a recent unrelated telephone	7		have been suggested in typewritten form, and we see an
8		conversation, during which I reassured him that we	8		example of that in paragraph 4.
9		recognised that compensation in this area would set	9		Just so that we can understand who's providing
10		a very difficult precedent for the Government, given the	10		what comments, were your comments the handwritten ones
11		many claims for compensation that it receives."	11		or the typed ones, do you know? We can go over the page
12		Now, bearing in mind Ms Dora's role was to	12		if it might help.
13		investigate whether there had been fault on the part of	13	Δ	Yes, please.
14		SNBTS or negligence on the part of SNBTS, and to reach	14		Yes, so if we go over the page, there's some and can
15		conclusions, why was it relevant for you to remind her	15		we have a look at the next page as well? Can we put
16		that the Department of Health was very nervous about the	16		this page and the following one on screen at the same
17		possibility of financial help?	17		time? It might help Professor Keel.
18	A.	Well, because it was a material issue that was	18		So I don't know whether that assists in working
19		discussed being discussed at that time. I mean, it's	19		out which comments you authored or not.
20		not directly relevant to the investigation but clearly	20	A.	· · · · · · · · · · · · · · · · · · ·
21		from previous documents we have seen that the	21	7.	really see it clearly.
22		Scottish Office, Scottish Executive subsequently, had	22	Q.	
23		over the years already done some pre-planning around the	23		It's page 3 internally, so if you go to page 5
24		impact that setting up a compensation scheme would have.	24		electronically, Lawrence.
25		Not expecting that that would be the case, but in	25		Does that assist at all, Professor Keel?
		53			54
1	A.	I think I think the retyped text probably came from	1		And then there's text "as quickly as possible",
1 2	A.	I think I think the retyped text probably came from me.	1 2		And then there's text "as quickly as possible", somebody else has crossed that out and suggested
	A. Q.				
2		me.	2		somebody else has crossed that out and suggested
2 3		me. I'm not going to go through the detail of the suggested	2 3		somebody else has crossed that out and suggested "reasonably":
2 3 4		me. I'm not going to go through the detail of the suggested amendments. It was just to try to understand who was	2 3 4		somebody else has crossed that out and suggested "reasonably": " under the circumstances."
2 3 4 5		me. I'm not going to go through the detail of the suggested amendments. It was just to try to understand who was amending what.	2 3 4 5		somebody else has crossed that out and suggested "reasonably": " under the circumstances." And then I think the suggestion is the words "as
2 3 4 5 6		me. I'm not going to go through the detail of the suggested amendments. It was just to try to understand who was amending what. In terms of the conclusion that you'd wanted	2 3 4 5 6		somebody else has crossed that out and suggested "reasonably": " under the circumstances." And then I think the suggestion is the words "as quickly as they could" go in there:
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2 3 4 5 6 7 8 9		me. I'm not going to go through the detail of the suggested amendments. It was just to try to understand who was amending what. In terms of the conclusion that you'd wanted strengthening, if we go to page 11, bottom of the page, so the "Conclusion": "The episode of HCV infection of haemophiliacs is	2 3 4 5 6 7 8 9	A.	somebody else has crossed that out and suggested "reasonably": " under the circumstances." And then I think the suggestion is the words "as quickly as they could" go in there: " to develop a Factor VIII product free of the risk of Hepatitis C." Can you recall why it was you wanted that
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INQY1000234\_0014

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1	Q.	Then if we turn to SCGV0000171_077, this is a minute	
2		from Christine Dora, 4 April 2000 that appears on	
3		page 4 but we don't need to go to that to the	
4 5		Minister for Health and Community Care. We can see, if we just look at the purpose of the minutes, so if we go	
6		a little further down the page, it's to "let the	
7		Minister see and comment on a draft report", and then	
, 8		various matters in which the minister's approval was	
9		sought in terms of the process of publishing the report,	
10		and so on.	
11		I just want to ask you about something that's on	
12		page 2 of the minute, which was copied to you. It's	
13		paragraph 7., so towards the bottom of the page, where	
14		Ms Dora says this:	
15		"The second part of our remit was:	
16		"to examine evidence about the information given	
17		to patients with haemophilia in the 1980s about the	
18		risks of contracting HCV from blood products'."	
19		Then Ms Dora says this:	
20		"This was much more difficult to research than the	
21		first part, since we could not find many papers from so	
22		long ago. However, Haemophilia Centre directors told us	
23		verbally that what they could remember, and we have	-
24		detailed this in the report. I believe some of them are	
25		worried about possible litigation, and we have been	-
		57	
1	Q.	You've told us already that the Department essentially	
2		accepted at face value what the Haemophilia Centre	
3		Directors said about their approach to providing	
4		information to patients. We have here Ms Dora setting	
5		out her belief that some of them were worried about	
6		possible litigation. Would that not ring alarm bells as	
7		to whether the Department could safely simply rely upon	
8		what the directors were saying on this particular issue?	
9	A.	Why would it ring alarm bells?	
10	Q.	Because if they're worried about possible litigation	
11		they may be less than forthcoming about what information	
12		was or wasn't provided to patients.	
13 14	Α.	Well, that may or may not be the case, but I think they	
14		could be worried about possible litigation and still disclose all of the information available to them. The	
16		two are not mutually exclusive.	
17	Q.	The report itself, in final form, was published in	
18	ω.	October 2000 but I'm not going to take time going	
19		through that with you, Professor Keel, and we can pick	
20		that up with Ms Deacon later in the week.	4
21		I want, then, to look at some documentation and	4
22		decision making from 2000 onwards on the issue of	4
23		financial support for hepatitis C. Some of it overlaps	4
24		with the time period of the investigation. So if we	2
25		start with DHSC0032292_045.	-
		59	-

1		
		unable to obtain some of the papers they have mentioned.
2		I am willing however to accept that there was no
3		evidence that clinicians had a policy to deliberately
4		mislead their patients about the risks of using
5		Factor VIII."
6		Now, Professor Keel, would you accept that the
7		issue that Ms Dora addresses in that final sentence of
8		paragraph 7, whether there's a policy of deliberately
9		misleading patients, is a narrower issue than the
10		broader question contained within the remit, which was
11		to look at what information was given to patients; it's
12		a significantly narrower issue, isn't it?
13	A.	Yes, Lagree.
14	Q.	Why was it, do you know, that the remit having been that
15		this broader issue, reflecting what
16		The Haemophilia Society was saying to the Department,
17		that only the narrower issue was answered?
18	Α.	Well, I think that the broader issue is perhaps better
19	м.	addressed in the report but, in relation to this
		• •
20		paragraph, I think Christine Dora is reflecting the
21		difficulty that we had in obtaining the papers that the
22		Haemophilia Directors said were available during the
23		period in question, and it's not surprising that there
24		was that difficulty, given the gap between the activity
25		we're talking about and the report in 2000.
		58
1		This is an email chain in April 2000, so it's
2		after the first draft of the report has been produced
3		and it's while the report is being finalised. If we go
4		to the second page, we can pick up the email chain. So
5		the bottom half of the page we have, if we go just up
5 6		
6		a few lines, please, Lawrence, further up, so I can see
6 7		a few lines, please, Lawrence, further up, so I can see who the email thank you, perfect.
6 7 8		a few lines, please, Lawrence, further up, so I can see who the email thank you, perfect. So we can see Ms Dora is sending an email on
6 7 8 9		a few lines, please, Lawrence, further up, so I can see who the email thank you, perfect. So we can see Ms Dora is sending an email on 19 April to you and to a number of others and she says
6 7 8 9 10		a few lines, please, Lawrence, further up, so I can see who the email thank you, perfect. So we can see Ms Dora is sending an email on 19 April to you and to a number of others and she says in the body of the email:
6 7 8 9 10 11		a few lines, please, Lawrence, further up, so I can see who the email thank you, perfect. So we can see Ms Dora is sending an email on 19 April to you and to a number of others and she says in the body of the email: "Thanks to those of you who have commented up to
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22		a few lines, please, Lawrence, further up, so I can see who the email thank you, perfect. So we can see Ms Dora is sending an email on 19 April to you and to a number of others and she says in the body of the email: "Thanks to those of you who have commented up to now on my attempts to draft a report. Please find attached what I hope is now a pretty final draft Ministerial submission with recommendations on handling." Then if we go to the top of the page, we've got an email from John Aldridge, and we can pick it up in the third paragraph of the email, where he says this: "I note the issues on which you are seeking the Minister's views. I think she should be pointed very
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24		a few lines, please, Lawrence, further up, so I can see who the email thank you, perfect. So we can see Ms Dora is sending an email on 19 April to you and to a number of others and she says in the body of the email: "Thanks to those of you who have commented up to now on my attempts to draft a report. Please find attached what I hope is now a pretty final draft Ministerial submission with recommendations on handling." Then if we go to the top of the page, we've got an email from John Aldridge, and we can pick it up in the third paragraph of the email, where he says this: "I note the issues on which you are seeking the Minister's views. I think she should be pointed very firmly in the direction of not agreeing to compensation or special priority treatment for Hep C sufferers who may have been infected by NHS treatment. That would have huge implications for other areas of NHS activity,

(15) Pages 57 - 60

1		in the other parts of the UK and the Treasury as well as	1		m
2		by me!"	2		ye
3		Then if we go to the first page, we can see	3		CC
4		there's a name there about a third of the way down the	4		ye
5		page, Francis Gibb. What was the role of Francis Gibb	5	_	th
6		within the Department?	6	Q.	lf
7	Α.	He wasn't in the Department, he was chief exec of the	7		W
8		Common Services Agency.	8		yc
9	Q.	We can see, if we just look I'm sorry.	9		-
10	Α.	Sorry, I was just going to add: within which SNBTS was	10		E
11	~	situated.	11		
12	Q.	Then we can see the comment from Mr Gibb, so just below	12		
13		the list of attendees, is this:	13		
14		"I agree with these sentiments as they are in tune	14		cc
15 16		with the advice we gave at the meeting. Beware of going	15		а
16 17		down a path which could have serious repercussions for	16 17		~
17 18		the future. We could open the floodgates if we are not careful."	18		Cá
			10		1100
19 20		Do the views there expressed by Mr Gibb and Mr Aldridge reflect the general thinking in the	20		lir
20 21			20 21		
21		Department in Scotland at the time, which was, essentially, fundamentally opposed to financial support	21		qu
22		or compensation for those infected with hepatitis C?	22	A.	yc Ye
23 24	A.	Yes, for the reasons that we discussed in some detail	23	Q.	Tł
24 25	А.	yesterday, setting yet another precedent, which would	24 25	ω.	
20		61	20		
,			4		
1		don't need to look at the detail of it, but this is part	1		re
2		of the same email chain, so we've got Christine Dora's	2 3		th
3		email at the bottom, John Aldridge's response at the	3		W
4		top.			CC
5		If we go back to the first page, we can see, at the bottom half of the page, Ms Dora's response to	5 6	A.	M
6 7		Mr Aldridge. She says this:	0 7	А.	N
		с ;			re
8 9		"I note what you say about pointing the Minister	8 9		in br
9 10		away from compensation. I'm intending to leave the arguments about compensation and other possible action	9 10		ha
11		to a future minute, for the sake of digestibility.	10		ar
12		I agree that the arguments tend against the award of	12		ρι
12		compensation (or hardship payments). The	12		m Di
14		Macfarlane Trust for people infected with HIV is an	14		
14		uncomfortable precedent in this respect, so we'll need	14		do
16		to marshal the arguments carefully. I also understand	16	Q.	ne If
17		that Lord Hunt at the Dept of Health has been reflecting	10	ч.	
18			18		go Cl
		on the idea of a possible hardship fund for Hepatitis C victims"			
19 20			19 20		re
20 21		Then this:	20 21		a D
21 22		" I really think it would be wise to have both	21		D
22 23		Ministers discuss and at least decide whether to operate	22 23		ра
23 24		in step with each other (although I am hoping they will			
24 25		decide the same thing and it won't be compensation)."	24 25		Lo
25		Now this is the author of the investigation 63	25		ot

