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1	Tuesday, 24th October 2000
2	(10.35 am)
3	MR JUSTICE BURTON: Mr Underhill, I have arranged for my CAC
4	hearing to be at 3.00 on Friday and here so that I
5	suspect we will have a hearing on Friday and I can go
6	until 2.45.
7	MR UNDERHILL: My Lord, I am sure I speak for my learned
8	friend when I say we are most grateful to your Lordship
9	for doing so much to accommodate us.
10	MR JUSTICE BURTON: The only person obviously who may be
11	suffering from this is Mr Brown. I think the main thing
12	is we have to do our best to see if we can finish
13	Mr Gunson this week.
14	MR BROWN: I have made those arrangements already, my Lord.
15	DR HAROLD GUNSON (continued)
16	Examination-in-chief by MR UNDERHILL
17	MR UNDERHILL: Dr Gunson, just a couple of points from
18	yesterday. We were looking at the fourth meeting of the
19	ACVSB. That is the one in November 1989. We had not
20	looked in detail at your paper in its final form because
21	I had looked at it a little in its draft form, but
22	perhaps there are a couple of points we ought to note
23	about it which I did not bring out last night.
24	Could you go to page 185 in Q1? You told us by
25	reference to the draft that at the previous meeting of
26	the ACTTD all the changes made by your Committee were to
27	the final sections, I think 6 and 7. We can, in fact,
28	see that you made some changes not at the instance of
29	your Committee but simply to bring in further
30	information in the earlier factual sections?
31	A. Yes.
32	Q. The tables in particular to the paper are more extensive
33	than they were in the original draft paper?
34	A. Yes, the information available at the TTD was not as
35	substantial as that which came later, but before the
36	ACVSB meeting.
37	Q. It is not important I think to pick up everything. The
38	most substantial additional materials are the table at
39	page 192, which is tables 3A and 3B, referred to in
40	paragraph 5.1 of the text of the paper, which set out
41	the results of the first evaluations of the Ortho tests
42	in the multicentre study centres and in Scotland?
43	A. That is correct.
44	Q. They showed what was to become a consistent pattern,
45	that the number of repeat positives, though varying
46	between different centres was an average for those three
47	centres and Scotland of 0.62?
48	A. That is correct.
49	Q. As was subsequently to be discovered, the great majority
50	of those were false positives?

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51	A. Yes.
52	Q. Thank you. I thought we ought to --
53	MR JUSTICE BURTON: Can I compare that with what was there
54	if anything in bundle Q?
55	MR UNDERHILL: Yes. My Lord, the --
56	MR JUSTICE BURTON: The cross-reference is page 158.
57	MR UNDERHILL: My Lord, basically, what happened was section
58	3 had --
59	MR JUSTICE BURTON: I am sorry, bundle R, for the
60	transcript.
61	MR UNDERHILL: Dr Gunson is finding it as well. If we look
62	at section 3 it has an extra paragraph --
63	MR JUSTICE BURTON: Do you mean section 3 or section 5?
64	MR UNDERHILL: I was actually starting at section 3. It has
65	an extra paragraph, 3.2, which merely introduces an
66	extra table, table 1, not one I think which we have
67	spent or need spend time on, and then section 4 also
68	contains an extra paragraph, 4.4. Then section 5,
69	paragraph 5.1, is much longer, largely because it
70	incorporates and comments on the tables we have just
71	been looking at.
72	MR JUSTICE BURTON: Table 2 has become table 4, has it?
73	MR UNDERHILL: It has. You also refer for the first time,
74	confirming what you said yesterday, to the Scottish NBTS
75	evaluation and you exhibit as an appendix the results
76	section of the Scottish study, though not the full
77	paper?
78	A. Yes.
79	Q. Those are the principal differences.
80	It is quite clear, Dr Gunson, by this stage that
81	the ACVSB was taking the reins of decision-making
82	subject ultimately obviously to the Minister's approval
83	about whether and when anti-HCV screening should be
84	introduced. As the court has been told, no further
85	advice was sought from the TTD until early 1991. Do you
86	see anything wrong in that?
87	A. No, I do not see anything wrong in it because I think
88	the major decision had to be taken by the Department of
89	Health, and it was in accordance with that policy that
90	their Committee chaired by a senior Deputy Chief Medical
91	Officer of the Department would be the appropriate group
92	to take the decision.
93	Q. Very well. We can now move on to the fifth meeting of
94	the ACVSB, just pausing to note from the chronology that
95	during December the pilot study which had been agreed on
96	in the fourth meeting took place at three centres,
97	Birmingham, Sheffield and Brentwood?
98	A. That is correct.
99	Q. As we will see, the results of that were reported to the
100	next meeting which was in January and we will all find

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101	it in Q1 behind big tab 5.
102	MR JUSTICE BURTON: That is Pilot Study 1?
103	MR UNDERHILL: That is what I have been calling Pilot
104	Study 1, yes. As we have already seen from the minutes
105	of the fourth meeting, the purpose of that was to see
106	how these kits would work on the ground in real
107	conditions?
108	A. Yes, it was a study to see how the tests could be
109	incorporated into the general work of the Blood
110	Transfusion Service.
111	Q. The minute is at page 218. The relevant part starts at
112	paragraph 13 on 219. One can see that the first item
113	discussed was a paper which you had tabled which is at
114	page 237 which is a report on that pilot trial. We see
115	that, for the first paragraph, about 5,000 tests were
116	performed in each of three Regional Transfusion
117	Centres. The test kits were purchased by the DoH,
118	ancillary equipment provided on loan by Ortho.
119	What sort of equipment would that have to be?
120	A. That was the equipment for developing the colour
121	reaction and the washer.
122	Q. And the washer?
123	A. Yes.
124	Q. I do not think the court needs to know in great detail
125	about how these tests work, but what is the washer?
126	A. Well, a washer is -- at the end of the first incubation
127	phase you have to wash the plates before you put in the
128	antiglobulin reagent and colour developing dye.
129	Q. Not just for water; it is a special washing?
130	A. Yes.
131	Q. I do not think we need to discover any more about that.
132	Then we see the results; the repeat reactives vary
133	between different regions between just under 0.2 and
134	just over 0.6. You set out the comments from the
135	participants:
136	"All commented the test was straightforward and
137	easy to perform. Difficulties were encountered at all
138	three ... with the washer."
139	There is a comment made that:
140	"Additional flexibility of the software for the
141	computer readout will be required to allow
142	standardisation ... The test takes two and three
143	quarter to three hours to complete which may cause
144	disadvantages with emergency release of products."
145	That was the point that you were describing to his
146	Lordship yesterday?
147	A. That is indeed.
148	Q. "A comment from [two of the centres] was that a
149	proportion of results had higher OD [optical density]
150	than the bulk of negatives, but were below the cut-off

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151	value for positive reactors."
152	What was the significance of that?
153	A. Well, it made them wonder whether there might be some
154	false negatives in the results that had not been
155	detected because the -- perhaps the cut-off was not
156	necessarily in the correct position.
157	Q. In a perfect test, positives would be very, very black
158	and negatives would be no colour at all?
159	A. You would have a great gap between the optical densities
160	of the negatives and then the positives and the cut-off
161	would be in between the two.
162	Q. It will probably be easier for his Lordship to
163	understand when he has had Dr Barbara's slideshow?
164	A. Dr Barbara is more expert on this than I.
165	MR JUSTICE BURTON: What does it suggest, then? That there
166	might after all be positives?
167	A. That there might be false negatives.
168	MR UNDERHILL: In the final section, you describe that two
169	of the centres reported that:
170	"Weaker reactions were observed with plasma than
171	with serum samples."
172	In the note that I gave his Lordship with your
173	blessing it was described that, once you had a little
174	way down the line an initial positive reaction and
175	indeed a repeat reaction, you would test not only the
176	original serum sample, what in the note we call the
177	whole blood sample, but you would also test a sample of
178	the blood in the bag?
179	A. Yes.
180	Q. Those were chemically different because blood in the bag
181	is diluted to some extent?
182	A. Yes.
183	Q. What is the significance of the fact that weaker
184	reactions were observed in the plasma than the serum
185	samples?
186	A. Well, the test on the plasma was done at that time to
187	ensure that all three samples that you got positive came
188	from the same donor, because the specimens -- the
189	clotted specimens in the tubes were taken at a different
190	time in the donation when the actual donation bag had
191	been separated from the donor.
192	Q. At least in principle there is a chance they might have
193	got misattributed?
194	A. If they had got mixed up, you would find out by getting
195	a different result on the plasma from that in the
196	clotted sample, and this is part of the routine quality
197	assurance that was carried out at the centres.
198	MR JUSTICE BURTON: When you say "the clotted sample", is
199	that described here as the serum sample?
200	A. That is the serum sample, yes. It is clotted blood

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201	which, when the clot --
202	MR JUSTICE BURTON: I do not know why I get the feeling that
203	is the wrong way round, but there it is. The liquid to
204	start with is what you call the plasma; the clotted
205	blood is what you call the serum?
206	A. Yes, you take a sample of blood into a tube which is an
207	empty tube and that blood will within 10 to 15 minutes
208	clot, and the clot retracts and the clear fluid that
209	appears around the clotted blood is called serum.
210	MR JUSTICE BURTON: I see. So you are not testing the
211	clotted blood; you are testing the serum?
212	A. You are testing the serum from the clotted sample.
213	MR JUSTICE BURTON: Whereas the plasma is that which has the
214	anticoagulant?
215	A. Plasma is anticoagulated.
216	MR JUSTICE BURTON: I remember your note, not in any detail,
217	but I do not think I need to understand it fully at the
218	moment.
219	MR UNDERHILL: It is there if you need it.
220	MR JUSTICE BURTON: I remember one had anticoagulant and
221	that is what is called the plasma?
222	A. Yes.
223	MR JUSTICE BURTON: Then I had got them the right way
224	round. Serum is clotted, but of course you do not
225	actually test the clotted blood; you test the liquid?
226	A. You take the serum off the red cells.
227	MR JUSTICE BURTON: Thank you.
228	MR UNDERHILL: You comment in your paper:
229	"It is known from previous studies that the test
230	is susceptible to dilution effects and this may be the
231	cause of this observation."
232	Can you explain that to his Lordship?
233	A. When you add anticoagulant to the blood you dilute the
234	plasma approximately 1 in 3, and this is how that
235	dilution effect occurs, and the suggestion that it may
236	be subject to dilution effects was found by Dr Barbara
237	when he did the samples from the multicentre trial.
238	Q. In his initial evaluation?
239	A. In his initial evaluation.
240	Q. If that were the case, would it be something you needed
241	to know?
242	A. A very serious matter, yes.
243	MR JUSTICE BURTON: Why in that case do you do the main
244	test, because I think I have understood that the main
245	test is done on the unclotted blood, the one that has
246	had the anticoagulant added to it? Why do you not do it
247	on the clotted one?
248	A. Because it is technically easier to use serum for the
249	test than plasma, because the other factor, my Lord, is
250	that it may have been -- we did not know at this time,

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251	it may have actually been the anticoagulant that was
252	causing the problems.
253	MR UNDERHILL: Perhaps I should not have stopped and asked
254	you the question at that point because your very next
255	sentence says:
256	"On the other hand, there may be a specific effect
257	on the test by one or more of the constituents of the
258	anticoagulant/nutrient solution used in blood
259	collection. This will have to be investigated further
260	since at Trent, out of seven positive reactors, four
261	could only be determined as repeatable using serum
262	samples."
263	In other words, once you did them on the plasma,
264	three of them did not react?
265	A. It got a negative result.
266	MR JUSTICE BURTON: They would still count as repeat
267	reactive, as long as they reacted on one of the tests;
268	is that right?
269	MR UNDERHILL: Yes, they would, but you would then have a
270	serious problem, because you would have them not
271	marrying up with the blood in the bag. Sorry, I gave
272	that evidence. That is right, is it not?
273	MR JUSTICE BURTON: I have understood that.
274	A. Yes.
275	MR JUSTICE BURTON: The only thing I had wanted to get into
276	my mind is, provided that they test positive on one of
277	the tests, then they count as a repeat reactive.
278	MR UNDERHILL: It goes on to say:
279	"The result with a plasma sample from the donation
280	itself had a raised OD [so it had gone a bit darker] but
281	was below the cut-off value."
282	A. Yes.
283	Q. "Confirmation of positive results from the donation
284	itself is essential for RTC testing."
285	I think you have explained why. Could you say
286	again in a sentence?
287	A. It is to ensure the clotted samples were taken from the
288	same donor as you found in the plasma sample, because
289	you obtained the plasma sample from the donor line
290	attached to the bag. If you get a discrepancy like
291	that, the whole of the blood from that day would have to
292	be quarantined -- from that session would have to be
293	quarantined -- and the whole session retested from
294	plasma samples, because it may be there is another
295	donation which is positive in that session which had
296	reacted negative on the serum sample.
297	Q. As soon as there is a suspicion of a mismatch, you have
298	to test the whole lot again?
299	A. Indeed.
300	Q. Then you point out that, as we have seen, there was

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301	quite a wide variation of repeatable reactions between
302	the different areas, and you point out that that makes
303	it difficult to estimate costs because one of the
304	principal costs you were concerned with was loss of
305	product, counselling and further testing of donors, and
306	that would depend on what the repeat reactive rate
307	really was?
308	A. Yes.
309	Q. And it looked as if it was going to vary enormously
310	between regions. Then you say:
311	"With the number of tests now being routinely
312	carried out on donor blood some automated sample
313	handling is required. Without this direct sample
314	identification is difficult to achieve and the chances
315	of error will increase with the introduction of another
316	test."
317	Perhaps you could explain that aspect to his
318	Lordship.
319	A. The test as initially devised was semi-automated. You
320	could get automated sample handling, but you had then to
321	take the plate and do washing on a manual basis, and in
322	order for the test to go through in an appropriate
323	manner you would really wish to have the thing fully
324	automated and then the optical density results picked up
325	on the machine and translated to a computer to analyse
326	the results, and this is eventually what happened.
327	Q. Any manual element is a risk of human error?
328	A. There is a risk of human error, yes.
329	Q. You say:
330	"Such handling devices are available in certain
331	RTCs but would have to be purchased in others. Such
332	equipment would minimise the additional staff required
333	but this [that is additional staff] would comprise one
334	additional MLSO at each RTC, at least, dependent on the
335	throughput."
336	MLSO is scientific officer?
337	A. Medical Laboratory Scientific Officer.
338	MR JUSTICE BURTON: I get the impression this is just one
339	extra test on top of all the others that were being
340	done, hepatitis B, HIV and all the others, so it might
341	be a good moment to get these automated, but can it
342	really be said that this is anything other than the
343	straw which would break the camel's back?
344	A. No, I think -- yes, I agree with you, my Lord. Because
345	you are increasing the number of tests --
346	MR JUSTICE BURTON: By one?
347	A. Yes, the greater degree of automation that you have is
348	an advantage.
349	MR JUSTICE BURTON: You would have had to have gone
350	automated anyway?

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351	A. Inevitably.
352	(11.00 am)
353	MR UNDERHILL: That was the paper you put to the Committee.
354	We see what you said is set out in paragraph 13, and you
355	explain in paragraph 14 what you now explained to his
356	Lordship -- I am going too fast for you. Page 220.
357	A. Yes.
358	Q. You explained the most important problem, being the
359	difference between the reactions observed with the
360	plasma as compared to sera, and why that was important.
361	You also refer to the time, the difficulty with the
362	emergency release of products:
363	"In conclusion, Dr Gunson said these were some of
364	the aspects that would have to be discussed with Ortho.
365	"It was noted that Ortho were holding a symposium
366	on hepatitis C in London in February, on the same day
367	that Abbott (who are expecting to produce a test
368	shortly) will be holding one in Chicago. Members of the
369	Committee would be attending both ..."
370	Then you have reported, paragraph 16:
371	"The Chairman invited the Committee to address the
372	question of whether the time has now come for the
373	introduction of routine Hep C testing."
374	There were before the Committee two papers, or
375	they are described as papers, they are actually in the
376	form of letters, one from Professor Zuckerman and one
377	from Professor or Dr Elias. We ought to look at those.
378	They are at pages 239 and 241.
379	MR BROWN: My Lord, I am seeking to assist again. I am
380	aware that when I took your Lordship to the Professor
381	Zuckerman letter I did so by reference to that which
382	appears in the A bundles, and it may be better to move
383	it.
384	MR JUSTICE BURTON: What is the page?
385	MR BROWN: A3/903.
386	MR JUSTICE BURTON: Thank you very much. Certainly I have
387	not got the Zuckerman letter marked up here. Yes, 902,
388	thank you.
389	MR BROWN: It is actually 902, sorry.
390	MR JUSTICE BURTON: I have a reference at the top,
391	19/12/39.
392	MR BROWN: 19/12/89, that was the date.
393	MR UNDERHILL: The date, my Lord, appears somewhere else.
394	It is on the second page in that version, although it
395	has been cut off in others. We can see from this that
396	Professor Zuckerman had been asked by Dr Rejman who was
397	the Senior Medical Officer working for or with the
398	Committee effectively for his views?
399	A. Yes.
400	Q. I do not want to spend time reading all through it when

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401	we have read it already. Just points to note, my Lord
402	and Dr Gunson, that broadly he is positive about the
403	test, it is an important advance, but at point 3 he
404	makes the point that one of the most important and
405	urgent problems is the lack of confirmatory assays for
406	repeatedly reactives or borderline reactions. 4:
407	"Another difficulty, which does not necessarily
408	apply to blood donor screening, is the apparent high
409	number of false positive reactions when the test is
410	applied to frozen ..." and that you had samples.
411	One can see that would not apply once it was in
412	routine use?
413	A. No.
414	Q. A problem for research problem purposes?
415	MR JUSTICE BURTON: Indeed it is irrelevant, is it not?
416	MR UNDERHILL: Absolutely, yes. 5, next point, there is a
417	degree of correlation with surrogate markers in the
418	United States, but most people who are anti-HCV positive
419	do not have surrogate markers.
420	Then:
421	"On balance, my recommendations are that:
422	"1. Introduction of the current test for routine
423	blood donor screening in the United Kingdom should await
424	the decision on licensing by the FDA in the USA, due at
425	the end of March 1990.
426	"2. The data available to date indicate that the
427	current test will identify a significant number of
428	chronically infected donors. The number of false
429	reactions cannot be determined, but all reactive donors
430	may be deferred temporarily until a confirmatory test or
431	a test for another marker of hepatitis C virus becomes
432	available, probably within 12 months", something I know
433	my learned friend will want to ask you about and I will
434	not deprive him of the pleasure.
435	"The projected cost of this screening test is, at
436	least initially, very high, but considering the overall
437	morbidity of chronic non A non B hepatitis (including
438	apparently autoimmune liver disease and hepatocellular
439	carinoma) and litigation which would be indefensible,
440	the introduction of screening could not be delayed much
441	beyond FDA approval.
442	"3. An improved format of the test is under
443	development by another large and experienced
444	manufacturer (Abbott) and this test should also be
445	evaluated. Other tests are under development.
446	"4. A case can be made for the introduction of
447	routine surrogate testing, particularly for ALT
448	elevations, for detection of early infection with
449	hepatitis C on NANB. However, this aspect of screening
450	is also subject to debate in view of the non-specifity

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451	of the test.
452	"I look for ward to a more comprehensive
453	discussion ..."
454	MR JUSTICE BURTON: Was he there at the meeting, Professor
455	Zuckerman?
456	MR UNDERHILL: He was, and we are going to hear what he
457	said. Indeed he spoke to that paper. But we also want
458	to see what Dr Elias had to say. The significance of
459	Dr Elias is he is a liver specialist. That is right, is
460	it not?
461	A. He is indeed.
462	Q. Writing from the Liver Unit at the QEH in Birmingham,
463	which I do not think your Lordship was taken to before.
464	My learned friend describes him as someone from Wales.
465	MR BROWN: I do apologise. I do not know where I got that
466	from.
467	MR UNDERHILL: He is a Welshman, I think.
468	MR BROWN: It is Elwyn Elias and I obviously --
469	MR UNDERHILL: A Welshman in Birmingham. I will go through
470	this in slightly more detail because as I say we have
471	not seen it before:
472	"Thank you for your letter ..."
473	MR JUSTICE BURTON: Can I know where it is referred to?
474	MR UNDERHILL: It is one of the papers before the
475	Committee. That is why I am taking your Lordship to it.
476	MR JUSTICE BURTON: I understand that entirely. I am just
477	wondering where it is referred to, that is all.
478	MR UNDERHILL: Where it is referred to by?
479	MR JUSTICE BURTON: In the minutes.
480	MR UNDERHILL: I do not think it is explicitly referred to.
481	It assumed that the Committee members had read it.
482	Perhaps I should ask you, Dr Gunson, would you have read
483	this if it was circulated to the Committee?
484	A. I hope so.
485	Q. He says:
486	"I believe the issue presents considerable
487	difficulties and that the answer is not immediately
488	obvious. On the one hand, it can be verified that a
489	test is now available which detects an antibody to
490	hepatitis C virus and that a positive test has a
491	reasonably high predictive value in predicting the risk
492	of transmission of post-transfusion hepatitis C to the
493	recipient. One might argue in absolutist terms that the
494	mere availability of a test which has the potential to
495	prevent any post-transfusion hepatitis has a certain
496	moral obligation on us to introduce it into routine
497	clinical practice. However, realistically we have to
498	accept that we are in a service which rations its
499	resources on a day-to-day basis and I believe that the
500	benefit per unit expended in this area does not

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501	immediately overwhelm one when considering alternative
502	priorities.
503	"The problem with the test is that it only detects
504	the antibody transiently in a few patients with acute
505	[emphasising the "acute"] hepatitis C and otherwise
506	becomes positive in patients with chronic hepatitis.
507	There is therefore a significant time during which
508	patients who are carrying the hepatitis C virus and have
509	the potential to transmit it in their blood products
510	yield negative results with the available test. The
511	introduction of the test routinely would not therefore
512	eliminate the risk of transmitting hepatitis C and
513	indeed it is difficult for me to hazard a guess of what
514	proportion of post-transfusion hepatitis C might be
515	prevented in this way.
516	"The incidence of post-transfusion hepatitis C in
517	Britain appears to be much lower than it is in the
518	United States. Having said this, I am not aware of any
519	formal study in the UK which is comparable to those
520	performed in large surveys in the USA. There it appears
521	that up to 10 per cent of patients develop
522	post-transfusion non A non B. Furthermore in that group
523	of patients, 50 per cent are said to become chronic and
524	20 per cent of those go on to develop cirrhosis within
525	five years or so. The argument in favour of introducing
526	a test would therefore be that it more than pays for
527	itself in terms of the prevention of health care
528	expenditure which would be involved in managing the
529	complications of cirrhosis in the 1 per cent or so who
530	develop it subsequently. The precise cost benefit
531	analysis in this area would be a complicated
532	mathematical calculation based upon lots of
533	assumptions. To the best of my knowledge, the incidence
534	of a positive test in blood donors in Britain is of the
535	order of 0.5 per cent although of course it may vary
536	from one region to another around the country ..."
537	MR JUSTICE BURTON: That is about right, is it?
538	MR UNDERHILL: It is about right for the repeat reactive,
539	yes. It is a gross overestimate for actual true
540	positive.
541	MR JUSTICE BURTON: That is all it says, the incidence of
542	positive test.
543	MR UNDERHILL: Yes, so sorry, my Lord. That was about right
544	at that time, was it?
545	A. That was almost the same as was obtained in the London
546	centres. It tended to be rather lower outside London.
547	MR JUSTICE BURTON: When you say "at that time", this is
548	because the second generation test brought it down, is
549	that it, by eliminating false positives?
550	MR UNDERHILL: Perhaps I should not have said "at that

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551	time". When I said "at that time" I meant nobody knew
552	how many of those were false positives.
553	With the second generation test, did the number of
554	repeat reactives come down?
555	A. No. It remained about the same.
556	Q. The advantage of the second generation test was it
557	increased sensitivity rather than --
558	A. It increased sensitivity, but did not materially
559	increase specificity.
560	MR JUSTICE BURTON: I follow. Not that it matters at this
561	stage of the story, but it is helpful for me to have it
562	down. Can I note that down? Second generation
563	increased sensitivity, but not specificity. That was
564	dependent on the confirmatory test, was it?
565	A. The specificity is the number of instances in which the
566	test will pick up a true positive. Therefore you had to
567	have a confirmatory test before you could --
568	MR UNDERHILL: I think what his Lordship was putting to you
569	was that the advances that came were from the
570	development of a confirmatory test?
571	A. Indeed.
572	MR JUSTICE BURTON: Coming back, then, to this, this
573	actually probably remained right at all material times.
574	MR UNDERHILL: I think it did, yes.
575	MR JUSTICE BURTON: Incidence of a positive test, thank
576	you.
577	MR UNDERHILL: Then where we broke off, just before the end
578	of that paragraph:
579	" ... my impression [he of course is a liver
580	doctor] is that clinically significant hepatitis is even
581	rarer than might be expected if all positively testing
582	units proved infectious.
583	"We have done a survey of all the patients
584	admitted to our unit recently to look for the presence
585	of antibody to hepatitis C. The antibody is present in
586	a proportion of patients with chronic liver disease
587	which we believe to be typical of other conditions such
588	as primary biliary cirrhosis. A major difficulty in
589	assessing the impact of hepatitis C is that the results
590	we have tend to be retrospective. Whether or not the
591	hepatitis C virus has had any role in exacerbating that
592	disease or has any other morbid implications, it is
593	impossible to tell. A significant proportion of the
594	patients we see do, in fact, have sporadic non A non B
595	hepatitis, i.e. they give no history of exposure to
596	blood products or of contact with anyone who has been
597	suffering from hepatitis. The mode of spread of non A
598	non B hepatitis in our community is therefore still a
599	mystery.
600	"In summary, therefore, I would say that as a

	A
601	practising clinician with an interest in life disease,
602	that post-transfusion non A non B hepatitis is a
603	relatively rare occurrence except when, as in the
604	haemophiliac population, the patients are transfused
605	with pooled blood products. I suspect that in order to
606	eliminate the low incidence of non A non B hepatitis
607	following transfusion in this country will require a
608	more sensitive test than the one currently available.
609	It would seem reasonable to be testing pooled blood
610	products since the likelihood of positivity and of
611	transmitting the infection is increased by virtue of the
612	pooling.
613	"I am sorry if these comments are rather vague and
614	inconclusive."
615	That was the liver doctor's view expressed to the
616	Committee. Then if we go back to page 220 we see that
617	Professor Zuckerman spoke to his letter:
618	"He emphasised the problems posed by the lack of a
619	confirmatory test and the apparent high number of false
620	positive reactions obtained when the test is applied to
621	samples which had been frozen and then thawed."
622	It is really just a summary. Then 18:
623	"In attempting to give an indication of the number
624	of possible cases of chronic liver disease that could be
625	prevented by the introduction of routine testing,
626	Professor Zuckerman emphasised that his figures would
627	represent gross assumptions and estimates."
628	We may have to ask Professor Zuckerman. Can you
629	from your recollection or having been there help us on
630	what point he was making when he said he was talking
631	about gross assumptions?
632	A. Well, of course, the major problem was without doing a
633	large survey of patients, it was difficult to analyse --
634	determine exactly who had hepatitis.
635	Q. I am sorry, I have been reading "gross" as opposed to
636	"net". I think he may have meant "gross" meaning -- we
637	will ask him.
638	MR JUSTICE BURTON: I would have thought it is by reference
639	to the next sentence:
640	"On that basis, he offered the figure of 5,000 ...
641	50 per cent could be false negatives."
642	It seems to me "gross" means inclusive of false
643	results.
644	MR UNDERHILL: I think we have already decided it is false
645	negatives as distinct from false negatives.
646	MR JUSTICE BURTON: That is why I paused before I said it.
647	That must be right. When you say we had already
648	decided, I had not noted it.
649	MR UNDERHILL: Perhaps we have not. Maybe I had just
650	already decided.

