Tuesday, 2 November 2021 that people can find the documents, should they wish (9.59 am) to look at them. Presentation by Counsel to the Inquiry relating to As I've said, the focus is on those four knowledge of and response to risk by pharmaceutical companies and is on the United States. But at stages companies involved in blood products in the narrative I will also draw upon what was going SIR BRIAN LANGSTAFF: Yes, Mr Hill. We have on in the United Kingdom, partly to provide some pharmaceutical companies and risk. context of what was happening in the States, and also MR HILL: That's right, sir, it's the last in the series just to allow us to get our bearings with the rest of of the presentations on pharmaceutical companies. It the evidence. should be considered alongside the others but I've There was, as we know, one further company that tried not to repeat that which we heard earlier in imported bloods into the UK in the 1970s and 1980s, September and October. and that was Immuno, the Austrian firm. I will be The presentation today, as you've said, concerns referring to them on occasions in this, but the focus the response to the emerging risk of AIDS, and the has been on American documents and on the interaction, focus is on the United States, and in particular on in particular of those four companies, with the four companies: Alpha; Armour; Hyland, also known as American regulators and other interested parties Hyland Travenol in some of the documents; and Cutter, within America, and for that reason Immuno doesn't get also known as Miles Cutter. as much coverage as it otherwise would have done so. It's accompanied by a written presentation which But you'll recall, sir, that we spent some time on the has been disclosed and will be placed on the website. Immuno and its products --The references to the documents cited are all in SIR BRIAN LANGSTAFF: Yes, we also heard, of course, that that written presentation, so everybody is going to be Immuno did take plasma from the United States. spared me reading agreed lengthy URN numbers as we go MR HILL: Absolutely. And by 1983 the dominant product in the Factor VIII market that Immuno was offering was through, and instead I will refer to the paragraph numbers in the written presentations, so sourced from American plasma.

SIR BRIAN LANGSTAFF: Yes.

MR HILL: So these events are of relevance to then, particularly in relation to donor screening. We just don't have as much internal documentation, in part because much of the documents that we have is drawn from the US litigation, in which Immuno -- or there was an awful lot of litigation but most was focused against the US companies rather than Immuno, so we don't just have as much about them as we do with other companies.

I should say, at this point, sir, that we are grateful to all of those who have provided documents that have allowed for this analysis, including many of the Core Participants. You will see from the URN numbers who it is who has been providing those documents.

The written presentation begins with a series of caveats and comments on what is not included, and I won't go through them all. The key points are that this presentation is made from an independent perspective. It is intended as a neutral factual narrative. It inevitably involves a degree of judgment about which documents to select and how to summarise them. What we're looking at today is the tip of an iceberg in terms of the amount of documents

that are available to you and to the Core Participants.

No special status attaches to a document because I'm referring to it today, and nor is any such status absent from another document because I haven't referred to it. The intention is to provide you, the Core Participants, those infected and affected, and the wider public, with an overview of this topic. It doesn't pretend to be exhaustive. The analogy I use in the written presentation is that it's like trying to navigate through a forest without getting lost and stuck in a thicket.

All Core Participants have access to the documents to which I will refer today, and to many, many others. All will have opportunities to make submissions on them, and ultimately, sir, it will be for you to consider those submissions, to consider the evidence and come to your own findings.

It may help if I provide a short route map about where we're going to be going today and tomorrow.

The presentation begins chronologically from the first reports of AIDS in people with haemophilia in 1982, and then moves chronologically through 1983 and the first half of 1984.

In that period, 1982 to June/July 1984, there

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are four particular themes and issues that emerge. The first is donor screening. That is the question of how to minimise blood and plasma donations from those in high-risk groups. The three key high-risk groups at this time were identified as being intravenous drug users, male homosexual donors and people who were either Haitian or who had relatively recently resided in Haiti.

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The most contentious of those three areas was about the exclusion of gay donors.

The second main issue that arose in this time was the related question of the geographical siting of plasmapheresis centres in what were often referred to as high incidence areas or high risk areas. Such group of centres were those that had purposely targeted gay men as donors in order to obtain plasma that was high in hepatitis antibodies -- we discussed this in September and October -- the purpose being to provide plasma that would be used to create products that would boost immunity for hepatitis.

The second high risk area was prisons. Again, that was something that we touched upon in September and October, and we'll be coming back to in the next two days.

The third set of high risk centres were those

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that were located in cities which were known to have high incidence of AIDS. New York, San Francisco were the two main cities so identified. Also cities like Miami, New Orleans, Hollywood, and New Jersey as well.

The third issue that emerges in 1982 to 1984 is surrogate testing. In this period the virus causing AIDS had not been identified, and indeed there was a debate as to whether or not a virus was the causative agent. Consideration was therefore given to whether a surrogate test could be used. That is, testing for another virus or another set of clinical markers which may indicate that that individual is at high risk of AIDS.

Various candidates were discussed and projects were run on various different types of testing. The one that gained most traction was testing for the antibody to hepatitis B core antigen. I'm going to refer to that as anti-HBC testing as we go through. I will try hard not to use too many acronyms, particularly for various bodies and organisations, but there will be some I'm afraid.

The fourth main issue that emerged in this time was the recall of products. That had two related but distinct limbs. The first of those was that as measures taken by fractionators increased -- these are

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the protective measures, the donor screening and the cutting down of centres in high risk areas -- as those increased, it raised the question of what to do with products that had been manufactured before those measures were put in place.

You will recall, sir, the evidence of Dr Kingdon of Hyland we referred into September and October, about the long pipeline between plasma being obtained from a donor, and that plasma, or part of that plasma being injected by a patient, and that could be as much as two years afterwards.

The second limb of the recall of products issue is this: when a donor is found to have AIDS, or develop symptoms that may be suggestive of AIDS, what should be done about the products that have been manufactured from previous donations given by that donor? Should they be recalled? The issue -- sorry, this issue, at least as far as the companies were concerned, and as far as they claimed, threatened the worldwide supply of factor concentrates, and at points it's even put in terms of threatening the continuation of the industry itself. We will come on to see why that was claimed.

From mid-1984, the presentation departs from a strictly chronological approach, to look at two

matters thematically. The first is the introduction of heat-treated products and the licensing and increased use of those products, particularly from autumn 1984.

Heat treatment is something that runs throughout this period and I will make reference to it as we go along, but it will be after the June/July 1984 point where I address that as a matter in its own right.

The second of the issues is the development and deployment of a screening test for HTLV-III, as the virus was known at that time, HIV. It's something that became available in spring and summer in 1985, following on from the isolation of the virus the year

Now, that is the map, and it may be helpful to introduce some of the features of the landscape that we're going to see as we move along, starting with some of the organisations, and this is from paragraph 9 of the written presentation onwards. I don't seek to explain all of these organisations and their legal status and their various roles. This is just to introduce them, because they are, some of them, organisations that we may not have considered much before in the evidence.

The federal government department within the

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(2) Pages 5 - 8

US administration that had responsibility for blood supply and its regulation was the Department of Health and Human Services, the DHHS, so the equivalent, as it were of the DHSS in the UK. That was overseen by its secretary, a woman called Margaret Heckler, who was a member of Ronald Reagan's Cabinet, and underneath her there were various undersecretaries, one of whom was Dr Edward Brandt Jr, and we'll see his name in some of the documents.

One of the agencies within the Department of Health and Human Services was the Public Health Service. I'll come back to that in a second. That was, as the name suggests, responsible for public health management within the United States.

The Food and Drink Administration, or FDA -- and that is one of the acronyms I'm afraid I'm going to use, the FDA -- was the body charged with regulating and reviewing the blood supply system. It comprised various divisions, the most significant of which for our purposes was the Bureau of Biologics; that was the area that dealt with blood and blood products. In 1982 that was merged into the Center for Drugs and Biologics, but often you'll see in the documents references to the "Bureau of Biologics", or the "BOB" or just "the Bureau". That means the organisation

within the FDA that was responsible for blood and blood products.

The FDA consulted formally and informally with a wide range of groups, had a number of standing committees. One of those was the Blood Products Advisory Committee, often referred to in the documents as BPAC. It contained various individuals drawn from relevant medical, commercial and charitable establishments, and its purpose was to provide advice on blood products matters.

The blood banking industry was particularly strongly represented. And by "blood banking", I mean collectors of whole blood within the United States, and some of those were blood banks that were run voluntarily, others were run for profit, some were connected to hospitals, some were community-based blood banks. They should be differentiated from plasmapheresis centres, which were there to collect plasma, usually for fractionation into blood products.

The Centers for Disease Control and Prevention were based in Atlanta, and they were part of the Public Health Service. Up until 1980 the name was singular, Center for Disease Control and Prevention. After 1980 it becomes Centers for Disease Control and Prevention, so that's the CDC. And again, that's one

of the acronyms that I'm going to allow myself to use because it was almost always referred into the documents as the CDC.

SIR BRIAN LANGSTAFF: So, for what it matters, the time for which we are most interested, the 1980s onwards, it's in the plural, is it?

7 MR HILL: Yes, that's right, "Centers". I have mistakenly
 8 referred into the singular in the written document,
 9 and we can correct ---

SIR BRIAN LANGSTAFF: But it is actually one organisation even though it's expressed in the plural?

MR HILL: It is one organisation. As with the FDA,
 a number of divisions within it but one organisation
 that oversees them.

It was part of the Public Health Service, so if we go back to the DHHS, the Government body, that has the Public Health Service within it, and within that the Centers for Disease Control based in Atlanta.

Another organisation which comes up in some of the documents is the National Institutes of Health, which again has a number of institutes within it.

That was the Government's principal biomedical research agency, and we will see individuals from the NIH, National Institutes of Health, attend various meetings, including Dr Fauci.

There were two trade bodies for fractionation interests in this period. The Plasma Manufacturers Association, often referred into the documents as the PMA, that represented those pharmaceutical companies that were affiliated to it, so you've got Armour and Cutter and Hyland. The membership changed at various points and I don't think that strictly matters for our analysis today, but it was generally regarded as the fractionators' trade body.

There was also the American Blood Resources Association. That was a slightly wider body that incorporated not just the fractionators, the manufacturers, it also involved those who were involved in running independent plasmapheresis centres, and, as we have seen, those independent centres would often contract with the main companies in order to provide them with plasma.

A number of organisations involved in whole blood collection are also of relevance: the American Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers. I won't break those down individually, but they are the equivalent -- the two last groups that I mentioned are the equivalent trade bodies for someone in the blood banking industry.

(3) Pages 9 - 12

One thing that you may feel emerges as we go through this is that those groups are not monolithic. There was considerable disagreement and tension between different government agencies. In general terms, the CDC, elements within the CDC, were more hawkish about the threat of AIDS than some of the other agencies. They had some difficulty persuading others within government, as well as those outside it. Even within the CDC itself there were some tensions.

The fractionators and the blood banking industry also had different views and different interests.

This was particularly evident in the debate about donor screening and donor exclusion. There, as we'll see from the documents, fractionators proved more responsive to change than the blood bankers did, including the voluntary blood bankers.

But nor were the fractionators themselves the uniform group. We will see that there were occasions on which they would seek to present a single view, even a script, and they were particularly united on the issue of product recall. But there was also a divergence in policies, including in respect of donor screening, approaches to prison donations and on surrogate testing as well. It shouldn't be forgotten

that, as well as having shared interests, these companies were market competitors, and while I refer to the fractionators as a whole, I do so without losing sight of the fact that they were individual companies.

One other body that is worth mentioning at this stage is the National Hemophilia Foundation. That was the main representative body within the United States for people with haemophilia and their families.

The National Hemophilia Foundation, often known as the NHF, also had within it a medical and scientific advisory committee, very often referred to as MASAC. That was a committee of leading haemophilia clinicians from the United States, and it was, in effect, the body that set out recommendations for clinical care of people with haemophilia.

The National Hemophilia Foundation would also attend relevant meetings. As we'll see, it called meetings itself and invited interested groups such as the fractionators along to them, and the NHF would also issue public statements on policy.

Having identified those groups, I will begin the chronological narrative. A document that I will draw on frequently when going through the chronology is an article written by Dr Bruce Evatt, entitled

"The Tragic History of AIDS in the Haemophilia Population 1982 to 1984", which was published in the Journal of Thrombosis and Haemostasis in 2006. The reference to it is at paragraph 17 of the written presentation, there is actually also an introduction to it at paragraph 6.

Dr Evatt was a leading figure at the CDC, he would go on to become the Director of the Division of Hematology, and he was a central protagonist in these events. He wrote the article in 2006, so looking back about a quarter of a century earlier, as an historical sketch. He drew on his own memory, but also on extensive documentation, which he footnoted in the article

In the "Tragic History", as I'm going to refer to it, Dr Evatt states that AIDS first became apparent in the United States in the last quarter of 1980. In July 1981, the CDC established a task force on some of the -- symptoms that came to be associated with AIDS and particularly Kaposi's sarcoma, that task force was led by a CDC scientist called Dr James Curran.

In March 1982, the first interagency meeting took place, relating to issues connected with what became known as AIDS.

SIR BRIAN LANGSTAFF: May I just ask if you may have

missed a date here, because I think 5 June 1981 was when the MMWR first reported five cases of AIDS.

3 MR HILL: There are many dates that I've missed.

4 SIR BRIAN LANGSTAFF: But that would be the first report

in any recognised literature, I think, and I have it noted as that date. If anyone wants a reference to it, it's CGRA0000242. That would then lead on

8 naturally to the development of the task force, so it

9 may be just a step in the history.

10 MR HILL: Yes, sir.

11 SIR BRIAN LANGSTAFF: That's how, at the moment, I would 12 like to understand it, I may be wrong, of course, and

13 if so I'll be corrected in submissions, but I think

5 June 1981, to me, is an important date.

15 MR HILL: Yes, sir.

There are many different landmarks and milestones that are not included in this presentation --

19 SIR BRIAN LANGSTAFF: Yes.

MR HILL: -- and others will have an opportunity to point out those that they consider to be of relevance.

So March 1982, first interagency meeting took place between representatives of the CDC, the FDA and other Government bodies, and Dr Evatt and Dr Curran were in the lead from the CDC at that meeting.

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According to Dr Evatt's history, there was a turning point in June and July 1982, in his understanding and the CDC's understanding of AIDS. He referred to these as being "pivotal months". The cause of this change of understanding was that the CDC was beginning to learn of patients with haemophilia who had developed pneumocystis carinii pneumonia, PCP.

The CDC were learning of these, in part, because they were the body that was charged with providing a drug that was used to treat PCP, and so people had to report cases to them in order to get the drug. The CDC began to notice that people with haemophilia were being affected in 1982 and, in June and July, the CDC was informed of the second and third patients who had developed immune disorders.

This led Dr Evatt and his colleagues to become, and I quote him again:

"... reasonably convinced that haemophilic patients were another risk group or AIDS."

So that is in addition to the three that I've already mentioned.

Dr Evatt raised the issue of senior figures within the CDC. Remember, the CDC did the same with other bodies and agencies leading, on 9 July 1982, to Harry M Meyer, who is the director of the FDA's

National Center for Drugs and Biologics to write a circular to all manufacturers of plasma fractionation products. He informed them of the three cases of PCP in people with haemophilia, and he stated, and I

"Although the cause of this outbreak is unknown, the information suggests that a transmissible agent might be involved and concern about transmission through blood and blood products has been raised."

That's paragraph 19 of the written presentation, 9 July 1982, a circular sent to all fractionators.

Five days later, on 14 July 1982, the National Hemophilia Foundation issued a patient alert. That concerned and raised the three cases and also the possibility of an infectious agent transmitted through blood or blood products. The NHF statement stated, and I quote:

"It is important to note that at this time the risk of contracting this immunosuppressive agent is minimal and CDC is not recommending any change in blood product use."

That's paragraph 20 of the written presentation.
Two days later, so 16 July 1982, the CDC
publishes a report of the three cases in Morbidity and
Mortality Weekly Reports. We will hear, as we go

through, how the number of cases increases as time progresses.

This evidence suggests that US pharmaceutical companies were, as of mid-July 1982, given notice of PCP infections in patients with haemophilia, and were given notice of a possibility of transmission of an infectious agent through blood and blood products. Lest there be any doubt about that matter, if we could bring up. Soumik, CGRA0000668.

This is a memorandum, an internal memorandum, within Hyland Travenol. We can see that it is from HS Kingdon, that is Dr Kingdon, whose evidence we heard about in October and September. He is the man who gave a witness statement in 1990 as part of the UK HIV litigation. That was always a draft statement, but we saw that Dr Kingdon looked at that draft and proved what was contained in it and made amendments where he felt it was necessary to do so.

This is a memorandum from 5 January 1983, so six months after the events that we have just been discussing. What Dr Kingdon says is this, in the first paragraph:

"We have been closely monitoring the AIDS issue at Hyland since the original description of the syndrome in male homosexuals in the December 10, 1981 issue of The New England Journal of Medicine, and more intensively since the first three hemophilia cases were reported in the Morbidity and the Mortality Weekly Report from the CDC on July 16, 1982."

He goes on to say, and I quote:

"Many of us have been involved in considering the problem and in discussions with CDC on its implications for our blood products. Dr Rodell [who at that stage was with Hyland Travenol] has attended the bulk of the meetings held at the CDC or [National Institutes of Health] on the subject."

So we can see there acknowledgements from January 1983 that Hyland Travenol have been following that issue closely, particularly from July 1982.

SIR BRIAN LANGSTAFF: Again, if I can just pick up something for my own understanding of the subject -- again, obviously to correction if it proves later to be wrong -- but the date there of 10 December 1981, in reference to the NEJM may well be right but he also refers to the MMWR in the words that follow. My understanding, at the moment, is that in the MMWR in August 1982 -- sorry, August '81, 28 August, there were 70 cases of pneumocystis carinii pneumonia and Kaposi's sarcoma amongst gay men, which is reported

with a 40 per cent mortality rate. Now, if that's the

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	1	MR HILL: If we could just go over to the next page I'm
		sorry, just before we leave that, actually: Dr Kingdon
growth, perhaps of symptoms related to AIDS, even if	3	goes on to point out the NEJM is the most widely read
not necessarily diagnostic precisely of them.	4	medical journal in the US and every article is peer
MR HILL: Yes, sir. I'm trying to remember, I think if we	5	reviewed, so peer review was involved, and so that is
could have, please, on screen, Soumik, the next	6	another reason why the NEJM pricked his interest in
reference, which is paragraph 23 of the written	7	a way that the MMWR article may not have done as much.
presentation. That's CBLA0000011_005, at page 26.	8	If we could go over to the next page, please,
This is Dr Kingdon's statement from 1990 and, from	9	Soumik.
memory, I think that he comments on this.	10	At paragraph 75, we see Dr Kingdon, this, as
If we could just have the previous page. This	11	I say, from this draft statement from 1990. His
is electronic page 25 and it's paragraph 73. This	12	evidence here is consistent with that memorandum that
says yes:	13	we've just read, that in July 1982, the first reports
"Although the diseases had been regularly	14	of cases in people with haemophilia appeared in the
reported in the MMWR since June 1981, it did not	15	MMWR and he says, and I quote:
receive particular attention from the scientific and	16	"This report crystallised the concern that
medical communities until the articles appeared in the	17	haemophiliacs may develop AIDS and raised a question
NEJM."	18	of whether the diseases may be blood borne. There was
SIR BRIAN LANGSTAFF: So that explains it: it was there to	19	however still much controversy about the disease and
be seen, but wasn't necessarily picked up?	20	its causes and modes of transmission."
MR HILL: Yes, and at that time the link to blood and	21	He goes on to explain why there was controversy
blood products wasn't as pronounced as it came to be	22	about and about the fact that patients had used
·	23	a mixture of blood products and an issue therefore
	24	arose about which, if any, contained the causative
SIR BRIAN LANGSTAFF: Yes.	25	agent.
21		22
60-1		ta ta
	MR HILL: Yes, sir. I'm trying to remember, I think if we could have, please, on screen, Soumik, the next reference, which is paragraph 23 of the written presentation. That's CBLA0000011_005, at page 26. This is Dr Kingdon's statement from 1990 and, from memory, I think that he comments on this. If we could just have the previous page. This is electronic page 25 and it's paragraph 73. This says yes: "Although the diseases had been regularly reported in the MMWR since June 1981, it did not receive particular attention from the scientific and medical communities until the articles appeared in the NEJM." SIR BRIAN LANGSTAFF: So that explains it: it was there to be seen, but wasn't necessarily picked up? MR HILL: Yes, and at that time the link to blood and blood products wasn't as pronounced as it came to be from July 1982, with the cases reported in people with haemophilia.	MMWR, if it was read, to the growth, the exponential growth, perhaps of symptoms related to AIDS, even if not necessarily diagnostic precisely of them. MR HILL: Yes, sir. I'm trying to remember, I think if we could have, please, on screen, Soumik, the next reference, which is paragraph 23 of the written presentation. That's CBLA0000011_005, at page 26. This is Dr Kingdon's statement from 1990 and, from memory, I think that he comments on this. If we could just have the previous page. This is electronic page 25 and it's paragraph 73. This says yes: "Although the diseases had been regularly reported in the MMWR since June 1981, it did not receive particular attention from the scientific and medical communities until the articles appeared in the MEJM." SIR BRIAN LANGSTAFF: So that explains it: it was there to be seen, but wasn't necessarily picked up? MR HILL: Yes, and at that time the link to blood and blood products wasn't as pronounced as it came to be from July 1982, with the cases reported in people with haemophilia. SIR BRIAN LANGSTAFF: Yes.