1		mean that other groups and I mentioned some of them
2		yesterday who felt that they would be entitled to
3		compensation would not being allowed access to it. So,
4		yes, this was the general feeling in the Department at
5		that point.
6	Q.	If we go to your statement, WITN5736003, page 44, you
7		were referred to that email exchange and then we can see
8		your answer at A76. You say:
9		"These views were held in SE [so Scottish
10		Executive] and the health department around this time
11		
12		Then in paragraph (b) you set out your view:
13		"I agreed that the establishment of a scheme for
14		compensation of HCV infected patients would set
15		a dangerous precedent."
16		Then you go on to explain about other possible
17		categories of patients, and (c) says your:
18		" advice to Ministers would have been along the
19		lines outlined above"
20		Now "dangerous precedent" is, it might be said,
21		quite a strong way of putting it. Does that reflect
22		your own strength of feeling at the time?
23	A.	Yes.
24	Q.	Then if we could go, please, to SCGV0000171_031.
25		If we look at the second page, we'll see we 62
		ŬĽ.
1		report. Why is it part of the role or is it part of
2		the role of a civil servant to hope that people infected
2 3		the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get
2 3 4		the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which
2 3 4 5		the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which Ms Dora, the author of the report, expressed herself?
2 3 4 5 6	A.	the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which Ms Dora, the author of the report, expressed herself? No, I can't say I'm concerned by it. You have to
2 3 4 5 6 7	A.	the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which Ms Dora, the author of the report, expressed herself? No, I can't say I'm concerned by it. You have to remember, compensation was not part of the remit of this
2 3 4 5 6 7 8	A.	the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which Ms Dora, the author of the report, expressed herself? No, I can't say I'm concerned by it. You have to remember, compensation was not part of the remit of this internal investigation. However, it was foreseen, and
2 4 5 6 7 8 9	A.	the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which Ms Dora, the author of the report, expressed herself? No, I can't say I'm concerned by it. You have to remember, compensation was not part of the remit of this internal investigation. However, it was foreseen, and had been for many years, that compensation was an issue,
2 4 5 6 7 8 9	A.	the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which Ms Dora, the author of the report, expressed herself? No, I can't say I'm concerned by it. You have to remember, compensation was not part of the remit of this internal investigation. However, it was foreseen, and had been for many years, that compensation was an issue, and could become an even bigger issue following the
2 3 4 5 6 7 8 9 10 11	A.	the role of a civil servant to hope that people infected with a serious potentially fatal virus do not get compensation? Does it concern you the way in which Ms Dora, the author of the report, expressed herself? No, I can't say I'm concerned by it. You have to remember, compensation was not part of the remit of this internal investigation. However, it was foreseen, and had been for many years, that compensation was an issue, and could become an even bigger issue following the publication of the report. I think Christine Dora was
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(16) Pages 61 - 64

1		for Hep C positive haemophiliacs. I understand this may	1
2		be prompted by political considerations; I also however	2
3		understand that Lord Hunt inclines naturally towards	3
4		sympathy for the plight of the affected haemophiliacs.	4
5		Officials' advice has not changed, but they have been	5
6		asked to put together costings for various options and	6
7		to offer an assessment of the extent of any precedent	7
8		which might be created."	8
9		Then this:	9
10		"Charles and I acknowledged that if one of the 4	10
11		administrations should crack, it becomes	11
12		presentationally much more difficult for the others not	12
13		to, and he said he would keep us informed."	13
14		Now, of course, this is two years into or	14
15		more into devolution by this point in time, and	15
16		Scotland has responsibility for its own health issues	16
17		and is free to take its own course. What, if anything,	17
18		do you recall about the concern of holding a common line	18
19		between the four administrations and the presentational	19
20		difficulty referred to there? Do you recall that being	20
21		discussed?	21
22	Α.	Well, I can't specifically recall the discussions, but	22
23		reading this and other papers has reminded me that it	23
24		was indeed a matter of concern as to whether Lord Hunt	24
25		was going to deviate from the previously agreed position 65	25
4		abo commented that it rave has another account	
1 2		she commented that it gave her enormous concern", et cetera.	1 2
2		Which is why I inferred that that handwriting is	2
4		by or on behalf of the minister.	4
5		If we just go to the top of this email, just to	5
6		see where we get to within February 2001, we can see	6
7		Sandra, presumably Sandra Falconer, to Karen saying:	7
, 8		"I have been informed by colleagues in DH(E) that	8
9		Lord Hunt made it clear to Lord Morris and Eddie O'Hara	9
10		MP that the Government had decided against compensating	10
11		haemophiliacs with HCV when Frank Dobson held his	10
12		review"	12
13		Which we know was 1998.	13
14		" and that the subject is now closed."	13
15		Then the response at the top of the page:	15
16		"The Minister will be vvv relieved!"	16
17		Would it be right to understand that as at	17
18		February 2001, the position in Scotland is still set	18
19		firmly against financial support for those infected with	19
20		hepatitis C from their treatment?	20
21	A.	Yes.	20
	м.		
22	Q.	Now as you'll recall, Professor, the Health and	22
		Now as you'll recall, Professor, the Health and Community Care Committee of the Scottish Parliament	22 23
22			
22 23		Community Care Committee of the Scottish Parliament	23

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... emphasising that we have withstood enormous pressure on this issue -- not least after discussions directly with him -- any movement from the previous position, without discussion with other administrations, would, in my view be quite unacceptable. "Happy to have conversation directly if [necessary]." I think there's another email from this time which might suggest that's coming from the minister or the minister's office. In any event, that is not your handwriting? A. No. Q. If we go to SCGV0000174\_066, we can pick it up in the middle of the page with an email addressed to Christine from Karen which summarises those handwritten comments: "The Minister was grateful for this -- although 66 That's at MACK0001929\_001. I don't propose to go through the detail of it. We can see the title of the report there. If we just go to page 23, we can pick up what the Committee said about financial assistance. So you'll see, Professor, the heading "Targeted financial and other assistance regardless of negligence". Then the report reads, in paragraph 83: "The more that we as a Committee have investigated the issues raised in the two petitions, the more our conviction has grown that what lies behind both is a fundamental question of fairness and consistency. "84. The individuals who petitioned us contracted a serious and incurable virus many years ago as a result of medical treatment, or are relatives of those people. Understandably, they feel wronged, and have campaigned over many years for recognition and redress. To these individuals the relatively narrow question of whether or not any particular agency or individual within the NHS has been legally negligent, while important and worthy of exploration, is of secondary importance. What it they consider more important is that the Executive recognise what they would classify as the moral case for providing support, and that it provides the concrete practical assistance that they consider would be fair 68

across the UK that there would not be a compensation scheme. So I recall that element of it, but specific

this document, the bottom -- we can see some handwriting there, and then the bottom half of the page includes

for urgent contact to be made with Philip Hunt's office

"This gives me enormous concern. Please arrange

Q. Then just for the sake of completeness in relation to

discussions, no.

some other that handwriting:

(17) Pages 65 - 68

1	and appropriate."	1		compensation scheme.
2	Then the paragraphs go on to set out in 85 and 86	2		At paragraph 91, they say this:
3	the general principle about not paying out unless	3		"The Committee therefore wishes to stress the
4	there's negligence and then referring to exceptions	4		narrowness of the view to which it has come. We are not
5	within that, the Consumer Protection Act, and then in	5		advocating the principle that all injury caused through
6	paragraph 86 the Macfarlane Trust.	6		NHS treatment should be compensated. Nor are we asking
7	If we go over the page, and pick it up at the	7		the Executive to establish any new, wide-ranging
8	bottom half of the page no, in fact, I'm sorry, could	8		precedent on the management of risk in clinical
9	we pick it up at paragraph 88, first of all, towards the	9		decision-making. Instead we simply seek to correct
10	top of the page:	10		an inconsistency in the operation of an already created
11	"The example cited by [and the name is redacted	11		and narrow precedent; namely the precedent create when
12	but it's someone on behalf of The Haemophilia Society]	12		the Macfarlane Trust was set up. We do not envisage
13	is a simple and striking one. It is difficult to	13		that any ad hoc decision to provide financial or other
14	disagree that it highlights the inconsistency of the	14		help to individuals infected with hepatitis C through
15	current position, especially given that the effects of	15		NHS treatment, would necessarily require the NHS to
16	hepatitis C can, when severe, be practically as	16		change any of its current medical policies and practices
17	devastating as those of HIV."	17		on risk arising from treatment."
18	Then paragraph 90 says this:	18		So, professor, it's right, isn't it, that the
19	"Having considered the issues raised in the	19		Committee did not share your view and the Department's
20	petitions, the Committee has become persuaded by what we	20		view that this would establish a dangerous precedent?
21	classified as the 'moral' case for providing financial	21	Α.	Yes, I think you can certainly conclude that from their
22	assistance to those individuals infected with	22		report.
23	hepatitis C through blood transfusions."	23	Q.	Then if we just go to the "Recommendations" on page 26,
24	Then the Committee goes on to say that they're not	24		we can pick it up at the bottom of the page:
25	advocating a transition to a complete no-fault	25		"We recommend that the Executive set up
	69			70
1	a mechanism for providing financial and other	1		you an email you sent in response. It's at
2	appropriate practical support to all hepatitis C	2		SCGV0000247_094. This is from you, 3 October 2001, to
2	sufferers who have contracted the virus as a result of	2		Mrs Falconer, copied to others. Paragraph 1:
4	blood transfusions provided by the NHS in Scotland, or	4		"You were right to emphasise in our initial
5	which involve blood or blood products produced by the	5		response to this that we will require time to consider
6	SNBTS."	6		its recommendations! No surprises in the sense that we
7	Then if we go to the next page, I won't read the	7		were expecting the Committee to recommend compensation
8	recommendations in full, but paragraphs 2, 3 and 4	8		for those who have contracted Hep C through blood
9	provide as follows:	9		transfusion and fall outside the terms of the Burton
10	"2. We recommend that this mechanism for	3 10		Judgment."
11	providing financial and other support comes into	11		Then you go on to make number of points. I don't
12 13	operation within a period of twelve months. "3. The level of financial assistance awarded to	12 13		think I need to take you through those. You suggest in paragraph 2 that the Committee has underestimated the
14	any claimant should be determined on the basis of need,			difficulty in determining levels of compensation based
14	•	14 15		
16	having regard to the physical or psychological loss individually suffered, and should include redress for	15 16		on need. What do you recall of your response to and your
17	-	10		thoughts about the Committee's report? I don't mean
18	practical difficulties such as the inability to obtain	18		some of the finer points of detail, but the broad thrust
19	an affordable mortgage or life insurance." Then:	19		of it, which is the Executive should set up a scheme for
20 21	"4. In determining an appropriate package of	20 21		compensation and recommending something which went
	assistance, and in particular in clarifying what			directly against the policy which the Executive and its
22 23	practical help can be offered, the Executive should	22 23	٨	predecessor had maintained for a number of years?
	consult hepatitis C sufferers both haemophiliac and	20	Α.	Well, a number of observations if I may. First of all,
24	non baamonhiliac "	24		going back to the report, it talks shout becomenhilized
24 25	non-haemophiliac."	24 25		going back to the report, it talks about haemophiliacs
24 25	non-haemophiliac." Now, before I ask you about that, can I just show 71	24 25		going back to the report, it talks about haemophiliacs and probably recipients of blood transfusion feeling 72

(18) Pages 69 - 72

,			,		
1		wronged. As I pointed out yesterday and again today:	1		for compensation when there were other groups of
2		those groups were not unique. There were other groups	2		patients out there who would feel equally wronged and
3		which we were aware of, and doubtless others that we're	3	~	equally eligible for such compensation. And as far as you can recall, were your views about
4 5		not aware of, who were interested in pursuing compensation. So the report, in using that phase,	4 5	Q.	the Committee's report shared by your colleagues within
6		doesn't acknowledge the wider context and possibility	6		the Scottish Executive and in particular within the
7		nay, reality that others would come forward if	7		Health Department?
, 8		a compensation scheme was set up for this group of	8	Α.	As far as I can recollect, yes.
9		individuals.	9	Q.	Now the Government, as we know, the Scottish Government,
10		l've commented in my in paragraph 2 here on how	10	ω.	didn't proceed to implementation of the Committee's
11		you would go about setting up the difficulties in going	11		recommendations. Instead, it set up what's been
12		about setting up such a scheme based on need. How would	12		referred to in the Inquiry's hearings as the Ross Group
13		you define physical or psychological loss at individual	13		or the Ross Committee. So the expert group under the
14		level? I could already envisage real difficulties in	14		chairmanship of Lord Ross.
15		defining categories of patients and the level of their	15		Do you know why the Government went down that
16		suffering to be compensated.	16		route rather than simply proceeding to implement the
17		So I guess my reading of the report was that it	17		recommendations of the Health and Community Care
18		was slightly naive in its assumption that you could just	18		Committee? And in particular, are you able to comment
19		set up a scheme and that would be very straightforward.	19		on a submission that may be made to the Inquiry that
20		And I also think that their conclusion that they	20		that was a delaying tactic?
21		didn't want to compensate everybody who had been injured	21	A.	My recollection of the setting up of the Lord Ross
22		at the hands of the NHS, in their view they didn't	22		expert group is I really had very little to do with it.
23		want a compensation scheme that covered everybody, and	23		This was a matter for officials and legal advisers to be
24		that seemed to me rather illogical in singling out	24		fully involved in. You would need to ask ministers what
25		hepatitis C infected individuals as a special category	25		was in their minds in terms of setting up the expert
		73			74
1		group. Part of it certainly was, as far as I could	1		principle, that no compensation was due if there had
2		recollect, to get a better handle on the difficulties	2		been no negligence proven, was a sound one. And the
3		I've already mentioned, and are covered in paragraph 2	3		Burton judgment clearly opened or exposed the NHS to
4		here, of defining levels of compensation and I think at	4		much wider, a much wider range of liabilities ie,
5		least part of the expert group's task was to try to	5		providing compensation where no negligence had been
6		better understand those difficulties.	6		proven.
7	Q.	Can I ask you then to look at something you say in your	7	Q.	Now, the Ross Committee or the Ross Group produced its
8		witness statement more broadly on the question of	8		preliminary report in, I think, September 2002 and it's
9		compensation.	9		HSOC00033499. I'm not going to take you through the
10		It's WITN5736003, and if we could go to page 60	10		detail of either the preliminary or the final reports,
11		and it's the bottom half of the page.	11		Professor Keel, but is it likely that you would have
12		You were asked in question 105 about some emails	12	_	read these reports at the time?
13		regarding the costs of a scheme. I'm not going to ask	13	Α.	Yes.
14		you about that. But you say in paragraph A105, third	14	Q.	What was, as far as you can recall, your view about what
15		line:	15		was being recommended by the Expert Group, in terms of
16		"I regretted that the Burton judgment had forced	16		compensation/financial support?
17		a move away from the previous principal [sic] that no	17	Α.	Well, I have no direct memory from that time. I mean,
18		compensation was due where there was no negligence	18		I've obviously read papers referring to the Expert Group
19		proven on the part of NHS."	19		and, certainly, the levels of compensation being
20		Now the expression of regret about the Burton	20		proposed were perceived as rather high and therefore
21		judgment is not, I think, a view that the Inquiry has	21		unaffordable. But I can't say that was my original
22		heard from others so far in the course of its hearings.	22	~	thought. It's been derived from reading the papers.
23		Why did you feel that way about a judgment of the High	23	Q.	If we look at SCGV0000251_018, and we go to the second
24	,	Court?	24		page, this is from Bob Stock, 29 January 2003, to the
25	А.	Because it seemed logical to me that the previous 75	25		Minister who, by now, is, I think, Malcolm Chisholm. 76
					, <b>v</b>