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651	MR JUSTICE BURTON: At any rate, assuming false negatives
652	means false positives, gross surely means inclusive of
653	what turns out to be false positives. As you say, we
654	can probably ask Dr Zuckerman. That does seem to me
655	what it means, because he says "on that basis".
656	MR UNDERHILL: Maybe that is right.
657	MR JUSTICE BURTON: I am sure you are right that that must
658	be another of Mr Brown's errors in the minutes.
659	MR UNDERHILL: "As it was not possible to estimate how many
660	recipients there would be for each donation, it would be
661	impossible to expand the estimate further."
662	Then he gave some information about Japan, the
663	substance of which was that there was another hepatitis
664	C which was a further complicating factor, and he says:
665	" ... this strengthened the argument that we must
666	keep an open mind about other tests, which should be
667	available within the next 12 months. He felt that it is
668	unlikely that the FDA would licence the Ortho test in
669	the absence of a confirmatory test, and it would be
670	difficult for us to approve a test which was not
671	approved in its country of origin. The proposed Abbott
672	test would not really be an independent test.
673	Dr Rotblat ..."
674	We see she is not formally a member of the
675	Committee; she is an other observer. What was her
676	particular speciality?
677	A. Dr Rotblat was from the Medicines Control Agency.
678	Q. She added it was also her understanding the FDA was
679	unlikely to approve the tests at this stage. So she is
680	effectively a sister body to the FDA, or the same sort
681	of body?
682	A. Yes. The Medicines Control Agency are the group that
683	provide the regulatory provisions for drugs, but also
684	including blood products.
685	Q. Then 21:
686	"Dr Tedder stated it was very difficult to make
687	any recommendations based on scientific criteria at this
688	time as so little was known about the virus and its
689	antibody markers."
690	Professor Zuckerman adds an extra point about the
691	incompleteness of the information in --
692	MR JUSTICE BURTON: Mr Underhill, you will have to remind
693	me -- of course it is not your case; it is Mr Brooke's
694	case -- dramatis personae, I cannot remember whether we
695	have one. I do not think we have.
696	MR BROOKE: No, my Lord, one of the pages of our opening was
697	headed "Dramatis Personae", and there is nothing after
698	that, I am afraid.
699	MR JUSTICE BURTON: That is what I seem to remember.
700	MR BROOKE: It is a case of not getting round to it.

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701	MR JUSTICE BURTON: It would be very helpful if one of your
702	juniors -- I speak collectively --
703	MR UNDERHILL: They are all chiefs and only one Indian.
704	MR JUSTICE BURTON: That is the disadvantage of having so
705	many fellow leaders -- can pick it up, or one of
706	Mr Underhill's team, possibly from the transcript.
707	I think it will be terribly helpful and will be
708	necessary, if you are going to say at the end of the
709	day, well, there was overcaution here or something of
710	that kind, Mr Brown's case on that aspect, and really
711	they should have overridden so-and-so if he was the only
712	one who was moaning, then one needs to know where he
713	stood in the hierarchy or alternatively what specialism
714	he had in order for me to decide whether that is indeed
715	right.
716	MR BROOKE: Yes, my Lord. At the very least the members of
717	the committees.
718	MR JUSTICE BURTON: Yes.
719	MR BROOKE: Possibly not all the authors of the learned
720	papers.
721	MR JUSTICE BURTON: No, you will have to be selective.
722	Those who are going to be important -- as you say,
723	I think perhaps the most significant of the people like
724	Dr Cash, or whatever, who feature in the articles, and
725	then certainly the members and observers at the
726	Committee and I suppose others involved in the decision
727	or non-decision, like those, Mr Anderson or whoever,
728	from the Civil Service.
729	MR BROOKE: Yes, my Lord. We will get on to it.
730	MR UNDERHILL: Paragraph 23, Dr Minor -- and you did explain
731	and I have now forgotten. Remind me what Dr Minor's
732	specialism was.
733	A. He was a Senior Medical Officer at the National
734	Institute of Biological Standards and Control.
735	Q. He was concerned effectively with quality?
736	A. He was concerned with quality, yes.
737	MR JUSTICE BURTON: He was a member?
738	A. He was a member.
739	MR UNDERHILL: He was a full member of the Committee. He
740	posed a question:
741	"If 10 per cent of the Ortho test positives
742	transmit ..."
743	Perhaps if I interpolate, he seems to have guessed
744	about right, does he not?
745	A. Yes.
746	Q. "If 10 per cent of the Ortho test positives transmit,
747	how many of the Ortho negatives also transmit?"
748	Was that a question that could be answered at that
749	time?
750	A. I think it was a question that was impossible to answer

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751	at that time.
752	Q. "Dr Mortimer felt that ..."
753	MR JUSTICE BURTON: Pausing a moment, that only becomes
754	relevant, does it, on the second generation, which is
755	more sensitive? There is nothing that happens before
756	the second generation which improves specificity, which
757	is what that relates to?
758	MR UNDERHILL: Sensitivity.
759	MR JUSTICE BURTON: I am sorry, sensitivity, which is what
760	that relates to?
761	A. Yes, nothing -- the first generation tests did not have
762	improved sensitivity. This came with the second
763	generation test.
764	MR UNDERHILL: "Dr Mortimer felt that as the perceived risk
765	is higher than that of HIV, we would be inconsistent in
766	our screening procedure if we did not introduce routine
767	screening. If we began routine use of this test we
768	should soon have a better test to move on to.
769	"Dr Mitchell discussed the potential problem of
770	handling donors. He felt that it was possible to deal
771	with the donors who proved positive to the test without
772	causing undue alarm."
773	MR JUSTICE BURTON: You are going to ask this witness a
774	question, are you, about this, because we have read --
775	MR UNDERHILL: I am in two minds, my Lord, frankly. I could
776	and if encouraged by your Lordship I will. I am keen
777	not to prolong evidence in chief longer than I have to.
778	I know most of the points which will be picked up by my
779	learned friend, although it is quite fun spiking his
780	guns --
781	MR JUSTICE BURTON: It is a matter entirely for you. I do
782	know Mr Brown drew particular attention to paragraph 24,
783	and it is a matter entirely for you as to whether you
784	deal with it in chief or leave it to Mr Brown.
785	MR UNDERHILL: Can I ask you to comment firstly on the first
786	sentence of that paragraph where Dr Mortimer said he:
787	" ... felt that as the perceived risk is higher
788	than that of HIV, we would be inconsistent in our
789	screening procedure if we did not introduce routine
790	testing."
791	That was obviously inconsistent with what we did
792	about HIV?
793	A. He was basically saying that there were more cases of
794	HCV hepatitis as a result of transfusion than had
795	developed with respect to HIV as a result of
796	transfusion, and it would be inconsistent for us to not
797	use the test when we had introduced the HIV test
798	screening procedure within about six months of tests
799	becoming commercially available.
800	Q. In terms of the seriousness, not in terms of prevalence,

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801	but the actual seriousness of the condition, how did HCV
802	as then perceived, compare with HIV?
803	A. Well, HCV was regarded as a relatively mild illness
804	which could of course, in about half the cases, become a
805	chronic illness. Even when chronic, symptoms were not
806	necessarily extensive, and even with cirrhosis, which
807	was the usual terminal part of that disease, patients
808	could live often a reasonably normal life. With HIV, of
809	course this was a serious illness which usually within a
810	few months of that time, because the drugs that we have
811	now were not available, could lead to death.
812	Q. Then:
813	"If we began routine use of this test, we should
814	soon have a better test to move on to."
815	Perhaps I should ask you this: when the decision
816	in principle was taken a little later, which test was
817	the one which was then available?
818	A. The first generation test.
819	Q. Though it is fair to say that in the end there was a
820	degree of postponement as we are going to see because
821	second generation appeared to be on the horizon?
822	A. First generation tests were not used in routine
823	screening.
824	Q. Paragraph 26 you explained:
825	"... that the transfusion services were under a
826	great deal of pressure not just from Ortho but from the
827	press, increasingly from clinicians in the field."
828	What is that a reference to?
829	A. Well, Professor Sheila Sherlock at one of the London
830	teaching hospitals considered that we should be
831	introducing this test immediately.
832	Q. She communicated that to you or at any rate publicly?
833	A. She wrote articles about it in the press.
834	Q. "He felt that each centre must now consider how to set
835	up the test and what extra resources they would need to
836	do so. He also highlighted the fact that as further
837	tests are introduced the potential for labelling
838	mistakes will increase to a point where the time may
839	have come to introduce automation."
840	You perhaps --
841	A. That is the point we raised before.
842	Q. "Dr Tudman explained..."; remind us who Dr Tudman is?
843	A. Dr Tudman is a consultant physician whose main interest
844	was in haemophilia.
845	Q. "[He] explained that, to date, donors who have shown as
846	positive have not been recalled, but will be retested on
847	next appearance."
848	Of which centre was he talking when he said that?
849	A. Well, these are the three centres that did the trial.
850	Q. Was he involved in that?

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851	A. He was not involved in that, and I think what he should
852	be -- he assumed they would be retested on appearance,
853	because they were only given in December and this
854	meeting was in January.
855	Q. It rather reads as if he is someone who has
856	responsibility for a centre and is explaining what
857	happens there?
858	A. He did not have a responsibility for a centre.
859	Q. "In answer to questions about funding ... the Chairman
860	explained the funding would have to be found from the
861	existing health vote allocation."
862	Then at 29:
863	"The Chairman summed up the general consensus of
864	the Committee as follows:
865	"Routine testing should not be introduced in
866	advance of the FDA decision;
867	"scientifically, not enough is known yet, but
868	there is agreement that the test does detect some people
869	who will transmit; and
870	"the overall prevalence figure of non A non B
871	following blood transfusion for the UK may be 10,000 a
872	year, subject to very wide margins of error."
873	It is not apparent to me -- I do not know whether
874	you can help -- how the Chairman arrived at that figure
875	of 10,000 a year.
876	A. Mr Underhill, when I read these minutes again to prepare
877	my statement, it was not apparent to me, because all he
878	seemed to have done was double Professor Zuckerman's
879	figure.
880	Q. Perhaps we should just remind ourselves, in fact, in the
881	event what was the prevalence figure of non A non B
882	following blood transfusion?
883	A. Once we had the PCR to do the confirmatory testing, it
884	was between 1 in 1,000 and 1 in 2,000 donors.
885	Q. So you would have to multiply that by the number of
886	donors?
887	A. So you would have to multiply that by the number of
888	donors, yes.
889	Q. Or divide it.
890	A. Whatever.
891	Q. It is a great deal less than 10,000?
892	A. It is a lot less than 10,000.
893	Q. Subject to that point, which is a --
894	MR JUSTICE BURTON: Put another way if you can help me on
895	this, in terms of percentage, if one takes Professor
896	Zuckerman's 5,000 members of the donor population and
897	50 per cent were false positives, I think you are saying
898	it was in the end 90 per cent were false positives. Is
899	that right?
900	A. Yes, that is correct. There was a very high proportion

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901	of false positives.
902	MR JUSTICE BURTON: It would come out about 10 per cent of
903	5,000 if Professor Zuckerman was right?
904	A. If he was right.
905	MR UNDERHILL: We can actually do the sums quite easily, can
906	we not? It is about 2.5 million donors in rough figures
907	for England and Wales?
908	A. In that order.
909	Q. Taking a middle figure between your 1 in 1,000 and 1 in
910	2,000, take 1,500, if you divide 2.5 million by 1,500,
911	subject to someone behind me with a calculator, it comes
912	to 1,666. That, to be fair, nobody knew at the time?
913	MR BROWN: My Lord, in the first year of full donor testing,
914	they eliminated 890 donors from the pool.
915	MR UNDERHILL: Even smaller, yes.
916	MR BROWN: Of course those 890 donors may have given to more
917	than one recipient.
918	MR UNDERHILL: Can I ask you about that, Dr Gunson? Leaving
919	aside the question of pooled products, a donor could
920	indeed give to more than one recipient if he gave more
921	than once a year?
922	A. Yes, each donation was -- could be split into three
923	different types of products, possibly --
924	Q. You are quite right, I overlooked that. You have two
925	problems, one donor might give twice in one year and as
926	you were about to explain -- sorry I interrupted you --
927	the product could be divided into --
928	A. You could get nominally four products from a donation.
929	You could extract the granulocytes, these white cells,
930	you could take out the platelets, you could take off the
931	plasma and you had then the basic red cells remaining.
932	So there were potentially four products. Granulocytes,
933	the white cell transfusions were not used extensively.
934	MR JUSTICE BURTON: Am I right in thinking that pooled
935	products could all be heated?
936	MR UNDERHILL: Yes, so we can ignore pooled products?
937	A. Pooled products would be heated.
938	Q. The products you are talking about -- if every bit of a
939	donation was used -- was split so you did not give it as
940	whole blood, and all the three bits were used, or four
941	bits --
942	A. Four bits.
943	Q. How common would it be for a donation to be split and
944	used four ways?
945	A. Four ways, uncommonly. Three ways, quite common,
946	because the transfusion of whole blood, that is the
947	blood that you collect in the bag, became less common
948	because really patients needed either red cells or they
949	needed plasma or they needed platelets.
950	MR JUSTICE BURTON: Including all that, taking into account

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951	what you say, and the fact that it was twice a year,
952	what would one use, five times, multiply a donor by
953	five?
954	A. Five or six, yes.
955	MR BROWN: My Lord, the 890 was wrong. It is 807. The
956	reference is H4/99.3.
957	MR UNDERHILL: Very impressive.
958	MR JUSTICE BURTON: Thank you very much.
959	MR UNDERHILL: Perhaps just so we can run this down, the
960	average times a donor gives a year, you did give us a
961	figure for it. It was not quite 2, was it?
962	A. We have some -- we had at that time, as I recall,
963	something like 1.5 million donors and we collected
964	2.5 million donations, but some donors give twice a
965	year, some gave once a year, and occasionally donors of
966	the more uncommon groups, we asked to come three or four
967	times a year.
968	Q. As an average, it is simply whatever 1.5 is --
969	A. It is about 1.7 or something.
970	MR JUSTICE BURTON: Allowing, then, for the fact that some
971	whole blood was used and that it would be very rare for
972	all four packages to be used, I am going to use, unless
973	you think otherwise, 5 times as the appropriate marker
974	which allows for the fact that it is less than twice a
975	year. If it was four products twice a year, it would be
976	eight.
977	A. Yes.
978	MR JUSTICE BURTON: Very rare, four products?
979	A. Very rare.
980	MR JUSTICE BURTON: Some whole blood and in any event it is
981	less than twice a year. So I would have thought five
982	times is about right.
983	A. I would have thought that is very reasonable, my Lord.
984	MR UNDERHILL: Very helpful. That is in a sense a
985	digression but a helpful one, because we were trying to
986	see, quite apart from our not being able to understand
987	the Chairman's figure, how he got to it, whether it was
988	right. Subject to that quite important consideration,
989	his other two bits of summing-up and the general
990	consensus of the meeting --
991	MR JUSTICE BURTON: Pausing a second, do you think that may
992	be the answer, Mr Underhill, is that what you were
993	suggesting? Because if, in fact, one halves Professor
994	Zuckerman's 5,000 to 2,500, and if one uses the 5, it
995	may be what he means is 10,000 recipients, because the
996	overall prevalence figure of non A non B following blood
997	transfusion may be the recipient population rather than
998	the donor population.
999	MR UNDERHILL: There is an extra complication. It is right,
1000	is it not, that although this turned out to be the case

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1001	there was a feeling at the time that quite a lot of
1002	infective transmissions did not, in fact, infect, if you
1003	follow me?
1004	A. Yes, I think that was true. There was also a problem at
1005	this time that we really did not know how many cases of
1006	non A non B hepatitis following transfusion existed.
1007	MR JUSTICE BURTON: No one is calling Dr Metters?
1008	MR UNDERHILL: My Lord, no. The answer is it had not
1009	occurred to us to and ultimately I suspect, although one
1010	obviously wants to know as much as possible, it is
1011	not --
1012	MR JUSTICE BURTON: He will not remember?
1013	MR UNDERHILL: I will be amazed if he will. I doubt if it
1014	will be a decisive point in the case, because if it is
1015	right, it in a sense strengthens the case for --
1016	MR JUSTICE BURTON: For the claimant.
1017	MR UNDERHILL: In any event, subject to that query, the
1018	other two bullet points, does that accord with your
1019	recollection of the decision of the meeting, namely
1020	routine testing not to be introduced in advance of the
1021	FDA, scientifically not enough yet known?
1022	A. It does indeed.
1023	MR JUSTICE BURTON: Can you help me, it is a long time ago,
1024	Dr Gunson, you told us what your view was and it is
1025	apparent what Dr Mortimer's view was, et cetera, without
1026	going through all of it and no doubt you will be taken
1027	through all this in cross-examination, I am not going to
1028	tread that path now, or ask you to do so, but there was
1029	not a vote?
1030	A. There was never a vote in that Committee. It was a
1031	consensus decision.
1032	MR JUSTICE BURTON: How does the Chairman reach --
1033	A. He just took a consensus view of the members of the
1034	Committee. Much of the discussion, of course, is not
1035	reported in the minutes.
1036	MR JUSTICE BURTON: Then it is up to someone to say, "That
1037	is not my view, I think my view is shared by X, Y and Z
1038	as well, and I do not think, therefore, you are
1039	expressing the consensus correctly."
1040	A. And that was very rarely done.
1041	MR UNDERHILL: Perhaps I can follow that up. In the real
1042	world, we do know that sometimes things are expressed in
1043	a consensus which are not really. Looking at these
1044	meetings, maybe I should ask you about each meeting;
1045	would you say that from the discussions a consensus did,
1046	in fact, emerge, or is it concealing strong minority
1047	views?
1048	A. There were minority views. I think one cannot deny
1049	that. There is Dr Mortimer there and indeed Professor
1050	Zuckerman on other occasions. But in general, the views

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1051	expressed by the Chairman were the general views of the
1052	Committee.
1053	MR JUSTICE BURTON: Let me ask you, then, looking again now
1054	as you have done in relation to the minutes up to and
1055	including paragraph 29 and of course your own
1056	recollection, if one finds you have an independent
1057	recollection, is it correct to say that that was the
1058	general consensus of the Committee or not?
1059	A. The general consensus was that routine testing should
1060	not be done in advance of FDA, and --
1061	MR JUSTICE BURTON: I will put a tick against that.
1062	A. That scientifically not enough was known about the
1063	test. As I say, when I reread these minutes, I could
1064	not explain where the 10,000 came from or how this had
1065	been determined.
1066	MR JUSTICE BURTON: I will put a question mark against
1067	that.
1068	A. I think that is a query. The other three bullet points
1069	are really for --
1070	MR UNDERHILL: This is paragraph 30, is it?
1071	A. This is in paragraph 30.
1072	Q. I was about to come to those. I am sorry to grind so
1073	slow, but this is important. Perhaps we will come to
1074	that in a moment.
1075	MR BROWN: I was just going to help about the 10,000. I see
1076	that it is referred to on page 245 as part of the
1077	cost/benefit analysis within the Department. That only
1078	helps to a limited extent, but it shows where it came
1079	from.
1080	MR UNDERHILL: That is a possibility. May I throw out one
1081	other possibility, in case we can get Dr Gunson's views
1082	on it? Miss Merrett has gone against the consensus,
1083	that the reference to false negatives in paragraph 18 is
1084	wrong. She says, if it was really what Dr Zuckerman
1085	said, then it would be appropriate to double his figure
1086	rather than halve it.
1087	MR JUSTICE BURTON: Yes, I see.
1088	MR UNDERHILL: We will have to ask Dr Zuckerman whether he
1089	was correctly reported. It is fair to say he was pretty
1090	good at picking up mistakes in the minutes later.
1091	MR JUSTICE BURTON: 50 per cent could be false negatives.
1092	MR UNDERHILL: In fact, it was much more than that, but
1093	everyone was guessing, and that was as good a guess as
1094	any.
1095	MR JUSTICE BURTON: I see that. All I am really saying is
1096	it cannot mean 50 per cent of them could be false
1097	negatives.
1098	MR UNDERHILL: I think the context very strongly suggests
1099	false positives.
1100	MR JUSTICE BURTON: It must do. Otherwise it would say,

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1101	"But another 50 per cent could be false negatives", and
1102	even then it would only be 2,500 which would take us up
1103	to 7,500. I think, rightly or wrongly, the difference
1104	at the moment is that it is 5,000 members of the donor
1105	population and 10,000 members of the recipient
1106	population, but there it is.
1107	I cannot find this -- on page 245, I have not
1108	found the --
1109	MR BROWN: My Lord, it is a figure that appears in various
1110	documents, but it appears in that one on the middle of
1111	the page as being the number of confirmatories. So if
1112	it is 10,000 confirmatories you know that you have
1113	10,000 repeatable reactives.
1114	MR UNDERHILL: I was briefly going to go to this. Perhaps
1115	we could take it in turn.
1116	MR JUSTICE BURTON: Help me, the confirmatory tests would be
1117	taken on the donor.
1118	MR BROWN: Yes.
1119	MR JUSTICE BURTON: So I am wrong: it is 10,000 donors not
1120	10,000 recipients.
1121	MR BROWN: That is what it reads in the first place.
1122	MR JUSTICE BURTON: Because of the word "following",
1123	following blood transfusion.
1124	MR UNDERHILL: If you make the assumption which I have
1125	suggested was questioned at the time, that every
1126	infected donor creates an infected recipient, which
1127	turned out to be right, and if you ignore the point
1128	that, in fact, he may infect more than one person, then
1129	it may well be that the Chairman was indeed just moving
1130	over from one figure to the other. I do not think we
1131	are going to get to the bottom of this. It is probably
1132	not a profitable exercise at this stage unless Dr Gunson
1133	could give us the answer which he said puzzled him as
1134	well.
1135	Perhaps I can ask one question, Dr Gunson,
1136	following up the debate. You said -- and this I am sure
1137	will not come as a surprise -- that the minute does not
1138	record the full discussion?
1139	A. No.
1140	Q. In very broad terms, for how long would all of you have
1141	been discussing this issue on this occasion?
1142	A. These meetings used to last something between three and
1143	four hours.
1144	Q. Although on some of them, including this one, there was
1145	other business, there was not always?
1146	A. Yes.
1147	Q. Let us look at paragraph 30:
1148	"The Chairman then asked members for their
1149	opinions as to what action should be taken. Dr Tedder
1150	wanted it to be noted he would not give an opinion

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1151	before more scientific data had been generated ..."
1152	But the Committee agreed that:
1153	" ... the costs should be looked at now, with
1154	regions being called upon to consider the financial
1155	implications."
1156	That is effectively something you had already
1157	suggested as we see in the previous paragraph, 26?
1158	A. Yes.
1159	Q. "Professor Zuckerman's figures would be further refined,
1160	to present as close an estimate of cases of possible
1161	infection as possible. This would undoubtedly be called
1162	for by Ministers.
1163	"The Committee could give no further scientific
1164	advice at this point, but would discuss the matter
1165	further at the next meeting (April) which would be after
1166	the International Hepatitis Meeting in Houston.
1167	"Dr Pickles [from the Department] spoke to [her]
1168	paper", which is the one my learned friend has briefly
1169	referred us to and which we find at page 243 which was
1170	what one might call a proforma for a cost/benefit
1171	analysis. This is a paper she had written before the
1172	meeting. Do you have it?
1173	A. I do.
1174	Q. In the first paragraph she describes the Committee as
1175	having:
1176	" ... cautiously supported the introduction of
1177	routine testing [at previous meetings] ... provided the
1178	test itself satisfies the FDA and pilot studies in the
1179	UK show testing to be practicable ... Full examination
1180	of the cost/benefit would be needed to persuade senior
1181	NHS management that such testing was appropriate and
1182	worthwhile."
1183	She makes the point there are too many unknowns to
1184	create a proper cost/benefit analysis, but she sets out
1185	how you would set about it with lots of Xes and queries
1186	on page 244. Under 245 she does have some known costs
1187	which I would draw the court's attention to, because
1188	there was some discussion about these yesterday.
1189	Halfway down page 245, direct screening costs,
1190	materials, initial tests, £2.40 per test plus VAT;
1191	confirmatory test, much more expensive, £25 per test;
1192	additional staff for testing, £20,000 per centre, and
1193	cost of counselling for the positive donors, and a cost
1194	of replacement of lost donors. What sort of costs are
1195	involved in replacing lost donors?
1196	A. You have to recruit additional donors. It is a
1197	reasonably costly exercise.
1198	MR JUSTICE BURTON: Advertising, is that it?
1199	A. We have to advertise or you have to send out people on
1200	to shopping centres and other venues to actually ask

	A
1201	people if they will donate blood.
1202	MR JUSTICE BURTON: That is about 7 million, then, is it,
1203	those figures?
1204	MR UNDERHILL: Someone has totalled it to 6.35.
1205	MR JUSTICE BURTON: Up from Dr Gunson's 5 to 7.
1206	MR UNDERHILL: Then some additional costs, one which my
1207	learned friend thought was funny, but we will hear in
1208	due course whether it really was, about potential
1209	litigation from stigmatised donors and a whole variety
1210	of others.
1211	That was what was being said about cost/benefit at
1212	that time. I think that is almost all we need from this
1213	meeting. On page 222, there are a few more paragraphs
1214	we need to look at briefly. Have you found page 222
1215	again?
1216	A. Yes.
1217	Q. Paragraph 32:
1218	"It was pointed out by Dr Gunson that another
1219	aspect that would have to be worked into the equation
1220	was the action to be taken regarding the positive donors
1221	once they were counselled. They could represent 8,000
1222	to 10,000 annual referrals to gastroenterologists along
1223	with concomitant treatment costs."
1224	Then Mr Fuller said that they would be talking to
1225	Ortho and Abbott about their pricing policies and
1226	members were invited to send further observations before
1227	the next meeting and a submission to be made to
1228	Ministers.
1229	(11.45 am)
1230	That was that meeting.
1231	MR JUSTICE BURTON: Do we have the submission of the
1232	Ministers?
1233	MR UNDERHILL: I think it may well have been a document that
1234	my learned friend took your Lordship to. I am afraid
1235	I have shown much less interest than him in the
1236	Government side of this.
1237	MR JUSTICE BURTON: I thought that was a later one which
1238	took a long time drafting.
1239	MR BROWN: I do not think one went at this particular time.
1240	The only reason I have taken an interest in it is
1241	because Dr Gunson has said that this was always going to
1242	be a Department decision.
1243	MR JUSTICE BURTON: I think you showed me one after the
1244	April meeting that took until November or December to
1245	finalise.
1246	MR BROWN: My Lord, there was one after the July meeting,
1247	very short, and then it took until the end of December
1248	to finalise.
1249	MR JUSTICE BURTON: You have not shown me anything after
1250	January. I wondered whether it --

	A
1251	MR BROWN: I was actually just looking to check now, but
1252	I have not found one.
1253	MR UNDERHILL: There we are. If there is one, I am not
1254	aware of it.
1255	Perhaps we could therefore put away hopefully
1256	forever, or at any rate for a long time, Q1A. I suspect
1257	it will not be for a long time, for the rest of today.
1258	MR JUSTICE BURTON: There are no more meetings, then, of --
1259	MR UNDERHILL: There are, but we have simply come to the end
1260	of that bundle. We have two or three more important
1261	meetings. We are coming to the next, which is the
1262	sixth meeting which took place on 24th April 1990, and
1263	that is in Q2 behind big tab 6, which is the first in
1264	the bundle, and the relevant parts of the minute are at
1265	296 to 299.
1266	MR BROWN: Sorry, my Lord, I hesitate to rise, but for your
1267	Lordship's cross-reference I have actually found a note
1268	which partly falls within the category of a note to
1269	the Minister, and it is at A4/983. I am not asking your
1270	Lordship to look at it now.
1271	MR JUSTICE BURTON: I will put the cross-reference in, that
1272	is all.
1273	MR BROWN: It says submissions are being prepared, and this
1274	is as it were the early part. I do not think a formal
1275	submission was ever prepared. This is the nearest one
1276	gets to it.
1277	MR UNDERHILL: My Lord, at page 296 we have the start of the
1278	discussion which again is the principal, almost the only
1279	matter, discussed at this committee meeting, the
1280	committee meeting in April. There was a miscellany of
1281	papers in front of the Committee which I am afraid got
1282	rather muddled up in the bundle despite the best efforts
1283	of people to work them out.
1284	Could we look first at page 309 which was a paper
1285	before the Committee, as it is described, for
1286	information only, or an article? In fact, it is an
1287	editorial from a magazine called Transfusion, which is
1288	the magazine of the American Association of Blood Banks?
1289	A. Yes.
1290	Q. The editorial relates to an article in the journal which
1291	we find at page 311 by Bove. I refer to it now because
1292	it was a paper before this Committee, but it is also a
1293	paper to which you refer directly with approval in your
1294	witness statement at paragraph 97?
1295	A. That is correct.
1296	Q. Therefore it is convenient to take it now. Dr Bove is
1297	at the Yale University School of Medicine in the
1298	Department of Laboratory Medicine. What is his
1299	association with transfusion?
1300	A. Well, he is -- in his Laboratory Medicine there was the

