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1	Thursday, 19th October 2000
2	(10.30 am)
3	Submissions by MR UNDERHILL
4	MR UNDERHILL: My Lord, various pieces of unfinished
5	business from yesterday: the first was a question about
6	what exactly the date of 1st September involved.
7	MR JUSTICE BURTON: Just one second. I have left a file
8	behind. (Pause). The first with the defendants'
9	evidence in is file J1, is it?
10	MR UNDERHILL: Yes. By strange coincidence, I was missing
11	my J1. I think it is in there.
12	MR JUSTICE BURTON: I think the coincidence is more apparent
13	than real in the sense that that is the first bundle in
14	issue today.
15	MR UNDERHILL: Quite.
16	MR JUSTICE BURTON: What exactly the date of 1st September
17	involved?
18	MR UNDERHILL: That is when screening was introduced. It is
19	a question of what exactly did it mean. Did it mean
20	that all blood would be --
21	My Lord, what was announced and what happened was
22	that all donations given on or after 1st September 1991
23	were to be and were screened, if they were not being
24	already, because your Lordship will remember that
25	screening had already been introduced in five -- not
26	just Newcastle, but four other centres in England and
27	Wales.
28	It was not an announcement that all products given
29	after 1st September 1991 would be derived from screened
30	blood. There would, therefore, have been a period --
31	MR JUSTICE BURTON: A run-off?
32	MR UNDERHILL: Yes, after 1st September 1991 during which a
33	recipient could still receive products derived from
34	unscreened blood. That period was almost certainly very
35	short, but it is impossible to say what the position
36	was, because it would involve looking at every centre in
37	the country. The reason it would be very short was that
38	most blood products are used within a very few days
39	after donation. In the case of platelets, within hours,
40	and the idea that there would be months or even many
41	weeks' worth of "stock" to be used up has no
42	application. I think this question arose in relation to
43	what happened in France with the AIDS. That involved a
44	quite different sort of product. That involved the --
45	MR JUSTICE BURTON: Frozen?
46	MR UNDERHILL: Factor 8 given to haemophiliacs which is a
47	powder which has a two-year shelf life and obviously in
48	France was kept for many months.
49	So that is the position. There is, therefore, not
50	much of a point here, but your Lordship should know that

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51	there are two cases of people infected in the first half
52	of September 1991 who are very probably cases of this
53	kind.
54	MR JUSTICE BURTON: Because there is then a gap until May
55	1992 at any rate --
56	MR UNDERHILL: Exactly, and the May 1992 is an internal
57	transmission case where the actual transfusion had been
58	in 1989. There are no more direct cases until 1996
59	which are window period cases, it is to be assumed.
60	MR JUSTICE BURTON: Yes, I follow.
61	MR UNDERHILL: My learned friend is quite right to ask for a
62	clarification of the position. I think actually it was
63	correctly stated in the evidence. But that is the
64	position, and, therefore, 1st September does not mean
65	that as from that date you would never get product
66	derived from unscreened blood, but very shortly
67	thereafter you would.
68	My Lord, that is the first point. The second bit
69	of unfinished business from yesterday, not so much
70	unfinished business but a point I forgot to make when
71	I was talking about surrogate testing, unless I have
72	missed it, which I do not think I have, we have never
73	had a statement from the claimants of the cut-off which
74	they say should have been applied if surrogate testing
75	had been introduced, if ALT screening had been
76	introduced.
77	Your Lordship will have seen from the evidence
78	that in the United States the cut-off used I think
79	everywhere, certainly the principal centres, was anyone
80	with an ALT above 45 national units per litre. I do not
81	know whether it is the claimants' case that that is the
82	cut-off that should have been introduced, but it is
83	something on which I would welcome clarification, not
84	necessarily now. It could conveniently go in the list
85	of issues Mr Brooke is providing, but it is clearly
86	important to know what, quite apart from anything else,
87	at a later stage, Dr Caspari in Germany argued for and
88	got a higher cut-off. He said we are losing too much at
89	the cut-off of, I think, 45 that was being used in
90	Germany, and --
91	MR BROWN: My Lord, he made that argument -- I do not want
92	your Lordship to be misled -- in relation to the
93	continued use of surrogate after the second and possibly
94	after the third generation.
95	MR UNDERHILL: That is perfectly correct and I was not
96	intending to mislead your Lordship.
97	MR JUSTICE BURTON: Mr Brown, I had understood you to be
98	going for 45, because you were somewhat sceptical about
99	35 in one of the articles.
100	MR BROWN: My Lord, I have to say that I would have thought

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101	that, if this was a matter that the defendants required
102	clarification of, this litigation has been going on long
103	enough for them to have asked for a clarification.
104	MR JUSTICE BURTON: Never mind. Is it 45?
105	MR BROWN: My Lord, on my feet and without prejudice, yes.
106	MR JUSTICE BURTON: That is what I had understood so far,
107	but your position is reserved for the time being, and
108	that is the present indication, Mr Underhill.
109	MR UNDERHILL: I am grateful. I am sorry, there is slightly
110	a rag bag of points. One other small point that I just
111	thought might have crossed your Lordship's mind or
112	probably will at some point: I said there has been
113	relevant law in the United States. Your Lordship might
114	ask what has happened about blood in the United States?
115	The answer there is that in an early case a court
116	I think in New Jersey said that the supply of blood
117	transfusion could not be treated as a supply of a
118	product. Therefore it was a supply of a service and a
119	different set of rules applied to it. That route is not
120	available to us in our legislation here, but I thought
121	your Lordship should know that.
122	MR JUSTICE BURTON: Has that been ever questioned?
123	MR UNDERHILL: Not as far as I am aware. Certain states,
124	perhaps on a belt and braces basis have passed special
125	legislation in relation to blood. So I thought your
126	Lordship should know that.
127	Then the last, I think, piece of unfinished
128	business from yesterday: my learned friend picked me up
129	on a reference in relation to ALT testing for 5 or
130	10 per cent. He said it was not clear to him and indeed
131	it was not clear to me reading the transcript on the
132	screen what exactly I had said and whether what I had
133	said was what I had meant to say.
134	Can I attempt to clarify this as far as I can,
135	because it is an important area. There are two
136	questions about ALT screening. The first question: how
137	sensitive is it? To put the same question another way,
138	how effective or efficacious is it, i.e. how many of the
139	total number of people who are actually infected does it
140	pick up?
141	The original US studies predicted 30 to 40 per
142	cent. In fact, the first predicted 40 per cent, the
143	second predicted 30 per cent and commented that, if the
144	first had been done properly it would have been 30 per
145	cent as well.
146	That is the first question. The second question
147	is how specific is ALT? If you have a cut-off of let us
148	say 45, what proportion of the donations that you throw
149	away will, in fact, be infected? With a curious
150	symmetry, the US figures again suggested about 30 per

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151	cent will be infected, so if you threw away 100 bags, 30
152	of them would actually be infected and the other 70
153	would not. That is specificity. I think what my
154	learned friend said about that was, well, so be it, but
155	it does not really matter, because it is 70 per cent of
156	3 to 4 per cent. If you had thrown away 3 to 4 per cent
157	of the bags and so it is 70 per cent of that that may be
158	wasted, unnecessarily thrown away.
159	MR JUSTICE BURTON: It is common ground, is it, that 3 to
160	4 per cent is the thrown away bags, not the wastage,
161	thrown away bags resulting from ALT?
162	MR UNDERHILL: Yes, something like that. I think 4 per cent
163	for ALT and anti-HBc. You would actually have to do a
164	survey of your own population to see how many people had
165	raised ALT at all before you could work out if you were
166	in a high drinking population or a population which for
167	one reason or another had a lot of incidence of raised
168	ALT. That is one of the things the UK studies actually
169	looked at and I cannot off the top of my head remember
170	what the figure that that threw up was, but we will come
171	to it.
172	MR JUSTICE BURTON: It may be that it is different, (a)
173	because the population is different and (b) because one
174	might want to look at ALT without anti-HBc. It is not
175	going to be more than 4 per cent, is it?
176	MR UNDERHILL: At a cut-off of 45, no. If you went for a
177	cut-off of 30, it would be a lot more, I think the
178	figure is 9 per cent.
179	Both those questions, sensitivity and specificity
180	are highly relevant to the contemporary consideration of
181	whether or not ALT screening should be introduced.
182	Contemporary information -- and I am talking about the
183	late 1980s and now it is clear that my learned friend's
184	case is it should have been introduced even after
185	anti-HBc was available, right up, therefore, to 1991 --
186	MR JUSTICE BURTON: I have the first hint that it is
187	possible that it may be ALT with a higher cut-off
188	point.
189	MR UNDERHILL: No doubt that can be debated later, but yes,
190	my Lord. Contemporary information certainly up to
191	1989/1990 was almost wholly based on the US experience.
192	Such information as there was from anywhere else was
193	patchy and unsatisfactory. There is only one, I think,
194	paper from Europe which I will not take your Lordship
195	to, but I will just mention so that the light bulb comes
196	on perhaps when we come to it later in evidence, by a
197	Dutch study called Katchaki, which suggested that the US
198	experience did not apply in Europe.
199	Once anti-HCV screening became available, some
200	more information came out, because one of the first

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201	things that a lot of people did, not actually everybody,
202	was look at those who were showing up anti-HCV positive
203	on the first tests and see how that correlated with
204	raised ALT.
205	MR JUSTICE BURTON: Did they do fresh ALT tests or did they
206	compare them with previous samples of those donors'
207	tests', blood against which tests had been done?
208	MR UNDERHILL: I cannot remember. That is the material
209	which I included in my annex 3B and which my learned
210	friends took your Lordship through, adding, glossing,
211	commentating. If you take my paper and his glosses on
212	it, you have effectively the substance of that.
213	Perhaps if your Lordship would not mind taking
214	annex 3B in front of you, look first at sensitivity,
215	that is to say how many positive cases would ALT testing
216	catch, what proportion of the truly positive cases would
217	ALT testing catch. Part of the problem with most of
218	these studies, as I myself pointed out in one of my
219	footnotes and as my learned friend emphasised, is that
220	they were done in the very early days when there were no
221	confirmatory tests, and the figures are of very limited
222	value because, if you see a low correlation with the
223	screened positives that might conceal a much higher
224	correlation once you had got rid of all the rubbish, got
225	rid of all the ones that were false positives. But the
226	most you can say --
227	MR JUSTICE BURTON: Or a lower, I suppose, because the
228	confirmatory tests may knock out the ones which actually
229	on the face of it did correlate.
230	MR UNDERHILL: Yes, I think that is right as well. My Lord,
231	all I say -- we will obviously go through this properly
232	at some later stage -- is that a decision-maker would
233	not look at this material and say: oh, well, the US
234	experience, the US prediction of 30 per cent
235	sensitivity, has been brought out, and it was extremely,
236	as I put it, patchy.
237	MR JUSTICE BURTON: Let us see where we are before you take
238	me to it in any more detail. As at 1988, this is
239	irrelevant and so if the view in 1988, it shows 30 per
240	cent sensitivity and 30 per cent specificity, it is
241	worth doing. The bad news, if this is bad news, that it
242	actually was not as good as that, would not yet have
243	come through.
244	MR UNDERHILL: My Lord, may I pause there? Your Lordship
245	says, if it is 30 and 30, it is worth doing. There are
246	two important glosses to that. Even in the United
247	States they did not at first think it was worth doing.
248	When those figures first came out, there was a long
249	debate, and the initial advice was this is not worth
250	doing. It is not sufficiently specific. It is not

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251	sufficiently sensitive. After four years, they changed
252	their mind. I will be going through all of that.
253	MR JUSTICE BURTON: When did they do that?
254	MR UNDERHILL: They started to do it towards the end of
255	1986
256	MR JUSTICE BURTON: At any rate by 1988, which is what I am
257	asking about, if it is appropriate to say it is 30 and
258	30 and only 4 per cent wastage it is worth doing, if
259	this --
260	MR UNDERHILL: That is your Lordship's --
261	MR JUSTICE BURTON: I am saying if that is the case, if that
262	is the position, then the bad news that is shown here,
263	if it is bad news, is irrelevant, does not falsify the
264	earlier position at least --
265	MR UNDERHILL: I think that is right. The way I am putting
266	this is, on the question of sensitivity -- I have not
267	got to specificity at the moment -- the figures that
268	came out for Europe did not clarify the picture at all.
269	MR JUSTICE BURTON: Indeed it showed from what you are
270	I think going to say to me that 30 per cent was
271	optimistic, and certainly indeed if it ever had been
272	thought likely to be the same in the UK. What it is
273	relevant for, on your case, is, if it was appropriate to
274	wait for the HCV tests and/or in any event if one is
275	considering HCV tests and carrying on ALT alongside,
276	then you are saying this is of help and in your case you
277	are saying there certainly was not any point in
278	introducing ALT once it became clear that by comparison
279	with HCV, the sensitivity was considerably less than
280	30 per cent.
281	MR UNDERHILL: I am not saying, because I do not think I can
282	say that, on sensitivity -- which I think is part of my
283	learned friend's point -- these papers are extremely
284	patchy; they set out to look at it but you cannot draw
285	any clear conclusion. That is all I am saying on this
286	point.
287	Can I, however, just on this point say one thing
288	about a paper which I refer to and my learned friend
289	referred to which is the Caspari paper, H3/91.7.
290	This is a paper which I quoted as saying,
291	"it found more than 95 per cent of donors with elevated
292	ALT were negative for HCV", which is a quote from
293	page 271, and my learned friend's point was, yes, but
294	there was a correlation although he very fairly
295	acknowledged that Dr Caspari said it is surprisingly
296	weak. If your Lordship sees the third paragraph on that
297	page:
298	"In view of the generally accepted theory that HCV
299	is a directly liver pathogenic virus, it is not
300	surprising the prevalence of anti-C 100 3 correlates to

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301	a certain degree with elevations of ALT. It was,
302	however, surprising how weak this correlation was in
303	relation to our study."
304	Then it goes straight on to the figure that I
305	quoted. There was a certain amount of shuffling and
306	juniors trying to work out precise figures while
307	Mr Brown was on his feet, certainly on our side, I think
308	so on his. We have overnight worked out what the
309	precise figures are. The precise figures are these:
310	that there were 842 positive donors, repeatedly reactive
311	donors.
312	MR JUSTICE BURTON: I am going to write this on the
313	article. Where are you drawing this from?
314	MR UNDERHILL: I am drawing that from the abstract, fourth
315	line, very front page, N equals 842. That is the number
316	of positives, of whom 31 had ALT of above 45. That is
317	raised ALT. That figure does not as such appear. You
318	have to work it out, that is why a calculator was
319	needed, because he gives figures in percentages. I
320	actually have a handwritten sheet with it all on which
321	I am happy to share with my learned friend, if he wants
322	to check these figures. Mr Brook Smith actually did it
323	overnight. So you have a figure where, subject to one
324	important qualification I am about to make, you have 842
325	people who are positive, only 31 of them would have been
326	caught by raised ALT tests.
327	MR JUSTICE BURTON: You said 31; you mean 41.
328	MR UNDERHILL: No, I meant to say 31.
329	MR JUSTICE BURTON: I am sorry, I noted it down wrong. 31,
330	thank you.
331	MR UNDERHILL: The important qualification is this: it is
332	the same one as I have made for some of the other
333	papers. All that Dr Caspari was doing was looking at
334	people who were repeatedly positive on the screening
335	test. I suspect, because of the date at which he did
336	the studies, published in 1991 but I suspect it must
337	have been done earlier, he did not have or at any rate
338	did not use a confirmatory test. So it is pretty clear
339	that a large number of those 841 were false positives.
340	So the true figure may have been, but it is anyone's
341	guess just looking at the paper and you never know --
342	the true figure of positives may well have been half,
343	quarter, tenth of that.
344	MR JUSTICE BURTON: It may have been that all 31 raised ALT
345	survive the confirmatory test, and so it becomes 31 out
346	of 84. It may on the other hand be none of the 31
347	survive the confirmatory test and that there will be
348	none out of 84.
349	MR UNDERHILL: That is a point in my favour, but I am not
350	sure it is right. I think the position is, let us

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351	assume, guessing that the rate of false positives in
352	Germany, the haema counter was much the same as the
353	count in the UK.
354	MR JUSTICE BURTON: I have taken a tenth only for ease of
355	calculation.
356	MR UNDERHILL: Let us say 100. Then you would have had --
357	the 100 is only a guess -- 30 per cent, much like the
358	American figure.
359	MR JUSTICE BURTON: I was putting to you the possibility --
360	and it would be a point in your favour, as you say, and
361	it is a only a question to see where the ambit of the
362	argument is. If it is not your point, you abandon it.
363	Am I not right in, if I am not understanding the
364	argument, the possibility that none of those ALT people
365	actually had hepatitis C and that under confirmatory
366	tests it could have come out as none.
367	MR UNDERHILL: I am looking a gift horse in the mouth. My
368	juniors who are quicker thinkers than I am think your
369	Lordship is right.
370	MR JUSTICE BURTON: Clearly it is most unlikely it would be
371	none, but on your case it is a possibility.
372	MR UNDERHILL: Absolutely. The only reason I have gone to
373	this paper, because the same problem arises on almost
374	all of them, is that, as I say, when my learned friend
375	took your Lordship to it no one was quite sure what it
376	was saying, and it is also by far the largest study.
377	They were looking at 110,000 donors.
378	MR JUSTICE BURTON: And Dr Caspari's giving evidence.
379	MR UNDERHILL: That might have been a reason as well. If
380	I had been more tactical than my learned friend I might
381	have kept this point up my sleeve for
382	cross-examination. He has on the whole made his points
383	in opening and I practically did not see any point in
384	keeping it up my sleeve. It is not a trump card for the
385	reason I have identified.
386	The burden of my message on this information about
387	sensitivity is not that it shows one thing or the other,
388	but it shows a thoroughly patchy picture. You could not
389	get the confirmation you might have been looking for
390	that these US predicted figures are indeed true.
391	MR JUSTICE BURTON: I see all that. At the moment, I can
392	only see it going to the question as to whether, if ALT
393	had not already been introduced, one would then have
394	introduced them, on your case wholly unlikely now we
395	have a much more satisfactory screening test. If they
396	had already been in place, whether you would have kept
397	them alongside, you say not much point.
398	MR UNDERHILL: Quite. There is always an inertia factor.
399	Once the test is there, one can see why people were a
400	bit reluctant to stop doing it. In the end they did in

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401	America. It is a different question once you have not
402	started it. My Lord, that is the sensitivity side. If
403	you look at the specificity side a much stronger picture
404	emerges. That is to say what proportion of the ones you
405	throw away will actually be infected? Again, the US
406	predicted figure was 30 per cent. On my annex 3B
407	figures, that was wildly too much.
408	MR JUSTICE BURTON: Too much? What does that mean?
409	MR UNDERHILL: You can put it either way. What I mean is
410	that a much higher proportion of the blood that was
411	thrown away would have been wasted.
412	MR JUSTICE BURTON: Then is the specificity is lower.
413	MR UNDERHILL: The specificity is lower. The 30 per cent is
414	too much. The 30 per cent --
415	MR JUSTICE BURTON: I see.
416	MR UNDERHILL: Your Lordship has the point. The specificity
417	is much, much lower. That had been predicted from the
418	start, because of most European populations being lower
419	prevalence.
420	MR JUSTICE BURTON: It is still not increasing above 4 per
421	cent wastage.
422	MR UNDERHILL: No. My learned friend's basic point that
423	what these figures are percentages of is 4 per cent, or
424	whatever it is, is a correct point.
425	MR JUSTICE BURTON: Just so I am clear, leaving aside the
426	fact it may well be affected by anti-HBc as well, that
427	relates to the number of successful showing up ALT
428	tests. That is what that is, and that remains --
429	MR UNDERHILL: Yes, out of 1,000 donors --
430	MR JUSTICE BURTON: Four will show up positive --
431	MR UNDERHILL: Of 100, four will show up positive with
432	raised ALT. Of those, on the US figures, one and a bit
433	might have actually have been infective, but on the
434	figures from Europe it is much much smaller than that.
435	Those are the figures --
436	MR JUSTICE BURTON: But not much smaller in relation to the
437	4 per cent, because England may have made up on alcohol
438	and fat what America gained on infection; is this it?
439	MR UNDERHILL: We will see all the material on this in due
440	course. The only point I am making is the 30 per cent
441	figure, the equivalence that began to be shown up on
442	these other studies were -- these are the ones in 3B.
443	On my item 4, which is Scotland it is 3 per cent. On my
444	item 5, England and Scotland, 2 per cent. Australia,
445	slightly bigger, 8 per cent. Caspari, he said more than
446	95 per cent. I think if we actually look back it is --
447	MR BROWN: It is 97.8.
448	MR UNDERHILL: Exactly, it is 2 per cent. So a pretty
449	consistent picture. Very low specificity. Let us be
450	clear about this, not the actual chemical specificity of

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451	the test but the predictive -- perhaps I should use the
452	term predictive value.
453	MR JUSTICE BURTON: I have understood the word specificity,
454	it means now the number of real positives.
455	MR UNDERHILL: I am using it in that sense. Perhaps I
456	should be using it in the sense predictive value. What
457	really matters is the number that you have taken out of
458	the donations which actually were infective.
459	MR JUSTICE BURTON: Out of 97 thrown away, only 3 were real
460	positives and possibly I suppose they were only --
461	MR JUSTICE BURTON: That is a maximum figure. Some of those
462	would, in fact, not survive the confirmatory test.
463	MR UNDERHILL: Exactly.
464	MR JUSTICE BURTON: We know some of those. In fact, it
465	might be one seventh of 3 per cent.
466	MR UNDERHILL: Exactly, tiny.
467	What I think I had in mind -- this is really old
468	history, if I set up my stall correctly here -- what
469	I think I had in mind when I was talking about figures
470	of 5 and 10 per cent, rather generously to my learned
471	friend I was thinking of that figure. Actually looking
472	back at the transcript I think I stated it right, though
473	I was not so sure that I had when he challenged me five
474	minutes later. Anyway, that is the --
475	MR BROWN: My Lord, I am grateful for the clarification,
476	because we have understood the defendants' statistician
477	to accept that, in a low incidence population such as
478	the United Kingdom there would still be a 30 per cent or
479	40 per cent, about that figure, thereabouts, reduction
480	in the incidence of post-transfusion hepatitis, if you
481	used elevated ALT. My Lord, the reference to that is
482	paragraph 8.3 in Dr Charlett.
483	MR UNDERHILL: I am coming to that. I may as well come to
484	it now. Up to this point we have been directed entirely
485	to the question of what material is available at the
486	time, because that question is relevant to what ought to
487	have been done. On the question of quantum, in
488	principle you are entitled to look at what would have
489	happened based on studies not available at the time.
490	MR JUSTICE BURTON: Pausing a second, you are entitled, if
491	you are right about the definition of defect.
492	MR UNDERHILL: Exactly. That is one of the questions that
493	Mr Charlett does indeed address.
494	MR JUSTICE BURTON: Where are we looking?
495	MR UNDERHILL: We are looking behind tab 16 in bundle L1,
496	under the heading, chapter 8: "Estimation of what might
497	have been prevented if surrogate market screening was
498	performed in the UK".
499	Paragraph 8.1, he says:
500	"Using the results of these non-European studies",

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501	that is the original studies, "the predicted proportion
502	of post-transfusion hepatitis that could be prevented if
503	this blood was not transfused could be calculated
504	below."
505	I am not going to go through the detail of this
506	now because I have not prepared to do so and the figures
507	are complicated and not expressed in quite the way we
508	have been discussing. Over the page, we see the
509	paragraph my learned friend has in mind:
510	"When the incidence of non A non B
511	post-transfusion hepatitis is low, then the predicted
512	adjusted accuracy would be 33 per cent and 27 per cent",
513	and so on.
514	He is basically working out what the figures are.
515	Then at 8.4 he says:
516	"Depending on the incidence of non A non B
517	post-transfusion ..."
518	MR JUSTICE BURTON: Just a second, because this is where
519	I think Mr Brown is getting his quotation from. It is
520	the second sentence in 8.3:
521	"Therefore, for every 10,000 transfusions there
522	will be 100 cases of non A and non B of which 33 or 27
523	would be prevented if elevated ..."
524	MR UNDERHILL: That is where he quoted from, but you will
525	see at the moment all he is doing is extrapolating from
526	the old US studies, the predictive studies. He is
527	saying, how would you predict they would apply in a low
528	prevalence population?
529	MR JUSTICE BURTON: I see.
530	MR UNDERHILL: Then he says, depending on the incidence of
531	non A non B post-transfusion hepatitis and the
532	specificity of elevated ALT as a diagnostic test,
533	approximately 25 per cent ...", which is saying the same
534	thing the other way round.
535	MR JUSTICE BURTON: Is that it? Is that all there is in
536	Charlett?
537	MR UNDERHILL: No, because what he then does --
538	MR JUSTICE BURTON: Forget anti-HBc.
539	MR UNDERHILL: Yes, forget anti-HBc. Firstly, his point
540	throughout is that is based on the US experience.
541	MR JUSTICE BURTON: Of course, he says that.
542	MR UNDERHILL: Then section 9 on page 34 he says:
543	"It has often been stated", and he refers to
544	Alter, Holland and Julian, "that the predicted estimates
545	of the accuracy of screening for surrogate markers do
546	not necessarily represent what we found in practice if
547	donor units were actually to be withheld. To reliably
548	assess whether withholding surrogate markers would
549	result in reduction, a randomised controlled trial is
550	required."

	A
551	He looks at three studies. He looks at a Canadian
552	study called Blatchman --
553	MR JUSTICE BURTON: Are these going to appear in annex 3B?
554	MR UNDERHILL: No, they do not, because that was directed
555	entirely at the contemporary position. Blatchman, he
556	says you cannot get any statistical -- it does not have
557	sufficient statistical power to get a statistically
558	significant figure out of it. That is the only
559	randomised control trial. Then in paragraph 10 he looks
560	at other evaluations. He looks at two historically
561	controlled trials. What that means is where you have a
562	group of patients, and halfway through you introduce
563	screening, and you look at whether the proportions
564	infected are different in the earlier group than the
565	later group. There is a risk of bias, because there
566	might be other factors operating at the two times.
567	He refers to two, one which we are going to have
568	study in France look at quite soon in Dr Gunston's
569	evidence, a report by Alter himself, who introduced
570	screening ahead of most people on an experimental basis,
571	stopped after three years, or looked after three years
572	and said: is my rate of infection after three years
573	lower than in the three years before I introduced it.
574	He found it was not and he was puzzled by that, because
575	he had expected it would, and he gives various
576	possibilities why there might have been a bias that
577	prevented the expected drop happening.
578	MR JUSTICE BURTON: The expected drop in post-transfusion
579	hepatitis?
580	MR UNDERHILL: It did not drop.
581	MR JUSTICE BURTON: Even after the introduction of
582	screening?
583	MR UNDERHILL: In that trial, done by Alter in 1985.
584	MR JUSTICE BURTON: Which of course is not the British
585	experience.
586	MR UNDERHILL: The British never introduced it.
587	MR JUSTICE BURTON: 1991.
588	MR UNDERHILL: So sorry, perhaps I did not listen to your
589	Lordship carefully enough. Of course it dropped after
590	1991. No, he introduced ALT screening.
591	MR JUSTICE BURTON: I am sorry, I thought this was anti-HCV
592	screening. Yes, I see.
593	MR UNDERHILL: He introduced ALT screening.
594	MR JUSTICE BURTON: He introduced ALT screening and it did
595	not drop?
596	MR UNDERHILL: The incidence of hepatitis did not drop, that
597	is hepatitis defined then in the only way it could be
598	defined by looking at recipients and seeing if they had
599	raised ALTs over a prolonged period. That is Alter.
600	Then there is Julian --

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601	MR BROWN: My Lord, perhaps my learned friend would read the
602	last sentence, because the author was not quite sure
603	whether he had done it right.
604	MR UNDERHILL: I will if you like, but I actually said that
605	to your Lordship already.
606	MR JUSTICE BURTON: You will be going to it, you said.
607	MR UNDERHILL: (a) we will be going to it, I then said he
608	was surprised by the results.
609	MR JUSTICE BURTON: And there were various explanations.
610	MR UNDERHILL: I do not think --
611	MR JUSTICE BURTON: I did not pay any attention to it at the
612	moment.
613	MR UNDERHILL: We are going to be looking at this one fairly
614	early on in Dr Gunston's evidence. Then Julian, this
615	was a study in France, and he looked at patients before
616	and after the French introduced ALT and anti-HBc
617	screening. So ignore anti-HBc for the moment, because
618	I am on ALT. At 10.4, we see that the reduction in risk
619	for elevated ALT screening alone was 17 per cent. That
620	is the end of 10.4.
621	"The authors conclude a reduction in the risk of
622	HCV transmission of 66 per cent when screening for both
623	surrogate markers is in accordance with the predicted
624	adjusted accuracy."
625	That is what the TTV thought would happen if they
626	introduced both anti-HBc and ALT. The ALT component in
627	the introduction of this was actually much smaller than
628	the anti-HBc.
629	MR JUSTICE BURTON: I see that. No doubt I will have it
630	explained to me. The common ground about predicting
631	percentage appears to be 30 per cent rather than for ALT
632	at any rate, and dubiety cast on the anti-HBc. Whatever
633	the predictive may have been, what these authors are
634	concluding in relation to the historic comparative test
635	was a reduction in risk of 17 per cent.
636	MR UNDERHILL: That is on that --
637	MR JUSTICE BURTON: What does that mean? That means that
638	comparing the ALT levels of the donor blood and the
639	recipient blood, and this is on the basis that alcohol
640	and fat would not --
641	MR UNDERHILL: I think by this time the Julian study, unlike
642	the Alter study --
643	MR JUSTICE BURTON: There was now a screening?
644	MR UNDERHILL: There was now a screening test so you could
645	look whether you had HBC so you knew whether you had
646	your end point test.
647	MR JUSTICE BURTON: Probably a confirmatory test, too.
648	MR UNDERHILL: Yes, they use the second generation.
649	MR JUSTICE BURTON: This is an actual comparison between
650	people with HBC and the raised donor ALT?