(19) Pages 73 - 76

1	It's copied to you, your name is on a long list of	1		fund a scheme that would make payments along these
2	recipients on fourth page. We can see what it records	2		lines.
3	in paragraph 1 is:	3		Do you have any recollection of what your
4	"To record and confirm the decision taken today to	4		involvement in that decision-making process was and in
5	inform the Health and Community Care Committee that the	5		what was obviously a change of position on the part of
6 7	Executive would be prepared to fund a scheme that would	6	٨	the Scottish Executive?
7 8	make lump sum payments to those who now have Hepatitis C as the result of receiving blood, blood products or	7 8	Α.	I think my involvement was minimal. Clearly this was
о 9	tissue from the NHS in Scotland."	0 9		a political decision made in Cabinet, and I don't
9 10	Then reference is made in paragraph 3 and 4 to	9 10		recollect being involved in any of the discussions around it.
10	there having been a brief discussion at Cabinet, and the	10	0	
12	<b>o</b>	12	ω.	Can I ask you to look at a document at DHSC0020742_071, please. I think that's the right reference, Lawrence.
13	costing of a scheme, this is paragraph 4: "On the basis of making lump sum payments of	12		This is to take you back in time to 2001. If we
14	£20,000 to all those who now have Hepatitis C with	14		go to page 3, this picks up on the Burton judgment, and
14	a further £25,000 to those who have cirrhosis, liver	14		we can see the first paragraph reads:
16	cancer or liver failure."	16		
17	lt's said:	17		"In March 2001, the High Court in [England] awarded damages", et cetera.
18		18		That's a reflection of Mr Justice Burton's
19	"This was put forward, with the agreement of the First Minister, to the Committee today."	19		judgment. Then the second paragraph says this:
20	So in terms of the chronology of events,			
20 21	Professor Keel, we have the preliminary report in	20		"Following the CPA High Court ruling, the Scottish
21		21		Executive announced in August [August 2001] a decision
	September 2002 and then, whilst the final report is	22		to settle outstanding legal actions brought under the
23 24	awaited and it was published in, I think, March 2003 the Minister makes an announcement along	23 24		Act by Scottish blood recipients infected with hepatitis C."
24 25	•	24 25		-
25	the lines that we see referred here of a willingness to 77	20		Then there's a reference to the Health and 78
1	Community Care Committee report.	1		prompt your memory, Professor Keel, but do you have any
2	So bearing in mind that decision to settle	2		recollection of your involvement with the process
3	outstanding legal actions brought under the Consumer	3		referred to here of deciding how outstanding claims
4	Protection Act, can I now ask you to look at a different	4		should be dealt with?
5	document which I hope you were provided with overnight,	5	Α.	No, I don't and clearly I was only going to be at the
6	Professor Keel. It's a very short document.	6	л.	meeting for half an hour. So I think I infer from that
7	SBTS0000357_059.	7		that my involvement was minimal, and not particularly
, 8	This is from Bob Stock to Susan Murray, you,	8		material to the discussion around eligibility of these
9	Steve Lindsay, Brian McClelland, copied to Lynda Towers	9		litigants under CPA to have a claim settled.
10	and Angus Macmillan Douglas. The date is 29 June 2001,	10	0	Leaving aside this particular document, do you know
11	and it's then headed "Scrutiny of Outstanding claims",	11	ч.	whether you had any broader involvement with providing
12	and it says:	12		advice from a medical perspective about how individual
13	"I propose primary recipients of this message	13		claims should be assessed and what approach should be
14	[which would include you] meet on Monday [2 July] to go	14		taken to the payment of compensation or otherwise?
15	through the list of court actions which has been	15	А.	No, I suspect that this discussion around whether they
16	prepared by CLO/SNBTS. The main purpose will be to	16	<b>n</b> .	should be settled or not was entirely on legal grounds
17	endorse the proposed categorisation into those where CLO	17		and not medical.
18	will enter into discussions with the legal	18	Q.	We can take that down, thank you.
19	representatives of claimants and those where they	19	· .	Now, in relation to events in 2003,
20	will not.	20		Professor Keel, we've looked at that document that
21		20		refers to the announcement in January 2003 of two levels
C 1	"Honefully this will be a straightforward matter			refere to the announcement in bandary 2003 of two levels
	"Hopefully this will be a straightforward matter but the Minister was anyious that the list is thoroughly			of financial support, the navment of £20,000 and the
22	but the Minister was anxious that the list is thoroughly	22		of financial support, the payment of £20,000 and the
22 23	but the Minister was anxious that the list is thoroughly scrutinised (particularly by [Scottish Executive]	22 23		payment of £25,000. I'm not going to take you through
22 23 24	but the Minister was anxious that the list is thoroughly scrutinised (particularly by [Scottish Executive] solicitors) before any letters are sent out."	22 23 24		payment of £25,000. I'm not going to take you through lots of documents relating to 2003 but if I just give
22 23	but the Minister was anxious that the list is thoroughly scrutinised (particularly by [Scottish Executive]	22 23		payment of £25,000. I'm not going to take you through

(20) Pages 77 - 80

1		it.	1		that was fixed the parameters of a scheme in
2		The Inquiry knows from other evidence that there	2		Scotland, or was the position about what the payments
3		were discussions between Mr Chisholm and the Secretary	3		might be still still flexible and open for the
4		of State for Health within the UK Government, at that	4		further consideration?
5		point Alan Milburn. Advice was sought from Law Officers	5	Α.	I don't recall. I mean, I imagine I thought that that
6		as to whether Scotland could set up a financial support	6		was broadly the framework with which we were going to
7		scheme using its devolved powers or whether this was	7		proceed. But with John Reid's change of direction south
8		a reserved matter.	8		of the border, I suspect the figures were further
9		Then in June 2003, Mr Milburn was succeeded by	9		discussed and refined.
10		Dr Reid, John Reid, as Secretary of State for Health in	10	Q.	But you don't recall being party to those discussions?
11		the UK Government, and he took a different view in	11	Α.	I don't recall being part of that.
12		relation to what the position should be in England,	12	Q.	You did, however, I think, have some involvement in
13		resulting in a press announcement at the end of	13		discussions about the medical trigger for the second
14		August 2003 that England would be setting up a scheme.	14		stage payment. We can look at two or three documents in
15		Did you, as far as you can recall, have any	15		that regard, but before we do so, what do you recall
16		involvement with that process, so the process of going	16		about the decision-making process in relation to that?
17		to the Law Officers for advice, or discussions as to	17	Α.	Well, clearly the second payment of £25,000 on the
18		what might be the position in England and the effect	18		diagnosis of cirrhosis was a key point in determining
19		that might have upon the schemes or a scheme in	19		the level of payment.
20		Scotland?	20		Now, the gold standard there is no other test
21	Α.	I'm afraid I've no recollection of being involved in	21		other than liver biopsy that really meets the criteria
22		those in that particular part of the chronology.	22		for a definitive test to diagnose liver cirrhosis. And
23	Q.	Did you have any understanding in 2003 as to whether	23		I think I say in my written statement or highlight
24		that announcement we looked at, in January 2003 of the	24		the issues that that would have given rise to for the
25		20,000 and the 25,000, was it your understanding that 81	25		haemophilia patients in particular. Liver biopsy is 82
		01			02
1		a highly investive medical procedure, which carries	1		If we do over the page, if we pick it up at the
1 2		a highly invasive medical procedure, which carries with it the risk of haemorrhage, which clearly in	2		If we go over the page, if we pick it up at the bottom of the page this is a general meeting about
2		with the lisk of haemornage, which cleany in	2		bottom of the page this is a general meeting about
		baemonhilia nationts would be extremely serious. So it	з		henstitis C but then an issue is nicked up at the bottom
Λ		haemophilia patients would be extremely serious. So it	3		hepatitis C but then an issue is picked up at the bottom
4		was would not be a routine or an investigation	4		of the page where it says:
5		was would not be a routine or an investigation routinely embarked on in that group of patients.	4 5		of the page where it says: "Aileen Keel acknowledged that in line with
5 6		was would not be a routine or an investigation routinely embarked on in that group of patients. So I had discussions with, I recall,	4 5 6		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive
5 6 7		was would not be a routine or an investigation routinely embarked on in that group of patients. So I had discussions with, I recall, Professor Peter Hayes, who was the departmental adviser	4 5 6 7		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been
5 6 7 8		was would not be a routine or an investigation routinely embarked on in that group of patients. So I had discussions with, I recall, Professor Peter Hayes, who was the departmental adviser in hepatology at that point, to see if there was any	4 5 6 7 8		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been crossed out and '253' put in] persons who may be
5 6 7 8 9		was would not be a routine or an investigation routinely embarked on in that group of patients. So I had discussions with, I recall, Professor Peter Hayes, who was the departmental adviser in hepatology at that point, to see if there was any other non-invasive test that might act as the trigger	4 5 6 7 8 9		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been crossed out and '253' put in] persons who may be eligible for the higher level of ex-gratia payment of
5 6 7 8 9 10		was would not be a routine or an investigation routinely embarked on in that group of patients. So I had discussions with, I recall, Professor Peter Hayes, who was the departmental adviser in hepatology at that point, to see if there was any other non-invasive test that might act as the trigger for that second payment.	4 5 7 8 9 10		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been crossed out and '253' put in] persons who may be eligible for the higher level of ex-gratia payment of compensation, having contracted their infection through
5 6 7 8 9 10 11		was would not be a routine or an investigation routinely embarked on in that group of patients. So I had discussions with, I recall, Professor Peter Hayes, who was the departmental adviser in hepatology at that point, to see if there was any other non-invasive test that might act as the trigger for that second payment. My recollection is that discussions with	4 5 7 8 9 10 11		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been crossed out and '253' put in] persons who may be eligible for the higher level of ex-gratia payment of compensation, having contracted their infection through infection <i>[sic]</i> blood or blood products. Dr Keel
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q.	<ul> <li>was would not be a routine or an investigation routinely embarked on in that group of patients. So I had discussions with, I recall,</li> <li>Professor Peter Hayes, who was the departmental adviser in hepatology at that point, to see if there was any other non-invasive test that might act as the trigger for that second payment. My recollection is that discussions with</li> <li>Peter Hayes and more widely failed to yield any real substitute for liver biopsy. So I think ultimately the conclusion was that any diagnosis of cirrhosis would have to be based on the available clinical information from the consultants involved in that patient's care, and their feeling, based on other, less specific tests, as to whether the individual did indeed have cirrhosis. So it was not a clear-cut trigger point, particularly for haemophilia patients.</li> <li>I think we can see an example of the discussions that were held at SCGV0001034_014. There's certainly some</li> </ul>	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been crossed out and '253' put in] persons who may be eligible for the higher level of ex-gratia payment of compensation, having contracted their infection through infection [sic] blood or blood products. Dr Keel explained that she and Bob Stock were to meet with colleagues in DH to work out a trigger for the 2nd level of payment which could include up to 580 patients with 30% of these being paid in the first year. She explained that it was not going to be easy to define the trigger and that whatever was agreed would need to be agreeable to the Haemophilia Society." Then if we go to just, I think, one further document, SCGV0000265_004, we've got here a meeting which is then specifically focused on the ex gratia payment scheme. This is 14 October 2003. It refers to
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q.	<ul> <li>was would not be a routine or an investigation routinely embarked on in that group of patients. So I had discussions with, I recall,</li> <li>Professor Peter Hayes, who was the departmental adviser in hepatology at that point, to see if there was any other non-invasive test that might act as the trigger for that second payment. My recollection is that discussions with</li> <li>Peter Hayes and more widely failed to yield any real substitute for liver biopsy. So I think ultimately the conclusion was that any diagnosis of cirrhosis would have to be based on the available clinical information from the consultants involved in that patient's care, and their feeling, based on other, less specific tests, as to whether the individual did indeed have cirrhosis. So it was not a clear-cut trigger point, particularly for haemophilia patients.</li> <li>I think we can see an example of the discussions that were held at SCGV0001034_014. There's certainly some earlier exchange with Dr Hayes in February 2003. This</li> </ul>	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been crossed out and '253' put in] persons who may be eligible for the higher level of ex-gratia payment of compensation, having contracted their infection through infection [ <i>sic]</i> blood or blood products. Dr Keel explained that she and Bob Stock were to meet with colleagues in DH to work out a trigger for the 2nd level of payment which could include up to 580 patients with 30% of these being paid in the first year. She explained that it was not going to be easy to define the trigger and that whatever was agreed would need to be agreeable to the Haemophilia Society." Then if we go to just, I think, one further document, SCGV000265_004, we've got here a meeting which is then specifically focused on the ex gratia payment scheme. This is 14 October 2003. It refers to a number of people being present and the purpose of the
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	Q.	<ul> <li>was would not be a routine or an investigation</li> <li>routinely embarked on in that group of patients.</li> <li>So I had discussions with, I recall,</li> <li>Professor Peter Hayes, who was the departmental adviser</li> <li>in hepatology at that point, to see if there was any</li> <li>other non-invasive test that might act as the trigger</li> <li>for that second payment.</li> <li>My recollection is that discussions with</li> <li>Peter Hayes and more widely failed to yield any real</li> <li>substitute for liver biopsy. So I think ultimately the</li> <li>conclusion was that any diagnosis of cirrhosis would</li> <li>have to be based on the available clinical information</li> <li>from the consultants involved in that patient's care,</li> <li>and their feeling, based on other, less specific tests,</li> <li>as to whether the individual did indeed have cirrhosis.</li> <li>So it was not a clear-cut trigger point,</li> <li>particularly for haemophilia patients.</li> <li>I think we can see an example of the discussions that</li> <li>were held at SCGV0001034_014. There's certainly some</li> <li>earlier exchange with Dr Hayes in February 2003. This</li> <li>now is, I think, October 2003 and it's reference to</li> </ul>	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24		of the page where it says: "Aileen Keel acknowledged that in line with David Goldberg's previous modelling work, the Executive was working on an estimate of [and then '400' has been crossed out and '253' put in] persons who may be eligible for the higher level of ex-gratia payment of compensation, having contracted their infection through infection [sic] blood or blood products. Dr Keel explained that she and Bob Stock were to meet with colleagues in DH to work out a trigger for the 2nd level of payment which could include up to 580 patients with 30% of these being paid in the first year. She explained that it was not going to be easy to define the trigger and that whatever was agreed would need to be agreeable to the Haemophilia Society." Then if we go to just, I think, one further document, SCGV0000265_004, we've got here a meeting which is then specifically focused on the ex gratia payment scheme. This is 14 October 2003. It refers to a number of people being present and the purpose of the meeting is to discuss the medical trigger point for the