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1301	Blood Transfusion Department of which he was I think in
1302	charge.
1303	Q. What this paper does -- it is a paper prepared in early
1304	1989, or published in 1990 -- is it attempts to get a
1305	new and systematic approach to blood testing and
1306	screening, and its eventual conclusion is one that does
1307	not directly concern us because it is to do with what
1308	institutions should take these decisions in the United
1309	States, but the discussion that leads up to that
1310	conclusion is of interest and we see in the second
1311	column on the first page:
1312	"The usual and most obvious reason for testing is
1313	to enhance the safety of transfusion. There can be no
1314	doubt that the overriding concern when considering any
1315	testing is the furthering of the best interests of the
1316	patient. But what has become apparent in recent years
1317	is that many other factors enter into the decision to
1318	test or not to test. Some of these factors are easy to
1319	understand and justify, both to ourselves and to
1320	others. Others are less easily defended, but they
1321	definitely exist. What is needed now is a way to
1322	approach testing so that we will be able to make
1323	intelligent decisions, know why they were made, and be
1324	comfortable that such decisions can stand public
1325	scrutiny."
1326	He divides his recall up into reasons to test and
1327	reasons not to test. He reviews them under a number of
1328	headings. If we look under the heading on the next
1329	page, "Patient Safety", he says this:
1330	"It would seem almost axiomatic that testing
1331	intended to increase patient safety has to be
1332	worthwhile, but there can and must be continued
1333	evaluation of all tests with an eye to the relationship
1334	between the benefits and the costs, especially when
1335	costs are considered in the broadest sense. At some
1336	point, it will be necessary to decide that a slight
1337	increase in safety will not justify the cost. As Zuck
1338	stated so clearly, the search for an entirely safe blood
1339	supply is futile. But the question of how safe is safe
1340	enough becomes a matter for interpretation, and the
1341	perception of 'safety', like the perception of risk, is
1342	highly personal. What a donor centre considers safe
1343	enough may not be safe enough for the patient's
1344	physician, whose criteria, in turn, may not satisfy the
1345	patient or the patient's lawyer. Clearly, the concept
1346	of additional testing to make any transfusion safer has
1347	to be considered by the standards: how much safer and
1348	at what cost?
1349	"A second, and equally important, consideration in
1350	the evaluation of testing to increase safety relates to

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1351	the interpretation of scientific data at hand. A recent
1352	example is the institution of surrogate testing for non
1353	A non B. The experiments that were the basis for the
1354	surrogate testing decision were done in the 1970s,
1355	almost twenty years ago. Despite what appeared to be
1356	unequivocal data as to efficacy, and despite the
1357	institution of surrogate testing by several large blood
1358	centres, there was no large scale movement towards such
1359	donor testing until the late 1980s. Even now, when the
1360	testing is universal, there are those who honestly doubt
1361	that it has increased the safety of transfusion. I cite
1362	this example only to indicate the decision about which
1363	tests actually do contribute to patient ..."
1364	MR JUSTICE BURTON: Universal in the United States, I take
1365	it. A rather unusual meaning of the word "universal".
1366	MR UNDERHILL: He was writing for an American audience, my
1367	Lord.
1368	"I cite this example only to indicate that the
1369	decision about which tests actually do contribute to
1370	patient safety is not easy, even in the face of
1371	well-executed studies. Other examples come to mind ...
1372	The important point is that several persons or groups,
1373	each evaluating the same data, can reach different
1374	conclusions. While the addition of a test to enhance
1375	patient safety is an easy concept to accept, the
1376	practical aspects of the evaluation by different persons
1377	of the same data may make implementation difficult."
1378	Is that one of the passages that you had in mind
1379	when you wrote approvingly of this article in your
1380	witness statements?
1381	A. Yes, that is one, but there were others.
1382	Q. I am not going to read them all. There is donor
1383	safety. That is concerned principally with certain
1384	sorts of tests which can actually damage donors. I do
1385	not think we need spend time on those at the moment?
1386	A. No.
1387	Q. Staff safety, improvement in quality, Federal
1388	regulations, requirements of voluntary accrediting
1389	agents.
1390	Then over the page:
1391	"Reduced medicolegal vulnerability.
1392	"For blood banks and transfusion services, one of
1393	the most frightening consequences of the AIDS epidemic
1394	has been the hostile legal climate that now exists. The
1395	rash of AIDS-related suits and financial judgments
1396	against blood banks have added a new dimension to
1397	decisions about testing. Such decisions may no longer
1398	be made only on the basis of what appears to be good for
1399	the patient or donor. Medicolegal consequences must be
1400	considered in the decision whether to add tests. For

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1401	example, there are good arguments for the institution of
1402	anti-HTLV-1 testing, but one can question whether this
1403	addition would have been made so quickly without blood
1404	banking's recent experience with AIDS."
1405	Then he refers to other considerations, liability,
1406	reduction in costs, marketing advantage. Then over the
1407	page, reasons not to test, and he gives some of these:
1408	increased costs, he makes the point you cannot just go
1409	on spending money for very limited extra benefit, lack
1410	of trained staff, increased potential for error; that is
1411	a point you yourself I think made earlier?
1412	A. Indeed.
1413	Q. As he points out:
1414	"It is an inescapable fact that, as more tests are
1415	done, the chance for error increases. This is
1416	especially true in settings where large numbers of donor
1417	units, each requiring some special approach, are
1418	involved."
1419	Then:
1420	"Loss of donors.
1421	"The application of new tests of the donor supply
1422	will result in a loss of donors. In some case, the loss
1423	will be minimal and can be justified by the benefit of
1424	the test. In other cases, such as surrogate tests for
1425	non A non B, donor loss will be greater, and there may
1426	be less consensus about the advisability of adding the
1427	tests. With the limited supply of donors and the
1428	difficulty of increasing the donor base, adding a new
1429	test can lead to problems. That is not to say that new
1430	tests will no longer be added, but each newly added test
1431	will need to be evaluated ..."
1432	MR JUSTICE BURTON: Remind me, do we have any evidence about
1433	what the loss of donors was in the United States after
1434	the introduction of compulsory surrogate testing?
1435	MR UNDERHILL: Yes, we do. I think it is in your witness
1436	statement. I cannot remember. We can easily find it.
1437	Can you remember without us looking?
1438	MR JUSTICE BURTON: It was higher than the anticipated
1439	English 4 per cent, was it?
1440	MR UNDERHILL: Yes.
1441	A. It was, yes. I think it was something in the order of
1442	7 per cent.
1443	MR BROWN: I have a feeling it was 7 per cent, but it is
1444	just a feeling, as it were.
1445	MR JUSTICE BURTON: That is US donor loss post-1986, 7 per
1446	cent. It is interesting that Mr Bove here does not
1447	actually talk in the past or present tense, but he talks
1448	in the future tense.
1449	MR UNDERHILL: Yes. Between 4 and 6 per cent is the figure
1450	that you gave in your witness statement. The reference

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1451	is paragraph 49. That is supported by a paper which we
1452	did not go to. Then he talks about the need to counsel
1453	donors. Then in the discussion section there is a
1454	general point about how the public focus is now much
1455	more on blood banks than it used to be. Then this
1456	paragraph which I think is one you cited specifically in
1457	your witness statement:
1458	"Pressures to add a new test often arise before
1459	adequate data are available because interested parties
1460	demand immediate action. Such parties include
1461	researchers who have a special interest in the test,
1462	reagent and kit manufacturers, health care activists,
1463	legislators who perceive a problem or seek an issue and
1464	the press, all of whom have their own agendas and
1465	goals. What is needed is a mechanism to reach proper
1466	decisions in such a setting."
1467	Then he goes on to suggest who ought to be doing
1468	it in the United States. I think it was that particular
1469	paragraph, if I am right in saying, that you referred to
1470	in your witness statement?
1471	A. It was indeed.
1472	Q. Why was that?
1473	A. Well, because we were suffering in the transfusion
1474	service such pressures at about this time, in early
1475	1990
1476	MR JUSTICE BURTON: From whom?
1477	A. Well, there were articles in the press about poisoned
1478	blood. There were certain other programmes on the
1479	television about this particularly -- I remember one
1480	Panorama programme at that time. We were having
1481	pressures from Ortho particularly, not Abbott because
1482	they had not yet developed their tests in a commercial
1483	sense, and some clinicians were saying: it is about time
1484	you started this test.
1485	MR UNDERHILL: Just for the record, I think the Panorama
1486	programme to which you referred was somewhat later?
1487	A. No, there was an earlier one, which I think I took part
1488	in, in around 1988. It was either Panorama or ITN's
1489	equivalent, I cannot now remember.
1490	Q. Anyway, this article was before the Committee. Just to
1491	see the other material was, if we look at 301, a report
1492	which on the internal evidence I think is from
1493	Dr Rejman.
1494	MR JUSTICE BURTON: I do not need to see the editorial?
1495	MR UNDERHILL: No, not as far as I am concerned, my Lord.
1496	It is a report on the Ortho symposium which had taken
1497	place in London in February 1990. It says:
1498	"We append the Ortho abstracts recently received
1499	and supplementary notes. The overall impression
1500	reinforced by informal discussion with delegates is that

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1501	the test is not sensitive or specific enough and, in the
1502	absence of appropriate confirmatory testing, is unable
1503	to give data upon which appropriate clinical
1504	decision-making can be reliably based."
1505	Pausing there, I have said that on the internal
1506	evidence that appears to be Dr Rejman. Do you know who
1507	from the Committee attended that symposium?
1508	A. I was not aware at the time who attended. I certainly
1509	was not there.
1510	Q. There is a note:
1511	"Many speakers mentioned 'supplementary testing'.
1512	This it is felt related to the projected Ortho RIBA
1513	test, which is being pre-market trialed in the UK
1514	presently. It does not refer to the desire for a
1515	secondary, alternative technology/antigenicity based
1516	test."
1517	That was a reference to PCR, was it not?
1518	A. That is a reference to PCR.
1519	Q. I do not think we need look at any of these in great
1520	detail. In case anyone has to look at them later, what
1521	we have is the printed presentations. We actually have
1522	them somewhere else as well, but together with short
1523	notes of the actual written presentation. So, for
1524	example, 303 to 305 is the presentation by Professor
1525	Howard Thomas. That can be confirmed by looking at the
1526	C bundle. But at 302, we have whoever it was who
1527	attended making their own notes of the oral
1528	presentation.
1529	If we pause on Professor Thomas's presentation,
1530	under heading 303, "Epidemiology ...". What is
1531	Professor Thomas's expertise?
1532	A. He is I think a gastroenterologist who specialises in
1533	liver diseases at one of the London hospitals.
1534	Q. Under the heading, "Epidemiology", he says this, at the
1535	very bottom of the page:
1536	"Although HCV was characterised in the context of
1537	post-transfusion hepatitis, only 10 per cent of NANB
1538	hepatitis patients (before the availability of HCV
1539	antibody testing) gave a history of blood
1540	transfusion ..."
1541	What he is saying is that of the patients whom the
1542	liver doctors were dealing with NANB, only 10 per cent
1543	had such a background.
1544	" ... although 40 per cent gave a history of
1545	parenteral drug abuse and 10 per cent a history of
1546	sexual activity with multiple partners or known NANB
1547	sufferers."
1548	Pausing on that last point, I think it is common
1549	ground now that NANB is extremely rarely sexually
1550	transmitted?

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1551	A. There was one article written by Professor Tedder which
1552	intimated that there was a sexual transmission, but
1553	largely this has been discounted.
1554	Q. In any event looking at what people were thinking in
1555	February 1990, the remaining 40 per cent had no obvious
1556	risk factors for NANB.
1557	"The combined results of some more recent studies
1558	examining the prevalence of HCV antibodies in different
1559	risk groups are presented ..."
1560	That is an interesting summary of a liver doctor's
1561	view of the role of transfusion in NANB prior to the
1562	discovery of anti-HCV.
1563	Then rather tiresomely the Bove article has been
1564	slotted in the middle of that but those abstracts
1565	continue from page 316 where we have a paper from
1566	Dr Barbara and then at 318, notes of whoever it is of
1567	that paper. It goes on with others we need not look
1568	at. You had in any event a fair degree of material
1569	relating to that recent symposium. The last page of
1570	that material is page 339.
1571	MR JUSTICE BURTON: I think I am going to take out -- no one
1572	else needs to bother -- but it does seem you are right
1573	that exhibit 6.1 of 309 should come before the whole of
1574	exhibit 6.2 at 301. I think I am going to take it out
1575	just so that we can renumber it, I suppose, as 300A.
1576	Whether we do or not is a matter for people's choice.
1577	I think it sensible to have it first and then 301 runs
1578	on right the way through and all those are papers that
1579	were produced for and at the Ortho seminar.
1580	MR UNDERHILL: Yes, exactly. The very last is 339, which is
1581	described as a postscript and refers to an article which
1582	appeared in a magazine called Clinica. It simply
1583	records that a second generation test has already been
1584	developed in Japan, and Chiron are intending to evaluate
1585	one in mid-1990.
1586	MR JUSTICE BURTON: To begin clinical evaluation.
1587	MR UNDERHILL: Yes. That is an early hint of the second
1588	generation coming. Then just so we can identify these,
1589	because they are rather a muddle, at pages 340 to 344 is
1590	a paper we can see at 344 that is dated February 8th,
1591	1990, produced by the three American blood collection
1592	institutions for planning the implementation of anti-HCV
1593	testing which of course at that stage they were not
1594	doing but they were expecting to do and did start to do
1595	in May.
1596	Then a short paper at 345, a single sheet which is
1597	a note on economical appraisal by the Economic Advisers'
1598	Office.
1599	MR JUSTICE BURTON: This is a new exhibit, then, is it,
1600	starting at 340?

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1601	MR UNDERHILL: It is.
1602	MR JUSTICE BURTON: 6.3, is it?
1603	MR UNDERHILL: No. It is, in fact, 6.6 as it says at the
1604	top.
1605	MR JUSTICE BURTON: Mine is lost at the top.
1606	MR UNDERHILL: Which page are you on? 345?
1607	MR JUSTICE BURTON: Page 340.
1608	MR UNDERHILL: Yes. Mine is also lost. We do not know what
1609	it is meant to be, because it is not trailed in the
1610	agenda.
1611	MR BROWN: I took your Lordship to it. Again I am afraid I
1612	did it by reference to the A bundle. It is page 1023
1613	which I think will be A4/1023.
1614	MR JUSTICE BURTON: Thank you.
1615	MR BROWN: It is the American Association of Blood Banks'
1616	guidelines which were produced in February.
1617	MR JUSTICE BURTON: Do you think we should transfer it or
1618	not?
1619	MR BROWN: My Lord, I fear all my efforts have gone to vain
1620	and we should remove this one as well, my Lord.
1621	MR JUSTICE BURTON: I think we should. As it happens there
1622	are two copies of this in bundle A, only one of which
1623	I have marked up. It may be we can simply remove it
1624	without needing to replace it. I do not know.
1625	MR BROWN: Yes, I think your Lordship probably marked 1023.
1626	MR JUSTICE BURTON: I have, and indeed I have noted what you
1627	told me to note in it. It is an exhibit of some kind at
1628	any rate?
1629	MR UNDERHILL: Yes. Unfortunately I do not think history
1630	will ever relate. It may well have been 6.3.
1631	MR JUSTICE BURTON: I am going to put "6.3?" . There was
1632	before this meeting the pre-planning that the Americans
1633	had done in February with a view to starting in May?
1634	MR UNDERHILL: Yes.
1635	MR JUSTICE BURTON: Or whensoever the FDA should be --
1636	MR UNDERHILL: It was either circulated beforehand or
1637	tabled. At 345, we need not say anything about that.
1638	That is a note from the Economic Advisor's Office. 346,
1639	a letter from the Lancet about screening plasma for
1640	fractionation, not relevant to our present purposes.
1641	Then finally -- and this is perhaps important -- 6.9 is
1642	notes made by Professor Zuckerman of a meeting he had
1643	attended in the United States at which some early
1644	results were given of anti-HCV screening or anti-HCV
1645	testing of the TTV samples which your Lordship now knows
1646	were kept and got out and tested again. That is of
1647	importance. I am not going to take this out of order,
1648	but just so your Lordship knows, one of the things he
1649	noted was what he was told at that conference about the
1650	value of the RIBA 1, the first potential confirmatory

	A
1651	test, and one sees that part starting at the bottom of
1652	page 350 and going over to 351.
1653	MR JUSTICE BURTON: Yes, meaning what?
1654	MR UNDERHILL: I am going to come to that, because
1655	I think -- basically showing it was not very good.
1656	MR JUSTICE BURTON: Because most of them show a positive.
1657	Is that right?
1658	MR UNDERHILL: The basic problem was a third of people who
1659	almost certainly were not positive were confirmed
1660	positive by the test. My Lord, I can with Dr Gunson's
1661	help --
1662	MR JUSTICE BURTON: I see 21, not implicated, but 7,
1663	positive on the confirmatory?
1664	MR UNDERHILL: That is the essence of it.
1665	MR JUSTICE BURTON: So too few were weeded out and some were
1666	positively weeded in?
1667	MR UNDERHILL: Well, yes, that is right. We have taken that
1668	rather quickly. Is that right, Dr Gunson?
1669	A. Yes.
1670	Q. The problem identified here is just as his Lordship has
1671	put?
1672	A. The problem that he expressed was that only 88 per cent
1673	of implicated donors were shown to be positive by RIBA,
1674	whereas a third of those that were not implicated in
1675	transmission were also positive.
1676	Q. There we are. I thought that was going to take a long
1677	time but your Lordship has got straight to the heart of
1678	it.
1679	The very last thing is page 353, the first of many
1680	action charts that people prepared to produce a sort of
1681	flowchart of how you would deal with testing.
1682	We have now looked at all those materials. We can
1683	look at the discussion in the light of them.
1684	Paragraph 8 records Dr Rejman's comments, merely records
1685	what we have already seen him saying on the first
1686	page of the comments I took everyone to. Paragraph 9:
1687	"Dr Mortimer thought there had been an underlying
1688	feeling against screening because of the lack of
1689	confirmation. He thought confirmatory testing would
1690	become available in a reasonable time and that the
1691	routine screening of blood donors could not be delayed
1692	for a long time."
1693	It rather reads from that as though Dr Mortimer
1694	had been present at that conference. Can you recall
1695	whether he was?
1696	A. No, Mr Underhill, I cannot, but all I can say is that
1697	Dr Mortimer's remarks here are consistent with those
1698	that he made at the previous meeting.
1699	Q. "Professor Zuckerman showed disappointment at the
1700	outcome of the symposium and said the non-specificity

	A
1701	and sensitivity of the test had been the main talking
1702	points."
1703	Again, it rather looks as though he was there
1704	but --
1705	A. Yes, it seems as though he was there.
1706	Q. Then there is the Abbott symposium. That we do not have
1707	any notes from. I am afraid your Lordship's 6.3 query
1708	is almost certainly wrong.
1709	MR JUSTICE BURTON: Yes.
1710	MR UNDERHILL: That has gone astray.
1711	"Dr Mitchell reported that, following this
1712	symposium the American Association of Blood Banks had
1713	directed that testing for hepatitis C antibody should be
1714	introduced as soon as FDA approved the test. It was
1715	confirmed that approval had not yet been given. Concern
1716	about litigation was the main influence on the US blood
1717	banks. Dr Mitchell thought there would be problems
1718	counselling donors in view of the state of knowledge
1719	about the significance of a positive reaction to the
1720	test.
1721	"Dr Mitchell said papers presented at the
1722	symposium showed that the vast majority of hepatitis C
1723	cases were not transfusion related. Where high risk
1724	groups were tested concordance with hepatitis C
1725	positivity is high but among a cross-section of blood
1726	donors concordance is much lower. He understood that
1727	the US would retain ALT and hepatitis core antibody
1728	testing."
1729	Is there anything you wish to comment on in those
1730	two paragraphs where Dr Mitchell is reporting back on
1731	that symposium?
1732	A. I do not think so, Mr Underhill. I think they are
1733	fairly clear.
1734	Q. Then:
1735	"Professor Zuckerman stressed that the major cause
1736	of post-transfusion hepatitis is non A non B virus, and
1737	even so not all cases were recognised."
1738	Then over the page, we get to the hepatitis
1739	conference in the United States which Professor
1740	Zuckerman had attended and where he made those notes
1741	that we just looked at.
1742	MR JUSTICE BURTON: I see. So Professor Zuckerman's notes
1743	were not made at the Ortho symposium?
1744	MR UNDERHILL: Sorry, I had not made that sufficiently
1745	clear.
1746	MR JUSTICE BURTON: No, I did not realise it.
1747	MR UNDERHILL: "[He] would be preparing a full report in due
1748	course but he had provided some notes ... for the
1749	meeting."
1750	If he ever did produce a full report, it is not

	A
1751	among the papers.
1752	MR JUSTICE BURTON: What was the difference? The Ortho
1753	symposium was where?
1754	MR UNDERHILL: London.
1755	MR JUSTICE BURTON: I have a note rightly or wrongly -- if I
1756	have it Mr Brown must have told me -- at the top of
1757	page 297, "Hepatitis conference", I have a note "Ortho
1758	in London".
1759	MR UNDERHILL: I do not want to attribute blame. I am
1760	pretty sure it is wrong. I do not know who made the
1761	mistake. Ortho in London is the one we see on the
1762	previous page, Ortho symposium.
1763	MR JUSTICE BURTON: That is what you have just told me.
1764	Where is the hepatitis conference, then?
1765	MR UNDERHILL: It was in the United States.
1766	MR JUSTICE BURTON: Thank you.
1767	MR UNDERHILL: I do not know where.
1768	MR BROWN: It was in Houston on April 4th to 8th.
1769	MR UNDERHILL: I think it is the Houston one, in which case
1770	we do have some other notes of it, but not many.
1771	MR BROWN: We do have them in C1, pages 364 onwards.
1772	MR JUSTICE BURTON: I am going to cross out "Ortho in
1773	London" in that case. I do not know where I got it
1774	from. It would not have been my own initiative.
1775	MR BROWN: It might have been me, but it certainly related
1776	to the previous entries, the Ortho.
1777	MR JUSTICE BURTON: This is Ortho as well?
1778	MR UNDERHILL: No. If -- and I think my learned friend is
1779	right about this -- it is the one in Houston, it appears
1780	to have not been a commercially organised one. I am
1781	sure it is commercially sponsored, because these things
1782	always are, but it was not Ortho or Abbott. The front
1783	page simply says, "The 1990 International Symposium on
1784	Viral Hepatitis and Liver Disease, Contemporary Issues
1785	for Future Prospects" and we do have some papers from it
1786	though none I think precisely track Professor
1787	Zuckerman's notes.
1788	MR JUSTICE BURTON: I am not going to go to it unless you
1789	want me to. Houston, C1, reference page --
1790	MR BROWN: 364 onwards.
1791	MR JUSTICE BURTON: Thank you.
1792	MR UNDERHILL: For completeness, the Ortho -- we have a few
1793	more of the Ortho papers, but they really track the ones
1794	that were provided to the Committee, in C1 at 343. They
1795	are really the same as the ones that were provided to
1796	the Committee apart from one or two that were missed
1797	out.
1798	MR JUSTICE BURTON: I have a cross-reference here --
1799	MR UNDERHILL: The only ones we have no papers for as far as
1800	I know is the Abbott symposium. If my learned friend

	A
1801	would correct me on that I am very willing to be
1802	corrected. We do not even know where it was.
1803	MR JUSTICE BURTON: I have a cross-reference, no doubt from
1804	Mr Brown, to A4/1210.
1805	A. The Abbott symposium was in Chicago.
1806	MR UNDERHILL: Dr Gunson said the Abbott symposium was in
1807	Chicago, but we do not have papers for it.
1808	MR JUSTICE BURTON: I thought I remembered that Zuckerman
1809	note. A4/1208 is my marked up copy of that Zuckerman
1810	note. I will leave it there, but at least I had
1811	remembered seeing it.
1812	MR UNDERHILL: In paragraphs 14 to 16, Professor Zuckerman
1813	spoke to his paper. In paragraph 17, he said:
1814	"The RIBA test has confirmed positivity in 33 per
1815	cent of ELISA positive donors who were not implicated in
1816	a hepatitis incident ..."
1817	That is to say you look at people who you are
1818	pretty sure were not infective and if they turn up
1819	positive on the test that is a bad sign.
1820	" ... but among ELISA ..."
1821	Sorry, we have looked at all of that.
1822	"Professor Zuckerman remarked the RIBA was not
1823	good enough to use routinely as a confirmatory test.
1824	"[He] drew attention to the seroconversion
1825	table ..."
1826	That is also in his note.
1827	" ... and said the findings should be improved by
1828	adding another epitope."
1829	That is adding more to the antigens than have been
1830	picked up by the test, which is effectively what
1831	happened to the second generation. Is that right?
1832	A. That is correct.
1833	Q. "Improvements were already being introduced ...
1834	"Professor Zuckerman summed up the conference as
1835	having been rather promotional in character and the data
1836	had been generally well known. Little information had
1837	been given about the Japanese and Abbott tests."
1838	Then another heading, "Detection of Hepatitis C by
1839	PCR"; annoyingly again we do not have the paper but on
1840	internal evidence it is almost certainly the same as the
1841	published paper at H3/90.19.
1842	MR BROWN: My Lord, I agree.
1843	MR UNDERHILL: Again, I do not think we need look at the
1844	detail but it is the first UK report of using PCR to
1845	detect the virus and he says:
1846	"Although the PCR assay in its present form was
1847	not suited for the mass screening needs of RTC
1848	laboratories, recent modifications of PCR technology
1849	indicate its potential for large scale testing", which
1850	we now know years later has come in.