	A
651	MR UNDERHILL: That is right.
652	MR BURTON: That shows a 17 per cent reduction in risk.
653	What does that mean? Just translate that into figures
654	for me. The reduction in risk was 17 per cent. That
655	means --
656	MR UNDERHILL: That means you would have kept out 17 per
657	cent out of every 100 people who were actually infected.
658	(11.15 am)
659	My Lord --
660	MR JUSTICE BURTON: Put the other way round, with the ALT
661	test, which might have a low specificity, you would
662	succeed in keeping out 17 people who actually had HCV.
663	MR UNDERHILL: Out of every 100.
664	MR JUSTICE BURTON: In every 100?
665	MR UNDERHILL: That is right.
666	MR JUSTICE BURTON: When you say reduction in risk you might
667	have kept none out, I suppose, but for the ALT. You
668	would have kept none out.
669	MR UNDERHILL: Exactly.
670	MR JUSTICE BURTON: So you are saving 17 lots of infected --
671	MR UNDERHILL: That is right.
672	MR JUSTICE BURTON: I am puzzled about the words "reduction
673	in risk". Elimination from the pool?
674	MR UNDERHILL: We are going to look at all these papers so
675	far as necessary.
676	MR JUSTICE BURTON: It is an elimination from the pool of 17
677	out of every 100, in fact, infected with HCV. Now, that
678	is not as good as 30 per cent, but it is a pretty good
679	level, is it not?
680	MR UNDERHILL: Yes. This is not a paper available at a
681	material time. It is a 1993 paper.
682	MR JUSTICE BURTON: Yes, it was not available at the time.
683	MR UNDERHILL: The point we are making, my Lord, is these
684	are the materials that Charlett has looked at which will
685	be relevant to quantum.
686	MR JUSTICE BURTON: Or not.
687	MR UNDERHILL: Or not. Only if things turn out a certain
688	way. The other one he looks at is Donahue, an American
689	multicentre study.
690	MR JUSTICE BURTON: If it had come out as 0 per cent or
691	2 per cent, you would say it is relevant on quantum, but
692	you would not be able to say that shows that 30 per cent
693	was a nonsense in 1988.
694	MR UNDERHILL: I would not say it was a nonsense. There
695	were two respected US studies that suggested that was
696	the case. My Lord, then Donahue he looks at, and that
697	looks at both surrogate markers, again after the
698	introduction of HCV screening, and that --
699	MR JUSTICE BURTON: Just before we go on, the reason you
700	went to this, as I recollect it, was at least partly

	A
701	because of specificity as well as sensitivity. Do these
702	tests have anything to say on specificity?
703	MR UNDERHILL: No, this part of Charlett's evidence is
704	related only to sensitivity.
705	MR JUSTICE BURTON: Because of the quantum point?
706	MR UNDERHILL: Yes. Donahue, an American study, shows a
707	figure at 10.6 of 60 per cent or 50 per cent for units
708	transfused, 60 per cent overall, for both surrogate
709	markers.
710	MR JUSTICE BURTON: And did he not split the two off, or did
711	he --
712	MR UNDERHILL: I have not looked at the study overnight.
713	Charlett does not say that he did, and I suspect that is
714	because he did not.
715	MR JUSTICE BURTON: That is pretty good, 60 per cent, is it
716	not?
717	MR UNDERHILL: One of the puzzles about this is that some of
718	the studies continue to show some value for HCV. Can we
719	leave it at that? The point I am trying to make is that
720	my learned friend is not quite right to say simply that
721	Charlett agrees that the figure would have been 30 per
722	cent, and indeed I thought actually my learned friend
723	put it quite right yesterday, what I understood him to
724	say -- whether he said it or not this is what I say --
725	that the burden of Charlett's report is that, working on
726	the predictive studies for a low prevalence population,
727	you would expect 27 to 33 per cent.
728	He looks at three studies, the ones I have briefly
729	summarised there. The only European one, which is
730	Julian shows a value of 17 per cent for ALT, but it is
731	an historical study, there may have been biases there.
732	He does not commit himself. I do not mean it rudely,
733	this is a number-crunching report, and he does not
734	commit himself and we have not, I am afraid, finally
735	committed ourselves, nor has my learned friend, to
736	saying what figure we are going to invite your Lordship
737	to find.
738	MR JUSTICE BURTON: I see that.
739	MR UNDERHILL: There is actually one partial reason for
740	that, other than natural caution, which is that this is
741	an area that is also covered -- and I have only been
742	reminded of this morning so I cannot take your Lordship
743	to the detailed references, I am afraid -- as you would
744	expect by Dr Caspari, and he has given certain
745	references on the efficacy of ALT testing, which we have
746	asked for in correspondence, and I have not yet been
747	supplied and which we are quite keen to have.
748	MR BROWN: My Lord, that is not right. I knew this point
749	was going to be raised. Those instructing my learned
750	friend wrote as long ago as 4th September pointing out

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751	that the medical library which runs to 24 or 25 volumes
752	was not complete and that anyone, either Dr Caspari on
753	the one hand or Dr Barbara on the other -- where we had
754	not been able to find the references, people should say
755	straightaway which are the ones they wanted. So we
756	wrote to them again on 20th September saying tell us
757	which ones, if any, you want. I think we finally got a
758	letter on 13th October. My Lord, that I think
759	accurately summarises the history.
760	MR JUSTICE BURTON: As you can rather imagine I am not going
761	to be very interested in this. Mr Brown, all I am
762	saying is, without any criticism or any of this kind, if
763	there are some documents which the other side is going
764	to need to have looked at by the time Dr Caspari gives
765	evidence, is it going to be possible to give them?
766	MR BROWN: My Lord, we do not think it is, and we told them
767	it was not going to be, as long ago as 4th September.
768	MR JUSTICE BURTON: Why is that?
769	MR BROWN: My Lord, there is a limit to how far you search
770	through the medical libraries.
771	MR JUSTICE BURTON: If Dr Caspari has referred to them in
772	his statement.
773	MR BROWN: My Lord, we made it plain as long ago as
774	4th September that there were difficulties on both
775	sides; the request is repeated when the trial is already
776	up and running.
777	MR JUSTICE BURTON: We are going to be going until Christmas
778	and Dr Caspari is not going to be called until November,
779	is he?
780	MR BROWN: Of course. My Lord, we will continue to do what
781	we can. What my learned friend cannot say is, as he
782	just said -- and I shall look at the transcript if I
783	need to -- "we have asked for these and we have not had
784	them"; they asked for them on 13th October effectively.
785	MR JUSTICE BURTON: I do not think that factually is right,
786	is it not, Mr Brown? He has asked for them and he has
787	not had them. Maybe you rose too early, because perhaps
788	in the next sentence he was going to say this is a
789	disgraceful piece of diligence on the part of someone or
790	other. That would have been when you could have risen.
791	MR BROWN: We are very troubled about this sort of late
792	matter. We have had the opening delivered in bits. The
793	factual section of the opening has been with my learned
794	friend for five or six weeks; we are still receiving it
795	now. We are troubled about delays. I will now sit
796	down, my Lord.
797	MR JUSTICE BURTON: Thank you. Mr Brown, do not sit down
798	before I have simply asked you -- I think I have
799	understood what you are saying -- that you are saying
800	that it may be difficult to get hold of these, and

	A
801	certainly, if they are available, it may take a little
802	time. Are steps being taken to do so, simply because if
803	Dr Caspari is relying on them, he must at the very least
804	have copies in his own files?
805	MR BROWN: The problem is that Dr Caspari is presently in
806	Portugal.
807	MR JUSTICE BURTON: That makes it difficult to get things
808	from him perhaps, although there is a fax machine. He
809	must have them in his own files, if he has referred to
810	them.
811	MR BROWN: Not in Portugal certainly, and he has been in
812	Portugal since this letter was received. He is going to
813	be in Portugal until, we anticipate, he comes to give
814	evidence, which is not where he works.
815	MR JUSTICE BURTON: Where does he keep his file?
816	MR BROWN: Somewhere in Germany.
817	MR JUSTICE BURTON: Does he not have a secretary?
818	MR BROWN: It is not a question of files, my Lord. It is a
819	question of going back -- my Lord, no doubt what he has
820	been doing is looking at references in papers he has
821	previously written without necessarily going back to
822	them. I do not imagine he has a nice tidy file with
823	each and every paper, because that is not the way it
824	works.
825	MR JUSTICE BURTON: I do not know.
826	MR BROWN: It is not, my Lord. My Lord, I am not going to
827	be argumentative. If we can do it, we will. It would
828	have been much nicer had we had a response to the letter
829	of 4th September.
830	MR UNDERHILL: My Lord, I only learned about this particular
831	problem this morning, and I am not going to have a
832	battle about it. I do not know whether what my learned
833	friend says is the whole picture or not. I do not
834	believe from what I have been told that it is. The
835	bottom line is where an expert puts references in his
836	report you would expect him to (a) have access to them
837	and (b) to be able to provide them on demand. That is a
838	surprising situation. I suspect my learned friend is
839	quite right, and it may be no particular criticism of
840	Dr Caspari's expertise that he has just borrowed them
841	from earlier publications of his, but that is the fact.
842	He has referred to them and we want to look at them.
843	MR JUSTICE BURTON: Can I ask you this, Mr Underhill: are
844	they references to publications, because it may be you
845	can get hold of them yourselves. It may cost extra. No
846	doubt that can be a matter that could be referred to in
847	costs.
848	MR UNDERHILL: The answer is I am told that -- and indeed
849	I can see from the schedule we provided on 13th October
850	where we set out all of them -- they just have

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851	references like " Videl et al, 1988" i.e. they do not
852	give a reference to the journal.
853	MR JUSTICE BURTON: At the very least, Mr Brown, can you
854	not -- because I am sure he can, by fax at least from
855	Portugal, if he cannot get hold of them -- he can
856	elucidate the references?
857	MR BROWN: I have to say he is absolutely uncontactable,
858	effectively, at the moment. He has a family holiday, he
859	locks himself away, it must be a lovely thing to be
860	doing, that is what he is doing. My Lord, I do not want
861	to be on my feet any longer.
862	MR JUSTICE BURTON: I cannot think of anywhere better to be
863	than here, Mr Brown.
864	MR BROWN: Enjoying himself as much as the rest of us. I am
865	very troubled about this, because my learned friend says
866	if he is relying on them, we should have them. My
867	learned friend knows very well that an awful lot of the
868	papers which Professor Zuckerman, Dr Barbara et al are
869	relying on, we do not have copies of either, and there
870	is a limit to searching.
871	MR JUSTICE BURTON: That does not necessarily seem agreed.
872	Mr Brown, let us cut it through. There are three
873	possibilities here. The fourth, I do not want to
874	contemplate, and that is that when Dr Caspari comes to
875	give evidence he does not have them and cannot get hold
876	of them and nor can the other side and we are all
877	swimming around in the dark, because it does sound as
878	though they may be helpful. Let us leave aside the
879	fourth possibility, but there are three others.
880	One is that Dr Caspari somehow or other manages to
881	enable someone or other, be it a secretary or research
882	assistant or a colleague, to find them even though he is
883	in Portugal.
884	The second possibility is that he gives your
885	instructing solicitors over the phone, or by fax, the
886	references, and that you get someone to chase them up.
887	The third is whether with the assistance of some
888	references from Dr Caspari or otherwise the defendants
889	rustle round and try to find them.
890	MR BROWN: You will not be surprised that I suggest the
891	third, given the delays.
892	MR JUSTICE BURTON: The third may need still the assistance
893	of Dr Caspari.
894	MR BROWN: We will cooperate as best we can.
895	MR JUSTICE BURTON: Good. Thank you.
896	MR UNDERHILL: I do not want to say any more about this. It
897	was simply an additional reason why at this stage we
898	have not committed ourselves to a final figure, and I do
899	not think we are obliged to at the moment. We have said
900	this is the relevant evidence.

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901	MR JUSTICE BURTON: That in any event goes to quantum. Can
902	you tell me, do you get the impression that these
903	Dr Caspari references -- I think you said 1988 -- all
904	relate to matters going only to quantum, because they
905	may go, on what you have told me, if there really is a
906	1988 article, to the middle ground, which you have not
907	really fully completed either. Can I summarise what I
908	mean by that?
909	The early period, pre-1988, it seems to be common
910	ground that the literature shows 30 per cent, 30 per
911	cent, 4 per cent. The later period goes only to
912	quantum, and neither of you has yet analysed your
913	position. But the 1988 to 1991 position will go to the
914	continued or indeed introduced ALT screening during that
915	period. On that, we have your annex 3B articles, which
916	you say attach it. If there is anything else that
917	assists in there, then clearly that might be helpful.
918	MR UNDERHILL: I hear what your Lordship says and I see
919	exactly the distinction your Lordship makes. As I say
920	very frankly, I was asked to raise this point this
921	morning and given the correspondence and briefly
922	briefed. I have not myself looked at the text of these
923	particular paragraphs and seen to which they go,
924	although I know some of them go to this issue we are on
925	now because that is what I have been told. Looking at
926	the page references, I suspect some of them go to other
927	points as well. There are in all 28. I can say now --
928	I am trying to be as helpful about this as possible --
929	one or two I have a shrewd suspicion of what they are,
930	because they are authors and dates I recognise. That is
931	certainly not true of all of them. It is only true of a
932	handful. I suspect with goodwill, which is certainly
933	present on our side, we will be able to track a lot of
934	these down, but we will need a bit of help. I do not
935	think we will be able to track all of them down.
936	MR JUSTICE BURTON: I think the first step would be, given
937	what Mr Brown has said about Dr Caspari's present
938	unavailability at all, although one hopes that he must
939	have left some kind of following number even if it is
940	only an occasional one, given that he is on holiday, is
941	that you could let them know in a further letter which
942	ones you are particularly interested in and have not
943	been able to find anything about.
944	MR UNDERHILL: We do not want to make points just for the
945	sake of it. I will, or I will get one of my juniors, to
946	go through them and see if we can weed any out on the
947	basis that we are pretty certain which they are, or that
948	they seem to go to something which is not really an
949	issue. There will, I think, be an irreducible core
950	which we are keen to see, and frankly if he refers to

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951	them he ought to be in a position to show us.
952	I have been through that material really only
953	because I was challenged by my learned friend to clarify
954	our position, and I hope I have done so as far as I can.
955	Returning at last to where I broke off
956	yesterday -- and I am going to be a bit longer than I
957	thought I was --
958	MR JUSTICE BURTON: You have been the hour which you
959	threatened being.
960	MR UNDERHILL: I am sorry about that. These things happen.
961	MR JUSTICE BURTON: It has been a valuable period.
962	MR UNDERHILL: Your Lordship will have noticed that in all
963	the submissions I made yesterday I said comparatively
964	little about the legislative history. My Lord, let us
965	ignore for the moment questions of admissibility and
966	assume that all my de bene esse marker points were in.
967	I am still actually, if I may say as a footnote, rather
968	hopeful that we can come to some sensible accommodation
969	on admissibility because, if all my learned friends
970	actually wanted to refer to out of the much longer files
971	that they actually provide were those, I do not think
972	there is anything that I need seriously object to.
973	I have already put that marker down and I want to put it
974	down in open court; I am sure we will be talking again.
975	Let us ignore those sorts of questions. Our
976	position is not that the legislative history is
977	inadmissible, it plainly is not, or that it is wholly
978	unhelpful. On certain big picture points, the
979	legislative history at least confirms points which you
980	could probably get clearly enough from the recitals. It
981	confirms there was an intention to introduce no fault
982	liability. It confirms, perhaps, a point in our favour,
983	that the phrase "all the circumstances" as not just mush
984	and puff; someone took the trouble of insisting it went
985	in. It confirms in the shape of the answer from the
986	Commission that the question of the non-defectiveness of
987	unavoidably dangerous products was at least addressed
988	and views expressed about it as part of the legislative
989	process.
990	There are probably some other big picture points
991	which one can get out of it. But on the particular
992	points which your Lordship is going to have to decide in
993	this case, the legislative history does not really help.
994	MR JUSTICE BURTON: Which one is that? I thought there was
995	more than one.
996	MR UNDERHILL: For example --
997	MR JUSTICE BURTON: I am so sorry, you have said "on these
998	particular points". I thought you said "particular
999	point." I see from the transcript you used the plural,
1000	the particular points being what is a defect in Article

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1001	6 and what defects in the population of product in
1002	Article 7?
1003	MR UNDERHILL: Yes, those are probably the two particular --
1004	it is not so much what is a defect, but how does it
1005	apply in circumstances like this, if there are any
1006	circumstances like this.
1007	MR JUSTICE BURTON: I think it comes to the same thing. As
1008	long as we understand what it meant by what is a defect,
1009	I think it summarises the issue.
1010	MR UNDERHILL: Very well, my Lord. So our position about
1011	the legislative history is not a sort of Luddite one
1012	that you should not look at it, but you get pretty
1013	limited help. I am sure your Lordship was instructed by
1014	Mr Forrester's opening and there were parts in it which
1015	if I had been opening I would have wanted your Lordship
1016	to know as well. I do not think this is going to be a
1017	case where the answers are going to be found in the
1018	legislative history; put it that way.
1019	There is one minor point on which, if your
1020	Lordship would like the answer, we can briefly give it,
1021	although frankly the way the issues have turned out I am
1022	not sure it is particularly central, which is the status
1023	of unilateral declarations.
1024	Mr Brook Smith has found what we believe are the
1025	two leading cases on this, and he is in a position to
1026	address your Lordship very briefly on that, and I would
1027	be very happy to let him do so.
1028	MR JUSTICE BURTON: I think that may be helpful. Thank you
1029	very much.
1030	Submissions by MR BROOK SMITH
1031	MR BROOK SMITH: My Lord, one of the cases is actually in
1032	the yellow file, which is the attachments to subannex
1033	1A. It is at tab 9. Does your Lordship have tab 9? It
1034	is the Antonissen case.
1035	MR JUSTICE BURTON: Yes, in my bundle, that is the written
1036	question that we looked at yesterday.
1037	MR BROOK SMITH: No, there are two yellow files. There is a
1038	further fat yellow file which is attachments to subannex
1039	1A.
1040	MR JUSTICE BURTON: No, I only have one yellow file, apart
1041	from J1 which is yellow and the L one is yellow.
1042	MR BROOK SMITH: Perhaps we can hand up another, my Lord,
1043	together with the additional case. (Handed).
1044	MR JUSTICE BURTON: This is called attachments to subannex
1045	1A?
1046	MR BROOK SMITH: Yes.
1047	MR JUSTICE BURTON: Subannex 1A --
1048	MR BROOK SMITH: Was dealing with the legislative history.
1049	This is a clutch of European material.
1050	MR JUSTICE BURTON: I see that, so I know where I am on your

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1051	bundles. I have the pink bundle which I must have open
1052	because I have been following it, which is called
1053	opening overview. Then there defendants' opening, annex
1054	1, the law. That I thought had annex 1, the law,
1055	attachments, but now it has a second attachment.
1056	MR BROOK SMITH: It has a subannex 1A which should be in
1057	that slim yellow file, the legislative history. That
1058	should be at the back of that slim yellow file,
1059	annex 1.
1060	MR JUSTICE BURTON: I want to be sure about this. I have
1061	annex 1, the law.
1062	MR BROOK SMITH: Included within that you should find
1063	subannex 1A.
1064	MR JUSTICE BURTON: Yes, thank you. You gave it to me
1065	separately. I have it.
1066	MR BROOK SMITH: The fat yellow file is the attachments to
1067	subannex 1A.
1068	MR JUSTICE BURTON: Thank you. What is it called? Plus 1A
1069	yellow file. Thank you very much. While I have you,
1070	Mr Brook Smith, annex 2 is the litigation, annex 3 is
1071	surrogate testing, annex 5 is miscellaneous. I still
1072	have sitting here waiting to be inserted somewhere annex
1073	4A, because I do not have an annex 4.
1074	MR BROOK SMITH: It is on its way.
1075	MR UNDERHILL: I was going to come to it in a minute. Now
1076	your Lordship is doing this exercise, you can have it
1077	now. All the bits in it my learned friends have had for
1078	a couple of days.
1079	MR JUSTICE BURTON: Will I need to insert annex 4A?
1080	MR UNDERHILL: It will be a good idea, yes. (Handed).
1081	MR BROOK SMITH: Tab 9, my Lord. This is the Antonissen
1082	case concerning freedom of movement for workers, and
1083	this dealt with the question of the status of a
1084	declaration of the Council itself. One sees that from
1085	the judgment at page I746, paragraph 2: does your
1086	Lordship have that? On the left-hand side, second
1087	column:
1088	"A declaration recorded in the Council minutes at
1089	the time of the adoption..."
1090	The terms of the declaration itself one sees from
1091	I778 in the judgment of the court, paragraphs 17 and 18
1092	on I778. Does your Lordship see there that the
1093	declaration was recorded in the Council minutes and it
1094	was actually a declaration of the Council itself. The
1095	judgment of the court at 18:
1096	"However such a declaration cannot be used for the
1097	purpose of interpreting a provision of secondary
1098	legislation where, as in this case, no reference is made
1099	to the content of the declaration in the wording of the
1100	provision in question. The declaration therefore has no

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1101	legal significance."
1102	The Attorney General dealt with it slightly
1103	differently, if one looks back at page I765. He dealt
1104	with it in paragraph 27. He concluded the declaration
1105	could have some effect but could not serve to fill a
1106	lacuna in the provisions, and one sees that, even upon
1107	that analysis, the analysis he adopted, the top of
1108	paragraph 28 it was of no actual help in that case.
1109	MR JUSTICE BURTON: That is because it talked about allowing
1110	a minimum period of three months, which I assume was not
1111	anywhere in the Directive. That said, whatever might
1112	have been sensible about what the Advocate General said,
1113	the court did not adopt it.
1114	MR BROOK SMITH: The court did not adopt it.
1115	MR JUSTICE BURTON: No legal significance, finished, end.
1116	That is a Council --
1117	MR BROOK SMITH: That is a Council declaration. The
1118	question I think your Lordship was addressing with
1119	Mr Forrester was the question of unilateral declaration.
1120	MR JUSTICE BURTON: There are some naughty Latin words
1121	creeping in. A fortiori, is that what you were going to
1122	say?
1123	MR BROOK SMITH: I was going to say that, my Lord, and do
1124	so.
1125	MR JUSTICE BURTON: I am sure you will not. Find some other
1126	way round, which will probably take at least 12 times
1127	the time.
1128	MR BROOK SMITH: The other loose case which I handed up and
1129	should have come up with the file a moment ago is The
1130	Commission v Denmark. That deals expressly with the
1131	question of unilateral declarations. The Advocate
1132	General does not deal with it in his opinion, but the
1133	court deals with it on page 435 at the bottom in
1134	paragraph 12:
1135	"The Danish Government entered a
1136	declaration ... to the effect that 'Denmark is of the
1137	view that the expression "same work" can continue to be
1138	used in the context of Danish labour law'", dealt with
1139	swiftly over the page at paragraph 13 in the court:
1140	"The court has consistently held that such
1141	unilateral declarations cannot be relied upon ... since
1142	the objective scope of rules laid down by the common
1143	institutions cannot be modified by reservations or
1144	objections which Member States may have made at the time
1145	the rules were formed."
1146	MR JUSTICE BURTON: Objections are of course what
1147	Mr Forrester referred to as the "crossing fingers".
1148	MR BROOK SMITH: Exactly.
1149	MR JUSTICE BURTON: Reservations may not be, and the
1150	significance is that they cannot be relied on for the

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1151	interpretation of measures. It does seem one is left in
1152	a little bit of an uncertainty, at least I am. That
1153	would accord with what my initial feeling was about it,
1154	in the sense that what one country says about the
1155	interpretation of a Community measure cannot possibly
1156	bind all the others, and on the other hand it cannot
1157	allow that one country to be out of step with all the
1158	others, unless of course it is a provision which is left
1159	to the national law to implement, which is a different
1160	matter.
1161	But if a unilateral declaration, either of the
1162	Council or the Member, is just irrelevant for the
1163	purposes of interpretation, no legal significance,
1164	cannot be relied upon, makes it difficult to see how
1165	something which has a lesser status than a Government
1166	declaration or a Council declaration or a declaration
1167	made and recorded in the minutes of Council is really
1168	going to be very helpful, and yet both sides appear to
1169	accept now, Mr Underhill with a little degree of
1170	discomfort, that I can look at all these travaux
1171	preparatoires which on the face of it must bear less
1172	weight than a declaration. There it is. No doubt
1173	Mr Forrester will read all this on the transcript.
1174	MR BROOKE: My Lord, I am sure he will. Here it is
1175	declarations after the promulgation of the Directive,
1176	whereas the documents your Lordship has just referred to
1177	are in the legislative process.
1178	MR JUSTICE BURTON: I follow. That is your contrast.
1179	MR BROOKE: It is the first one I think of.
1180	MR JUSTICE BURTON: Mr Forrester may have something else to
1181	say, but anyway, that is your submission, that therefore
1182	it is one thing to interpret the Directive by what has
1183	gone on during it and another thing to interpret the
1184	Directive by what is said at the same time.
1185	MR BROOKE: Yes. If you are looking for legislative
1186	intention.
1187	MR JUSTICE BURTON: I see that. On the other hand that
1188	would result in such a statement by the European court
1189	to say that declarations may be of value if they, from
1190	them, can be deduced something about the intention of
1191	the Directive but are completely irrelevant if they
1192	amount to the mere statement of an objection or a
1193	reservation, or something of that kind. But they have
1194	gone further.
1195	MR BROOKE: They appear to have done.
1196	MR JUSTICE BURTON: As the European Court so often does,
1197	making broadbrush statements, no reliance whatever can
1198	be placed apparently.
1199	MR UNDERHILL: My Lord, there it is. A point having been
1200	raised and we having found what we thought was the

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1201	answer, we thought your Lordship should know about it.
1202	We do not attach enormous importance on it and I think
1203	the distinction that emerged just now in the debate
1204	between yourself and Mr Brooke is a fair one that this
1205	is different from a travail preparatoire. There it is.
1206	We are not entirely sure the European Court has been
1207	entirely consistent in its practice. Those are the two
1208	statements we found.
1209	MR JUSTICE BURTON: The reality is, probably for the
1210	purposes of this hearing, but you will no doubt all
1211	think about it later, unilateral declaration is as
1212	irrelevant as the statute, which is of course either
1213	correct or an incorrect embodiment of the unilateral
1214	declaration as far as Britain is concerned, all of which
1215	must be read now subject to the European Courts'
1216	decision in the Commission case.
1217	MR UNDERHILL: I am not yet on the last lap. I think I am
1218	on the penultimate lap. It is a very short one.
1219	MR JUSTICE BURTON: Where do you want me to put this?
1220	MR UNDERHILL: Would your Lordship put it in the back of the
1221	attachments to annex 1A, in the second bundle.
1222	MR JUSTICE BURTON: In due course the 14 will materialise,
1223	presumably.
1224	MR UNDERHILL: We will produce that. My famous five red
1225	herrings, your Lordship will remember those are in the
1226	pink file at page 20. Can I run through them and see
1227	the extent to which they still are red herrings?
1228	MR JUSTICE BURTON: You can.
1229	MR UNDERHILL: Page 20. The first is autologous
1230	transfusion. My learned friend has said how he puts
1231	it. We frankly still do not understand it. If it is a
1232	point -- I do not think it is a point at all -- it is
1233	one that helps us, because the fact that people are out
1234	there trying to find ways whereby you have your own
1235	blood implies a view that your own blood is safer than
1236	other people's blood. That must be right.
1237	Frankly we think it is pretty marginal on either
1238	basis. It looks as though we are boiling up to a
1239	situation in which your Lordship is allowed to see and
1240	read the reports of the two experts and give them such
1241	weight as your Lordship thinks fit. But my learned
1242	friend does not put very much weight on it. Such weight
1243	as he puts on it in my submission is ill founded,
1244	because actually the logic is the other way. All that
1245	is all I want to say about that.
1246	Heat treatment I think has gone. I put it in
1247	because it is referred to in the claimants' pleading as
1248	a relevant circumstance. My learned friend has not
1249	referred to it at all as a relevant circumstance.
1250	Your Lordship I am sure has the point by now, that