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1		Now, I'm not going to go through the detail of	1
2		what was discussed, but do you recall whether there was,	2
3		at this point in time, a series of meetings to discuss issues relating to the parameters and the working out of	3
4 5		5 1 5	4 5
6		the ex gratia payment scheme or whether there were just one or two such encounters?	5
7	A.	I honestly can't remember.	7
, 8	Q.	One of the issues regarding the scope of the ex gratia	8
9	ч.	payment scheme was the inclusion or otherwise of natural	9
10		clearers. Do you recall any involvement with that	10
11		decision-making process?	11
12	A.	Well, I would have been involved because clearly it's	12
13		a clinical matter but, I mean, a lot of my recollection	13
14		in this area is has been jogged by reading the	14
15		papers, rather than actual recollection of the events	15
16		themselves.	16
17	Q.	If we just look at one document, or possibly two, on	17
18		natural clearers, DHSC0004510_080, "Meetings of Skipton	18
19		Fund Teleconference 29 September 2004", and we can	19
20		see there are a number of attendees from different	20
21		departments, so you're there on behalf of the Scottish	21
22		Executive, as is Mr Stock. There are representatives	22
23		from the Welsh Assembly and from the Department of	23
24		Health in England, with an apology from the Department	24
25		of Health and Social Services in Northern Ireland.	25
		85	
1		first payment of 20.000.	1
1 2	Q.	first payment of 20,000. If we just look at so that I can finish this topic	1 2
1 2 3	Q.	first payment of 20,000. If we just look at so that I can finish this topic before we break one further document.	
2	Q.	If we just look at so that I can finish this topic	2
2 3	Q.	If we just look at so that I can finish this topic before we break one further document.	2 3
2 3 4	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so	2 3 4
2 3 4 5	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's	2 3 4 5
2 3 4 5 6	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in	2 3 4 5 6
2 3 4 5 6 7	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue	2 3 4 5 6 7
2 3 4 5 6 7 8	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance.	2 3 4 5 6 7 8
2 3 4 5 6 7 8 9	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance. If I could ask you to look at paragraph 3, and the	2 3 4 5 6 7 8 9
2 3 4 5 6 7 8 9 10	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance. If I could ask you to look at paragraph 3, and the italicised passage below that. So Mr Gutowski records in paragraph 3 that Claimants had made claims to the Skipton Fund "outside the stated eligibility criteria"	2 3 4 5 6 7 8 9 10
2 3 4 5 6 7 8 9 10 11 12 13	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance. If I could ask you to look at paragraph 3, and the italicised passage below that. So Mr Gutowski records in paragraph 3 that Claimants had made claims to the Skipton Fund "outside the stated eligibility criteria" and that the Skipton Fund had "held on to those claim	2 3 4 5 6 7 8 9 10 11 12 13
2 3 4 5 6 7 8 9 10 11 12 13 14	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance. If I could ask you to look at paragraph 3, and the italicised passage below that. So Mr Gutowski records in paragraph 3 that Claimants had made claims to the Skipton Fund "outside the stated eligibility criteria" and that the Skipton Fund had "held on to those claim forms rather than reject them", and had asked for	2 3 4 5 6 7 8 9 10 11 12 13 14
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance. If I could ask you to look at paragraph 3, and the italicised passage below that. So Mr Gutowski records in paragraph 3 that Claimants had made claims to the Skipton Fund "outside the stated eligibility criteria" and that the Skipton Fund had "held on to those claim forms rather than reject them", and had asked for further clarification.	2 3 4 5 6 7 8 9 10 11 12 13 14 15
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance. If I could ask you to look at paragraph 3, and the italicised passage below that. So Mr Gutowski records in paragraph 3 that Claimants had made claims to the Skipton Fund "outside the stated eligibility criteria" and that the Skipton Fund had "held on to those claim forms rather than reject them", and had asked for further clarification. Then he says this: "We have asked them to include the following explanatory paragraph in the letter:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance. If I could ask you to look at paragraph 3, and the italicised passage below that. So Mr Gutowski records in paragraph 3 that Claimants had made claims to the Skipton Fund "outside the stated eligibility criteria" and that the Skipton Fund had "held on to those claim forms rather than reject them", and had asked for further clarification. Then he says this: "We have asked them to include the following explanatory paragraph in the letter: "patients would only be eligible for the first	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q.	If we just look at so that I can finish this topic before we break one further document. DHSC0006798_072. This is from Mr Gutowski, so Department of Health in London, 19 November 2004. It's not copied to you, although it is copied to Mr Stock in the Scottish Executive, and it's dealing with the issue of spontaneous clearance. If I could ask you to look at paragraph 3, and the italicised passage below that. So Mr Gutowski records in paragraph 3 that Claimants had made claims to the Skipton Fund "outside the stated eligibility criteria" and that the Skipton Fund had "held on to those claim forms rather than reject them", and had asked for further clarification. Then he says this: "We have asked them to include the following explanatory paragraph in the letter: "patients would only be eligible for the first payment if (i) there was evidence they had developed chronic hepatitis C infection but this had resolved spontaneously (thought to be a reasonably rare	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22

1		If we go to the heading "2. 'Natural Clearers'",
2		we can see reference to Professor Lee being invited to
3		speak, and that's obviously Professor Christine Lee at
4		the Royal Free Hospital, regarding her concerns about
5		inconsistency in the reviewing of natural clearers by
6		clinicians.
7		The issue I have been asked, in particular, to
8		raise with you, Professor Keel, is why it was that
9		Professor Lee, a haemophilia clinician, not
10		a hepatologist or virologist, was being invited to
11		address the meeting on this particular issue, and what
12		weight was given to her views on the question of whether
13		natural clearers should receive payments or not
14		sorry, in deciding whether natural clearers should
15		receive payments or not?
16	Α.	Well, again, I infer this from reading the document that
17	<u>~</u> .	Christine Lee was concerned about inconsistencies.
18		······································
		I think, which related to the fact that, yes, further
19		down at 2.4, very, very late clearance of hepatitis C.
20		The 20 per cent who naturally clear the virus usually do
21		so within the first six months. So this case that she
22		was describing is very unusual and I imagine that she
23		was concerned about that and wondered whether such
24		an individual should be compensated or not, because the
25		majority of natural clearers were not eligible for the
		86
1		have, eliminated the virus in the acute stage, when they
1 2		have, eliminated the virus in the acute stage, when they would most likely have been asymptomatic or when any
2		would most likely have been asymptomatic or when any
2 3		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived
2 3 4		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed
2 3 4 5 6		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase
2 3 4 5 6 7		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves,
2 3 4 5 6 7 8		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient
2 3 5 6 7 8 9		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended
2 3 4 5 6 7 8 9		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness."
2 3 4 5 7 8 9 10 11		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you,
2 3 4 5 6 7 8 9 10 11 12		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there
2 3 4 5 6 7 8 9 10 11 12 13		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the
2 3 4 5 6 7 8 9 10 11 12 13 14		would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the acute phase unless robust medical evidence is cited was
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2 3 6 7 8 9 10 11 12 13 14 15 16	A.	would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the acute phase unless robust medical evidence is cited was based on your advice? I'm not at all sure that that's the case, but I think
2 3 6 7 8 9 10 11 12 13 14 15 16 17	A.	would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the acute phase unless robust medical evidence is cited was based on your advice? I'm not at all sure that that's the case, but I think this part about (ii) the Christine Lee issue, where
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A.	would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the acute phase unless robust medical evidence is cited was based on your advice? I'm not at all sure that that's the case, but I think this part about (ii) the Christine Lee issue, where clearly she wanted to know whether her patient, who had
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A.	would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the acute phase unless robust medical evidence is cited was based on your advice? I'm not at all sure that that's the case, but I think this part about (ii) the Christine Lee issue, where cleared the virus after 20 years, was eligible for
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A.	would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the acute phase unless robust medical evidence is cited was based on your advice? I'm not at all sure that that's the case, but I think this part about (ii) the Christine Lee issue, where cleared the virus after 20 years, was eligible for treatment, and the for payment. The conclusion was
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A.	would most likely have been asymptomatic or when any symptoms that did occur would have been short lived because of the transient nature of the infection, would not be eligible for this payment. It should be assumed that the virus has been cleared in the acute phase unless a robust medical evidence is cited that proves, on the balance of probabilities, that the patient experienced chronic infection ie infection that extended after the first six months of illness." The question I have been asked to ask you, Professor Keel, is whether that requirement that there be an assumption that the virus has been cleared in the acute phase unless robust medical evidence is cited was based on your advice? I'm not at all sure that that's the case, but I think this part about (ii) the Christine Lee issue, where clearly she wanted to know whether her patient, who had cleared the virus after 20 years, was eligible for treatment, and the for payment. The conclusion was yes, because obviously during that lengthy period, the
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3         eventually obserd the virus, were given payment, first stage payment, because they'd been suffering from a chronic micetion vere a long peoind of rine.         3         MS RICHARDS: Thank you.           4         Sit ms space/bits from the subset of the suffering from a chronic micetion vere a long peoind of rine.         5         RI RINA LANCSTAFF: Lefts lake lunch new.           5         If we just look a DMSC000520, DS 70, DS 70, Inc.         5         SIT RINA LANCSTAFF: Lefts lake lunch them and come back.           6         Use payment, land har's ny fault, Photsson Keel.         5         SIT RINA LANCSTAFF: Lefts lake lunch them and come back.           7         Thate discussed this with Aleen and offer the following amendments.         10         (105 pm)         (105 pm)           11         Yeach         These discussed this with Aleen and offer the following amendments.         11         SIT RIRAN LANCSTAFF: Yes.         11           12         Co - and then we see the following amendments.         11         11         205 pm)         11           14         Following amendments.         11         11         120 pm)         11         120 pm)           15         The we discussed this with Aleen and offer the discussion with M Stock -         12         12         120 Pm)         11           16         Miss McCorene, who was an effer the discussion with M Stock -         12						•
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25 between the blood services and the public. It would 25 <b>Q.</b> In paragraph 2 of this minute which I referred to,						
					Q.	-

(23) Pages 89 - 92

1

Transfusion", and it says:

1		Dr McGovern says that local audits still suggest highly	
2		variable use of blood components as between clinicians	
3		and hospitals. Was that the case in Scotland as well as	
4		the rest of the United Kingdom, that there was still	
5		a problem here about the way in which blood and blood	
6		components were being used?	
7	Α.	Indeed. Yes.	
8	Q.	Then the other matter which this touches on in the	
9		passages which I read out is the importance of ensuring	
10		a clear and common understanding about the risks of	
11		blood transfusion, and that might suggest that there had	
12		not been such an understanding, a public understanding	
13		at least previously. Again, would it be fair to say	
14		that that was as applicable to Scotland as it was to the	
15		rest of the United Kingdom?	
16	Α.	Yes, it would be.	
17	Q.	Can I then ask you to look at a couple of documents,	
18		then, which post-date the Better Blood Transfusion	
19		conference referred to here.	
20		SCGV000096_014.	:
21		This is a minute from you to Mr Stock dated	:
22		28 June 2002, and it's obviously in anticipation of	:
23		a meeting of the MSBT. We don't need to look at most of	:
24		the material. If we just go to the third page, we can	:
25		see the last paragraph is headed "Better Blood	:
		93	
1		Health Service circular, SCGV0000098_179.	
2		This is towards the middle of the following year,	
3		we can see the date, 19 May 2003, and it's issued by the	
4		Scottish Executive.	
5		If we look down the right-hand side, bottom half	
6		of the page, it says:	
7		"General enquiries to:	
8		"Dr Aileen Keel.	
9		"Deputy Chief Medical Officer"	
10		Then we can see the text of it:	
11		"Dear Colleague	
12		"1. Better Blood Transfusion Programme;	
13		"2. Availability of imported fresh frozen plasma	
14		from [SNBTS]; and	
15		"3. SNBTS information leaflets on blood	
16		products."	