	A
1851	Then after all that material had been put before
1852	the Committee, the discussion starts. The Committee is
1853	told that France, Belgium and Luxemburg have introduced
1854	routine screening and Italy has done so on a voluntary
1855	basis.
1856	"The Chairman also remarked that from the reports
1857	the science seemed to have advanced little from the time
1858	of the previous meeting. There were still questions to
1859	whether the anti-HCV test was reliable and a useful step
1860	forward or created too many problems at this stage.
1861	"Dr Mitchell mentioned a report from Harefield
1862	Hospital that six of the seven hepatitis C positive
1863	donors identified in a study did not transmit infection
1864	and four had been found not to be positive after a
1865	year."
1866	That is the study carried out by North London, is
1867	it not?
1868	A. It is.
1869	Q. They have been doing their own recipient study using the
1870	hospitals in their catchment area and Harefield Hospital
1871	in particular?
1872	MR JUSTICE BURTON: What does that mean, "six of the seven
1873	hepatitis C positive donors identified in a study",
1874	identified with anti-HCV tests, presumably or with
1875	raised ALT?
1876	MR UNDERHILL: As I understand it these were with raised
1877	ALT. It was a study just like the TTV study in
1878	principle. You look at people after they have had
1879	blood. You have diagnosed them as having NANB if they
1880	have raised ALT levels. This was originally intended as
1881	part of the research into surrogate markers but they
1882	then had as I understand it seven who on that basis --
1883	MR BROWN: My Lord, my learned friend is giving evidence.
1884	MR UNDERHILL: Yes, and I am giving it wrongly too.
1885	MR BROWN: My learned friend accepts that he is now giving
1886	it wrongly. It is a dangerous exercise. It should be
1887	done through the witness.
1888	MR UNDERHILL: That is quite right. I apologise for that.
1889	MR JUSTICE BURTON: It was my fault for asking the
1890	question.
1891	MR UNDERHILL: It was my fault for answering it.
1892	MR JUSTICE BURTON: Dr Gunson, are you able to help? Do you
1893	know?
1894	A. I think the reference to this, my Lord, is in Contreras
1895	et al, 1991, H3/1990, tab 11.
1896	MR UNDERHILL: Very impressive. It shows you can leave it
1897	to witnesses. That is a paper which we had better
1898	therefore just get out?
1899	A. It is not tab 11. It is wrongly recorded.
1900	Q. There is such a paper at 1991, tab 11. It is easy to

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1901	miss a year.
1902	MR JUSTICE BURTON: You have taken this from your witness
1903	statement, have you, Dr Gunson?
1904	A. This is from my witness statement, paragraph 38.
1905	MR JUSTICE BURTON: So there is a misprint in your witness
1906	statement. It should be H3/1991, tab 11.
1907	A. Yes, because it was I11/1991.
1908	MR UNDERHILL: This would be as it were a pre-publication
1909	report. Of course we are now in April 1990. It was
1910	what the Committee were told before it appeared in an
1911	article?
1912	A. Yes.
1913	Q. Perhaps we should go through the abstract:
1914	"To see whether the introduction of screening
1915	tests for NANBH ... would be worthwhile, the incidence
1916	of such hepatitis was assessed among patients receiving
1917	blood during operations at five hospitals served by the
1918	North London Blood Transfusion Centre. 387 patients,
1919	who each received blood or blood components from an
1920	average of 3 donors, were followed up prospectively and
1921	blood samples were taken every 2 weeks for 3 months and
1922	then each month for a further 3 months. 229 patients
1923	also provided a sample at 12 months. All available
1924	patient and donor samples were tested for ALT and for
1925	antibody to anti-HCV by ELISA. Repeatedly anti-HCV
1926	positive samples were submitted to the supplementary HCV
1927	assays."
1928	We can see that that is a reference to RIBA 1
1929	because one can see that on the table at 755 in the
1930	article. You had better confirm this, Dr Gunson,
1931	because I have been rightly rebuked.
1932	A. I think the other table as I read it was table 3 where
1933	they list six donations, and only one, donation A, is
1934	PCR positive.
1935	Q. It was also -- perhaps if you would look at that
1936	table --
1937	A. It was also RIBA positive, because it reacted both with
1938	511 and C100-3. There are two other donations. B
1939	reacts with C100 but not anything else, and D reacts
1940	with 511 but not C100. The others were all negative.
1941	MR JUSTICE BURTON: In fact, the supplementary HCV assays are
1942	RIBA 1 and PCR; is that it?
1943	MR UNDERHILL: Yes. That is no doubt why it said "assays",
1944	plural.
1945	"One of the 387 patients showed biochemical
1946	evidence of acute post-transfusion NANBH after exclusion
1947	of non-viral causes. Anti-HCV developed in this patient
1948	and the seroconversion was confirmed by RIBA and by
1949	PCR."
1950	That is the one you have just been referring to at

	A
1951	A in table 3.
1952	So effectively what you have is six out of seven
1953	false positives?
1954	A. Yes.
1955	MR JUSTICE BURTON: Sorry, you are testing the donors and
1956	the recipients?
1957	MR UNDERHILL: I should have read on:
1958	"Anti-HCV developed in this patient ... Serum from
1959	1 of the 8 donors whose blood he received was positive
1960	for anti-HCV by all three methods. In another patient,
1961	HCV seroconversion was shown by ELISA but ALT
1962	concentrations remained normal throughout follow-up.
1963	His sample and those of his 2 donors were negative for
1964	HCV by the PCR chain reaction. A third patient showed
1965	rises in ALT with post-transfusion NANBH but serology
1966	and polymerase chain reaction assays for HCV were
1967	negative for her samples and those of her donors.
1968	Anti-HCV reactivity likely to be false positive
1969	(negative by both confirmatory tests and no adverse
1970	effects in recipients) was seen in 6 of 1,283 donors."
1971	That may be the one that --
1972	MR JUSTICE BURTON: Yes, can you help me then to try to
1973	summarise this article, Dr Gunson? We have donors
1974	tested and recipients tested. Is that right?
1975	A. That is correct.
1976	MR JUSTICE BURTON: There are seven apparently positive
1977	donors?
1978	A. I think it is six, is it not?
1979	MR UNDERHILL: It says six in the article. Dr Mitchell in
1980	the note says 7.
1981	A. I think we should really go by the article.
1982	MR JUSTICE BURTON: Wait a minute, because it is 6 false
1983	positives. It is 7. It is the 6 false positives plus
1984	the one actual positive. So 7 positive donors of which
1985	6 were false positives?
1986	A. That is correct, yes.
1987	MR JUSTICE BURTON: Then in the recipients there was only
1988	one recipient; is this right?
1989	A. There was only one that could be confirmed.
1990	MR JUSTICE BURTON: He presumably got it from the one
1991	genuinely positive donor.
1992	MR UNDERHILL: I think they do show that, yes. They say
1993	that in the middle of the abstract.
1994	MR JUSTICE BURTON: That shows -- am I right -- a rather
1995	efficient exercise, admittedly with the benefit of
1996	confirmatory tests of both RIBA and PCR -- and PCR might
1997	not always have been available in every centre?
1998	A. Well, PCR was a specialised test in only two or three
1999	specialist laboratories.
2000	MR JUSTICE BURTON: Would you have to send it there?

	A
2001	A. You have to send it there.
2002	MR JUSTICE BURTON: Which you could not possibly do as
2003	routine. With the benefit of PCR as well as routine,
2004	this came to a rather satisfactory conclusion?
2005	A. It did indeed.
2006	MR BROWN: My Lord, at the risk of adding to the confusion,
2007	your Lordship ought to mark against the 1991.11 paper
2008	the need to look in due course -- but I am not
2009	suggesting now -- at 1995, H4, because they doubled the
2010	1 when they did the second generation.
2011	MR UNDERHILL: They perhaps doubled the 1.
2012	MR BROWN: Yes. Dr Barbara thought it important enough four
2013	years after the event to write a correction.
2014	MR UNDERHILL: Yes, they possibly found another one in the
2015	second generation, but there was a doubt about it.
2016	MR JUSTICE BURTON: Using the same old samples?
2017	MR UNDERHILL: Yes.
2018	MR BROWN: 1995, I think your Lordship now has it as tab 8,
2019	H4.
2020	(12.30 pm)
2021	MR UNDERHILL: With a little help from my friends, and more
2022	importantly with help from Dr Gunson, we have got to the
2023	bottom of that, but Dr Mitchell obviously was aware of
2024	the results of that study. He reported it, and the
2025	point that he was making was one about false
2026	positivity. He was concerned from the results of the
2027	study that screening might result in -- that does not
2028	make sense, but it is corrected in the later minutes --
2029	1 in 200 donors being deferred, but perhaps
2030	unnecessarily.
2031	MR JUSTICE BURTON: That is 6 out of whatever the figure
2032	was?
2033	MR UNDERHILL: 1 in 200 is the --
2034	MR JUSTICE BURTON: 6 out of 1,283. That is the answer.
2035	MR UNDERHILL: Yes, I think it probably is, although the
2036	rate of repeat reactives at that time was around 0.5 per
2037	cent, which is 1 in 200.
2038	MR JUSTICE BURTON: I think it looks as though it is because
2039	of that study which says 6 out of 1,283 donors were --
2040	MR UNDERHILL: Whatever, but almost all of them will be
2041	unnecessary.
2042	MR JUSTICE BURTON: Yes, thank you.
2043	MR UNDERHILL: "Professor Zuckerman was concerned that the
2044	Ortho test had a false positive rate of 50 per cent but
2045	that litigation concerns might force its use. He
2046	recalled, though, that in the early days of HIV-1
2047	testing the UK had been prepared to accept high false
2048	positive rates."
2049	You said little about this yesterday, Dr Gunson.
2050	Is that a fair characterisation or adequate

	A
2051	characterisation of what happened in relation to HIV-1
2052	testing in the UK?
2053	A. Yes, I think it is.
2054	Q. "Professor Zuckerman thought viraemic testing could be
2055	developed with recombinant proteins being developed."
2056	What is he referring to there as recombinant
2057	proteins? Let us start with this, what is it referring
2058	to as viraemic testing?
2059	A. That is basically the PCR.
2060	Q. Perhaps that is all we need to know. So he is
2061	interested in PCR?
2062	A. Yes.
2063	Q. "A field trial could be run in RTCs using the prototypes
2064	and introduce them generally when sufficiently
2065	developed."
2066	MR JUSTICE BURTON: That took five years.
2067	MR UNDERHILL: Even longer than that, I think. Dr Gunson,
2068	perhaps you could help us on this: in this country, PCR
2069	testing, now called NAT testing, is even now not
2070	universal, is it?
2071	A. No.
2072	Q. In some countries it was introduced in the late 1990s?
2073	A. In Europe, particularly Germany, and I think in the
2074	United States on fractionated products.
2075	Q. Then yourself:
2076	"Dr Gunson said he found the US data about
2077	eliminating positive donors, in some series leading, to
2078	a 50 per cent reduction in post-transfusion NANB
2079	hepatitis persuasive, but he recognised there were
2080	problems in what to tell the donors. The RTCs had
2081	already ..."
2082	That must be "tested", must it not?
2083	A. "Tested", yes.
2084	Q. " ... tested 15,000 donations and found rates between
2085	0.2 per cent and 0.8 er cent to be hepatitis C
2086	positive."
2087	That is a reference to the first pilot study?
2088	A. That is the first pilot study.
2089	Q. "Among 9,000 frozen samples tested, the rate had been
2090	0.67 per cent."
2091	That a reference to the testing of the multicentre
2092	study samples?
2093	A. It is.
2094	Q. "His suggestion for a further study was that selected
2095	RTCs would use both Ortho and Abbott tests and refer
2096	repeat positives to laboratories with access to ..."
2097	That is effectively PCR, is it?
2098	A. PCR.
2099	Q. Thank you. Why were you suggesting that at that time?
2100	A. Well, Abbott was about to appear. We had not looked at

	A
2101	it, and I felt it was important to -- if we were going
2102	to do an evaluation -- to do it against both the Ortho
2103	first generation and the Abbott. We could not use the
2104	original samples from Brentwood, Birmingham and Trent,
2105	Sheffield, and, therefore, it would have to be a new
2106	study.
2107	Q. "Dr Tedder said that the technology was already
2108	available to test which of the positives were reactive
2109	but irrelevant, which had other markers and which were
2110	viraemic."
2111	What technology is he there referring to?
2112	A. He is referring to the PCR test which he had developed.
2113	If I might also add, the Scots in Edinburgh had also
2114	developed a PCR at this time.
2115	MR JUSTICE BURTON: Can I go back to 25? "The RTCs had
2116	already tested 15,000 donations ..." What is that a
2117	reference to?
2118	A. That is a reference to the first pilot trial. It was
2119	not quite 15,000; it was nearer 13,000, but it was in
2120	that order, my Lord.
2121	MR UNDERHILL: Going back to paragraph 27:
2122	"Professor Zuckerman expressed the view that large
2123	scale experience was necessary to learn more about the
2124	prevalence of reactivity and the methods referred to for
2125	information of findings but he questioned whether donors
2126	should be told at this stage. He was still a little
2127	concerned, though, that the FDA had not approved the
2128	Ortho test."
2129	Leaving out that last sentence for a moment, both
2130	in this meeting and I think in his letter, Professor
2131	Zuckerman had referred to not telling repeatedly
2132	reactive donors. What was and is your attitude to
2133	whether that is a possible course to take?
2134	A. Mr Underhill, I was not happy with that suggestion
2135	particularly if it was for a prolonged period. You see,
2136	I think in the previous meeting he said even up to 12
2137	months. As we have heard, donors come more than once a
2138	year in many instances and if you were to call a donor
2139	who had been found positive you would then risk someone
2140	at the desk saying, when they computed -- looked at his
2141	records, "I am sorry, we cannot use your blood today",
2142	and there would be a difficult situation on the
2143	session.
2144	A donor who you did not call for his usual -- his
2145	or her usual donation may phone the centre and would
2146	have to be told there was an abnormality in one of their
2147	tests and that is why we were not doing it, because you
2148	had to be honest with such donors and over the telephone
2149	is not the best way of doing it. You are better doing
2150	it face-to-face. Therefore I felt that we must have

	A
2151	some positive policy on what we should tell the donors.
2152	I agree that the major consideration for the transfusion
2153	service is the care of patients, but the care of donors
2154	has to be carefully balanced with this because, if you
2155	lose donors unnecessarily, then the care of patients
2156	becomes more difficult.
2157	Q. Then there is a slightly different point being made in
2158	his last sentence which I think speaks for itself; he
2159	was concerned the FDA had not approved the Ortho test,
2160	although as we now know they were just about to. Then:
2161	"Dr Mortimer considered the argument now was not
2162	whether we should test for hepatitis C but whether the
2163	tests were adequate. He thought that the Ortho and
2164	Abbott tests should be run together in some RTCs and the
2165	positive samples referred to for PCR testing."
2166	He seems to be making essentially the same
2167	suggestion as you?
2168	A. He was supporting what I had said, yes.
2169	Q. "A sample which would produce 50 to 100 reactive donors
2170	would be sufficient to get ..."
2171	MR JUSTICE BURTON: Pausing a moment, is that right,
2172	Dr Gunson? I do not know, I am sure you were there, you
2173	would know, but is he saying that there ought to be a
2174	further set of trials? Is that what he is saying?
2175	A. I understood him to say that, yes.
2176	MR JUSTICE BURTON: Thank you.
2177	MR UNDERHILL: "A sample which would produce 50 to 100
2178	reactive donors would be sufficient to get meaningful
2179	results. It was estimated this would require 25 to
2180	50,000 donors."
2181	I am not quite sure how he did that arithmetic.
2182	In the end you --
2183	A. In fact, it was 10,000.
2184	Q. You got 70 -- you got 69 reactive donors later in the
2185	year with --
2186	A. 10,600.
2187	Q. -- With 10,600. Anyway, that was the estimate he
2188	apparently gave. We now have the Chairman's summing-up
2189	of the discussion. As we did with the last meeting, we
2190	should check whether you regard it as an accurate
2191	summing-up from your recollection and understanding.
2192	Firstly:
2193	"There was inadequate scientific data to support
2194	the introduction of the Ortho test for routine
2195	screening."
2196	Is that a fair summary of the mood of the meeting?
2197	A. I think so, because there was Dr Mitchell's 6 out of 7
2198	in paragraph 23, Professor Zuckerman saying there was a
2199	50 per cent false positive rate, and my comments, and so
2200	I think that is a reasonable statement to make.

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2201	Q. "A confirmatory test was needed which could be used in
2202	the RTCs and not just in specialised laboratories"?
2203	A. There was some difficulty with this. That was
2204	suggested, but I think it has to be said that in many of
2205	the RTCs, the expertise was not available for
2206	confirmatory testing within the RTC.
2207	Q. That would apply to RIBA as well as to --
2208	A. To RIBA as well as -- certainly PCR, but to RIBA as well
2209	and those RTCs preferred to send repeatedly positive
2210	samples to a specialist laboratory.
2211	Q. If we split it up into two, if it simply said that a
2212	confirmatory test was needed, would that have been the
2213	mood of the meeting?
2214	A. Oh, yes.
2215	Q. You are putting a question mark about whether it was
2216	essential that it would be one that could be used in the
2217	RTCs?
2218	A. Yes.
2219	Q. Thirdly:
2220	"The FDA had not yet approved the test and it
2221	would be reassuring if the regulatory authority in the
2222	country of origin had done so."
2223	A. I think that -- certainly, yes.
2224	Q. "There was a need to learn more about donor panels and
2225	the significance of positive reaction to the hepatitis C
2226	antibody test."
2227	A. Yes.
2228	Q. Just to spell it out, what is meant by the significance
2229	of positive reaction?
2230	A. Whether the positive reaction to the hepatitis C
2231	antibody test -- that is the ELISA test -- as to whether
2232	the confirmatory tests would identify all those positive
2233	with ELISA or a large majority of those positive with
2234	ELISA as positive, or whether it would only be a
2235	fraction of the ELISA test.
2236	Q. So effectively the false positivity rate?
2237	A. The false positivity rate.
2238	Q. Then:
2239	"A prospective study involving 25,000 to 50,000
2240	donors would generate sufficient positives for
2241	confirmatory testing."
2242	You have said that the view that there should be
2243	such a study was yours and Dr Mortimer's. Is it fair to
2244	say that it was also a consensus of the meeting?
2245	A. It was agreed at the meeting that such a study would be
2246	helpful.
2247	Q. "It was agreed that a sub-group of Dr Gunson,
2248	Dr Mitchell, Dr Mortimer and Dr Tedder would prepare a
2249	protocol for the pilot study and an estimate of the
2250	funds needed for the study and the laboratory services

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2251	to support it.
2252	"The Chairman remarked that the paper by the
2253	Economic Advisor's Office [we looked at that; it was a
2254	single sheet of paper] reflected the lack of data.
2255	"A note would be prepared for Ministers telling
2256	them the outcome of the discussion.
2257	"Any Other Business."
2258	Perhaps we should just look at this in view of the
2259	line my learned friend has been taking on this:
2260	"The Chairman said he was concerned that there
2261	should be no confusion over the roles of the ACVSB and
2262	the UK Blood Transfusion Service Committee on
2263	transfusion transmitted disease."
2264	That is what we have been calling the ACTTD?
2265	A. Yes.
2266	Q. "He would therefore be writing to Dr Gunson, Chairman of
2267	the ACTTD, so that they could agree the respective
2268	roles. The ACVSB advised Ministers on the virological
2269	safety of blood. The UKBTS Committee considered the
2270	operational implications of the policy, gave the
2271	Department advice on safeguards against non-viral
2272	threats to blood ... Dr Gunson confirmed that he shared
2273	this view of the roles and thought there was no conflict
2274	between the Committees."
2275	Is that an accurate reflection of --
2276	A. That is an accurate reflection of what was said, yes.
2277	Q. Do you believe that the use of the ACVSB, rather than
2278	the ACTTD, to take the decisions that we see under
2279	consideration here, was the cause of any delay or
2280	problem?
2281	A. I find that a very difficult question to answer,
2282	Mr Underhill, because at the time the decisions of the
2283	ACVSB did appear to be appropriate decisions, taken on
2284	the evidence that we had for the value, sensitivity,
2285	specificity of the tests available.
2286	Q. I think you perhaps answered -- I did not want to stop
2287	you -- a broader question than the one I was asking.
2288	I was really asking simply about whether the use of one
2289	committee rather than the other was --
2290	MR JUSTICE BURTON: Let us split it up so that you are clear
2291	about this. You have answered the question: did the
2292	decision-making process of the ACVSB cause any delay,
2293	and you have said you thought that was a difficult
2294	question, but that you were satisfied that they were or
2295	appeared to be appropriate decisions, taken on the
2296	evidence you had at the time. That is your answer, is
2297	it, in relation to simply a question that you thought
2298	you were being asked, namely, did the decision-making
2299	process of the ACVSB cause delay, namely, that they were
2300	appropriate decisions at the time. Do you want to

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2301	complete that? Are you relying on "at the time" and
2302	saying that --
2303	A. I am relying on "at the time".
2304	MR JUSTICE BURTON: What is your view now, then?
2305	A. I think it is always easier in retrospect, my Lord, and
2306	I think I have said in my statement that later on I
2307	thought there should have been more positive action to
2308	start routine testing earlier than we did.
2309	MR JUSTICE BURTON: When is that?
2310	A. Well, I came to this decision in the period between
2311	April and September 1991. I mentioned it, as Mr Brown
2312	commented, at a meeting of the Transfusion Service,
2313	I think it was in York or somewhere like that, but I
2314	also feel that we could have evaluated the second
2315	generation test with all centres testing and not just
2316	six.
2317	MR JUSTICE BURTON: We will come to that obviously when you
2318	are asked a few more questions by Mr Underhill. But
2319	there came a time. Looking back at the distance we have
2320	so far, which is the meeting in April 1990, are you in
2321	hindsight --
2322	A. No, I think at this time the decision was the correct
2323	one made at this meeting.
2324	MR JUSTICE BURTON: I think that was only because of a
2325	misunderstanding, Mr Underhill.
2326	MR UNDERHILL: I am very grateful. It was a point I was
2327	going to come to sooner or later.
2328	MR JUSTICE BURTON: Of course you were.
2329	MR UNDERHILL: I am very happy Dr Gunson has answered it
2330	now.
2331	MR JUSTICE BURTON: The next question?
2332	MR UNDERHILL: That is fine, Dr Gunson. As I say I was
2333	very --
2334	MR JUSTICE BURTON: No doubt we will come back to that.
2335	MR UNDERHILL: We may come back to that.
2336	MR JUSTICE BURTON: Up to date April 1990 there was no
2337	delay.
2338	MR UNDERHILL: I was really asking you a question arising
2339	out of this question of demarcation of roles, whether
2340	there was any possible confusion, or things being
2341	considered by the wrong committee led to any delay.
2342	MR JUSTICE BURTON: Can we split that up? Do you think
2343	there was any confusion?
2344	A. I do not think there was any confusion. The
2345	transfusion -- the Diseases Committee of the Transfusion
2346	Service were not really in a position to take policy
2347	decisions. That had to be done by the ACVSB. But we
2348	were involved with the implementation of any activities
2349	that were proposed by the ACVSB.
2350	MR JUSTICE BURTON: Did the split of the roles, if there was

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2351	a split of the roles, cause in your view any delay at
2352	any time?
2353	A. I do not think it did.
2354	MR JUSTICE BURTON: Can I find the original question,
2355	Mr Underhill, to see if you are satisfied that it has
2356	been answered:
2357	"Do you believe that the use of the ACVSB rather
2358	than the ACTTD to take the decisions that we see under
2359	consideration here was the cause of any delay or
2360	problem?"
2361	A. No, I do not.
2362	MR JUSTICE BURTON: Thank you.
2363	MR UNDERHILL: Perhaps we can move on to the next meeting of
2364	the ACVSB, which was on 2nd July. We see that behind
2365	tab 7. The minutes start at page 356. Perhaps I can do
2366	what I did before and just take you and the court
2367	through the materials that were before the Committee.
2368	At page 361 behind the blue tab we find a single sheet
2369	of paper which is a later version of the flow chart --
2370	MR JUSTICE BURTON: Just before you do, Mr Underhill,
2371	inevitably because we are looking at this trial so many
2372	years later by reference to documents, you are examining
2373	in chief by reference to the documents, but can I just
2374	get a picture? First of all, is there anything in his
2375	witness statement and if there is not is there any oral
2376	evidence that should be given as to what Dr Gunson has
2377	to say, if anything, about the time between April 1990
2378	and July 1990? I.e. we are looking at, inevitably,
2379	meeting by meeting.
2380	MR UNDERHILL: Yes.
2381	MR JUSTICE BURTON: There is a passage of time between the
2382	meetings.
2383	MR UNDERHILL: It seemed to me there was nothing I needed to
2384	draw attention to in the intervening period. There are
2385	things your Lordship knows, like the FDA decision and so
2386	forth.
2387	MR JUSTICE BURTON: I am talking about what Dr Gunson is up
2388	to, if there is any evidence he has to give about --
2389	otherwise the impression might be given on the one hand
2390	that nothing important ever happens except at these
2391	meetings and on the other hand that nothing is done
2392	except at these meetings.
2393	MR UNDERHILL: The answer is I was not proposing -- but at a
2394	later stage -- and this perhaps points up the structure
2395	that I suggested in opening -- once as we see eventually
2396	in November a decision is taken to go for it subject to
2397	ministerial approval, then I shall be taking your
2398	Lordship to various things that Dr Gunson did. My
2399	learned friend may take a different view about this, but
2400	it is no part of my case that Dr Gunson should have been

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2401	or was doing things between the meetings at this stage
2402	to help this decision to be taken.
2403	MR BROWN: My Lord, I shall be trying to fill in the gaps
2404	between the dates.
2405	MR UNDERHILL: So be it. The answer is his witness
2406	statement says very little about things that happened at
2407	this stage between meetings. 1991 is very different.
2408	There was lots he was doing, letters he was writing and
2409	so forth.
2410	MR JUSTICE BURTON: At this stage there was a proposal that
2411	there be a pilot study, pilot study number 2, at the
2412	April meeting.
2413	MR UNDERHILL: Yes.
2414	MR JUSTICE BURTON: Seemingly by the July meeting that had
2415	not occurred.
2416	MR UNDERHILL: No, that is absolutely right. I shall be
2417	taking your Lordship to the protocol for that pilot
2418	study which was submitted to the meeting.
2419	MR JUSTICE BURTON: Dr Gunson will not have anything to say
2420	in chief at least as to why Pilot Study 2 did not occur
2421	after the April meeting.
2422	MR UNDERHILL: I am very happy to ask him. Dr Gunson, as we
2423	see, definitely the decision of the last meeting had
2424	been in favour of such a pilot study. We can see that a
2425	sub-group was asked to prepare a protocol for the pilot
2426	study and an estimate of the funds needed for it. I am
2427	about to take you to that protocol which was submitted
2428	to the meeting in July. Was it your understanding that
2429	it was intended that that study should go ahead before
2430	the ACVSB had looked at the protocol?
2431	A. No, it was not.
2432	MR BROWN: My Lord, I am very troubled, because my learned
2433	friend has just given evidence again.
2434	MR UNDERHILL: I do not think I have.
2435	MR BROWN: What he has said is:
2436	"We are about to look at the protocol which was
2437	agreed in April."
2438	My Lord, the protocol which we agreed in April was
2439	for 25,000 to 50,000 tests.
2440	MR JUSTICE BURTON: He did not say that, actually,
2441	Mr Brown. He was simply reciting page 299, that the
2442	sub-group would prepare a protocol and was saying that
2443	that was not submitted until July and then was asking
2444	this witness as to whether that was in accordance with
2445	his understanding.
2446	MR BROWN: My Lord, what I am troubled about is your
2447	Lordship is now going to be taken to page 384 which is
2448	an entirely different protocol and which only arises
2449	because --
2450	MR JUSTICE BURTON: Let us get there slowly, Mr Brown, in

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2451	that case. I think I know what you are going to say.
2452	Can you tell us, Dr Gunson, in your own words,
2453	rather than anticipations or anything of that kind, here
2454	you are about to set up a sub-group of you and
2455	Dr Mortimer and in particular the two proponents of the
2456	idea of a pilot study, and Dr Tedder similarly. What
2457	happened thereafter and why did it take until July for a
2458	protocol to be produced and did it change in some way
2459	along the way?
2460	A. Well, we had discussions about the possibility of this
2461	second pilot study. We each put forward proposals. We
2462	circulated these and then eventually it came to a common
2463	proposal, and it was realised when we had looked into it
2464	in more detail that we did not need 25,000 to 50,000
2465	donors. We only needed in the order of 10,000 to 12,000
2466	donors.
2467	MR JUSTICE BURTON: So this was the subject matter of
2468	telephone discussions or meetings?
2469	A. I think we held one meeting in Manchester but the bulk
2470	of it was done by telephone and circulating our drafts
2471	to each other.
2472	MR JUSTICE BURTON: By when was that all done?
2473	A. Well, we did it between April and July, because it is
2474	quite true that we, all of us, considered that the ACVSB
2475	would need to approve the final protocol because of
2476	course the Department were being asked to finance the
2477	study.
2478	MR JUSTICE BURTON: Thank you.
2479	MR UNDERHILL: I was about to take you through the materials
2480	before the Committee. At page 361 is another version of
2481	the flow chart. We do not need to spend any time on
2482	that for the moment, just to identify them. At 362 is
2483	I think the FDA approval, or at any rate the materials
2484	lying behind the FDA approval. At 384 is what my
2485	learned friend was upset about my showing you without
2486	more explanation. This is a protocol for a comparative
2487	study of anti-HCV testing using Ortho and Abbott, and it
2488	is -- if we look at the final page, 387 -- dated
2489	27th June 1990. So that is a week or so before the
2490	meeting and signed by yourself and Dr Mitchell?
2491	A. Yes.
2492	Q. 388 is a paper we do not need to spend any time on. 393
2493	is an article from the Journal of the American Medical
2494	Association which sets out as it were the state of
2495	opinion in the United States in April 1990 at a time
2496	when the introduction of anti-HCV screening is
2497	anticipated but has not yet happened and it contains as
2498	it were a cross-section of views.
2499	I was going to ask you to look at a few passages
2500	from that. I do not know whether that would be a good