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1251	the particular types of specialised blood product given
1252	to haemophiliacs are the principal type of what are
1253	called fractionated products. You take plasma, you put
1254	it through an industrial process. Really, there is only
1255	one place in the country that does it, the Blood
1256	Products Laboratory in Elstree, run by the Central Blood
1257	Laboratories Authority. That makes this product, it
1258	also makes some products which it tries to export and
1259	that leads to another point I will come to in a minute.
1260	Those products we are not concerned with here,
1261	because they did not transmit, whether or not derived
1262	from unscreened blood --
1263	MR JUSTICE BURTON: Because they were heat treated?
1264	MR UNDERHILL: Because they were heat treated.
1265	MR JUSTICE BURTON: And that antedated 1988.
1266	MR UNDERHILL: Drug licensing, we say a complete red
1267	herring. My learned friend, it was not clear, I may
1268	have forgotten, but certainly he does not put much
1269	weight on it. I still do not quite see how the point is
1270	put.
1271	MR JUSTICE BURTON: Again, as I understand it, you may be
1272	prepared simply to allow me to read Dr Ward's
1273	statement.
1274	MR UNDERHILL: We are checking it for accuracy. Subject to
1275	that we think that is the simple way forward. We say it
1276	is not helpful at all.
1277	MR JUSTICE BURTON: He says it is an analogy, but there it
1278	is.
1279	MR UNDERHILL: There it is. The history of screening for
1280	hepatitis B and HIV, it is clear my learned friend is
1281	still intending to attach some importance to this, but,
1282	from the way again it was put, it does not appear to be
1283	going to be very central, and we are awaiting one sheet
1284	of paper on it which your Lordship asked for, I think.
1285	MR JUSTICE BURTON: I am hoping to slim it down to that, in
1286	the sense of, as I understand it, Mr Brown, to an
1287	extent, discouraged by you and to an extent discouraged
1288	by me, so one cannot at this stage say that he will not
1289	seek to expand it all, but I am hoping we are going to
1290	be able to have a sheet of paper which can be agreed, in
1291	which a certain amount of facts are set out which
1292	include dates of implementation or discovery of viruses,
1293	dates of implementation of tests, et cetera, so that we
1294	do not have to go through the whole factual scenario.
1295	MR UNDERHILL: Our stance is this: that you cannot say what
1296	should have happened for HCV by reference to what did
1297	happen for HBV and HIV without looking at those in an
1298	equal degree of detail. That just distracts attention,
1299	while I think at any time the court would have
1300	discouraged it, in these post-Woolfian days even more

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1301	so. There we are, let us see how it is put.
1302	MR JUSTICE BURTON: What that does mean is of course that
1303	when we come to those -- Dr Gunson I do not think deals
1304	with HIV and hepatitis A and B in a great deal of
1305	detail, does he?
1306	MR UNDERHILL: Not in great detail, no.
1307	MR BROWN: My Lord, that is the point; everybody deals with
1308	it in some little detail. My learned friend says we
1309	cannot look at it all. Dr Gunson deals with it in a
1310	short way. If he deals with it at all, then as it were
1311	I will cross-examine him in relation to it in short
1312	form.
1313	MR JUSTICE BURTON: Let us see how it goes. The first point
1314	may be -- and I only raise Dr Gunson because he is on
1315	today -- hopefully if we can get some agreement on all
1316	the facts that are necessary for me to know about, it
1317	can then disappear from the witness statement. If we
1318	cannot do that, which we cannot before Dr Gunson is
1319	called, it may be that Mr Brown will get everything he
1320	wants from admissions by Dr Gunson in which case that
1321	may solve the problem for the future.
1322	MR UNDERHILL: May I focus on, if there is a point here,
1323	what it is? I do not quite see what point there could
1324	be on the defendants' side.
1325	MR BROWN: May I make it plain the point I seek to make and
1326	it is only one? My Lord, in HBV, I will not be taking
1327	any special point in relation to the speed with which
1328	HBV was introduced. I make that plain. I think I will
1329	be making a short point in relation to HIV in relation
1330	to the speed --
1331	MR JUSTICE BURTON: When you say "no special point", do I
1332	need to know, apart from the fact that the hepatitis B
1333	virus was discovered 15 years earlier by Dr Blumberg and
1334	that an antigen was discovered fairly shortly afterwards
1335	and then tests have been implemented such that hepatitis
1336	B and hepatitis A were eliminated from the problem by
1337	the early 1980s at the latest and yet another form of
1338	hepatitis still continued on which no one could
1339	decipher -- do I need to know anything else about A and
1340	B?
1341	MR BROWN: Your Lordship needs to know this about HBV: it
1342	is of importance, that the tests in relation to HBV were
1343	equally insensitive and unspecific, and indeed more so,
1344	but nonetheless they were introduced, and secondly that
1345	they did not wait for the best ones to come along
1346	because very quickly they were finding enormous
1347	improvements in later tests and introducing them as and
1348	when.
1349	MR JUSTICE BURTON: When you say "no specific point", you
1350	have those two general points?

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1351	MR BROWN: Those are the general points I seek to make.
1352	MR JUSTICE BURTON: You have said them now and no doubt they
1353	will be on the piece of paper in relation to HIV, and
1354	that aspect you no doubt may explore with Dr Gunson and
1355	he may agree with you in 10 minutes. On HIV --
1356	MR BROWN: My Lord, essentially I think there are three
1357	points and again I am on my feet and I was not prepared
1358	to deal with this, but the first point is the nature of
1359	the validation done in relation to HIV and your Lordship
1360	will recall I took you to a paper that dealt with that,
1361	A1/100. Secondly, the speed with which that was done,
1362	and third, it is the same point, the same sorts of
1363	objections about specificity, false positives, were all
1364	made at that time. My Lord, those are the three points
1365	I will be taking in relation to HIV.
1366	MR JUSTICE BURTON: I do not understand the first. Can you
1367	help me? I have the second one, which is speed and the
1368	third one, which is efficacy.
1369	MR BROWN: Yes.
1370	MR JUSTICE BURTON: What was the first point?
1371	MR BROWN: I took your Lordship to a document which I am
1372	99 per cent certain is A1/100 which you do not need to
1373	go to.
1374	MR JUSTICE BURTON: That is a sufficiently high sensitivity
1375	to make me think it is likely you are right.
1376	MR BROWN: The only point was this: the nature of the
1377	validation that was done in relation to HIV was what I
1378	described as a proper validation, two-stage; one, check
1379	it works and we can use it, then introduce it, then do
1380	your field research thereafter. What we say is that is
1381	what they should have done in relation to HCV. I took
1382	your Lordship to that document.
1383	MR JUSTICE BURTON: Is it a different point from speed and
1384	efficacy?
1385	MR BROWN: Perhaps not. I was on my feet, my Lord.
1386	MR JUSTICE BURTON: I think what I am understanding is this:
1387	on HBV the point is efficacy. That is they brought in
1388	the HBV tests before they were fully confident about
1389	their effectiveness. On HIV you have the same point on
1390	efficacy, but you also have a point on speed?
1391	MR BROWN: Yes. My Lord, I will take them very shortly.
1392	MR JUSTICE BURTON: That may mean either that the vast
1393	chunks -- I say vast in terms of relativity -- the vast
1394	chunks of statement in relation to hepatitis A, B and
1395	HIV, either I read as general background but are not
1396	challenged, or are positively agreed to come out from
1397	the evidence.
1398	MR BROWN: I think your Lordship needs the general
1399	background. I do not think anyone objects to the
1400	reading of it. The passages in Dr Carman which my

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1401	learned friend takes objection to are, in fact, four
1402	long citations from Dr Barbara amongst others:
1403	Dr Carman almost completely in his whole reports has
1404	quotations from other people's work.
1405	MR JUSTICE BURTON: At some stage I think we are going to
1406	need a carve-up on the statements so I can be told these
1407	parts are not coming in at all; if there are any, these
1408	ones are agreed and can be read by agreement, and that
1409	will save a lot of time.
1410	MR BROWN: I will move the piece of paper on HBV to the top
1411	of the pile for tonight.
1412	MR JUSTICE BURTON: Thank you.
1413	MR UNDERHILL: The last thing we said was a red herring was
1414	body parts. I heard the exchange between Mr Brooke and
1415	your Lordship. Indeed I think I said we were seeking
1416	instructions. We are still and that does not mean we
1417	are sitting back. Some discussions have taken place and
1418	more will. The point is being actively addressed. As
1419	soon as I have a position to state to your Lordship
1420	I will do so.
1421	Rather oddly, my learned friend kept referring, as
1422	one of Mr Underhill's red herrings, to the question
1423	about ALT testing and plasma.
1424	MR JUSTICE BURTON: That is not one of your red herrings.
1425	MR UNDERHILL: That is not one of my specified red herrings
1426	here. He is right I think in spirit that we have said
1427	in correspondence that we do not think this is going to
1428	assist the court very much, but it is a point that my
1429	learned friend wants to take in cross-examination and I
1430	cannot stop him. We will see where we go.
1431	My Lord, that is that. Then the last substantial
1432	task that I have not yet done -- and I am not going to
1433	do in great detail -- is address your Lordship about the
1434	facts in the post-A day period, effectively what took
1435	the time between early 1990 and September 1991.
1436	My learned friend -- no objection to this at
1437	all -- he approached his opening what I might call
1438	thematically. That involved quite a lot of backwards
1439	and forwards. What your Lordship has not yet had is a
1440	systematic, chronological introduction to the facts.
1441	I am not going to do that now. I need to do it with
1442	Dr Gunson, subject only to this: that in a moment
1443	I will show your Lordship a chronology and just try to
1444	divide it into certain stages.
1445	MR JUSTICE BURTON: Thank you.
1446	MR UNDERHILL: There is not very much I need to say about
1447	the facts. I just want to make a number of particular
1448	points, and for the first your Lordship will need what I
1449	call annex 5, which I think is up-to-date. It contains
1450	a paper of my authorship and it is 5.1, and it applies

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1451	really to all stages of the evidence, called the
1452	seriousness of infection with HCV/non A non B. As your
1453	Lordship identified to my learned friend, that is
1454	actually an ambiguous phrase, because there are two
1455	aspects to seriousness: one, how prevalent is the
1456	condition in the population, which is the subject of my
1457	second paper, its prevalence, and how serious is the
1458	infection when you get it. This is concerned only with
1459	the second of those questions. I am not going to read
1460	the whole thing through with your Lordship. I might ask
1461	your Lordship, if your Lordship has any time out of
1462	court, to read it at an early stage.
1463	MR JUSTICE BURTON: I think I have read it. I have
1464	certainly speedread it.
1465	(12 noon)
1466	MR UNDERHILL: Can I go through it, not reading it all out,
1467	but just making clear what the points being made are?
1468	The first paragraph simply makes this point, which your
1469	Lordship has known from the start -- I will at least
1470	read the first sentence of it:
1471	"It is a striking feature of infection with HCV
1472	that the great majority of those infected at any given
1473	time (including the claimants) are either entirely
1474	asymptomatic or (at most) suffer from unspecific
1475	complaints"; that is not a derogatory term, it is a
1476	technical term, "e.g. tiredness, which do not prevent
1477	them leading reasonably normal lives."
1478	There has been reference to that in some of the
1479	papers your Lordship has seen and perhaps I will read on
1480	a little further:
1481	"Most of those infected only know they are
1482	infected because doctors have told them so, on the basis
1483	of laboratory tests carried out as part of the lookback
1484	exercise."
1485	What your Lordship knows is most, not all, of the
1486	claimants in this case were identified and know they
1487	have HCV because the Department carried out an exercise
1488	of looking at infected donors turning up after 1991, and
1489	seeing all the people in the past who have had blood
1490	from that donor.
1491	MR JUSTICE BURTON: Some of the people may have said: I now
1492	realise why I have been feeling X, Y and Z; but others
1493	may have been entirely symptomless at least until that
1494	date.
1495	MR UNDERHILL: Yes. Again, this is a very delicate area,
1496	because I do not want in any way to downplay the
1497	seriousness of this disease, but one has to acknowledge
1498	also the human risk, the people who would say, "I now
1499	know why I have been feeling X, Y and Z" are actually
1500	making a false association.

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1501	MR JUSTICE BURTON: They may be.
1502	MR UNDERHILL: As we say at the end of this, and I do want
1503	to emphasise this, because it is easy -- I do not think
1504	my learned friends would do this -- for my position to
1505	be mis-characterised as an unsympathetic or a
1506	downplaying one, which it is not. We fully accept the
1507	"minor", and I put minor in quotes to make that point,
1508	"the minor symptoms (where proved) and/or the knowledge
1509	of infection" and I make the point the two may be
1510	interrelated.
1511	One reason why you may be feeling lousy is the
1512	effect of this knowledge on you that can in some cases
1513	actually lead to a depressive illness are significant
1514	matters. Your Lordship is going to be hearing about that
1515	on quantum. "Nevertheless the most serious aspect of
1516	HCV infection is unquestionably the risk that the
1517	infected person may at some stage progress to serious
1518	liver damage."
1519	That is what the rest of that paper is about:
1520	"The purpose of the note is to summarise the
1521	evidence about how serious that risk really is and
1522	[importantly] the varying perceptions at different times
1523	about the seriousness of infection with HCV and NANB."
1524	These are relevant to, one, damages, but two, this is
1525	why I need to deal with it now:
1526	"The seriousness of infection with HCV/NANB,
1527	actual and perceived, is relevant to the issues whether
1528	surrogate testing should have been introduced or HCV
1529	screening introduced earlier."
1530	We then go through some basic concepts under head
1531	4, and we make this point; again perhaps it is worth
1532	making though I know your Lordship knows it but it has
1533	to be focused on:
1534	"Prior to the discovery of HCV, that is the actual
1535	virus, 'hepatitis' (which means inflammation of the
1536	liver) which nearly always diagnosed on the basis of
1537	persistently raised ALT levels: that is, they were
1538	diagnosed on a laboratory test (typically as part of a
1539	study of some kind), not as a result of a patient
1540	turning up saying: "Doctor, I feel ill", or "Doctor,
1541	I have jaundice." As we say in the footnote:
1542	"There were of course cases of patients presenting
1543	with post-transfusion jaundice 'icteric hepatitis' which
1544	was thought to be due to NANB, but these were very
1545	rare."
1546	So this is a laboratory diagnosed disease,
1547	diagnosed only in the great majority of cases in people
1548	who are being looked at for evidence of it.
1549	Then, as your Lordship knows:
1550	"A raised ALT level found on a given occasion may

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1551	be due to one or more of a number of reasons, but
1552	persistently raised levels may mean there is a chronic
1553	disease process at work, you cannot tell for certain
1554	whether that is so unless you take a biopsy and see
1555	changes."
1556	MR JUSTICE BURTON: This is because the alcohol and/or the
1557	fat level lead to not only raised ALT levels but also
1558	lead to damage to the liver which can lead to jaundice,
1559	so neither liver damage nor jaundice necessarily
1560	indicate hepatitis.
1561	MR UNDERHILL: We all know cirrhosis of the liver which is
1562	one of the possible consequences of NANB is also a
1563	well-known consequence of alcoholism.
1564	In section 5 we set out what I hope is some
1565	controversial material simply about what chronic liver
1566	disease is. We see:
1567	"Chronic inflammation", a phrase often found in
1568	the papers is "chronic active hepatitis", which I
1569	understand to be effectively the same as chronic
1570	inflammation, "may in due course lead to fibrosis of the
1571	liver tissue which can be detected on a biopsy.
1572	Fibrosis will not in itself cause symptoms and does not
1573	as such constitute serious liver damage."
1574	MR JUSTICE BURTON: Can I ask you this: leave aside your
1575	understandable, indeed all our shared sensitivity about
1576	not causing any upset to those 130-odd plaintiffs who
1577	have this problem for which they are suing, so forget
1578	that for the moment. It is most important that we do
1579	not have to mince words in the course of litigation if
1580	we can avoid doing so, so let me take you back to the
1581	point you make on page 2 about the seriousness of
1582	infection being relevant to the issues whether surrogate
1583	testing should have been introduced, i.e. you are coming
1584	back to your balancing.
1585	Can you help me as to what you mean or where in
1586	the balancing act it comes? Is it that you are saying
1587	that, because the effects were not that serious or
1588	because they were only serious in a very, very small
1589	minority of cases, that meant that the risks could be
1590	accepted or could be -- it was one of the weighing
1591	scales? If so, how does it compare if it is relevant at
1592	all, as Mr Brown has put it, to HIV?
1593	MR UNDERHILL: I am saying both, and it is clear that,
1594	though a much more common disease, it is a much less
1595	serious disease than HIV. We all know -- I am no expert
1596	on HIV -- nearly everybody -- there are some fortunate
1597	exceptions -- who is infected with HIV eventually gets
1598	AIDS, a very unpleasant illness, and dies. That is
1599	certainly not the experience with HCV.
1600	MR JUSTICE BURTON: It is a test which, if you are right, is

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1601	part of the circumstances I have to bear in mind?
1602	MR UNDERHILL: Yes.
1603	MR JUSTICE BURTON: It comes to that "only" X per cent of
1604	those with hepatitis C have a sufficiently severe
1605	disease to die of it, whether it is cirrhosis or liver
1606	cancer.
1607	MR UNDERHILL: Even to get seriously ill. I am putting on
1608	one side with all the caveats, the "minor" symptoms.
1609	I am talking about serious liver disease, liver
1610	disease. I am not simply saying most people do not die
1611	of it. I am saying most people do not even progress to
1612	serious liver symptoms.
1613	One of the reasons why it is terribly important to
1614	make this point in opening is you go through the
1615	documents, you see references which jar, particularly in
1616	the early stages, but at all stages, how serious a
1617	disease is this? You are wondering what on earth these
1618	people meant. But, in fact, they meant something
1619	perfectly sensible, particularly in the early days when
1620	not very much was known about it. It was very unclear
1621	then. It is not even entirely clear now, which is one
1622	of the reasons why they are going for provisional
1623	damages, how many of these people will actually get
1624	seriously ill.
1625	MR JUSTICE BURTON: Can you give me a percentage?
1626	MR UNDERHILL: It is in here, as far as it is known.
1627	MR JUSTICE BURTON: We will come to it. In terms of the
1628	kind of balancing act we are talking about, which
1629	Mr Brown -- I think even Mr Forrester, though I do not
1630	know -- would accept one may have to look at. Mr Brown
1631	certainly accepted that he would not say, or indeed it
1632	would be very difficult to say that one should have
1633	introduced a test if there was 5 per cent sensitivity
1634	and 5 per cent specificity, and 50 per cent or more
1635	wastage, something of that kind. If one adds to that
1636	the fact that all you would thereby be eliminating would
1637	be an itchy back then that goes into the --
1638	MR UNDERHILL: That goes into the pot. Again, I am very
1639	anxious not to be misunderstood on this. I am not
1640	saying that by the time that surrogate testing was being
1641	considered nobody thought it was ever serious. There
1642	are plenty of contemporary quotes, including from
1643	Dr Gunston, everyone, that in some cases -- and everyone
1644	was trying to guess how many cases -- hepatitis non A
1645	non B could lead to cirrhosis. But nobody knew how
1646	many.
1647	There was a suggestion from Dr Alter no less. It
1648	was what he called a mild form of cirrhosis. Even
1649	cirrhosis is not a symptomatic condition until it
1650	progresses to a stage called decompensated cirrhosis.

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1651	Your Lordship will forgive me if I am talking in
1652	broadbrush terms. I am sure there are some refinements
1653	that can be made to that: but, yes, that is the point.
1654	We say in 5 there are various ways of grading
1655	fibrosis of the liver. At the end of 5 we say:
1656	"Only patients graded 4 or 5 are likely to develop
1657	serious symptoms."
1658	Your Lordship's point:
1659	"Fibrosis may of course be caused by many other
1660	things, including excess alcohol."
1661	Then under the heading "Serious Liver
1662	Damage/Cirrhosis":
1663	"Cirrhosis refers to irreversible liver damage as
1664	a result of fibrosis: it is equivalent to
1665	Dr Alexander's stage 4 and is what is referred to in
1666	this Note as 'serious liver damage'. At this point the
1667	disease is inevitably progressive; but even so a patient
1668	with cirrhosis is not necessarily symptomatic. It may
1669	be very many years before he or she reaches 'stage 5'
1670	(broadly equivalent to what is called 'decompensated
1671	cirrhosis'), where the liver can no longer cope and the
1672	patient will certainly develop serious symptoms,"
1673	jaundice, something called ascites, something my learned
1674	friend mentioned, "and the prognosis (unless a
1675	transplant is performed) is very poor."
1676	MR JUSTICE BURTON: It says it may be very many years before
1677	the patient reaches stage 5. Is it accepted that,
1678	subject of course to the patient otherwise surviving, it
1679	will lead to stage 5 or may in some patients,
1680	assuming --
1681	MR UNDERHILL: Putting it very crudely, they may die first
1682	of other reasons. That is very common.
1683	MR JUSTICE BURTON: Assuming they die first of other
1684	reasons, will they stop at stages 1, 2 or 3 or will the
1685	virus, even if treated, inevitably lead on to stage 5?
1686	MR UNDERHILL: My Lord, this is a difficult question, which
1687	I some time ago tried to get to the bottom of with
1688	Dr Alexander, and I think if it is important it will
1689	have at some point to be considered with Dr Alexander or
1690	Dr Dusheiko, the two hepatologists your Lordship will be
1691	hearing. But the broad picture, as I understand it,
1692	very much subject to correction by the experts, is
1693	firstly that this condition -- given it is a condition
1694	with a very long natural history -- has not actually
1695	been known and studied for long enough to be absolutely
1696	clear, but I think the broad picture is as I have put it
1697	in paragraph 6 that when you have fibrosis of the lower
1698	stages, you do not necessarily ever get any worse. Some
1699	people do; some people do not.
1700	MR JUSTICE BURTON: I understand. Once you move to

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1701	fibrosis, to cirrhosis --
1702	MR UNDERHILL: I believe that the hepatologist will tell you
1703	cirrhosis is probably always progressive, but the rate
1704	may vary enormously, and at some point it almost becomes
1705	a theological question. It may be progressive, but if
1706	it is progressive over 20 years and you have got it in
1707	mid-life, you may as well say it is not progressive,
1708	because progressive at the rate your life is finished
1709	first -- that is the sort of area we are in.
1710	MR JUSTICE BURTON: Sadly not in some cases.
1711	MR UNDERHILL: Absolutely not. This is what I keep wanting
1712	to emphasise. I am not trying to pooh-pooh this
1713	disease. For those to whom it turns nasty, it is very
1714	serious.
1715	MR JUSTICE BURTON: Does that depend on the amount of blood
1716	they have had?
1717	MR UNDERHILL: I believe it is thought not, no. Again,
1718	there are studies of what are the cofactors. If you
1719	have HCV, what sorts of things are likely to make you
1720	more likely to progress or to progress quickly: your
1721	sex is one of those, whether you drink is a very
1722	important one, and the rate of progression is much
1723	slower, epidemiologically, for people who do not drink.
1724	The first thing you tell someone when they are diagnosed
1725	with HCV is to stop drinking; that makes an awful lot of
1726	difference to the outlook. Age.
1727	MR JUSTICE BURTON: The older, the slower?
1728	MR UNDERHILL: The older, the quicker. That may be to some
1729	extent balanced by the fact that, as you are old, you
1730	are more likely to develop other conditions, and
1731	particularly in this group of patients who -- some of
1732	them of course it was just road accidents, but many of
1733	them were for example heart surgery -- were people who
1734	had other conditions anyway.
1735	MR JUSTICE BURTON: Then they have to cope with the problem
1736	of an organ which is not functioning properly.
1737	MR UNDERHILL: Yes. Then in 7 we say:
1738	"The current state of knowledge about the natural
1739	history of HCV infection is described in the evidence of
1740	Dr Alexander."
1741	It is also, to be fair, referred to by Professor
1742	Dusheiko, but he was not largely focusing on this
1743	question, but he does not say much, but he does say a
1744	bit.
1745	"It will be seen that he points out that there is
1746	a fundamental distinction between our understanding of
1747	the disease pre- and post- the development of adequate
1748	tests for HCV. After summarising some of the pre-1991
1749	studies, which appeared to show a grave prognosis in a
1750	high proportion of cases, he says (at page 21):

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1751	"'The natural history of hepatitis C defined
1752	following the introduction of routine testing in 1991
1753	sheds a different and more benign light on outcome.
1754	This more benign course was predictable in view of the
1755	fact that non-A non-B hepatitis followed transfusion
1756	from donors who were seen and known to be healthy, often
1757	had normal ALT levels and yet were clearly infectious'."
1758	He is making the obvious point, if you had to
1759	guess, you have this population of donors out there, but
1760	by definition, they appeared fine, otherwise they would
1761	not be giving blood in the first place. He refers to a
1762	series of recent studies:
1763	"These do not all express the risk in the same way
1764	and it is impossible to summarise them accurately in
1765	'headline' terms."
1766	MR JUSTICE BURTON: Can you help me with this, the whole
1767	case is about post-transfusion hepatitis which was
1768	eliminated in 1991 with the hiccups we know about. What
1769	is the position in terms of hepatitis C other than post
1770	transfusions?
1771	MR UNDERHILL: That is a very good question. I do not
1772	know. Maybe Mr Brooke will remember. Certainly one of
1773	the questions that has been looked at is whether
1774	sporadic NANB, which is the name given for
1775	non-transfusion associated, has a better or worse
1776	prognosis than transfusion associated hepatitis. My
1777	recollection -- but I will be corrected from all
1778	sides -- is that there has not been found to be a
1779	difference. I could be wrong about that.
1780	MR BROWN: I think there are papers relating to this. We
1781	had all better look at them.
1782	MR JUSTICE BURTON: Sporadic, by mouth?
1783	MR UNDERHILL: By far the most likely form of sporadic is a
1784	needle injection. There are broadly -- transfusion
1785	associated until 1991, needle injection throughout and,
1786	as the studies show, a surprisingly high proportion,
1787	still obviously small, of iatrogenic -- perhaps that is
1788	a too pompous way of putting it -- basically people
1789	getting it in hospital, obviously small, but more than
1790	you would think, doctors accidentally having blood from
1791	patients, patients accidentally having blood from
1792	doctors. Every now and then they appear in the
1793	headlines, do they not, that HCV or HB sometimes, it can
1794	be either, doctors have infected some patients. The
1795	poor doctor probably got it from a patient in the first
1796	place, so blame, if he is to blame, is not all one way.
1797	That is much smaller. We are really looking
1798	historically at two main sources: transfusion and
1799	people who injected drugs.
1800	Sexual transmission is very, very rare indeed.

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1801	There may be other sources; if so they are going beyond
1802	the limit of my knowledge.
1803	Dr Alexander, we say, refers to a series of recent
1804	studies. Your Lordship not going to have to worry about
1805	this. This is exactly what provisional damages will
1806	do. The studies are still at an early stage and will be
1807	proved right or wrong in the results, but in two large
1808	studies of HCV infected patients the numbers who had
1809	progressed to cirrhosis at the time of the study, after
1810	many years, were respectively, one, 2 per cent and the
1811	other, 11 per cent.
1812	MR JUSTICE BURTON: I have to be interested from your point
1813	of view on what the state of thought was between 1988
1814	and 1991.
1815	MR UNDERHILL: Precisely, my Lord. Because this paper had
1816	two roles, one was a background one, I am here dealing,
1817	as I hope is made quite clear by the heading, with the
1818	seriousness of HCV infection as now known, and I proceed
1819	in a page and a half's time to past perceptions.
1820	MR JUSTICE BURTON: That goes to quantum.
1821	MR UNDERHILL: This will go to quantum but perhaps, just so
1822	your Lordship has the picture, we can look at paragraph
1823	9. There has been a much quoted study by Seeff, one of
1824	the main people in this field, which has followed a
1825	group of 17 HCV positive servicemen who were infected
1826	between 1948 and 1954, and it has been possible from
1827	stored samples -- it is wonderful what you can do in the
1828	United States; their blood was still sitting somewhere,
1829	frozen, 30 years later. They tested a huge batch of
1830	army samples. They found 17 who were HCV positive.
1831	They have followed them through ever since then. Two of
1832	them have developed serious liver damage after 45
1833	years. Only one of them died from liver disease. The
1834	authors observe:
1835	"If our data represent an accurate estimate of the
1836	frequency and rate of progression of chronic HCV
1837	infection, only a small fraction of HCV-infected persons
1838	progress to end-stage liver disease."
1839	MR JUSTICE BURTON: That is very good news for those
1840	claimants who are not already suffering from liver
1841	damage.
1842	MR UNDERHILL: Yes, that is right.
1843	"The current concern that such a progress is
1844	common or inevitable may be a result of the fact ..."
1845	Anyway, for liability your Lordship is more
1846	interested in the second part of this note, past
1847	perceptions of the seriousness of HCV/NANB:
1848	"When post-transfusion hepatitis NANB was first
1849	recognised as a distinct disease in the 1970s, it was an
1850	entirely laboratory-based diagnosis. All that was known

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1851	was:
1852	"(a) that the 'sufferers'", I put that in quotes
1853	not in any derogatory way, "had persistently raised ALT
1854	levels, which was likely to be (though it was not
1855	necessarily) an indication of an inflammatory process in
1856	the liver;.
1857	"(b) that they were not clinically ill;.
1858	"(c) that [they] had a history of transfusion,
1859	which was most likely (though by no means certain) to be
1860	the cause of the inflammatory process", that is drink,
1861	drugs, other possible causes.
1862	"No one knew whether, when, or in how many cases
1863	that disease process might develop into serious
1864	illness. On any view the numbers predicted by studies
1865	such as [the two earlier studies] as being infected ...
1866	were not reflected in patients presenting themselves
1867	with clinical disease.
1868	"Against this background, the initial perception
1869	was that 'hepatitis NANB' was a relatively benign
1870	condition, or at least there was no evidence to suggest
1871	otherwise."
1872	I have some headline points here. No doubt the
1873	papers will be gone to in the evidence so far as is
1874	necessary. Conrad, an American author, from 1981:
1875	"It is highly unlikely that liver disease is
1876	progressive in the vast majority of these patients. If
1877	it was progressive, we would anticipate the development
1878	of more than 100,000 patients annually with clinical
1879	chronic active hepatitis or cirrhosis in the United
1880	States. Since this is not the case, we may presume that
1881	the complication resolves spontaneously in the majority
1882	of patients."
1883	That turned out to be wrong, but that was a
1884	typical early perception. The theme of the next one is
1885	just an English study relating specifically to
1886	haemophiliacs, sufficiently stated by its title "Liver
1887	Disease in Haemophiliacs: An Overstated Problem?"; the
1888	paper my learned friend referred you to was "Liver
1889	Disease in Haemophiliacs: An Understated Problem?",
1890	about five years later.
1891	Bayer, contributing to something called the Vox
1892	Sanguinis debate which your Lordship will see, a debate
1893	in the leading journal of haematology about whether or
1894	not ALT screening should be introduced. One of the
1895	contributors said:
1896	"We must remember ... that infection in itself
1897	does not mean disease ... The long range effects in
1898	terms of the amount of liver caused debilitation in
1899	populations that have had an infection with NANB is not
1900	known other than to say that it does occur."