And the second of those obviously is in relation

But the first paragraph refers to an annex

Programme now being progressed across NHS Scotland.

documentation but can you tell us in very general terms,

relation to the Better Blood Transfusion Programme at 95

providing details of the Better Blood Transfusion

I'm not proposing to go to any further

the kind of steps that were taken in Scotland in

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to vCJD risks.

		Transidolori , ana il odgo.
2		"Apparently the HSC on this is to issue during the
3		first week in July."
4		That's Health Service circular, I assume.
5		"Clearly we will have to think about producing
6		a Scottish equivalent, which hopefully will be able to
7		point to proper funding for the effective use of blood
8		project!"
9		Now, I'll show you in a minute the circular that
10		was produced in Scotland, but can you assist us in
11		understanding the reference to "the effective use of
12		blood project" and "proper funding" for that project?
13		What was that?
14	A.	What ultimately transpired was a Better Blood
15	7	Transfusion Programme, which needed a programme manager
16		and people to implement its recommendations in the
17		Service. So clearly funding would be needed, because
18		this was additional work for the Service. So I can't
19		remember whether that funding was ultimately found from
20		within the SNBTS allocation or whether additional
20		funding was provided from the centre for the project,
21		but I suspect it was the former. But whatever the
23		funding mechanism was, it was clearly identified as a need and found.
24	~	
25	Q.	Then just to complete the picture in relation to the 94
1		this time?
2	A.	Yes. Well, as I say, a proper program was set out,
3	л.	programme manager appointed, and I say in my written
4		submission I recall him as a very energetic and
5		effective programme manager. And reporting to him,
6		there were 18 nurses appointed throughout the country to
7		lead small teams within hospitals to spread the word
, 8		about the need for more appropriate use of blood and
9		blood products.
10		We also established our steering group, which was
11		chaired by a cardiac surgeon actually from Aberdeen,
12		which oversaw the programme over a period of years.
13	Q.	For the benefit of others, I won't take time going to it
14		but there's a newsletter from the Better Blood
15		Transfusion Programme towards the end of 2003 which
16		gives some details of the programme, and it's at
17		SCGV000098_124.
18		Professor Keel, you'd been obviously working in
19		the field of haematology clinically throughout the
20		1980s. Do you have any recollection on clinical
21		practice or, sorry, reflection on clinical practice
22		in relation to the use of blood and blood products
23		during that time, in the context of the kind of issues
24		then later explored through the effective use of blood
25		project in the Better Blood Transfusion Programme?
		96

(24) Pages 93 - 96

1	Α.	Yes, I think broadly, the perception of blood amongst	1		through those, not least because in terms of the
2		non-specialists was that it was a very safe product and,	2		national UK-wide picture in relation to vCJD, the
3		of course, it was and is, but not 100 per cent safe, as	3		Inquiry has already received quite a lot of evidence.
4		this Inquiry knows very, very well. But amongst	4		l just want to ask you about, really, a couple of
5		clinicians, I think the perception in general was that	5		issues.
6		it was an entirely safe thing to do to transfuse	6		The first arises from your statement, WITN5736003,
7		a patient. So for example, in contrast to today's	7		page 27. It's the bottom half of the page. You were
8		practice, patients would often be "chalked up" following	8		asked a question at question 50 about an MSBT meeting,
9		surgery in a way that wouldn't be done now unless the	9		in fact a meeting that you were not at, and advice from
10		haemoglobin level had really fallen much lower than the	10		Professor Kennedy that recipients of blood from a CJD
11		trigger points used in those days.	11		patient should not be informed. You were asked your
12		So perceptions amongst the general clinical	12		view and you say this you weren't at that meeting
13		professionals have changed radically over the last 20 or	13		you, as far as you can remember, you were unaware of
14		30 years. When I was training and practising as	14		Professor Kennedy's advice until reading the minutes
15		a junior doctor, blood was used much well, much more	15		but then you say this:
16		widely, particularly in the area of surgery, or even,	16		"I agreed with his view. It seemed to me that
17		for example, patients coming into the general medical	17		telling individuals that they <b>might</b> be at risk of
18		wards with anaemia. I mean, nowadays we would withhold	18		an infection which had a universally fatal outcome, but
19		blood. We'd identify the cause of the anaemia, treat	19		no diagnostic test and certainly no treatment, would not
20		it, and only if the haemoglobin was very low would blood	20		be the right thing to do."
21		transfusion be used as a means of getting it up.	21		Now, set against that might be the idea that
22	Q.	I'm going to turn now to the issue of vCJD. Now, you	22		that's and I don't mean this pejoratively but
23		were provided with a lot of documents in relation to	23		a paternalistic approach: there's the patient's right to
24		vCJD and you referred to a significant number of them in	24		know, issues of autonomy. To what extent was that
25		your statement, and I'm not going to take time going	25		weighed as part of your thinking or the thinking of your
		97			98
1		colleagues at this time in the late 1990s; do you have	1		termed elsewhere. Again, I'm not proposing to go
2		any recollection of that?	2		through the detail of them. Some of the documentation
3	Α.	Well, I think the way that I thought about it, and	3		is referred to in your statement and the Inquiry has
4		I think I was not alone by any means in this view, is	4		a wealth of information on that issue.
5		that the patient's right to know, which is extremely	5		But do you again recall your own views as time
6		important, nonetheless needs to be set in context. But	6		went on, about some categories of patients, at least in
7		what we're talking about here was an absolutely	7		due course, being notified of the possibility of having
8		devastating diagnosis for anybody to be given:	8		received implicated products? In other words, did your
9		universally fatal, no diagnostic test apart from [audio	9		views change?
10		disruption] treatment. And what we were dealing with in	10	Α.	Well, I think you may be referring to a question that
11		the context of blood transfusion was a highly	11		I was asked further on in this statement around the
12		theoretical risk.	12		names of individuals being on a central registry without
13		The evidence here was well, there was no	13		their consent.
14		evidence, it was a theory that blood transfusion might	14		It seems to me, as in so many other areas relating
15		be a means of transmitting the variant CJD organism.	15		to blood transfusion, the thinking involved over
16		So, against that background, I agreed with	16		a period of time between 1996, when variant CJD was
17		lan Kennedy's advice that we shouldn't be burdening	17		first identified, through the following decade or so,
18		individuals with the worry or concern those aren't	18		and part of that thinking evolution was thinking around
19		adequate words. I mean, I can imagine myself being	19		the ethics of retaining data centrally on individuals
20		given that news that I'd received an implicated blood	20		who had received implicated products and whether that
21		donation, it would have been one of great distress. So	21		was the right thing to do or not.
22		that was the thinking behind my views and, obviously,	22		And I think my I think my thinking was along
23		lan Kennedy's views.	23		the lines of: they should at least be given the
24	Q.	Now, we know that as matters proceeded, there were	24		opportunity to know more about the situation.
25		certain notification exercises, as I think they've been	25	Q.	Can we turn to the next page, and this is a slightly
		99			100

(25) Pages 97 - 100

1		different topic in relation to vCJD. We can pick it up	1	
2		in the bottom half of the page. So we can see in that	2	
3		first paragraph on screen reference to plans in relation	3	
4		to the introduction of leukodepletion of blood donations	4	
5		and then, in 1999, the use of UK plasma in the	5	
6		manufacture of blood products being abandoned. Then you	6	
7		say this:	7	
8		"In December 1997 a policy of withdrawal/recall of	8	
9		blood components and tissues from patients who had gone	9	
10		on to develop vCJD was instituted. Over subsequent	10	
11		years, additional precautionary measures were	11	
12		introduced, including deferral of previously transfused	12	
13		donors in 2004."	13	
14		Now, you've referred there to precautionary	14	
15		measures and certainly that's the concept that appears	15	Q.
16		throughout a lot of the documentation relating to the	16	
17		decision making regarding vCJD in the material that	17	
18		you've been supplied with. Did you, at the time, as far	18	
19		as you can recall, have any particular views about	19	
20		whether the precautionary approach, in introducing the	20	
21		kind of measures that you've referred to here, whether	21	
22		that was the right approach or whether too precautionary	22	
23		an approach was being adopted?	23	
24	Α.	I certainly had supported a precautionary approach. But	24	Α.
25		I do think that the risks, such as they were, were 101	25	
		101		
1		plasma, its operations had changed radically, but it was	1	
2		still fractionating plasma, albeit from abroad. So	2	
3		I don't think, in my memory, there was ever any ruled	3	
4		out as to the future of the PFC and, you know, that	4	
5		would not anyway, or should not anyway have stood in any	5	
6		way in the path of precautionary measures.	6	
7	Q.	The last issue in relation to vCJD I wanted to ask you	7	
8		about is this: the Inquiry has heard evidence from	8	
9		individuals who had been informed that they may be at	9	
10		risk, having received an implicated product experiencing	10	
11		difficulties in accessing medical and surgical	11	
12		treatment, being put to the bottom of lists, issues	12	
13		relating to the sourcing of surgical equipment for the	13	
14		purposes of medical procedures and the like, and	14	
15		I should say that's not specific to Scotland. That,	15	
16		again, appears to have been a concern UK-wide.	16	Q.
17		Were you aware of that difficulty, and do you know	17	
18		whether any particular steps were taken by the Scottish	18	
19		Executive to try to address that problem?	19	
20	Α.	Well, I was very aware of the issues arising from the	20	
21		need to manage patients who were considered at risk of	21	
22		variant CJD because they'd had human growth hormone	22	
23		treatment or dura mater patch or whatever. I mean,	23	
24		there was really a dual system set up to deal with them	24	Α.
25		in terms of surgery, in that special surgical sets were	25	Q.
		103		

1		perceived as greater, for example, in relation to whole
2		blood and blood components than to fractionated blood
3		products. And albumin comes to mind. I think as part
4		of the raft of measures to abandon use of UK plasma, of
5		which albumin is a product, a very frequently used
6		product in the NHS, in that the suggestion was that
7		we should stop using UK-sourced albumin.
8		Now, albumin has, because of the way it's
9		manufactured, an incredibly safe track record, had never
10		been known to transmit anything in the way of viruses or
11		other infections. So I felt that the precautionary
12		principle was entirely appropriate in relation to whole
13		blood and blood components but perhaps could be more
14		nuanced in relation to fractionated products.
15	Q.	Is it right to understand from the documentation that
16		there was a particular concern in Scotland about the
17		implications of this raft of precautionary measures for
18		the future of the PFC, and from time to time it appears
19		those concerns were voiced with you and you were asked
20		to raise them, albeit, as I understand it, decision
21		making effectively was on a UK-wide basis, so Scotland
22		didn't take, in practice, a different course. Was that
23		an issue that you recall coming to the fore at all?
24	Α.	I don't recall ever being concerned about the future of
25		the PFC. Certainly in the light of the ban on UK
		102
1		used for those patients clearly identified and sent for
2		sterilisation separately.
3		There was a greatly increased emphasis on use of
4		single-use instruments, disposable instruments, rather
5		than resterilisation, because even the sterilisation
6		processes were certainly not, from the beginning,
7		adequate to get rid of the prime protein that was
8		associated with vCJD transmission. So, in parallel with
9		all that was happening in hospitals, there was loads and
10		loads of research going on in terms of decontamination
11		of surgical instruments.
12		So it certainly added to the operational burden on
13		the NHS having to manage these patients in very specific
14 15		and in a way that enhanced the safety of the whole
15 16	0	system.
16 17	Q.	I'm going to move now to a separate topic, which is the question of public inquiries. It's right, I think, to
18		understand that throughout the 1990s and into the 2000s
18 19		the policy of the Scottish Home and Health Department,
19 20		continued by the Scottish Executive, was that there
20 21		should not be a public inquiry into the circumstances by
21		which people had come to be infected through blood and
22 23		blood products; that's right, isn't it?
23 24	Α.	Yes.
24 25	Q.	What was your understanding, in broad terms, of the
20	×.	104