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2501	moment.
2502	MR JUSTICE BURTON: It would, thank you very much. 2.00.
2503	(1.00 pm)
2504	(Luncheon adjournment).
2505	(2.00 pm)
2506	MR JUSTICE BURTON: Yes, Mr Underhill?
2507	MR UNDERHILL: Dr Gunson, we were on the papers that were
2508	before the seventh meeting of the ACVSB, that is the
2509	July meeting. We were just going to look very briefly
2510	at the article from the Journal of the American Medical
2511	Association, which was exhibit 7/5, and is at page 393.
2512	It is a long article, which contains a number of
2513	different points. If I can just draw your attention to
2514	one or two which echoed the considerations of the
2515	Committee on which you sat, in the first column, in the
2516	fourth paragraph, right in the middle, we see:
2517	"However, blood bank officials are apprehensive
2518	that falling incidence and prevalence rates in
2519	recipients may be accompanied by a rise in anxiety on
2520	the part of prospective donors, whose blood will be
2521	screened for antibodies to yet another disease
2522	transmissible by body fluids. Primary care physicians
2523	can expect to face patients whose donation may have left
2524	them merely puzzled victims of "false-positivitis", or
2525	may have, indeed, uncovered a previously unsuspected
2526	serious health situation."
2527	So we see there, do we not, a reference to one of
2528	the concerns that members of your Committee were
2529	expressing.
2530	A. Yes, indeed.
2531	Q. In the second column, just really next to that, the
2532	author says:
2533	"It is repeatedly stated that much more needs to
2534	be learnt about both the transmission and the natural
2535	history of HCV. It is agreed, for example, that many
2536	totally asymptomatic persons who have been exposed to
2537	HCV become chronic carriers."
2538	The question of what to tell donors is reviewed in
2539	some detail, in the context of the Abbott symposium in
2540	Chicago, which the author starts describing at the
2541	bottom of the second column on the first page, and he
2542	refers to points made by Thomas Zuck, the Medical
2543	Director of the Blood Centre at the University of
2544	Cincinnati.
2545	Towards the bottom of the third column:
2546	"Zuck and others say that assuming a prevalence
2547	during the first run-through of the test of
2548	approximately 7.5 per cent of positive results
2549	nationwide, approximately 100,000 donors will be
2550	counselled regarding the test results and 60,000 of them

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2551	will be uninfected. This obviously implies some waste
2552	of resources, not to mention the alarm engendered in
2553	healthy people."
2554	Then there was obviously some debate about what
2555	should be told to people. Dr Prince of the New York
2556	Blood Center said they should not be told. Paul Holland
2557	of the California Blood Center said:
2558	"I implore manufacturers to come up with
2559	specificity tests that tell if donors are false
2560	positive, or if they are true positive, whether they are
2561	non-infectious, because that is what people want to
2562	know."
2563	There is then a review of the lack of any
2564	knowledge at the time about whether it was transmissible
2565	to sexual partners, and Dr Zuck is reported as saying:
2566	"'The significance of sexual transmission may be
2567	one of the most difficult issues we face. Donors are
2568	now sensitised to this possibility and we have to tell
2569	them something - but I do not know what to tell them.'
2570	"The dilemma stems from contradictory research
2571	findings, some investigators reporting an important role
2572	for HCV in heterosexual transmission and others
2573	considering the role to be negligible."
2574	As I think you have already said, the latter group
2575	turned out to be right in the end?
2576	A. It was true, yes.
2577	Q. And then other difficulties referred to in Dr Zuck's
2578	presentation. At the bottom of the second column on
2579	that page, after considering the difficult question of
2580	lookback, another of the speakers, Dr Sayers, dwelt more
2581	on what donors may face:
2582	"They are ill prepared for some of the possible
2583	outcomes of their altruism. They may not want to hear
2584	this information. They will have to go to their family
2585	physicians, who will have to go scampering to their
2586	text ... and all because of what is really tantamount to
2587	an epidemiologic exercise.'
2588	"Sayers says, 'There are so many questions we are
2589	going to have to answer before we can enter upon HCV
2590	screening with enthusiasm.' But answers must come, he
2591	added, because 'we cannot afford to make blood donation
2592	an alienating experience.'
2593	"Among relevant considerations are that the
2594	specificity of the tests is unknown, their efficacy in
2595	detecting antibody in transfusion recipients is unknown,
2596	and whether lookback may prove important in dictating
2597	therapy is unknown."
2598	Then there is discussion of what treatments were
2599	possible, some early reference to interferon, and then
2600	they return to the question of what the public can be

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2601	told, and indeed whether doctors know enough to tell
2602	them anything. Dr Krugman, at the age of 82, we are
2603	told, in the left hand column on 395, said:
2604	"We have really got to educate the doctors
2605	better."
2606	At the bottom of that column, he continued:
2607	"'This is an example of what goes on all over the
2608	country. There is not a Saul Krugman or a Paul Holland
2609	or a Harvey Alter around the country, for example, to
2610	sit there answering questions. The same situation
2611	happened with the HCV antibody. So the question is: how
2612	do we educate, not the public, but the physicians?'"
2613	Set up an HCV hotline -- I think perhaps that is
2614	enough, simply to make the point that the types of
2615	concerns that you were considering were also being
2616	considered in the United States, and you were aware of
2617	those considerations from these papers.
2618	A. Indeed.
2619	Q. Then let us go back to the meeting itself. The minutes
2620	are at 356, and the circumstances in which the meeting
2621	was called are set out in paragraph 5. The meeting had
2622	originally been intended to take place towards the end
2623	of July, had it not?
2624	A. It was. I think it was the 27th, originally.
2625	Q. Dr Rejman was asked to summarise the course of events
2626	since the last meeting in April, resulting in the
2627	necessity of a reconsideration of the Committee's
2628	decision:
2629	"Dr Rejman said that the FDA had decided to
2630	approve hepatitis C screening and that America had
2631	already introduced screening and other countries were
2632	following. More studies had been carried out confirming
2633	that hepatitis C testing reduced infection, and RIBA was
2634	now available as a supplementary test. It was now felt
2635	that a study along the lines of those talked about in
2636	April was no longer viable and the meeting had therefore
2637	been brought forward so that a decision on the
2638	introduction of UK hepatitis C testing could be
2639	reached."
2640	Perhaps we had better just look at how it had come
2641	to be brought forward. I do not think you have there,
2642	but you will be given, bundle A4 --
2643	MR JUSTICE BURTON: What is the reference to "more studies",
2644	Mr Underhill?
2645	MR UNDERHILL: I was going to ask Dr Gunson that.
2646	Are you aware of what particular studies Dr Rejman
2647	had in mind as saying "having confirmed that hepatitis C
2648	testing reduced infection", that is to say, studies
2649	appearing in that interval?
2650	A. At this present moment, Mr Underhill, I am not, but a

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2651	look through the literature might be of some help during
2652	this period.
2653	Q. Yes.
2654	MR BROWN: My Lord, it was a matter I was going to raise.
2655	If Dr Gunson wants the opportunity to do so, he should,
2656	of course, have it.
2657	MR JUSTICE BURTON: Well overnight then, if you have
2658	anything available. Do you have bundles available to
2659	you overnight?
2660	MR BROWN: My Lord, it can be done by those behind my
2661	learned friend in that way.
2662	MR UNDERHILL: Dr Gunson comes in in the mornings to court
2663	by 10.00. We will have a look and he can have a look at
2664	the bundles that are here.
2665	MR JUSTICE BURTON: So that is on the housekeeping list for
2666	tomorrow morning. Thank you very much.
2667	MR UNDERHILL: You are being given bundle A4 now; look at
2668	page 1186. This is a letter from Dr Metters to you of
2669	5th June. It starts by recalling that at the last
2670	meeting, it was agreed a subgroup should be set up to
2671	prepare a protocol for a study, and recording that that
2672	group, comprising yourself, Drs Mitchell, Mortimer and
2673	Tedder, met in May with Departmental officials, and the
2674	group considered that in the light of subsequent
2675	developments, an extended study of RIBA and PCR
2676	techniques might not be now appropriate:
2677	"As you will be aware, some additional scientific
2678	information is now available."
2679	So that looks like what Dr Rejman was echoing a
2680	month later. That does not help you at the moment to
2681	say what it was, does it?
2682	A. No.
2683	(2.15 pm)
2684	Q. And the FDA have approved the hepatitis C antibody test:
2685	"In the changed circumstances, I think it would be
2686	prudent to bring forward the next meeting to 2nd July,
2687	as I feel the Committee need to consider further whether
2688	UK blood donations should be routinely screened for
2689	hepatitis C antibody. I appreciate the difficulties in
2690	making time available for meetings at short notice.
2691	However, I hope as many as possible will be able to
2692	attend in view of the importance of the issue to be
2693	discussed.
2694	"This special meeting will be devoted entirely to
2695	hepatitis C screening. I outline in the annex specific
2696	questions which I believe we will need to address when
2697	formulating our advice to Ministers. If you think of
2698	any other let me know."
2699	If we look at the annex, we can see he has asked
2700	five questions:

	A
2701	"1. What new information is available about the
2702	tests or the use of RIBA or confirmatory PCR methods?
2703	"2. Has the FDA decision to implement testing
2704	been influenced by some further information which has
2705	now become available?
2706	"3. Are there any advantages attached to either
2707	of the two tests currently available in respects of
2708	specificity, sense activity, operational ease of use or
2709	cost?
2710	"4. If routine testing were to be introduced,
2711	what implications would this have for the UKBTS? How
2712	would positive [findings] be dealt with? What
2713	supplementary or confirmatory testing would be
2714	required", and so forth, "how would the donor be
2715	counselled? Could you put forward a revised version of
2716	the action chart?
2717	"5. If testing is to be introduced in the UK,
2718	should it be limited to whole blood or also extended to
2719	plasma donations, bearing in mind the supposed efficacy
2720	of heat treatment? Are all current methods of viral
2721	inactivation successful in respect of hepatitis C?"
2722	Just so we are aware of it and spot it when we see
2723	it in the documents later, that became a live sub-issue,
2724	did it not, the question of what you do about plasma.
2725	A. Yes, it did.
2726	Q. And whether it was enough to say it would be heat
2727	treated. It does not affect us for these purposes, but
2728	we see it coming up from time to time in the papers.
2729	A. It will indeed.
2730	Q. And then going back to the letter, we see:
2731	"It would be helpful if those of you preparing the
2732	protocol and the UKBTS action chart could make them
2733	available ... prior to the meeting.
2734	"I apologise for the short notice of this meeting
2735	but events are now moving fast and strongly indicate
2736	that we should consider again at an early date our
2737	advice ..."
2738	So that is what got the ball rolling for an
2739	earlier meeting and it also reflects what you have
2740	already told his Lordship, that there had been a meeting
2741	of the subgroup in May.
2742	A. Yes.
2743	Q. As you were asked to do, you continued with developing a
2744	protocol. We can see at page 1193 in the same bundle a
2745	fax from Dr Mitchell to you, with a draft proposal and
2746	chart, going to 1196.
2747	At page 1214, we can see you writing to
2748	Dr Metters, enclosing a revised action chart, explaining
2749	its status, and also explaining that the draft protocol
2750	was still being discussed, but you hoped to have it

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2751	ready in advance for circulation.
2752	So that puts a bit of flesh on the bones of
2753	paragraph 5. When it says it was now felt that a study
2754	along the lines of those talked about in April was no
2755	longer viable, can you recall what you understood by
2756	that?
2757	A. Well, Dr Rejman I think had discussed this with
2758	Dr Metters, and it is reflected, of course, partly in
2759	Dr Metters' letter, but Dr Rejman was putting forward
2760	the proposition that we should really get on with the
2761	introduction of screening, and not carry out another
2762	study of the Ortho versus Abbott tests.
2763	Q. What I was hoping for clarification on was Dr Metters'
2764	letter was clearly not saying to you, "do not test",
2765	because he was asking for the protocol.
2766	A. Yes. Dr Rejman went a little further. He felt the
2767	proposed study was not at this stage viable.
2768	Dr Metters, I think, says in his letter:
2769	"An extended study might not be appropriate, but
2770	let us have the protocol anyway and look at it."
2771	Q. Over the page, the Chairman said he was aware of the
2772	testing carried out in other countries. However
2773	operational matters need to be considered --
2774	MR JUSTICE BURTON: Can I be clear about that, I am sorry.
2775	It is not then that the study as proposed was not
2776	appropriate but maybe a different one, that was not what
2777	was meant. What was meant was, do not let us bother
2778	with the study at all.
2779	A. Should we do a study or not?
2780	MR JUSTICE BURTON: Thank you.
2781	MR UNDERHILL: What may have lain behind that question of
2782	his Lordship was, as Mr Brown pointed before lunch, the
2783	original proposal in April was for a study with 25,000.
2784	By the time we look at your proposal which I was going
2785	to in a moment, but we can see it at 384, you were
2786	thinking that you would simply look at 10,000
2787	donations. How had that change come about?
2788	A. Well, you quoted in this bundle --
2789	Q. Yes, the black one.
2790	A. -- the fax that was sent to me by Dr Mitchell. Sorry,
2791	perhaps I am on the wrong one. I thought there was one
2792	from Dr Mortimer.
2793	Q. There may have been, I am sorry. If so, I have not
2794	spotted it.
2795	A. Dr Mitchell faxed this to me, and in his fax, he
2796	suggests that we do 3,500 to 4,000 random donor tests at
2797	each centre. When we worked out the percentage of 0.5
2798	to 1 per cent positive, we realised we would get
2799	sufficient numbers of positives with 10,000 rather than
2800	Dr Mortimer's original estimate of 25,000 to 50,000.

	A
2801	Q. May we just be clear what you are saying? Are you
2802	saying that, as it were, the first time the idea of
2803	10,000 came out was with Dr Mitchell's fax, which we
2804	have just seen, or had it already been discussed between
2805	you on some earlier occasion?
2806	A. Oh no, it had been discussed, I am fairly certain it had
2807	been discussed, because, you see, this memo of
2808	Dr Mitchell's is 11th June, and we had met on 23rd May,
2809	and the basis of the protocol was decided at that
2810	meeting.
2811	Q. Yes.
2812	MR JUSTICE BURTON: So the stage is, original suggestion
2813	much larger, 23rd May discussion, slim it down, and now
2814	Dr Rejman and possibly Dr Metters are saying, "May not
2815	bother at all".
2816	A. That is correct.
2817	MR UNDERHILL: At the top of page 357, paragraph 6, we have
2818	read half of that, but it picks up with this:
2819	"The meeting's main purpose was to reconsider the
2820	principle of hepatitis C screening. The secondary
2821	purpose was to look at the draft protocol and decide
2822	which tests to use."
2823	We do not have to read every bit of it. The next
2824	paragraph has Professor Zuckerman saying he now thought
2825	it was time to go ahead, although he was still concerned
2826	about counselling anti-HCV donors because of false
2827	positives, which he called a difficult public relations
2828	exercise, but overall, he thought it should go ahead.
2829	You are recorded as saying at the end of that that
2830	there was scanty information, but there appeared to be
2831	only a 60 per cent overlap of positive results for the
2832	two tests.
2833	What was the significance or potential
2834	significance of that?
2835	A. That there were a large number of false positives.
2836	MR JUSTICE BURTON: What are the two tests, I am sorry?
2837	A. Ortho and Abbott, my Lord.
2838	MR UNDERHILL: By this stage, was there some information
2839	available about Abbott?
2840	A. There must have been and it must be in these other
2841	papers.
2842	Q. In fact, I am sorry, we have ended up doing things in a
2843	slightly different order, but if we look at page 384,
2844	your protocol, the introduction sets out a bit of
2845	background, and then says:
2846	"Based on evidence obtained from screening blood
2847	donations in Finland, the supplementary tests should
2848	eliminate approximately two-thirds of the reactive
2849	samples."
2850	I may be leading you there, I suspect I am, and

	A
2851	I may not necessarily be leading you right, but might
2852	that have been where you got your information from?
2853	A. I will reserve judgment until I see it.
2854	Q. Very well.
2855	MR JUSTICE BURTON: Reserve judgment until you see what?
2856	A. The paper, the published paper from Finland.
2857	MR UNDERHILL: I have just been asking my juniors to find
2858	it.
2859	MR BROWN: It is the Ebeling paper, 1990, tab 14, I think.
2860	MR UNDERHILL: It does fit into this period. My Lord, let
2861	us not spend time on this. The Ebeling paper, which was
2862	a Finnish paper, including Dr Leikola as one of the
2863	authors, was published in the Lancet on 21st April, but
2864	as far as we can see, they were looking only at the
2865	Ortho test, so that would not answer our question about
2866	Ortho and Abbott.
2867	In any event, if we can continue for the moment,
2868	leaving that as an unanswered question, paragraph 8:
2869	"After further discussion, the Committee concluded
2870	they should recommend to Ministers that hepatitis C
2871	testing should be introduced in the UK but that first a
2872	pilot study using the Ortho and Abbott tests was
2873	necessary to decide which was the better test for the
2874	RTCs."
2875	First question to ask you: from your recollection,
2876	was that a fair summary of the decision which the
2877	Committee reached?
2878	A. As far as I am aware, yes.
2879	MR JUSTICE BURTON: Can I understand it? You would agree
2880	with me so far: big study, as per April meeting, you
2881	yourselves in May, the 23rd, concluded that was
2882	inappropriate or unnecessary.
2883	Then Dr Mitchell sent you a draft protocol for a
2884	smaller one, the 10,500 at three centres, to which you
2885	put together or agreed his protocol, and it was your
2886	joint protocol which went before the meeting, but
2887	against the background of suggestions by Dr Metters and
2888	Dr Rejman that it might not be necessary to have any
2889	study at all, but the meeting then concluded that it was
2890	necessary to have such a study.
2891	Is that it, or is it something different?
2892	A. The only thing is, I think that when we met in May, we
2893	decided that we did not need 15,000 to 20,000 or 50,000
2894	donors, we needed a smaller one, and an outline of a
2895	proposal was agreed at that meeting.
2896	Subsequently, Dr Mitchell sent me a rough draft of
2897	a proposal, which I then made into a much more
2898	substantive one for the Committee.
2899	MR JUSTICE BURTON: I understand all that. All I am trying
2900	to ask you is whether you are clear in your mind -- and

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2901	if you want to reconsider it please do -- that the
2902	position was that when Dr Metters or Dr Rejman said it
2903	was now felt that a study along the lines of those
2904	talked about in April was no longer viable, he was
2905	meaning no tests at all, or no test as big as the one in
2906	April, but let us consider the protocol for 10,500,
2907	because ten minutes or so ago, you said he meant no test
2908	at all and that is what you thought Dr Metters meant as
2909	well, when he said, in your letter, that "an extended
2910	study might not be appropriate", but nevertheless,
2911	despite that view expressed, the Committee decided to
2912	have one, along the lines of your draft protocol.
2913	Or is it that all they were saying was, "Do not
2914	need a big one but might have a small one"?
2915	A. No, I do not think it was the latter, my Lord. I think
2916	Dr Rejman thought the study was not viable. Dr Metters
2917	was less positive by saying it might not be advisable,
2918	but when the Committee met, they decided that the
2919	original proposal for the study should go ahead.
2920	MR JUSTICE BURTON: Albeit slimmed down?
2921	A. Albeit slimmed down.
2922	MR JUSTICE BURTON: And how did that happen?
2923	A. Sorry, how --
2924	MR JUSTICE BURTON: How did that happen? Given Dr Rejman
2925	was the secretary, and Dr Metters was the Chairman and
2926	they were thinking that it may not be a good idea to
2927	have it at all, how did the Committee come to decide
2928	that they would have it?
2929	A. By the time the Committee met, the Chairman, Dr Metters,
2930	had rather overruled Dr Rejman, who was his junior, and
2931	said that the purpose of the meeting was to reconsider,
2932	and the secondary purpose was to look at the draft
2933	protocol.
2934	When they had looked at it, they agreed that it
2935	would be a good idea to go ahead with the trial.
2936	(2.30 pm)
2937	MR UNDERHILL: That is your recollection --
2938	A. That is my recollection of what happened.
2939	Q. Speaking first, as it were, for yourself, and then
2940	I will ask you later about any views you may remember
2941	being expressed at the Committee, what was your view
2942	about the value of such a test?
2943	A. I thought it would be valuable to certainly look at the
2944	Abbott test, which we had not had any experience with in
2945	the past, and that certainly to compare it with Ortho
2946	was sensible, so that one might determine whether there
2947	was a preferential test between Ortho and Abbott for use
2948	in routine screening.
2949	MR JUSTICE BURTON: Again I am unclear. Was the May plan,
2950	May 23rd, "compare Ortho with Abbott"?

	A
2951	A. Yes.
2952	MR JUSTICE BURTON: When did "compare Ortho with Abbott"
2953	come in, because that was not what had been discussed in
2954	April, or was it?
2955	A. Yes.
2956	MR UNDERHILL: I think it was, my Lord, yes.
2957	MR BROWN: My Lord, my learned friend really must not give
2958	evidence at this point, because this is an important
2959	point. Our understanding, and I make it plain on this
2960	side of the court, is that the April proposal was not
2961	primarily Abbott v Ortho; it was primarily directed
2962	towards confirmatory.
2963	My Lord, I do not want to confuse matters, but
2964	I shall be asking Dr Gunson a series of questions about
2965	how the study got increased from 25,000 to 50,000 to
2966	100,000, before it came back down to 10,000.
2967	My Lord, the reason we say it cannot have been
2968	Abbott v Ortho primarily, in the outset, is that Abbott
2969	still was not on the market at this time.
2970	MR UNDERHILL: My Lord, I am not going to fight any battles
2971	about this. I think I have been scrupulous when it
2972	comes to any matter of importance in not giving any
2973	evidence, and I did not believe there was anything
2974	contentious in answering your Lordship's question, "was
2975	it an Ortho v Abbott test in April?", because if we look
2976	at page 298, paragraphs 25 and 28, one sees that the
2977	Ortho and Abbott tests should be run together in some
2978	RTCs. If my learned friend thinks there is some arcane
2979	point about the exact purpose of that, he can explore it
2980	in cross-examination, but the simple answer to
2981	your Lordship's question was evidently yes.
2982	I am in your Lordship's hands. My learned friend
2983	has very helpfully indicated what he wants to explore
2984	and on the whole, I would rather let him explore it. On
2985	the other hand, it is in your Lordship's mind, and I am
2986	very happy to ask the questions myself.
2987	MR JUSTICE BURTON: No, I have understood in general terms,
2988	and the position is that on the evidence as it is so
2989	far, unexplored in cross-examination, it was to be a
2990	test -- a run-off of Ortho against Abbott, big, small,
2991	et cetera. You have asked the question, which is when
2992	I interrupted: what did you think -- where are we?
2993	MR UNDERHILL: I think I asked him what in his mind was the
2994	value of doing this test.
2995	MR JUSTICE BURTON: Yes. Can I ask you to add, when you are
2996	answering Mr Underhill's question, at that time, rather
2997	than going ahead with introducing screening, i.e.
2998	I think what would help me is: what was the value of
2999	doing it, if it was going to mean a further postponement
3000	of introducing routine screening, or with a view to

	A
3001	considering whether screening should be implemented, or
3002	whatever; i.e., were you in favour of having another
3003	test, rather than introducing screening then, and if so
3004	why?
3005	A. I think by July, the decision to introduce screening
3006	was -- had been taken, but the Abbott test had come on
3007	the market from 1st July, and at that time I considered
3008	that an evaluation of Ortho and Abbott tests would be of
3009	advantage, to see whether one was superior to the other,
3010	and which could be used with advantage in the
3011	transfusion service, or were both tests of equal value?
3012	MR JUSTICE BURTON: Even if it meant postponing
3013	implementation of routine screening, as it did?
3014	A. Even if it meant postponing routine screening.
3015	MR JUSTICE BURTON: Why was that?
3016	A. Because I thought it was an advantage to have further
3017	knowledge about the test before we introduced it
3018	routinely.
3019	MR JUSTICE BURTON: Thank you.
3020	MR UNDERHILL: My learned friend has intervened, and we may
3021	well at least deal with this now, to point out that in
3022	the April meeting, an advantage of the testing of the
3023	two was perceived to be -- indeed he would say this was
3024	its main reason -- in order to deal with the question of
3025	false positives, and to test the confirmatory assays
3026	then available, the RIBA and the PCR.
3027	To what extent was that still a consideration?
3028	A. Oh, that still was a consideration, because we did agree
3029	to send any repeatable positives to the reference
3030	laboratories.
3031	Q. How valuable would the information coming out of that
3032	be?
3033	A. Very valuable indeed, because we would then determine
3034	the extent of false positivity.
3035	Q. You mentioned apparently in paragraph 9 that Wellcome
3036	were expected to be introducing a test. The Committee
3037	decided effectively that you should not wait for that;
3038	pilot screening should go ahead without delay but
3039	samples should be kept to test against the Wellcome test
3040	when it became available?
3041	A. Yes.
3042	Q. Your protocol was then considered and, it says here,
3043	generally supported. I do not think we need look at
3044	it. If my learned friend wants to, he can when he gets
3045	there. As you have pointed out, it would involve first
3046	of all the testing of both kits at all three centres and
3047	secondly their being referred for supplementary testing
3048	at specialist laboratories.
3049	In paragraph 11, you made the point that, because
3050	the number of screen positives was predicted to be

	A
3051	relatively low, the problem of counselling affected
3052	donors should not be unmanageable. You said you were
3053	aware that donors might need convincing they did not
3054	have HIV; that is HIV, is it?
3055	A. That is HIV.
3056	Q. Why might that need to be --
3057	A. Well, this was the major topic, even at this time, that
3058	when a positive test was found, it was usually HIV.
3059	Q. It was agreed donations found to be infected would not
3060	be used, consideration of lookback was postponed. It
3061	was felt there needed to be national consistency on
3062	counselling, which the working group would look at.
3063	Which working group was that?
3064	A. This was the working group of Mitchell, Tedder, Mortimer
3065	and myself.
3066	Q. Professor Zuckerman decided it ought to be published.
3067	Then the debate moved on to the question of testing of
3068	plasma. We can jump over that. And then there is a bit
3069	more discussion of the pilot scheme, the cost was
3070	discussed, Procurement Directorate had some of the money
3071	straight away, but obviously not all.
3072	You reported that Abbott would provide kits at
3073	50 per cent of the normal cost, and that Ortho were
3074	happy to supply their kits free of charge for the study,
3075	provided they were kept informed of progress with a view
3076	to publication:
3077	"The Committee felt this was unacceptable, and it
3078	was decided the Procurement Directorate would pursue
3079	pricing in the normal way."
3080	What was the thinking behind that?
3081	A. They did not wish Ortho to publish the results of the
3082	study, because they felt that this was a confidential
3083	matter for the transfusion service, and not a commercial
3084	company.
3085	Q. And then this, paragraph 20:
3086	"It was estimated that the overall timescale for
3087	the study would be approximately four months after
3088	finance had been agreed."
3089	Can you remember how the figure of four months was
3090	arrived at?
3091	A. No, I cannot, Mr Underhill.
3092	Q. Can you, as it were, reconstruct it, even if you cannot
3093	remember it?
3094	A. Well, I suppose it was arrived at by the fact that to
3095	get the kits in it may have been necessary for equipment
3096	to be in place at the transfusion services, and then to
3097	organise the testing and collation of the results of the
3098	study, that would take four months.
3099	Q. Just looking at the individual processes, how long would
3100	it take to run the screening tests for this number?