So, although there was an open debate, it is Dr Kingdon's evidence from 1990, supported by the memorandum from 1983, and the other documents that we have looked at, that, as of July 1982, fractionators were on notice that the CDC had these concerns.

From a UK perspective, paragraph 24 of the written submission, the written presentation, we can see that in July 1982 some information was getting back to the DHSS about this, although it was in a slightly garbled form at that stage.

SIR BRIAN LANGSTAFF: Well, I think the chronology from the UK -- just to intersect, I think the first reported case, or it may be death, I don't know, but case of AIDS in the UK, was in December of 1981, and it was certainly in July '82 that Terrence Higgins died

MR HILL: Yes. I should have made clear that in
 July 1982, there was a knowledge of AIDS beforehand.
 July 1982, I'm talking specifically about a knowledge
 about AIDS in people with haemophilia.

SIR BRIAN LANGSTAFF: Yes. The question here is the link
 with those who suffered from haemophilia.

MR HILL: Yes, yes, and that's the MMWR publication and the NHF alert and the FDA alert.

SIR BRIAN LANGSTAFF: But it goes wider than that because

it must be also a link, potentially, to those who have transfusions of blood.

3 MR HILL: Yes.

SIR BRIAN LANGSTAFF: If it's blood borne, then it will come in however one may get blood passed from one person to another or whether it's with a needle or a transfusion or a blood product.

MR HILL: Yes. In Dr Meyer's directive of July 1982 he talks about, and I quote:

"... transmission through blood products."

11 SIR BRIAN LANGSTAFF: Yes.

MR HILL: That was also a phrase that was used by the NHF, so there is an awareness at that time that it affects both. Indeed, as we've seen from Dr Kingdon's statement, one of the causes of uncertainty in his mind at that time, according to his 1990 evidence, was the fact that the people who had received -- the people who had developed AIDS who had haemophilia had received a range of blood and blood products, and they weren't sure which part, if any, were involved.

So, yes, it absolutely applies to people who were having transfusions as well, although, of course, as we will see, the risk of a transmission in a transfusion is lower than that in a blood product because of the way in which plasma was pooled for

24 (6) Pages 21 - 24

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1	blood products.	1	Hemophilia Foundation, American National Red Cross,
2	That, of course, not necessarily known at that	2	various blood banking organizations, National Gay Task
3	time.	3	Force"
4	27 July 1982 saw the first meeting, an open	4	It's relevant to note here, sir, that this was
5	meeting, which took place between relevant groups.	5	a lobbying organisation for gay rights in the United
6	I'm going to ask if we could bring up, please,	6	States, who were heavily involved in the meetings at
7	JREE0000019. This is the first meeting with groups	7	this time:
8	between representatives of the Government and it's	8	" New York City Health Department, and the
9	page 280, Soumik.	9	New York Inter-Hospital Study Group on [AIDS] and
10	It's a meeting, the first meeting between	10	Kaposi's Sarcoma", New York being a particular centre
11	government agencies and interested bodies who were	11	for high instance of AIDS.
12	connected with blood and blood products. It was	12	We know from another source, which is cited in
13	an open meeting, and it was formally a meeting of the	13	the written presentation, that Dr Evatt attended, as
14	Public Health Service Committee on "Opportunistic	14	did Dr Meyer on the Government side. For the
15	Infections in Patients with Haemophilia". This is the	15	fractionators, Dr Mike Rodell attended. Dr Rodell at
16	formal record of it. We can see from the first	16	that time was still with Hyland, he would later move
17	paragraph it says:	17	to Armour, but he was there on behalf of the Plasma
18	"The meeting on July 27, 1982, [took place] from	18	Manufacturers Association, the trade body. He
19	8.30 am to 4.30 pm [and it] was held to consider the	19	reported back to other members and other fractionators
20	significance of the occurrence of opportunistic	20	after the meeting.
21	infections with Pneumocystis carinii pneumonia	21	If we move down to section II, "Aspects of
22	(PCP) in three patients with haemophilia."	22	Discussion", I'll read through this, occasionally
23	So the three patients that the CDC reported:	23	pointing out some features that we learned from the
24	"[The] Invited participants included	24	other documents. The record says, and I quote:
25	representatives of the CDC, FDA, NIH, National	25	"AIDS (and the sequelae of [Kaposi's sarcoma]
	25		26
4		4	
1	and [opportunistic infections]) are occurring in	1	from these precipitates called antihemophilic factor
2 3	several populations homosexual men, recent Haitian	2	or Factor VIII. Such therapy has allowed the
4	entrants and IV [intravenous] drug abusers. The	3	development of home treatment regimens which permit
5	possibility exists that it is occurring in patients	4	patients to live a more normal life, including sharing
	with hemophilia. "If the PCP observed in three patients with	5	educational and vocational opportunities and pursuits
6 7	·	6 7	with the rest of the population. The number of days
8	hemophilia represents the same process as seen in		of hospitalization annually has decreased markedly for hemophilia patients on home treatment programs.
9	other groups with AIDS, then a possible mode of	8 9	
-	transmission is via blood products, in this case	_	Hemorrhage (spontaneous and traumatic) remains a major
10	Factor VIII concentrate. This finding would	10	cause of death in hemophilia patients."
11	strengthen the existing hypothesis that AIDS is caused	11	I just pause there to note that from another
12	by a transmissible agent."	12	source, Dr Rodell's note of the meeting, we know that
13	C talked about other unusual disorders among	13	this information was given to the meeting by Dr Louis
14 15	haemophilia patients, which have been mentioned, but	14 15	Aledort, a leading haemophilia clinician who was
15 16	which were had not been studied sufficiently to	15 16	connected to the National Hemophilia Foundation and
16 17	establish a relationship with AIDS.	16 17	sat on the Medical and Scientific Advisory Committee.
17 10	Point D, and I quote:	17	I should also note that from Dr Rodell's note we
18 10	"There are 11,000 to 15,000 persons with	18 10	know that it was Dr Evatt and Dr Curran from the CDC
19	hemophilia in the United States with varying severity	19	who presented the data about the infections in people
20	of condition. The morbidity and mortality from	20	with haemophilia at that meeting.
21	hemophilia, as well as the lifestyle of hemophilia	21	Returning to the note, paragraph E:
22	patients has changed considerably over the past	22	"Almost all patients regularly receiving
23	10 years. These patients are treated with either	23	Factor VIII or cryoprecipitate develop hepatitis B and
24 25	a product derived from fresh frozen plasma (cryoprecipitate) or a protein concentrate prepared	24 25	non-A non-B infections. These products have been shown to transmit these infections. Because of the
			Solowo do dausono dese infections. Recallse of the

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freedom and reduction of suffering permitted hemophilia patients by Factor VIII concentrate, the product's benefits are perceived by patients to vastly outweigh currently known risks.

"The Factor VIII normally present in fresh plasma is heat labile and inactivated by many types of chemical or physical treatment. For this reason, the

plasma is heat labile and inactivated by many types of chemical or physical treatment. For this reason, the techniques developed for the production of Factor VIII concentrate from fresh plasma are known to have little effect on hepatitis viruses. There are five commercial producers of Factor VIII concentrate. Lots of Factor VIII concentrate are prepared from plasma pooled from 1,000-5,000 donors. Donors come from many parts of society. Most material is pooled from paid donors in plasmapheresis centres. Hemophilia patients use large amounts of Factor VIII (40,000 to over 65,000 factor units per year) from multiple preparations with subsequent potential exposure to material derived from thousands of donors.

"The occurrence of PCP in three patients with hemophilia is disturbing, particularly since there is no previous evidence that this infection is common in hemophilia patients. The two patients who had immunologic studies performed demonstrated a T-cell abnormality similar to that among other patients in

other high-risk groups with AIDS/KS. There is no known intrinsic immune disorder in hemophilia patients that would permit or promote such opportunistic infections."

We take it from Dr Rodell's note that that information is coming from Dr Evatt and Dr Curran, and as we can see, points towards the finding or a working hypothesis that the condition which is being observed in people with haemophilia is the same condition that is being observed in the other risk groups of intravenous drug abusers, gay men, patients, and is AIDS.

The conclusions of the meeting were set out in the following way:

"1. The pathological process should be termed Acquired Immune Deficiency Syndrome ..."

So this is an agreement that they're going to call this AIDS and that is something that Dr Evatt welcomes from this meeting.

"Kaposi's Sarcoma and various opportunistic infections are sequelae of the AIDS state."

The CDC will go on to form a definition of what amounts to AIDS.

The second conclusion:

"2. AIDS has characteristics which suggests

an infectious etiology.

"3. There is an increased risk of AIDS for homosexual men, [intravenous] drug abusers, and among Haitians who have recently entered the United States. The recent occurrence of PCP in three patients with hemophilia raises the question whether the underlying immunodeficiency seen in these patients has the same etiology as among other groups with PCP. High priority should be given to obtaining information that will answer this question.

"4. There is need to determine if certain blood products, particularly Factor VIII are risk factors for AIDS."

SIR BRIAN LANGSTAFF: So just summarising for a moment, is it a fair summary to say that the working hypothesis, the working assumption, is that AIDS is caused by an infectious agent? The question, which is posed by the case of the three haemophiliacs who were found to be suffering from AIDS, is whether the AIDS in them was caused by the same cause as the cause of the AIDS in others.

MR HILL: Yes, that is a fair summary of the consensus view at the meeting. It doesn't mean that everybody shared that view, some were more persuaded, that there was a link between people with haemophilia and AIDS,

and some were less persuaded even that AIDS was caused by an infectious agent. But the consensus view of the meeting was as you have just summarised there, sir, yes.

5 SIR BRIAN LANGSTAFF: Thank you.

MR HILL: The meeting made five recommendations, I won't go through those in detail, but they included an active surveillance system, detailed laboratory studies, an urgent need to determine practical techniques to decrease or eliminate the infectious risks from Factor VIII, a call for broad input into the areas, including from gay community groups, haemophilia groups, and so forth, and the fifth was the eternal concern over adequacy of funding for all this work.

Dr Evatt said that the second positive that he took from the meeting was that the CDC was therefore encouraged to continue in its work of tracking and surveilling the development of AIDS, particularly in the haemophilia community.

But, overall, Dr Evatt was disappointed by that meeting. We can see what he said about it in his Tragic History, if we could have CVHB0000042, at pages 4 to 5. What we have just been discussing, sir, was the consensus view of the meeting, and this is want

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		1	
1	Dr Evatt, looking back on it, thought. If we could	1	three groups, and hepatitis B core antigen, a
2	pick it up from the final paragraph on the second	2	blood-borne infectious agent, present in all of the
3	column, beginning "It was a long day", just underneath	3	groups. Dr Evatt was saying that we'll go on to
4	the heading "Confronting 'existing wisdom'", you can	4	exactly what he says in his words, and I quote:
5	see the second paragraph down, beginning "It was	5	"Only the high risk for blood-borne infections
6	a long day". Thank you.	6	could explain a risk common to all four groups. But,
7	He said this, and I quote:	7	rather than expressing alarm at a possible blood-borne
8	"It was a long day. Detailed histories of the	8	infection and suggesting ways to reduce a blood-borne
9	hemophilia cases were systematically presented,	9	risk, the audience expressed an almost universal
10	followed by data from other risk groups and comparison	10	reluctance to act. The scientific community had yet
11	of hypothetical risks posed by various etiological	11	to see 'published evidence that the syndrome was
12	theories to each risk group."	12	indeed an infectious disease' let alone blood borne
13	If we can expand, Soumik, and I'm just going to	13	and sexually transmitted. Homosexuals were major
14	show you that table that he refers to here. The	14	blood donors in the large cities on the east and west
15	bottom of the first column, table 1. So the four	15	coasts. It was thought that singling out homosexuals
16	potential risk groups, drug users, Haitians, people	16	for exclusion would unnecessarily stigmatize them
17	with haemophilia and homosexuals, gay men, those are	17	without evidence that they were indeed transmitting
18	the four population groups there.	18	the disease. The blood industry, threatened by losing
19	The different columns show the different ideas	19	a large donor pool, strongly support the position of
20	of what could be causing AIDS in this group. The	20	the gay groups on this issue"
21	first is anti-sperm antibodies, which might be present	21	If we could just highlight the first paragraph
22	in homosexuals, but not in the other three groups.	22	there. Thank you. Dr Evatt quotes people at the
23	Amyl nitrate is a type of drug associated with	23	meeting says:
24	the gay community, amyl nitrate inhalants, again,	24	" 'three hemophilia patients with the
25	present in the gay community, but not in the other	25	syndrome did not mean that they should spend millions
	33		34

of dollars' changing recruitment and screening practices. The hemophilia groups expressed concerns that the data showing immune suppression in hemophilic patients could have reflected the effects of prolonged use of blood products and did not necessarily mean that they had the new syndrome. They also feared the stigma of having a disease associated with homosexual patients and were concerned that reducing the use of clotting factor concentrates would bring back old issues of deformities and early death, the fate of hemophilic patients before concentrate treatment. The FDA, which had regulatory authority over the blood industry, had not yet accepted the collection of disorders related to immune deficiency as a single disease, and was also skeptical that hemophilic patients represented another risk group. Thus, no consensus was reached concerning blood donors."

He goes on to mention the two important steps that were accomplished, namely the naming of the disease as AIDS and the fact that the CDC was encouraged to continue its work.

So a rather different tone in Dr Evatt's recollection than the collegiate tone of the note that formally recorded the meeting.

A number of themes and tensions can be discerned

from those two records. The first is the tension between, on the one hand, the potential gravity of the problem and resulting calls for immediate action and, on the other hand, the scientific and medical uncertainties involved and the resulting calls for further information and research before firm decisions were taken.

The second theme is the association between the suspected risk of AIDS and the known risk of hepatitis for people with haemophilia.

The third is the reliance on plasma from paid donors from, as it was put euphemistically in the formal record, "many parts of society".

The fourth theme is the emphasis placed on the beneficial effects of the use of factor concentrates and consequent concerns about the risk to the supply of these products.

The fifth theme is the approach to the way in which the conclusion and recommendations of the meeting were expressed, and indeed the way that the meeting was conducted. Instead of identifying the opinions of individuals and the differences of opinion between those individuals, the note was drafted to record the view of the meeting as a whole and, inevitably, this gives rise to a broader and less

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specific set of observations, a more consensual view.	1	Scepticism on that point was also expressed by
In his note of the meeting I won't take you	2	other representatives of whole blood groups.
to it, sir, but we know that Dr Rodell produced one	3	According to Dr Rodell, he spoke privately to
and I summarise it at paragraphs 33 onwards of the	4	Dr Dennis Donohue, who was the director of the
written presentation he wrote that he provided	5	Division of Blood and Blood Products at the FDA.
information in response to questions at the meeting.	6	Dr Donohue said that his division could and
Presumably that included the information about	7	I quote here from Dr Rodell's note:
the donor pools that we saw from the other note.	8	" find itself in the position of having to
Among the information that he gave to the	9	make a politically expedient decision to disapprove
meeting, according to his note, was information about	10	the operation of plasmapheresis centers specifically
the existence of six to eight plasma collection	11	intended to collect anti-HBs plasma [so that's plasma
centres in prisons. He also said that about	12	rich in hepatitis antibodies] from homosexuals."
2 per cent of the total plasma collected in	13	So Dr Rodell is referring to the FDA as seeing
the country came from those prison sources.	14	that as a "politically expedient decision", whereas
He also said that other centres were located	15	I'm sure that the CDC, or at least Dr Evatt, would
throughout the country, including in inner cities and	16	have put it in rather different terms.
university locations.	17	As we have heard, Dr Donohue did approach
According to Dr Rodell's note, Dr Sandler of the	18	fractionators in August 1982, so the following month,
American Red Cross said at the meeting that:	19	in an effort to persuade them voluntarily to exclude
" the CDC had not yet proved that AIDS is	20	plasma obtained from donors, typically gay men, who
transmissible by blood or blood products and that no	21	had been recruited because of the likeliness that they
donor population should be implicated at this time."	22	would have antibodies to hepatitis B.
So that was the voice of somebody from	23	I pause there to make the point that this was an
the American Red Cross, one of the old blood	24	attempt to persuade fractionators to take voluntary
collection organisations.	25	action. The FDA did have regulatory powers, and those
37		38
	In his note of the meeting I won't take you to it, sir, but we know that Dr Rodell produced one and I summarise it at paragraphs 33 onwards of the written presentation he wrote that he provided information in response to questions at the meeting. Presumably that included the information about the donor pools that we saw from the other note. Among the information that he gave to the meeting, according to his note, was information about the existence of six to eight plasma collection centres in prisons. He also said that about 2 per cent of the total plasma collected in the country came from those prison sources. He also said that other centres were located throughout the country, including in inner cities and university locations. According to Dr Rodell's note, Dr Sandler of the American Red Cross said at the meeting that: " the CDC had not yet proved that AIDS is transmissible by blood or blood products and that no donor population should be implicated at this time." So that was the voice of somebody from the American Red Cross, one of the old blood collection organisations.	In his note of the meeting I won't take you to it, sir, but we know that Dr Rodell produced one and I summarise it at paragraphs 33 onwards of the written presentation he wrote that he provided information in response to questions at the meeting. Presumably that included the information about the donor pools that we saw from the other note. Among the information that he gave to the meeting, according to his note, was information about the existence of six to eight plasma collection centres in prisons. He also said that about 2 per cent of the total plasma collected in the country came from those prison sources. He also said that other centres were located throughout the country, including in inner cities and university locations. According to Dr Rodell's note, Dr Sandler of the American Red Cross said at the meeting that: " the CDC had not yet proved that AIDS is transmissible by blood or blood products and that no donor population should be implicated at this time." So that was the voice of somebody from 23 the American Red Cross, one of the old blood collection organisations.

are set out in some of the reports, particularly the report of the Institute of Medicine, to which I refer in the presentation, but the feeling was that statutory powers would take a long time to implement and could get caught up in bureaucratic wrangling, and indeed legal wrangling, whereas if you can persuade a company to do something voluntarily then that will take effect more quickly. But the FDA did have powers to compel as well as powers to persuade.

I'm not going to go back over the evidence that we've already heard about the response of the companies to Dr Donohue. When we looked at it before it was to try to understand what was taking place before 1982 and 1983. Here, we're looking at what happens once that approach was made by Dr Donohue.

In summary, Cutter agreed to suspend collection from such centres, although it was noted in an internal document, which is cited at paragraph 36 of the written presentation, that they wouldn't be fractionating any of that material into factor VIII and IX for sale anyway.

Alpha also agreed to voluntary suspension until further notice.

The documentation suggests that Hyland itself didn't fractionate such plasma into their own

products, although they may have sold it to Alpha.

Interestingly, in an internal Cutter memorandum, Dr Rodell, of Hyland, is said to have, and I quote:

"... expressed great surprise that we [that is Cutter] would even consider fractionating this material into factors VIII and IX (anything other than HIBG) because of the history of hepatitis problem."

So we can see there differences between the companies on how they approached this matter in the past, but all agreeing to do what Dr Donohue had asked them to do. Armour's position is not clear from the documents obtained by the Inquiry.

As we have seen, Dr Rodell had referred to this as being a decision that was taken for political rather than scientific considerations, and at paragraph 37 of the written presentation we can see that that was also the view of some others, including Dr Hershberger of Cutter. Dr Hershberger, in an internal memorandum recording his conversation with Dr Donohue, said that Dr Donohue, and I quote:

"... feels that the hold will not be necessary for more than two or three months unless more donors develop AIDS."

If accurate, that shows Dr Donohue's thinking at

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1	the time within the he was within the FDA, about	1	MR HILL: It could be, sir. The difficulty is trying to
2	the threat, the prediction of it not being necessary	2	interpret what one word or a sentence in a memorandum,
3	for more than two or three months unless there were	3	which is reporting somebody else says
4	further cases that developed.	4	SIR BRIAN LANGSTAFF: Yes. Absolutely.
5	SIR BRIAN LANGSTAFF: It's specifically cases amongst	5	MR HILL: What is clear from that and from other
6	donors	6	correspondence is that these commitments were
7	MR HILL: Yes.	7	prospective, they were about what was going to happen
8	SIR BRIAN LANGSTAFF: so it's looking at what's going	8	in the future, and no comment was made on what was
9	into the product at the base level, as opposed to	9	going to be done about existing stocks of plasma that
10	what's coming out at the recipient's end.	10	had been or were being processed into blood products
11	MR HILL: The only caveat I would to add to that is that	11	at that time.
12	it is a brief reference in a memorandum passing on	12	Counsel to the Inquiry have seen no evidence
13	information. But the logic would clearly mean if	13	that efforts were made to withdraw or withhold
14	you are putting this suspension in place because of	14	factor concentrates that had been produced from such
15	your concerns about three cases of potential AIDS in	15	plasma. That's not to say that such evidence does not
16	people with haemophilia, if more cases in people with	16	exist but it's certainly not clear, on the face of
17	haemophilia came forward, then the logic would surely	17	these documents, that there was an intention to take
18	apply that the suspension must continue.	18	those kind of steps.
19	SIR BRIAN LANGSTAFF: Well, it depends what he meant. If	19	What we can see, though, is a document from
20	he is talking about donors, he is talking about people	20	12 August 1982, in which the FDA Bureau of Biologics
21	whose blood or plasma is being taken, as opposed to	21	have requested that Cutter quarantine four units of
22	those who are receiving it. And equally the logic	22	plasma from a donor hospitalised for AIDS.
23	might be: there are a number of people who are known	23	If we could have on screen, please, Soumik,
24	to have AIDS; if a greater number come forward to	24	CGRA0000652.
25	donate then there may be a bigger risk.	25	This is an internal Cutter memorandum written by
	41		42
1	Dr Hershberger. It's actually the final paragraph	1	Not "until we know that AIDS is transmitted".
2	that walte interested in far this number	'	hut

that we're interested in for this purpose.