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1901	Collins is a paper we come to:
1902	"We conclude that non-A, non-B hepatitis after
1903	blood transfusion from a largely British blood donor
1904	group probably leads to clinically significant chronic
1905	liver disease very rarely indeed."
1906	I am not at the moment saying all these were
1907	justified but those were typical early perceptions.
1908	Reading on:
1909	"However, it was fairly soon established that a
1910	significant proportion of patients with persistently
1911	raised ALTs did on biopsy show signs of 'chronic active
1912	hepatitis'", that means a continuing inflammatory
1913	process in the liver, "with some cases of cirrhosis. By
1914	the mid-1980s, it was generally accepted that hepatitis
1915	NANB could sometimes have serious consequences. Thus
1916	Alter [who your Lordship has heard is very much --
1917	protagonist is the wrong word, someone very interested,
1918	one of the leading figures in the field] summarised his
1919	perception at a paper we are going to be going to. He
1920	suggested -- tentatively --
1921	MR JUSTICE BURTON: Protagonist means in the front rank of
1922	the contest.
1923	MR UNDERHILL: That is not actually quite right, because
1924	oddly enough he was not in the front rank of the contest
1925	for introducing screening. He was rather cautious about
1926	it.
1927	" ... summarised his perception of the position
1928	at this time in the paper .... He suggested --
1929	tentatively -- that 5 per cent of infected recipients
1930	might progress to cirrhosis ["10 per cent of those
1931	developing chronic ALT elevations" is my footnote]
1932	though he observed that that cirrhosis appeared to be
1933	'milder and less clinically apparent than that which
1934	evolves in the alcoholic patient'. But he recognised
1935	that these figures were frail.
1936	MR JUSTICE BURTON: Is that right, 5 per cent of infected
1937	recipients progressing?
1938	MR UNDERHILL: Even now we still do not know. He got to it
1939	by a route which almost certainly is not right. The
1940	figures I showed your Lordship in Dr Alexander's -- we
1941	have two -- if you go back to page 4, paragraph 8, the
1942	first bullet point:
1943	"In two large studies ... the numbers who had
1944	progressed to cirrhosis were respectively 2 per cent and
1945	11 per cent."
1946	So it is bang in the middle. Another way of
1947	calculating it, which assumes that it is all ultimately
1948	progressive, is you calculate a so-called average time
1949	to cirrhosis.
1950	MR JUSTICE BURTON: What about liver cancer; is that a

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1951	separate number?
1952	MR UNDERHILL: That is separate. There is no doubt that the
1953	activity of the virus in the liver which is leading to
1954	the fibrosis, also in some way I do not understand, and
1955	I rather suspect nobody understands, in some way
1956	triggers a cancer process.
1957	MR JUSTICE BURTON: That is on top, is it?
1958	MR UNDERHILL: That is on top, yes, but that is a much
1959	smaller number. Again, it does happen. Mr Brooke says
1960	it takes longer to get to that stage.
1961	My Lord, paragraph 14, we say:
1962	"Higher figures for the development of cirrhosis
1963	were found in some later studies of post-transfusion
1964	NANB; but the figures varied and all pre-date the
1965	identification of the HCV virus."
1966	It was really very difficult, until you could
1967	identify the virus, to get any handle on the numbers.
1968	MR JUSTICE BURTON: And still difficult even now.
1969	MR UNDERHILL: Still difficult even now:
1970	"There was thus by the late 1980s a recognition
1971	that in some cases NANB could lead to serious liver
1972	damage ..."
1973	MR JUSTICE BURTON: As is very often the case in this
1974	litigation, very often it may be that this case itself
1975	will generate the kind of research that others can rely
1976	on. We have 130 sufferers here.
1977	MR UNDERHILL: Absolutely, yes. I honestly cannot say about
1978	that. I do not know whether they are being studied as a
1979	group. Obviously their consent would be required.
1980	My Lord, there was thus by the late 1980s, a
1981	recognition that in some cases NANB could lead to
1982	serious liver damage; but it was acknowledged that such
1983	cases were comparatively few -- just how few was
1984	unknown.
1985	The reason I have spent time on this is, when one
1986	sees, as one does in the contemporary documents,
1987	cautious noises about how serious this disease was, they
1988	were not silly or callous; they were reflecting a
1989	genuine uncertainty in the scientific community as to
1990	whether this was going to be a real problem for
1991	patients, and in particular an acknowledgment, partly
1992	anecdotal, partly supported by studies though not many,
1993	that, putting it crudely, where are these patients?
1994	They are not actually crowding out the liver doctors'
1995	clinics, people are not turning up with jaundice,
1996	cirrhosis, which appears to be -- in large numbers,
1997	therefore a puzzle as to how serious it is going to be.
1998	That does not prove much. It may just turn out to be
1999	the case that it is a very long lasting disease. But
2000	there is a genuine state of real doubt about this.

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2001	My Lord, that is the seriousness paper. Behind it
2002	is a prevalence paper. Your Lordship has been over this
2003	very fully with my learned friend and I think we are all
2004	now, at least when we remember, using these terms in the
2005	right sense, or at any rate in a consistent sense.
2006	Prevalence is how often you find HCV or hepatitis non A
2007	non B in the donor population. Incidence is how often
2008	people get infected.
2009	MR JUSTICE BURTON: Prevalence is the existing state of
2010	things and incidence is new cases; is that right?
2011	MR UNDERHILL: That is one way of putting it, yes. I am not
2012	sure it is the most helpful way of putting it.
2013	Prevalence is simply looking at 1,000 donors and saying
2014	how many of these have the disease.
2015	MR JUSTICE BURTON: Is that not the existing state? It is a
2016	status situation. It is static. I do not know whether
2017	I can say that, but prevalence is static and incidence
2018	is dynamic.
2019	MR UNDERHILL: I will think about that, my Lord. Your
2020	Lordship may well be right. Incidence is obviously
2021	completely related to prevalence, especially as we now
2022	know -- though this was not known at the time -- that
2023	virtually every true positive is infective. Virtually
2024	every donor who has the viruses passes it on. In a
2025	small proportion of cases -- this is another point --
2026	the recipient clears it and does not become ill again,
2027	it does not recur. That is unusual. In most cases, in
2028	all cases as far as we can tell, the virus goes over.
2029	MR JUSTICE BURTON: So you can never get rid of the
2030	hepatitis C virus?
2031	MR UNDERHILL: That is not quite the same point. You can
2032	get rid of the virus in that small proportion of cases.
2033	You may be able to get rid of it in treatment. Again,
2034	that is why a lot of these people have Interferon
2035	treatment which clears the virus. Some of these
2036	claimants had the virus and have not got it any more.
2037	One of them had the virus, it was cleared, but appears
2038	to have come back which may suggest it was not cleared
2039	in the first place but was merely at an undetectably low
2040	level. Broadly speaking what your Lordship says is
2041	right.
2042	MR JUSTICE BURTON: If one starts with a prevalence of 0 and
2043	someone with hepatitis C arrives from abroad, you then
2044	have a prevalence of 1 and an incidence of 1 in that
2045	year. Then there are 5 new cases as a result of
2046	infection and next year you have a prevalence of 6 and
2047	an incidence of 5. Is that right? Then next year you
2048	have 10 new cases so you have a prevalence of 16 and an
2049	incidence of 10 -- do I have the picture right -- unless
2050	someone ceases to have it, in which case he drops out of

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2051	the prevalence picture.
2052	MR UNDERHILL: I suppose that is right. I think what your
2053	Lordship is saying is that every time the donor donates,
2054	he will give it to a different recipient.
2055	MR JUSTICE BURTON: He remains part of the prevalence but
2056	the incidence is only the recipient. Looked at for
2057	post-transfusion hepatitis -- of course there are other
2058	forms as well.
2059	MR UNDERHILL: I am told your Lordship is right.
2060	MR JUSTICE BURTON: Then I will use, rightly or wrongly,
2061	prevalence as being static and incidence as being
2062	dynamic.
2063	MR UNDERHILL: Very well. That is fine.
2064	(12.30 pm)
2065	At any one point, taking a snapshot, the ratio
2066	between prevalence and incidence will depend on how many
2067	units are transfused. If one unit is transfused to one
2068	recipient, that recipient has the same chance of being
2069	infected as the proportion of donors in the population.
2070	MR JUSTICE BURTON: We are talking about PTH only.
2071	MR UNDERHILL: That is right. If he has two or three units,
2072	then his chance goes up, and if you are looking at a
2073	high transfused population, the incidence will be much
2074	more than the prevalence.
2075	Item 4:
2076	"The studies in the US showed widely varying
2077	incidence of NANB among recipients. The figures quoted
2078	in the study varied from 18 per cent to 4 per cent ..."
2079	MR JUSTICE BURTON: Can I ask about virulence? Is it a
2080	certainty that if a donor with hepatitis C donates blood
2081	the recipient will get hepatitis C?
2082	MR UNDERHILL: Yes, a virtual certainty. I am being told
2083	no. I had understood that -- although there may be rare
2084	exceptions -- the positive person with virus in their
2085	blood almost always infects.
2086	MR BROWN: Almost always, yes.
2087	MR JUSTICE BURTON: General yeses all round. So that is not
2088	part of your balancing factors that I need to consider.
2089	MR UNDERHILL: That was not known at the time. You can only
2090	tell that when you -- at the time, we can see plenty of
2091	studies suggesting that a lot of them did not infect.
2092	MR BROWN: Because they were the false negatives.
2093	MR UNDERHILL: We now know -- perhaps I can make this
2094	point --
2095	MR JUSTICE BURTON: I do not want to raise a hare which is
2096	not there.
2097	MR UNDERHILL: Perhaps could I make this point, which I have
2098	skipped over, paragraph 3:
2099	"Prior to the emergence of a test for HCV,
2100	prevalence in donors could not be measured. The only

	A
2101	thing you could measure was the incidence of non A non B
2102	in recipients ..."
2103	MR JUSTICE BURTON: The incidence in recipients of a raised
2104	ALT level or of symptomatic hepatitis.
2105	MR UNDERHILL: Exactly right, my Lord, of which the former
2106	is by far the more significant, because the other cases
2107	are extremely rare. Yes, that is absolutely right. You
2108	can only do that in large prospective studies where you
2109	look at recipients and the recipients agree to come back
2110	and have their blood tested over a long period. (b):
2111	"The measurement was imprecise and indirect
2112	because it was dependent on persistently-raised ALT
2113	levels."
2114	That is what we have been discussing.
2115	On that basis incidence in the United States was
2116	thought to average 10 per cent, higher in some places,
2117	less in others. Incidence rates in other countries
2118	range from Japan where it is huge, probably the reason
2119	why they rushed in with the test as early as they did,
2120	but that is by the by, a different figure for Sweden and
2121	very low in the Netherlands.
2122	MR JUSTICE BURTON: If we had not had heat testing almost
2123	fortuitously, then the real danger would have been when
2124	one person's blood was mixed with others and given to
2125	hundreds of different people.
2126	MR UNDERHILL: That is why haemophiliacs and indeed I think
2127	before heat treatment, that is why haemophiliacs did get
2128	liver disease, that is absolutely right.
2129	"Only two such studies [of incidence] (of a
2130	limited nature) were done in the UK.
2131	The first is one by Collins. I suspect we are
2132	going to hear a bit about that and I am not going to
2133	deal with it now. That, however, for what it is
2134	worth -- I think everyone agrees it is not an ideal
2135	study, but it is the best there was -- suggested an
2136	incidence of around 3 per cent, and if you wanted to
2137	work out the prevalence, since they were all people who
2138	were having heart transfusions and had a lot of blood,
2139	an average of 6 units per person, that equated to a
2140	prevalence of about half a per cent. That was a study
2141	done in the early 1980s. As we say over the page, at
2142	the top of page 3:
2143	"There was reason to believe that by the late
2144	1980s that that rate of incidence/prevalence (already
2145	low by international standards) would have gone down
2146	markedly as a result of stricter donor exclusion
2147	policies; but it was unknown by how much."
2148	I think it has been referred to more than once,
2149	but just so I can focus on it, because of the AIDS
2150	scare, if I can call it that, the blood transfusion

	A
2151	services all over the world very much tightened up their
2152	criteria on who could give blood. They asked more
2153	elaborate questions and excluded much larger groups.
2154	The result was, as was found in the United States and
2155	was almost certainly the case in the UK as well, that a
2156	lot of people who were carriers of hepatitis C were
2157	screened out although it was principally aimed at people
2158	with HIV.
2159	The other study was done in 1981/1983 reported by
2160	Anderson et al, and that appeared to show only 0.5 per
2161	cent ALT above the levels which were used in the
2162	American studies.
2163	"It only became possible to establish the true
2164	position once a definitive HCV test ... was available.
2165	As to that the key studies are ...", these ones that we
2166	have set out here: Contreras and Barbara found only 1
2167	out of a group of 1,284 was positive, another figure
2168	over the page, found 3 out of 9,000, and probably the
2169	most definitive one, certainly the largest study, 6 out
2170	of 10,000, which I think is the figure I gave to your
2171	Lordship.
2172	MR JUSTICE BURTON: These are when?
2173	MR UNDERHILL: These are 1991.
2174	MR JUSTICE BURTON: If we are looking at your basket,
2175	whatever it is, weighing scales --
2176	MR BROWN: My Lord, my learned friend is I am sure going to
2177	make it plain. The work on all of these was done in
2178	1988/1989, not written up until 1991/1992.
2179	MR UNDERHILL: Yes, I think that is right.
2180	MR JUSTICE BURTON: That is very fair, Mr Brown. Thank
2181	you.
2182	MR UNDERHILL: Yes, that is right. I am not sure about 1988
2183	or even 1989, but they were done in 1990. The point I
2184	make at the beginning --
2185	MR JUSTICE BURTON: It does not matter to me at the moment.
2186	The question I was going to ask is, if we are looking at
2187	your weighing scales or basket, together with all the
2188	factors you have thrown in -- you have thrown in this
2189	morning seriousness of effects or seriousness of
2190	consequences -- is prevalence then also in the basket,
2191	that is against the cost and wastage and the lack of
2192	sensitivity and specificity and the lack of serious
2193	consequences or with them also throws in the fact that
2194	not many of our population are affected by it anyway.
2195	Is that what you are putting?
2196	MR UNDERHILL: Exactly so.
2197	MR JUSTICE BURTON: So from that point of view we are only
2198	interested in 1988/89/90, are we not, perhaps 1987.
2199	MR UNDERHILL: That is right. These are to some extent ex
2200	post facto --

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2201	MR JUSTICE BURTON: We would need to look at the earlier
2202	ones because they would also be considered between 1988
2203	and 1991, but we would not be interested in anything
2204	after 1991.
2205	MR UNDERHILL: Yes. Once HCV screening came round, the
2206	latest figure for the UK population was the one in the
2207	Anderson study which I referred to, on page 3, item 2,
2208	which is 0.5 per cent incidence.
2209	My Lord then really just an obvious point, but we
2210	say:
2211	"These studies [the 1990 studies which are
2212	summarised at the bottom of page 3, the top of page 4]
2213	will somewhat underestimate the prevalence because the
2214	first generation ELISA was only, say, 65 per cent
2215	effective. Adjusting for that [and just doing the
2216	arithmetic] would give a true prevalence ... of between
2217	1 in 1,000 and 1 in 2,000."
2218	That is probably all your Lordship needs to know,
2219	because as your Lordship rightly says that figure only
2220	became clear -- it became clear before we finally
2221	introduced screening, but it did not become clear in the
2222	early stages of the debate.
2223	MR JUSTICE BURTON: Of course, what you have to deal with on
2224	this basket point, as I put to you some days ago, is
2225	that it is all well and good if you have never
2226	introduced it. Really you take the view that it is not
2227	that serious, and it is not that prevalent, so we will
2228	not introduce tests at all. Once you accept that you do
2229	introduce tests, then this can only go to the speed with
2230	which you had acted.
2231	MR UNDERHILL: Your Lordship is entirely right. That
2232	perhaps conveniently brings me to where I was about
2233	to -- your Lordship has now had annex 4 handed up.
2234	Annex 4A is the chronology of introduction in other
2235	countries which your Lordship has had for some time,
2236	although it did not have a home. I forget whether my
2237	learned friend's caveat that he wants to check this
2238	applies to this one as well.
2239	MR BROWN: I have checked it. My learned friend's junior
2240	will have it at lunchtime with the suggested
2241	alterations. Again, it is marginal; there are one or
2242	two differences.
2243	MR UNDERHILL: Perhaps we can quickly run through it,
2244	Australia, February 1990, very early. Austria, about
2245	May 1990, middle position. Belgium, 1st July 1990;
2246	Canada, June 1990; Cyprus, we last heard in March 1991
2247	and they had not. Denmark, June 1991. Finland started
2248	on 1st February 1990, all donations by 1st April 1990.
2249	France, 1st March 1990.
2250	Perhaps I should say now what I meant to say at

	A
2251	the beginning: these are dates where the contrary is
2252	not stated; these are the dates by which all blood had
2253	to be routinely tested. Different countries have
2254	different systems. Some appear to have introduced it
2255	all at one stage rather like we did, but others, it
2256	seems to have been rolling. Some centres did it earlier
2257	than others. We do not always know, with each of these,
2258	whether, for example, if you have a particular date,
2259	whether some centres started earlier. Where we do know
2260	that we put it in as a footnote.
2261	MR JUSTICE BURTON: We also do not know I assume, probably
2262	in any case, whether there was a run-off period.
2263	MR UNDERHILL: No, I suppose not. I suspect the answer was,
2264	if there was, it would have been like here, a very short
2265	one.
2266	MR JUSTICE BURTON: The dates in each case for the A days
2267	are dates of introduction of tests.
2268	MR UNDERHILL: These are X days. A day, I think in your
2269	Lordship's terminology --
2270	MR JUSTICE BURTON: Was the date of availability, yes, of
2271	course, I am sorry. X days. We do not know whether it
2272	is X day for implementation of test or X day for no
2273	further usage of unscreened blood.
2274	MR UNDERHILL: We do not. I do not want to pooh-pooh that
2275	point. It might make a real difference in a very small
2276	number of cases. But it is actually marginal in the big
2277	picture because certainly, if their experience is like
2278	ours, blood is used very quickly, you do not have huge
2279	stocks and it would make a difference of a week or two.
2280	Anyway, these are the dates we have, and the sources we
2281	were given.
2282	Germany, by 1st July 1990. As the footnote makes
2283	clear and as Dr Caspari explains, screening had already
2284	started voluntarily, I forget whether it is everywhere
2285	or somewhere, but to a certain extent -- that is right,
2286	voluntarily, between April and July 1990. So 1990 was
2287	really an end date.
2288	Greece, not before March 1991. Hungary, not
2289	before March 1991; Ireland, September/October 1991;
2290	Iceland, not before March 1991. Italy, by October 1990,
2291	in many centres, by August 1991 in all, so they were
2292	quite like us in their end date. Japan, very early, end
2293	November 1989. Luxemburg, staggered, earlier for new
2294	donors, later for other donors, I imagine because of the
2295	difficulty of introducing it all in one go, I do not
2296	know. Malta, not before March 1991.
2297	Netherlands, about which we have quite a lot of
2298	evidence, became mandatory on 1st April 1991, introduced
2299	voluntarily at different centres on dates varying from
2300	May 1990, which is Amsterdam, the very first, to April

	A
2301	1991, which is Leiden, majority December 1990 to March
2302	1991
2303	There is something wrong with the English there.
2304	I think that last bit -- the words "had already" down to
2305	"onwards" I think are left over from an earlier stage
2306	of the text. We got some later information about that.
2307	Norway there is a muddle about. It is either in
2308	1990 or in 1991. Portugal, not mandatory before March
2309	1991. Spain, October 1990. Sweden, legal requirement
2310	published on 24th January 1991, testing as soon as
2311	possible and from 1992 at the latest; one centre began
2312	in 1990. Others, spring 1991, several not until
2313	1st January 1992. That is the latest we have anywhere.
2314	Switzerland, August 1990; USA May 1990.
2315	There is no doubt, as I think I said in opening,
2316	that the UK was towards the end, but it was not at the
2317	very end.
2318	My Lord, finally, I said I would give your
2319	Lordship some broad stages from the chronology. The
2320	chronology itself appears at 4C. Your Lordship has not
2321	seen this before. It is not intended to be a
2322	comprehensive chronology, but it has in it all the key
2323	meetings. Your Lordship might want to have that open
2324	while I speak.
2325	My Lord, what I want to say and why I am doing
2326	this exercise now is this: there are a lot of
2327	considerations of all sorts of different kinds being
2328	considered by different people at different times. My
2329	learned friend has given you all sorts of snapshots of
2330	people saying this sort of thing in letters, this sort
2331	of thing in meetings, between the whole period 1989 and
2332	1991. Not all of those are factors which actually
2333	affected the speed of implementation or which we would
2334	rely on as factors affecting the public's legitimate
2335	expectation as to the speed of implementation. In order
2336	to understand which factors actually counted at what
2337	time one does need to have this sort of structure in
2338	mind.
2339	In broad terms it goes as follows: firstly, the
2340	period 1989 to the beginning of 1990. During this
2341	period, the ACTTD and the ACVSB which between them have
2342	four meetings, which your Lordship can see set out in
2343	our minute, are simply finding out more. They had
2344	people at the Rome study and so forth.
2345	We say -- and I am not going to go through it in
2346	any detail at all -- that in that period the finding out
2347	time was wholly legitimate. We are at a very early
2348	period, a period even before A day; not likely I think
2349	to be much issue, although I am sure my learned friend
2350	will take whatever point he can, about the legitimacy of

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2351	the sort of thinking going on in this time.
2352	Then we have the first half of 1990, up to
2353	2nd July, because your Lordship will see over the
2354	page the ACVSB's seventh meeting was on 2nd July 1990.
2355	That was the meeting at which, as we put in italics, a
2356	decision was taken to recommend introduction subject to
2357	a further multicentre trial.
2358	My Lord, throughout that period, up to that
2359	meeting, the decision-making process was effectively
2360	wholly in the hands of the ACVSB. I will come back to
2361	my learned friend's point about which committee ought to
2362	be dealing with it, which I say there is nothing in but
2363	in any event, this was the committee meeting, meeting
2364	regularly -- we see it met in November, January, April
2365	and July -- considering this very question.
2366	During this time, that committee was concerned
2367	with what we say were entirely legitimate factors about
2368	the benefits and possible disadvantages of the testing
2369	process. This is not meant to be a wonderful
2370	authoritative list, but things like the numbers of
2371	people who were going to be found positive, the numbers
2372	of those who would be false positive, the availability
2373	of a confirmatory test, what to tell donors, cost
2374	effectiveness, not a factor I am embarrassed about at
2375	all, the reliability of the screening process in
2376	practice, was it actually a reliable test, and including
2377	FDA approval.
2378	I do not for a moment suggest that anyone thought
2379	it was a legal bar, i.e. you could not introduce it
2380	before FDA approval, but for reasons which seemed good
2381	to them and I say were good they thought it was sensible
2382	not to introduce it before it had been introduced and
2383	before it was legitimate in the country of origin of the
2384	test.
2385	At the end of that period a decision was taken in
2386	principle to go ahead.
2387	MR JUSTICE BURTON: Let me be sure I have those. I have the
2388	number of people -- number of likely positives.
2389	MR UNDERHILL: Yes.
2390	MR JUSTICE BURTON: Number of false positives.
2391	MR UNDERHILL: Yes.
2392	MR JUSTICE BURTON: Cost effectiveness.
2393	MR UNDERHILL: Availability of confirmatory test.
2394	MR JUSTICE BURTON: Availability of confirmatory test,
2395	cost-effectiveness, reliability of screening test, FDA
2396	approval and I think I have missed one.
2397	MR UNDERHILL: Donor counselling. Up to that point, up to
2398	2nd July, I shall be in due course strongly submitting
2399	that those factors, and the need to investigate them,
2400	and to weigh them, were such that persons generally

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2401	could not legitimately expect implementation prior to
2402	that date.
2403	MR JUSTICE BURTON: Help me, that is January to July 1990,
2404	decision-making process, I understand, and then we have
2405	the seven points which you say are legitimate to be
2406	considered during that period.
2407	MR UNDERHILL: Yes.
2408	MR JUSTICE BURTON: But on 2nd July you do not implement.
2409	MR UNDERHILL: I am doing this in stages, my Lord, because
2410	I think that is important.
2411	Just pausing there, a non-implementation prior to
2412	that date is broadly in line with most other countries.
2413	There were undoubtedly, as your Lordship has heard, the
2414	front runners, Japan, France, Australia, but there were
2415	many others who implemented in mid-1990, the US in May,
2416	Germany in July, as an end point I accept, Spain in
2417	October -- I will not go through the whole list again.
2418	We would say that during that period, again, it would be
2419	very surprising if persons generally could expect a test
2420	to be implemented, which had not been implemented at
2421	that stage in most other countries in the world.
2422	During this period, an important point, Government
2423	decision-taking has no impact on the timetable at all.
2424	The ACVSB was in practice the decision-making body. It
2425	was not in form the decision-making body. What it did
2426	was it made a recommendation to ministers, but I suspect
2427	the expectation was ministers would accept the
2428	recommendation and indeed ministers did accept the
2429	recommendation when it was eventually made.
2430	MR JUSTICE BURTON: As there now seems to be no option.
2431	MR UNDERHILL: Precisely. In any event, that was the body
2432	where all the factors were being weighed.
2433	My Lord, then we come to the second half of 1990.
2434	That was mostly occupied by setting up and carrying out
2435	and analysing the results of the multicentre study
2436	comparing Ortho and Abbott.
2437	MR JUSTICE BURTON: You said there were three periods.
2438	MR UNDERHILL: I did not say how many there were. I have
2439	four.
2440	MR JUSTICE BURTON: I thought there were going to be three.
2441	There are four?
2442	MR UNDERHILL: Yes.
2443	MR JUSTICE BURTON: Thank you. This is period 3. This
2444	relates to what, July 1990, till when?
2445	MR UNDERHILL: Effectively until November. I have called it
2446	rather loosely the second half of 1990.
2447	MR JUSTICE BURTON: That is all right. From July until
2448	November?
2449	MR UNDERHILL: Yes.
2450	MR JUSTICE BURTON: That is the two next entries. I am

	A
2451	doing a little chopping exercise on your chronology.
2452	This is period 3. How do you describe it? Multicentre
2453	trial?
2454	MR UNDERHILL: Yes, most of that was the multicentre trial
2455	which your Lordship sees referred to between September
2456	and October, that is when it is actually carried out,
2457	and the results are reported to the meeting on
2458	21st November, and that is when the actual
2459	recommendation that we should now go for it is made.
2460	MR JUSTICE BURTON: Remind me -- tell me -- in relation to
2461	your seven decision-making points -- there may have been
2462	more, of course, I do not want to limit you to the
2463	seven, but those are the ones you have mentioned --
2464	which of those were going to be affected or determined
2465	by the multicentre trial?
2466	MR UNDERHILL: Numbers of positives, numbers of false
2467	positives absolutely crucially, because the multicentre
2468	trial was the first time that it was possible to test
2469	the screened positives --
2470	MR JUSTICE BURTON: Against the analogous ones?
2471	MR UNDERHILL: Against PCR, in fact, which was regarded as
2472	the gold standard.
2473	MR JUSTICE BURTON: Sorry, to test ALT against --
2474	MR UNDERHILL: No, no one is interested in ALT by this
2475	stage. That is not entirely true, but as a shorthand
2476	that is true. No, what they were doing was they were
2477	looking at the number of positives, people who actually
2478	showed positive on the screening test.
2479	MR JUSTICE BURTON: I see, I had forgotten this. The ALT
2480	were not being used as a substratum in a multicentre
2481	test at all.
2482	MR UNDERHILL: Not this one.
2483	MR JUSTICE BURTON: It was just the first generation Ortho
2484	plus PCR?
2485	MR UNDERHILL: Yes. There are a number of advantages. You
2486	actually had a double test. Because, if you run two
2487	kits together and they both have 100 results each, and
2488	they overlap for 10, the 10 are probably the true
2489	positives, but we did not actually have to use that. We
2490	had a better test still. We had the PCR.
2491	MR JUSTICE BURTON: It does assume that both those tests are
2492	reliable. That is what I am a little puzzled about.
2493	That is why I had forgotten. I thought you were --
2494	MR UNDERHILL: There are different sorts of reliability of
2495	test. A classic one is you put it in for the first test
2496	and it comes up positive. You then put it back again
2497	and does it come up positive again? If it does not, you
2498	have a lousy test.
2499	MR JUSTICE BURTON: They did two Orthos, did they and the
2500	PCR?