(26) Pages 101 - 104

1		reasoning for the maintenance of that line?	
2	Α.	I think, in the main, that there had been examination in	
3		various fora, including the internal departmental report	(
4		that we talked about earlier, there'd been examination	4
5		of the issues in some depth, and no new evidence had	
6		emerged which ministers felt merited a public inquiry.	(
7	Q.	It could be said that there's a degree of circularity to	
8		that position, because it may only be through the	6
9		holding of a public inquiry, with its powers to call for	ç
10		evidence from a wide range of sources and scrutinise it,	1
11		that such evidence might come to light. Do you have any observation on that?	1
12 13		Of course you're right, it could be that additional	1
13 14	Α.		1
14		information would have emerged in the course of a public inquiry. But the view held at that point was that it	1
16		wouldn't be appropriate, because the evidence as	1
17		available at the time that the calls for public	1
18		inquiries were being generated had been examined, and	1
19		that it would only be if additional evidence emerged	1
20		that a public inquiry might augment, improve or enhance	2
20		that evidence gathering?	2
22	Q.	Leaving aside the internal investigation that we looked	2
23		at before lunch, in what other ways had these issues	2
24		been examined in Scotland?	2
25	A.	I'm not sure I quite understand the question.	2
		105	
1		Minister of State for Public Health in England] was	
2		particularly concerned that this issue should not be	2
3		forced in England because of decisions in Scotland.	:
4		"7. We have consulted Dr Aileen Keel DCMO in	2
5		Scotland. Advice from SE officials to Scottish	Ę
6		Ministers continues to be very strongly against holding	(
7		a public inquiry. The Executive is examining the	-
8		validity of a vote in the Scottish Parliament Health	8
9		Committee in support of a public inquiry. It is	ę
10		understood that the casting vote of the Chairman may be	1
11		disallowed."	1
12		disallowed." First of all, do you know anything about that	1
12 13		First of all, do you know anything about that latter issue there, about the voting issue?	1 1
12 13 14	A.	First of all, do you know anything about that latter issue there, about the voting issue? No, I don't.	1 1 1
12 13 14 15	A. Q.	First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at	1 1 1 1
12 13 14 15 16		First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own	1 1 1 1 1
12 13 14 15 16 17		First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own views on the issue remained the same: strongly or very	1 1 1 1 1 1
12 13 14 15 16 17 18	Q.	First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own views on the issue remained the same: strongly or very strongly against holding a public inquiry; is that fair?	1 1 1 1 1 1 1
12 13 14 15 16 17 18 19	Q. A.	First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own views on the issue remained the same: strongly or very strongly against holding a public inquiry; is that fair? Yes.	1 1 1 1 1 1 1 1
12 13 14 15 16 17 18 19 20	Q.	First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own views on the issue remained the same: strongly or very strongly against holding a public inquiry; is that fair? Yes. Was the question of holding a public inquiry at this	1 1 1 1 1 1 1 2
12 13 14 15 16 17 18 19 20 21	Q. A.	First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own views on the issue remained the same: strongly or very strongly against holding a public inquiry; is that fair? Yes. Was the question of holding a public inquiry at this time or any earlier time ever looked at from the	1 1 1 1 1 1 1 2 2
12 13 14 15 16 17 18 19 20 21 22	Q. A.	First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own views on the issue remained the same: strongly or very strongly against holding a public inquiry; is that fair? Yes. Was the question of holding a public inquiry at this time or any earlier time ever looked at from the perspective of wanting to understand how it could be	1 1 1 1 1 1 1 2 2 2 2
12 13 14 15 16 17 18 19 20 21 22 23	Q. A.	First of all, do you know anything about that latter issue there, about the voting issue? No, I don't. So it is, I think, clear from this document that as at mid-2006, the Scottish Executive position and your own views on the issue remained the same: strongly or very strongly against holding a public inquiry; is that fair? Yes. Was the question of holding a public inquiry at this time or any earlier time ever looked at from the perspective of wanting to understand how it could be that so many people were infected and dying, or had	1 1 1 1 1 1 1 2 2 2 2 2
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1	Q.	You referred to there having been examination in various
2		fora, including the internal departmental report, and
3		you said there'd been an examination of the issues in
4		some depth.
5		If we leave aside the internal investigation
6		report, because of course that had a very specific
7		scope, what other fora do you have in mind in giving
8		that evidence?
9	Α.	Well, I suppose there's reference in an earlier
10		document, which I think you called up, to DH having
11		looked at such issues over the years. You know, the
12		Advisory Committee structure, ACVSB, latterly MSBT, had
13		also examined well, had looked at all of the issues
14		over the years. I think that's what I had in mind. But
15		obviously the internal inquiry on the specific issues of
16		Factor VIII safety had gone into that in some detail.
17	Q.	Then if we look at DHSC0041159 205.
18		This is an internal Department of Health minute,
19		not copied to you, dated 20 May 2006, and it's from
20		Gerard Hetherington. I just want to ask you about
21		something on the second page which refers to you. So if
22		we look at the bottom of the second page, we have the
23		heading "Demand for a Public Inquiry":
23		"6. Ministers pointed out that demands for
24		a public inquiry were intensifying. MS(PH) [the
23		a public inquiry were intensitying. MO(PT) [the 106
1		justify the establishment of an inquiry?
2	Α.	I don't know what the criteria are for setting up public
3		inquiries but I guess maybe scale of problem might be
4		one of them but, again, I'm not sure that the scale of
5		the issue here, while of course absolutely horrendous
6		for those who contracted viruses through blood and blood
7		products, I'm not sure that I agree that it was on
8		a massive scale.
9	Q.	We know, of course, that in due course in Scotland the
10		Penrose Inquiry was instituted and we saw yesterday that
11		you'd given evidence to the Penrose Inquiry. Did you
12		have any role in giving advice in the decision-making
13		process that led up to the decision to establish that
14		Inquiry?
15	А.	Well
16	Q.	As far as you can recall?
17	А.	I can't recall clearly, but I'm sure my advice would
18		have been sought.
19	Q.	I don't think we've got any particular documentation
20		that answers that or provides any further information in
21		regard to that.
22		Once the Penrose Inquiry was established and up
23		and running, obviously you gave evidence, as we saw, on
24		the issue of look-back. Did you have any other role in
25		relation to the Inquiry in the course of it, in terms of
		108

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		siving advice on weathers valated to the locating			Healf Dut as regarded as use
1 2		giving advice on matters related to the Inquiry? Not that I recollect.	1 2		itself. But paragraph 1 says: "As you can see from the attached, I raise the
2	A. Q.	One of the issues that's been explored with other	2		issue of the possible need for a public education
4	ω.	witnesses is the difficulties that might arise if a body	4		campaign arising from this judgment"
5		that might itself be criticised if there were to be	5		Then if we go to paragraph 3:
6		a public inquiry is the body charged with deciding if	6		"I think I am fairly clear in my own mind that
7		there should be a public inquiry, and an issue that's	7		while public education campaigns will not remove
, 8		been explored with other witnesses is whether there	, 8		liability in such cases, they may well reduce it. In
9		should be an independent body or independent position	9		any case, such a policy is consistent with the trend
10		that might be able to either take the decision as to	10		towards greater openness in general in the NHS."
11		whether there should be a public inquiry or provide	11		I wanted to ask you about that general issue that
12		advice, at least, in that regard. Do you have any views	12		you referred to there: the trend towards greater
13		on that suggestion?	13		openness in the NHS. Now, that might suggest that there
14	A.	Well, I haven't thought about it before now but I guess	14		had not previously been as much openness in the NHS as
15		that such a body would have to draw up the criteria	15		perhaps there could or should be, would that be a fair
16		that I mentioned earlier around what would trigger	16		inference to draw?
17		a public inquiry. So I suppose there might be some	17	Α.	Yes, I think the NHS in, let's say, the first 50 years
18		benefit in that.	18		of its existence, was a thing of its time. Society was
19	Q.	Just a couple of then miscellaneous issues I don't	19		much less open in those days than it is nowadays. So
20		mean to undermine their importance by describing them in	20		the NHS was simply a reflection of society. Our
21		those terms that I wanted to ask you about now.	21		thinking, as I said a while ago, of course, has evolved
22		If we go, please, to SCGV0000246_051. This is	22		immensely over the decades. You use the word
23		a minute from you, 18 June 2001, to the Chief Medical	23		"paternalistic" in reference to a comment that had been
24		Officer. It's triggered by, again, I think, the Burton	24		made earlier by somebody, I think a non-medic but the
25		judgment but I'm not going to ask you about that case	25		medical profession is often accused of paternalism, and
		109			110
1		I think that probably not probably, definitely in	1		and by whom. I don't know whether you're going to able
2		years gone by, led to a lack of openness with the	2		to cast much light on the issue in light of the limited
3		patient about what exactly, you know, was happening.	3		material available but I just want to ask you about it.
4		And certainly it's only in, I would say, the last	4		If we go, first of all, to SCGV0000170_150, please.
5		20 years or so that we've begun to talk about coming to	5		So this is from you to Mrs Towers, 24 September
6		joint decisions with the patient, rather than the doctor	6		1999. And so, in terms of timing, it's whilst the
7		handing down on high to the patient what is going to be	7		internal investigation is ongoing and you say this:
8		done.	8		"In the course of our investigations in this area
9		Now, I think that is exactly the way things should	9		it has emerged that Professor John Cash took him on
10		be but, nonetheless, it is still not an infrequent	10		his retiral some files which may be relevant, which he
11		occurrence that a doctor will have a conversation with	11		has 'gifted' to the Royal College of Physicians in
12		a patient and say, "Well, we could do course A or	12		Edinburgh. Both Angus Macmillan Douglas and I have
13		course B, what do you think?" and for the patient to	13		tried without success to persuade him that it would be
14		turn round and say, "Doctor, you know best, so you	14		much more convenient to allow SNBTS and Departmental
15		decide".	15		staff access to the files in another location, eg
16		However, that doesn't take away from the fact that	16		St Andrew's House. Professor Cash is extremely
17		having the conversation, giving the patient the option	17		resistant to this idea, for reasons best known to
18		to share more fully in the implications of their	18		himself. In the course of our conversation he actually
19		diagnosis and what treatment or treatments are on offer	19		said to me that the files now belong to the College!
20		is absolutely the right thing to do.	20		I said that I did not see how that could be, but that
21		So I think that this comment here about more	21		I could seek your advice on the question of ownership."
22		openness in general in the NHS, and that trend, is just	22		We saw from a document that we looked at earlier
23		consistent with the trend in general society.	23		that obviously some files from Professor Cash did become
24	Q.	The next topic I want to ask you about relates to	24		available because we saw Christine Dora's comments on
25		documentation and issues about what files were retained 111	25		them, but what, if anything, do you recall about the 112