	A
3101	A. Well, I should suppose that a centre of the size that we
3102	are talking about would do something between 500 and 800
3103	tests per day.
3104	Q. So we just have to do a bit of arithmetic in our head.
3105	A. So, you are talking about seven working days, probably.
3106	Q. What about the next stage? What about the reference to
3107	the supplement to the laboratories for PCR testing?
3108	A. They, of course, would take considerably longer to do
3109	these tests, and it would depend -- the time would
3110	depend on the number of tests that had to be submitted
3111	to them.
3112	Q. Yes. Because these tests are done one by one?
3113	A. They were done one by one, yes.
3114	Q. And then we have the Chairman summing up:
3115	"The UK should introduce hepatitis C testing."
3116	I have already asked you about that:
3117	"The public relations aspect needed to be handled
3118	very carefully."
3119	I notice that same phrase appears, used by
3120	Professor Zuckerman, in relation to counselling donors.
3121	Do you know what it is a reference to?
3122	A. It is a reference to the counselling of donors, directly
3123	from Professor Zuckerman's statement at the meeting,
3124	because, of course, they are part of the general public,
3125	and we would have to handle them in a very careful
3126	manner not to cause them any great anxiety.
3127	Q. And then, I think most of these are uncontroversial, but
3128	bullet point 4:
3129	"The decision as to which hepatitis C test to use
3130	will be made after the results are known."
3131	That follows I think from what you said earlier,
3132	and then the remaining points I do not think I need
3133	spend time on.
3134	MR JUSTICE BURTON: I suppose the nub of it, Dr Gunson, is,
3135	once you have made the decision to introduce it, whether
3136	you introduce it straight away or whether you have four
3137	months to decide which system to use, given that Ortho
3138	has been in existence for a good long time and Abbott
3139	has only just come on the market. You have indicated
3140	what your view was at the time. Looking back on it now,
3141	do you conclude it was right to wait that extra four
3142	months? Of course, in the end it was a lot longer than
3143	four months, but looking back now to where we were in
3144	July 1990, with the benefit of hindsight --
3145	A. An alternative would have been to introduce the test
3146	using Ortho at some centres and Abbott at other centres,
3147	and then combine the results of that screening with --
3148	into a formal study. That is with hindsight a
3149	possibility that could have been done.
3150	MR JUSTICE BURTON: Was it considered?

	A
3151	A. I do not think it was.
3152	(2.45 pm)
3153	MR UNDERHILL: Matters then proceeded, and the trial took
3154	place in September and October and, as my learned friend
3155	has pointed out, the formal funding did not come through
3156	straight away, but the trial in any event proceeded in
3157	September and October, and the results, or such as were
3158	then available, were considered at the meeting of the
3159	ACVSB on 21st November, which is behind tab 8.
3160	(Pause).
3161	I am so sorry, I have just misled myself for a
3162	moment. The minute is at page 399, perhaps we will go
3163	to the papers that were before the Committee as they are
3164	referred to in the minute.
3165	The Chairman recalled the summing-up of the last
3166	meeting, and said a note had gone to Ministers telling
3167	them that the ACVSB was in favour of introducing routine
3168	testing in the UK:
3169	"Further decisions are awaiting the decision of
3170	this meeting as to which test would be the most
3171	suitable."
3172	He then just refers to the question of plasma, he
3173	refers to the question of lookback, and says the
3174	previous minute was slightly misleading in suggesting
3175	that had been ruled out, and then you introduced your
3176	paper on the results of the pilot study, saying that the
3177	results of the supplementary testing would be the
3178	decisive factor when considering whether one screening
3179	test was better than another; both screening tests could
3180	be deemed to be satisfactory for routine use from an
3181	operational viewpoint, and the choice would be
3182	influenced by the equipment available in the RTCs.
3183	We can see the results at page 405. We need not
3184	go through them in enormous detail, but we see that the
3185	date on the front is 29th October, so that the results
3186	of phase 1 of the trial were available by that date.
3187	Perhaps we can just be clear: what was phase 1? I am
3188	sorry, am I ahead of you?
3189	A. No.
3190	Q. What was phase 1?
3191	A. Phase 1 was the testing of the donations with the ELISA
3192	test at three Regional Transfusion Centres.
3193	Q. And phase 2 was the passing on to the reference centres?
3194	A. And their report of the test.
3195	Q. And their report. So this was available by
3196	29th October, and we can see that in the introduction,
3197	you refer to various technical difficulties which had
3198	arisen. We can just briefly summarise those. Firstly,
3199	at paragraph 1.4, you say the North London kits were
3200	found to give negative control OD results which

	A
3201	invalidated the quality control of the plate.
3202	Could you perhaps explain that to his Lordship?
3203	A. Each plate has a positive and negative control, in fact
3204	it may be two positives and two negatives, and these
3205	have to react appropriately before you can accept the
3206	remaining results on that plate. And since some of the
3207	batches from Ortho give negative control results, in
3208	other words you could not get the positive control to
3209	work, the other tests on that plate were invalidated and
3210	the whole plate had to be repeated.
3211	Q. So you had to start again, or had to replace that
3212	batch --
3213	A. Yes. The company were advising -- they gave another
3214	batch of test kits.
3215	Q. For safety's sake, that was done at the other two RTCs,
3216	though they had not had the same problem?
3217	A. That is correct.
3218	Q. 1.5, you refer to the fact that Abbott had installed a
3219	computer programme at North London, but that had to be
3220	replaced. At 1.6, you deal with another problem with
3221	Abbott. Is it possible to summarise that?
3222	A. Well, they installed particular processing equipment
3223	specifically for the trial, and when the equipment was
3224	used, the cut-off points were different from those
3225	predicted by Abbott for the use of their test.
3226	MR JUSTICE BURTON: I do not know what a cut-off point is
3227	for this purpose. Do I need to know?
3228	A. The cut-off point is the division between a positive and
3229	negative result.
3230	MR UNDERHILL: And it is measured by effectively the degree
3231	of darkness -- degree of optical density?
3232	A. Indeed, it is the degree of optical density.
3233	Q. 1.7:
3234	"All three RTCs reported the tests were easy to
3235	perform."
3236	1.8, Northern RTCs said they needed a computer
3237	package for statistical analysis of the many manual
3238	calculations:
3239	"They also commented that the Adams assay data
3240	analysis and management systems used by Ortho had some
3241	operational problems."
3242	These were all simply operational problems with
3243	these tests?
3244	A. They were, and indeed were not unresolvable.
3245	Q. They were not?
3246	A. Unresolvable. They could have been resolved.
3247	Q. Yes, I was wondering what way to put that.
3248	Then a summary of the results, and they are at
3249	page 412, that is where they start. We see what has by
3250	now become a familiar pattern of repeat reactive rates

	A
3251	between about 0.3 and 0.5. One sees that, as you would
3252	expect, the initial screen positives are slightly
3253	greater than the repeat reactives, but not much
3254	greater.
3255	A. No, it is larger with Ortho basically than Abbott.
3256	MR JUSTICE BURTON: Do I understand the position that those
3257	are not necessarily the same ones, that is that the 18
3258	that Abbott tested positive out of 3,516 at Glasgow were
3259	not necessarily the same as the 23 that Ortho --
3260	A. Oh no.
3261	MR JUSTICE BURTON: There must be another test which shows
3262	that up, is there?
3263	A. Each test, at each centre, was done on the same donor
3264	serum.
3265	MR JUSTICE BURTON: Yes, I understand that.
3266	A. So the 18 and the 23 came from the same donor serum.
3267	MR UNDERHILL: I think what his Lordship was saying was that
3268	effectively the Ortho positives and the Abbott positives
3269	were not the same, although they overlap.
3270	A. There was an overlap --
3271	MR JUSTICE BURTON: You told me 60 per cent, but I was
3272	wondering, is there a table which shows that?
3273	MR UNDERHILL: We are coming to that, my Lord.
3274	MR JUSTICE BURTON: Right, but at the moment, the percentage
3275	is the same, is that right, but they are not necessarily
3276	the same ones; that is what we have seen so far.
3277	A. That is correct.
3278	MR UNDERHILL: And the table your Lordship was thinking of
3279	is at 414, where one sees a total of 69 positives on
3280	both tests, of which 26, the middle figure, were
3281	positive in both. So if you had a Venn diagram, there
3282	would be a big overlap but there would be quite a bit on
3283	either side.
3284	That was as much as you could tell in your phase
3285	1; unless something had gone seriously wrong, you would
3286	expect the true positives to be found among the overlap
3287	ones.
3288	A. Yes.
3289	MR JUSTICE BURTON: I do not see that 60 per cent overlap.
3290	MR UNDERHILL: I think Dr Gunson had said that was a figure
3291	he was predicting from some other source. In fact, this
3292	did not show a 60 per cent overlap, did it?
3293	A. It was not anything like a 60 per cent overlap. There
3294	was an overlap of a good deal less than 60 per cent.
3295	Q. All this would do by itself was show you, as had always
3296	been predicted, there were an awful lot of false
3297	positives?
3298	A. It does indeed.
3299	Q. Then what you need to do is phase 2, where it goes to
3300	the reference centres, to the specialist centres for

	A
3301	supplementary testing.
3302	We have here directly following on at 416 the
3303	report from Dr Tedder's laboratory, dated 21st November,
3304	the very day of the meeting, I think.
3305	A. Yes.
3306	Q. The other two, the Scots and Dr Mortimer, we do not have
3307	results from. Do you know why that was?
3308	A. Well, they had not yet completed the study. Professor
3309	Tedder had, at this date; he tabled this paper at the
3310	meeting.
3311	Q. Yes. So they had had these samples for how long,
3312	roughly? We know they must have had them since at least
3313	29th October, because that is when you had written your
3314	paper.
3315	A. Oh, they would have had them before that, because this
3316	paper must have taken me a few days to write, so I would
3317	guess probably a week before 30th October, last week in
3318	October.
3319	Q. So it would have taken at least five weeks, and
3320	Professor Tedder had just got there and the other two
3321	had not yet?
3322	A. That is correct.
3323	MR UNDERHILL: Just for your Lordship's note, we have the
3324	paper from Dr Follett in Glasgow, and he was able to do
3325	it by 26th November. If we have Dr Mortimer's, I have
3326	missed it.
3327	MR JUSTICE BURTON: Mortimer is Northern, is he? Tedder is
3328	North London?
3329	A. Tedder is at the Middlesex Hospital.
3330	MR JUSTICE BURTON: So he tested the North London ones?
3331	A. Yes -- well, in fact, the positive samples from all
3332	centres were sent to the three specialist laboratories.
3333	MR JUSTICE BURTON: I see, so they all did the same ones?
3334	A. They all did the same ones, yes.
3335	MR JUSTICE BURTON: I see.
3336	MR UNDERHILL: This was the first time anyone had had the
3337	chance to do this, was it not?
3338	A. Yes.
3339	MR UNDERHILL: So they all did the same ones. I was just
3340	hoping to add to my brownie points by being able to give
3341	your Lordship the reference for the Follett but, apart
3342	from having noted down it was 26th November, I cannot at
3343	once find the page reference. But if there is a
3344	Dr Mortimer one, I will be happy for someone else to
3345	tell me.
3346	MR JUSTICE BURTON: Thank you. But looking at Tedder then,
3347	the ones that showed positive for him were largely, if
3348	not entirely, the 26 that had been shown to be both
3349	positive by Abbott and Ortho.
3350	A. That is correct.

	A
3351	MR JUSTICE BURTON: Did that ever suggest the idea of using
3352	both Abbott and Ortho?
3353	A. The reference laboratories did use to do this. A
3354	transfusion centre having to use both Ortho and Abbott
3355	would have been impracticable.
3356	MR JUSTICE BURTON: Because?
3357	A. Because of the cost and also the time involved, but once
3358	repeat reactives were sent to the confirmatory
3359	laboratories, they did then test them with both tests.
3360	MR JUSTICE BURTON: I see.
3361	A. My Lord, if I could --
3362	MR UNDERHILL: Do go on.
3363	A. -- anticipate what Mr Underhill is going to say, the
3364	crucial part of this is on 418.
3365	Q. Yes. That is the meat of it, and that shows --
3366	MR JUSTICE BURTON: What does it show?
3367	MR UNDERHILL: You say what it shows.
3368	A. Shall I say what it shows?
3369	Q. Yes, please do. It is better from you.
3370	A. He has reviewed four sera from the North London, two
3371	from Newcastle and four from Glasgow, and these are all
3372	Ortho and Abbott positive, which is in the second
3373	column. The RIBA tests are in the third column --
3374	MR JUSTICE BURTON: Sorry to interrupt, two of them appear
3375	to be Abbott -- I do not know what "A minus" means.
3376	A. Ortho positive, Abbott negative.
3377	MR JUSTICE BURTON: So two of them are Abbott negatives; is
3378	that what you said?
3379	A. Sorry, two are Abbott negatives and the others are both
3380	Ortho and Abbott positive.
3381	MR JUSTICE BURTON: Now there were 26 that were Abbott and
3382	Ortho positive.
3383	A. Yes.
3384	MR JUSTICE BURTON: Not all of those feature in --
3385	A. Not all of those feature in this table.
3386	MR UNDERHILL: The table is specifically those that were
3387	reactive in one or more of the supplemental assays.
3388	A. This is in the supplementary tests. There are some --
3389	MR JUSTICE BURTON: Humouring me just a little more, can we
3390	not go back to 416, so I am sure I understand 416 before
3391	we go on to 418? Concordant positive means what?
3392	I thought that meant concordant, in the sense that
3393	Abbott and Ortho both showed them as positive, and they
3394	were also positive on the supplementary test. That
3395	would suggest that 18 --
3396	MR UNDERHILL: Perhaps the key to this, my Lord, is one sees
3397	"concordant positive number 25". There is some wrinkle
3398	why it is not 26, but that is essentially the 26 we are
3399	looking at. They retested them. The first thing they
3400	did was they retested them simply on the screening, and

	A
3401	they only found 18 concordant.
3402	MR JUSTICE BURTON: Right, so 25 comes down to 18. Fair
3403	enough, we do not need to worry about the rest perhaps.
3404	So there were 25 which came through the original tests.
3405	How does that compare with the fact that there are only
3406	10 on page 418?
3407	MR UNDERHILL: If we look over the page, my Lord.
3408	MR JUSTICE BURTON: I follow.
3409	MR UNDERHILL: 10 samples, see table, were considered
3410	reactive by one or more of the supplemental assays and
3411	HCV RNA was detected by PCR in six of these specimens.
3412	So regarding PCR as the gold standard, that is how we
3413	get to our six out of 10,000 which your Lordship has
3414	heard from time to time.
3415	(3.00 pm)
3416	MR JUSTICE BURTON: So 25 comes down to 18 on page 1, and
3417	somehow or other 18 gets down to 10 in some documents
3418	which we are not shown, and then the 10 is given the
3419	breakdown on page 418.
3420	MR UNDERHILL: And the six -- if you look in the PCR column,
3421	the first one, I will ask Dr Gunson the difference in a
3422	minute, but the first three are positive, then a
3423	negative, then a positive, then a negative, then two
3424	more positives, and that is six, and only four are
3425	positive on the second of the two PCR tests.
3426	Are you able to tell us, Dr Gunson, what the
3427	difference is between those two PCR tests?
3428	A. I am sorry, Mr Underhill, that is beyond my competence.
3429	MR JUSTICE BURTON: At any rate, it appears that,
3430	notwithstanding that three of the six did not show
3431	positive on the second PCR test, all six which qualified
3432	on the first PCR test are regarded as what you call the
3433	gold standard.
3434	MR UNDERHILL: And your Lordship will observe that the two
3435	which your Lordship noticed, which were only Ortho
3436	positive but Abbott negative, were in the end negative
3437	on PCR.
3438	MR JUSTICE BURTON: Yes. I find it puzzling that they went
3439	in at all, given that the 18 came down to 10, but
3440	I suppose ...
3441	MR UNDERHILL: It looks as though what they did was they
3442	supplemental tested all of them, and only those that
3443	came up on any of the supplemental tests did they then
3444	look at in that final table.
3445	MR JUSTICE BURTON: So in fact the 18 came down to 10 --
3446	that may be the answer, that there were 18 concordant,
3447	slimmed down to 10, not on the basis that they had
3448	ceased to be concordant, but that those were the only
3449	ones that showed up on any of the supplemental tests.
3450	Yes, I follow.

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3451	MR UNDERHILL: And in his conclusions, Dr Tedder says:
3452	"69 samples were referred. On retesting, 51
3453	remained reactive, 22 concordantly [yet another
3454	figure]. Six samples only were considered to have come
3455	from currently infected donors. Five of them were
3456	positive for antibody in all the supplemental assays."
3457	Then the sixth -- there is some rather technical
3458	stuff.
3459	So that was the material that was put before the
3460	Committee?
3461	A. Yes.
3462	Q. And had that exercise of doing a PCR test on a group of
3463	screened positives been done before in this country?
3464	A. No, that was the first time it had been done.
3465	MR UNDERHILL: My Lord, can I just, while I remember it, so
3466	I can now put it down, Dr Follett's laboratory reported
3467	not, as I said, on 26th November but on 29th November,
3468	and their report is at A5, page 1440. That was too late
3469	for the meeting.
3470	But in broad terms, did it come to the same
3471	findings as Dr Tedder?
3472	A. Dr Follett found the same six samples positive with PCR.
3473	Q. Can you remember about Dr Mortimer?
3474	A. Again, the same six samples.
3475	MR JUSTICE BURTON: So it was six out of how many?
3476	A. 10,633, I think it was.
3477	MR UNDERHILL: I see what has happened. We will go through
3478	the note and then we will see it:
3479	"Dr Gunson introduced his paper on the results of
3480	the pilot study, saying the results of the supplementary
3481	testing would be the decisive factor."
3482	Then at 7:
3483	"Dr Tedder then spoke to his paper [the one we
3484	have been looking at] and Dr Mortimer tabled a paper."
3485	I am embarrassed I had not spotted that. Are we
3486	missing it? I think we are missing it; that is why. So
3487	it looks as though Dr Mortimer had also got in, although
3488	he had had to table the paper rather than circulate it
3489	beforehand.
3490	Does that accord with your recollection, or can we
3491	only go on the minutes?
3492	A. I think you can only go on the minutes, Mr Underhill.
3493	Q. But that is what it says:
3494	"Although broadly there was agreement, there were
3495	some discordance close to the cut-off point. Overall,
3496	there seemed little to choose between the two screening
3497	kits. Of the 68 screen positive samples, six were shown
3498	to be positive using PCR."
3499	MR JUSTICE BURTON: And it might have been said, "And all
3500	those six had been shown to be positive by both Abbott

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3501	and Ortho."?
3502	A. That is correct.
3503	MR UNDERHILL: And to just be clear about this, this was now
3504	RIBA 2?
3505	A. They used RIBA 2 in this study on an experimental basis.
3506	Q. "That was shown to be preferable to the neutralisation
3507	test as a supplementary test. It was suggested that a
3508	combination of RIBA followed by PCR would provide a
3509	useful confirmatory service."
3510	Then the results from Glasgow, that was
3511	Dr Follett, were not yet available:
3512	"Professor Zuckerman pointed out that while the
3513	study was very worthwhile and encouraging, he felt it
3514	was impossible to choose between the two screening tests
3515	because of the discordant results. He agreed there were
3516	difficulties with the neutralisation test."
3517	I do not think that I need read all of that.
3518	MR JUSTICE BURTON: Remind me what the neutralisation test
3519	was?
3520	A. This, my Lord, was the Abbott supplementary test.
3521	MR JUSTICE BURTON: Thank you.
3522	MR UNDERHILL: At paragraph 10:
3523	"The Committee agreed it was important to start
3524	screening as soon as practicable as a measure which
3525	would further enhance the safety of the blood supply."
3526	Does that fairly reflect what you recall that
3527	Committee having decided?
3528	A. Yes, it does.
3529	Q. Then we can take the rest fairly shortly. In
3530	paragraph 11, you deal with counselling. At
3531	paragraph 13, there is a further reference to the fact
3532	that second generation tests were expected, and you
3533	yourself referred to the fact that one had been offered
3534	for testing already in North London.
3535	A. Yes.
3536	Q. And the Chairman put forward a proposal about what would
3537	happen with counselling, which donors would have to be
3538	counselled; effectively only those who were confirmed
3539	positive by the reference centre, and that was agreed,
3540	and work would need to start on protocols and so forth.
3541	Paragraph 18, over the page, the Chairman summed
3542	up the discussion by saying there was agreement that the
3543	UK should introduce hepatitis C testing as soon as
3544	practicable; that is what we have already seen over the
3545	page:
3546	"RTCs would decide individually whether to use
3547	Ortho or Abbott tests. The blood from any repeat
3548	positives would be set aside. Test samples would then
3549	be sent to the reference centre where both the Abbott
3550	and Ortho tests, followed by the RIBA test, would be

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3551	performed. At this stage, some cases would no longer
3552	need to be deferred and the reference centre should
3553	inform the RTC of these cases. The repeat positives
3554	would then be subjected to PCR. The RTC would be
3555	informed which samples were confirmed positive and which
3556	were negative. The reference centres would determine a
3557	common protocol for supplementary testing, and would
3558	advise in the light of developments in the testing
3559	field. A submission would go to Ministers regarding
3560	this significant policy decision and the Management
3561	Executive would consider the funding aspect", and the
3562	results of the pilot study would be published in a
3563	scientific journal.
3564	There is then a consideration of counselling. On
3565	counselling, there was a paper to consider, to which you
3566	spoke. For everyone's reference, it is at -- sorry,
3567	I had marked it up, but I have now lost it. We will
3568	find it in a moment.
3569	At paragraph 21:
3570	"In addition, two further aspects would be
3571	considered: the question of lookback and date of
3572	introduction. [You] reported that some centres had
3573	asked for a six-month period in which to set up
3574	testing."
3575	Just to pause there, it follows from that that
3576	presumably you had spoken to some centres about this
3577	question?
3578	A. I had indeed.
3579	Q. When had you done that?
3580	A. During the period between July and October when we were
3581	doing the planning and carrying out the pilot study.
3582	Q. And why had you done that?
3583	A. Because I felt that the time was coming when routine
3584	testing would have to begin, and so I informally
3585	discussed the introduction of testing with quite
3586	a number of the directors, and some had said to me --
3587	not all, but some had said that they thought they would
3588	need six months.
3589	MR JUSTICE BURTON: Why was that?
3590	A. To -- because they did not have the equipment, they did
3591	not have the staff, some needed additional
3592	accommodation, and matters such as that, my Lord.
3593	MR UNDERHILL: We are going to see, and this will perhaps
3594	give a clearer overall picture to his Lordship, when you
3595	then approached them formally, the kinds of responses
3596	you got.
3597	But you thought this to be excessive, but you said
3598	you would need to consult with other directors first.
3599	A. Yes.
3600	Q. That was your view, was it?

	A
3601	A. It was my view. I thought six months was a long time.
3602	Q. It was agreed you would hold off consultation until the
3603	submission had been put to Ministers. Who asked you to
3604	do that?
3605	A. The Chairman.
3606	MR JUSTICE BURTON: Why was that?
3607	A. I think they were concerned that if I started to
3608	consult, matters would become in the public domain
3609	before the Minister had had a chance to see the
3610	submission put to him.
3611	MR UNDERHILL: "The Chairman stressed the importance of a
3612	common date of introduction throughout the UK."
3613	Why was that?
3614	A. Well, when we introduced hepatitis B testing, it was
3615	over a period of about 18 months, and it was felt even
3616	at that time that some patients were having the
3617	advantage of tested blood whilst others were not.
3618	When we introduced HIV testing, it was done on
3619	14th October 1985, all centres starting on the same day,
3620	having tested all the units in their bank, and it was
3621	generally considered that this was a much more
3622	advantageous way to introduce a routine screening test,
3623	so that all patients would have the same privileges at
3624	the same time.
3625	MR JUSTICE BURTON: What does that mean, having the same
3626	privileges?
3627	A. Well, having the screened blood at the same time.
3628	MR UNDERHILL: Why was it regarded as unsatisfactory that
3629	people should have different access to screened blood at
3630	different times?
3631	A. Well, you may get adjacent hospitals, only a few miles
3632	apart, one having screened blood and the other having
3633	unscreened blood, and it was felt that patients in the
3634	latter hospital might have a justifiable complaint.
3635	MR UNDERHILL: I have been given the reference incidentally
3636	for our counselling paper, it is 421. I had just
3637	skipped over it.
3638	Perhaps we should just look at it briefly because
3639	there is one point which arises from it. Page 421. We
3640	can see from this that you proposed on 19th November,
3641	that is shortly before this meeting we are looking at,
3642	to convene a meeting of the TTD to consider this matter
3643	and provide recommendations. Did you regard counselling
3644	policy as a matter for the TTD?
3645	A. I thought that was an operational matter, yes.
3646	Q. Can we then look at your statement? Because this is
3647	quite a key point in the story. You refer to this
3648	meeting at the bottom of page 33. At the end of that
3649	paragraph, which I think is paragraph 80, near but not
3650	quite at the top of the page, you make the point that

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3651	you have just made to me orally about why there was it
3652	was thought important that everyone should have tested
3653	blood at the same time.
3654	And in paragraph 81, you say this:
3655	"It was effectively at the meeting of
3656	21st November 1990 that a final decision was made to
3657	proceed with HCV testing, although that decision had to
3658	be confirmed by Ministers and I was not informed that
3659	approval had been received until shortly before
3660	22nd January 1991."
3661	Perhaps we can just pin that down, although we are
3662	going to have to come back to things in the interval: it
3663	was on that date that you wrote a letter to all RTDs,
3664	Regional Transfusion Directors --
3665	MR JUSTICE BURTON: Sorry to interrupt, Mr Underhill, but
3666	what the witness said was -- that HIV had come in over
3667	18 months, and that was awfully undesirable, and that is
3668	not what he says in the witness statement.
3669	MR UNDERHILL: With respect, my Lord, I think it is. If you
3670	look seven lines up from the end:
3671	"When hepatitis B was introduced during the 1970s,
3672	there was a period of over one year", and that was
3673	undesirable. He said when the next was introduced,
3674	anti-HIV, considerable efforts were made to ensure the
3675	test was introduced on the same day.
3676	MR JUSTICE BURTON: That is what I had in mind. Unless it
3677	is a misprint on the transcript. The witness said:
3678	"When we introduced" -- I am sorry. You are
3679	absolutely right, it is my fault entirely. I have
3680	misread:
3681	"When we introduced hepatitis B, it was over
3682	a period of 18 months ..."
3683	I am sorry, thank you.
3684	MR UNDERHILL: It was the B experience which had been
3685	thought to be unsatisfactory, and they got it right with
3686	HIV and they were trying to do it the same way.
3687	We were just trying to pin down this question of
3688	when you were finally informed. You wrote your letter
3689	on 22nd January. About how long before that was it that
3690	you were told what the Minister had decided?
3691	A. I know exactly, Mr Underhill, it was the day before.
3692	Q. So that means the 21st?
3693	A. Yes.
3694	Q. And then you say in paragraph 82, and I think we should
3695	just go through this:
3696	"I do not believe that the decision of
3697	21st November 1990 was one which ought to have been made
3698	earlier. The factors which influenced the ACVSB in not
3699	making a final recommendation earlier appear from the
3700	minutes. But I should emphasise in particular the