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What Dr Hershberger wrote is that:

"We were extremely fortunate that we were able to quarantine the 4 units of Source Plasma ... before they were pooled. Had they been pooled the [Bureau of Biologics] might have found it politically expedient to make hard line decisions regarding the fate of the products made from the pool. This kind of risk will continue for some time until there is solid data to prove that AIDS is not transmitted by blood products. Meanwhile we should try to help the BoB develop a rational policy for dealing with AIDS that will withstand political panic."

This is, sir, one of the earlier hints at the issue about recalling products that will become increasingly important as we move through the months and years ahead.

SIR BRIAN LANGSTAFF: Just before we leave this document, the way he puts the matter in the second-last sentence -- you highlighted it, I think, the emphasis you gave, but the transcript may not pick that up entirely. It's:

24 "This kind of risk will continue for some 25 time ..."

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"... until there is ... data to prove that [it] is not transmitted ..."

MR HILL: Yes, sir. 5

SIR BRIAN LANGSTAFF: So it puts it the other way around.

In other words, if there is known to be a risk that it might happen, you need to disprove it before you stop taking preventative action, rather than you need to

9 10 prove it before you start taking preventative action.

11 MR HILL: He does, sir, yes.

12 SIR BRIAN LANGSTAFF: So this is -- if one goes back to 13 the line "no conclusive proof", for instance, this is 14 the opposite. So, no conclusive proof that it isn't

15 the cause.

16 MR HILL: Yes. Yes, sir. No conclusive -- he's putting the burden on proving the negative. 17

18 SIR BRIAN LANGSTAFF: Yes. Yes.

19 MR HILL: You will have also seen, sir, in that quotation, 20 several references to "political panic" and 21 "politically expedient" decisions. The suggestion 22 being that such measures are being driven not by

23 science and data, but by political pressure.

24 Soumik, thank you, I think we can take that down

now.

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1	That was 12 August. Just before the break	1	The minutes also record there was a discussion
2	I mention a couple of events from September 1982. The	2	of the issue of AIDS, at the end of which the
3	first is that there was a meeting that took place on	3	Committee concluded, and I quote:
4	9 September 1982 to discuss technical issues about	4	" there are insufficient data to suggest that
5	heat treatment of Factor VIII products. It's	5	any immediate action [be taken] with licenced blood
6	notable and this is at paragraph 40 that that	6	products."
7	meeting discusses the heat treatment of products in	7	That is 23 and 24 September 1982, and relevant
8	respect of inactivation of hepatitis viruses. At	8	to note that Armour, Hyland, Cutter and Alpha,
9	least in the official record of the meeting there is	9	I think, were all represented at that meeting.
10	no reference to the relevance of heat treatment to	10	I wonder, sir, if that is a convenient point
11	AIDS at that time. So the focus of heat treatment in	11	because I'm about to move on to the further
12	September 1982 is still very much on hepatitis.	12	investigations that were undertaken by the CDC in the
13	The second meeting to which I make reference in	13	autumn of 1982.
14	September 1982 occurred on 23 and 24 September. It	14	SIR BRIAN LANGSTAFF: Yes, it is. We'll take a break now
15	was a meeting of the Blood Products Advisory	15	until quarter to 12. Quarter to 12.
16	Committee, summarised at paragraph 41 of the written	16	(11.13 am)
17	presentation. There is a brief note on this in	17	(A short break)
18	a document which was prepared for a Congressional	18	(11.47 am)
19	investigation a few years later, and it said that that	19	MR HILL: Before returning to the chronological account,
20	meeting discussed, and I quote:	20	there is something I should make clear. I mentioned
21	" non-specific methods of detecting	21	earlier that counsel to the Inquiry didn't have
22	infectious agents in donated blood."	22	a clear understanding of Armour's position on the
23	Which would seem to be a reference to surrogate	23	question of targeting gay donors for plasma rich in
24	testing. That is one of the themes that will grow in	24	hepatitis antibodies. We understand that this may be
25	importance as time passes.	25	because Armour never never had any such centres,
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and it's very difficult then to prove a negative because there are no documents to show that. So it's something that we will continue to look into, but that may be one of the explanations as to why there is no documentation, or at least no documentation that we have seen.

Returning then to the autumn of 1982, I'm going to read from Dr Evatt's Tragic History about the CDC's work at that time.

Soumik, can we have on screen please, CVHB0000042, and electronic page 5.

If we could highlight the third paragraph down on the left-hand side, beginning "In the fall of 1982."

Dr Evatt wrote this:

"In the fall of 1982, we identified four additional and one probable case of AIDS in hemophilic patients, two of whom were children. In addition, we investigated and identified AIDS in a number of individuals who had received transfusions. Invoking donor confidentiality, some blood banks severely hampered investigations by refusing to share donor lists of persons who contributed blood given to recipients who later developed AIDS. They feared we would unduly alarm or embarrass donors with sexual

questions, thereby discouraging donations. Without linking an AIDS patient's donation to the recipient of a blood component, it was impossible to show transmission. Also, transfused patients often received transfusions for other underlying illnesses (ie cancer surgery), conditions that were possible sources of secondary immunodeficiency. As these cases accumulated, the author routinely provided briefings to the blood industry, FDA panels and [National Institutes of Health] conferences of blood banking experts, who seemed only to request more patients and proof, without yielding on recommendations for changes in blood policy. Frustration and impatience grew at the CDC."

I pause there to note, sir, that the primary subject of that frustration of the CDC at this time was blood banks, not necessarily the fractionators, although Dr Evatt does refer to the briefings that he gave to the blood industry more generally, but we'll see shortly how some of the fractionators responded.

In October 1982, the National Hemophilia
Foundation resolved that no plasma should be sourced
from gay men, intravenous drug users, or people
from Haiti. The response of the pharmaceutical
companies to that recommendation is something that we

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will look at in due course. The recommendation was go back and look at the MMWR reports at that time and made in October 1982, paragraph 44 of the written see if we can discern that. SIR BRIAN LANGSTAFF: The reason I ask is that it may presentation. Relating things again to what was going on in demonstrate something of the perspicacity of Dr Craske, if indeed he had spoken at some time before the United Kingdom at that time, it's relevant to note that it was at around then that Dr Craske produced September, which it would be if Dr Evatt is talking his initial report on AIDS, and in the covering letter about September, for instance, in his recollection, that accompanied that report he said that he had and drawn the conclusions that he did, which he then spoken to somebody he described as the "project leader presented in September to those who were listening. of the team looking into the epidemiology of the MR HILL: We will look into that, sir. disease", at the CDC, which is a reference probably SIR BRIAN LANGSTAFF: Thank you. In other words, it might either to Dr Evatt or Dr Curran. have been there to be seen at an earlier stage than The next meeting that I will draw your attention September. to, sir, took place on 3 and 4 December 1982. It was MR HILL: We will conduct some further studies on that. a meeting of the Blood Policy Advisory Committee. SIR BRIAN LANGSTAFF: Thanks. A large number of items were discussed there, among MR HILL: Perhaps, sir, as we're on the topic, perhaps them, many of them not to do with AIDS or --I can read, just from paragraph 45 of the written SIR BRIAN LANGSTAFF: Just on that last -- what you presentation, a section from what Dr Craske was saying recited, paragraph 45 in the presentation, do we know in the autumn. I think that this is from his covering when in the autumn Dr Evatt had recalled the CDC letter rather than the report. What he said, and identifying four additional cases, and one probable I quote, is this: case of AIDS? Because that would make seven, and one "The hypothesis at present being used to explain probable case, whereas Craske was talking about the acquisition of these cases ... is that one or two five people. patients in the incubation period of the disease MR HILL: The short answer is that I don't know. We can donated plasma which has since been used to prepare

Factor VIII or IX concentrates. All of the haemophiliacs who have had the disease have had severe coagulation defects requiring regular treatment with Factor VIII. The likelihood is, therefore, that other cases will be identified amongst severe haemophiliacs, though probably at a low prevalence."

So that is what Dr Craske was writing in his covering letter.

Moving on to the meeting of the Blood Policy Advisory Committee on 3 and 4 December 1982. As I say, it discussed a range of topics, many not connected with AIDS or matters of relevance to this Inquiry, but some of the things that they did discuss were methods for decreasing the infectivity of Factor VIII and Factor IX concentrates in respect of hepatitis B, but it was noted at the meeting that that might also be of some interest because of the occurrence of AIDS in some patients with haemophilia.

They also discussed the risk groups for hepatitis B and donors, including intravenous drug users and gay men. And they also discussed a study showing lower T4/T8 cell ratios in patients using factor concentrates when compared to those using cryoprecipitate, and it was noted that similar changes have been found in patients with AIDS.

At that meeting, Dr Evatt reported on the CDC investigations, and he said that the epidemic was growing at an almost exponential rate, doubling every six months. He expressed a concern that transfusion cases, and I quote him:

So going back, sir, to the point that you raised earlier, Dr Evatt is clearly drawing attention to the fact that this is a matter might affect patients receiving whole blood transfusions as well as blood products.

He told the meeting that eight people with haemophilia had been reported with AIDS, only three of whom were still alive. Five transfusion cases had been reported, including a child who had received a transfusion at birth. I take that to be a reference to the San Francisco infant case, which we'll come on to shortly, a case of some importance because it provided what Dr Evatt describes as an "unequivocal transfusion case"; that's the word that he uses in his Tragic History. So it's a way of demonstrating that his hypothesis that the transmissible agent is passed through blood, which had been questioned by many of the blood banking industry. He saw the case of the

1	San Francisco infant as being an unequivocal	1	symptomatic, followed by a period symptomatic but not
2	transfusion case.	2	yet full-blown AIDS, followed by full-blown AIDS?
3	Dr Evatt also commented on the CDC's studies of	3	MR HILL: That is my reading of it. I think that's the
4	the incubation period of AIDS, and he looked at	4	least strained reading of the quotation, I would
5	35 cases where there had been person to person	5	suggest: four to seven months before the prodromal
6	transmission, and in those cases the incubation period	6	period and then four to seven months afterwards to
7	he described as being:	7	AIDS.
8	" about 4 to 7 months with a prodrome before	8	SIR BRIAN LANGSTAFF: Unless there is a better reading,
9	diagnosis of about the same period. The	9	that's what I take from it. The only concern that
10	epidemiological pattern seems to be similar to that of	10	I have is that it may be informed by a bit of
11	hepatitis B."	11	retrospectivity, knowing that, indeed, AIDS turned out
12	Now I'm afraid I'm not able to discern precisely	12	to have a very lengthy incubation period, including
13	what Dr Evatt meant about the four to seven months,	13	the difference between the symptomatic and
14	whether he's saying that it's four to seven months	14	asymptomatic.
15	without anything, and then four to seven months with	15	MR HILL: I think that quotation is actually taken from
16	some symptoms before what was termed at the time	16	the contemporaneous minutes, rather than from
17	"full-blown AIDS" developed, or whether or not it's	17	Dr Evatt's Tragic History. So that is what he was
18	a single four to seven-month period. This is at	18	telling the Blood Policy Advisory Committee at the
19	paragraph 48 of	19	time.
20	SIR BRIAN LANGSTAFF: Well, if it's an incubation period,	20	SIR BRIAN LANGSTAFF: Yes.
21	then presumably it's before full-blown AIDS, but it	21	MR HILL: So it would seem to be free of that element of
22	may be a difference between the first symptoms	22	retrospectivity, but, as we know, the further evidence
23	recognisable as symptoms of the AIDS syndrome	23	comes to light about how long the incubation period
24	developing, and a period before that, after infection.	24	is.
25	In other words, the prodromal period, infected but not	25	SIR BRIAN LANGSTAFF: Yes.
	53		54

MR HILL: It's also relevant to note to that the cohort from which the CDC were drawing this information were people who had received person-to-person transmission of AIDS, rather than people who had received it through blood and blood products.

The Blood Policy Advisory Committee discussed some steps intended to reduce the risk of infection, including relying on cryoprecipitate and viral inactivation techniques, surrogate testing and excluding high risk donors. The meeting concluded, and I quote:

"... there was a sense of urgency because of the continuing spread of AIDS and because of its long incubation time."

Which goes back to the debate that we've just been having. However:

"The committee did not recommend any immediate changes in the biological regulations or regulatory activities at that time.

Again, it is relevant to note the distinction between action being taken on a voluntary basis and action which is being mandated by changes to regulations and regulatory activities.

On 9 December 1982, so five and six days after that meeting, the National Hemophilia Foundation

informed its members of four new cases of AIDS among people with haemophilia, and stated that, and I quote:

"... while there is insufficient data to directly link the spread of AIDS to concentrates, there is an increased concern that AIDS may be transmitted through blood products."

Interestingly, the NHF, as of 9 December 1982, also advised, and I quote:

"... patients and parents should be aware of the potential risks."

That's 9 December 1982.

On the same day, Dr Rodell, of Hyland, sent a letter to the NHF responding to its recommendations about excluding high risk donors. In the letter, Dr Rodell said, first, that Hyland had consistently sought to exclude all intravenous drug users by checking forearms for needle marks. Second, he said that the company had "within the past several months" made a commitment to withhold plasma obtained through targeted recruitment of gay donors.

That is a phrase that we looked and a letter that we looked at in September and October.

The third point that Hyland made was that in terms of seeking to determine the sexuality of donors, there were going to be difficulties involved in how

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1	you identify those donors, and he indicated in the	1	Cutter.
2	letter that the company would rely instead on donor	2	If we could start from the first paragraph,
3	education and donor self-exclusion. We'll come on to	3	we'll work our way down this page:
4	see how Hyland did that in the months that followed.	4	"Dr Donohue asked for an informal meeting with
5	He did say, however, that donors would be asked	5	four Blood Product Manufacturers following the PMA/FDA
6	directly about whether they had been residents in or	6	Liaison Committee Meeting on Friday to explore
7	visitors to Haiti. Dr Rodell also referred the NHF to	7	possible actions to minimize the risk of AIDS.
8	the difficulties that the fractionation companies had	8	Although the transmission of AIDS via blood products
9	in respect of plasma that they obtained from whole	9	(and specifically AHF) has not been conclusively
10	blood donations, recovered plasma. Again, that was	10	demonstrated, there is some evidence that a
11	something that we looked at in September and October,	11	possibility does exist. [Dr] Donohue wanted to know
12	but we will come back to it in the months that follow.	12	what we manufacturers could do immediately to minimize
13	On the following day, 10 December 1982, an	13	the risk of potential exposure."
14	informal meeting took place between representatives of	14	Can we have the next paragraph, please:
15	the FDA and the fractionators, and this had been	15	"Dr Donohue specifically asked if we could
16	convened at the request of Dr Donohue. We have	16	simply exclude high risk plasma taken from areas such
17	a memorandum of it by Dr Steven Ojala of Cutter. Many	17	as New York, San Francisco and Hollywood from AHF
18	of the memorandums that we're going to look at come	18	productions. Mike Rodell (Hyland) responded that he
19	from Dr Ojala, who made records of these meetings.	19	felt a more meaningful effort would be to attempt to
20	If we could bring it up on screen, please,	20	educate the high risk populations (homosexuals,
21	Soumik, it's CGRA0000425.	21	Haitians and drug users) and have them voluntarily
22	We can see at the top the date is	22	exclude themselves from the plasmapheresis programs.
23	13 December 1982, so reporting back three days later	23	Not everyone was convinced that a voluntary program
24	on the meeting that was held on the 10th. The	24	would be completely successful, but it would be
25	distribution list is a number of people from within	25	a first step. It was recommended that any educational
	57		58

programme be coordinated between the manufacturers. Rodell made it clear that they intended to specifically ask their donors if they are high risk (ie homosexuals or drug users). He maintained that public health risks overrode any concerns with discrimination. The consensus was that the education programme be formulated by a professional firm

experienced in this kind of presentation."

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I pause there, sir, to say that what Dr Rodell appears to be telling this meeting is that it's slightly firmer than the information that he gave in the letter to the NHF. It seems that, by this stage, Hyland were considering or intending to implement a policy where donors were asked directly whether or not they were gay, male donors were asked if they were

gay.
SIR BRIAN LANGSTAFF: There are marginal notes.
MR HILL: Yes, sir. I have struggled to decipher these,
and I don't know who made them. As we can see on the
bottom right-hand corner of this document, we can see
it's an exhibit from litigation. So we can't even be
sure that these notes were made by somebody within
Cutter. I'm afraid we simply don't know.

SIR BRIAN LANGSTAFF: Do we know from which side of the
 litigation the document comes?

1 MR HILL: I don't. I don't, I'm afraid. It will have

2 been disclosed -- to adopt the terminology from this

jurisdiction, it will be have been disclosed in the

4 litigation, which is why it became public.

5 SIR BRIAN LANGSTAFF: But it doesn't look as though it's

6 a litigation note, given the very last of the third of

those entries, which is a reference to John Hink,

8 isn't it --

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9 MR HILL: Yes, it is.

10 SIR BRIAN LANGSTAFF: -- and John Hink needing to do

11 something?

12 MR HILL: "This will be a problem ..."

13 SIR BRIAN LANGSTAFF: "... at Cutter ..."

14 MR HILL: "... at Cutter ..."

15 SIR BRIAN LANGSTAFF: "... John Hink will need to look at

16 the [percentage and] costs."

17 MR HILL: Yes. So that would certainly suggest that

18 it's -- well, I think it's overwhelmingly likely that

19 that means that the marginalia was made at the time.

20 I suppose it's theoretical that Mr Hink might have

21 been asked about that in the later litigation.

22 SIR BRIAN LANGSTAFF: I think that's the working

23 assumption.

24 MR HILL: Yes.

5 SIR BRIAN LANGSTAFF: If so, then probably is this, do you

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(15) Pages 57 - 60

1	think, a Cutter document or a Cutter annotation?	1	problem with this suggestion, but it was pointed out
2	MR HILL: I would have thought so. The memorandum is	2	that this was the source of our hyperimmunised donors.
3	circulated within Cutter and, certainly, that note	3	Donohue then suggested that we exclude this plasma
4	would seem to suggest that it's somebody within Cutter	4	from any AHF productions. It is my opinion that they
5	identifying, either for themselves or for others	5	will remain relatively non-negotiable on this point.
6	SIR BRIAN LANGSTAFF: In case it matters, the marginal	6	It was indicated that there has been no causes of AIDS
7	notes, the first is fairly clear, I think:	7	reported from prison, and Donohue responded that was
8	"To educate the high risk is good."	8	because of the etiology of the syndrome and
9	What about the second?	9	insufficient time had transpired."
10	MR HILL: "This makes" I think it says:	10	I pause there to note, as we've just discussed,
11	"This makes no sense"	11	this is a Cutter document, so when referring to how
12	SIR BRIAN LANGSTAFF: "Homosexual"?	12	the "other" manufacturers had no issue with this, we
13	MR HILL: Yes.	13	can see in this document and others that it was
14	SIR BRIAN LANGSTAFF: " [and] drug user who sells	14	a source of concern for Cutter.
15	plasma has no concern for others."	15	"The final item of discussion related to
16	MR HILL: Yes.	16	recovered plasma [that is, plasma taken from whole
17	SIR BRIAN LANGSTAFF: Yes, and this may be the working	17	blood donations]. Donohue pointed out that we would
18	assumption is that it's an internal Cutter document?	18	have distinctly less leverage over any voluntary
19	MR HILL: Yes.	19	reduction of high risk donors in recovered plasma. He
20	SIR BRIAN LANGSTAFF: Yes. Thank you.	20	said that he felt that we should consider very
21	MR HILL: Returning to the third paragraph down:	21	carefully if we should accept recovered plasma
22	"Donohue then asked if we were willing to	22	collected from high risk populations. (He indicated
23	exclude plasma collected at prisons because the	23	the Irwin Blood Bank specifically.)"
24	homosexual link, and because it constituted only 2% of	24	That is the Irwin Memorial Blood Bank in
25	collected plasma. The other manufacturers had no	25	San Francisco.
	61		62

Going over onto the following page, there's a record of a brief discussion about Fraction V, and then if we could expand the first paragraph, please, Soumik. I quote:

"I have the impression" -- so this is the second sentence in:

"I have the impression that while the agency is concerned about the question of AIDS, they are not going to overreact to the situation. Concerns have been expressed about the safety of 'paid' donors versus voluntary sources and there are those who are championing the return to single donor cryo. I think the Bureau will take a more studied and scientific approach until sufficient information is available."