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2501	MR UNDERHILL: With each of Ortho and with Abbott, each of
2502	the two kits, absolutely standard, they did what
2503	everybody always did, they did it twice.
2504	MR JUSTICE BURTON: That is Abbott as well?
2505	MR UNDERHILL: Yes.
2506	MR JUSTICE BURTON: Did they do both two Orthos and two
2507	Abbotts on this one?
2508	MR UNDERHILL: Yes.
2509	MR JUSTICE BURTON: Two Orthos and two Abbotts and how many
2510	PCRs?
2511	MR UNDERHILL: Then what you do is you get all the
2512	positives -- there were 69 out of my head -- and you
2513	send them off to a specialist laboratory to have a PCR.
2514	Out of those 69, 6 were true positives. So the way it
2515	went was 10,000 tests, 69 positive on one or other of
2516	the two tests, that is repeat reactive positive. Of
2517	that 69, 6 true positives.
2518	MR JUSTICE BURTON: When you say one or other of the tests,
2519	did they survive through all four tests, or did you use
2520	two Orthos on some and two Abbotts on another.
2521	MR UNDERHILL: No, as I understand it -- I will be corrected
2522	if I am wrong -- in this trial all the centres tested a
2523	sample both with Ortho and with Abbott.
2524	MR JUSTICE BURTON: That would mean four tests?
2525	MR UNDERHILL: Yes, I suppose it would.
2526	MR JUSTICE BURTON: 69 survive four tests.
2527	MR UNDERHILL: Yes.
2528	MR JUSTICE BURTON: And they need to show positive on each
2529	one?
2530	MR UNDERHILL: If they showed negative -- they do not all
2531	have four. If you come up with positive first time, you
2532	do it again. If you come up negative first time you do
2533	not do it again.
2534	MR JUSTICE BURTON: Is that right? That rather assumed that
2535	Ortho and Abbott were equally effective.
2536	MR UNDERHILL: In the end that is what turned out to be the
2537	case, but it was not known to be the case.
2538	MR JUSTICE BURTON: Unless you are going to test negatives
2539	again to see whether Ortho might show up as positive
2540	what Abbott has shown as negative, you cannot really do
2541	a proper test for that, can you?
2542	MR UNDERHILL: I am not sure that is right, because, one
2543	thing you want to know is -- there are various
2544	adjectives used for this -- how robust the test is, and
2545	all you mean by that is is there a big discrepancy
2546	between the initial screen positives and the repeat
2547	reactives.
2548	MR JUSTICE BURTON: I see that. All I am suggesting to you
2549	is if you have something that shows up as a negative on
2550	an Abbott it might have shown up positive on an Ortho

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2551	but you never discovered that.
2552	MR UNDERHILL: Yes, that is what took the time in the second
2553	period.
2554	MR JUSTICE BURTON: Coming back to my question, that clearly
2555	helps you on numbers of positive; how does it help you
2556	on number of false positives?
2557	MR UNDERHILL: That is exactly the point, because it shows
2558	you how many are false positives.
2559	MR JUSTICE BURTON: As between PCR, which you are regarding
2560	as terribly reliable.
2561	MR UNDERHILL: Yes.
2562	MR JUSTICE BURTON: But could not then be used and no one is
2563	suggesting it could have been used nationally.
2564	MR UNDERHILL: On a screening basis, no.
2565	MR JUSTICE BURTON: I see. So your guideline at all times
2566	is PCR?
2567	MR UNDERHILL: Once it becomes available, it was regarded as
2568	the gold standard. There are two twists to this I ought
2569	to mention, one which really does not matter too much
2570	but your Lordship should know about: in the end it
2571	became clear that actually, not that there was anything
2572	wrong with the test, but it was much more difficult to
2573	use than people had at first thought, and the results
2574	with PCR now in the late 1990s are a lot better than
2575	they were thought to be in the mid-1990s. The other
2576	thing is that, in fact, the sequence of events for a
2577	confirmatory or supplementary test is first you have
2578	RIBA 1; unsatisfactory, we say, though I think my
2579	learned friend will say not too bad. Then you have
2580	PCR. Much the same time as PCR, you have RIBA 2 just
2581	coming in, and when RIBA 2 is used alongside PCR it is
2582	proved to be almost 100 per cent reliable. So after a
2583	bit you say: we will not bother with PCR.
2584	MR JUSTICE BURTON: RIBA 2 can be used by the centres?
2585	MR UNDERHILL: It can be used more easily than PCR.
2586	MR JUSTICE BURTON: Whereas PCR you have to send --
2587	MR UNDERHILL: I think RIBA 2 was sent to a laboratory, but
2588	it was a much easier test. I may be wrong about that.
2589	MR JUSTICE BURTON: Coming back to your list, number of
2590	positives is plainly shown by yet another trial, the MC
2591	trial. It happens to have been 69. Number of false
2592	positives, by reference to PCR, is now shown as being
2593	63
2594	MR UNDERHILL: Yes.
2595	MR JUSTICE BURTON: Confirmatory test availability, by
2596	definition, it is there, the PCR.
2597	MR UNDERHILL: Yes.
2598	MR JUSTICE BURTON: So you did not need a multitest
2599	centre --
2600	MR UNDERHILL: I think we wanted to see how good the

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2601	confirmatory test was and RIBA 2.
2602	MR JUSTICE BURTON: You would not know whether the PCR --
2603	MR UNDERHILL: I understand what your Lordship is saying.
2604	MR JUSTICE BURTON: You are assuming it is good by taking it
2605	for granted that it is right. If it was bad it could
2606	have been that all those 69 --
2607	MR UNDERHILL: In the sense you could never know, but there
2608	was every reason to believe because of the kind of test
2609	it was it was inherently much more likely to give you
2610	the right results.
2611	MR JUSTICE BURTON: At the moment I do not necessarily see
2612	that that necessarily arose as a result of the
2613	multicentre trial.
2614	MR UNDERHILL: I am not going to argue --
2615	MR JUSTICE BURTON: Question mark. What about cost
2616	effectiveness?
2617	MR UNDERHILL: We must be careful what we mean by cost
2618	effectiveness. It would not show you cost effectiveness
2619	in the sense of the sorts of studies that Dr Gunston did
2620	very early on, simply saying taking the best stab at it
2621	that we can, how much is this test going to cost, and
2622	what sort of cost to the Health Service is it going to
2623	prevent?
2624	MR JUSTICE BURTON: Let me write it down. There is wastage
2625	cost.
2626	MR UNDERHILL: It will help you on that.
2627	MR JUSTICE BURTON: There is counselling cost, there is
2628	equipment cost, staff and equipment cost.
2629	MR UNDERHILL: Yes.
2630	MR JUSTICE BURTON: And there is --
2631	MR UNDERHILL: The cost of the kit itself.
2632	MR JUSTICE BURTON: That is why I have said equipment.
2633	MR UNDERHILL: I am so sorry.
2634	MR JUSTICE BURTON: Staff, kit and equipment. There is cost
2635	of false positives. Are there any other elements to
2636	cost effectiveness? Wastage cost, counselling cost,
2637	cost of false positives, in so far as it is not
2638	necessarily additional to counselling cost, and staff,
2639	kit and equipment?
2640	MR UNDERHILL: Yes. My Lord, this exercise was not
2641	primarily intended as a cost effectiveness exercise in
2642	that sense, though I am quite sure that a useful element
2643	of it is to know which is the better test and to know
2644	that there are two people in the market you can deal
2645	with.
2646	MR JUSTICE BURTON: I do not know that you could have told,
2647	as I have been putting to you, which was better out of
2648	Ortho and Abbott.
2649	MR UNDERHILL: You could definitely have told that. Suppose
2650	the position was, as indeed it was to a limited but not

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2651	a significant extent, that Ortho nearly always came up
2652	positive first time, came up positive second time,
2653	whereas with Abbott twice as many came up positive first
2654	time as second time, you would say this is a much less
2655	reliable test.
2656	MR JUSTICE BURTON: But you would not have. You did not
2657	know that twice as many came up positive as came up
2658	first time because you did not test the negatives again.
2659	MR UNDERHILL: No, but even too many positives first time is
2660	a very significant matter. It means you have to do the
2661	tests again.
2662	MR JUSTICE BURTON: We are repeating ourselves. That
2663	assumes that Abbott, which is the first one you happened
2664	to do and showed more positives, might have been right
2665	and Ortho might have been wrong in showing them as
2666	negatives. There it is.
2667	MR UNDERHILL: My Lord, I see the time. I am embarrassed I
2668	gave a completely misleading estimate to the court and I
2669	gave a completely misleading estimate to Dr Gunston who
2670	expected to be on his feet at least some time this
2671	morning. I really am not going to be that much longer.
2672	I really just have to do two things. I have to finish
2673	this exercise dividing up into stages and showing
2674	actually what counts at each stage and then just remind
2675	your Lordship what is in one or two of the bundles.
2676	MR BROWN: May I raise one matter because it relates to the
2677	question of time? My learned friend said about 5 or 10
2678	minutes ago that this is what took the time, as it were,
2679	the PCR and checking the two against each other. My
2680	Lord, the time specified for this study by the
2681	Department was three weeks. It was a three-week
2682	programme.
2683	MR UNDERHILL: I am puzzled by that, because what appears in
2684	the ACVSB minutes says the whole thing from start to
2685	finish will take four months. That is a matter that
2686	will have to be explored in cross-examination rather
2687	than between counsel.
2688	MR JUSTICE BURTON: I am sorry, I have taken the last ten
2689	minutes because I have been trying to tidy it up,
2690	because it is helpful to me. Can we very quickly finish
2691	this and then I will rise?
2692	MR UNDERHILL: Yes, of course.
2693	MR JUSTICE BURTON: Cost effectiveness, you say that is
2694	nothing to do with the multicentre trial, not much at
2695	any rate?
2696	MR UNDERHILL: Yes, not much.
2697	MR JUSTICE BURTON: I will write "not much". Reliability of
2698	test, you say yes although you are not comparing it with
2699	ALT?
2700	MR UNDERHILL: No.

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2701	MR JUSTICE BURTON: Certainly you are seeing how it runs,
2702	how they both run. I am going to put a tick. Donor
2703	counselling, no?
2704	MR UNDERHILL: No, donor counselling ceases to be a problem
2705	at the time that you have a confirmatory test you are
2706	confident in. The problem about donor counselling is --
2707	this was much more serious with surrogate testing but
2708	also with the early stages of screening -- as it turned
2709	out you have 69 people who, if you did not have a
2710	confirmatory test, you have to go and see and say,
2711	"Awfully sorry, you may have hepatitis C." "What is
2712	that, doctor?" "I am not really sure." "Will I get
2713	ill, doctor?" "I am not really sure." "Have I really
2714	got it?" "I am not really sure". Once you can say, "We
2715	will send it off to the laboratory; we will know in a
2716	week", or however long it takes, but it is not much
2717	longer than that, but it is only 6, you do not have to
2718	count the remaining 63 at all.
2719	MR JUSTICE BURTON: It rather ties in with (iii) and (vi)
2720	which is the confirmatory test available, they rather
2721	tie in together is what you are saying.
2722	MR UNDERHILL: They do.
2723	MR JUSTICE BURTON: FDA licensing, that had gone by the
2724	board?
2725	MR UNDERHILL: That had happened on May 2nd, 1990.
2726	MR JUSTICE BURTON: I know, but it has gone by the board.
2727	Good.
2728	2.05. Thank you very much.
2729	(1.07 pm)
2730	(Luncheon adjournment)
2731	(2.10 pm)
2732	MR UNDERHILL: My Lord, some of your Lordship's questions
2733	led me to think it might be useful just to refer your
2734	Lordship to the last but one item in the annex 5 file,
2735	miscellaneous, the one we were looking at had the
2736	seriousness paper in it. If your Lordship looks at the
2737	front sheet first, your Lordship will see that it
2738	purports to contain five papers, one on seriousness, one
2739	on prevalence, one on PCR testing, one called "How
2740	Donated Blood is Tested" and one called "The Relevant UK
2741	Studies".
2742	PCR testing did once exist; it got lost on my word
2743	processor, and I do not know whether your Lordship has
2744	had that experience but the enthusiasm to do it again is
2745	much less than it was to start it. If it still is
2746	likely to be helpful -- I frankly doubt if it is,
2747	because things have moved on, this was done at the stage
2748	before your Lordship had any opening -- we will produce
2749	it, but it was really to be a summary on what the
2750	relevant papers about PCR were.

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2751	The one I was taking you to was 4, "How Blood is
2752	Tested". Sooner or later, in order to understand some
2753	of the points that were made during the consideration
2754	period, your Lordship is going to have to understand
2755	this in slightly more detail than has yet had an
2756	opportunity and I might as well do it now as ever.
2757	"The note sets out to explain in layman's language
2758	the process by which donated blood is tested ... It is
2759	based partly on what is said in the witness statements
2760	but its accuracy has been confirmed by Dr Gunson."
2761	Any points that need to be followed up with him
2762	can be.
2763	"It is not intended to be contentious. It is
2764	intended to describe the procedures at the relevant time
2765	at the time that routine testing was first introduced,
2766	that is in 1991."
2767	We can take most of this very quickly. Paragraph
2768	1 just describes how the main donation is taken. 2:
2769	"When the donation is finished, various samples
2770	are taken:
2771	"Specimens are taken from the blood at the 'donor
2772	end' of the bleed-line [the bit nearest the hole in your
2773	arm] and is emptied into two glass tubes, one of which
2774	contains anticoagulant and is used for determining the
2775	blood group [and we can ignore that] and the other of
2776	which is allowed to clot and is used for microbiological
2777	testing (including our 'screening') and other
2778	investigations. The former is irrelevant for present
2779	purposes. The latter is referred to in this Note as
2780	'the whole blood sample'."
2781	That is different from the blood in the bag,
2782	because the blood in the bag has been anticoagulated.
2783	Already in the bag before the blood goes in there is a
2784	certain amount of liquid to stop it clotting.
2785	Then secondly:
2786	"The rest of the blood in the bleed-line is
2787	allowed to flow into the pack but then to flow back, in
2788	anticoagulated form [as they will have picked up the
2789	anticoagulant from the bag]. The bleed-line is then
2790	sealed with several clamps into several sections which
2791	will be available for further testing if necessary.
2792	This is referred to as the second sample.
2793	"Samples and pack are labelled with a barcode
2794	specific to that donor and taken back from wherever the
2795	donor session has taken place [school or parish hall, or
2796	wherever] to the Regional Transfusion Centre.
2797	"At the Centre the pack (and the second sample)
2798	[I do not know why that is in square brackets] is put
2799	into quarantine (e.g. into a caged-off section or in a
2800	colour-coded crate and the whole blood sample is taken

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2801	for testing to the laboratory. This will be performed
2802	within one working day -- or sooner if necessary."
2803	Then 5:
2804	"The whole blood sample (not having been diluted
2805	with anticoagulant) will, by the time it comes to be
2806	tested have clotted, so that what is tested is serum
2807	i.e. the clear liquid left over after a clot has
2808	formed. The number of samples requiring to be screened
2809	will vary from Centre to Centre and from day to day, but
2810	a typical number of donations being handled by, say,
2811	North London [which is one of the bigger though not the
2812	biggest] would be approximately 800 a day. The samples
2813	will be tested not only for HCV but also for HIV, HBV
2814	and syphilis. The process of carrying out this battery
2815	of tests on every sample takes several hours. Strict
2816	procedural controls are required in order to ensure that
2817	for each test the identity of the sample is preserved so
2818	that the correct pack can be released/discarded
2819	according to the result of the test.
2820	"The nature of the HCV test is difficult to
2821	describe clearly without visual aids ..."
2822	Can I pause here? Dr Barbara prepared long ago
2823	for the purpose of instructing myself and our team a
2824	little small slide show. We thought that would be quite
2825	useful for your Lordship, and indeed we have showed it
2826	to my learned friend and suggested it might be shown
2827	even before your Lordship had heard any evidence. For
2828	reasons I well understand -- I am not going to fight
2829	about it -- he said, no, he would rather it was given as
2830	part of ordinary evidence. The result will be that I am
2831	afraid your Lordship will not have this explanation
2832	before Dr Gunson gives evidence, but you will have it at
2833	the beginning of Dr Barbara's evidence and we will have
2834	to think about setting it up so that there is a slide
2835	screen. I hope we can manage without for the moment.
2836	" ... very broadly, the Ortho test kit (the first
2837	to become available) consists of a tray containing about
2838	96 'wells', which have been pre-coated with an antigen
2839	which will react if exposed to the HCV anti-body."
2840	That is an oversimplification but will do for
2841	present purposes.
2842	"The process is described as Elisa. The serum
2843	samples (i.e. samples from the whole blood sample) will
2844	be put into each well and left for a sufficient
2845	time ... about two hours ..."
2846	Again I do not know why -- does your Lordship's
2847	have square brackets? I suspect it was something I was
2848	going to check, then did not take out after I had
2849	checked.
2850	MR JUSTICE BURTON: But it is right?

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2851	MR UNDERHILL: I believe so.
2852	" ... for any reaction to occur. The reaction
2853	will be manifest by the development of colour. Dark
2854	indicates a positive reaction, but there will be degrees
2855	of darkness which have to be measured on an optical
2856	scale ..."
2857	That is how you get indeterminates with a little
2858	grey.
2859	" ... the manufacturer defines the minimum score
2860	which indicates positive.
2861	"If the test is positive," and there are two
2862	phrases your Lordship will come across a lot, "initial
2863	reactive" or "initial screen positive", they mean the
2864	same thing, "it is repeated on a further sample of the
2865	whole blood sample."
2866	One further refinement I did not realise when I
2867	wrote this, but it has been made clear to me now, in
2868	fact, it is repeated twice. You do the test in
2869	duplicate. The result is that, if you are going to do
2870	it a second time, you, in fact, do it a second and third
2871	time.
2872	If it is positive again -- on either the second or
2873	the third, though I am told in practice it is nearly
2874	always the same with the second and the third -- it is
2875	called repeat reactive and the blood in the pack will
2876	not be used in any event.
2877	MR JUSTICE BURTON: I thought I had seen IRR and RRR but I
2878	obviously have not.
2879	MR UNDERHILL: I do not think so, my Lord. There are all
2880	sorts of terms around, but that is not one that I
2881	remember.
2882	" ... the test is done again, but this time on
2883	plasma taken from the second sample. NB, this is not
2884	biochemically identical to the serum in the whole blood
2885	sample because (a) it has been diluted with
2886	anticoagulant; and (b) the fact that it has been
2887	prevented from clotting means that there will still be
2888	'active clotting agents' in the plasma, which in the
2889	case of the whole blood sample were 'used up' by the
2890	clotting."
2891	I mention that which may sound like unnecessary
2892	refinement because it does explain one of the concerns
2893	that is expressed later.
2894	"This further test is important as a check that
2895	the whole blood sample and the blood in the pack do
2896	indeed come from the same donor (i.e. that there has
2897	been no 'mix-up')."
2898	Then you get to supplementary or confirmatory
2899	testing:
2900	"The next step is to use one or more of the

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2901	available supplementary/confirmatory tests -- broadly
2902	speaking a RIBA or PCR. As explained elsewhere, these
2903	are conceptually quite different types of test, but one
2904	or bother were used for essentially the same purpose,
2905	namely to try to confirm or otherwise a positive result
2906	obtained on Elisa testing.
2907	"These supplementary/confirmatory tests would be
2908	performed on both samples, i.e. the whole blood sample
2909	and the second sample. The samples would have to be
2910	sent away for testing in a specialist laboratory, which
2911	could in principle perform the entire
2912	battery -- starting with another Elisa, then a RIBA, and
2913	finally PCR. But which were in fact performed would
2914	depend on local factors."
2915	I hope that has been helpful. My Lord, that is a
2916	slight digression. The last of my four stages is
2917	implementation, because on 21st November 1990, you had a
2918	decision to recommend we go ahead, as soon as possible.
2919	MR JUSTICE BURTON: When do you start then your period 4?
2920	MR UNDERHILL: I start it with that decision on
2921	21st November 1990.
2922	MR JUSTICE BURTON: On the face of it, your chronology has
2923	nothing between November 1990 and 8th January 1991.
2924	MR UNDERHILL: That is right. I said it was not a complete
2925	chronology. What is happening during that period is two
2926	things. Firstly, the ACTTD has been reconvened to start
2927	discussing implementation issues, but also at the same
2928	time the Minister has been asked for her decision. I do
2929	not know, I do not think anybody knows, the exact date
2930	that the decision was notified. I think 16th was the
2931	date that the Minister wrote on the bit of paper "I do
2932	not see we have any option". The day that Dr Gunson was
2933	told that we do not know, but I do not think it was --
2934	I think it was several days later. That is why this
2935	says "notified". On 22nd he writes to all RTCs seeking
2936	the earlier start date. From then on, we are into
2937	implementation. Dr Gunson is saying, how soon can we
2938	get this going?
2939	Now, there is, therefore, that initial period
2940	between 21st November effectively and 22nd January, of
2941	exactly two months before he actually gets the letter
2942	out. I am reminded that Dr Gunson believes he was told
2943	on 21st January which is why he sent his letter on
2944	22nd.
2945	Your Lordship will have to form a view about that
2946	period of two months, but we say at least this: it is
2947	not unreasonable that a decision of this importance has
2948	to be taken at a high level after proper consideration
2949	by the Government as well simply as by the expert
2950	advisers on the Committee.

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2951	My Lord, thereafter, it is clear -- the facts
2952	speak for themselves -- it took eight months from
2953	January to September actually to implement the decision
2954	which had been taken by the Committee on 21st November
2955	and endorsed by the Minister in mid-January.
2956	The reasons which I rely on as factors relevant to
2957	the public's legitimate expectation relating to that
2958	period were twofold: firstly, they were the actual
2959	business of tooling up with the right equipment,
2960	recruiting, training staff, and in one or two cases
2961	indeed finding and equipping a new laboratory.
2962	MR JUSTICE BURTON: Could that have been done during
2963	period 3?
2964	MR UNDERHILL: I am sure that is one of the things my
2965	learned friend will be suggesting. I am not going to
2966	argue the point now. All I would say is that until a
2967	decision in principle is taken to do it, that is
2968	premature. That assumes that there has been a definite
2969	decision to do it. No doubt what your Lordship has put
2970	to me is what my learned friend will put to the
2971	witnesses.
2972	MR JUSTICE BURTON: Second?
2973	MR UNDERHILL: May I just say on that first, although
2974	obviously this is something Dr Gunson knows a great deal
2975	about, the principal witness is Mr Garwood. I have
2976	forgotten his title, but your Lordship will have seen
2977	his statement in bundle J1. He was effectively the man
2978	responsible for the nuts and bolts of implementation at
2979	a particular Centre, namely the South London Centre, and
2980	he is now National Processing Testing and Issue Director
2981	of the National Blood Authority. At the relevant time
2982	he was the Scientific Director of the South Thames Blood
2983	Transfusion Centre.
2984	His statement explains -- I am not going to do it
2985	now myself -- that this is not, as it is easy to assume
2986	without thinking about it, just a question of buying a
2987	few bits of equipment and plugging them in and off you
2988	go.
2989	My Lord, your Lordship was told very briefly by my
2990	learned friend that the Centres when asked to give their
2991	time they would need, varied enormously, but none of
2992	them said, "We can start tomorrow".
2993	The second of the factors was that a decision was
2994	taken slightly later in this implementation period to
2995	wait for the second generation tests, i.e. not to
2996	implement first which were on their way out, to wait
2997	till the second were available, and then, once they were
2998	available, there was also a period of evaluation before
2999	it was finally introduced.
3000	MR JUSTICE BURTON: I asked Mr Brown whether different

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3001	equipment was needed for the first generation from the
3002	second generation and he believed not. Do you agree
3003	with that?
3004	MR UNDERHILL: I do believe that is correct, yes. I asked
3005	behind and I was told it was so.
3006	The point I want to make about this implementation
3007	period, again, because it narrows the issues, was this
3008	was again not as a result of any Government action; the
3009	Government had already given its go-ahead. It was, for
3010	better or for worse, a result of decisions taken by
3011	the ACVSB and the ACTTD and Dr Gunson.
3012	The one area where the Government could have had
3013	an input was into the question of funding. There is a
3014	lot of reference in the correspondence to some of the
3015	Centres being worried who is going to pay for this. In
3016	the end, they were told simply that the regions have to
3017	find the money and the regions did, and Dr Gunson's
3018	evidence is that although various people -- Dr Contreras
3019	in particular -- expressed concerns about where the
3020	money would come from, in the end the money was found
3021	and did not contribute in any way to the timetable that
3022	was followed. So this is not a question where things
3023	could have happened but we are held up for lack of
3024	funds.
3025	My Lord, with hindsight, there is clearly a strong
3026	case for arguing that the end result of those last
3027	decisions was that this process -- the implementation
3028	process -- took too long, that X day was earlier than
3029	1st September 1991. Your Lordship has already referred
3030	to the fact Dr Gunson in his statement says that, with
3031	hindsight, one at least of the decisions he took in that
3032	period he with hindsight would not have taken.
3033	It is because it is recognised that there is an
3034	area of vulnerability there, that the defendants have
3035	made an offer to all those infected by blood donated
3036	between 1st April 1991 and 1st September 1991, and I am
3037	now able to tell your Lordship that offer has been
3038	accepted by every such claimant in the litigation.
3039	MR JUSTICE BURTON: Do I need to know, or am I invited to
3040	know what that offer is?
3041	MR UNDERHILL: I am prepared to tell your Lordship, but when
3042	I last discussed it with my learned friends they would
3043	rather your Lordship did not. I think sooner or later
3044	your Lordship will have to know, but if there is a
3045	sensitivity about it, I would rather not --
3046	MR BROWN: We are not sure that your Lordship needs to
3047	know. There has been an arrangement in relation to
3048	those claimants.
3049	MR JUSTICE BURTON: Was confidentiality a term? I am not
3050	going to resolve it at the moment. I am throwing out

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3051	points at the moment. Certainly I do not expect to be
3052	told this afternoon. If it was not confidential, then
3053	it will come out.
3054	MR BROWN: My Lord, I think it is a matter we may have to
3055	revisit, but there is a matter that causes concern,
3056	proper concern, on this side.
3057	MR UNDERHILL: My learned friend has told me that. That is
3058	why I have not told your Lordship. I think sooner or
3059	later it will have to be resolved, but your Lordship
3060	certainly does not need to know at this minute. I
3061	appreciate your Lordship would probably like to know.
3062	We will either resolve it between ourselves or, if there
3063	has to be an argument about it, we will do so.
3064	MR JUSTICE BURTON: I suppose there are three aspects. One
3065	is confidentiality. The second is, if it is not
3066	confidential it is all going to come out anyway and I
3067	suppose I am in the forefront of those who would benefit
3068	being at least as well informed as the public. The
3069	third, however, is admissibility, and that is that, if
3070	there is some ground whereby it becomes inadmissible, to
3071	such an extent that I would find difficulty in putting
3072	it from my mind if I were told it, then that would be a
3073	reason for not telling me.
3074	(2.30 pm)
3075	MR UNDERHILL: There we are. I am not going to say any more
3076	about that now.
3077	I am not making any statement about the subjective
3078	reasoning of anybody as regards that date, but I would
3079	just point out April is a date with several resonances,
3080	trying to put it that way. It is the month in which
3081	testing did, in fact, start in Newcastle, with
3082	Dr Lloyd. It is the month in which second generation
3083	became available. Indeed, April 1st is the date at
3084	which testing became mandatory in the Netherlands, a
3085	country with many similar characteristics in terms of
3086	prevalence and so forth to this country.
3087	MR JUSTICE BURTON: What is the consequence of that? If I
3088	were told the terms of the agreement, that would be one
3089	thing, and I would draw such inferences or conclusions
3090	as I can from inter alia the terms of the settlement.
3091	On the basis that I am not being told the terms of the
3092	settlement, or at least not today -- I may or may not be
3093	told -- where do I go from there? Do I still have to
3094	decide the issue as to when X day was, or do I take
3095	it -- I assume, unless I am told otherwise, that it is
3096	not conceded that 1st April is the relevant date, unless
3097	of course I am told it was conceded for the purpose of
3098	this settlement and this settlement is X. Absent my
3099	being told the whole picture, either there is an
3100	admission of 1st April as the date or I cannot draw any