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1		issue thrown up by this minute, the documentation that	1	Chief Medical Officer. April 2015 was when you ended
2		had been retained by Professor Cash and your ability to	2	that role. Were you involved in advising the Scottish
3		access that?	3	Government about the Inquiry report and its one
4	Α.	At the risk of sounding flippant, what it really reminds	4	recommendation and how that should be implemented, as
5		me of is John Cash's desire always to be mysterious and	5	far as you can recall?
6		to hold in his ownership something that others don't	6	A. Yes, I think I was, before I moved out of Government.
7		know about and I think the files are an example of that.	7	<b>Q</b> . And in broad terms, do you recall the nature of the
8		Again, my recollection, although it's hazy, is	8	advice that you provided in relation to the Penrose
9		that the files, actually, when we finally got our hands	9	Inquiry report?
10		on them, added nothing to the sum total of knowledge	10	A. Well, the only thing that sticks in my mind is the one
11		here. But of course we had to try to get hold of them	11	recommendation, and the advice would have been that that
12		and actually it should have been much more	12	was already or had already been implemented, ie the
13		straightforward than it was because the files did not	13	offering of an HCV test to anyone who was concerned that
14		belong to Professor Cash, they were not in his gift to	14	they may have contracted the virus through blood
15		give to the College of Physicians, and he should just	15	transfusion.
16		have handed them over to us.	16	<b>Q.</b> Two final questions, Professor Keel, from me. The first
17	Q.	And as I say, I think it's right to understand from	17	is this: during the time you worked in your governmental
18		later documents I don't think we need to put them on	18	position, so from 1992 through to 2015, was any
19		screen but I'll just read an example into the	19	assessment ever undertaken by Scottish Home and Health
20		transcript, SCGV0000173_044 that there were then	20	Department, Scottish Executive, Scottish Government,
21		files handed over by Professor Cash which were looked at	21	into the needs of the infected and affected communities
22		in the course of the investigation.	22	in Scotland?
23		Then I'd asked you earlier about your involvement	23	A. I'm not absolutely sure. However, needs assessments
24		in the Penrose Inquiry. When the Penrose final report	24	were conducted by various other agencies, if you like.
25		was produced, I think you were still, just, the Acting	25	For example, Health Protection Scotland and other bits
		113		114
1		of CSA did conduct needs assessment. However, I can't	1	seeking compensation for other ills that the NHS
2		be confident that the needs of those affected by this	2	allegedly had inflicted on them. I didn't see the logic
3		virus were part of that collective endeavour. However,	3	in that.
4		I do recall that in terms of practical support short of	4	And in terms of public inquiries, well, I mean,
5		providing financial support, that we did engage with the	5	I hope this one will indeed shed further light on the
6		ABPI over the difficulty that some individuals with	6	issues but, at the time that the public inquiry was
7		hepatitis C were encountering in relation to life	7	being resisted in Scotland, I believed and I still
8		insurance and mortgages, and I know that we also	8	believe that, at that stage, no additional evidence had
9		explored with the NHS their access to whatever	9	emerged that would have merited a public inquiry and,
10		treatments it would have been interferon at the	10	therefore, I think that, at that stage anyway, it would
11		beginning were available to treat the condition.	11	not have been appropriate for Scotland.
12	Q.	Then, Professor Keel, looking back now, is there any	12	<b>MS RICHARDS:</b> Those are the questions I am proposing to ask
13		aspect of the Scottish Government's response to those	13	Professor Keel, sir. We obviously need to give
14		infected and affected that you consider was misjudged or	14	an opportunity to Core Participants through their legal
15		wrong?	15	representatives to suggest any further lines of
16	Α.	While notwithstanding the existence of this Inquiry and	16	questioning.
17		certainly notwithstanding the compen or the financial	17	Could I ask that we take a slightly longer break,
18		support that has been provided for these patients, and	18	having finished earlier than our normal break time.
19		fully recognising the fact that they have been through	19	Could we take 45 minutes?
20		significant physical and mental problems arising from	20	SIR BRIAN LANGSTAFF: Yes, certainly.
21		their infection, I still believe that the logic here	21	Let me explain. Those who are participating in
22		would have been not to set up a financial assistance	22	the Inquiry have a right, through their Recognised Legal
23		scheme specifically with this group of patients, because	23	Representatives, to put questions through counsel to
24		it elevated their problems to a higher level than many	24	you. Plainly, they have to be given an opportunity to
25		other groups, who were pursuing equally justifiably, 115	25	formulate those questions in the light of everything 116

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1	that you have said and, since you have only just	1	
2	finished, they have to be given time to do that.	2	
3	I don't know how long that will be, I don't know how	3	
4	many questions there will be, but your evidence has been	4	
5	of such interest I wouldn't be surprised if there are	5	
6	quite a lot. We'll find out.	6	
7	But we won't sit again until 3.40. We may not sit	7	Α.
8	then if there are questions coming in still or questions	8	Q.
9	coming in late, so we won't sit before 3.40, in other	9	
10	words you're free completely until then, and then	10	
11	I can't tell you how long you'll be detained after that.	11	
12	It depends how long it takes for the various issues	12	
13	raised by the questions to be properly ventilated. But	13	
14	that's what we'll do.	14	Α.
15	3.40, not before 3.40. You'll be told, of course,	15	
16	if it's going to be any later.	16	
17	MS RICHARDS: Thank you, sir.	17	
18	A. Thank you.	18	~
19	(2.56 pm)	19	Q.
20	(A short break)	20	
21	(3.44 pm)	21	
22	SIR BRIAN LANGSTAFF: Yes.	22	
23	MS RICHARDS: Professor Keel, the questions I'm going to ask	23	
24	now, because they've been suggested on behalf of	24	
25	Core Participants, may dot around from topic to topic 117	25	
1	Scottish Executive's position was that those patients	1	Q.
2	were misremembering or providing the investigation with	2	ч.
3	unreliable information?	3	
4	A. We certainly didn't disbelieve them, but there seemed no	4	
5	easy way of proving that they hadn't been told double	5	A.
6	negative there, sorry but I can see where you're	6	Q.
7	heading. You're suggesting that we were inconsistent in	7	
8	our approach to the evidence or the allegation that	8	
9	the the evidence that the consultants presented,	9	
10	which I have already acknowledged was patchy because of	10	
11	the lapse of time between the mid-'80s and 2000 when the	11	Α.
12	Inquiry was taking place.	12	
13	They said, and we believed them, that there was	13	
14	patient literature available in the mid-80s which	14	
15	patients had access to, but we weren't able really to	15	
16	lay our hands on that.	16	
17	So there was a lack of confirmatory evidence.	17	Q.
18	really, on both sides, I suppose. But we certainly	18	
	didn't disbelieve the patients.	19	Α.
19	<b>Q</b> . The next question requires you to cast your mind back to	20	
19 20			
	the time you were working in Glasgow with	21	
20			
20 21	the time you were working in Glasgow with	21	
20 21 22	the time you were working in Glasgow with Professors Forbes and Lowe. Were you involved in the	21 22	
20 21 22 23	the time you were working in Glasgow with Professors Forbes and Lowe. Were you involved in the testing of immune function deficiencies in bleeding	21 22 23	

1		rather than following a single thread at any one time.
2		The first question arises out of the issues of
3		Better Blood Transfusion and educating clinicians on the
4		better use of blood. Was there resistance from
5		clinicians to the Scottish initiative to ensure the
6		better use of blood?
7	Α.	Not that I recollect.
8	Q.	And then turning next to the internal investigation
9		report, we explored the question of whether, for
10		example, patient records could have been looked at.
11		Would it be your expectation that it would be recorded
12		in patient records that a patient had been informed of
13		a positive test result?
14	A.	Certainly in the case of HIV I would expect that to be
15		recorded in the notes, because explicit consent was
16		needed for taking blood for HIV. As far as HCV is
17		concerned, I can't be confident that it would uniformly
18		be recorded that the patient knew the result.
19	Q.	And then I explored with you when we were considering
20	ч.	the internal investigation the Scottish Executive's
21		acceptance of the evidence provided by consultants, in
22		terms of the information that was provided to patients.
23		Does it follow from that acceptance that the Scottish
23		Executive disbelieved the patients who said that they
25		had not been provided with information, or that the
25		118
1	Q.	And did you have any awareness at that time of the
1 2	Q.	And did you have any awareness at that time of the thinking that immune deficiencies might be indicative of
	Q.	
2	Q.	thinking that immune deficiencies might be indicative of
2 3	Q.	thinking that immune deficiencies might be indicative of HTLV-III positivity due to exposure to factor
2 3 4		thinking that immune deficiencies might be indicative of HTLV-III positivity due to exposure to factor concentrates?
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			4		- II that is a line that we had a set in Demonstrate of
1		through patient records, probably many thousands, tens	1		all, that is a line that we've seen in Department of
2	0	of thousands of them.	2		Health material as well, as in the Department of Health
3	Q.	In relation to I think your earlier evidence that there	3		in London. Do you know what the origin, from the
4		might be tens of thousands of patients treated in that	4		Scottish perspective, was of that particular line to
5		way, as DEFIX was a pooled product and not heat treated	5		take?
6		until October 1985, does this mean that there are	6	A.	No, I don't know what the origin was.
7		potentially thousands of patients who were HCV-infected	7	Q.	
8		as a result of this treatment, and some who may have	8		children at Yorkhill the best available treatment in
9		been infected with HIV as a result of that treatment?	9		light of medical knowledge at the time?
10	A.	I guess those possibilities can't be excluded.	10	Α.	I suppose with hindsight the answer is no. That was
11	Q.	And was that issue ever investigated by the Scottish	11		Dr Willoughby's preferred clinical practice, and he would definitely have had views on the relative safety
12		Health Service or the Scottish Health Department, to	12		5
13	٨	your knowledge?	13		of those products compared with the SNBTS products. But
14 15	Α.	Not on a population basis, but I suspect that if a patient treated with non-heat treated DEFIX appeared	14 15		he also had views, I think I mentioned this yesterday,
16			16		on the ease of administration to paediatric patients of
10		to be suffering from hepatitis, then the clinician looking after them would have been monitoring them, and	17		the PFC product, and my recollection is he felt that the commercial products were easier to make up in volumes
18		then, maybe when the test appeared, testing them for	18		appropriate for children.
19		HCV.	19	Q.	Was the PFC product NY the best available treatment in
20	Q.	Can I ask you next about the line to take, or the policy	20	ω.	light of medical knowledge at the time for a previously
20	α.	position that we see articulated in the various	20		untreated or minimally treated patient in 1986?
22		briefings about the best available treatment in the	22	A.	Well, again with hindsight, clearly not. But in that
23		light of medical knowledge at the time.	23	Λ.	chronology, the only safer product would have been 8Y,
23		Now as I think I may have mentioned,	23		which, as we discussed this morning, was not available
25		Professor Keel, when I asked you about that first of	25		in sufficient quantities. Even if we had known for sure
20		121	20		122
1		that it didn't transmit non-A, non-B, it wouldn't have	1		demonstrate that haemophiliacs would have died if they
2		been available in sufficient quantities to supply	2		did not receive Factor VIII concentrates as opposed to
3		Scotland. So clearly NY transmitted HCV. There's no	3		treatment with cryoprecipitate?
4		doubt about that. Anybody who got it, got hepatitis C.	4	Α.	Again, I think we partially covered this this morning.
5		But the risks of transmission of that virus, which	5		In the event of a potentially life-threatening bleed,
6		hadn't even been identified at the time, were, in the	6		such as intracranial bleeding, then cryoprecipitate
7		views of clinicians, outweighed by the benefits from	7		would definitely not have been the best treatment for
8		using that product, which, as I've already said on more	8		these patients to receive. You would have to give
9		than one occasion, were potentially life saving.	9		enormous volumes of cryo to try to stop the bleeding.
10	Q.	You told us your understanding that the mean age of	10		So absolutely clear in my own mind that giving
11		haemophiliacs in the '60s was 37. To what severity of	11		coagulation factor concentrates in the event of
12		haemophilia patients	12		a life-saving bleed was potentially life saving.
13	A.	Of death.	13	Q.	If the severity of non-A, non-B hepatitis testing was
14	Q.	l'm sorry?	14		not appreciated in the first half of the 1980s or the
15	Α.	Mean age of death.	15		mid-1980s, why was so much time, effort and money put
16	Q.	Yes, I'm sorry, you're absolutely right. To what	16		into research at BPL and PFC to produce a product that
17		severity of haemophilia patients did that statistic	17		did not transmit non-A, non-B hepatitis?
18		apply in your understanding?	18	SIR	R BRIAN LANGSTAFF: I'm not sure that's really a question
19	Α.	It would have been severe haemophiliacs, maybe some	19		which she can answer. That really is a comment.
20		moderate were in that. I don't know how the number was	20	MS	RICHARDS: It's a (overspeaking)
21		calculated.	21	SIR	R BRIAN LANGSTAFF: A question dressed up as a comment,
22	Q.	And can you recall what the source of your knowledge was	22		which I think is ultimately for me to evaluate.
23		in relation to that issue?	23	MS	RICHARDS: I absolutely take that point, sir.
24	Α.	No, I can't, sorry.	24		Surrogate testing, Professor Keel, and we touched
25	Q.	And is there any evidence that you can point to	25		on this earlier. We saw from the documentation
		123			124

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1		references to ALT testing and not anti-HBc testing.	1
2		When you were providing advice on these issues in the	2
3		various respects in which we looked at in the course of	3
4		your evidence, was it your understanding that only ALT	4
5		testing was a possibility?	5
6 7	Α.	I think at that time that ALT was the main factor under consideration. Now, I my recollection, again, is	6 7
8		very unclear in this. But I think probably that the	8
9		anti-HB core testing issue had been put to bed before	9
10		I came into post. So the ALT issue was still current in	10
11		a way, and it was the one that cropped up rather than	10
12		HBc testing.	12
13	Q.	Does it follow then that it was your understanding that	13
14		in the 1980s, the question of using anti-HBc testing as	14
15		a form of surrogate testing was not a live issue in the	15
16		1980s?	16
17	A.	I'm not I didn't say it was not a live issue. It	17
18		wasn't the forefront of the issues raised with me when	18
19		I came into post.	19
20	Q.	Then, in your evidence earlier about what might be done	20
21		if donors had elevated ALTs, your evidence was to the	21
22		effect that what would you tell them about the reason	22
23		for the elevated ALTs, as it might be drinking or being	23
24		overweight or other matters.	24
25		The question arising from that is this,	25
		125	
1		haemophilia patients would have contracted	1
2		non-A, non-B hepatitis. Was that advice that you	2
3		provided to ministers, as far as you can recall?	3
4	Α.	I think it does appear in some of the briefings, maybe	4
5		earlier on. And the reason for saying that is well,	5
6		it's a fact, because of the large donor pools that	6
7		were from which the factor concentrates were made.	7
8		It only took one positive donation amidst the 3,000	8
9		I think was what SNBTS were dealing with commercial	9
10		producers were dealing with [live stream froze] of	10
11		30,000. So you therefore "contaminate", I use that word	11
12		in inverted commas, an enormous plasma pool that is then	12
13		being made into various products, all of which carry the	13
14		virus.	14
15	Q.	The Inquiry has heard evidence about a paper from 1983	15
16		by Fletcher and others, which suggested that the fact	16
17		that you've just referred to 100 per cent of	17
18		haemophilia patients contracting non-A, non-B hepatitis.	18
19		I'm hesitant to ask you about a paper that you haven't	19
20		been provided with in advance of your evidence but, in	20
21		any event, do you know whether that was a paper that you	21
22		were aware of? Does it ring any bells at this stage?	22
23	A.	No, I'm afraid not.	23
24 25	Q.	The next question moves to 2003. The announcement in January 2003 of the potential figures of 20,000 and	24 25
20		127	25