That's where we'll leave that document, sir. If we could take it down, please, Soumik.

Relevant to note that the CDC were not present at that meeting; it was a meeting between the FDA, specifically Donohue, and the fractionators.

On the same day that that meeting took place, 10 December, the CDC published in MMWR the report relating to the San Francisco infant, a 20-month old child infected with AIDS. After the blood transfusion had taken place at birth and the incubation period was identified to be 18 months. The same report indicated

that three people with haemophilia, whose cases had been reported in July, had all died.

In his Tragic History, Dr Evatt says this about the -- specifically about the San Francisco case, but more generally about the point reached by 10 December:

"We" -- that's a reference to he in his colleagues the CDC:

"We were now convinced that in spite of the absence of an identified agent, the pattern of the epidemiological evidence was sufficient to implicate a blood-borne disease. This evidence can no longer be ignored. In our opinion urgent changes in blood policy were needed to reduce the risk."

That is his view as of 10 December 1982.

Turning to the response of one pharmaceutical company to the situation then pertaining. The company is Alpha. On 15 December 1982, Alpha's executive committee met for what was described as an AIDS meeting and there the committee decided on a number of steps. In essence, they put in place a new screening process, patients were to be given information leaflets -- sorry, not patients, donors, forgive me -- were to be given information leaflets. The donors would be encouraged to self exclude if they were in any of the three identified risk groups. Male donors

report indicated 25 any of the three identified risk 64

(16) Pages 61 - 64

	The Inf	ected Blood Inquiry	2 November 2021
1	would be asked directly if they had had sex with	1	If we could now go, please, to page 3. This is
2	another man, and if they answered yes, then they would	2	the second of those documents. I should say that the
3	be excluded.	3	first of them, the background memo, is summarised from
4	This new process was to be implemented in	4	paragraph 58 onwards of the written presentation, but
5	Alpha's own centres, and in centres with whom it had	5	I'm going to take you to the document that was given
6	contracted. So these were some of the independent	6	to donors.
7	plasmapheresis centres that provided plasma to Alpha.	7	It says, and I quote:
8	Alpha would also encourage whole blood centres	8	"Dear Donor:
9	to adopt these measures, and we will see from some	9	"Recently, the medical community has noted the
10	documents from a few months later that this caused	10	occurrence of a very serious disease known as Acquired
11	problems for Alpha because some of those with whom	11	Immune Deficiency Syndrome (AIDS). The Centers for
12	they were used to dealing were not prepared to do so,	12	Disease Control have documented an increasing number
13	and so the relationship between them broke down.	13	of cases of this disease across the country.
14	Alpha was the first of the fractionators to put	14	"As the name indicates, the disease seems to
15	in place these enhanced measures, and it did so from	15	disrupt the patient's immune system, that is, their
16	mid-December 1982. I'm just going to take you to	16	ability to fight off disease. Though very little is
17	a couple of the documents that show what was done and	17	known about the disease or about its cause, this
18	how it was phrased, and if we could have on screen,	18	disease has been fatal, as there is no known
19	please, Soumik, CGRA0000627. This is the covering	19	treatment.
20	note from Dave Gury at Alpha, and it refers to:	20	"It appears that the disease occurs more
21	" a series of urgent communications of AIDS.	21	frequently in certain groups of people which include
22	[They are] a background memo [to be sent to] centre	22	male homosexuals, Haitians, and drug abusers.
23	personnel a memo to be xeroxed [that's	23	"In past years, you have helped us help others
24	photocopied] and given to donors. Third, a memo to be	24	through your plasma donations. We are now faced with
25	given to AIDS deferred donors."	25	a situation in which only you can help us ensure
	65		66
1	a safe product to those who lives depend on it.	1	make it clear that, in addition to providing the donor
2	Because of our shared goal of producing a continuing	2	with that document, a new protocol was put in place,
3	safe supply of plasma products for use worldwide,	3	such that the medical receptionist at any Alpha centre
4	Alpha has committed its resources to reducing the	4	would say directly to a male donor, "Have you ever had
5	possibility that this disease might be transmitted	5	sexual contact with a man", and if the answer was
6	through our products. We are now asking for your	6	"Yes", then they would be deferred from donating other
7	commitment also.	7	than for the special plasma process.
8	"Until the cause of this disease is determined,	8	So we can see that the terminology used in that
9	we are asking that people who are a part of any of the	9	question combined with that in the document is very
10	following groups do not donate:	10	clear, there is no confusion about promiscuous male
11	"Haitians	11	homosexuals, as occurred in some other literature
12	"Drug abusers	12	around the time. It is a straight question, "Have you
13	"Male homosexuals	13	ever had sexual contact with a man?"
14	"People who are a part of any of the above	14	We will see that other fractionators didn't pose
15	groups may be eligible for a special plasma program.	15	the question directly of the donor, and there are, of
16	If you think you may be eligible, please discuss this	16	course, arguments as to why different approaches might
17	with our Medical Receptionist."	17	be more effective.
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A similar letter to the one that -- a similar note to the background note was sent to plasmapheresis centres, and they were instructed that plasma obtained after 26 December 1982, from donors who had not been screened in the way that Alpha required them to be screened, should not be sent to Alpha. They concluded their letter to their contracting centres with the following words:

Other documents, which I won't take you to, sir, 67

that Alpha put in place, whereby plasma from those

groups was segregated and could be used for other

purposes, other than the fractionation of factor

The special plasma programme, sir, was a system

Other documents -- thank you, Soumik, we can

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concentrates.

take that down.

68 (17) Pages 65 - 68

The Infected Blood Inqu	irv
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1	"While we recognise the potential of the	1	involvement of blood products, Alpha is taking all
2	rejection of long-term donors, we strongly believe	2	possible steps to reduce the potential risk for the
3	that the loss of these donors is more than offset by	3	haemophiliac receiving our Factor VIII and Factor IX
4	the protection of our patients."	4	concentrates."
5	Alpha's measures were introduced unilaterally.	5	It is, sir, relevant to note that those steps
6	They were not part of an industry-wide approach, it	6	were prospective.
7	was a decision that Alpha took on its own. They went	7	Returning to the minutes of the Alpha executive
8	beyond the measures that many voluntary and commercial	8	committee on 15 December 1982, as well as putting in
9	blood banks were willing to put in place, and we'll	9	place this new scheme that meeting also considered
10	see that in documents that follow.	10	what to be done with products that had been produced
11	Alpha would later report that 308 homosexual	11	using three units of plasma that had been obtained
12	donors had been excluded from donating in the first	12	from what was described as "the AIDS donor."
13	three weeks of implementation, and that an even larger	13	It's not clear from the minutes how many lots
14	number had voluntarily excluded themselves. Alpha's	14	were affected, but reference is made to one lot in
15	assessment by the summer of 1983 was that, in that	15	particular, which comprised 2,841 vials and had been
16	first six months or so, 800 potential donors had	16	shipped in April and August 1982. The minutes record
17	voluntarily disqualified themselves from the pool.	17	that the situation was going to be reported to the
18	You may feel, sir, that it is significant that so many	18	FDA, and that the company, and I quote:
19	donors from high-risk groups could be excluded so	19	" would wait for the Bureau of Biologics'
20	quickly with a relatively simple measure.	20	opinion on what should be done."
21	The company provided regular newsletters, and	21	We haven't as yet, sir, been able to trace
22	the one that was published in winter 1982 set out	22	through all of the steps as to what happened to those
23	these new arrangements, and quoted the medical	23	products and what the decision of the FDA was on it.
24	director, Dr Clyde McAuley as saying this:	24	The same meeting also included a discussion on
25	"So long as there is any question about the	25	the possibility of a reversion to cryoprecipitate as
	69		70
1	an alternative to the use of factor concentrates. The	1	for 7 million units. There would be, it was said,
2	calculations are set out at paragraph 70 of the	2	additional costs which were not set out or calculated
3	written presentation. In short, the Committee	3	for shipping at minus 20°C.
4	concluded that within a year the average patient who	4	That was an internal discussion within the Alpha
5	had severe haemophilia would be exposed to	5	organisation.
6	700 donations, even with a reversion to	6	On 21 December 1982, the NHF made
7	cryoprecipitate, and a patient using 20 per cent of	7	recommendations on the treatment of people with
8	that 70,000 unit average would be exposed to	8	haemophilia in light of the risk of AIDS. This is
9	140 donations a year by using cryoprecipitate. The	9	quoted at paragraph 73 of the written presentation:
10	meeting concluded, and I quote:	10	"The organisation said that there was no
11	"The use of cryo may do nothing to solve the	11	conclusive evidence that the use of cryoprecipitate or
12	incidence of AIDS related to AHF transfusion."	12	fresh frozen plasma would reduce the risk of AIDS, but
13	It also recorded, and I quote:	13	it recommended that patients who had not yet used
14	"Risk would be approaching that of pooled	14	concentrates should not begin to do so unless there
15	[anti-hemophilic factor]."	15	was an overriding medical indication for so doing."
16	The minutes don't record the discussion and the	16	And that group included children, those under
17		17	four, people who had been newly diagnosed with
18	reasons as to why that conclusion was reached. There is some discussion of the costs of	18	haemophilia and those with mild haemophilia.
			·
19 20	switching to cryoprecipitate. It was estimated that	19	"All other patients were advised to continue
20 21	it would cost an additional \$1 per unit because of	20 21	using concentrates."
21	labour costs, so the estimate was of 7 million		That was 21 December 1982, and there was a
22	donations per year, so that would mean an additional	22	slight tweak to the guidance in January 1983, where
23	cost of \$7 million in terms of labour alone.	23	physicians were also advised to use desmopressin for
24	There was also an estimate of \$20 million to	24	patients with mild or moderate haemophilia.
25	\$30 million in respect of equipment and shipping costs	25	In January 1983, as well, there was
	71		72 (18) Pages 69 - 7

(18) Pages 69 - 72

a recommendation that the advantages and disadvantages thought to be hot spots for AIDS, were under of postponing elective surgery be considered. consideration. But one company, Alpha, had gone We've reached the end of 1982, and it's perhaps considerably further and had unilaterally introduced helpful just to give a very brief summary. By the end its new screening process. As the events in January 1983 would show, there was, however, still of 1982, pharmaceutical companies and other relevant bodies were aware of the potential risk of a gulf between the steps that the blood industry transmission of AIDS through blood products, and blood generally were willing to take at that stage, and transfusions, though there was no consensus about those that the leading figures within the CDC the aetiology of the disease or the nature and extent considered to be necessary. of the risk That brings us, sir, to perhaps the most prominent and controversial event in the United States That lack of consensus was evident between government agencies, as well as between those agencies in this debate in this period, and that was the and those involved in blood banking and in meeting held on 4 January 1983 in Atlanta. We have fractionation. In broad terms the CDC, or at least various sources for this meeting, and they're set out leading figures within the CDC, were considerably more at paragraph 77 of the written presentation. concerned about AIDS than were other participants in The meeting was convened by the assistant the debate. secretary for health, Dr Edward Brandt, at the urging of the CDC. It was a public meeting, and it was Some steps had been taken to seek to reduce risk. Companies had agreed voluntarily to forego widely attended, including by figures from the future manufacture of blood products from -- or fractionation industry, each of those firms. from -- factor concentrates from plasma obtained from It was chaired by Dr Jeffrey Koplan, and donors specifically recruited because they were gay. although Dr Koplan came from the CDC, there is some There was a consensus amongst the fractionators about evidence that he was chosen as chair because he was educating donors. Other measures, such as avoiding considered to be a neutral figure in the emerging plasma from prisons and from geographical areas debate.

I'm going to take you, sir, to a summary of the meeting, which was contained in the Krever Report, which is a helpful way of beginning our understanding of the meeting. We will be looking at some other sources for it as well.

Soumik, can we have on screen, please, KREV0000001, and it's electronic pages -- beginning at electronic page 752.

Sir, there is a *mea culpa* here: I tried to transpose the internal page numbers of the Krever Report to the external -- to the electronic page numbers, and to my immense frustration I was one page out. So all references in the written report to the Krever Report are one page short on the electronic version. I apologise for that. As I say, it's a source of considerable frustration.

If we could expand, please, the first full paragraph, beginning "A meeting". This is Mr Justice Krever's summary, which is, in my submission, a helpful one:

"A meeting of the advisory group was held on 4 January 1983."

I should note there, sir, that formally this was a meeting of something that was often described as a "Workgroup to Identify Opportunities for [the] Prevention of AIDS". It was an *ad hoc* meeting, it wasn't a formal meeting of the Blood Products Advisory Committee:

"A meeting of the advisory group was held on 4 January 1983. More than 200 persons were present at that meeting, including the employees of the CDC, the Food and Drug Administration and the National Institutes of Health, representatives of the blood and plasma centres, the plasma sector, the four large US blood product manufacturers, the gay community, and the National Hemophilia Foundation, as well as some treating physicians.

"At the meeting, Dr Evatt presented evidence suggesting that AIDS could be transmitted by blood. He discussed the cases of AIDS seen in hemophiliacs, described the case of an infant in California who had received a transfusion at birth, and said that five unconfirmed cases of transfusion-associated AIDS were investigation.

"Several measures were suggested to reduce the risk of transmission. Dr Donald Francis, the assistant director for medical science in the CDC's division of virology, advocated direct questioning of blood donors about behaviour that would have placed them at risk of contracting AIDS. He also recommended

(19) Pages 73 - 76

1	that donations be tested for the presence of antibody	1	methods of donor screening or testing to reduce the
2	to the hepatitis B core antigen, in the belief that	2	risk of transmission. Instead, the CDC, the Food and
3	persons who had been exposed to hepatitis B would also	3	Drug Administration and the National Institutes of
4	be at greater than normal risk of contracting AIDS.	4	Health were each asked to submit a set of
5	Representatives of the gay community objected to his	5	recommendations after the meeting for the prevention
6	first proposal because it would be discriminatory, and	6	of AIDS in patients with hemophilia and for other
7	representatives of the blood banks and plasma industry	7	recipients of blood and blood products, so that
8	objected to the second, primarily because it would be	8	a uniform set of recommendations might be developed."
9	too expensive. Dr Oscar Ratnoff, a physician at Case	9	That's where we'll leave that document. Thank
10	Western Reserve University who treated hemophiliacs,	10	you, Soumik.
11	recommended that haemophiliacs used cryoprecipitate	11	Looking at the wider documents, we can see
12	instead of factor concentrates. Ultimately, the	12	a little more of the debate and the nuance of the
13	meeting endorsed none of these measures. Although	13	argument about surrogate testing that
14	the participants reached a general consensus that 'it	14	Mr Justice Krever mentioned. As he said, the CDC's
15	would be desirable to exclude high-risk donors to	15	case was presented by Dr Don Francis. He and his
16	reduce the risk of AIDS transmission', there was no	16	colleagues had conducted studies that in their view
17	agreement about a method of accomplishing that goal.	17	showed that 90 per cent of known definite AIDS cases
18	There was also no consensus on the question of whether	18	were positive for the antibody to hepatitis B core
19	AIDS was caused by a transmissible agent, on the risk	19	antigen. This compared to a 5 per cent figure in the
20	of AIDS from blood donations, or on the	20	general population of voluntary donors. It's
21	desirability"	21	important to stress we're looking at voluntary donors
22	Sorry, I've just lost my place there.	22	there, not paid donors at plasmapheresis centres.
23	SIR BRIAN LANGSTAFF: About halfway down.	23	Those figures would later be contested, and we
24	MR HILL: Thank you:	24	will see some further figures as we go through the
25	" or the desirability of introducing new	25	documents, but the CDC's case at the time was that if
	77		78

you run a surrogate test for hepatitis B core
antibody, then there is a prospect of identifying
90 per cent -- or, 90 per cent of people who may have
AIDS or develop AIDS will have that antibody, and
only 5 per cent in the general population will have
that antibody, at least in respect of voluntary
donors.

Now, his position won some support. There we

Now, his position won some support. There were some blood centres that indicated a willingness to run programmes in which anti-HBC would be tested, and there were also some other surrogate tests.

12 SIR BRIAN LANGSTAFF: Could I just come back to those13 figures?

14 MR HILL: Yes.

15 SIR BRIAN LANGSTAFF: I just wonder if you will be showing
16 me in due course what was recorded as to what he was
17 saying, because 90 per cent of known definite AIDS
18 cases is looking at the matter retrospectively, it's
19 after they've had whatever it is that caused AIDS -20 MR HILL: Yes.

SIR BRIAN LANGSTAFF: -- compared to a 5 per cent figure in the general population of voluntary donors. So the issue -- if this is saying, as it seems to be, that voluntary donors are a safer source, how does it make

25 that out? Because you're looking at donations on the

one hand and you're looking at the results/consequences on the other.

MR HILL: I don't think it's necessarily saying -comparing voluntary donors with paid donors, it's just
that the voluntary donors were the cohort that the CDC
drew their data from.

The point that they were seeking to make, I think, from this, is that if you introduce anti-HBC testing, then you can expect to lose 5 per cent of your donors at a voluntary blood donation centre, because they will test positive. So your loss is 5 per cent of donors. The potential gain is that the test, as a surrogate test, has a good correlation with people who subsequently developed AIDS, because 90 per cent of people in their cohort who developed AIDS were positive for anti-HBC.

It doesn't, as you say, necessarily tell you whether or not somebody who was in the incubation period for AIDS will -- it doesn't give you any figures at all for that cohort because that's not the group that they were using, they were using only people who had developed AIDS, but I think that the inference is that, as a surrogate test, it was one that potentially could assist in identifying and excluding high risk donors, even though it would come

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there was some support for this proposition, there were also objections. Those objections were, as Mr Justice Krever said, on the grounds of cost and expense, and also on the grounds that it was going to lead to the destruction of plasma without direct evidence that that plasma was infected with AIDS. Some concerns were raised about the availability of materials for the test and about the need for additional training for staff to carry it out. According to the Cutter note of the meeting, one participant who is not named estimated the cost of introducing anti-HBC testing on all donations as being at least \$100 million per year. Dr Robert Gerety commented that he didn't think that
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Dr Robert Gerety commented that he didn't think that
the test was, in his words, or his quoted words,
"a good marker", and he noted that the test hadn't
been licensed and wouldn't be licensed that year.
Dr Gerety was the director of the hepatitis
branch of the FDA's division of blood and blood
products, and he is expressing scepticism about the
test as well.
Dr Hink, who wrote the Cutter note, and we saw
his name on the Cutter marginalia a moment ago, he
summarised the debate in this way, he said:
"[The] Question of cost and implementation
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bothered many but not CDC, several objected on scientific grounds."

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We will come back, sir, after lunch, to the terms of that debate. But looking more generally at the meeting as a whole, we can see a — the account given by Dr Evatt in his Tragic History, which summarises how he and some of his CDC colleagues felt about what happened.

If we could have on screen CVHB0000042. It's page 6.

If we could start with the first paragraph on the left-hand column, please. Sorry, the paragraph above it.

This is what Dr Evatt said of the meeting:

"Naively, we reasoned that the meeting would be routine and produce a *pro forma* stamp for action, that is, review the data, accept the evidence as significantly supporting the case for a blood-borne infection and produce recommendations that high-risk groups be excluded from the donor pool and/or adopt a surrogate test, for example, hepatitis B core testing, or immune complex tests to exclude possible infected donors."

He then cites the different attendees at the meeting. If we could move to the next paragraph,

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"Unfortunately, 4 January 1983 became possibly the most discouraging and frustrating day of the epidemic for CDC staff. Rather than a rational discussion of the data, the meeting quickly became a forum to advance individual agendas and 'turf protection'. In the presence of (and perhaps in reaction to) news reporters and TV cameras, each group voiced essentially the same sceptical reasoning they had at the earlier meeting in July 1982. On this occasion some were less polite, sometimes attacking CDC data as inadequate and over stated. The particularly vocal blood bank organisations still strongly adhered to the philosophy that transfusions were a life saving procedure; some adverse reactions were acceptable to save a life. A 'rare disorder' that affected only eight haemophilia patients and one transfusion patient should not force a change in blood policy. Calls were to 'Show us the agent ... subject it to Koch's postulates'. The attendees regarded the data as only anecdotal evidence, without merit. Two views emerged. To us, the attendees' reactions seemed to be those of a group approaching an idealized science problem in an abstract world; to the audience, their position was that of a group acting as careful

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scientists in accordance with their training.
"All attendees underestimated the already high
disease incidence in the population because AIDS was
obscured by a long, still undetermined incubation
time. Dismissed as inadequate were our data on the
high frequency of immune disorders affecting the
haemophilia population that were identical to those
found in homosexual patients with lymphadenopathy
associated syndrome. Above all, the blood bank
organizations remained unconvinced that the CDC had
shown the condition to be a blood-borne disease and
some FDA officials remained unconvinced that AIDS was
actually a distinct disease. Dr Koplan proposed a set
of consensus recommendations at the end of the day,
and all were soundly defeated.
"The blood banking organizations were clearly
displeased with what, in truth, was the CDC's
intrusion into areas considered FDA's responsibility.