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3101	inferences from it at all. Therefore I have to reach my
3102	own conclusion.
3103	MR UNDERHILL: I knew your Lordship would be troubled by
3104	this. My learned friend and I have had very sensible,
3105	constructive discussions, unfortunately where we cannot
3106	reach agreement. My position is simply this: since
3107	every claimant infected by a donation given after
3108	1st April 1991 has their case settled as regards
3109	liability, there is no longer an issue in this
3110	litigation as regards any date after that. So your
3111	Lordship's finding should be either whenever X day was
3112	it was no earlier than 1st April, or it was even earlier
3113	than 1st April. That is my position. My learned friend
3114	can speak for himself, if your Lordship wants him to,
3115	but the headline is, no, your Lordship should
3116	nevertheless make a finding as regards the interim
3117	period.
3118	May I say one other thing before your Lordship
3119	invites my learned friend to speak, if you wish to, and
3120	that is this: even if your Lordship accepted my
3121	analysis, which I submit is clearly formally correct, I
3122	cannot suggest that everything that happened after
3123	1st April is for that reason irrelevant, but it is only
3124	relevant in so far as it helps your Lordship decide the
3125	remaining issue of whether X date is earlier than
3126	1st April, and, if so, when.
3127	MR JUSTICE BURTON: At the moment it does seem to me on
3128	Woolfian principles, if none other, that to look at what
3129	happened after 1st April is going to be a waste of time.
3130	MR UNDERHILL: That is what we think, unless my learned
3131	friend says any particular line of questioning actually
3132	helps your Lordship about any matters which are still in
3133	issue.
3134	My Lord, I can see my learned friend wants to
3135	rise, and I understand he wants to rise, and I will sit
3136	down and let him say what he wants to say.
3137	MR BROWN: My Lord, it is a very odd situation. Our
3138	position is very much as your Lordship identified a few
3139	moments ago. If one had had a straightforward admission
3140	of liability that product supplied after 1st April 1991
3141	was defective and that the virus was discoverable, do
3142	not even bother with the discoverability, that the
3143	product was defective, then my learned friend is right,
3144	that the only way in which what happened after
3145	April 1991 becomes relevant is in so far as it casts
3146	light on what had happened before, and I would certainly
3147	give an undertaking that I would keep my
3148	cross-examination in relation to that period to a very
3149	short compass.
3150	My Lord, my learned friend is not prepared to make

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3151	that admission. Imagine that one has a claimant -- and
3152	I hope there is one -- who was infected in March 1991.
3153	My learned friend is still inviting your Lordship to
3154	say, because he said it yesterday and indeed he said it
3155	a few moments ago, that one can excuse that last period,
3156	his implementation period, for the two reasons he
3157	identifies.
3158	When we look at the case of the person infected in
3159	March 1991, if your Lordship were won over -- which your
3160	Lordship may be -- by my learned friend's arguments, and
3161	says, actually, not only was what they did reasonable,
3162	the public were not entitled to expect any more from
3163	their blood. Your Lordship would, as it were, be
3164	throwing, because your Lordship is looking at the entire
3165	period and it is still being said that it is relevant,
3166	they were entitled to use the whole of the eight
3167	months.
3168	If another court, heaven forbid, were called upon
3169	to look at your Lordship's results and verdict in any
3170	way, one as it were has no evidence but what led your
3171	Lordship to the particular conclusion. Your Lordship
3172	would not have to express any views as to matter.
3173	MR JUSTICE BURTON: I am vaguely surfacing in the direction
3174	as to where you are going, but help me: by reference to
3175	March, why would Mr Underhill's suggestion not be the
3176	answer to that, namely that I would be satisfied that
3177	there could be no criticism of them, if I put it in the
3178	broader sense, no finding under article 6 or article 7
3179	against them, in respect of any period prior to
3180	1st April and I did not need to reach a decision as to
3181	what the position was after 1st April?
3182	MR BROWN: Because, my Lord, what my learned friend would be
3183	saying on appeal -- imagine your Lordship picked an
3184	earlier date, and your Lordship said actually it could
3185	all have been done rather more quickly. We would then
3186	have to be saying hang on, we still have the tooling up
3187	to do, the arrangements for funding, the evaluation of
3188	the other, all of which your Lordship has heard nothing
3189	about. In other words, all of this would be solved if
3190	one had a straightforward admission.
3191	In the absence of that straightforward admission,
3192	your Lordship's reasoning may, as it were, be influenced
3193	by the absence of evidence as to that period. In other
3194	words, was that which was done in the last six months
3195	something that needed to be done then, and could not
3196	have been done any earlier, or could it have been done
3197	earlier? My Lord, we are just concerned at your
3198	Lordship's reasoning processes.
3199	MR JUSTICE BURTON: I suppose I am also concerned in the
3200	background -- I am a great encourager of settlements,

	A
3201	I think they are very good things. Let us assume that
3202	there has been some settlement on a basis, say, a
3203	proportionate basis, an X per cent success basis,
3204	perhaps, and you have settled on behalf of your clients
3205	at a 60 per cent chance of success, and I then conclude,
3206	because you invite me to do so in my judgment at the end
3207	of the day, that it could not possibly be justified,
3208	8th September, I construe in your favour on the law, on
3209	Mr Forrester's basis or on your basis, and on the facts
3210	and I reach a judgment that you are 100 per cent right,
3211	does that not cause problems?
3212	MR BROWN: My Lord, it might cause embarrassment. My Lord,
3213	we are content with that embarrassment. There are all
3214	sorts of other reasons. I have identified the main
3215	concern that we have, which is that your Lordship would
3216	be asked, as it were, to make findings without looking
3217	at what actually happened in any detail. My learned
3218	friend is still saying, as he said yesterday at Day 135,
3219	wherever your Lordship asks me I could not do anything
3220	sooner than 1st September.
3221	MR JUSTICE BURTON: It may of course all tumble out because
3222	Dr Gunson and Dr Barbara may say, "We as a matter of
3223	fact cannot defend what happened after 1st April".
3224	MR BROWN: They do not say it yet. The earliest date that
3225	appears in either of their statements is July. There
3226	are all sorts of questions that are posed in relation to
3227	cross-examination of them. May I identify two other
3228	problems that could arise? Your Lordship knows
3229	multiparty litigation is constantly bedevilled by what
3230	is connected second wave litigation. The time for
3231	anyone to sue, outside this litigation, does not run out
3232	assuming that the limitation period in the Act is as it
3233	were bulletproof from a human rights points of view,
3234	assume that is the case, it does not run out until
3235	2001. Imagine an infant affected, learning he has the
3236	condition, at the end of this year. Is he going to have
3237	to litigate all over again because your Lordship did not
3238	look at the last period? My Lord, it would be most
3239	undesirable.
3240	My Lord, imagine an infant who might require
3241	approval from your Lordship of whatever arrangement has
3242	been made on his behalf --
3243	MR JUSTICE BURTON: I think what you are saying is not just
3244	or not even addressing the question of admissibility of
3245	the settlement, but really what you are saying is the
3246	settlement is irrelevant -- it is all very interesting,
3247	but I have to decide the factual issue, the fact that
3248	the two parties, with Legal Aid or otherwise, may have
3249	compromised on some commercial basis is neither here nor
3250	there, actually has no impact on the trial at all.

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3251	MR BROWN: I would not wish to say that, my Lord, because
3252	the word "Woolf" will be thrown at me and I would have
3253	to, as it were, deal with it.
3254	If we were going to spend a long time dealing with
3255	those six months in several days of evidence, I would
3256	not wish to make a submission in quite the bold way your
3257	Lordship just described. My Lord, that is not the
3258	case.
3259	To cut out this evidence in the absence of an
3260	admission -- and there is a simple solution to this, a
3261	straightforward admission -- in the absence of that
3262	admission we say that both for the reasons I identified
3263	at the outset and for what may be less good reasons,
3264	other potential claimants -- one hopes there are not any
3265	more out there -- for those reasons we say, as my
3266	learned friend has said, whenever your Lordship asks
3267	him, he is going to say September 1991 was a proper
3268	date.
3269	MR JUSTICE BURTON: The problem of course is what you refer
3270	to as admission of liability, if one is looking forward
3271	to future claimants. Again, let us assume there has
3272	been some percentage basis, X per cent. That is
3273	inconsistent with an admission of liability, if it is
3274	something short of 100 per cent. It is very convenient
3275	so far as these claimants are concerned, who have
3276	compromised on a very sensible basis, I am sure,
3277	whatever that percentage was, to take into account,
3278	apart from the risks of losing whatever the bullishness
3279	of the advice they have no doubt been given, but also
3280	Legal Aid and other concepts. But an admission of
3281	liability by Mr Underhill in this action, even coupled
3282	with an X per cent settlement with you is going to then
3283	have an impact in relation to these future claimants who
3284	are going to be able to recover 100 per cent, are they
3285	not?
3286	MR BROWN: My Lord, we say, for the reasons I have
3287	identified, that this is still relevant and material,
3288	both evidentially and if my learned friend had said, "We
3289	accept the product supplied after that date is
3290	defective", then the matter might be somewhat different.
3291	MR JUSTICE BURTON: The answer to my question is yes, is it
3292	not? The first wave of claimants will have settled on
3293	X per cent, which is less than 100, I am assuming. The
3294	second wave of claimants who will not have had all the
3295	benefit of your advice, and such like, and all the
3296	expenditure that you have had, will be able to rely on
3297	Mr Underhill's admission of liability and would cover
3298	100 per cent.
3299	MR BROWN: What one does not want is a second wave
3300	relitigating matters that have been exhausted.

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3301	MR JUSTICE BURTON: No, but in terms of what you are putting
3302	to me, if one really is regarding the second wave, even
3303	if there is one, as a factor, there are two sides to
3304	it.
3305	MR BROWN: Entirely. That may be why my learned friend does
3306	not wish to make the admission. What we cannot do is
3307	shut out a period which might influence, in a variety of
3308	ways, both ways.
3309	MR JUSTICE BURTON: I think my present view, Mr Brown, is
3310	any curiosity I might otherwise have had I will entirely
3311	eliminate, because it has changed from being I would
3312	like to know or may I know the terms of the settlement
3313	into a much more important question, which is: is the
3314	evidence after 1st April now admissible and relevant in
3315	this trial? My present view, although I am happy to
3316	hear further argument and I am happy to hear
3317	Mr Underhill in reply, is that I would, provided you do
3318	not go into very large compass, hear evidence in
3319	cross-examination de bene esse, and hear argument at the
3320	end of the trial, in the light of the way the evidence
3321	has come out and in the light of further submissions, as
3322	to whether I should make findings in relation to a
3323	period which is not any longer relevant to this case, or
3324	simply limit myself to such inferences as you invite me
3325	to say can properly be made in relation to what has
3326	happened earlier.
3327	MR BROWN: My Lord, if I may say so, matters may be much
3328	plainer after Dr Gunston and Dr Barbara have given
3329	evidence in any event.
3330	MR JUSTICE BURTON: Mr Underhill?
3331	MR UNDERHILL: Your Lordship has understood the position
3332	very well. I cannot and do not make an admission.
3333	Nothing my learned friend has said has addressed my
3334	basic points, that there now remains no issue in the
3335	litigation relating to any claimant after 1st April
3336	1991
3337	MR JUSTICE BURTON: What about my compromise? Is that
3338	prejudicial? Do you want to think about it?
3339	MR UNDERHILL: I want to think about it. May I let your
3340	Lordship know tomorrow morning?
3341	MR JUSTICE BURTON: The compromise is expressly conditional
3342	upon my right to do a bit of guillotining, which I do
3343	not normally like doing, if necessary with Mr Brown,
3344	because, if it is going to be on this basis it has to be
3345	in short compass. My present view is that that is the
3346	compromise unless you feel that you would be prejudiced
3347	by it or otherwise want to argue me out of it.
3348	MR UNDERHILL: I am grateful. May I think about it?
3349	MR JUSTICE BURTON: Yes.
3350	MR UNDERHILL: That was something that had to be said at

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3351	some point. We have dealt with it now. The purpose of
3352	the analysis, however, in the course of which I told
3353	your Lordship that, was to show that what your Lordship
3354	must do is to look in a systematic manner at the actual
3355	factors which accounted for the timetable, stage by
3356	stage.
3357	My learned friend said, with engaging frankness,
3358	that in his opening he would give your Lordship what he
3359	called poison and prejudice, and I have to say that, in
3360	at least some parts of it, he was as good as his word.
3361	Your Lordship has heard a good deal about such bit
3362	part players as Professor Cash, who is the head of the
3363	Scottish National Blood Transfusion Service, clearly
3364	with a penchant for expressing himself trenchantly in
3365	correspondence, not always in the same direction, and
3366	the hapless Mr Anderson, a man about whom I know
3367	absolutely nothing, he was merely as I understand doing
3368	his job as an economist in the Department of Health
3369	working out how much this would cost and how much this
3370	would save and has found himself pilloried for doing so.
3371	My Lord, I dare say that there is room for
3372	criticism of some of these gentlemen. I do not know
3373	whether there is or not, and I am not going to be asking
3374	your Lordship to make findings about it.
3375	MR JUSTICE BURTON: The good Dr Lloyd and his hornets'
3376	nest?
3377	MR UNDERHILL: Exactly. Your Lordship may know the
3378	so-called hornets' nest about Dr Lloyd and some people,
3379	including Professor Cash, most extravagantly expressed
3380	themselves strongly on the subject of what Dr Lloyd had
3381	done. It did not include Dr Gunson who was playing a
3382	diplomatic role trying to keep together 13 Regional
3383	Transfusion Directors, some of whom at least were pretty
3384	strong characters.
3385	What I am asking your Lordship to do is simply to
3386	keep your Lordship's eye on the ball and look at the
3387	deliberations of the people whose decisions actually led
3388	to the timetable which, in fact, occurred.
3389	They were a serious, careful, distinguished body
3390	of experts. That does not mean that your Lordship may
3391	not say, at the end of the day, that they got some
3392	things wrong, or that the factors that they took account
3393	of were not ones that affected the public's legitimate
3394	expectation.
3395	MR JUSTICE BURTON: On the basis of your submission, I think
3396	clearly on the basis of both sides' submissions on any
3397	view of this case, I am not here to decide whether they
3398	were right or wrong, or indeed, as per our discussion
3399	yesterday, whether they acted reasonably. It is just
3400	the question as to whether the factors, which they took

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3401	into account, when thrown into the basket by you and
3402	looked at again by me, do or do not come out on the
3403	right side of legitimate expectation.
3404	MR UNDERHILL: That is absolutely right, although of course
3405	as your Lordship knows -- we had this argument again --
3406	I think your Lordship will at least be influenced by the
3407	fact that, if you are impressed by these people and the
3408	kind of people they are, that will affect your
3409	Lordship's judgment. Only in that way.
3410	MR JUSTICE BURTON: I cannot come to this cold. Plainly
3411	I have to understand the medical and political (with a
3412	small "p"), psychological and indeed philosophical bases
3413	for these factors.
3414	MR UNDERHILL: My learned friend's opening at times -- and
3415	he must be allowed his fun -- suggested that some
3416	people -- Dr Gunson to some extent though it seems he
3417	had his targets particularly on Dr Barbara -- were
3418	people who in some way were actuated otherwise by
3419	motives of good science and good public health. That I
3420	hope your Lordship will have no difficulty in finding
3421	was not the case.
3422	My Lord one other small point I think I have on
3423	that timetable.
3424	My learned friend seems to attach importance to
3425	the question of which committee was doing the
3426	deliberating. He can no doubt put that to Dr Gunson,
3427	who will explain that it was indeed the ACVSB that was
3428	the right body to be taking the decisions and making the
3429	recommendations that it did.
3430	Even if, in some theological sense it was the
3431	wrong body, I ask rhetorically what does it matter? An
3432	important and highly qualified committee containing, in
3433	fact, a more appropriate range of expertise than the
3434	ACTTD by itself, was considering these questions, and
3435	some as it were Civil Service question as to whether
3436	they should come within the terms of reference or
3437	another committee, quite apart from being ill-founded in
3438	the first place, really is irrelevant.
3439	My Lord, that is all I want to say, except on just
3440	nuts and bolts matters and to make sure your Lordship
3441	has all the right documents and knows what they are.
3442	Your Lordship is already very familiar with my
3443	annex 1 and the 1A that goes with it. Your Lordship has
3444	already said you found helpful our annex 2 which has
3445	just the facts and figures about the litigation in it.
3446	Annex 3 on surrogate testing your Lordship I think has
3447	seen both the factual annexes to it. I do not think
3448	there is anything more your Lordship needs to see in
3449	that. Annex 4 on HCV screening your Lordship has only
3450	seen today, but the meat of it is in the subannexes.

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3451	Your Lordship has seen two of the three of those.
3452	Annex 4A, which is the dates of introduction of HCV
3453	screening I have just shown your Lordship. Annex 4C is
3454	the chronology we have just been looking at which I
3455	repeat is not put forward as a complete chronology. It
3456	is just to show the stages.
3457	What your Lordship has not seen -- and I do not
3458	think I am going to spend any more time doing it now --
3459	is shown your Lordship annex 4B on false positives and
3460	confirmatory tests, but that was gone into so fully in
3461	debate between your Lordship and my learned friend that
3462	I do not think it will contain any surprises. In so far
3463	as there are papers and so on referred to in it, I can
3464	deal with them in evidence.
3465	The one thing that I was concerned to show was
3466	that the concern about false positivity which all the
3467	members of the ACVSB expressed and indeed Dr Barbara who
3468	is not a member of the ACVSB expressed in his
3469	publications, was not some peculiar English quirk; it
3470	was raised by a whole variety of commentators and I have
3471	set out the articles in paragraph 4. That is annex 4.
3472	MR JUSTICE BURTON: I cannot remember what the concern about
3473	false positivity was.
3474	MR UNDERHILL: The concern about false positivity -- let us
3475	take the figures as they finally turned out -- you will
3476	have for every one donor who was true positive nine who
3477	were not positive.
3478	MR JUSTICE BURTON: I understand what false positivity is.
3479	You say the concern about false positivity which all the
3480	members of the ACVSB expressed was not some peculiar
3481	English quirk. Summarise; was there a particular
3482	concern?
3483	MR UNDERHILL: A concern that the test, when it was
3484	eventually possible to work out how many false positives
3485	there were, would turn out to have a lot of false
3486	positives, as it did, I suspect we could ask, nobody
3487	suspected the relationship of false to true to be quite
3488	as high as it turned out to be, but everyone predicted
3489	that not all the positives that were coming up on the
3490	initial evaluations would be true. Until you had a
3491	confirmatory test and a good confirmatory test, you
3492	would not know how many.
3493	MR JUSTICE BURTON: I do not think the claimants suggest for
3494	one moment that that was not -- I do not think so -- a
3495	proper concern to have. They say, fair enough, but you
3496	should have got on with the tests anyway.
3497	MR UNDERHILL: I think there are two strings there. They
3498	certainly say the latter. I certainly detected in my
3499	learned friend's opening -- but we will wait and see
3500	whether it appears in cross-examination -- a feeling

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3501	that the concerns were exaggerated.
3502	MR JUSTICE BURTON: You say that, in fact, they were too
3503	little. It was the reverse of exaggeration as it turns
3504	out.
3505	MR UNDERHILL: In a sense it is my speculation. Nobody
3506	wrote down "guessing", because scientists do not get
3507	"what the rate of false positives was to be". I rather
3508	suspect that 9 out of 10 or 6 out of 7, depending on
3509	whose figures you look at, was probably more than they
3510	were expecting. That is my guess. Perhaps I should not
3511	have even said it. If anyone is interested, we can ask.
3512	That is annex 4. Annex 5, although promising 5
3513	notes in it, only has 4. Your Lordship has seen three
3514	of the four. Your Lordship has not yet seen the fifth.
3515	Again, I will not take you through it. It is a paper
3516	which I hope is helpful. There are an awful lot of UK
3517	studies knocking about. It is often quite difficult to
3518	keep one's eye on the ball of which is which. I am not
3519	going to read this to your Lordship. It is a hopeful
3520	aide-memoire. I have called them -- you can call them
3521	different things -- one the North London Study which was
3522	a recipient study, two the Scottish Surrogate Testing
3523	Study --
3524	MR JUSTICE BURTON: Can I put a date in the heading? North
3525	London Study is 1987 to 1989?
3526	MR UNDERHILL: Yes.
3527	MR JUSTICE BURTON: Scottish Surrogate Testing Study is
3528	1986?
3529	MR UNDERHILL: Yes.
3530	MR JUSTICE BURTON: That is not the one with the odd
3531	results?
3532	MR UNDERHILL: No, your Lordship has not heard much about it
3533	yet. It is important on the question of surrogate
3534	testing because it led to quite a trenchant view by the
3535	Scottish Blood Transfusion Service that surrogate
3536	testing was not a good idea.
3537	MR JUSTICE BURTON: That is not something I have seen?
3538	MR UNDERHILL: No. I have not had a full opening until my
3539	learned friend has, but you will see it. If you want to
3540	read it overnight the reference is given there, H2/88.1.
3541	MR JUSTICE BURTON: Dr Gunson is going to deal with it?
3542	MR UNDERHILL: Yes. Then some other Scottish studies, the
3543	importance of those is that they resulted in the
3544	evaluation of the assay which is the one that your
3545	Lordship has seen which had what everyone regards,
3546	I think I would regard as well, as a low figure.
3547	MR JUSTICE BURTON: That is the one?
3548	MR UNDERHILL: That is the one. It is the one under --
3549	MR JUSTICE BURTON: The date for that? That is the one that
3550	took six years?

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3551	MR UNDERHILL: No, it did not take six years. What it did
3552	was -- it was rather different -- the actual evaluation
3553	that your Lordship has been told about was done in
3554	August and October 1989, but it was done on whatever
3555	frozen samples they had to hand. So the samples
3556	actually came from different dates. That is why I have
3557	dealt with it in the rather general way I have: frozen
3558	samples taken during various studies in the 1980s were
3559	used for the Scottish evaluation.
3560	Then there is the multicentre study. You will
3561	hear a lot about that. It is slightly confusing,
3562	because actually more than one of these studies is
3563	multicentre with a small "m" and a small "c", but both
3564	people call this the Multi-Centre Study with a big "M"
3565	and a big "C", and this was a study that started in 1988
3566	into the prevalence of surrogate markers. It started in
3567	order to try to get a handle on the value of doing
3568	surrogate testing, but it was transmogrified to some
3569	extent when anti-HCV screening came along. The samples
3570	taken in the study were used for the first evaluation of
3571	the anti-HCV.
3572	MR JUSTICE BURTON: First of all dates, 1988 to 1989, is
3573	it?
3574	MR UNDERHILL: That depends what you mean by what dates the
3575	dates are meant to refer to. The donors were tested in
3576	1988, the blood was taken in 1988, but it was looked at
3577	again in 1989 for a different purpose.
3578	MR JUSTICE BURTON: It does not help me of course when it is
3579	all in capitals to say that it is capital M, because
3580	everything is in capitals. Can we give it a number? Is
3581	this Multi-Centre Study 1?
3582	MR UNDERHILL: Yes, let us call it that. I do not mind what
3583	we call them.
3584	MR JUSTICE BURTON: We have just been looking at another
3585	multicentre study, the one that was commissioned
3586	specifically for the purposes of implementation in
3587	1990
3588	MR UNDERHILL: Quite right. I will come to that in a
3589	minute.
3590	MR JUSTICE BURTON: Will that be Multi-Centre Study 2?
3591	MR UNDERHILL: It would be inconsistent. The next one,
3592	which I have called the First Pilot Study, if we are
3593	being consistent in our terminology, we should call that
3594	Multi-Centre Study 2. It is different multi-centres.
3595	It is Birmingham, Sheffield and Brentwood. It is a
3596	study which your Lordship will be taken to least, but it
3597	did happen and it was important at the time.
3598	MR JUSTICE BURTON: 1989?
3599	MR UNDERHILL: Yes, the second pilot study we could call
3600	Multi-Centre Study 3.

	A
3601	MR JUSTICE BURTON: Which one is that?
3602	MR UNDERHILL: That is my last one, the second pilot study.
3603	MR JUSTICE BURTON: That is the one we have been looking at
3604	in quite some detail in the chronology?
3605	MR UNDERHILL: That is absolutely right. That was one that
3606	started the study to evaluate the Ortho against the
3607	Abbott test, but in the usual way the samples were kept
3608	and used again later: Newcastle, North London and
3609	Glasgow. We have try to be consistent about that
3610	terminology, but I cannot promise.
3611	MR BROWN: I am trying to be consistent about it, I am
3612	slightly troubled because the multicentre study has a
3613	specific protocol, specific designation who was doing
3614	it, whereas things like what appears on my learned
3615	friend's list as number 5 is, in fact, entirely
3616	independent of the multicentre study, but it was in no
3617	sense part of it.
3618	MR JUSTICE BURTON: I do not mind what we want to --
3619	MR BROWN: I am happier with pilots, I have to say.
3620	MR UNDERHILL: I am perhaps being sycophantic. I have
3621	chosen this terminology, because I, like my learned
3622	friend, thought it was the best terminology.
3623	MR JUSTICE BURTON: You started it, Mr Underhill, if we can
3624	come back to this morning, because in the chronology you
3625	called it admittedly "trial" rather than "study",
3626	multicentre trial. I do not want to be muddled. If I
3627	change the chronology to call it Pilot Study 2 and then
3628	we are all happy.
3629	MR UNDERHILL: Yes. I am happy with that.
3630	(3.00 pm)
3631	MR JUSTICE BURTON: It is not your fault -- it may be your
3632	fault -- but in the minute 2nd July 1990: "Decision to
3633	recommend introduction, subject to further multicentre
3634	trial" is your quotation.
3635	MR UNDERHILL: Yes.
3636	MR JUSTICE BURTON: Has that come from the minutes or is it
3637	your summary? If it comes from the minutes I would
3638	rather keep it as "multicentre".
3639	MR UNDERHILL: I think that might turn out to be a chimera,
3640	my Lord, because I suspect even the minutes are not
3641	wholly consistent. "Multicentre" only means you are
3642	looking at more than one Centre.
3643	MR JUSTICE BURTON: It does say: "Subject to further
3644	multicentre study".
3645	MR UNDERHILL: I cannot remember if that is a quote or not.
3646	MR JUSTICE BURTON: I am going to change it. "Decision to
3647	recommend introduction, subject to further trial".
3648	MR UNDERHILL: I am perfectly happy with that.
3649	MR JUSTICE BURTON: Then the further trial is Pilot
3650	Study 2?

	A
3651	MR UNDERHILL: Yes.
3652	MR JUSTICE BURTON: "(Pilot Study 2)", then
3653	September-October, Pilot Study 2, Glasgow,
3654	North London --
3655	MR UNDERHILL: We are now using these terms consistently and
3656	I am sure my learned friend will try to do so, but your
3657	Lordship must not be surprised if the documents do not
3658	obey our rules entirely or even the witnesses who have
3659	been used to calling them different things.
3660	MR JUSTICE BURTON: For the moment we are going to call it
3661	"Multi-Centre Study" full stop, then Pilot Study 1 and
3662	Pilot Study 2?
3663	MR UNDERHILL: I do not think I can think of any other good
3664	excuse for staying on my feet, but Mr Brook Smith has
3665	thought of one for me.
3666	Your Lordship mentioned your Lordship had seen the
3667	phrases IRR and RRR. What that probably is is a
3668	shorthand for initial reactive rate. That is how many
3669	initial reactives out of a given group.
3670	MR JUSTICE BURTON: And then repeat reactive rate?
3671	MR UNDERHILL: Yes.
3672	MR JUSTICE BURTON: I had seen it. I am glad for that
3673	information. So I had not imagined it. If and when it
3674	comes up, it is what? The number of times there is an
3675	initial reaction out of something?
3676	MR UNDERHILL: Out of the total number being looked at,
3677	yes.
3678	MR JUSTICE BURTON: Out of 1,000 samples, the initial
3679	reaction rate, i.e. initial positives, would be 100?
3680	MR UNDERHILL: Yes.
3681	MR JUSTICE BURTON: And the repeat reaction rate would be
3682	the number of positives which survived to the second and
3683	third, as you have told me, test, would therefore be
3684	likely to be less?
3685	MR UNDERHILL: Yes, that is right. They would still be
3686	expressed as a proportion of the overall amount.
3687	MR JUSTICE BURTON: X per cent.
3688	MR UNDERHILL: The initial reaction rates found early on
3689	with first generation Ortho were something like 0.6, and
3690	the repeat reactive rates were something like 0.5, 0.4.
3691	MR JUSTICE BURTON: Coming back, then, to IRR and RRR, is an
3692	IR and an RR always positive?
3693	MR UNDERHILL: Yes, because there is a reaction. Negative
3694	is there is no reaction. I will sit down, but I shall
3695	get up again at once to invite Dr Gunson to give
3696	evidence.
3697	Your Lordship wondered whether we needed some
3698	sorting out time, a break. I would not have thought
3699	frankly we did, but if anyone else wants one, I am --
3700	because of this pillar I either have to stand a very

	A
3701	long way this way or over this way: I am ready to go
3702	now if your Lordship wants.
3703	MR JUSTICE BURTON: I want to make sure you are comfortable
3704	with your witnesses, Mr Underhill. What can be done
3705	about it?
3706	MR UNDERHILL: I think I am going to stand here where I can
3707	see him and I can see your Lordship.
3708	MR JUSTICE BURTON: That is fine, then you will need to
3709	remove those boxes out of your way, will you not?
3710	MR UNDERHILL: They are not in my way.
3711	MR JUSTICE BURTON: Mr Brown, was there anything you wanted
3712	to say in response?
3713	MR BROWN: No, my Lord, I have done the best I can.
3714	MR JUSTICE BURTON: I think it was Mr Forrester who I
3715	discouraged from intervening.
3716	MR UNDERHILL: Now he has lost his chance because I went on
3717	too long.
3718	May I say Dr Gunson is not able to stand for
3719	long. Once he has given the oath I am sure he would
3720	welcome the opportunity to sit.
3721	MR JUSTICE BURTON: Yes, that is of course fine. I just
3722	wondered whether there is a slightly higher chair that
3723	can be found, not today. Once you sit down you are
3724	rather lost, Dr Gunson. Please sit down whenever you
3725	want. Are there any particular files, Mr Underhill, we
3726	will need earlier rather than later?
3727	MR UNDERHILL: I am afraid we are going to be looking at the
3728	H files, the Q and R files, though probably those not
3729	today; in fact, today it will really only be H files.
3730	MR JUSTICE BURTON: H1 and 2?
3731	MR UNDERHILL: Yes, and one your Lordship has not yet seen
3732	called H5, but we will cross that bridge when we come to
3733	it.
3734	MR JUSTICE BURTON: I do not suppose we will get to that
3735	today, will we?
3736	MR UNDERHILL: We might. We will.
3737	MR JUSTICE BURTON: 1, 2 and 5?
3738	MR UNDERHILL: Yes. Also of course Dr Gunson's statement
3739	which is in J1.
3740	MR JUSTICE BURTON: That I have.
3741	MR UNDERHILL: There is going to be a difficulty, not at
3742	once, and perhaps not this afternoon, because I am going
3743	to be referring to quite a few of the I documents, but
3744	what we are going to do is take them out and put them
3745	into H. That is the plan.
3746	MR JUSTICE BURTON: Thank you.
3747	DR HAROLD GUNSTON (sworn)
3748	Examination-in-chief by MR UNDERHILL
3749	MR UNDERHILL: Dr Gunson, do sit. Will you take your
3750	statement which you will find behind the first tab?