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3701	related problems of false positives, confirmatory
3702	testing and donor counselling. The early indications
3703	were that the Ortho ELISA test threw up a very large
3704	number of false positives", and you have given various
3705	references there which I do not think we need go to, my
3706	learned friend can follow them up if he wishes.
3707	MR JUSTICE BURTON: Is there a reference for the
3708	22nd January letter?
3709	MR UNDERHILL: There is, and it is A5/1570.
3710	MR JUSTICE BURTON: Thank you.
3711	MR UNDERHILL: But the point is that Dr Gunson was not
3712	notified in writing of the Minister's decision; is that
3713	right?
3714	A. I was telephoned -- I received a telephone call from
3715	Mr Canavan of the Department, telling me the Minister
3716	had approved testing and would I find out the earliest
3717	date at which the RTCs could implement testing and
3718	I wrote my letter the following day -- or at least
3719	I wrote it on the 21st and it was despatched on the
3720	22nd.
3721	MR JUSTICE BURTON: It must be A6 if it is 570.
3722	MR UNDERHILL: I am sorry, that is actually what appears on
3723	my chronology, but I had corrected my chronology, so the
3724	correction is wrong.
3725	MR JUSTICE BURTON: A6.
3726	MR UNDERHILL: 1570.
3727	MR JUSTICE BURTON: So 22nd January is that note, and you
3728	say you were told orally the day before?
3729	A. I was told orally the day before.
3730	MR UNDERHILL: We were I think in paragraph 82 of your
3731	statement, and you were explaining essentially there the
3732	difficulties about false positives and the inability to
3733	confirm them. Perhaps, as it is important, could I just
3734	ask you to read the rest to his Lordship, picking up at
3735	"matters of concern", at the bottom of page 82?
3736	A. "Matters of concern included the definition of a true
3737	positive result and the failure to confirm initial
3738	positive reactions using serum with the plasma of the
3739	donation, an essential step for quality assurance. The
3740	latter suggested that false negative results could
3741	occur."
3742	That relates to the first pilot trial in December
3743	1989
3744	Q. Which we saw this morning I think.
3745	A. Yes.
3746	Q. Then carrying on?
3747	A. "SNBTS [the Scottish service] found differences in
3748	sensitivity in the two batches they received", that is
3749	at paragraph 77 of my statement:
3750	"Unless these could be reliably checked by

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3751	a supplementary or confirmatory test, the consequences
3752	would be very serious. Not only would it mean
3753	discarding a large quantity of donated blood which was
3754	not in fact infective, with the consequences for the
3755	blood supply, but large numbers of donors, few of whom
3756	would be in fact infected, would be left in complete
3757	uncertainty as to what their true condition was. That
3758	was unacceptable."
3759	MR JUSTICE BURTON: I am not sure we gain anything by
3760	reading this out.
3761	MR UNDERHILL: My Lord, I am sorry. I am very much in
3762	your Lordship's hands. Your Lordship can read to the
3763	end and see what he says there, but it is, as it were,
3764	an important statement summarising what had happened up
3765	to that point, on 21st November.
3766	MR JUSTICE BURTON: I think the way to deal with it is to
3767	see whether you want to add anything by way of
3768	supplement or explanation of what is in that paragraph.
3769	A. My Lord, at the time, I was certain that this was the
3770	proper procedure to -- as we discussed a few minutes
3771	ago.
3772	MR JUSTICE BURTON: At what time?
3773	A. The time of November 1990.
3774	MR JUSTICE BURTON: So we are not in January 1991; we are in
3775	November 1990.
3776	A. November 1990, yes, when the decision was made. And in
3777	retrospect, as we discussed earlier, it could have been
3778	done in another way, but at this time, we felt, with all
3779	these pressures of the large number of false positives,
3780	this was the appropriate manner in which to handle the
3781	testing before introduction was proceeded with.
3782	MR UNDERHILL: Perhaps I could just pick up on one part of
3783	that answer. You said as you discussed earlier with his
3784	Lordship, it could have been done in another way. What
3785	I think in particular his Lordship had put to you was
3786	that in July 1990, you might have started introducing
3787	Ortho and Abbott in all centres.
3788	A. Yes.
3789	Q. And, as it were, done your test as you went along.
3790	A. Yes.
3791	Q. And he asked you whether that had been considered, and
3792	I think you said, "No, it had not."
3793	A. That is correct.
3794	Q. Had it been considered then, as best you can at this
3795	stage, what do you think your view would have been, in
3796	July 1990, if someone had made that suggestion?
3797	A. Well, I would have had to have found out whether the
3798	centres were in a position to introduce the tests at
3799	that early date, and I must say, with respect to the
3800	responses that I received the following January, there

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3801	may well have been a delay until this sort of time
3802	anyway, because I had already, as I have said, discussed
3803	informally with some of them whether they were able to
3804	test, and they had told me that they really needed about
3805	six months in certain places.
3806	Q. As to the merits of the exercise itself, if someone had
3807	said, "Well, subject to whether they can do it, would it
3808	be a good thing to do, to introduce it now, as opposed
3809	to testing the two first?", can you say how you would
3810	have approached such a suggestion?
3811	A. I think I would have said that if we can introduce it,
3812	let us do so, but it is difficult, a decade later,
3813	trying to cast your mind back as to what you might have
3814	said at that time.
3815	MR JUSTICE BURTON: How far would your opinion have been
3816	influential at that stage, as head of this service?
3817	A. Well, I did not have any executive authority in the
3818	service; I could only advise people. I got a good deal
3819	of response from the majority of the centres, and if
3820	I had put pressure on, I think they would have responded
3821	positively.
3822	MR JUSTICE BURTON: That deals with what I think
3823	Mr Underhill has called the practical side. Now what
3824	about the merits, as he puts it, of the exercise? If
3825	you had said, because someone had raised it, that you
3826	supported that idea, what do you think would have been
3827	the outcome at the Committee?
3828	A. It is more difficult to predict, my Lord, but you have
3829	already read that in the previous meeting, Professor
3830	Zuckerman felt that we should really be proceeding to
3831	testing, and Dr Mortimer had already said so on two
3832	previous occasions, so there might well have been some
3833	support in the Committee, and powerful support like that
3834	could influence other members of the Committee to go
3835	along with it.
3836	MR UNDERHILL: Now let us turn to what in your statement you
3837	call implementation planning. While you were awaiting
3838	the Ministerial decision, as you say at paragraph 84,
3839	you convened a meeting of the ACTTD, and we can see that
3840	on 8th January, in the R bundle, behind tab 6.
3841	The detail I do not think we need spend a lot of
3842	time on. You deal with this subject under head 4 on
3843	page 277, and a principal part of the discussion was the
3844	flow chart which basically showed the procedure that
3845	would have to be gone through, and we see that at
3846	page 288, and various changes were made to that.
3847	But I think all we need note was that there were a
3848	large number of operational decisions that needed to be
3849	taken, and you went through and took them.
3850	A. We did.

	A
3851	Q. Then as we have heard, you were notified about a
3852	fortnight later of the Ministerial decision, and you
3853	wrote to all the Regional Transfusion Directors, and we
3854	see that -- you will need to be given this, I think --
3855	in the A6 bundle, at page 1570. I am sorry, I had a
3856	collapse of my bundle. It will just take me a moment.
3857	(Pause). I have reconstructed it. We can see it starts
3858	by saying:
3859	"The Department has agreed that routine testing of
3860	all blood donations for anti-HCV can be put into
3861	operation.
3862	"I have been asked to try and ensure that testing
3863	starts simultaneously in RTCs in England and Wales and
3864	that it is co-ordinated with commencement of testing in
3865	Scotland.
3866	"Will you please advise me what you consider to be
3867	the earliest date you could commence testing? It would
3868	be helpful if I could have this response by Tuesday,
3869	29th January."
3870	You tell them financial arrangements still have to
3871	be concluded, and you will let them know when they have
3872	been, and the TTD has met and put forward proposals for
3873	a protocol which will be put to the Department at a
3874	later meeting, and those will be circulated in due
3875	course, and Ortho and Abbott are going to be told.
3876	I think it would be helpful, so that his Lordship
3877	sees the flavour of the response, to just go through
3878	those responses, though we need not look at every word
3879	of every one of them. Just before we pass on, simply
3880	because this is a convenient place to do it -- I am
3881	sorry, it is on a different point, but if you look at
3882	page 1572, we see a copy of a letter from Dr Mortimer to
3883	Dr Rejman, on the question of PCR testing and whether
3884	that can be done on a routine basis, and one sees in the
3885	second paragraph:
3886	"As you know, the main difficulty is the expense
3887	and labour intensiveness of PCR. Richard [Tedder] and
3888	I agree in feeling that, as a maximum, and with the
3889	scientists working flat out, about 18 specimens can be
3890	done in a week in one laboratory."
3891	We can see therefore why it took them so long to
3892	test those 69 samples that they did.
3893	A. Yes.
3894	(3.30 pm)
3895	Q. Sorry, that was just a digression. The first of the
3896	answers that you got was at --
3897	MR JUSTICE BURTON: Do I understand that the new style PCR
3898	you can use as a basic test, and it is so effective that
3899	you do not need anything else? Have I misunderstood
3900	that? I am talking about what is happening now or is

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3901	capable of happening now.
3902	A. My Lord, I would prefer that to be answered by --
3903	because I have been in retirement for seven years.
3904	MR JUSTICE BURTON: Of course.
3905	MR UNDERHILL: The first reply you got on the same day was
3906	from Dr Contreras, at page 1575, and she simply said she
3907	could not give you a date until she had definitive
3908	information on financial arrangements, supplementary
3909	tests, counselling and follow-up, and said what a busy
3910	time she was having, particularly with the extra
3911	workload incurred as a result of the Gulf War, and she
3912	could not give anti-HCV screening the priority required
3913	by the Department of Health.
3914	I think it was to that letter that you replied
3915	with the reply to which my learned friend drew attention
3916	at page 1589, where you said in the first sentence:
3917	"I want to clarify that the DoH have not asked for
3918	any priority to be given to anti-HCV screening."
3919	That was the context of that reply.
3920	MR JUSTICE BURTON: Why did you say that?
3921	A. Because that was true; what the Department of Health had
3922	asked me was to find out the earliest date at which
3923	transfusion centres could begin testing.
3924	MR UNDERHILL: I am just trying to find an adjective to
3925	describe the tone of her letter, but perhaps I will
3926	leave that to others.
3927	You get the next reply, which is at the following
3928	page, page 1576, from Cambridge. It makes the same
3929	point as Dr Contreras in the first sentence about the
3930	Gulf commitments, and puts forward four points: they
3931	need to know about funding; they would need a computer
3932	programme; they would have to retrain and recruit extra
3933	staff, considerable requirements for counselling; they
3934	would have to decide which product to use; and they say
3935	that they could not start or at any rate it is unlikely
3936	they would be able to start before 1st October.
3937	It is fair to say that is the most pessimistic
3938	response you got, by quite a long chalk?
3939	A. That was by far the most pessimistic response.
3940	Q. Over the page, 1577, Birmingham reply, saying they could
3941	start by April, provided they had the financial support
3942	for two additional members of staff; without that
3943	support they could not?
3944	MR JUSTICE BURTON: Am I right in recollecting that in fact
3945	no funding was available; they all to meet the cost out
3946	of their own funds?
3947	A. The Regional Health Authorities were informed at a
3948	rather later date that they would have to find money out
3949	of their reserves to start the routine testing schedule.
3950	MR JUSTICE BURTON: So when the point is made by

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3951	Dr McDougall, "We would need to ensure that additional
3952	funding was made available", that was never available,
3953	never forthcoming; is that right?
3954	A. Well yes, funding did not become, my Lord, a problem in
3955	the end, because the Regional Health Authorities, with
3956	one exception, found the money to start testing.
3957	Following April 1st 1992, the cost of testing was put on
3958	to the price of blood charged to the hospitals.
3959	MR UNDERHILL: But for that first year -- you meant 1992,
3960	did you? I am not saying you were wrong, but just to be
3961	clear.
3962	A. From September 1991 until April 1992, the Regional
3963	Health Authorities funded the testing, with one
3964	exception, where they only partially funded it, and
3965	after April 1st 1992, the cost of testing was put on to
3966	the price of the products.
3967	MR JUSTICE BURTON: Really my question, just taking
3968	Dr McDougall's letter as an example, where it says, "We
3969	would need to ensure that additional funding was made
3970	available", what does that mean?
3971	A. He was hoping that the additional funding would come
3972	directly from the Department.
3973	MR JUSTICE BURTON: Yes, and given that it did not?
3974	A. Given that it did not, his Chief Executive of the Health
3975	Authority would be informed by the Department at a later
3976	date -- it took until about June, I think, to do this --
3977	MR JUSTICE BURTON: "No, you must find it yourself"?
3978	A. "You must find it yourselves, out of money we have
3979	allocated to you for developments."
3980	MR JUSTICE BURTON: And the Regional Health Authority and
3981	the Blood Transfusion Service are, for that purpose,
3982	seen as one, are they?
3983	A. The transfusion service was managed by the respective
3984	Regional Health Authority.
3985	MR UNDERHILL: In paragraph 87 of your statement you deal
3986	with this very point. Perhaps we should deal with it
3987	now, as his Lordship has asked a question:
3988	"In view of the number of enquiries [which we have
3989	already seen and will go on to see] concerning the
3990	financing of routine testing of blood donations for
3991	anti-HCV, I held discussions with Department of Health
3992	officials. As a result, I wrote to all RTDs on
3993	5th February 1991, informing them that it was proposed
3994	that the costs for the implementation of testing would
3995	be charged on products issued from RTCs and be borne by
3996	the users."
3997	It sounds from what you say that that is not quite
3998	the complete picture, because in the interim it would
3999	have to be found by the regions.
4000	A. Yes.

	A
4001	Q. You then say:
4002	"I should say that despite the concerns expressed
4003	(in particular by Dr Contreras) this approach gave rise
4004	to no serious difficulties in practice, and I do not
4005	believe that it had any consequences for the
4006	implementation date eventually achieved."
4007	Do you want to say anything further about that?
4008	A. No, I stand by that entirely.
4009	Q. Going back to where we were, page 1579 -- I am sorry,
4010	page 1577, but going to page 1579, Dr Martlew in Mersey
4011	and North Wales said that they were in the middle of
4012	changing over in any event from an RIA technology for
4013	hepatitis B testing to an ELISA technology, and they
4014	would like to run the two together, and that would mean
4015	1st August.
4016	A. Yes. May I say, she eventually started in June, at my
4017	request.
4018	Q. And why was that?
4019	A. It was when we did the extension to the second trial.
4020	Q. And she makes the point that she would like some more
4021	money. And then over the page, or two pages on, 1581,
4022	Dr Fraser in Bristol suggests the optimum time would be
4023	1st July. They say their main problem is the lack of
4024	sufficient staff, and they would have to appoint two
4025	extra MLSOs to help with this development:
4026	"Our other problem, like many other centres, is
4027	that we prepare most of our platelets in the evening and
4028	many of these are issues either during the night or on
4029	the road ferries the next morning."
4030	Why would that make a difference?
4031	A. Because of the length of the tests and the fact of
4032	having to employ more staff in the evening session.
4033	Q. "It is clear the introduction of the anti-HCV test will
4034	prove a problem initially", and then I think he ought to
4035	have put a full stop in.
4036	"However, I think that with full training of
4037	staff, we would be able to cope with this extra test at
4038	the beginning of July. My main worry about attempting
4039	to start on 1st June" is that quite lot of the staff
4040	will be on holiday.
4041	Then over the page we see Professor Cash replying
4042	on behalf of the Scottish National Blood Transfusion
4043	Service, expressing himself in his usual strong terms --
4044	the strongest possible terms, he calls them, though
4045	coupled with the greatest respect -- that the Gulf
4046	conflict is creating far too great a problem and the
4047	whole problem should be put off for a couple of months
4048	until it could be seen what was likely to happen "in the
4049	Gulf", is that --
4050	A. Yes.

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4051	Q. However, over the page, he says:
4052	"We remain firmly committed to starting on the
4053	same day as our NBTS colleagues and if pressed by
4054	Ministers, I would suggest in the circumstances
4055	a May/June date should be considered."
4056	MR JUSTICE BURTON: But he would prefer another month.
4057	MR UNDERHILL: Yes, I am sorry, I summarised that by saying
4058	a couple of months. He says another month.
4059	MR JUSTICE BURTON: May/June, but he would prefer July,
4060	effectively.
4061	MR UNDERHILL: Let me just see if I have summarised this
4062	correctly. I may have misread it myself.
4063	It is not really important how I read it.
4064	MR JUSTICE BURTON: Perhaps you are right, perhaps the month
4065	is not -- I took it it meant a month after May/June.
4066	MR UNDERHILL: That is a point against myself. I think what
4067	he was saying is, "We could do it May/June, but we would
4068	rather wait" -- the thrust of the whole of the first
4069	sentence is, "This is the worst possible time to ask us
4070	because of the Gulf problem". Perhaps you can just
4071	explain to his Lordship in a couple of sentences, what
4072	was the Gulf problem? Why were all these directors
4073	referring to it?
4074	A. Well, at that time, we were collecting three times more
4075	blood than we normally did, and there was great pressure
4076	on every centre for testing and storage of the blood,
4077	and in fact some centres ran out of storage, and we had
4078	to arrange for blood to be transported elsewhere to be
4079	stored.
4080	Q. This was because you had been asked to get blood in to
4081	deal with the casualties?
4082	A. We were asked by the Ministry of Defence to increase
4083	blood stocks so blood could be transported to the Gulf,
4084	in case there was the expected rate of casualties that
4085	they had forecast.
4086	Q. Then the next is at 1588 --
4087	A. Can I just say, Mr Underhill, the month that the -- that
4088	his Lordship referred to is at the last sentence of
4089	Professor Cash's letter:
4090	"I would prefer to wait another month and then
4091	respond to your letter."
4092	MR JUSTICE BURTON: Yes, it is a month from January.
4093	MR UNDERHILL: I think you and I had read it in the same
4094	way.
4095	MR JUSTICE BURTON: Yes, I think I was misled by the way the
4096	witness statement reads, which is:
4097	"If pressed a date of May/June 1991 might be
4098	appropriate but Professor Cash would prefer to delay the
4099	decision for one month."
4100	I had misread it, but I now see what the point

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4101	is. Yes, thank you.
4102	MR UNDERHILL: I am doing this by reference to the letters,
4103	because it is somehow more vivid to see what people
4104	actually wrote.
4105	MR JUSTICE BURTON: Thank you.
4106	MR UNDERHILL: Then at 1588, we see the response from Trent,
4107	where Dr Wagstaff, who was I think your deputy on the
4108	ACTTD.
4109	A. Yes, Deputy Chairman.
4110	Q. He says:
4111	"I have thought about this extremely carefully and
4112	find it difficult to give you a definitive answer. If
4113	finances were secured, if the company who supplies us
4114	could produce both disposables and hardware in time, and
4115	if we did not have the prospect of even more frantic
4116	activity on land-based action in the Gulf hanging over
4117	our heads, then we might have been able to start on
4118	1st April, with 1st May as a more probable time. This
4119	would have given us time to take on extra staff and
4120	carry out required training et cetera, and would have
4121	represented the minimum interval necessary to guarantee
4122	proficiency and safety.
4123	"However, I feel the biggest fly in the ointment
4124	is the Gulf. There is no doubt whatsoever that we could
4125	not have taken on extra microbiological testing during
4126	the organised chaos of the past ten days, and with the
4127	obvious certainty of this happening again, as and when
4128	there is a significant development in the Middle East,
4129	I think it would be idle speculation to give an early
4130	date for this. We are not going to be able to persuade
4131	the generals to delay action until such time as we are
4132	up and smoothly running, and so I feel sincerely that we
4133	should earnestly consider the question of putting off
4134	a start date until there has been resolution of the Gulf
4135	affairs.
4136	"I accept this is a negative approach in many
4137	ways, given the fact that we are all eager to start, and
4138	under normal circumstances could do so within two to
4139	three months of being told to go ahead. These are not
4140	normal circumstances."
4141	Then if you go to 1591, it is difficult to read
4142	this one. This is from Brentwood, which is the
4143	north-east Thames region. We can just about read it.
4144	Dr Harrison:
4145	"You asked me to let you know by 29th January the
4146	earliest date on which this centre could introduce
4147	anti-HCV testing.
4148	"I have considered this question very carefully.
4149	We are in a difficult position at the moment, being
4150	without a permanent Head of Microbiology and short of

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4151	staff in that department. It is very difficult to
4152	recruit MLSO staff in this region, and we have failed to
4153	recruit sufficient MLSO 2 grade staff over a
4154	considerable period of time now. We have major building
4155	works at the Brentwood centre, including the building of
4156	a new microbiology department. Before we could start
4157	anti-HCV testing, in a safe and efficient manner, we
4158	would have to recruit sufficient staff for the
4159	microbiology department, move into the new microbiology
4160	department and arrange for appropriate counselling and
4161	follow-up with local GPs and specialists for persons
4162	found to be anti-HCV positive.
4163	"The planned move into the new department is
4164	scheduled for the first week of April 1991, though it
4165	could well be a week or two later. If you 'twist my
4166	arm', the earliest I could possibly attempt to make
4167	arrangements to start anti-HCV testing would be
4168	15th April 1991."
4169	After all that, you would have expected it might
4170	have been later:
4171	"However, for all the reasons given above I would
4172	prefer the date to be 1st May 1991, or even 1st June
4173	1991, in order to enable us to make the appropriate
4174	arrangements. I do hope that we will not be pushed into
4175	commencing our testing too soon, as I am concerned that
4176	there is a risk of reducing the quality of the products
4177	that we prepare and issue, because in our rush to
4178	introduce the anti-HCV test, the quality of other types
4179	of testing and checking is reduced."
4180	Then 1593, a very succinct answer from
4181	Dr Robinson. She says they will be able to commence
4182	testing at the beginning of May, in preparation for
4183	universal release of tested product on 1st June; that is
4184	the first person to make the distinction his Lordship
4185	made between the -- I forget what we called it -- a
4186	carry-over period. So they would actually start in May,
4187	with a view to being able to get everything tested by
4188	1st June:
4189	"... providing satisfactory financial
4190	arrangements" --
4191	MR JUSTICE BURTON: Run-off I think I called it.
4192	MR UNDERHILL: Run-off, yes. Then 1599, this is from South
4193	London. This one you got from the Finance Director, and
4194	they make the same point:
4195	"We would recommend that any projected start
4196	date ... should be contingent on developments in the
4197	Gulf. We would consider it to be most unwise to
4198	implement a new mandatory test at a time when existing
4199	arrangements are under stress.
4200	"We have not been notified officially of data

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4201	relating to the proposed new test system. We are
4202	advised by Ortho that the test system that would be used
4203	is significantly different to that originally evaluated
4204	by the NBTS. On the information provided by Ortho, we
4205	estimate South Thames will be finding one to eight
4206	confirmed anti-HCV positive donors per day, i.e. a rate
4207	of approximately 0.1 per cent. Is this correct?"
4208	What is he referring to there, where he says that
4209	the test system which will be used is significantly
4210	different to that originally evaluated?
4211	A. Well, it was the second generation test, which is --
4212	Q. Ortho had obviously been telling him about the second
4213	generation test?
4214	A. Had been telling him about the second generation test,
4215	yes.
4216	Q. The point has come in the course of my learned friend's
4217	opening, the extent to which the second generation kits
4218	or tests required different equipment from those
4219	required by the first generation.
4220	Could you just say what the position was about
4221	that?
4222	A. It was basically the same equipment.
4223	Q. So the concern here was --
4224	A. On numbers, I think.
4225	Q. Yes, on numbers.
4226	MR JUSTICE BURTON: What do you mean, "on numbers", I am
4227	sorry?
4228	A. The number of positive findings will have been greater
4229	with the second generation test than the first, because
4230	of the increased sensitivity of the test.
4231	MR UNDERHILL: It is obviously important to a centre to know
4232	how many people they are going to --
4233	A. This was, of course, the largest centre in the country.
4234	Q. That is the largest centre in the country, right. And
4235	he raises a point about protocols, and then this:
4236	"We are arranging necessary building changes at
4237	Tooting to allow anti-HCV testing to take place."
4238	This is an area which Mr Garwood will cover, but
4239	this was a case where they actually had to build a new
4240	lab, or extend a lab in any event:
4241	"We have also recently implemented measures which
4242	hopefully will improve recruitment of qualified
4243	laboratory staff and implement a computer system.
4244	Subject to the above, and particularly timely completion
4245	of the building changes, we consider 1st June would be
4246	an achievable date for the South Thames Blood
4247	Transfusion Service as a whole."
4248	There were, as I think you explain in your
4249	statement, two different units for South Thames, one at
4250	Hither Green and one at Tooting?

	A
4251	A. The main transfusion centre was at Tooting, there was a
4252	subcentre at Hither Green hospital.
4253	Q. And then 1623, we get the reply from Manchester, your
4254	home ground. Dr Lee says 1st June, and they raise some
4255	of the difficulties; financial arrangements,
4256	confirmation the DoH will provide funding; if not, will
4257	we get the money from the region?
4258	Then 1634, Newcastle says 1st April; Abbott have
4259	told them they could supply the first generation by that
4260	date without any problems, and he is awaiting
4261	developments on the second generation:
4262	"Our main concern over the introduction of HCV
4263	testing is the relatively low incidence of positive
4264	confirmations of repeatably positive tests."
4265	Putting that the other way round, false
4266	positives.
4267	A. Yes.
4268	Q. "If the introduction could be associated with the
4269	availability of a second generation test which has been
4270	shown to have improved specificity, this would be
4271	particularly advantageous."
4272	There was hope, was there not, that the second
4273	generation test would have better specificity?
4274	A. Yes, but it had never been shown to have improved
4275	specificity and indeed it turned out to have no increase
4276	in specificity.
4277	Q. The improvements were on sensitivity?
4278	A. The improvements were on sensitivity.
4279	Q. But anyway, that Dr Lloyd was hoping it might. I think
4280	that brings me to the end; as you say in your statement,
4281	there were two centres from whom you do not have written
4282	answers in the files; Oxford and Southampton, and you
4283	cannot recall whether you did get written responses.
4284	Would you be likely to have received oral if not
4285	written?
4286	A. I would have thought I probably got written but they
4287	have been mislaid. It did not, however, I am sure,
4288	substantially alter the picture from the other centres.
4289	Q. In your paragraph 86, you, as it were, give a bit of
4290	background to those explanations, but I think that has
4291	been sufficiently apparent as we have gone along, and
4292	the evidence as to what is involved in the practical
4293	introduction of a test is dealt with in more detail by
4294	Mr Garwood, who will be giving evidence next week, we
4295	hope.
4296	A. Indeed.
4297	Q. On the basis of those responses, at page 1660, you wrote
4298	to all centres sending them a good deal of material, and
4299	notifying them, on the second page, under head 10:
4300	"The agreed date for commencement of anti-HCV

	A
4301	screening will be 1st July", provided matters were not
4302	further disrupted by developments in the Gulf?
4303	A. Yes.
4304	Q. Shortly after that, there was a further meeting of the
4305	ACVSB, which we will find in bundle Q2 --
4306	MR JUSTICE BURTON: When did the Gulf War crisis come to an
4307	end?
4308	A. My Lord, Mr Brown said that the last supply to the Gulf
4309	was on 27th February. That indeed is true, but, of
4310	course, we did not know on 27th February that this was
4311	going to be the last supply to the Gulf, because we were
4312	unaware of what the campaign -- how the campaign was
4313	going to continue.
4314	MR JUSTICE BURTON: When did the campaign end?
4315	A. It was in June, I think, that the matter became wholly
4316	resolved, and the paper to which Mr Brown referred,
4317	I gave in July, in Prague.
4318	MR JUSTICE BURTON: Did it become apparent prior to June
4319	that you were not going to have to supply any more?
4320	A. Yes, it became apparent during May that the casualties
4321	were going to be a lot lighter than the Ministry of
4322	Defence had forecast. They had forecast something up to
4323	10 per cent casualties, and it became quite apparent
4324	from how the campaign was proceeding that during --
4325	certainly during May, that this was not going to require
4326	any extensive supply of blood.
4327	MR UNDERHILL: When the ACVSB met on 25th February, it is at
4328	page 436, the question of hepatitis C was considered,
4329	starting on page 437, and two papers are referred to,
4330	only one of which we have, unfortunately, which is 9/1,
4331	we do not have 9/13, but they are papers giving more
4332	formally the results of the September/October second
4333	pilot study, as we have called it. That is right, is it
4334	not?
4335	A. It is.
4336	Q. And it was formally reported on by Dr Mortimer because
4337	by that stage all the results were in, and I do not
4338	think we need spend any time on that.
4339	At the top of the next page, however, he said:
4340	"It would be important for the evaluation of other
4341	candidate HCV tests, to retain the population of 10,000
4342	samples."
4343	He thought the Committee may wish to see the
4344	results from the second generation Ortho and Abbott
4345	tests. Professor Tedder then tabled a paper, which is
4346	unfortunately missing, but the Committee discussed the
4347	likely availability of second generation tests, and
4348	operational factors which might influence the decision
4349	by RTCs as to which screening test to choose:
4350	"Licensing of the test by the FDA had not yet been