1		Professor Keel: why would that be a bad thing or
2		a reason not to do the testing and telling a donor that
3		they have a deranged liver function which might be due
4		to non-A, non-B hepatitis infection or might be due to
5		one of those other factors would then enable a donor to
6		make good choices for their health as a consequence?
7	Α.	Well, certainly telling them that they had deranged
8		liver function which might be the result of a virus as
9		yet unidentified, I think, would have been pretty
10		unsatisfactory from that individual's point of view.
11		Yes, of course you could say you could screen for
12		elevated ALT and tell people to lose weight, stop
13		drinking, but that really is not the function of our
14		blood screening test. The blood screening test is to
15		protect the population from donors who might be carrying
16		viruses.
17		So allied to the issue of how you deal with donors
18		with elevated ALT levels, theoretically speaking, is the
19		issue of what that would mean for the Blood Service.
20		What proportion of the population might fall into that
21		category could be very significant and, therefore, erode
22	~	the blood supply available to the population. You said in your evidence earlier that we know with
23 24	Q.	hindsight that, prior to the introduction of successful
24 25		viral inactivation, et cetera, 100 per cent of
20		126
1		25,000 for stage 1 and stage 2. Now, you've told us
2		about the extent of your involvement with that earlier.
3		We touched in your earlier evidence on interactions you
4		had with Peter Hayes about the stage 2 issues, and the
5		documentation referred to in your statement suggested
6		that you made contact with Peter Hayes in February 2003.
7		At that stage, was it your understanding that there
8		would be a Scotland-specific scheme or did you
9		anticipate that there would be a UK-wide scheme?
10	A.	I can't recall. I'm not really sure of the relevance to
11		the issue of deciding on a trigger point or not. I did
12		further, of course, discuss that matter with colleagues
13		in the Department of Health. So it wasn't it wasn't
14		confined to Peter Hayes. So I suppose that fully
15		reflects the desire, at that stage, to see the scheme
16		implemented on a UK-wide basis.
17	Q.	The next question relates to natural clearers. Do you
18		know when and by whom it was decided that acute natural
19		clearers would be excluded from the scheme?
20	Α.	I think we decided that fairly early on, on the grounds
21		that those who cleared the virus within six months of
22		acquiring certainly had not suffered any long-term harm,
23		and most of them would have been asymptomatic anyway,
24	~	even during the first six months.
25	Q.	So is it your understanding that that had already been 128
		(32) Pages 125 - 12
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1		effectively decided by the time of the January 2003	1		eng
2		announcement?	2		life
3	Α.	I can't recollect the timing of it.	3		ultir
4	Q.	And did you provide, as far as you can recall, any	4		eng
5		medical advice about the possible impact, in particular	5	Α.	l ca
6		psychological impacts, of hepatitis C infection on such	6		roo
7		patients?	7		insu
8	Α.	I can't specifically recall but I'm sure the	8		But
9		psychological potential psychological distress would	9	~	or v
10		have been discussed. But if you're talking about	10	Q.	Nex
11		natural clearers, as I've already said, most of them	11		rati
12		wouldn't have known that they had a virus during that	12		lool
13		period before they cleared it. Many were totally	13		it?
14 15	0	asymptomatic. I think most were asymptomatic.	14 15	۸	We
15 16	Q.	And then still on the topic of natural clearers, given that chronic clearance of hepatitis C was unusual, how	16	Α.	l do
10		would the typical transfusion patient who did not,	10		issi nati
18		unlike bleeding disorder patients, potentially, have the	18		pati
10		benefit of previous regular results of blood testing,	10		exe who
20		prove that they had cleared at the chronic and not the	20		ast
20		acute stage?	20 21	Q.	The
21	Α.	I think that would have been very difficult unless they	21	α.	blo
22	л.	were being monitored by some other clinician, and their	23		first
23		LFTs tested on a regular basis.	23		in N
25	Q.	Moving to a different issue entirely. You referred to	25		disa
20	ω.	129	20		aiot
1	Α.	Well, there have been many other treatment disasters.	1		rela
2		Thalidomide comes to mind. I think it's very difficult	2		des
3		to categorise such events by degree of severity and	3		exp
4		I don't think I'm in a position so to do.	4		Gov
5	Q.	In terms of the issue of precedent setting, and	5		box
6		financial assistance, are you aware of any group other	6		a so
7		than those infected through blood and blood products,	7	Q.	Υοι
8		relying on the financial assistance given to recipients	8		follo
9		of infected blood or blood products as a precedent for	9		an
10		wider no-fault compensation?	10		hep
11	Α.	Am I now relying on is that your question?	11		-
12	Q.	Yes. Were you at any time aware or are you now aware of	12		Ski
13		any groups pointing to the provision of financial	13		fea
14		support to the cohorts of individuals with whom this	14	Α.	No,
15		Inquiry is concerned in saying: well, they've had	15		dis
16		financial support, so too should we?	16		able
17	Α.	Well, I've been seconded out of Government for 7 years,	17		The
18		so I certainly can't comment on current thinking in that	18		the
19		area. But as I said, I've said many times, the concern	19		con
20		around introducing the HCV assistance scheme was that it	20	MS	RICI
21		would activate other groups that we knew were already	21		ask
22		out there, others unknown to us, to make claims.	22		Coi
23		l mean, l'm not in principle against a no-fault	23		whe
24		compensation scheme. Many countries have them. But	24		Dr
25		most of the payments arising from some such schemes are	25		
		131			

1		engagement by the Scottish Government with the ABPI on
2		life insurance and mortgages. Was any assistance
3		ultimately offered to the infected as a result of that
4		engagement, and if so, what?
5	Α.	I can only remember one meeting, and I can picture the
6		room that we were in, in the new Parliament, with the
7		insurance industry, at which these concerns were voiced.
8		But I really have no recollection of further follow-up
9		or what the outcomes of those discussions were.
10	Q.	Next question is about look-back again. Was part of the
11		rationale for requiring a UK-wide introduction of HCV
12		look-back influenced by who might be expected to pay for
13		it? In other words, would it assist in looking to
14		Westminster to fund the look-back if it was UK-wide?
15	А.	I don't remember that being a factor. I think the main
16		issues driving a UK approach were to avoid confusion of
17		patients who were potentially identified through the
18		exercise, and also to avoid confusion of clinicians
19		who'd be involved. So doing it across the UK was seen
20		as the best way forward.
20	Q.	The infection of thousands with hepatitis and HIV from
22	ч.	blood and blood products has been described. I think
22		first by Lord Winston, as the worst treatment disaster
23 24		in NHS history. Is that a characterisation that you
24 25		
25		disagree with? 130
1		relatively modest, and they take a great deal of
2		designing. So I mean, my mind was open as to whether we
3		explored that possibility. During my time in
4		Government, I think it was always in the 'too difficult'
5		box to really pursue and come out the other end with
6		a scheme that would fit with the NHS.
7	Q.	You were in Government for approximately 12 years
8		following the announcement in 2003 that there would be
9		an ex gratia payment scheme for those infected with
10		hepatitis C.
11		In those 12 years, did the establishment of the
12		Skipton Fund create the dangerous precedent that you'd
13		feared?
14	Α.	No, it didn't, but that doesn't mean that there aren't
15		disgruntled groups of people out there who have not been
16		able to bring the lobbying power that, for example,
17		The Haemophilia Society got to this area. So I think
18		the concern was valid. The fact that it hasn't actually
19		come to pass doesn't mean it wasn't a valid concern.
20	MS	<b>RICHARDS:</b> Sir, those are the questions I'm proposing to
21		ask from those put forward on behalf of
22		Core Participants. I'm just going to turn and see
23		whether there's anything no, there's nothing from
24		Dr Keel's legal representatives.
25		Do you have any questions for Professor Keel?
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	oin	DDIAN LANCETATE: Only one supplier which erises out of	
1 2	SIK	<b>BRIAN LANGSTAFF:</b> Only one question, which arises out of the questions you've just been asked on behalf of	1 2
2		Core Participants. You were asked why the look-back	2
4		exercise needed to be conducted on a UK basis, and you	4
5		said that otherwise the patients might become confused	5
6		and clinicians might be confused. Can you help me,	6
7		starting with clinicians, why would clinicians	7
, 8		practising in Scotland be confused that the Scottish	, 8
9		Government, Scottish Health Service, the NHS in	9
10		Scotland, was saying, "We want you to have a look-back	10
11		for those involved in Scotland"? What would be the	11
12		source of their confusion?	12
13	Α.	Well, it would have been perfectly feasible to proceed	13
14		on the basis of Scotland going it alone, if you like.	14
15		But you have to remember that patients cross the border	15
16		between Scotland and England, and vice versa, so that	16
17		there was that. It was just seen as desirable that in	17
18		such an important area, that the whole of the UK did it	18
19		roughly at the same time.	19
20		Now, the starting gun was fired but by no means	20
21		everybody was at the same place in terms of preparation.	21
22		So the time courses that were run across the UK, between	22
23		the different transfusion services, varied a bit, but	23
24		they all started roughly at the same time well, at	24
25		the same time, some had done more preparation before	25
		133	
1		introduced. Before it was introduced my understanding	1
2		is, at least the understanding of the Inquiry is, that	2
3		there were a number of pilot schemes operated, certainly	3
4		in England, which in which areas everyone was being	4
5		screened, whereas in other areas they weren't.	5
6		Do you recollect there being any particular	6
7		concern or confusion amongst patients and clinicians as	7
8		to why that was happening "there" when it wasn't	8
9		happening "here"?	9
10	Α.	No, I don't recollect. I suspect that that kind of	10
11		local testing was not visible to the wider patient	11
12		community.	12
13	SIR	<b>BRIAN LANGSTAFF:</b> So the difference is the degree of	13
14		publicity, is it?	14
15	Α.	In part, yes. Those centres that were ahead of the rest	15
16		of the country in introducing testing, were of course	16
17		using the first generation HCV test, which, for reasons	17
18		that I'm sure have been explained already, and I think	18
19 20		I mentioned yesterday, were not considered satisfactory	19
20		enough for screening the whole donor population, and	20
21 22		being able to absolutely depend on the results that were	21
22 23		emerging, and there were no confirmatory tests at the	22 23
		beginning.	23 24
24 25		So I imagine that those places that were using, in the early days, HCV tests were using the first	24 25
20		135	20

1	that starting date than others. But given that, you
2	know, public awareness was going to be raised around the
3	exercise, that was another reason for wanting to do it,
4	as far as possible, starting at the same time.
5	SIR BRIAN LANGSTAFF: So are you really describing confusion
6	or an element of "Why are they doing it there and not
7	here?"
8	A. I'm sure that question would have been raised, yes.
9	SIR BRIAN LANGSTAFF: Do you still want to maintain the word
10	"confusion"? It's your word. I'm just asking about
11	what gave rise to it and I'm not sure you've really
12	explained it to me so far.
13	A. Well, I think clinicians would have said well, if
14	we'd gone ahead in Scotland with our own exercise,
15	I think clinicians south of the border would have said,
16	"Why are we not doing it here?" Indeed, some small
17	areas in England had already, as Jack Gillon had done,
18	begun their own little exercises in various places.
19	So it didn't come as a bombshell to England that
20	this was going to happen, but I definitely think if we'd
21	gone it alone, so to speak, English clinicians would
22	have been a bit bemused as to why they weren't being
23	asked to do it at the same time.
24	SIR BRIAN LANGSTAFF: Now this leads on to the question,
25	really, about testing for HCV, hepatitis C, when it was 134
1 2	generation tests. SIR BRIAN LANGSTAFF: Yes, well, that's all that I'm going
3	to ask. Thank you very much.
4	MS RICHARDS: Professor Keel, was there anything further
5	that you wanted to add?
6	A. No, I don't think so. Thanks, Ms Richards.
7	SIR BRIAN LANGSTAFF: Well, can I thank you. You'll have
8	understood from the number of questions and the length
9	of time that it took to assimilate them the considerable
10	degree of interest which your evidence has given us.
11	I know it's taken two days, which is a long-ish time
12	compared to some of the evidence which we've heard, but
13	I'm sure that anyone listening will have thought the
14	two days entirely justified by the questions and answers
15	that have been asked and given. So thank you very much.
16	A. Thank you.
17	SIR BRIAN LANGSTAFF: Tomorrow?
18	MS RICHARDS: Tomorrow, sir, we have the evidence of
19	Jeremy Hunt, Secretary of State for Health in the
20	UK Government, 2012 to 2018.
21	SIR BRIAN LANGSTAFF: So Jeremy Hunt MP tomorrow.
22	MS RICHARDS: Yes.
23	SIR BRIAN LANGSTAFF: 10.00.
24	(4.21 pm)
25	(The hearing adjourned until 10.00 am the following day) 136
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