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The attitude was reflected in a memo from a senior

[American Red Cross] official that, 'It has long been noted that CDC increasingly needs a major epidemic to justify its existence ... In short, we cannot depend on the CDC to provide scientific, objective, unbias[ed] leadership ...'." Just a couple of points on that, sir, Koch's 85

postulates are a series of criteria that are used to test the causative link between a suspected infective agent and a disease, they include a criterion to identify and isolate the organism said to have caused the disease and, of course, that couldn't have been done at that time because that agent was unknown.

The quotation from the American Red Cross official about the CDC is also contained in another document. The longer quotation also refers to federal funding cuts as being relevant to the context in which the CDC were putting forward its proposals. It referred to a perceived marketing approach by the CDC, and a suspicion that AIDS probably played some positive role in the CDC's successful battle to fund a new \$15 million virology lab, the suspicion being expressed about the CDC's motivation.

That quotation is taken from a report prepared by the Institute of Medicine, which is referred to in the written presentation, and the Institute of Medicine also placed this in the context of a previous reaction to a potential outbreak of swine flu in the United States in 1976, which led to a mass vaccination programme, and indeed some deaths as a result of that vaccination programme, and it was felt by some that that had been a massive overreaction at the time and

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the IOM placed people's attitude towards the CDC within that context.

SIR BRIAN LANGSTAFF: So this is the IOM report of 1995? MR HILL: Yes, that's right.

There is a piece of video footage which I'll show after lunch, so that we can see it up properly on the machine, which has a snippet of information about Dr Francis and an interview with Dr Francis, and in that video he confirms accounts that have been given many times of him slamming his fist on the table during the meeting and asking, in effect, how many AIDS cases and how many deaths those attending needed before they would act.

The Cutter representative at the meeting, Dr Hink, he produced a memorandum which also contains some further insights. Could we have, please, CGRA0000300.

The memorandum is dated 6 January 1983, and it's an internal document. If we go to the second paragraph, please. This is Dr Hink's impression of

"Most of the meeting was devoted to presentation of information and data by individual experts ... there is little question that these individuals knew their subject but as the day wore on, it was evidenced

that experts in other fields paid little attention to these overviews."

He gives an example which I won't go through. If we could go to the next paragraph, please, Soumik:

"I believe, but am not certain, that the objective of this CDC sponsored Workshop was to arrive at a meaningful recommendation for action(s) which would reduce the rapidly increasing number of AIDS disease cases being identified in the US. In particular it appeared they directed attention to the 8 or 10 haemophiliacs with confirmed or suspected AIDS assumed to have been caused by infusion of blood products and what should be done quickly to prevent a further increase in these numbers.

"However, difficulties in communication and political power struggles made progress toward these objectives difficult. The anti-discrimination position of the gays, self-serving comments of blood bankers and lack of data to provide legitimacy to many proposals resulted in an overall stalemate. I felt a great deal of empathy for the meeting chairperson who I felt did a good job under the circumstances."

If we could turn to page 3 of this document. Dr Hink provides various pieces of information which he attributes to contributors to the meeting and those

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1	are set out in the written presentation. But if we go	1	on the cost, implementation and potential
2	to the bottom of page 3 we can see Dr Hink's	2	effectiveness of using new (to Cutter) assay
3	recommendations for Cutter resulting from the meeting.	3	procedures."
4	So this wasn't what was said at the meeting, but what	4	That's Dr Hink's perspective both on the meeting
5	Dr Hink is advising his colleagues should do:	5	and on what Cutter should do as a result.
6	"1. Institute a 'High Risk Donor'	6	You may, sir, wish to take particular note of
7	educational-voluntary exclusion programme at all	7	the position on prison donations.
8	Cutter source plasma collection facilities.	8	One further point to note from the meeting,
9	"2. Continue to exclude all plasma collected	9	apart from the plainly acrimonious terms in which it
10	from centers dealing predominantly with homosexual	10	took place; that is the suggestion that some attendees
11	populations (ie anti-HBs plasma collection facilities)	11	may have considered that the CDC itself had not
12	from use in coagulation products.	12	reached a settled view on how to proceed. Dr Gerald
13	"3. Take no extraordinary actions (other than	13	Sandler of the American Red Cross told investigators
14	[number] 1 above at our two prison centers which	14	from the Institute of Medicine in that 1995 report,
15	supply about 3000 liters [per month], (there are no	15	and I quote:
16	data to support the emotional arguments that prison	16	"Not one of Donald Francis' superiors had
17	plasma collected from adequately screened prisoners is	17	supported a recommendation to implement hepatitis core
18	'bad'. To exclude such plasma from manufacture of our	18	testing. As a result, few in attendance accepted
19	coagulation product would only be sop or gratuity to	19	Francis' suggestions as they did not have the support
20	the Gay Rights and would presage further pressure to	20	of CDC director William Foege."
21	exclude plasma collected from the Mexican border and	21	The FDA's attitude was that more research was
22	the paid donor.)	22	needed on surrogate testing before it be implemented.
23	"4. Continue to attend further meetings of this	23	As I say, sir, the one remaining piece of
24	type, accumulate and evaluate all information and data	24	evidence about that meeting that I would like to draw
25	developing on AIDS and make independent investigations	25	your attention to is the interview given by
20	89	20	90
	09		90
1	Dr Francis, but I think it will be easier to do that	1	professes but desen't prove possesses
2	after lunch, so that Soumik has an opportunity to	2	prefaces, but doesn't prove necessary. When we play the video, it comes from an ITV
3		3	• •
4	bring the relevant video up on screen. SIR BRIAN LANGSTAFF: Yes. Well, let's take a break then	4	television programme from the 1990s, The Cook Report: Profits before Patients. We've obtained the footage
5	until 2 o'clock. 2 o'clock.	5	· ·
	= 1 111 111 = 1 111 111		from ITV in accordance with your statutory powers.
6 7	(1.00 pm)	6 7	The first person speaking on the clip is
	(The luncheon adjournment)		Dr William O'Connor, who was described in the
8	(2.00 pm)	8	documentary as an adviser to the US Government on AIDS
9	MR HILL: Sir, we're now going to	9	from 1986, and after he speaks, describing what
10	SIR BRIAN LANGSTAFF: Just a moment. Yes?	10	happened at the meeting, you then see Dr Francis
11	MR HILL: We're now going to play the video clip of	11	giving his description of it as well. If we could
12	Dr Francis. I introduce this with a slight sense of	12	have that now, please, Soumik.
13	trepidation because the last time we played a video,	13	(Video played)
14	the live stream was cut due to an overzealous	14	MR HILL: If we could turn back then, sir, to the issue
15	algorithm from the providing company which kicked in	15	which you raised about surrogate testing, which was
16	because of misplaced concerns about copyright	16	one of the matters that Dr Francis was bringing to
17	infringement.	17	people's attention at that meeting.
18	So we're going to play this video. We hope that	18	If we could have on the screen, please, Soumik,
19	the algorithm won't kick in again. If it does, and if	19	CVHB0000042. This is Dr Evatt's Tragic History. If
20	the live feed goes down, then we would like to assure	20	we could have page 5, please. If we could highlight
21	people that, firstly, that is the reason why it has	21	the second paragraph down on the right-hand column,
22	gone down. Secondly, we will do everything we can to	22	beginning "Meanwhile." This is Dr Evatt describing
23	get it up and running as quickly as possible.	23	what took place in the autumn of 1982. He says:
24	Thirdly, the full presentation will be available on	24	"Meanwhile, the CDC's immunological studies of
25	the Inquiry's website in due course. But I hope that	25	AIDS patients showed an extremely high incidence of

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	i ne int	ectea Biooa inquii	ry 2 November 2021
1	antibodies to the blood-borne virus hepatitis B in	1	The first selection of groups are "AIDS cases".
2	affected patients and risk groups and a high incidence	2	So these are people who have been identified as having
3	of circulating immune complexes in AIDS patients	3	AIDS. Amongst those who were identified as having
4	compared with controls"	4	AIDS and who were homosexual or bisexual,
5	He refers to table 2, which we'll look at in	5	88.2 per cent were positive for antibodies to core
6	a second:	6	antigen, 81.9 per cent to antibodies for surface
7	"These data suggested, in the absence of	7	for hepatitis B surface antigen.
8	a specific screening test for blood donors, that such	8	IV drug users, the figures, the respective
9	surrogate markers might be useful in reducing the risk	9	figures were 100 per cent for core antigen, and
10	to blood recipients."	10	61.9 per cent surface antigen.
11	Then, Soumik, if we could expand the table at	11	Haitians, 86.7 per cent core, 66.7 per cent
12	the bottom, table 2. It is entitled "Frequency of	12	surface.
13	abnormal tests by group. From author's personal slide	13	Others, 42.9 per cent core, 33.3 per cent
14	collection, 1982".	14	surface.
15	We don't know, sir, if this exact slide was	15	The figures for the presumably for the actual
16	shown at the January 1983 meeting.	16	numbers of those groups are contained in brackets.
17	SIR BRIAN LANGSTAFF: Well, the information was plainly	17	The next population group of people who were
18	available if this was in 1982, this information?	18	described as "Probable AIDS", "Lymphadenopathy", so
19	MR HILL: Yes, sir.	19	people who were showing signs that might be associated
20	The left-hand column shows the different	20	with AIDS, the percentage who are positive to
21	population groups that were studied, and then the	21	antibodies for hepatitis B core antigen are
22	second column shows the percentage that were positive	22	81.3 per cent, and surface antigen 75.4 per cent.
23	for the antibody to hepatitis B core antigen, the	23	Then you've got "Risk group 'Controls'". So
24	right-hand column shows the percentage positive for	24	these are people who haven't been diagnosed as having
25	anti-hepatitis B surface antigen.	25	AIDS, but are in the two control groups that are
	93		94
1	mentioned.	1	significantly in those cases which have contracted
2	The first is homosexuals and bisexuals, and that	2	AIDS and they show a very strong correlation to
3	group, 79.2 per cent are positive for antibodies to	3	hepatitis B/C, the core antigen, then you've made the
4	hepatitis B core antigen, and a similar figure,	4	case.
5	79.5 per cent, to hepatitis B surface antigen.	5	And this is, I would have thought, highly
6	Amongst Haitians the figures are, respectively,	6	supportive figures to justify, potentially justify,
7	36.2 per cent and 39.3 per cent. So a much lower	7	the exclusion of those high-risk categories of donors
8	correlation amongst Haitians, but a higher one for	8	or at least to indulge in surrogate testing of those
9	homosexuals.	9	who do not self identify as being in one of the risk
10	Now then there is a group which are referred to	10	groups.
11	as "normal controls", and we can see that 5 per cent		MR HILL: That was certainly the position of Dr Evatt
12	of the normal control group are positive for both		SIR BRIAN LANGSTAFF: Well, I follow the logic.
13	antibodies to surface antigen and to core antigen.		MR HILL: It might be helpful just to look at the formal
14	SIR BRIAN LANGSTAFF: It provides the missing link which	14	record of the discussion that took place. That's
15	I was concerned about before lunch. The issue	15	at JREE0000019, and it's page 289. We can see here
16	is: which, if any, donations can be excluded, and have	16	how, according to that record, the CDC put its case.
17	a protective effect in respect of the contraction	17	If we could take it from the top, please,
40	a protective effect in respect of the contraction	40	Councile

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Soumik:

instance of hepatitis B and it's 90 per cent when you get to AIDS cases generally, but if you've got the

evidence that the risk groups have a large anti-HBC

of AIDS, without being able to identify the AIDS virus

Answer is not simply to focus on normal

precisely because you can't at this stage?

controls, so-called, say if we have a 5 per cent

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connection, the risk groups are over represented 95

to the blood collection process, both through test

of being objective and can be done on specimens

already being drawn for HBsAg [hepatitis B surface

effective in eliminating potential transmitters of

antigen]. They respect donor privacy and may be most

AIDS. They have the disadvantages of adding expense

"Surrogate laboratory tests have the advantages

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cost, administrative overhead, and loss of blood units		
already collected. Further, they may stigmatize as		
unsatisfactory many 'normal' donors for each potential		
AIDS transmitter that is rejected.		
"For example, if the presence of hepatitis B		

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core antibody is used as a laboratory surrogate screening test:

- "1. In CDC's specimen file, 90 per cent of known definite AIDS cases are positive for [anti-hepatitis B core antigen] and would be excluded as blood donors.
- "2. Approximately five per cent of the general population of voluntary donors [I stress voluntary again] are positive for [anti-hepatitis B core antigen], though this figure may vary by blood center. These results would be determined after collection. and the collected units would have to be destroyed unless they could be safely and practically processed into other blood products.

"The costs of the test might add to the cost of processing. The loss of each destroyed unit represents further expense and there might be additional overhead costs. The costs of preventing an unknown number of AIDS cases (and possibly non-A, non-B hepatitis cases) are unknown, but each such case

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is very costly in direct and indirect costs and the intangible costs of grief and suffering.

- "4. Concern was expressed over availability of adequate [anti-hepatitis B core] test materials. However, information suggests that some companies are already planning production of large quantities of [anti-hepatitis B core] and that demand would provoke an adequate supply.
- "5. As the epidemiology of AIDS changes, high risk groups may have lower rates of positivity for [anti-hepatitis B core].
- "6. This additional laboratory test will require new training and procedures for many laboratories."

So that is the formal record of the discussion, and we've heard, sir, some of the other contributions that were made and were recorded in the memoranda that were written by those present.

We will see in due course how other figures are put forward in respect of correlations between hepatitis B core antigen and known risk groups.

We will leave that meeting there, and move on a few days in time to 6 January 1983, when a meeting took place between the National Hemophilia Foundation and representatives of plasma fractionators.

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The NHF requested an end to plasma collection in what are termed "AIDS hot spots". Alpha indicated that they had already taken such steps and, according to the Krever Report, Armour, Cutter and Hyland did so shortly thereafter. So that is about the geographical areas of high incidence, and the pharmaceutical companies showing a willingness to cease collecting plasma from those areas, if they indeed collected from there in the first place.

A week later, on 13 January 1983, a joint statement was published by the major blood banking organisations, the American Red Cross, the American Association of Blood Banks, and the Council of Community Blood Centers.

Now, this statement stated that, in the opinion of those groups, the possibility of blood-borne transfusion of AIDS was "unproven" and the evidence was "inconclusive." Notwithstanding this, the organisations accepted that there were sufficient grounds of concern to warrant some steps being taken, particularly in respect of the "long incubation period", that they noted.

The recommended steps included further questioning of donors to elicit relevant features of medical history, things such as night sweats and

unexpected weight loss, lymphadenopathy and Kaposi's sarcoma. Some questions would be posed to see whether or not a donor had any history of those symptoms.

However, the organisations considered that:

"Direct or indirect questions about a donor's

sexual preference are inappropriate."

That was the position of the blood banking industry.

The statement appears to have been intended to pre-empt a strategy meeting that took place on the following day, 14 January 1983, at the behest of the NHF. The meeting involved representatives of fractionators, and those included Dr Eibl from Immuno. There were also representatives there from the voluntary and commercial blood banking industry, the CDC, including Dr Evatt, and the FDA, including Dr Donohue. A number of clinicians were present and of course members of the NHF.

On the morning before the meeting, so the morning of 14 January 1983, a meeting was convened of the major industry representatives from the fractionators, and that was done, and I quote from a record of that meeting, it was done:

"... to determine a consensus strategy to the actual NHF meeting."

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(25) Pages 97 - 100

1	So this is industry figures meeting before the	1	antibodies.
2	full meeting, to see if they could determine	2	The meeting agreed, and I quote from Dr Ojala's
3	a consensus strategy. And such meetings would be	3	note:
4	common in this period: before you have a full public	4	"We would support testing in concept, but defer
5	meeting, you would have such industry meetings.	5	until a more specific test was available."
6	Those attending included the representatives of	6	It was noted that Dr Donohue of the FDA was said
7	all of the major fractionation firms, as well as	7	to be "not particularly enthusiastic" about
8	a representative of the American Blood Resources	8	hepatitis B testing.
9	Association, but not, it seems, blood bankers. This	9	The meeting also agreed, and I quote again:
10	is a meeting of fractionators and plasmapheresis	10	" that the CDC was getting increasingly
11	centre representatives, not blood banks.	11	involved in areas beyond their areas of expertise and
12	A record of a meeting was made by Dr Ojala of	12	whenever possible we would try to deflect activity to
13	Cutter. Now, Dr Ojala said in his memorandum that the	13	the [National Institutes of Health and the] FDA."
14	primary concern of this meeting was the possibility of	14	The meeting then went on to discuss action that
15	a recommendation that anti-hepatitis B core antigen	15	could be taken to limit the risk of AIDS. The
16	testing should be introduced for all plasma.	16	representative from Alpha informed the meeting of its
17	Dr Rodell of Hyland is recorded as suggesting that	17	donor screening programme and informed the meeting
18	this would exclude approximately 10 per cent of all	18	about the 308 people who had identified themselves as
19	high-titred donors who are used for providing immune	19	homosexuals as a result of that screening programme in
20	serum globulin.	20	the first three weeks, in giving notice of the success
21	It's relevant to note here, sir, that the	21	of a programme to their fellow fractionators.
22	5 per cent figure quoted by the CDC was for voluntary	22	Hyland stated that it would have its own
23	blood donors. This group is concerned with donors who	23	programme on in place by 1 February and Armour said
24	are donating to plasmapheresis centres, and groups	24	that they were working on theirs.
25	that were donating to provide plasma high in hepatitis	25	There was a discussion about small pool
	101		102

fractionations but, and I quote:

"... everyone agreed [this] was of questionable benefit."

A hypothetical example was given, where it was said if you had a 10-donor pool and you employed some very effective manufacturing techniques, that might result in eight to 12 vials of product, but of those eight to 12 vials, eight of them would be required for quality control purposes. Manufacturers would have to keep four vials for testing for potency, purity and sterility, they would have to keep two vials for retention, presumably for the purposes of tracing back and testing back if needed, and the FDA would also require two vials for testing. So eight of those eight to 12 vials would not be marketable, and that would leave, obviously, between zero and four for sale. It was noted by Dr Ojala:

"The economics of this procedure are relatively discouraging."

That was the discussion that took place on small pool fractionation.

The meeting also discussed the fact that in the view of those present, whatever requirements were placed on fractionators about the way in which they collected plasma should also be applied to blood

banks, because the conceptual risk was the same for both whole blood and for plasma. We will see that in the weeks and months that followed that this was a bone of contention between the two different groups.

Some information was shared about the progress on heat treatment processes at that industry meeting as well.

One further point to note from Dr Ojala's memorandum of the meeting, he said, and I quote:

"Both Alpha and Hyland are taking the AIDS problem very seriously."

"Very" was underlined in the original. Dr Ojala was an employee of Cutter.

Turning to the full meeting, this is at paragraph 95 of the written presentation. The meeting began with a review about the evidence, the aetiology of AIDS, it included reference to an article in the New England Journal of Medicine, which had found that 40 to 60 per cent of patients using factor concentrates had a reverse T-cell ratio. As we saw earlier, that was something that was associated with groups who had developed AIDS.

That figure of 40 to 60 per cent with a reverse T-cell ratio was a higher proportion than people with haemophilia using cryoprecipitate. So there was

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1	a greater prevalence of such people amongst people	1	individuals who belong to groups at high risk of
2	with haemophilia who used factor concentrates.	2	transmitting AIDS, specifically male homosexuals;
3	It was noted, however, in the memorandum that no	3	intravenous drug users; and those who have recently
4	data was conclusive.	4	resided in Haiti.
5	The National Hemophilia Foundation then	5	"2. Evaluation and implementation (if verified)
6	explained its recommendations about the way in which	6	of surrogate laboratory tests that would identify
7	patients with AIDS should be treated. These develop	7	individuals at high risk of AIDS transmission.
8	from the medical and scientific advisory committee.	8	"3. In addition, the manufacturers should cease
9	There were three parts to these recommendations: one	9	using plasma obtained from donor centers that draw
10	was aimed at physicians, giving them advice about	10	from population groups in which there is a significant
11	actual treatment; one was aimed at fractionators,	11	AIDS incidence. It is clear from the epidemiologic
12	about how they should be preparing their products; and	12	data that the pool of individuals at risk for AIDS
13	the third was aimed at regional and community blood	13	transmission is not uniform throughout the country and
14	centres, about how they should be collecting blood.	14	that a great deal could be achieved by excluding
15	If we look at the recommendations that were made	15	donors from the 'hot spots'.
16	for fractionators, if we could have on screen, please	16	"B. Efforts should be continued to expedite the
17	JREE0000019, it's electronic page 293. If fifth we	17	development of processing methods that will inactivate
18	could highlight from where we can see II,	18	viruses potentially present in factor VIII
19	"Recommendations to factor VIII concentrate	19	concentrates"
20	manufacturers", these are the recommendations that the	20	If we go over the page, please:
21	NHF were making to the fractionators:	21	"C. There should be an evaluation of the
22	"A. Serious efforts should be made to exclude	22	possibility that the yield of factor VIII in
23	donors that might transmit AIDS. These should	23	plasmapheresis donors could be increased used DDAVP or
24	include:	24	exercise to maximize yield. This would permit
25	"1. Identification by direct questioning,	25	a reduction in the size of the donor pool and would
	105		106

compensate for losses in plasma that might occur due to steps noted above.