	A
4351	finalised. Members agreed it was important for proper
4352	evaluation of the Ortho and Abbott 1 and 2 tests to be
4353	carried out before RTCs decided which test they would
4354	adopt."
4355	By this stage, you had decided on a start date of
4356	1st July.
4357	A. Yes.
4358	Q. But what appears from this minute is that you were
4359	considering, or at least hoping, that you would be able
4360	at that date to introduce second rather than first
4361	generation tests; is that correct?
4362	A. That is correct.
4363	Q. And the Chairman summarises the discussion, and over the
4364	page at the top of 4:
4365	"Ortho and Abbott 1 and 2 should in principle be
4366	available, among others, from 1st July for RTCs to
4367	choose."
4368	I think that is all that we need look at from that
4369	meeting, but if we then go to the ACTTD, which means,
4370	I am afraid, having to go back to bundle R1.
4371	MR JUSTICE BURTON: What does that mean, "Ortho and Abbott 1
4372	and 2 should in principle be available among others from
4373	1st July for RTCs to choose", as a view of the
4374	Committee? It would be nice if they were available? It
4375	is likely they will be available? If they are not
4376	available, we will not be able to go ahead on 1st July?
4377	We will go ahead nevertheless? What does it mean?
4378	A. I think in "in principle" is really the wrong two words
4379	to use, and I would say "likely", because that was the
4380	information that we had at that time.
4381	(4.00 pm)
4382	MR JUSTICE BURTON: So it was a statement of information
4383	rather than a view.
4384	A. Statement of information.
4385	MR JUSTICE BURTON: Ortho and Abbott 1 and 2 ought with
4386	luck, I suppose is what it means.
4387	A. Or are likely to be available.
4388	MR JUSTICE BURTON: Let us say "are likely to be". Are
4389	likely to be available. So it is not a change of view
4390	or a change of decision; it is simply a statement of
4391	fact?
4392	A. A statement of fact, yes.
4393	MR JUSTICE BURTON: Or hoped for fact. Yes, thank you.
4394	MR UNDERHILL: The ACTTD met on 25th March. We have that
4395	behind tab 7 in R1, at page 321. The essential passage
4396	for our purposes is section 4.1 on page 322, where the
4397	minute says this:
4398	"The proposed starting date of 1st July presented
4399	difficulties, since it was considered essential that the
4400	second generation test, from both Ortho and Abbott,

	A
4401	should be evaluated prior to the commencement of routine
4402	tests. Ortho tests were being evaluated by Dr Barbara
4403	at the North London RTC and he had, to date, only
4404	received pre-production batches of the tests. It was
4405	known that there was procedural differences between the
4406	pre-production and production batches. These test kits
4407	should be available within ten days to two weeks."
4408	Does that mean the production batch?
4409	A. The production batch.
4410	Q. "The situation with Abbott was uncertain, since they had
4411	not yet given an official date for launching their
4412	second generation test.
4413	"The preliminary results obtained by Dr Barbara on
4414	the test kits from the three manufacturers were reviewed
4415	and it was agreed that further testing at all three RTCs
4416	was essential. It was agreed that Newcastle RTC would
4417	provide samples from their donors in the study for
4418	Dr Barbara and Glasgow RTC would do the same, once
4419	Abbott had provided second generation test kits since
4420	this was avoid thawing the samples more than once.
4421	"The Chairman was asked to contact Abbott and from
4422	the information he received, recommend a starting date
4423	for the commencement of tests.
4424	"It was agreed that testing of blood and plasma
4425	donations would commence on the specified date. There
4426	would not be retrospective tests carried out on
4427	donations collected prior to that date."
4428	As a result of that, you wrote to the RTDs on
4429	3rd April 1991 --
4430	MR JUSTICE BURTON: Before we go on to that, was that a
4431	decision, Dr Gunson? 411 says the proposed starting
4432	date presented difficulties. It was considered
4433	essential -- further testing was essential. What, if
4434	any, decision was taken at this stage?
4435	A. That decision in the TTD Committee came from the meeting
4436	of the ACVSB.
4437	MR UNDERHILL: We saw that the ACVSB in February had
4438	discussed the second generation testing.
4439	MR JUSTICE BURTON: But you were Chairman of this, so we do
4440	not need to worry about what Dr Metters would say. Is
4441	what you are saying, "If the second generation tests are
4442	not available by 1st July, we will not go ahead on
4443	1st July", or had it not reached that stage yet?
4444	A. It had not reached that stage yet, my Lord. Ortho had
4445	given a date for their second generation tests; Abbott
4446	had not. I contacted Abbott and they -- as far as I can
4447	recollect, they told me some time towards the end of
4448	April that the second generation tests would become
4449	available.
4450	MR JUSTICE BURTON: So all is still well.

	A
4451	A. So all is still well, except we did consider that we
4452	should do this testing, but we were still hoping to get
4453	it done in July, although that date was becoming less
4454	secure, as a result of the delays from Abbott.
4455	MR JUSTICE BURTON: The testing does not appear, does it,
4456	from the other one, VSB?
4457	A. If I can get the appropriate page, Dr Mortimer said he
4458	thought the test should be done. This is the February
4459	meeting, is it not?
4460	MR JUSTICE BURTON: Unless I have misunderstood it, he said
4461	the Committee may wish to see the results from the
4462	tests, but he at that stage, unless I have missed it, is
4463	not saying, "We must have these tests in place before we
4464	start routine screening"; nor was the Committee
4465	generally, was it? Certainly not in the light of your
4466	interpretation of the words at the top of page 439.
4467	Unless that is a misunderstanding -- or a
4468	misrecollection of the words at the top of 439.
4469	MR UNDERHILL: Shall we take this in stages, Dr Gunson?
4470	Looking at that February meeting, we can see that the
4471	question of the likely availability of the second
4472	generation tests was discussed, and at the end of
4473	paragraph 6, that members agreed it was important for
4474	proper evaluation of those tests to be carried out
4475	before the RTCs decided which tests they would adopt.
4476	At that stage, was it considered that this could be done
4477	within the 1st July timetable?
4478	A. It was.
4479	MR UNDERHILL: But -- I thought I had understood his
4480	Lordship's question; perhaps I did not.
4481	MR JUSTICE BURTON: I think you did, Mr Underhill. I am
4482	after this. At that stage, it is said it is important
4483	for there to be evaluation, and that ought to be okay,
4484	because it looks on-line for 1st July. There is no
4485	decision there taken as to whether it was essential for
4486	tests to be taken before they started, so that if tests
4487	were not possible before 1st July, the 1st July date
4488	would be put off. There does not appear to be a
4489	decision at that meeting to that effect.
4490	Then we come to your TTD meeting, at which you say
4491	the proposed starting date presented difficulties, since
4492	it was considered essential that the second generation
4493	tests should be evaluated. We appear to have moved to
4494	"being considered essential", but we are still not
4495	saying, if the tests could not be done before 1st July,
4496	then whether 1st July would have to be postponed.
4497	What I am really asking is: was there an implicit
4498	decision under your chairmanship of the TTD, or an
4499	implicit decision from the earlier meeting, to that
4500	effect?

	A
4501	A. I think probably, my Lord, I should have used the word
4502	"important" rather than "essential" in these minutes.
4503	MR JUSTICE BURTON: Right.
4504	A. The general view of both groups was that it would be an
4505	advantage if there could be a comparison of the tests
4506	before July. One of the problems that emerged was that
4507	Abbott had difficulty in providing the test at an early
4508	enough stage for that to be achieved.
4509	MR JUSTICE BURTON: Yes.
4510	A. And as a result, it was eventually decided to put it off
4511	for a further two months.
4512	MR JUSTICE BURTON: Right, but at this stage, March, no such
4513	decision --
4514	A. No such decision.
4515	MR JUSTICE BURTON: Even an implicit decision -- had been
4516	taken.
4517	A. No such decision had been made.
4518	MR JUSTICE BURTON: Thank you. That is all I wanted to
4519	know.
4520	MR UNDERHILL: Perhaps let us look at the letter which was
4521	sent to the regions and then work back from there as to
4522	exactly how and when the decision was taken. If you
4523	look at the black bundle, A6/1758, you we see there the
4524	letter which you wrote in standard form to all the
4525	Regional Directors. You refer to the date of 1st July,
4526	and you say in the next paragraph:
4527	"You may be aware that since the three-centre
4528	trial of the anti-HCV test was completed, Ortho and
4529	Abbott have produced second generation test kits which
4530	have additional antigens to the C-100 of the test we
4531	have evaluated. There may also be other companies
4532	supplying anti-HCV tests.
4533	"The Department of Health has agreed that there
4534	should be a 'second round' comparative evaluation of
4535	anti-HCV test kits at the Newcastle, North London and
4536	Glasgow RTCs, together with appropriate confirmatory
4537	testing. It has not yet been possible to commence the
4538	evaluation using production batches of the second
4539	generation tests referred to above and one of these will
4540	not be available until later this month.
4541	"It is undoubtedly in our interest that this
4542	evaluation takes place. However, to complete this study
4543	and become operational by 1st July 1991 is too tight
4544	a schedule. It is difficult to state precisely
4545	a revised date, but I think we should aim to commence
4546	routine screening for anti-HCV by 1st September 1991."
4547	Now that decision to postpone was not taken either
4548	at the ACVSB or the ACTTD, was it?
4549	A. No, it was taken after a discussion between myself and
4550	Dr Pickles.

	A
4551	Q. Who phoned whom?
4552	A. I think I phoned her.
4553	Q. And the gist of your discussion was?
4554	A. It looks as though we are going to have a problem
4555	completing these tests by 1st July, perhaps we ought to
4556	consider a later date, and I suggested 1st September, to
4557	which she agreed, and sent a memo to Dr Metters, who was
4558	her chief, because she -- it was she I was discussing it
4559	with, because he was on holiday at the time.
4560	MR JUSTICE BURTON: There are two decisions there then,
4561	Dr Gunson. I want to be clear about this. There are
4562	two decisions. The first decision is: it is an
4563	essential precondition of starting routine screening
4564	that there be prior tests on the second generation
4565	equipment; secondly, consequent upon that, it is decided
4566	to postpone from 1st July to 1st September.
4567	Now you have told us about the second decision,
4568	but who took, and how and when, the first decision,
4569	which does not appear, as you have told us, either to
4570	have been the express subject of discussion at either of
4571	these two meetings?
4572	A. It came I think also in that discussion I had with
4573	Dr Pickles, how advisable it would be, and I think it
4574	then got to essential; it was a sort of drift.
4575	MR JUSTICE BURTON: Thank you.
4576	MR UNDERHILL: I am concerned both about the time and indeed
4577	the stance that, as your Lordship knows, I have adopted
4578	as regards the evidence of things that happen after
4579	1st April.
4580	MR JUSTICE BURTON: Yes.
4581	MR UNDERHILL: It is probably enough simply to say, so far
4582	as we are concerned, that, the date having then been
4583	changed to 1st September, that was indeed the date at
4584	which testing started at all Regional Transfusion
4585	Centres but, as is apparent from the letter we have
4586	seen, it started at Newcastle -- I am sorry, leave
4587	Newcastle out of it for a moment, because as we know,
4588	there is a special story attached to Newcastle -- at
4589	which centres did the testing start before
4590	1st September?
4591	A. It is in my paragraph 94. It began at four English
4592	centres around the beginning of June, which are Leeds,
4593	Liverpool, Sheffield and Bristol, and in the Scottish
4594	centre at Glasgow.
4595	Q. Newcastle is the special story, which my learned friend
4596	may wish to review with you; you dealt with it briefly
4597	at paragraph 89 of your statement.
4598	MR JUSTICE BURTON: And he started mid-April?
4599	A. I think it was 21st or 23rd April, my Lord.
4600	MR UNDERHILL: Perhaps I can just ask this, a point I think

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4601	you ought to have the opportunity to deal with. We have
4602	seen that some of his colleagues spoke about him in
4603	very, very strong terms indeed. What were your own
4604	personal relations with Dr Lloyd, in relation to this
4605	episode?
4606	A. My personal relations with Dr Lloyd remained very good
4607	over the whole of the period. I heard that he had
4608	started testing from an outside source, and spoke to him
4609	on the telephone, and he confirmed it. I asked him why
4610	he had not told me that he was going to start testing,
4611	and he said because he thought I would try and persuade
4612	him otherwise, and I said, "Come, I do not accept that",
4613	and then he went on to say that he felt he should start
4614	testing in April so that all his products issued on
4615	1st July would be tested for anti-HCV, and I asked him
4616	to confirm this to me in writing, because I did not
4617	accept that that was a substantive reason. But our
4618	relationship continued in quite a good manner, because
4619	I did not join some of my colleagues in the robust
4620	manner in which they wrote to him, because I felt it was
4621	important to keep his co-operation at all times.
4622	MR UNDERHILL: In paragraph 95 of your statement, you say:
4623	"Given the date at which the decision to proceed
4624	was taken, with which I have dealt above, and given the
4625	importance reasonably attached to adopting a common
4626	start date for HCV screening, I am sure that a start
4627	date could not reasonably have been set much, if at all,
4628	before 1st July, because there was a great deal of work
4629	for the RTCs to do before screening could have been
4630	effectively introduced."
4631	You then go on to say -- I need not read it all
4632	out -- that with hindsight, you think the further
4633	postponement to 1st September could have been avoided?
4634	A. Yes, that is true. I think that is what I said to
4635	your Lordship this morning.
4636	MR JUSTICE BURTON: I do not think you put a date on it this
4637	morning, because we discouraged you because it was
4638	jumping ahead in your evidence. What is the date you
4639	think that it reasonably could have been introduced by?
4640	A. I think the preparedness of the centres could not have
4641	been before 1st July, from the evidence that I had
4642	received from them.
4643	MR JUSTICE BURTON: So it is only the extension of the two
4644	months which you now --
4645	A. Two months, yes.
4646	MR JUSTICE BURTON: -- would have wished not to have
4647	occurred.
4648	MR UNDERHILL: That is I suppose a period of just over five
4649	months from when you first wrote and asked them, and it
4650	will be put to you -- so I shall put it first -- that at

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4651	an earlier stage, you had thought six months was too
4652	long, but in the event you are saying you thought five
4653	and a bit months was reasonable.
4654	A. Yes.
4655	Q. What is the difference between --
4656	MR JUSTICE BURTON: Four and a bit, I think, is it not? It
4657	was 23rd or so of January.
4658	A. It was four months and --
4659	MR JUSTICE BURTON: You are quite right, yes, five. It is
4660	more or less five months.
4661	MR UNDERHILL: I thought I was missing a trick there.
4662	MR JUSTICE BURTON: No, you are absolutely right.
4663	MR UNDERHILL: It is five and a little bit, yes.
4664	MR JUSTICE BURTON: Thank you.
4665	A. I had to accept what they said, and, of course, at the
4666	time there were the problems of the Gulf War which we
4667	did not know how the outcome would be, there was the
4668	problem of financing, which in fact did resolve itself,
4669	but there were also two centres at least who had to have
4670	additional building, and others who had not been
4671	involved with any of the trial testing, and therefore
4672	had not a great deal of experience with the test.
4673	MR UNDERHILL: Perhaps I should ask about that last
4674	question: what is the value of experience with the
4675	test? Why is it not possible simply to plug it in and
4676	switch it on and go?
4677	A. Well, you have to train your staff, and therefore before
4678	July, they would have had to have some tests and run
4679	them through, so the staff could be trained, because
4680	some people were not using ELISA tests at this time,
4681	because they were doing -- except for -- they were doing
4682	it for HIV, but that was a different type of test, and
4683	they were doing hepatitis B by radioimmunoassay, as was
4684	explained at Liverpool.
4685	MR UNDERHILL: As your Lordship will guess, I am very nearly
4686	at the end. I will be frank with your Lordship, what
4687	I would like to do is I have one further question I want
4688	to ask. I would welcome the opportunity, since we are
4689	not going to start anyway, to have a locus penitentiae
4690	in case there is anything I need to sweep up tomorrow
4691	morning.
4692	But there is one further matter which I do need to
4693	ask you about, and it can easily be done now, I think.
4694	I have taken you to your second statement, most of which
4695	is concerned with the ALT testing of plasma. But you
4696	did deal with a couple of other points briefly at the
4697	end, and if you would go to page 6 of your second
4698	statement, paragraph 20, the question of the blood
4699	supply did come up, and you dealt with it briefly in
4700	answer to questions from his Lordship.

	A
4701	MR JUSTICE BURTON: Indeed I was hoping that you might have
4702	perhaps located --
4703	MR UNDERHILL: Perhaps we can just deal with that as best we
4704	can at the moment. What we have been asked to look for,
4705	and are going to try and look for, but I fear it will
4706	not be before you finish giving your evidence -- well,
4707	we will see -- is returns from the Department or figures
4708	kept by the Department. Would individual regions and
4709	the Directorate itself have kept papers, or have
4710	generated papers showing the blood supply day-to-day,
4711	week-to-week, month-to-month?
4712	A. I can tell you at the Directorate level, these are no
4713	longer available.
4714	Q. But they were generated at the time?
4715	A. Yes, but we only kept them for about a month.
4716	Q. These would be returns or surveys -- what sort of papers
4717	were they?
4718	A. These were the bank statements from all the Regional
4719	Centres on a daily basis, together with a record of the
4720	interregional transfers that were made, because we had
4721	to record these, and then inform the receiving region
4722	what they had to pay to the region who had given the
4723	blood to them.
4724	Q. Yes, but every day, therefore, statements as to what was
4725	available in each region were generated?
4726	A. Yes.
4727	Q. We will look for them anyway but is it likely that the
4728	figures that the Department keeps will be able to shed
4729	light on the question -- what one might call the
4730	tightness or otherwise of blood supply?
4731	A. No, the Departmental statistics show the number of
4732	donations collected, the number of donations used, and
4733	the number of donations that time-expired.
4734	MR JUSTICE BURTON: If we are talking in bank terms, that
4735	sounds like a Profit & Loss Account. Is there a balance
4736	sheet kept by anybody?
4737	A. Not that I am aware of, my Lord.
4738	MR JUSTICE BURTON: Except by you at the time, and that is
4739	destroyed.
4740	A. We only kept them for a month, until we had dealt with
4741	that month's supply, and then we destroyed them, because
4742	there was no reason to keep them; they were a sort of
4743	daily record, basically.
4744	MR UNDERHILL: Yes.
4745	MR JUSTICE BURTON: You did not supply copies to the
4746	Department?
4747	A. No, I did not.
4748	MR UNDERHILL: What you say in paragraph 20 is that the
4749	blood supply within the service was a constant source of
4750	concern, and during the period with which we are

	A
4751	concerned here, you spent several hours most days
4752	ensuring that blood supply met demand throughout the
4753	country.
4754	Is that an exaggeration?
4755	A. No, it is not an exaggeration at all. I spent a long
4756	time, and so did other members of the staff at the
4757	Directorate, trying to locate centres who could supply
4758	blood to other centres, where there was a shortage. The
4759	critical day, I have to tell you, in the week was
4760	Friday, when most of our time was spent on this
4761	activity, and it was made more difficult because even
4762	those centres who had a good stock of blood did not
4763	particularly want to give it away, in case they had
4764	emergencies they were unaware of come in during the
4765	weekend and they could find themselves then short, so it
4766	took a great deal of persuasion to obtain agreement to
4767	transfer blood from, say, Sheffield to London.
4768	Q. Yes.
4769	A. But the London centres all had difficulties, virtually
4770	on a daily basis, particularly, I have to say, North
4771	London, where they have to supply a large number of
4772	teaching hospitals.
4773	Q. An outsider might say: why is it not possible just to
4774	store blood and keep a reserve somewhere and draw on
4775	that as required, and keep it topped up?
4776	A. Well, you could not get enough donations in, you know,
4777	they were bleeding to their extreme capacity. Of course,
4778	another problem was -- which was assisted to a degree
4779	when charging -- cross-charging came in for blood
4780	products, that regions where there were capacities for
4781	increasing the blood supply did not do so because that
4782	would generate extra costs within that region. Once
4783	they were able to make a charge for that blood going to
4784	another region, then this did ease that problem, and
4785	that was only, as I say, from 1991 onwards.
4786	Q. But the suggestion I think that is made, and this is the
4787	context in which the question arose, particularly,
4788	I think, in relation to the possible loss from surrogate
4789	testing, is that 4 per cent or thereabouts of the blood
4790	supply does not sound like a very big amount, and would
4791	be comparatively easy to make up. What is your response
4792	to that?
4793	A. Well, I think I gave my response a little while ago, and
4794	that was, we already had 12 to 15 per cent of the panels
4795	to repair and regenerate each year because of donors
4796	lost through natural wastage. An additional 4 per cent
4797	was taking us almost up to a fifth of the panel size and
4798	this would not have been easy to do.
4799	MR UNDERHILL: My Lord, that was the last point that I had
4800	on my agenda to deal with. May I just review whether

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4801	there are any other matters I need to deal with, but
4802	I expect I will be very short indeed with Dr Gunson, if
4803	at all, tomorrow morning and I will then hand over to my
4804	learned friend.
4805	MR JUSTICE BURTON: You have done very well, thank you,
4806	Mr Underhill.
4807	Can I just ask one question arising out of annex
4808	2, the litigation? In relation to your date of -- is it
4809	April 1st 1991?
4810	MR UNDERHILL: Yes.
4811	MR JUSTICE BURTON: So I am to assume that there are
4812	excluded from any results, at any rate, in the
4813	litigation, leaving aside the factual history with which
4814	we are dealing, but the claimants from April onwards
4815	have their settlement agreed, independently of any
4816	conclusion of mine on liability, at the trial.
4817	MR UNDERHILL: That is right.
4818	MR JUSTICE BURTON: So that is April, May, June, July,
4819	August, September, the three in 1992 and the two in
4820	1996?
4821	MR UNDERHILL: No, those are different. We have I think
4822	flirted with what is going to have to happen about them,
4823	but they fall into one of two groups, assuming
4824	causation. Causation is in issue in one of two of
4825	them. I think there are one or two which are almost
4826	certainly window period cases, and the remainder,
4827	I think there are one or two which are maternal
4828	transmission, where the infection was not in the post
4829	April 1991 period.
4830	MR JUSTICE BURTON: I see. You will have to redo this
4831	chart, will you not, in that case, to make that clear
4832	but, subject to clarification, the only ones who
4833	disappear are April to September?
4834	MR UNDERHILL: Yes.
4835	MR JUSTICE BURTON: So that is 3, 7, 11, 14, 18, 20 of
4836	them. That brings our group down from 111 to 91.
4837	What about the unknown date of infection?
4838	MR UNDERHILL: That is a very good question, my Lord. I am
4839	not capable of answering it, but I may be able to get
4840	very quick instructions.
4841	MR BROOKE: I am not either, my Lord. (Pause).
4842	MR UNDERHILL: My Lord, I cannot give names. One of them
4843	has discontinued.
4844	MR JUSTICE BURTON: Good.
4845	MR UNDERHILL: The other I will need to take instructions on
4846	overnight. It is not a straightforward answer.
4847	MR JUSTICE BURTON: That is the back end. The front end of
4848	the list, what happens to the one in March of 1988?
4849	MR UNDERHILL: He was infected by a product given after
4850	March 1st 1988 so in principle, the Act was in force.

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4851	Obviously he will only succeed on the most extreme
4852	version of my learned friend's case.
4853	MR JUSTICE BURTON: Leaving aside that, of course -- well,
4854	not the most extreme.
4855	MR BROOKE: There are at least two cases, yes.
4856	MR JUSTICE BURTON: There is the surrogate test point, but
4857	his infection is March --
4858	MR UNDERHILL: The date he receives the product is March,
4859	and therefore his infection, but sorry, that is why it
4860	is important, that is why he gets within the Act.
4861	MR JUSTICE BURTON: He gets within the Act because --
4862	MR UNDERHILL: Because the product was supplied to him on or
4863	after 1st March.
4864	MR JUSTICE BURTON: I am sorry, I was thinking it was
4865	April. The Act came into force --
4866	MR BROOKE: 1st March 1988, my Lord.
4867	MR JUSTICE BURTON: That is my fault entirely. For some
4868	reason I thought the Act was April.
4869	MR UNDERHILL: There is an oddity. Such good boys were the
4870	United Kingdom, they actually introduced the Act before
4871	they had to, under the Directive. Most other countries
4872	did not introduce it at all. There were only three that
4873	did, and we introduced it first of all. I think we had
4874	until June. But that is a small point.
4875	MR JUSTICE BURTON: 1st March 1988; in that case, it was a
4876	non-question of mine. There is no front end, they all
4877	fall together. Thank you very much.
4878	There is one bit of housekeeping, is there not,
4879	tomorrow morning, to deal with any thoughts, Dr Gunson,
4880	you are going to have about what those articles were
4881	which showed further developments, I think it was prior
4882	to November, but you will --
4883	MR UNDERHILL: On that aspect, my learned friend has been
4884	most good and has not put Dr Gunson in quarantine, but
4885	I think from now on he will be, but that point we will
4886	discuss with him.
4887	MR BROWN: My Lord, just in relation to that matter,
4888	I thought it appropriate that Dr Gunson should be at
4889	least forewarned of which medical papers I propose to
4890	take him to. I think there are only five that he will
4891	not previously have seen within the H bundle. I have
4892	given my learned friend's junior a copy of those.
4893	I recognise, of course, that Dr Gunson might like some
4894	time to read those before, but they are very short
4895	papers; there are just five short papers.
4896	MR JUSTICE BURTON: Has he been given them now?
4897	MR UNDERHILL: He will be given them now. He has a train
4898	journey to make. I know from the past he has used it --
4899	I am very anxious -- it is a tiring business,
4900	especially, he will not mind my saying so, for a

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4901	gentleman of his age. I do not want him to sit up late
4902	reading them, but if he has the opportunity to read them
4903	without taking up court time, I am sure he will do so.
4904	He has read a great deal. But if he has not, I will not
4905	be embarrassed; my learned friend, I think, is
4906	indicating that if it needs a bit of extra time for him
4907	to read them properly --
4908	MR JUSTICE BURTON: Alternatively, Mr Brown is not going to
4909	be finished tomorrow and we can go into the following
4910	day for those questions.
4911	How long do you think, Mr Brown?
4912	MR BROWN: My Lord, as everyone has been at least
4913	100 per cent out in their estimates ... I think I may
4914	finish by Thursday evening, certainly. I will be
4915	disappointed if I do not finish by Thursday evening;
4916	I hope for Thursday lunch.
4917	MR JUSTICE BURTON: We have the position then that I am
4918	effectively here anyway, now I have arranged for this
4919	hearing to be --
4920	MR BROWN: We might try to do Mr Garwood.
4921	MR JUSTICE BURTON: That might be helpful, if that is all
4922	right. Then it means we can -- if that is right, we are
4923	helped to get a little bit back on level-pegging and we
4924	can comfortably then -- we are taking next Friday off in
4925	any event, so we will sit Friday then, almost certainly.
4926	MR UNDERHILL: Dr Barbara will start on Monday morning. His
4927	slide show -- I will consider it with him. We have done
4928	a lot of learning without the help of it, but I think
4929	your Lordship will probably still find it useful, but it
4930	will not last -- my learned junior has seen it, it is
4931	about 20 minutes. We will just see how the courtroom
4932	can be arranged so we can all see it, but I think it
4933	should not be a problem.
4934	MR JUSTICE BURTON: I did not know Dr Barbara was going to
4935	be free to come --
4936	MR UNDERHILL: Yes, it has all in the end, with all sorts of
4937	alarms and excursions, worked out quite well. It was a
4938	time when he was free anyway.
4939	MR JUSTICE BURTON: Very well. 10.30.
4940	(4.35 pm)
4941	(Court adjourned until 10.30 am
4942	the following day)
4943	DR HAROLD GUNSON (continued) 1
4944	Examination-in-chief by MR UNDERHILL 1