	A
3751	Dr Gunson, is this a copy of a statement signed by you
3752	on 21st March 2000? Your signature appears at page 44.
3753	A. It is, Mr Underhill.
3754	Q. We see in paragraph 101 you say:
3755	"I believe the facts stated in this witness
3756	statement are true."
3757	Does that remain the case subject to one or two
3758	small corrections which we will make as we go along?
3759	A. Subject to those few small corrections, I believe that
3760	that is true.
3761	Q. Dr Gunson, I am not going to take you through all of
3762	this statement, which his Lordship has of course already
3763	read. On the first page you describe who you are and
3764	your CV. On the second page, you describe the extent of
3765	your expertise specifically in virology which is one of
3766	the sciences that comes into the story that we are
3767	looking at. You say that you have no formal training in
3768	virology though you have had to acquaint yourself with
3769	its essentials as part of your job?
3770	A. That is correct.
3771	Q. Your special speciality is haematology and transfusion
3772	medicine?
3773	A. That is correct.
3774	Q. As you say you had access to a number of specialist
3775	virologists when you needed advice, including
3776	Professor Tedder who you mention specifically. Then the
3777	next section consists of a section on the organisation
3778	of the National Blood Transfusion Service.
3779	I am going to take this very quickly. Can I deal
3780	with one small correction which you made long ago and
3781	has not I am afraid found its way into the final
3782	version? If we go forward to page 8, the first
3783	paragraph of the next section, where you explain the
3784	sources for this section, saying that you have taken the
3785	material from a publication of yours, and
3786	Dr Dodsworth's, that, in fact, does not belong with that
3787	section; it belongs with the earlier section in which
3788	you set out the history and organisation of the Service?
3789	A. Yes, Mr Underhill. That should have followed
3790	paragraph 16 on page 7.
3791	MR JUSTICE BURTON: The whole of paragraph 17 --
3792	MR UNDERHILL: Yes.
3793	MR JUSTICE BURTON: -- should be paragraph 4?
3794	MR UNDERHILL: I suppose it could have gone under
3795	paragraph 4. I think what Dr Gunson is saying is the
3796	natural place is it still should be paragraph 17 but on
3797	the previous page.
3798	MR JUSTICE BURTON: I do not know if it is the natural
3799	place, but it is certainly convenient. There is room
3800	for it. 16(a). I just wonder whether for the avoidance

	A
3801	of muddle, given that there is space under 16(a), it
3802	could not be reproduced so that we are all given a fresh
3803	page 7.
3804	MR UNDERHILL: We will do that. I cannot think on my feet
3805	of any other correction. Can we wait until we finish
3806	the evidence in chief?
3807	MR JUSTICE BURTON: If there are more corrections I think
3808	quite honestly they are better made in handwriting, even
3809	if they are minor, in case any point will arise on
3810	them. I think this, which is simply a transcriptional
3811	error, would be better corrected given that particularly
3812	no one needs to retype any other page than page 7.
3813	MR UNDERHILL: Yes, very well.
3814	MR JUSTICE BURTON: We can put a line through paragraph 17,
3815	where it stands, and it can be retyped on the previous
3816	page.
3817	MR UNDERHILL: Yes. I can just pick up the absolutely key
3818	points. I do not think we need do more from section A.
3819	In paragraph 5 you mention:
3820	"There were by 1970 14 Regional Transfusion
3821	Centres, one for each region, except South London, in
3822	which there was a Centre for two regions together."
3823	I think that remained the position at the time
3824	with which we are concerned?
3825	A. Yes, that comprises the centres in England and Wales.
3826	Q. But not Scotland or Northern Ireland?
3827	A. Not Scotland or Northern Ireland.
3828	Q. In paragraph 6 you make the point that the Scottish
3829	National Blood Transfusion Service was a distinct
3830	service.
3831	In paragraph 7 you make the point that:
3832	" ... each Regional Transfusion Centre is managed
3833	by its own ... Regional Transfusion Director who is
3834	appointed by and answerable to the region" which is a
3835	shorthand for the Regional Health Authority.
3836	MR JUSTICE BURTON: Interrupting Mr Underhill -- I am sure
3837	I will know this -- subject to the pleasant fact we have
3838	Mr Forrester with us, we have no other Scottish
3839	connection with this case. Is that right?
3840	MR UNDERHILL: That is right. That is right, but there was
3841	a good deal of liaison and coordination, and that is
3842	why --
3843	MR JUSTICE BURTON: No Scottish claimant or defendant and no
3844	Scottish cause of action?
3845	MR UNDERHILL: Absolutely. Then in paragraph 8 you mention
3846	the other principal elements in the National Blood
3847	Transfusion Service, i.e. apart from the Regional
3848	Transfusion Centres, as being twofold: firstly, the
3849	Blood Products Laboratory which was at Elstree in
3850	Hertfordshire?

	A
3851	A. It was, yes.
3852	Q. There is also something called the BGRL which I mention
3853	only to say it does not come into our present story at
3854	all?
3855	A. BGRL stands for Blood Group Reference Laboratory, and
3856	they do not come into question in this litigation.
3857	Q. Indeed, in a way nor does the Blood Products Laboratory,
3858	except that they feature in the story of the ALT testing
3859	of plasma to which Mr Brown attaches some importance.
3860	A. Yes.
3861	Q. Just to be quite clear about it, their job is to make
3862	fractionated products of which the most important,
3863	though not the only, is what is normally called factor 8
3864	for haemophiliacs?
3865	A. That was the most important product with respect to
3866	transmission of hepatitis.
3867	Q. After 1982, that was managed by a separate authority
3868	called the Central Blood Laboratory Authority?
3869	A. That is correct.
3870	Q. At the relevant times, the director of that was Dr Lane?
3871	A. He became I think in 1990 the Medical Director when they
3872	appointed the Chief Executive.
3873	Q. In paragraph 9 you explain such coordination as there
3874	was between the Regional Transfusion Centres. It
3875	started with the post of Consultant Adviser to
3876	the Minister of Health, and that was the post that you
3877	succeeded to in 1981, and you explain, though I do not
3878	think we need go into it, the committee structure that
3879	existed at that time, but then over the page, you
3880	explain how in 1988, just at the beginning of the time
3881	of the first claimants, though we obviously will be
3882	going through the history a bit before this, the
3883	National Directorate to the National Blood Transfusion
3884	Service was set up and over the page in paragraph 13 you
3885	give the date for that, 28th July 1988, and that you
3886	were the National Director?
3887	A. That is correct.
3888	Q. Although that was a change in the direction of greater
3889	coordination than had been possible under the previous
3890	structure with a consultant, adviser and committees, it
3891	was nevertheless not a single executive authority. Your
3892	role was to coordinate the various Regional Transfusion
3893	Centres which remained the responsibility of their own
3894	regions?
3895	A. That is correct.
3896	Q. You make that point at the beginning of paragraph 14:
3897	"It is important to stress that the National
3898	Directorate did not have any executive authority and its
3899	successes came about by persuasion."
3900	You set out what some of those successes were.

	A
3901	Then after the period with which we are primarily
3902	concerned in this litigation, the National Directorate
3903	was itself replaced by the present defendant, the
3904	National Blood Authority, which is a single legal
3905	entity, an authority within the National Health Service,
3906	and has succeeded to the liabilities of the various
3907	regions, in so far as they related to blood transfusion?
3908	A. Yes, it became responsible for the management of the BPL
3909	and BGRL from April 1st, 1993 and for the Regional
3910	Transfusion Centres from April 1st, 1994.
3911	Q. Shortly after it took over its full responsibilities,
3912	you resigned, retired I should say --
3913	A. I retired.
3914	Q. That was in July 1994, and your role thereafter was
3915	part-time?
3916	A. That is correct.
3917	Q. Something which does not appear in your statement, but
3918	it is perhaps useful for the court to have -- it has
3919	been given already informally by my learned friend --
3920	can we have in very round figures at the relevant times
3921	how many donations per year were made in England and
3922	Wales, or collected?
3923	A. In England and Wales it was roughly 2.5 million. The
3924	figures including Scotland was 3 million.
3925	Q. Sticking with England and Wales, if at any rate that is
3926	the figure you have, about how many donors does that
3927	represent?
3928	A. Something in the order of 1.5 to 1.6 million.
3929	Q. So on an average, an individual donor would give blood
3930	slightly less often than twice a year?
3931	A. Many donors give blood twice a year, but there were some
3932	particularly commercial sites that we only visited once
3933	a year, because you could not disrupt the work of the
3934	factory.
3935	Q. Of course within that -- and we need not go into the
3936	detail of this now -- there are much smaller groups of
3937	donors who give very regularly by plasma phoresis?
3938	A. Indeed.
3939	Q. Just to get an idea of sizes, about how many donations
3940	would be collected by the largest of the Centres?
3941	A. I think the largest Centre was undoubtedly South London,
3942	and they collected something at that time in the order
3943	of 250,000 donations a year.
3944	Q. The smallest, I think --
3945	A. Something in the order of 80,000 to 100,000.
3946	Q. So in very, very rough terms -- I am doing mental
3947	arithmetic here -- South London would be processing
3948	something like 1,000 donations a day in very rough
3949	terms?
3950	A. In that order.

	A
3951	Q. Just one other general question: what is the broad
3952	turnover in the donor population? How many donors do
3953	you lose a year?
3954	A. From retirement, illness, donors moving from one venue
3955	to another, it is something in the order of 12 to
3956	15 per cent per year.
3957	Q. People just getting busier and --
3958	A. And stopping, yes.
3959	Q. Thank you. Then we can turn to the next section of your
3960	statement, which starts at page 8. You set out there a
3961	lot which is common ground, his Lordship has been told
3962	and I do not think I need spend any time on. You talk
3963	about the history of the discovery of hepatitis, the
3964	identification, in particular firstly of hepatitis A,
3965	secondly in paragraph 19 of hepatitis B, and at the
3966	bottom of page 21 you say:
3967	"Transfusion transmitted NANBH is generally a mild
3968	illness or is subclinical and in most instances jaundice
3969	does not result. In cases where there were no clinical
3970	signs ..."
3971	Let us pause there. Is there anything you want to
3972	add to that first sentence?
3973	A. No, I think the first sentence stands alone.
3974	Q. Then you go on to say:
3975	"In cases where there were no clinical signs ..."
3976	Was that the majority of cases?
3977	A. Yes.
3978	Q. " ... NANBH was diagnosed when the serum level of ALT
3979	reached two and a half times the upper normal limit."
3980	These phrases have been bandied around. I do not
3981	think there is any dispute about them. The broad
3982	distribution of ALT levels follows something like a bell
3983	shaped curve, does it not?
3984	A. Yes.
3985	Q. Two and a half times the upper limit of normal; it is
3986	very difficult to describe, but it means that on the
3987	whole there will be comparatively few people above that
3988	limit, it is normally defined as 3 per cent, I think?
3989	A. Yes, I think you are right in that.
3990	Q. In order to diagnose NANBH in the days before there was
3991	an anti-HCV test, what you would do is you would
3992	diagnose it when someone reached that limit on two
3993	occasions between two and 26 weeks after transfusion,
3994	two occasions three weeks apart in that period, provided
3995	the patient's ALT was normal prior to transfusion. You
3996	probably put it better there than --
3997	MR JUSTICE BURTON: What is the upper normal limit?
3998	A. In the American studies, it was normally taken as 45.
3999	Anything exceeding 45 would meet these criteria of 2.5
4000	times the upper normal limit. That makes it about 18.

	A
4001	MR JUSTICE BURTON: That is what I want to know. 18 is the
4002	upper normal limit. Therefore 2.5 times it is 45.
4003	MR UNDERHILL: There have been studies showing it varies
4004	between different populations a bit?
4005	A. It varies between different populations. It also varies
4006	between male and female.
4007	Q. Some more sophisticated studies have different cut-offs
4008	for men and for women?
4009	A. They do indeed.
4010	MR JUSTICE BURTON: This is a factual statement here,
4011	Dr Gunson. This is how, as I understand it, in England
4012	transfusion transmitted or NANBH was diagnosed, not
4013	clinical signs, but when the ALT level reached two and a
4014	half times the upper normal limit, twice in three weeks,
4015	and you have told me that the 45 was taken in the USA as
4016	being that limit. As a matter of fact, can you
4017	recollect what was the limit that was adopted in the UK?
4018	A. We had to follow the Americans, because we have no other
4019	evidence.
4020	MR UNDERHILL: Indeed the references you give there as being
4021	the references for that diagnostic criterion are both
4022	American references?
4023	A. They are.
4024	Q. I think, when we look at such English studies as there
4025	were, they expressly refer to the fact that they are
4026	adopting American criteria?
4027	A. Yes.
4028	Q. I do not think we need pause on paragraph 22 which just
4029	deals with some other hepatitis viruses.
4030	In paragraph 23, you talk about the occurrence of
4031	parenteral NANBH and you make the point that it varied
4032	throughout the world. You give a series of references,
4033	which I do not think we need follow up, but which
4034	support the proposition it was in general higher in the
4035	United States, Southern Europe and Japan than it was in
4036	Northern Europe and Australia.
4037	You then refer further on to three studies which
4038	we are going to have to look at it in more detail anyway
4039	and I think it is more convenient to come to them in
4040	their chronological sequence. Just so we identify them,
4041	they are a study by the Medical Research Commission
4042	Working Party in 1974, a study by Collins and others at
4043	a hospital in Newcastle published in 1983, and a study
4044	by Anderson and others at North London published in 1987
4045	which really contained the only UK material in the late
4046	1980s which would enable you to get a handle on the
4047	extent of NANBH in this country?
4048	A. Yes, true.
4049	Q. The most recent of those, the Anderson one, gives a
4050	frequency of transfusion transmitted NANBH -- that is

	A
4051	what we have been calling incidence -- of 1 per cent?
4052	A. Yes.
4053	Q. Or less than 1 per cent, I am so sorry.
4054	MR JUSTICE BURTON: Can I ask you to go back a little:
4055	"Using the criteria defined by the MRC that the
4056	diagnosis should only be made when the ALT value
4057	exceeded 100 units per litre", how does that tie up with
4058	what you have been saying about the 45? Is it a
4059	different measurement?
4060	A. My Lord, the Medical Research Council Working Party did
4061	their work in 1974, and they defined what they thought
4062	were levels which indicated non A non B hepatitis. When
4063	the American studies were published, they reduced the
4064	level of ALT considerably because they considered that
4065	two and a half times the normal value was more
4066	appropriate than 100 international units which is quite
4067	excessive.
4068	MR JUSTICE BURTON: That is more than five times the level?
4069	A. That is true.
4070	MR JUSTICE BURTON: That study, then, which only found
4071	2.4 per cent NANBH, or whatever it is, was measuring
4072	NANBH pretty drastically, pretty stringently. Is that
4073	right, because it would only --
4074	A. The 2.4 per cent was Collins, not the MRC study.
4075	MR UNDERHILL: My Lord, I am not sure I ever was going to
4076	come to the MRC study, though it is possible I might,
4077	because it was rather ancient history by the time we
4078	were looking at it. We have it. It is right to say, is
4079	it not, that it was at a time when the concept of NANBH
4080	and the label NANBH had not really been developed,
4081	although people were aware that there was hepatitis not
4082	caused by either A and B?
4083	A. Yes, I do not think in the MRC report non A non B
4084	hepatitis is mentioned as a term of reference.
4085	MR JUSTICE BURTON: I am sorry about this, Dr Gunson, it may
4086	be that this sentence is simply wrong or I have
4087	misunderstood it. It says:
4088	"Using the criteria defined by the MRC [which is
4089	100 per litre] Collins found ..."
4090	It was that question I was asking you about. That
4091	appears to suggest that by reference to Collins, Collins
4092	was adopting the MRC level of ALT and on that basis he
4093	did not find very much NANBH, and that is why I was
4094	inviting you to comment on the fact that on that basis
4095	he may have been underestimating the conclusion about
4096	the existence of NANBH if he was using the raised
4097	medical research limit.
4098	Your answer to me was, no, it was only the MRC
4099	that did that, whereas this appears to say that Collins
4100	did it.

	A
4101	MR BROWN: My Lord, if I can assist, Collins did use the
4102	100
4103	MR JUSTICE BURTON: Thank you. Can I ask you again,
4104	Dr Gunson --
4105	A. My apologies.
4106	MR JUSTICE BURTON: That is all right. My question was
4107	this, going back: that study, I said, having
4108	established that 100 was five times the level, that
4109	study then which only found 2.4 per cent NANBH, or
4110	whatever it is, was measuring NANBH pretty drastically,
4111	pretty stringently, and then your answer was the
4112	2.4 per cent was Collins, not the MRC study.
4113	A. That is true.
4114	MR JUSTICE BURTON: I think we may have been at
4115	cross-purposes. The fact is Collins apparently used the
4116	MRC test and only came up with 2.4 per cent. I have two
4117	questions, if I may. One is, if Collins was using 100,
4118	using a five times level, what does that say about his
4119	conclusions? My second question is I do not quite
4120	understand what it means by Collins found 2.4 per cent
4121	in cardiac surgery patients, but only two of two to
4122	eight patients, which is much less, had ALT, was he
4123	using two different tests to work out what NANBH was?
4124	A. They considered that I think it was seven or eight
4125	patients had non A non B hepatitis, but only two of the
4126	seven or eight had a persistently raised ALT. So they
4127	concluded although they may have had non A non B
4128	hepatitis this had resolved within a period.
4129	MR UNDERHILL: This is a complicated paper. I am not sure
4130	in the end how carefully we need to look at it. If we
4131	need to look at it at all, we need to look at the paper
4132	itself. I was going to come to it at a later stage.
4133	MR JUSTICE BURTON: I see that. Just to summarise my
4134	understanding, tell me if I have it wrong: the Collins
4135	paper tested NANBH at a much higher level very soon
4136	after what everyone else was doing by concluding that
4137	anybody with 100 ALT had NANBH, and there were
4138	apparently 2.4 per cent of such patients who
4139	occasionally so registered. Only two out of the total
4140	number of patients had a persistently raised ALT of that
4141	level?
4142	A. Yes.
4143	MR JUSTICE BURTON: That would mean that, if one was
4144	adopting a 45 level rather than a 100 level, a
4145	completely different picture might have been reached?
4146	A. It may well have, my Lord.
4147	MR UNDERHILL: In paragraph 24 --
4148	MR JUSTICE BURTON: Sorry, before you leave Anderson we will
4149	need to look at --
4150	MR UNDERHILL: It is just a question of when I do it.

	A
4151	MR JUSTICE BURTON: Not now. It is for my note. I do not
4152	know whether anyone knows, if Dr Gunson knows, whether
4153	Anderson was also adopting a 100 test with ALT or a 45.
4154	That is just a question that, if it cannot be answered
4155	now, will need to be borne in mind.
4156	MR UNDERHILL: I know the answer, even if Dr Gunson does
4157	not; it is actually she, and she says, and indeed as
4158	Dr Gunson has recorded, using the criteria for the USA.
4159	Then in paragraph 24 you refer to looking at
4160	people with liver disease how many of them had a history
4161	of previous transfusions, looking at it the other way
4162	round, or a different way round. You explain that at
4163	the relevant time the Japanese had found that high
4164	proportions, as there set out, of people with liver
4165	disease of various sorts had a history of previous
4166	transfusions. This could not be confirmed in the UK
4167	study. That is the study given the title "Wood and
4168	Others" though is so often the case the name is not the
4169	name of the principal mover, which was Dr Polakoff --
4170	A. Who was the last author.
4171	MR JUSTICE BURTON: That is the Polakoff Report, is that
4172	right?
4173	MR UNDERHILL: Yes. Again we will be going to that later.
4174	MR JUSTICE BURTON: Yes, absolutely.
4175	MR UNDERHILL: You refer to the problem in haemophiliacs.
4176	In 25 you make the point:
4177	"In many countries the principal concern between
4178	1980 and 1985 was the transmission of the HIV
4179	infection. NANBH was not regarded as a major clinical
4180	problem."
4181	What does "clinical" mean in that context?
4182	A. It means, Mr Underhill, that we did not receive reports
4183	of a lot of jaundiced patients following transfusion,
4184	although one has to say that earlier on I said that this
4185	is often a subclinical disease. But during the early
4186	1980s, we were not aware that a lot of patients were
4187	suffering from non A non B hepatitis, as a result of
4188	transfusion.
4189	MR JUSTICE BURTON: "Subclinical" means what?
4190	A. It means no symptoms but by chemical evidence of
4191	infection.
4192	MR UNDERHILL: It follows, therefore, that if there are no
4193	symptoms, you would only know there was biochemical
4194	evidence of infection if you tested patients?
4195	MR JUSTICE BURTON: "Subclinical" means the same thing as
4196	"asymptomatic", but it means something different from,
4197	I do not know, psychosomatic or whatever one might say,
4198	where someone is feeling ill, but there is no evidence
4199	at all?
4200	A. That is correct.

	A
4201	MR UNDERHILL: Then you set out again what is I think common
4202	ground, the discovery of the virus. Paragraph 26 is one
4203	that his Lordship put on his note of queries. What you
4204	are doing there is summarising some of the early
4205	unsuccessful attempts to identify the virus, there is a
4206	lot of technical description there, and unless his
4207	Lordship wants it explained, in which case it may well
4208	have to be explained by one with specialist expertise in
4209	that field, I suspect it is not going to be central to
4210	your evidence.
4211	MR JUSTICE BURTON: It is one of the paragraphs with a
4212	question mark against it, but if everybody thinks
4213	that --
4214	MR BROWN: I certainly will not be asking anything about
4215	it.
4216	MR JUSTICE BURTON: I am very happy to delete my question
4217	mark in that case.
4218	MR UNDERHILL: Then in paragraph 27, you refer to the moment
4219	at which the Chiron Corporation issued its press
4220	release, on 10th May 1988, at which they say -- this is
4221	an important document so I suppose I had better read it
4222	out:
4223	"Scientists at the Chiron Corporation have
4224	identified, cloned and expressed proteins from a long
4225	sought blood-borne hepatitis non A non B virus and have
4226	developed a prototype immunoassay that may lead to a
4227	screening test for non A non B anti-bodies."
4228	They refer to the fact that their partner was
4229	Ortho Diagnostics, the subsidiary of Johnson & Johnson
4230	which will market any immunodiagnostic products which
4231	result. As we know, Ortho were indeed producers of the
4232	first test when it did emerge?
4233	A. That is correct.
4234	Q. In paragraph 28, you set out the molecular biologic
4235	characterisation of HCV. I think it is fair to say
4236	there are witnesses still to come who have a greater
4237	expertise in this field, but you are simply setting
4238	out -- simply perhaps is the wrong word -- how the virus
4239	is made up, and which bits of it were identified in the
4240	Chiron clone?
4241	A. Yes.
4242	Q. Over the page, diagnostic assays for the detection of
4243	HCV, you say:
4244	"The first generation HCV was in the form of a
4245	radio active immunoassay."
4246	You refer briefly to the early trials. Then in
4247	paragraph 32 you refer to the first commercial kits
4248	using the Elisa technique. Perhaps just this important
4249	point, because it will come up later, the assay included
4250	antigen, that is a bit of a virus, as two components,

	A
4251	one called 511 and one called C100?
4252	A. That is correct.
4253	Q. We see those referred to again and again in the
4254	literature which follows. Then you say this in
4255	paragraph 33:
4256	"The sensitivity of the anti-C100 assay was
4257	restricted, since only about 65 per cent of transfusion
4258	transmitted NANBH was prevented by the transfusion of
4259	anti-C100 negative blood."
4260	You refer to one of the early papers that showed
4261	that. That is Van de Poel and others, including I think
4262	Dr Reesink. I do not think there is any dispute that
4263	65 per cent is about the right figure for the
4264	sensitivity of the first generation assay.
4265	You make the point:
4266	"It is shown that anti-C100 might take a year to
4267	develop after onset of infection."
4268	So there will be a long window period?
4269	A. Yes.
4270	Q. "Also some people who were found HCV positive ..."
4271	Perhaps I can pause there. There is some
4272	difference of usage. If you are being stripped, one
4273	would tend to say anti-HCV positive, because it means
4274	you are positive, it means it shows you have HCV
4275	anti-body, but it is a shorthand to say HCV positive?
4276	A. Yes, that should really read "HCV anti-body positive".
4277	MR JUSTICE BURTON: I do not quite understand that last
4278	sentence:
4279	"Some persons who were found HCV positive by the
4280	PCR lacked anti-C100 in their serum", i.e. they did have
4281	HCV as picked up by this terribly reliable PCR test, but
4282	for perfectly understandable reasons had not been picked
4283	up in the Ortho test, because they did not have
4284	anti-C100. You mean they never developed anti-C100? Is
4285	that it? Therefore they were never likely to fight the
4286	virus properly? Do you need an anti-C100 in order to
4287	fight the virus properly?
4288	A. My Lord, anti-C100 is only one of the antigens for HCV.
4289	MR JUSTICE BURTON: The most frequent one, is it?
4290	A. I would not like to be quoted on frequency, but the
4291	later test had two other antigens in it, C22 and C33.
4292	Some people who were PCR positive were anti-C22 positive
4293	only, without C100 or C33 positive only.
4294	MR UNDERHILL: Really, the more antigens you have in your
4295	test the more likely it is to catch everybody who is, in
4296	fact, incurring the virus?
4297	A. Yes, then in the third generation test they had an
4298	another additional antigen called NS5, so there were now
4299	five antigens.
4300	MR JUSTICE BURTON: Components are C1 and that does have its

	A
4301	own antigen?
4302	A. C100 is one of the antigens of the virus.
4303	MR UNDERHILL: Your Lordship may have said "antigen" when
4304	your Lordship may have meant "anti-body".
4305	MR JUSTICE BURTON: Thank you, anti-body. That had its own
4306	anti-body, C100?
4307	A. Yes.
4308	MR JUSTICE BURTON: 511 is another important component, you
4309	say. Does that have an anti-body?
4310	A. That is part of the C100 complex. So those two are very
4311	closely related.
4312	MR JUSTICE BURTON: Then the first generation only could
4313	pick up the anti-C100 antigen?
4314	A. And the anti-511 which are two related.
4315	MR JUSTICE BURTON: Thank you. Then there were other
4316	antigens which you have told us about in the later --
4317	A. In the second generation tests.
4318	MR JUSTICE BURTON: -- which picked up different components?
4319	A. Different components. One, the C22 is a separate
4320	component of the virus and C33 is the NS3 region of the
4321	virus.
4322	MR JUSTICE BURTON: I think there was a fifth one.
4323	A. Then the final one in the third generation test, there
4324	was NS5.
4325	MR JUSTICE BURTON: There is C100 and 511 which were picked
4326	up in the first generation?
4327	A. Yes.
4328	MR JUSTICE BURTON: C22 and C33 in the second generation?
4329	A. Plus the 511 and C100 in the second generation, picked
4330	up those four anti --
4331	MR JUSTICE BURTON: Then NS5 in the third, thank you. I now
4332	understand.
4333	MR UNDERHILL: You say that there is a geographical variance
4334	in the incidence of anti-C100 which, as you say is not
4335	surprising because the NANBH also had geographical
4336	variations. You give certain figures, which I do not
4337	think we need pause on.
4338	In paragraph 35, you point out that:
4339	"It was subsequently discovered in the UK that a
4340	high proportion of HCV 0 positive blood donors had been
4341	intravenous drug users in the past"?
4342	A. Indeed.
4343	Q. You say:
4344	"This may partly explain why NANBH was found with
4345	less frequency following the introduction of
4346	self-exclusion procedures for donors at increased risk
4347	of transmitting the HIV virus."
4348	That is what I was mentioning to his Lordship this
4349	morning. It is right, is it not, that in the middle
4350	1980s there were much more rigorous self-exclusion