- "D. There should be an evaluation of the feasibility of fractionating and processing plasma so that lyophilized small pool products are available. While this certainly be more costly, it may be the line way to break out of the present dilemma without going to an all-cryoprecipitate effort.
- "E. Concentrate manufacturers should immediately cease purchase of recovered plasma for factor VIII concentrate from blood centers that do not meet the criteria listed in II A above. These criteria should also apply to the production of cryoprecipitate.
- "F. Manufacturers should accelerate efforts towards the productions of coagulation factor concentrates by recombinant DNA technology."

The document then goes on to give recommendations for the blood banking industry, but we can take that off the screen, please, Soumik.

The minutes of the meeting go on to explain some of the discussion. I won't go through it in detail but, on donor screening, Alpha explained its programmes and the results of its programme, which we have discussed before. In general, the fractionators

expressed support for steps on donor screening and for the exclusion of geographical areas. The blood banking representatives expressed scepticism on those points, and we've seen --

SIR BRIAN LANGSTAFF: By geographical areas, in effect, one is reading hot spots, is one?

MR HILL: Yes, yes.

Dr Ojala recorded in his memorandum of the meeting, and I quote:

"It is unusual for us [that's the fractionators] to come away wearing the white hats while the 'volunteer' sector wear the black."

On surrogate testing, as per their meeting beforehand, the fractionators indicated a willingness to accept an exclusion rate of about 10 per cent of donations and the higher costs associated with testing if, and then it's recorded:

"... 'an appropriate test' could be identified."

It was agreed that more work was required on that matter.

On donor pool size, the problems with small pool production that the fractionators had discussed in the morning were again raised in the meeting in the afternoon. Nobody from industry who was present at the meeting foresaw an early breakthrough on

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1	recombinant products. In summing up the meeting, the	1	are pushing for further steps to be taken. We've
2	chair referred to, and I quote, "complicated issues	2	already heard about what Alpha had already done by
3	involved", and he said that:	3	that stage, but on 28 January 1983, the American Blood
4	" no regulations would develop from the	4	Resources Association, so the trade group, put out
5	meeting."	5	a statement in which it said that the cases of AIDS in
6	So, again, a lack of consensus amongst the	6	people with haemophilia, and I quote, "suggest that
7	people present about what should be done. There is	7	AIDS may be of infectious aetiology". Therefore the
8	a reference from the chair thanking the parties for	8	organisation urged that "steps be taken as soon as
9	entering into what he describes as an "open and frank"	9	possible to screen plasma donors to minimize" risk.
10	dialogue.	10	The recommendations that the group made focused
11	So that meeting took place on 14 January. The	11	on education of donors and plasma centre staff, and
12	day before, the New England Journal of Medicine had	12	screening measures including further questions on
13	published an editorial written by Dr Jane Desforges	13	medical history and seeking confirmation from donors
14	that urged consideration of the increased use of	14	that they were not in high-risk groups.
15	cryoprecipitate on clinicians, and I think that is	15	The first of those issues was one that the blood
16	a document that you looked before and I won't take you	16	bankers could agree with, more questions about medical
17	back to it now. The argument was put forward that	17	history, but the blood bankers had drawn the line at
18	cryoprecipitate might minimise the risk of infection	18	asking people about their sexuality, whereas the
19	and, that being so, the physicians should consider	19	American Blood Resources Association refer to asking
20	that as a treatment option, it's fair to say that the	20	questions about whether or not a donor was in
21	editorial doesn't go on to address the logistical	21	a high-risk group, which would of course include
22	issues concerned.	22	homosexual males.
23	Turning then to the screening measures that were	23	On surrogate testing, the Association's
24	introduced by the fractionators in January and	24	statement recommended that no large-scale testing be
25	February 1983, within this environment in which NHF	25	implemented at that time, but noted that the issue was
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"under study". Those recommendations, they said, were intended to apply not just to plasmapheresis centres, but also to whole blood institutions as well.

Now, as anticipated at earlier meetings, Hyland introduced revised donor screening procedures in January and early February 1982. These procedures included providing an information leaflet to donors before asking of them if they were in a high-risk category, and introducing the examination of the lymph nodes.

So this is a slightly different approach to the one taken by Alpha. As we saw, Alpha involved a direct question from a person at the desk to a male donor saying, "Have you ever had sex with a man?" Whereas Hyland produced a document, gave the document to the donor, the document identified the high-risk groups, including male homosexuals, and then they asked them, "Are you in a high risk group?" And if the answer was "yes" then they would be excluded from making the donation. So it is an indirect way of approaching that issue.

There are, of course, arguments one way and another as to which is best. There is a suggestion certainly in some of the literature that somebody asking a direct question of somebody who carries

a self imposed stigma of being gay, if you were asked that question directly, then there might be a higher possibility of you saying "No", rather than looking at a document and saying, "Yes, I am in a high risk group", without specifying what that is. But the psychology of that is something which I will make no further comment on.

But what is clear is that what Hyland were doing went beyond what the blood bank organisations were recommending because they considered that both direct and indirect questions about sexuality were inappropriate.

Hyland, by that time, had also closed plasmapheresis centres in San Francisco, Miami, Houston, New Orleans and New Jersey, and had elected not to contract with or open centres in those locations, or in New York or Hollywood. In his draft statement from 1990, Dr Kingdon stated that he was:

"... convinced by the available evidence ... that we were dealing with a virus that had an epidemiology similar to hepatitis and that we should take measures to reduce the risks of transmitting AIDS through blood products."

So that's Hyland in January and February '83. Cutter introduced additional physical

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examination of donors and additional screening questions in February 1983. Those included questions about medical symptoms, the unexplained dramatic weight loss, night sweats, recurrent fever. There was also an examination of lymph glands and a full body examination for lesions.

For Cutter, donors were required to sign the company's AIDS information notice, to state that they were not a member of any of the three high-risk groups, again including male homosexuals.

Armour introduced what it described as a "more aggressive programme" of donor screening in the same month, that is February 1983. The details of that are set out at paragraph 106, similar to Cutter and Hyland, and as with Cutter, donors were required to affirm in writing that they're not members of any of the several high-risk groups -- again, including male homosexuals.

At that time, February 1983, the company had no plasmapheresis centres in areas recognised as having a high incidence of AIDS, and nor did they source plasma from such areas. I take that from a letter that they sent to UK clinicians in May 1983.

So that's what the fractionators were doing, and it stands in contrast to what the trade bodies for the

blood banks were doing. But it is relevant to note that some individual blood centres were taking steps and were more receptive to change. February 1983 saw the implementation of donor screening programmes at both the Irwin Memorial Blood Bank in San Francisco, and the Greater New York Blood Program.

The latter pioneered a process by which donors could confidentially indicate that that their plasma should not be used for fractionation and transfusion, a system that became known as "confidential unit exclusion". This produced a 1.4 per cent deferral rate from donors. It's perhaps relevant, sir, that both of those centres were in areas of high incidence of AIDS, and hence there was a need for them to do something to try to reduce the risk from their donations, less they cease to exist.

But from a British perspective, it's worth noting that in January 1983, that is when you have the discussion of AIDS led by Dr Craske of the Haemophilia Centre Directors Working Party on Hepatitis and also the meeting at Heathrow Airport that we have discussed on past occasions.

On 7 and 8 February 1983, the further meeting of the Blood Policy Advisory Committee took place. This was a meeting that was held in both open and closed

session. The representatives of the fractionators were there for the open session and, it appears, for some of the closed sessions, but not all of them.

Dr Duncan Thomas of the (UK) National Institute for Biological Standards and Control attended both the open and closed parts of the meeting on what was described as a consultant basis. It's counsel to the Inquiry's understanding that Dr Thomas may have been seconded in the United States in this period.

The open meeting saw a discussion of viral inactivation of hepatitis through heat treatment.

This was in the context of the imminent licensing of the first heat-treated product, which was the Hyland product. There were also closed sessions with each of the fractionators in which each one described the work that they were undertaking on heat treatment. The focus was still on viral inactivation of hepatitis but the meeting also saw a discussion of AIDS.

In a closed session, at which the fractionators do not appear to have been present, a lengthy and often sceptical discussion took place of the cases of AIDS identified by the CDC. So this was a discussion by the members of the Blood Policy Advisory Committee, heavily populated by representatives of the blood banking industry. The CDC were not present, but their

work was being discussed.

Dr Donohue of the FDA was present. He reported on the National Hemophilia Foundation strategy meeting that we've just looked at, and he welcomed proposals for further donor screening that had been made there. He also stated that since that meeting the fractionators had agreed that the there would be no fractionation into Factor VIII from plasma which is collected in prisons.

Counsel to the Inquiry aren't sure, sir, that that's a correct assessment, at least in terms of Hyland, and we'll see a little later why we say that. It's not clear that all fractionators had ceased to obtain plasma from prisons and fractionation at that time.

SIR BRIAN LANGSTAFF: Well, what you say is that they -it was recorded that they agreed there would be no
fractionation. To say that you're agreeing that
something will happen doesn't make it happen.

20 MR HILL: No.

SIR BRIAN LANGSTAFF: Nor does it give any timescale within which it will.

MR HILL: No, it doesn't. It's fair to say, I think, that
 there is a split between the fractionators on prison
 plasma. Alpha and Armour do not appear to have used

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1	it or been interested in that way of obtaining plasma.	1	"[She] did not think there is a shred of
2	We'll see that from some of the other documents.	2	evidence that this [AIDS] is transmitted by blood as
3	Cutter and Hyland take a different approach.	3	of today."
4	Of course, we don't know why Dr Donohue was	4	So scepticism being expressed, particularly by
5	saying what he was saying and how accurately he had	5	members of the blood banking industry, and some
6	understood what the position of the fractionators was.	6	hostility towards both the CDC, and indeed the
7	Dr Donohue also stated, in closed, and I quote:	7	fractionators, for the steps they were taking.
8	"Everyone has agreed that there is not	8	However, there is what you may consider to be an
9	a screening test which is appropriate to attempt to	9	interesting exchange that then takes place, and we can
10	define immune deficiency as it applies to donors.	10	look at that from the transcript, and it's page 111 of
11	There just is not one that fits."	11	CGRA0000347_008.
12	Now, who he meant by "everyone" there isn't	12	So in the midst of this often sceptical
13	clear, and I'm not sure that Dr Evatt and Dr Francis	13	discussion you have Dr Bove, the chairman, saying
14	would have agreed with that assessment.	14	this, and I quote:
15	There was a lengthy discussion that followed on	15	"Well, one of the most vigorous, one of the most
16	donor screening and surrogate testing. The CDC and	16	outspoken, one of the shoe-pounding on the table
17	the American Blood Resources Association, so that's	17	people for the blood collecting community to do
18	the fractionators, were both criticised for what were	18	something, to be aggressive and get your heads out of
19	perceived to be their overreaction to events,	19	the sand is the Commissioner of Health of New York
20	•	20	City. And I want to say he must be absolutely
21	including by Dr Joseph Bove, the chairman of the	21	
22	meeting and the director of the Yale-New Haven	22	correct. The real problem that bothers me more than
23	Hospital blood bank.	23	anything bothered me in my professional life is that
23 24	Professor Dorothea Zucker-Franklin of		everybody who talks about this may be correct. And in
24 25	New York University Medical School stated that, and	24 25	the next 12 months there may be an amazing epidemic
25	l quote:	25	which will clearly implicate blood transfusion and
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1	show that the blood collecting community behaved	1	"Dr Arongon: Mo don't know that any is squad
1 2	show that the blood collecting community behaved	1 2	"Dr Roye: We don't know that any is caused.
	irresponsibly."	3	"Dr Bove: We don't know that there are any bad
3	Dr David Aronson cuts in and says:		units."
4	"But, Joe, we have that worry every day.	4	We'll leave that meeting there, sir.
5	"Dr Bove: I haven't had it quite like this.	5	A couple of days later, on 18 February 1983, the
6	I don't think there has been any situation that was	6	Alpha AIDS Task Force met and the topic was again this
7	quite this dramatic. I don't think we've ever had	7	issue of when products should be recalled. The news
8	a situation where we are talking about an illness with	8	that was discussed at the meeting was that Alpha had
9	anywhere from 40 to 100 per cent mortality"	9	received 11 plasma donations from a donor in Dallas.
10	Dr Aronson cuts in again:	10	Texas, who "possibly" had, I quote the note, "some
11	"And That could show up every day	11	AIDS symptoms". So "possibly some AIDS symptoms".
12	"Dr Bove: Yes, it could, but the question is,	12	The donor had not, however, been diagnosed with
13	has it? I mean, it is not whether it could or not; it	13	AIDS. The plasma which was in four lots of
	is whether it has and whether we ought to be much more	14	concentrate had been put on hold and there was
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15	aggressive.	15	a discussion about the patient's symptoms. The
15 16	aggressive. "One can predict that surrogate I hate the	16	patient's physician had suggested that the donor had,
15 16 17	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million	16 17	patient's physician had suggested that the donor had, and I quote:
15 16 17 18	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million dollars a year and is there any reason that we should	16 17 18	patient's physician had suggested that the donor had, and I quote: " symptoms of lymphadenopathy but little else
15 16 17	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million	16 17	patient's physician had suggested that the donor had, and I quote: " symptoms of lymphadenopathy but little else to connect him with AIDS."
15 16 17 18 19 20	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million dollars a year and is there any reason that we should delay instituting that?" Dr Louis Sullivan cuts in:	16 17 18 19 20	patient's physician had suggested that the donor had, and I quote: " symptoms of lymphadenopathy but little else to connect him with AIDS." The donor was being followed up. Alpha's
15 16 17 18 19 20 21	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million dollars a year and is there any reason that we should delay instituting that?"	16 17 18 19 20 21	patient's physician had suggested that the donor had, and I quote: " symptoms of lymphadenopathy but little else to connect him with AIDS."
15 16 17 18 19 20	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million dollars a year and is there any reason that we should delay instituting that?" Dr Louis Sullivan cuts in:	16 17 18 19 20	patient's physician had suggested that the donor had, and I quote: " symptoms of lymphadenopathy but little else to connect him with AIDS." The donor was being followed up. Alpha's
15 16 17 18 19 20 21	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million dollars a year and is there any reason that we should delay instituting that?" Dr Louis Sullivan cuts in: "But what percentage of possible bad units would	16 17 18 19 20 21	patient's physician had suggested that the donor had, and I quote: " symptoms of lymphadenopathy but little else to connect him with AIDS." The donor was being followed up. Alpha's decision was to release the concentrate, but not to
15 16 17 18 19 20 21 22	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million dollars a year and is there any reason that we should delay instituting that?" Dr Louis Sullivan cuts in: "But what percentage of possible bad units would be ruled out?	16 17 18 19 20 21	patient's physician had suggested that the donor had, and I quote: " symptoms of lymphadenopathy but little else to connect him with AIDS." The donor was being followed up. Alpha's decision was to release the concentrate, but not to use any plasma from a donor which had not yet been
15 16 17 18 19 20 21 22 23	aggressive. "One can predict that surrogate I hate the word surrogate testing would cost about 150 million dollars a year and is there any reason that we should delay instituting that?" Dr Louis Sullivan cuts in: "But what percentage of possible bad units would be ruled out? "Dr Bove: Who knows. We don't have any data at	16 17 18 19 20 21 22 23	patient's physician had suggested that the donor had, and I quote: " symptoms of lymphadenopathy but little else to connect him with AIDS." The donor was being followed up. Alpha's decision was to release the concentrate, but not to use any plasma from a donor which had not yet been pooled. So that which had already been made was to be

1	in any plasma pools. It was agreed that Dr Carr would	1	Assistant Secretary for Health, and Dr Evatt frankly
2	discuss the issue with the Bureau of Biologics, and	2	admits that the CDC was over stepping the mark and
3	the issue was posed in this way:	3	trying to by pass the FDA's regulatory authority by
4	"What if we do find a donor who comes down with	4	taking that step. The CDC draft recommendations
5	AIDS and we do have plasma in product in the field."	5	included both the exclusion of high-risk donors, and
6	I note that that meeting also raised the issue	6	surrogate testing. According to Dr Evatt, their
7	of hepatitis B core testing, and it was noted that	7	recommendations were promptly rejected by the other
8	Dr McAuley and Dr Carr both had objections to any	8	agencies, but the Public Health Service did put
9	project being undertaken on that.	9	together a set of guidelines which they published on
10	The issue of product recall would grow in	10	4 March. Dr Evatt says that, and I quote:
11	importance and significance in the months that	11	" although it was clearly short of what we,
12	followed.	12	as individuals at the CDC wanted these guidelines
13	We have reached March 1983 and, as we've heard	13	[did mark] the beginning of a slow change in public
14	regularly during the evidence, in that month, on	14	policy on transfusion associated AIDS."
15	23 and 24 March, the FDA made recommendations about	15	So those guidelines went out on the 4 March, but
16	how donations should be collected by both blood banks	16	they were subsequently replaced with the FDA
17	and fractionators. Now, those recommendations grew	17	guidelines that went out in the name of Dr Petricciani
18	out of the 4 January 1983 meeting, the very	18	on 23 and 24 March 1983. We've looked at those before
19	contentious meeting with Don Francis pounding the	19	so won't bring them up, it's relevant to note that
20	table. The only concrete outcome of that meeting was	20	they are non-binding guidelines, but they were
21	a recommendation that the CDC, the FDA and the	21	guidelines that, it appears, the fractionators and the
22	National Institutes of Health be asked to submit sets	22	blood banks took seriously and adhered to.
23	of recommendations which could then be considered.	23	Just to summarise briefly, and drawing from the
24	According to Dr Evatt, the CDC drew up a set of	24	Krever Report on them:
25	recommendations which were to be considered by the	25	"Plasma centres were told not only to give
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donors information about AIDS and to question patients about symptoms of AIDS but to examine donors physically for lymphadenopathy and weight loss. Standards imposed on plasma centres were considerably more stringent than those imposed on the voluntary sector because officials thought that voluntary donors posed less risk than paid donors. Finally, manufacturers were informed that plasma collected from donors suspected of being in a high-risk group might only be used in the production of derivatives not known to transmit infectious diseases."

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So that's what the FDA recommendations said. As we've seen, the four US fractionation companies had, by that time, already implemented their own donor screening procedures, which were broadly equivalent to those suggested by the FDA in March 1983. It was the blood banks that were proving to be more resistant to change.

The FDA notably, did not recommend the implementation of surrogate testing and did not say anything about the recall of products.

The other point to note, which Mr Justice Krever brought out there, was that the plasmapheresis centres and the fractionators had higher standards imposed on them than the blood banks, which became a source of

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tension and indeed a source of concern.

As the Inquiry has heard, it was shortly after the FDA recommendations were published that Dr Joseph Smith of the Committee on the Safety of Medicines wrote to Dr Keith Fowler at the DHSS proposing that there be a meeting of the Subcommittee of Biologicals to discuss issues relating to AIDS and blood products. That meeting would eventually take place in July.

Also in March 1983, we see the licensing of the first heat-treated product, which was Hyland's Hemofil-T. That was a licence that was granted interested by the FDA in that month. We're going to come back to the story about heat-treated products later, so I won't say any more on that now.

I'm going to turn in a second, sir, to the recall of heat-treated products, so I don't know if you would like me to do that before or after the

20 SIR BRIAN LANGSTAFF: Well, let's go on for quarter of 21 an hour, shall we --

22 MR HILL: Yes.

SIR BRIAN LANGSTAFF: -- thereabouts? 23

MR HILL: May 1983, so we've moved on a couple of months. 24 25 Hyland withdrew a lot of factor concentrate --

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1	a lot meaning a unit, rather than meaning many they	1	withdrew any of the companies withdrew pre-March
2	withdrew a unit of factor concentrate having	2	plasma manufactured product because it would be less
3	discovered that they had been manufactured from	3	safe.
4	a donor who was later diagnosed with AIDS.	4	MR HILL: Not that I have seen.
5	This counsel to the Inquiry understands this was	5	SIR BRIAN LANGSTAFF: So they went on effectively
6	the first such product withdrawal.	6	marketing product which was, if the recommendations
7	Paragraph 125 of the written presentation cites	7	were sound, on that assumption, would be less safe?
8	the references from which we draw that conclusion.	8	MR HILL: Yes.
9	If we could have on screen, please, Soumik	9	SIR BRIAN LANGSTAFF: Thank you.
10	PRSE00004496.	10	MR HILL: We can also put some figures on that, sir, in
11	SIR BRIAN LANGSTAFF: Just before we do that, same vein,	11	respect of the Alpha scheme, which was introduced in
12	the rationale for the 24 March 1983 recommendations by	12	December, where it saw within three weeks 308 people
13	the FDA was that the product needed to be safer.	13	who were in a known high risk group excluding
14	That I take for granted as being the purpose of the	14	themselves from donations, over 800 by the summer.
15	recommendations.	15	SIR BRIAN LANGSTAFF: Yes.
16	It will follow that product which had not been	16	MR HILL: If we then turn to PRSE0004496, this is a letter
17	manufactured from plasma collected in accordance with	17	that was written to the DHSS, so the UK Department of
18	those regulations, or those recommendations I should	18	Health and Social Security, on 9 May 1983, and it's
19	say, would be less safe, and the product manufactured	19	sent by Travenol Laboratories Ltd, so the UK
20	from it after 24 March would be safer.	20	subsidiary of Hyland Travenol.
21	Might it follow from that, that the logic ought	21	If we could I'll just find my place. The
22	to be that the less safe product ought not to be used?	22	first paragraph of the letter provides some
23	MR HILL: That is certainly a proposition which is	23	information about the steps that Hyland have been
24	supported by logic, yes.	24	taking in terms of donor screening, notes the
25	SIR BRIAN LANGSTAFF: Is there any evidence that anyone	25	recommendations by the FDA on 24 March 1983. And if
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we could expand out again, please, Soumik. Thank you. We look at -- and pick it up from paragraph 2, it says this:

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"In spite of these precautions, Hyland Therapeutics recently became aware that one of its plasma donors, though not finally diagnosed, has been identified as a possible victim of AIDS. The donor in question is a member of the high risk groups, although on several occasions prior to donating, he denied being a member of such group. While healthy at the time of donation, he subsequently developed some of the clinical findings associated with AIDS, including an inverted T4/T8 ratio and generalised lymphadenopathy. His final diagnosis is still in question.

"This donor's plasma was included in pools that were fractionated into several therapeutic products for haemophiliac, including Anti Haemophilic Factor VIII, Factor IX complex, and Anti Inhibitor Coagulant Complex. No therapeutic products fractionated from plasma pools that contained this donor's plasma have been shipped to any customer in Europe.

"In the United States, Hyland has recalled the only coagulation product fractionated from plasma

containing that donor's plasma that had been distributed to customers. The recall involves one lot of Anti Inhibitors Coagulant Complex and is being taken at Hyland Therapeutics initiative, and not at the request of the National Centre of Drugs and Biologics. As a precaution, all lots of Factor VIII and Factor IX Complex that were manufactured from this donor's plasma have been placed in quarantine pending further resolution of this donor's medical condition. 10 None of these quarantined products have been 11 distributed to customers in either the United States 12 or Europe." 13

The author of the letter goes on to stress the other measures that Hyland were taking, and said that the company intended to convert both its European and American facilities to manufacture only heat-treated Factor VIII product, and they would do this, and I quote, "as expeditiously as possible".

For the record -- the reference is at paragraph 128 -- a copy of the same letter was sent to Professor Bloom on the same date.

In the wake of the recall of the Hyland product, the National Hemophilia Foundation published a medical bulletin. This urged its members to continue using factor concentrates. It noted that the incidence of

> 128 (32) Pages 125 - 128

	The line	ica biooa iliqai	z November 2021
1	AIDS in people with haemophilia was very low, at	1	The letters were sent to Miles Cutter, and also
2	12 patients in a population of 20,000, and it also	2	sent to Armour. We, as you know, sir, don't have all
3	stressed, and I quote:	3	documents, and it's a reasonable inference that such
4	" the life and health of haemophiliacs	4	letters were sent to Alpha and possibly also to Hyland
5	depends upon blood products."	5	as well, depending on how much information Hyland had
6	So that was what the National Hemophilia	6	provided in their own letters to the DHSS following
7	Foundation was saying in May 1983.	7	the product recall.
8	The same month saw considerable activity within	8	It's helpful, perhaps, to look first at the
9	the DHSS in the UK on AIDS and on blood products.	9	response that was sent by Cutter. This is at
10	A number of internal memoranda. Dr Walford also	10	BAYP0000002_183.
11	produced annual update on AIDS which she was asked	11	The letter was sent by Dr JN 'Newt' Ashworth,
12	about when she gave her evidence.	12	who was the division vice-president for scientific
13	In paragraph 130 of the written presentation	13	affairs at Cutter. It is dated 3 June, and it's
14	contains reference to a number of documents that were	14	addressed to Dr Fowler. If we could go to the second
15	produced at that time. I won't take you through	15	paragraph and move through from there, Dr Ashworth
16	those, sir.	16	wrote this:
17	But during that same month, Dr Fowler wrote to	17	"The questions [these are Dr Fowler's questions]
18	at least two US fractionators, posing questions about	18	are expressive of the concern that exists everywhere
19	the precautions that they were taking over donors,	19	about this enigmatic syndrome. As you know, many
20	about whether they had received reports of AIDS in any	20	countries have now reported AIDS in the medical
21	users of their products, and about whether they had	21	literature.
22	received reports about any of their donors developing	22	"One of the major difficulties in dealing with
23	AIDS or AIDS-like symptoms.	23	the many issues concerning AIDS is the absence of
24	The references to both letters are at	24	persuasive data and this is complicated by the
25	paragraph 131.	25	oft-times sensationalistic and erroneous reporting in
	129		130
1	the press. We have seen recent examples in The Mail.	1	I pause there, sir, to say that we don't have
2	As a result, false conclusions are arrived at in	2	that attachment, but we suspect that it's a reference
3	patient treatment as well as product supply are	3	to Professor Bloom's address to the
4	endangered.	4	Haemophilia Society on 23 April 1983, which is at
5	"The facts about AIDS are very limited:	5	PRSE0000411.
6	"1. The syndrome is quite ill-defined and cases	6	SIR BRIAN LANGSTAFF: The Haemophilia Society published
7	may not be fully reported outside the US. The WHO	7	his letter of 4 May, didn't they?
8	World Health Organisation has recognised it as	8	MR HILL: I think that they did, yes.
9	a worldwide health problem.	9	SIR BRIAN LANGSTAFF: And that was actually published in
10	"2. The etiological agent is unknown. It is	10	one of the publications?
11	not known whether it is a virus.	11	MR HILL: It may well be
12	"3. Hence, it can only be an assumption that	12	SIR BRIAN LANGSTAFF: So that may well be what this is
13	AIDS can be transmitted by certain blood products.	13	referring to?
14	This has not been shown.	14	MR HILL: Yes, yes.
15	"4. Also, it is unclear whether the syndrome	15	"All participants in the procurement and supply
16	contracted by haemophiliacs really is the same as the	16	of Factor VIII (either cryoprecipitate or concentrate)
17	AIDS syndrome contracted by other high-risk groups.	17	face the same dilemma. There is no test for AIDS.
18	"As medicine the plasma suppliers (commercial	18	What we (and presumably other countries, including the
19	and NHS) struggle to find the correct actions to take	19	UK) are doing is to attempt an unproven and probably
20	to exclude the elusive AIDS donor it is imperative	20	inadequate screening of donors by certain gross
21	that the supply of products (in particular	21	definitions of the high risk groups and general
22	Factor VIII) not be reduce to levels where patients	22	physical examinations. Only time will tell if these
	1 acts. Villy not be readed to levels where patients		charles and decrease and account

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checks on donors are accurate.

"More specifically, addressing your questions:

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"1. By common agreement and with the regulatory

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Society is particularly pertinent."

can not be treated. The statement by Professor Bloom

in the attached communication from The Haemophilia

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pressure of the US DHSS [that's the Department of Health and Human Services], all plasma donors are screened to an extent consistent with present medical-scientific knowledge." He goes on to say that the processes that Cutter

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employ are in the documents which were provided to Dr Fowler. We have discussed those earlier.

"2. The cases of AIDS in haemophiliacs are of course complicated to follow up but our investigations indicate that none received Koate."

Which is the Cutter Factor VIII product:

"3. So far, we have not had to make a decision concerning disposition of a lot of Koate from a donor who has become an AIDS victim. It is our plan that if this circumstance should occur, the decision concerning the lot would depend on many factors including, most importantly, receipt of advice from government health authorities based on the latest knowledge concerning AIDS."

Those were the answers that Cutter gave to Dr Fowler's questions.

The third of those answers suggests that the approach to product recall would be one that was taken on a case-by-case basis.

I won't bring up the Armour response, in part

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1 because it is less definitive in that the response 2 came from a WJ Tarbit of Armour Pharmaceutical Company 3 Ltd, the UK-based company, and in the letter, I'm not 4 sure -- I'm afraid I don't know if it's the honorific 5 for WJ Tarbit, but the letter says that, amongst 6 certain points Armour in the UK would have to refer 7 back to Armour in the United States to get definite 8 information.

> But what the letter does say is that the British company were not aware of any reports of AIDS or AIDS-like illness arising from anywhere in the world from the use of Factor VIII specifically, but it does talk about how a letter in The Lancet on 28 May 1983 referred to an increased susceptibility of haemophiliac children, who have received Factor VIII, to opportunistic infection.

It says, as well, that the company -- the UK company -- had had no reports of donors subsequently developing AIDS or similar illnesses in any of its plasma centres but, in view of the constantly changing situation, they were going to redirect the question to the United States. The letter implies that further information would be forthcoming from the United States but we haven't found that document or that letter, if indeed it exists.

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On the same day that the WJ Tarbit letter was sent, which is 8 June 1983 -- I should have noted that Dr Ashworth's letter was of 6 June 1983. Also on 8 June 1983, KW Fitch, the chairman and managing director of Armour Pharmaceutical Company Ltd, wrote to Professor Bloom in response to a letter that Professor Bloom had written him, and the details are at paragraph 137 of the written presentation.

Dr Bloom's concern was what we've seen referred elsewhere as plasma dumping of pre-march plasma onto the UK. Professor Bloom used the phrase, we're concerned about Armour "preferentially exporting" to the UK product that was produced before the FDA recommendations.

So the same concern but expressed as "preferential export", rather than plasma dumping. The answer from KW Fitch was, and I quote:

"For your ... advice and assurance, you should know that we supplied plasma prior to February 24 [which is when Armour instigates its enhanced screening procedures], on a business-as-usual basis, but that most of this stock was supplied to customers in the [United States of America], since 70% of our Plasma business is in the USA. At no time have we preferentially exported Plasma stocks ex the USA

pre-February 24 or March 24."

My understanding of that letter and the quotation is at paragraph 137, is that Mr Fitch is saying that Armour haven't engaged in what others refer to as "dumping" of pre-march plasma. But we can also see from that letter that the approach has been a business as usual basis, going back to your earlier questions about what happened to plasma that was obtained before the enhanced screening methods were put in place.

11 SIR BRIAN LANGSTAFF: Just picking up on my question to 12 you about the logic of the position, this would 13 suggest that 30 per cent of the plasma business was 14 outside the USA, and that there had been supplies made 15 of pre-24 February and, for that matter, 16 pre-March 1983, plasma made products, to places 17 outside the USA, it may well have included the UK, 18 I suspect, given this letter, and that there had been 19 no withdrawal.

MR HILL: Yes, and we can -- we'll look -- I imagine after the break we'll look at a document to see how much Armour product was being supplied to the UK.

23 SIR BRIAN LANGSTAFF: Yes.

24 MR HILL: I wonder if that, sir, is a convenient time? SIR BRIAN LANGSTAFF: Yes, it is. We'll take a break

> 136 (34) Pages 133 - 136

	The Infec	ted Blood Inquiry	2 November 2021
1	until quarter to. Quarter to.	1	"3. If from the [United States], is all plasma
2	(3.20 pm)	2	collected at FDA-licensed plasma collection centres?
3	(A short break)	3	Please give the names of the centres and their
4	(3.45 pm)	4	locations.
5	SIR BRIAN LANGSTAFF: Yes.	5	"4. If non-USA plasma is used, name the
6	MR HILL: Still in June 1983, sir. Dr Walford prepared	6	countries involved and state whether the plasma
7	a questionnaire for fractionators requesting	7	collection centres in these countries are licensed by
8	information on a number of matters.	8	the national regulatory authorities.
9	If we could have on screen, please, Soumik,	9	"5. Are you able to identify the origin of the
10	DHSC0002229 _ 401. You can see from the bottom	10	plasma included in each batch of final product and the
11	right-hand corner that this is sent by Dr Walford, and	11	date on which it was collected?
12	the date is 14 June 1983.	12	"6. Is the plasma from each collection centre
13	At this stage it is an internal DHSS document,	13	fractionated separately or is plasma from several
14	but we know from other documents that this is the form	14	collection centres pooled prior to processing?
15	of the questionnaire that was sent to the	15	"7. If the plasma is of USA origin, are you
16	fractionators. It is easier to read on this version,	16	able to supply final products which do not contain
17	which is why we're using it.	17	plasma from the major 'epidemic' areas for AIDS eg
18	The questions posed are from number 1, and we'll	18	New York, San Francisco, Los Angeles, Miami?
19	go through them in turn:	19	"8. Can you confirm that all plasma of USA
20	"1: does your company manufacture coagulation	20	origin in your product is being collected in
21	factor concentrates for use in the UK? If yes, name	21	conformity with the FDA directive of 23 March 1983?
22	the products and state how much of each is supplied	22	"9. Did your company institute, in advance of
23	annually.	23	the FDA requirements, any special precautions to be
24	From which country or countries is the	24	taken by plasma collection centres in respect of AIDS?
25	source plasma obtained?	25	If so, what were those precautions and when were they
	137		138
1	introduced?	1	This is the table that we looked at repeatedly
2	"10. If USA plasma is used, are you able to	2	in September and October, which provides in tabular
3	confirm that all future supplies of coagulation factor	3	form the responses of the five companies to the
4	concentrates to be sold in the UK will be manufactured	4	questions that had been posed by Dr Walford, and we
5	from plasma collected in accordance with the	5	can see the product names included UK annual sales.
6	FDA directives of 23 March 1983 (or in accordance with	6	You asked about Armour earlier, sir. We can
7	special precautions, if any, instituted by your	7	look at the first row. The annual sales from Armour
8	company at an earlier date)?"	8	were in the region of 15-20 million international
9	"11. If the answer to (10) is No, from what	9	units of Factor VIII, and 1-1.5 million units of high
10	date can you meet this requirement?"	10	potency Factor VIII.
11	So those were the questions posed by Dr Walford	11	If we could go back out again, please, Soumik.
12	and the DHSS, and they were sent off to the principal	12	We can see that that is the largest single
13	fractionation companies, and indeed some other	13	supply by any company.
14	companies as well.	14	You may feel, sir, that it is a reasonable
15	The Inquiry has identified the direct responses	15	inference that among the 30 per cent of overseas sales
16	of the UK subsidiaries of the Miles Cutter and of	16	that were referred to in the previous document,
17	Armour, and the references are at paragraph 139 of the	17	some of those came to the UK.

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Armour, and the references are at paragraph 139 of the written presentation.

We know that the other companies replied as well, including Alpha, Hyland and Immuno, and we know that because of the table that we've looked at before, but I will ask to bring up again, it's

If we could go to the second page of this document, just so that we orientate ourselves.

DHSC0002229_055.

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 $^{\prime\prime}d.$ The following firms are suppliers of blood

If we could turn back to the previous page,

questionnaire given on this page by Mr Wrigglesworth

of the DHSS. You can see at (a), (b) and (c), there

is a reference to various firms who were approached

and who didn't supply blood products from human

coagulants, looking at Speywood there.

a helpful prose summary of the responses to the

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(35) Pages 137 - 140

	The Infe	ected Blood Inquiry	2 November 2021
1	products in the UK"	1	Biological Subcommittee on 13 July 1983.
2	That's Alpha, Armour, Travenol, Immuno and	2	As has been explored elsewhere in the Inquiry,
3	Miles. Then the quote from the document,	3	the DHSS officials turned to the debate taking place
4	Mr Wrigglesworth says this:	4	in the United States in the anticipation that the
5	"e. Annual imports of [Factor] VIII by the	5	British position would mirror that taken by the
6	above firms total about 42-50 [million] units.	6	American authorities. The focus across the Atlantic,
7	"f. With the exception of Immuno the firms	7	however, was moving away from questions about donor
8	state they do not or have ceased to collect in	8	screening, to the debate about what should be done
9	'Epidemic' areas. All state that their collection	9	about product recall. That debate, those existential
10	centres are FDA licensed.	10	questions of the fractionators, we turn to that now.
11	"g. The plasma in each case is pooled prior to	11	A meeting took place on sorry, actually,
12	processing. In the case of Immuno products, European	12	Soumik, can we bring the document up first,
13	plasma and USA plasma are pooled separately.	13	CGRA0000267, please.
14	"h. The origin of all plasma is identifiable.	14	This is a record made by Hyland Travenol of
15	"i. Each has given the assurance that future	15	a meeting that took place on 9 June 1983 between
16	sales will comply with FDA guidelines. However, Miles	16	representatives of the Plasma Manufacturers
17	Labs [that's for Cutter] state that [Factor] VIII	17	Association and the FDA. The fractionation companies
18	manufactured from plasma collected since March '83	18	were: Hyland, represented by Richard Srigley; Cutter,
19	will not be available until August, and Immuno in	19	Dr Ojala was there for them; Alpha, Dr Carr; and
20	September '83."	20	Armour, Dr Rodell.
21	You can take that down now, Soumik, thank you.	21	It's notable that Dr Rodell had moved to Armour
22	The answers contributed to a debate within the	22	by this time from Hyland, and Bill Wethersby was also
23	United Kingdom about whether a ban should be placed on	23	there for Armour.
24	pre-March plasma, a matter that was discussed, among	24	The FDA attendees included Dr Petricciani and
25	other places, at the Committee on Safety of Medicines	25	Dr Donohue. The CDC was not represented at the
	141		142
1	meeting.	1	hemophiliacs or cause a panic condition in the mind of
2	Paragraph 142 of the written presentation has	2	users. Given the degree to which a relatively small
3	the relevant references for that list.	3	number of donations can affect a large number of
4	The meeting was held at the request of the FDA,	4	product lots and the uncertain but long
5	with the intention of developing a policy to respond	5	gestation period for the disease, developing a policy
6	to situations where a donor whose plasma had	6	which is acceptable to the major interest groups is
7	contributed to a fractionation pool was later found to	7	seen as a real challenge."
8	have AIDS.	8	That, there, is reflecting the views of the FDA.
9	I am going to read now from the minute sorry,	9	If we go over to the next page, please, from the top:
10	not the minute, but the note that was made by Hyland.	10	"After considerable discussions, two alternative
11	If we could go to the fourth paragraph down, the	11	points of view began to emerge.
12	first three paragraphs deal with who was attending.	12	"1) When a donor is found to have AIDS, his
13	What is recorded is this:	13	plasma is excluded from pools. If the manufacturer
14	"This meeting was an opportunity to discuss with	14	has followed donor screening guidelines, product need

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the OB [that's the Bureau of Biologics] the concerns which manufacturers have in attempting to live with the potential that a donor whose plasma has been used in one or more pools over a period of time may later be found to have AIDS. The OB feels that there is a need to develop a policy to handle that eventuality and that the policy should be developed in a public forum involving the CDC, National Hemophilia Foundation and other interested parties. For their part, however, the policy must be one which does not interrupt the supply of coagulation products to

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not be recalled. If donor records show signs of prior illness and the manufacturer had continued to plasmapherese the donor the manufacturer may be required to recall product. Left unanswered are questions related to the status of processed, but undistributed product. One corollary to this plan which has discussed was the feasibility and legality of discontinuing the distribution of product under the

already been sold. While this appeared to be workable

company's control but not recalling product which

(36) Pages 141 - 144

has obvious shortcomings."	1	MR HILL: The logic is that which is contained in this
"2) Pick a time period prior to diagnosis which	2	document
the donor's plasma would be considered to be 'at risk'	3	SIR BRIAN LANGSTAFF: That's all we have?
and withhold from distribution (or recall) product	4	MR HILL: Yes.
manufactured from pools containing 'at risk' plasma.	5	SIR BRIAN LANGSTAFF: I see.
The difficulty pointed out with this plan was that	6	MR HILL: We will go on and we'll see in future documents
unless a very short (perhaps indefensibly short) time	7	a sense being expressed that there isn't a scientific
period were chosen, the amount of product affected	8	rationale, if I may put it this way, for these
could be very large."	9	proposals, it is an attempt to strike a balance
So those, sir, are the two main ideas that are	10	between what was seen as the need for maintaining
being floated at this meeting. The first can be	11	plasma supply, and concerns about the safety of these
summarised as an idea that if the manufacturer	12	products. So it is a pragmatic approach, rather than
involved had followed the correct procedures, then	13	a scientific approach, if I may put it that way.
there would be no need to recall previous plasma. The	14	It's fair to acknowledge that, in this document,
second was that if a time period were picked, then	15	references are made to, and I quote "the obvious
product that was produced during that time period	16	shortcomings" of the plans and the difficulty that the
would be recalled or would be withheld from	17	time period proposal puts forward as well.
distribution. These were the two ideas that were	18	SIR BRIAN LANGSTAFF: At the bottom paragraph there,
being floated at the meeting.	19	perhaps about six lines up from the bottom, is:
SIR BRIAN LANGSTAFF: Do we know any more about the basis	20	"Dr Petricciani [and he's of the FDA]"
for the suggestion that the following procedures which	21	MR HILL: Yes.
are designed to ensure that high risk donations are	22	SIR BRIAN LANGSTAFF: "stated that the March 24
not accepted is sufficient to deal with the problem	23	recommendations were interim, the OB would welcome
when it appears that a high-risk donation has become	24	comments from industry regarding the donor screening
very risky indeed, and has been accepted?	25	and examination provisions including the double
145		146
standard "	1	"1) The OB will be scheduling an open meeting in
_	"2) Pick a time period prior to diagnosis which the donor's plasma would be considered to be 'at risk' and withhold from distribution (or recall) product manufactured from pools containing 'at risk' plasma. The difficulty pointed out with this plan was that unless a very short (perhaps indefensibly short) time period were chosen, the amount of product affected could be very large." So those, sir, are the two main ideas that are being floated at this meeting. The first can be summarised as an idea that if the manufacturer involved had followed the correct procedures, then there would be no need to recall previous plasma. The second was that if a time period were picked, then product that was produced during that time period would be recalled or would be withheld from distribution. These were the two ideas that were being floated at the meeting. SIR BRIAN LANGSTAFF: Do we know any more about the basis for the suggestion that the following procedures which are designed to ensure that high risk donations are not accepted is sufficient to deal with the problem when it appears that a high-risk donation has become very risky indeed, and has been accepted?	"2) Pick a time period prior to diagnosis which the donor's plasma would be considered to be 'at risk' and withhold from distribution (or recall) product manufactured from pools containing 'at risk' plasma. The difficulty pointed out with this plan was that unless a very short (perhaps indefensibly short) time period were chosen, the amount of product affected could be very large." So those, sir, are the two main ideas that are being floated at this meeting. The first can be summarised as an idea that if the manufacturer involved had followed the correct procedures, then there would be no need to recall previous plasma. The second was that if a time period were picked, then product that was produced during that time period would be recalled or would be withheld from distribution. These were the two ideas that were being floated at the meeting. SIR BRIAN LANGSTAFF: Do we know any more about the basis for the suggestion that the following procedures which are designed to ensure that high risk donations are not accepted is sufficient to deal with the problem when it appears that a high-risk donation has become very risky indeed, and has been accepted? 145

standard " MR HILL: Yes. That is a reference to the fractionators complaint that they are being held to a higher standard than the blood banks. The fractionators said, "Well, the blood banks, you should have exactly the same requirements made of them because the risk for whole blood is the same as for plasma", and that debate was aired at this meeting as well, and Dr Petricciani is saying, well, we'll continue to listen to you on this issue, as it were.