	A
4351	procedures introduced for donors in order to deter or
4352	exclude those who were most likely to be at risk of
4353	carrying HIV?
4354	A. That is correct. One of the high risk groups for
4355	developing AIDS were intravenous drug users, and we
4356	discovered, when questioning those persons who had
4357	tested positive for anti-HCV, that quite a large number
4358	also had been intravenous drug users, often only on one
4359	or two occasions, maybe twenty years before.
4360	Q. In paragraph 36 you refer to what you have already told
4361	his Lordship about the introduction of second generation
4362	tests, including C22. Then we need not bother with 37,
4363	which is the third generation assay.
4364	Over the page, you deal with confirmatory tests
4365	for anti-HCV.
4366	A. Mr Underhill, could I just come back to 37, because it
4367	is a test that is involved, because UBI developed a test
4368	similar to the second generation Ortho and Abbott tests.
4369	Q. Indeed, with respect, Mr Gunson, you are obviously
4370	right, that was indeed one of the tests that was
4371	evaluated in the middle of 1991?
4372	A. That is correct.
4373	Q. When you were evaluating second generation assays?
4374	A. That is correct.
4375	Q. Shortly prior to introduction?
4376	A. That is correct.
4377	Q. Though it was not, in fact, I think one of the ones that
4378	came out well?
4379	A. No, it lacked the C33 which is the NS3 component. This
4380	fact was discovered in Scotland.
4381	(3.45 pm)
4382	Q. That is Follett. Follett is one of the top
4383	microbiologists in Scotland?
4384	A. He is indeed, yes.
4385	Q. Then over the page we come to the confirmatory tests for
4386	anti-HCV. You make the point that apart from the
4387	problems with the sensitivity of first generation
4388	assays, that is what we have just been looking at, which
4389	led to false negatives, they were also prone to yield
4390	false positives particularly in low risk populations.
4391	In order to deal with the possibility that a positive
4392	result may, in fact, be false, it is necessary to have a
4393	reliable confirmatory test. We will come in due course
4394	to your contemporary concern about that and all the
4395	documents in which that is expressed. For the moment,
4396	we are just concerned with just establishing when these
4397	various tests came along.
4398	In 1990, Ortho introduced what we call RIBA 1.
4399	MR JUSTICE BURTON: Do we have a date for that?
4400	MR UNDERHILL: Dr Gunson does not give one. I think

	A
4401	gradually a date has emerged. May.
4402	MR JUSTICE BURTON: Thank you.
4403	MR UNDERHILL: This comprised the two antigens. Those are
4404	the same ones for which the Elisa is already screening.
4405	Is that right, C100 and 511?
4406	A. That is correct.
4407	Q. " ... absorbed on to a strip."
4408	My Lord, may I intervene to say this is
4409	particularly an area where Dr Barbara's slide show will
4410	I think a picture will tell a thousand words, but we
4411	will do the best we can for the moment.
4412	MR JUSTICE BURTON: Yes.
4413	MR UNDERHILL: "To confirm a positive result, a visual
4414	band", basically a line, is that right?
4415	A. Yes.
4416	Q. " ... had to be produced against both the C100 and the
4417	511 antigens; a single band against either of them was
4418	treated as an indeterminate result. While RIBA 1 was
4419	useful in distinguishing true from false positives" and
4420	you refer particularly at the time to the letter to the
4421	Lancet from Ebeling:
4422	"It was a supplementary rather than a
4423	confirmatory assay because it tested for the presence of
4424	the same markers as the primary assay, and unfortunately
4425	non-specific results continued to occur."
4426	You refer to an article by Follett after the
4427	event, but that has a history section which explains the
4428	position?
4429	A. It does indeed.
4430	Q. I do not think we need go to that at present. It is
4431	obviously going to be a question when we come to look at
4432	what the ACVSB was thinking in about early 1990.
4433	"At the same time, Abbott introduced an the HCV
4434	neutralisation Elisa as a different form of
4435	supplementary test. The principle of this test was the
4436	C100 antigen would neutralise the corresponding
4437	anti-body, but anti-bodies to other components in the
4438	assay would not be neutralised."
4439	If his Lordship wants to have that explained you
4440	had better do that better than me, but it may be it is
4441	enough to say that the performance was similar to that
4442	of RIBA 1?
4443	A. It was.
4444	Q. We do not hear much about that assay in the contemporary
4445	papers?
4446	A. It has not been a popular assay. Most workers have used
4447	the RIBA series rather than the Abbott.
4448	MR JUSTICE BURTON: I may be barking up the wrong tree, but
4449	I thought Abbott had an alternative assay to Ortho and
4450	we have been calling it the first generation. This is

	A
4451	something different.
4452	MR UNDERHILL: Abbott manufactured both an original kit a
4453	bit later than Ortho, but also they, knowing there was a
4454	demand for confirmatory, tried this rather different
4455	route to confirmation.
4456	MR JUSTICE BURTON: This is an Elisa which I thought was the
4457	same as the first generation test.
4458	MR UNDERHILL: It is using the Elisa technique. It is using
4459	the Elisa technique to do a form of confirmation test.
4460	MR JUSTICE BURTON: This is unquestionably an Abbott
4461	confirmatory which we have not heard of before and it
4462	does not sound as though we are going to hear of again?
4463	A. It was not used a great deal apart from experimental
4464	work.
4465	MR JUSTICE BURTON: There is RIBA 1 and 2, there is PCR and
4466	there might have been, but was not, Abbott, Elisa and
4467	supplementary.
4468	MR UNDERHILL: Precisely. Subject to anything Mr Brown may
4469	ask my learned friend, I think that is the basis on
4470	which we both proceeded.
4471	MR JUSTICE BURTON: Thank you.
4472	MR UNDERHILL: You say:
4473	"The unsatisfactory nature of these two
4474	supplementary assays led to the development of a number
4475	of others."
4476	Rather in the same way you mention 3, but the only
4477	one that actually stuck was RIBA 2 but became popular in
4478	use?
4479	A. Yes, that is correct. The matrix assay with Abbott was
4480	used in certain parts of the United States, and Inno-Lia
4481	was investigated by the Scottish Blood Transfusion
4482	Service but they did not use it as a routine.
4483	Q. You then describe the RIBA 2 and you explain that it
4484	included in addition to the two original antigens which
4485	were used in the assay, two further antigens, which were
4486	the ones that were later incorporated into the second
4487	generation assay.
4488	A. That is correct.
4489	Q. Their first use was in the RIBA 2 for confirmatory
4490	purposes?
4491	A. Yes.
4492	Q. You say:
4493	"A positive result was obtained when a band was
4494	obtained against at least two recombinant antigens. A
4495	single band donated an indeterminate result. Once
4496	again, it was not a true confirmatory assay, since the
4497	antigens were not derived from an independent source,
4498	but as described below, it was in due course shown to be
4499	much more reliable than RIBA 1. It was introduced in
4500	the UK for experimental purposes during the autumn of

	A
4501	1990, not in regular use until April 1991."
4502	I think it is right, is it not, Dr Gunson, that
4503	the first time it was used was as part of the
4504	Ortho/Abbott trial in the autumn of 1990 about which we
4505	have all heard?
4506	A. Yes, that is what I would regard as the experimental --
4507	MR JUSTICE BURTON: Can I again make sure I am following?
4508	RIBA 2 was a confirmatory test. It picked up some
4509	antigens which you were telling me earlier only were
4510	picked up under the basic test, if I can call it that,
4511	in the second generation, which had not yet come into
4512	existence. So we were in the position of having a first
4513	generation test, which only related to antigen C100 and
4514	511, but a confirmatory or a supplementary test which by
4515	then was picking up more antigens, which, although may
4516	be only supplementary as you call it, may be inevitably
4517	much better than the first generation test?
4518	A. Yes, at this time they were generating the second
4519	generation Elisa tests, and the two were going together.
4520	MR JUSTICE BURTON: Except that you tested the first
4521	generation test, or multicentre --
4522	A. My Lord, we had some second generation tests for
4523	experimental purposes much earlier than they released
4524	them for routine testing.
4525	MR JUSTICE BURTON: I understand. What we have been calling
4526	them -- I am going to forget what we have been calling
4527	it. Not multicentre anything in the end, but Pilot
4528	Study 2 in the autumn of 1990 which was testing first
4529	generation assay with effectively second generation
4530	supplementary test?
4531	A. That is correct.
4532	MR UNDERHILL: In paragraphs 42 and 43 you deal with these
4533	other two assays which I think we are not going to spend
4534	time on, the Matrix and the Inno-Lia ones. Then at
4535	paragraph 44 you say something about PCR. You say that
4536	it was developed in the Middlesex Hospital in the course
4537	of 1990, the PCR chain reaction test detects the
4538	presence of the virus itself in the blood, which is
4539	referred to as viraemic. Just pausing there, it is
4540	right, is it not, that PCR, as a technique, had been
4541	developed some time previously for other viruses?
4542	A. Yes, indeed.
4543	Q. What happened in 1990 is people worked out how to do it
4544	with the new virus, so to speak?
4545	A. And I think, Mr Underhill, the group that discovered the
4546	virus had PCR earlier than UK.
4547	Q. I think that is right, because I think Dr Weiner
4548	published something in the Lancet in I think January
4549	1990
4550	A. Something like that.

	A
4551	Q. Referring to her use of it. She is part of the Chiron
4552	team, is she not?
4553	A. Yes.
4554	Q. In the UK, the first person to develop it was the
4555	Middlesex Hospital. That is Professor Tedder?
4556	A. That is Professor Tedder. There were others. The Scots
4557	of course were working on this as well.
4558	Q. Yes.
4559	MR JUSTICE BURTON: Why would PCR not be used as the basic
4560	test in that case? I had not realised that.
4561	A. Because it took a great deal of time to do a PCR test
4562	ten years ago. It is much better now, but it took a
4563	great deal of time, and we would never have been able to
4564	test every donation by PCR.
4565	MR JUSTICE BURTON: Trying to get into the thinking of the
4566	Chiron team, they discovered the virus by using the PCR
4567	test, but they thought to themselves that will never
4568	catch on, at least not for the moment, as a routine
4569	test, so having identified the virus with the PCR test
4570	we now have to find an assay which can be readily
4571	marketable and usable and therefore they then invented
4572	the first generation test. Do I have the general
4573	picture?
4574	A. I do not know. I have to say this is beyond my
4575	knowledge, whether they used PCR to develop the clone.
4576	Someone else would have to answer that question.
4577	MR JUSTICE BURTON: I thought that is what Mr Underhill was
4578	putting to you.
4579	MR UNDERHILL: I was not. My understanding is the same as
4580	Dr Gunson's. You discover the virus by quite different
4581	techniques, described loosely as cloning techniques; do
4582	not ask me how they work. Once you have identified it,
4583	then you can apply to it the PCR technique, which is a
4584	pre-existing technique. Perhaps I can ask you this,
4585	Dr Gunson: the gist of his Lordship's question, as I
4586	understand it, was that the team at Chiron would have
4587	recognised that PCR was never going to be usable as a
4588	primary screening test. That is why they developed --
4589	A. I am sure that is true.
4590	MR JUSTICE BURTON: I think I simply picked up and perhaps
4591	made too much of Dr Gunson's remark to you:
4592	"I think, Mr Underhill, the group that discovered
4593	the virus had PCR."
4594	I assumed that meant they had used PCR in the
4595	detection process.
4596	MR UNDERHILL: No, it is the other way round. You go on to
4597	describe PCR and the problems of using it. At the end
4598	you say:
4599	"It is technically a more complex test than the
4600	Elisa assays described above and is not suitable for

	A
4601	primary screening nor for use in Regional Transfusion
4602	Centres."
4603	You say it was first used in the UK to test
4604	selected samples from the Ortho/Abbott First Generation
4605	Study in September/October 1990.
4606	I think we can pass over paragraph 45 and come to
4607	a new section which is the one where you describe
4608	surrogate testing for hepatitis non A non B.
4609	I was going to deal with this, with his Lordship's
4610	leave, in a slightly different way than simply taking
4611	you through this word by word and following up the
4612	references.
4613	You start by identifying the two papers which
4614	first suggested an association between raised ALT levels
4615	in donors and NANBH in recipients. Those two papers are
4616	the paper by Aach and others and the paper by Alter and
4617	others. I think his Lordship has to see those papers
4618	because the whole debate starts with them. Can I
4619	therefore take you first to the Aach paper, which is at
4620	H1, year 84? I cannot remember, Dr Gunson whether you
4621	are familiar with these bundles. You may have been
4622	looking at the papers in another form. They have
4623	coloured tabs for the different years and numbered tabs
4624	within each year. So look for the coloured tab for 84
4625	which is a pale blue one. 84 is a slip of my own
4626	notes.
4627	A. 81?
4628	Q. 81. Sorry, my Lord, it is 81, tab 2.
4629	MR JUSTICE BURTON: No complaint at all, but I notice that
4630	someone has marked it up in my book, in my proof,
4631	witness statement, as tab 6.
4632	MR UNDERHILL: I tell you what has happened, and I hope this
4633	has been put right, but perhaps I have lost touch with
4634	what happened: initially, Dr Gunson's statement was
4635	marked up with references to the I bundles, the 26 green
4636	ones. Since both Mr Brown and I are very keen that we
4637	should try to keep a manageable bundle of papers, I had
4638	understood that they had been re-marked up with the
4639	references to the H bundles. If that has not
4640	happened --
4641	MR BROWN: I think all of them have or nearly all of them
4642	have bar this one. This is one that has slipped through
4643	the net.
4644	MR UNDERHILL: I am sorry. It may well be I said it need
4645	not happen. I am sorry, my Lord. The result of this is
4646	that your Lordship's references there are all to the I
4647	bundles and are going to be completely useless to your
4648	Lordship. All I can do -- and I must apologise -- is
4649	give your Lordship the H references as we go along.
4650	MR JUSTICE BURTON: The other possibility is that I simply

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4651	over a weekend or over a reading day -- or something of
4652	that kind, because it is obviously not urgent, probably
4653	a weekend because a reading day I might actually need
4654	it -- leave J1 behind with someone for someone to write
4655	them in.
4656	MR UNDERHILL: I am perfectly happy to do that.
4657	MR JUSTICE BURTON: I think we will have to substitute the
4658	statement, because I have done this already, because I
4659	marked up my original statement which had no references
4660	on and then had to re-mark it. I do not want to do that
4661	now.
4662	MR UNDERHILL: I quite understand. In practice I think --
4663	let us see how we get on today and tomorrow -- all the
4664	references to which I attach importance I will be taking
4665	obviously Dr Gunson to, and therefore your Lordship will
4666	get the H references, and the others probably therefore
4667	your Lordship will never need unless Mr Brown attaches
4668	importance to them, in which case the same thing will
4669	happen.
4670	MR JUSTICE BURTON: Can I while we have interrupted the flow
4671	of your evidence say this: I was planning to rise a
4672	little earlier this evening and suggest that I have a
4673	short meeting with counsel and solicitors in my room.
4674	If we rose about 4.10, are you going to be able to get
4675	there, Mr Brooke?
4676	MR BROOKE: With less difficulty than last week.
4677	MR JUSTICE BURTON: We will rise at 4.10 and gather in my
4678	room at 4.20, if that is convenient.
4679	MR UNDERHILL: Certainly.
4680	MR JUSTICE BURTON: I was going to say counsel and
4681	solicitors; probably one solicitor on each side if that
4682	is not too inconvenient and three counsel.
4683	MR UNDERHILL: Perhaps we will do this paper, which is an
4684	important paper. It may take a little time. That will
4685	be a good place to break.
4686	Let us get the basic background in. This is the
4687	final report, or at any rate at the time the final
4688	report, of something called the Transfusion Transmitted
4689	Viruses Study, TTVS for short. Is that right,
4690	Dr Gunson?
4691	A. That is correct.
4692	Q. In his opening, my learned friend took your Lordship to
4693	an interim report of the same study which appeared in
4694	1978
4695	MR JUSTICE BURTON: Assuming this is tab 2, this is the
4696	New England Journal of Medicine 1981?
4697	MR UNDERHILL: Very briefly, your Lordship was.
4698	MR JUSTICE BURTON: I was taken to page 993.
4699	MR UNDERHILL: I think that is right. When my learned
4700	friend was telling your Lordship generally about the

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4701	Transfusion Transmitted Virus Study he, in fact, I think
4702	took you -- he will correct me if I am wrong -- to
4703	tab 78.1 which is I hope your Lordship also has marked
4704	up --
4705	MR JUSTICE BURTON: I do, although I do not know that that
4706	was on the question of surrogate testing.
4707	MR BROWN: It was not. It was simply to indicate there was
4708	a major problem in the statements.
4709	MR UNDERHILL: There we are.
4710	MR JUSTICE BURTON: My colour coding is beginning to work in
4711	that case.
4712	MR UNDERHILL: I am glad about that. His Lordship need not
4713	be bothered with the names of everybody involved in the
4714	study, but the key names that will come up again and
4715	again are obviously Dr Aach himself, we see the name of
4716	Dr Hollinger quite often, and Dr Stevens, that is
4717	Cladd Stevens. These are all names that appear in
4718	subsequent literature.
4719	Perhaps I should just take his Lordship through
4720	the abstract:
4721	"To evaluate the incidence of post-transfusion
4722	hepatitis and factors influencing its occurrence, the
4723	study respectively followed 1,513 transfusion recipients
4724	from 1974 through 1979."
4725	So a five year period.
4726	"The attack rate for non A non B hepatitis was
4727	10 per cent."
4728	That means of that 1,513 recipients, 156
4729	recipients developed non A non B.
4730	"The incidence of hepatitis was directly related
4731	to ALT level in blood donors. In recipients of multiple
4732	transfusions of blood that had no donor ALT level above
4733	29, the attack rate was 6 per cent or less. At higher
4734	donor ALT levels, the attack rate increased
4735	progressively, reaching 45 per cent in recipients of
4736	units with an ALT of 60 IU or greater."
4737	MR JUSTICE BURTON: Can I know what an attack rate means?
4738	Does it actually mean they have symptoms of non A non B
4739	hepatitis?
4740	MR UNDERHILL: It means that they develop the disease by the
4741	criteria which I will be coming to in a moment.
4742	MR JUSTICE BURTON: By raised ALT?
4743	MR UNDERHILL: Yes. So ALT comes in two quite separate
4744	points into this exercise. You look at the ALT of the
4745	recipients to see whether they have the disease, and you
4746	also look at it in the donor to see whether there is an
4747	association.
4748	MR JUSTICE BURTON: That is what I understand now. So the
4749	attack rate of 10 per cent means that there was
4750	10 per cent raised ALT -- I know I am begging the

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4751	question, but this is the summary -- 10 per cent raised
4752	ALT in recipients.
4753	MR UNDERHILL: Yes.
4754	MR JUSTICE BURTON: The incidence of hepatitis -- that is
4755	another way of putting attack rate, is it?
4756	MR UNDERHILL: Yes.
4757	MR JUSTICE BURTON: Is directly related to the ALT level in
4758	the donor.
4759	MR UNDERHILL: Yes. I explained that correctly, did I,
4760	Dr Gunson?
4761	A. Yes.
4762	Q. "A similar relation was observed among recipients of
4763	single units of blood. Moreover, hepatitis developed in
4764	ten out of 11 recipients of two units with an ALT level
4765	of 55 IU or greater. These data indicate screening of
4766	blood for ALT levels would reduce the incidence of non A
4767	non B post-transfusion hepatitis."
4768	That is where the story really begins subject to
4769	the interim study in 1978?
4770	A. Yes.
4771	Q. We need not go through the detail of this paper, but
4772	perhaps we should just identify a few points. Firstly,
4773	on page 990 under the heading "Methods", the first
4774	paragraph identifies the four centres -- this was
4775	another multicentre study -- at which people were
4776	studied and the periods: New York, St Louis --
4777	MR JUSTICE BURTON: 990, that is different presumably from
4778	the first page. Do we start at 989?
4779	MR UNDERHILL: The first page, though it is not numbered, is
4780	989
4781	MR JUSTICE BURTON: I do not have 990.
4782	MR UNDERHILL: My Lord, how infuriating, I am sorry. Is
4783	this a systematic problem?
4784	MR JUSTICE BURTON: No, it is not. I have 992. It is the
4785	one page I am missing.
4786	MR UNDERHILL: We will see very quickly whether we can find
4787	it. Do you have it, Dr Gunson?
4788	A. I think they are listed on this page.
4789	Q. Very well. I dare say they are. Do you have that page,
4790	990?
4791	A. No.
4792	Q. There is one for Dr Gunson. I do not know why I am
4793	uniquely blessed. I do not know if I noted it and
4794	cannibalised it from somewhere else and forgot to tell
4795	anybody. This is for his Lordship. (Handed)
4796	MR BROWN: I have read it many times and without realising
4797	it I was missing a page.
4798	MR UNDERHILL: In fact, as Dr Gunson rightly points out you
4799	can actually see the centres also on the previous page,
4800	but I noted them up on this page. Under the heading in

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4801	the first column "Methods", one sees New York, St Louis,
4802	Houston and Los Angeles, and various different dates,
4803	not quite the same for each centre. These were all
4804	dates in the 1970s. That would be at a time before
4805	donor self-exclusion policies had become tighter?
4806	A. That is correct.
4807	Q. If we look under the heading "Patient Recruitment" and
4808	"Follow-up", these were all obviously patients who were
4809	attending hospital for reasons which required them to
4810	have blood, and various tests were done on them, I do
4811	not think we need worry about those, and then two of the
4812	little paragraphs up from the bottom of the page,
4813	"Recruitment" and "Follow-up", one sees that eligible
4814	patients were seen at 4, 6, 8, 10, 12, 15, 18, 21, 24
4815	and 40 weeks after transfusion. So they were seen very
4816	regularly, and at each visit, their blood was taken.
4817	Follow-up was discontinued if there was
4818	retransfusion or any other recognised exposure to viral
4819	hepatitis. That is to exclude people who might have
4820	been getting it for some other reason.
4821	Case evaluation, a patient was suspected of having
4822	viral hepatitis if, between 11 and 180 days after
4823	transfusion -- that is effectively during the first six
4824	months -- there were at least two consecutive blood
4825	samples with elevated ALT levels, one at 45 IU or more
4826	and another of 90 or more, and the specimens had to be
4827	collected not less than three days and not more than 17
4828	days apart.
4829	I think it is right, is it not, Dr Gunson although
4830	criteria like that are used in other studies, everybody
4831	has a slightly different way of defining it?
4832	A. There is a slight variation, but it is essentially
4833	similar.
4834	Q. The "essentially" is two highly raised ALTs in the six
4835	month period?
4836	A. That is correct.
4837	Q. One sees at the top of the next column:
4838	"Periodically records for each patient were
4839	evaluated by a panel."
4840	It says:
4841	"The diagnosis of non A non B hepatitis was made
4842	after the following possible explanations of ALT
4843	elevations had been excluded."
4844	One obviously hepatitis B, since then it would not
4845	be non A non B, or underlying disease, drug induced
4846	hepatitis, or chronic liver injury undetected during
4847	recruitment but detected later.
4848	So you are trying to exclude as far as possible
4849	people who might have hepatitis for some reason
4850	unrelated to the transfusion?

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4851	A. Indeed.
4852	Q. As far as we can see, however, from there, they did not
4853	exclude people who were drinkers or obese?
4854	A. No, that is not mentioned.
4855	Q. Then the results. My Lord, it is going to take a little
4856	time. Your Lordship wanted to rise at 4.10. Perhaps
4857	that is a good point at which to break.
4858	MR JUSTICE BURTON: That depends how long you are going to
4859	be. It may be sensible to finish the article.
4860	MR UNDERHILL: I will finish a bit more. We see the
4861	results, and at the bottom of the page we see the
4862	numbers of recipients. Over the page, at 991 -- which
4863	I hope everybody has -- one sees how the figure of
4864	10 per cent is arrived at. It is 156, which is almost
4865	10 per cent of 1,513, which is the total number of
4866	people.
4867	The incidents varied very considerably in the
4868	different centres. The lowest was St Louis at just over
4869	4 per cent and the highest was and the highest was
4870	Houston at 18 per cent.
4871	Then they looked at the donors. For those 1,513
4872	recipients there were a total of 5,500 donors, because
4873	on average as we see somewhere each recipient received
4874	just under four units of blood, and I really do not
4875	think it is necessary to go through the rest of this,
4876	but what it does is it establishes the association with
4877	raised ALT levels in donors, which is summarised in the
4878	abstract.
4879	Then under the heading "Discussion", there is a
4880	good deal of discussion of the history, and then over
4881	the page at 993, perhaps this rather long section --
4882	I think we should probably read it all, because this is
4883	where it all starts. Picking it up at the first
4884	paragraph in the first column:
4885	"We also conclude, on the basis of the results of
4886	this study, that ALT testing is a potentially useful
4887	method of screening donors to reduce the incidence of
4888	non A non B hepatitis. The advantages of the test are
4889	that it is available in an automated form, applicable
4890	to ...", then I am afraid there is a word missing I
4891	cannot read, but " ... large numbers of samples, that it
4892	is equally fit [I think it must be] for plasma or serum
4893	samples and is not influenced by the postprandial state,
4894	that hemolysis has no appreciable effect and that the
4895	enzyme is sufficiently stable to make extreme care in
4896	the handling of specimens unnecessary.
4897	"The observations in this report suggest that
4898	about 40 per cent of the cases of non A non B
4899	post-transfusion hepatitis among recipients in this
4900	study could have been prevented by discarding units with

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4901	an ALT level in the upper 3 per cent of the distribution
4902	(i.e. ALT 45 IU)."
4903	That is where all these figures your Lordship has
4904	been seeing all start.
4905	"A larger number of cases could have been
4906	prevented by lowering the 'cutoff' to 30 IU, but that
4907	procedure would have required discarding about
4908	9 per cent of the blood collected. If ALT screening is
4909	initiated nation wide, there will be fewer units of
4910	blood for transfusion than are presently available, no
4911	matter what cutoff level is chosen. The increased
4912	number of rejected units will undoubtedly require
4913	improved [I am not quite sure what that word is] efforts
4914	in recruiting donors to meet the transfusion needs of
4915	this country.
4916	"Consequently, the benefits of initiating ALT
4917	screening must be carefully weighed against the number
4918	of potential donors that would be excluded, the overall
4919	incidence of hepatitis in recipients and the severity of
4920	the disease. Although non A non B post-transfusion
4921	hepatitis is most often subclinical, approximately 20 to
4922	40 per cent of patients who contract this disease are
4923	symptomatic. At least 25 per cent of all affected
4924	patients have ALT lasting longer than six months.
4925	Moreover, a chronic non A non B carrier state who is
4926	often asymptomatic has been documented, a recent report
4927	described a patient who was infectious over a six-year
4928	period. The development of chronic hepatitis and
4929	progress to cirrhosis have been observed although the
4930	precise frequency of these complications is uncertain.
4931	"Other considerations must be taken into account
4932	if widespread ALT testing of blood donors is to be
4933	initiated. These include uncertainty about how long to
4934	defer a donor whose blood is rejected, as well as the
4935	problems that might occur in the quality control and
4936	proficiency of ALT testing on a nationwide basis.
4937	Advising donors of the implications of the ALT level
4938	would also pose a special problem. In addition,
4939	adjustments might have to be made for the observed
4940	differences between ALT levels in male and female donors
4941	and for the ages of donors. Nonetheless, it appears
4942	from this study that screening donor blood to eliminate
4943	units with elevated ALT levels would result in a
4944	substantial reduction in non A non B post-transfusion
4945	hepatitis.
4946	"Although ALT screening lacks the sensitivity to
4947	detect all infectious units and lacks the specificity to
4948	detect only infectious units, the high correlation
4949	between an elevated ALT level and infectivity of
4950	transfused blood provides a compelling argument that

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4951	such screening should be instituted. Obviously, if
4952	there were sensitive and specific serologic tests for
4953	the identification of non A non B agent or agents then
4954	ALT testing would be unnecessary. However, efforts to
4955	date to identify any such a test have not been rewarding
4956	despite extensive research."
4957	That, Dr Gunson was really the start of the
4958	debate, was it not?
4959	A. That began the debate, as you say.
4960	MR UNDERHILL: We will see how the debate developed and what
4961	decisions were reached in the United States.
4962	MR JUSTICE BURTON: If you would like to assemble in the
4963	hallway just to the south of the Royal Courts of Justice
4964	at the end of the corridor to my room, my clerk will
4965	come and fetch you, i.e. into the main building, across
4966	the stairs, into the main building and before you come
4967	out of the main building again into the car park, just
4968	there, there is a doorway.
4969	MR UNDERHILL: May I ask, there was some suggestion of
4970	sitting at 10.00 tomorrow, but I do not think that was
4971	pursued.
4972	MR JUSTICE BURTON: I do not think it was. I said I would
4973	rise a bit early in order to assist those travelling.
4974	(4.20 pm)
4975	(Court adjourned until 10.30 am the following day)
4976	Submissions by MR UNDERHILL..... 1
4977	Submissions by MR BROOK SMITH..... 42
4978	DR HAROLD GUNSTON (sworn)..... 150
4979	Examination-in-chief by MR UNDERHILL..... 150