He also goes on to point out that nothing prevents manufacturers from imposing their own standards on top of those recommended by the BoB. Penny Carr of Alpha said that Alpha had done just that and had lost vendors of recovered plasma as a result. That is the issue that I alluded to earlier: the plasma that -- when Alpha put in place its measures and insisted that other centres that it contracted with adhered to them, there was a breakdown in relations between Alpha and several of those centres. If we go on to the paragraph just below that,

the note records this:

"After some time it became apparent that no additional new issues remained to be discussed. The meeting adjourned with the following action taken.

"1) The OB will be scheduling an open meeting in July to discuss blood product issues related to AIDS; including the need for product recall.

"2) The manufacturers will meet prior to that to assemble information pertinent to the subject which would be of benefit to the OB in formulating a policy."

Three examples after given including:

"What action is recommended by the manufacturers to deal with this problem, given that the OB feels that it will be forced to take some sort of position on the matter which is scientifically defendable and, at the same time, politically responsive."

That was the challenge set then for the fractionators to try to come up with a policy that would meet those dual requirements.

A little further information is provided on this meeting by a note that was made by Dr Ojala of Cutter, if we could have on screen, please, CGRA0000231. The first page shows the note is 13 June, Dr Ojala, and it's about the same meeting that we've just been discussing. If we could turn to page 2, please. The second and third paragraphs, starting "A series of board meetings", Dr Ojala recorded this:

"A series of meetings will be held in Europe to

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The Infected Blood Inquiry

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review the screening process in the [United States], and Donohue stated that his mission was to defend our current procedures. He asked assistance from the manufacturers to convince those overseas that we are doing an acceptable jobs of screening out any AIDS donors.

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"I spoke with Donohue and Petricciani privately about our Orlando donor. They agreed that based on the evidence that they saw no need for any recall action. The donor was only drawn once and Donohue commented that his symptoms were common to active homosexuals, but not indicative of AIDS."

So a discussion there, sir, between a representative of Cutter and representatives of the FDA about what to do in a specific example where a donor had been identified, presumably, as being somebody who may have symptoms that were associated with AIDS. The decision was not to recall the product.

A further perspective on the meeting comes from the note that was provided by Alpha's representative, Dr Penny Carr. Can we have on screen, please, CGRA0000598, page 2 of that document. Again, it's a summary of what was said, the same meeting still. If we could highlight the third paragraph, beginning

"Dr Petricciani stated":

"Dr Petricciani stated quietly but firmly that he considered it essential that the manufacturers, in presenting their proposal [this is about product recall], discuss the feasibility of doing what we suggest, and the potential availability of product. The message is loud and clear. He stated frequently that this is a social, economic, public relations and emotional issue, not a scientific one. Please note. we must be prepared by the middle of July with a rational example of what could happen in terms of a long-term donor whose plasma has been used in the manufacture of AHF and PTC, and what the economic consequences would be to us in terms of cost and, secondly, in terms of availability of our ... products ..."

Note that this should cover not only AHF and PTC but all of the blood products manufactured.

"One issue discussed over and over again was the potential for this wiping out a manufacturer totally economically. Therefore, when you're talking about the availability of the product, you must also address the potential loss of products from AHF manufacture."

Dr Carr there recording what she perceived and what was discussed as the threat to the industry from

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a policy of product recall that would undermine their economic position.

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By the time of that meeting in June, there were 1,508 identified cases of AIDS, according to the CDC, in the United States, 575 deaths and 15 people with haemophilia had been identified as having AIDS.

The open meeting on this topic took place on 19 July 1983, so about a month later. The forum was the Blood Products Advisory Committee that met at the National Institutes of Health. Dr Petricciani introduced the topic and the difficulties involved, Dr Evatt provided an overview of the epidemiology of AIDS and stated that, by that time, July, there were 17 cases of people with haemophilia that had been identified by the CDC. There was further discussion of the criteria for AIDS and on research on its aetiology.

If we could have, please, BAYP0004674. This is the formal summary minute of the meeting. If we could turn to page 2, please, which is where the record begins of the discussion on product recall. Right at the bottom of the page, paragraph 6, the minute says this:

"Dr Michael Rodell represented the four member companies of the Pharmaceutical Manufacturers

Association (PMA) involved in the manufacturing of the Antihemophilic Factor [if we could go to the next page, please], Alpha Therapeutic Corporation, Armour Pharmaceutical Company, Miles-Cutter Laboratories, and Hyland Therapeutics. Dr Rodell outlined the donor education and screening programmes initiated by each of the companies in early 1983 to reduce the number of donors from the high risk groups. Approximately four to four and one-half million liters of source plasma 10 are fractionated on an annual basis which result in 11 800 million [Antihemophilic Factor] units. Primary 12 plasma pool sizes range from 1,000 to 10,000 liters, 13 with the result that a given pool would produce 14 between 0.5 million to 5 million AHF units and treat 15 an estimated 12 to 125 patients per year (or 500 to 16 5,000 individuals treatments). Because the industry estimates that the average frequent plasma donor makes between 40 and 60 donations a year, a single donor 18 19 could easily be represented in as many as 50 plasma 20 pools in one year. Were this donor subsequently found 21 to have AIDS and a decision made to recall all units 22 collected in a time period of one year prior to that, 23 25 to 250 million AHF activity units could be

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production, and distribution. Given the PMA estimate

affected, all in various stages of pooling,

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4	of 000 million ALIE activity units and dead agreed to be	4	and the street Da Dadall has a such as the combine
1	of 800 million AHF activity units produced annually by	1	contribution. Dr Rodell has spelt out the problem,
2	the fractionation industry, the potential for serious disruption of AHF supply described by Dr Rodell seems	2	and Dr Steven Ojala from Miles-Cutter puts forward
3 4		3	what the industry thinks should be the solution:
5	quite real."	4 5	"Dr Steven Ojala (Miles-Cutter Laboratories) presented the PMA recommendation against automatic
6	I pause there, sir, to note that, elsewhere in	6	recall. Automatic recall could lead to serious
7	the literature in dealing with, I believe, Mr Justice Krever's report, the point is made that, according to	7	
8		8	product shortages. PMA recommends that manufacturers
9	those figures given by Dr Rodell, then four	9	continue current screening and policies of discarding plasma from suspect donors. Dr Ojala stated that
10	AIDS-positive donors could jeopardise the entire	10	
11	supply that these manufacturers made. SIR BRIAN LANGSTAFF: Yes, I think Krever puts it as the	11	recall decisions should be made following each company's policy in close consultation with the FDA
12	entire world supply, which was what was being said,	12	and should be considered on a case-by-case basis, in
13		13	•
14	which may represent the American view of their control of the worldwide market.	14	light of current knowledge of AIDS. One lot of final
15		15	product has been voluntarily withdrawn from the market
16	MR HILL: From a British perspective, sir, the imported	16	and suspect units of plasma are routinely discarded by
17	products were overwhelmingly American at that time.	17	plasma derivative manufacturers. "Dr Louis Aledort presented the National
18	There was a small amount imported from Immuno but, as		•
19	we saw in Dr Walford's evidence, attempts to source	18	Hemophilia Foundation recommendation that any
	alternative supplies from Europe were unsuccessful at	19	product concentrate be recalled if it includes
20	that time. There was no spare supply. So at least in	20	material from an individual that has later been
21	terms of Britain, there is a very heavy dependence	21	identified as having AIDS or from an individual that
22 23	upon United States manufacturers for the product that	22	in the best medical judgment of the manufacturer has
	was imported.	23	characteristics strongly suggestive of AIDS. He
24	If we go back to the document, we can see how	24	noted, however, that the NHF did not have access to
25	the discussion developed after Dr Rodell's	25	the PMA data when the statement was formulated, and
	153		154
1	that there was great concern about the continued	1	lot, several Committee members and other participants
2	supply of AHF."	2	expressed the opinion that the risk of AIDS from
3	We'll come back to Dr Aledort's contribution in	3	transfusion of plasma derivatives or use of AHF
	We it come back to by Alcacite continuation in		
4	a second		
4 5	a second. The summary	4	concentrate has not been definitely established. They
5	The summary:	4 5	concentrate has not been definitely established. They cited the fact that nearly all of the hemophiliacs
5 6	The summary: "It was very clear that confronted with this	4 5 6	concentrate has not been definitely established. They cited the fact that nearly all of the hemophiliacs with AIDS had used material from different lots and
5 6 7	The summary: "It was very clear that confronted with this complex problem the Committee felt that a balance must	4 5 6 7	concentrate has not been definitely established. They cited the fact that nearly all of the hemophiliacs with AIDS had used material from different lots and that many other hemophiliacs receiving these same lots
5 6 7 8	The summary: "It was very clear that confronted with this complex problem the Committee felt that a balance must be struck between theoretical risk of a product to	4 5 6 7 8	concentrate has not been definitely established. They cited the fact that nearly all of the hemophiliacs with AIDS had used material from different lots and that many other hemophiliacs receiving these same lots had not developed AIDS. They stressed the need for
5 6 7 8 9	The summary: "It was very clear that confronted with this complex problem the Committee felt that a balance must be struck between theoretical risk of a product to recipients against the need for an uninterrupted	4 5 6 7 8 9	concentrate has not been definitely established. They cited the fact that nearly all of the hemophiliacs with AIDS had used material from different lots and that many other hemophiliacs receiving these same lots had not developed AIDS. They stressed the need for studies to followup recipients of blood products
5 6 7 8 9	The summary: "It was very clear that confronted with this complex problem the Committee felt that a balance must be struck between theoretical risk of a product to recipients against the need for an uninterrupted supply of a life-sustaining therapy. As several	4 5 6 7 8 9 10	concentrate has not been definitely established. They cited the fact that nearly all of the hemophiliacs with AIDS had used material from different lots and that many other hemophiliacs receiving these same lots had not developed AIDS. They stressed the need for studies to followup recipients of blood products derived from AIDS patients. The consensus of the
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Dr Rodell and Dr Ojala said. The description there is
consistent with the one that we've just read from the
formal minute. Dr Derrick says that there was then
a panel discussion, and I read from his note:
"Panel Discussion subsequent to these two
presentations centered on: present action with

presentations centered on: present action with reference to hepatitis contamination of pools and/or products; the possibility of reducing pool size (not considered a viable or well-based approach to the problem); the Hyland recall of an Autoplex lot because of a suspicion of AIDS contamination (this gesture lost some of its significance when it turned out that they were speaking of 187 vials); a significant question 'what is the risk associated with receiving blood from a donor later identified as an AIDS victim? (nobody knows)'."

Moving on to the next paragraph:

"Dr L Aledort made a presentation on behalf of the NHF and its MSAC [Medical and Scientific Advisory Committee] in which it was requested that 'any lot of Factor VIII concentrate should be recalled if it includes material from an individual either with AIDS or strongly suggestive of having AIDS'. Dr Aledort made this statement with some degree of embarrassment and actually disclaimed any personal responsibility for it. He stated that personally he feels that the recall position for AIDS contamination should be similar to the current practice with reference to Hepatitis B contamination (ie a similar position to that stated by Steve Ojala earlier). In an exchange on the floor it became apparent that the 'the current state of knowledge simply does not lend itself to such an uncompromising position [sici].

"The subsequent panel discussion identified the following pertinent points:

- "a. The Manufacturers had demonstrated in their presentation that they have a full appreciation of the need to respond to the present situation in a responsible manner.
- "b. I. For hemophilia patients, the current AIDS attack rate is no more and is probably less, than that of a year ago.
- "ii. The need for the coagulation products would appear to far outweigh the difficulties which would result from large scale recall. Further, there is no guarantee that product lots in which no AIDS positive donor has been identified are any less infective than products in which AIDS has been implicated.
 - "c. The present state of knowledge is simply

not adequate enough for blanket decisions involving large scale recall or the initiation of an hiatus on Factor VIII concentrate productions for an adjustment period (suggested 6 months) to allow for accumulation of plasma collected under more stringent conditions.

- "d. While individual physician committee members might find it a difficult decision to treat their patients with material with which an 'AIDS donation' has been implicated, there was nothing to be gained by recall in the face of the present state of knowledge.
- "e. 'Drying up' the supply of AHF would place haemophilia patients at greater risk to their health than continuing therapy under the present circumstances.

"The meeting concluded with the Chairman's summary that while it was abhorrent to the Committee to consider condoning the use of products from which there was a known risk of AIDS development in the recipient, there was an agreement on the part of the Committee that mandatory recall is not presently warranted in view of the lack of data and information on the extent of risk, and the potential for serious disruption of the supply of coagulation products."

A couple of points to pick up from that, sir.

The chairman who was referred to at the end there was the acting chairman of BPAC, Dr William Miller, not Dr Bove who we heard about earlier.

The second point, if we could go back to point (c) on that page, this, sir, picks up on your question about what was done about pre-March plasma, and what was not being done.

Although the focus of the discussion on this meeting seems to have been about recall of products where a donor was known or suspected to have developed AIDS, there does seem to have been some discussion about what to do with products that were created and produced before the enhanced screening methods were put in place.

According to this note, the view was taken by the meeting that there was simply not enough -- the present state of knowledge is simply not adequate enough for blanket decisions about either the large-scale recall or a suggested hiatus period, where, one suspects, there was a suspension of providing material for six months to allow enough stock to be produced from the screening methods, and then that would be distributed out. That was a proposal which did not find favour at the meeting.

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The Infected Blood Inquiry

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1	We don't have any further detail from this	1	the distribution or destruction of the final product		
2	document or from the previous document about what the	2	should consider such variables as: the degree of		
3	reasoning behind that was, although, given the general	3	specificity of the diagnosis, the time of onset of		
4	context of the discussion, it seems fair to say that	4 symptoms in relation to the time of donation, the			
5	the two points that were raised against such	5	potential effect upon immediate supply of Factor VIII		
6	a proposal were, firstly, the lack of scientific	6	and the long-term production of this essential plasma		
7	knowledge about the condition of the risk, and,	7	derivative. It is emphasized that all aspects of AIDS		
8	secondly, the need to maintain a plasma supply.	8	including the cause, method of transmission,		
9	Dr Petricciani sorry, no, it's Dr Donohue,	9	predisposing factors and definition of the syndrome		
10	who gives the FDA's impression of the meeting in	10	itself, are incompletely understood in spite of the		
11	a memorandum to Dr Petricciani a few days later.	11	extensive and intensive research activity focused upon		
12	If we could have that on screen, please, it's	12	these issues, and the benefit from life-threatening or		
13	JREE0000019. It's electronic page 313. We can see	13	disabling hemorrhage far exceeds the risk of acquiring		
14	that this is a memorandum that was dated 21 July 1983.	14	AIDS."		
15	What Dr Donohue wrote is this, and I quote:	15	SIR BRIAN LANGSTAFF: There must be something wrong with		
16	"My interpretation of the Advisory Committee	16	that, "the benefit from life-threatening or disabling		
17	review of the Safety of Factor VIII in relation to	17	hemorrhage".		
18	Acquired Immunodeficiency Syndrome is as follows:	18	MR HILL: I think that is intended to mean the benefit of		
19	"The risk of transmitting AIDS to an individual	19	avoiding life-threatening or disabling haemorrhage by		
20	hemophiliac from a specific lot of Factor VIII is	20	using the concentrates far exceeds the risk of		
21	very, very small, if it exists. Therefore,	21	acquiring AIDS.		
22	disposition of Factor VIII from a pool which contains	22	That was Dr Donohue's summation of the consensus		
23	plasma collected from a donor who may have the	23	view at that meeting.		

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is at DHSC0002231_063. Dr Fowler wrote this:

acquired immunodeficiency syndrome should be

considered as a discrete incident. A conclusion as to

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"We spoke yesterday about the FDA meeting held on 19 July 1983 to discuss the implication of AIDS for blood products. The meeting was attended by Dr Meyer and other senior members of the administration with representatives of the US and Canadian Red Cross, haemophilia organisations and the manufacturers. It lasted four and a half hours.

"Although the subject got a very thorough airing nothing new came to light. The possibility of banning all products made before the implementation of the March '83 regulations was discussed but was rejected on a majority vote. The hiatus in supplies which such action would cause was the deciding factor.

"There is likely to be a congressional hearing on the same subject next Tuesday and this is likely to be much more media orientated. I have been promised a report and will let you have it as soon as possible."

So that minute, sir, written in the knowledge and the context of the ongoing debate in Britain about what to do with the pre-March plasma.

The source of the information may have been Dr Duncan Thomas. We have seen that he was present at other meetings in 1983, and his name was included in

the list of those attending the meeting that we have just been looking at. So it may be that he was feeding back to Dr Fowler.

In Britain, Dr Fowler recorded his understanding

of the meeting in a minute dated 28 July 1983. This 162

The Congressional hearing that Dr Fowler referred to took place on 1 and 2 August 1983. It resulted in no change of approach in respect of product recall.

I intend, sir, to go to an extract from that hearing, but it is more in the context of showing what the US Government position was on AIDS at that time, rather than specifically about this issue of product recall, because although it was a debate that was happening amongst those who were closely involved in the topic, it doesn't seem to have been a major focus of the Congressional hearing. I can take you to that document now, sir, or, I note the time, you may wish to look to leave it to the morning.

18 SIR BRIAN LANGSTAFF: I think we're looking at the response by the pharmaceutical industry, I don't know that, unless it sheds some light on that, I'm particularly interested in what another Government 22 made of the situation.

23 MR HILL: Sir, the quotation is at paragraph 163 of the 24 written presentation --

SIR BRIAN LANGSTAFF: Thank you.

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1	MR HILL: people can look for it and decide if it's	1	INDEX	
2	going to help or not.	2	Presentation by Counsel to the Inquiry	1
3	SIR BRIAN LANGSTAFF: Well, it may be that it was picked	3	Presentation by Counsel to the Inquiry relating to knowledge of and response to risk by pharmaceutical companies involved in blood products	
4	up by the DHSS here, given that Dr Fowler was speaking	4	products	
5	about it, so perhaps we'd better have it because it	5		
6	might have informed debate.	6		
7	MR HILL: We do know from a minute, and the reference is	7		
8	at 164, that Dr Fowler was informed about the	8		
9	congressional hearing. Unfortunately, the minute in	9		
10	which Dr Fowler comments upon the Congressional	10		
11	hearing is one that we haven't been able to identify.	11		
12	So we know there was one, but we don't know what it	12		
13	said.	13		
14	SIR BRIAN LANGSTAFF: So we know that at least it was part	14		
15	of the material which fed into the debate in the UK?	15		
16	MR HILL: Yes, yes.	16		
17	SIR BRIAN LANGSTAFF: Well, in that case shall we deal	17		
18	with it tomorrow morning?	18		
19	MR HILL: Yes, sir.	19		
20	SIR BRIAN LANGSTAFF: So 10 o'clock then tomorrow.	20		
21	(4.35 pm)	21		
22	(The hearing adjourned until 10 am on	22		
23	Wednesday, 3 November 2021)	23		
24		24		
25		25		
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