GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council's Preliminary Proceedings and Professional Conduct Committee (Procedure Rules) 1988)

On:
Thursday, 16 August 2007

Held at:
St James's Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

JAYNE LAVINIA MARY DONEGAN MB BS 1983 Lond
Registration No: 2826367
(Day Seven)

Panel Members:
Mrs S Hewitt (Chairman)
Mr J Brown
Ms J Goulding
Dr M Goodman
Mr R Grey QC (Legal Assessor)

MR I STERN, QC, and MR S SINGH, Counsel, instructed by Clifford Miller, Solicitors, appeared on behalf of the doctor, who was present.

MR T KARK, Counsel, instructed by Field Fisher Waterhouse, Solicitors, appeared on behalf of the General Medical Council.

Transcript of the shorthand notes of Transcribe UK Ltd
Tel No: 01889 270708

INDEX

Page

FITNESS TO PRACTISE

THE CHAIRMAN: Good morning.

MR STERN: There is now an index for the defence bundle if that would be helpful and if you would like that now, that would probably be a good time to give it. *(Same handed to the Panel)*

THE CHAIRMAN: You do not need a number for that, just file it at the beginning.

Good morning, Dr Donegan, the questions will now come from Mr Kark.

Cross-examined by MR KARK

Q Dr Donegan, have you got everything you need in terms of references?
A I think I have.

Q I want to start obviously with your first report, but before we turn to it I just want to ask you this, who did you think were going to be the readers of that report? Who did you think was going to get it and read it?
A I thought that the two other experts, Dr Conway and Professor Kroll, were going to get it and read it and also the court.

Q What about the mothers?
A I thought the mothers and the fathers would read it.

Q It would be the mothers who you were writing the report for in a sense. The fathers, the judge, obviously, would read it, all the barristers in the case would read it?
A Yes.

Q Obviously, the other experts would read it. You understood that your report would form a significant feature of the evidence?
A That is correct.

Q Apart from what appears to be your fundamental differences and view on vaccination, there was no reason to think anything other than that the fathers were caring, yes?
A I had no information about the social or family aspects of the fathers' case or their treatment or otherwise of their children.

Q But appreciating, as you did, that the fathers were going to read your report because they were party to the action, yes?
A Yes.

Q You had no reason to think that they were anything other than caring and conscientious and wanted to do the best for their daughters?
A I had no reason to think otherwise than that.

Q You had no reason to think that they would not take your expert report just as seriously as all the other expert reports?
A I cannot comment on that.

Q You understood that your report could have a significant impact upon the reader?
A Yes, that is why I wrote it.

Q Yes, you expected it to be taken seriously?
A I did.

Q You, therefore, must have appreciated that your report could have an important effect upon the outcome of the case?
A Indeed.

Q Taking your report at face value, you appreciated presumably that the fathers could have decided to abandon their application?
A Yes, they could have.

Q Whether or not the other experts agreed with you, the parties could take their own line, could not they?
A I am not an expert on legal cases but I presume this is the case in all legal cases.

Q When you wrote your first report you did not know whether or not there would be any further expert reports in the case.
A No, I did not.

Q You did not know that Dr Conway was going to be instructed to write a response?
A That is correct.

Q Your report, when you wrote it, had to be written as an entity, as it were, as a stand alone report?
A When I wrote that report I was replying to the reports of the other two experts.

Q You say you were replying to them, you had received the other reports?
A I had.

Q Yes, but you must have understood that your report would be taken just as seriously on face value as theirs. Yes?
A Indeed.

Q You expected it to be so. I mean, you are not saying, are you, that the only reason you wrote your report in the way that you did was because you thought someone else would come along to correct it?
A Not at all.

Q The only reports that you had read before you wrote your first report were those of Dr Conway and Professor Kroll, which we have seen and we do not need to go back to them, and they, as you pointed out, cited no research.
A That is correct.

Q You were the first expert witness to do so.
A That is right.

Q I expect that you will accept it was important to reflect that research accurately?
A I, when I cited the references, had two reports that had no references and I was following the format they used in how I presented my information, and I was trying to improve what I had done by citing references because of the things that were in their reports that had no references and statements that were not, for example, backed up by any references or evidence.

Q I understand that, but the question is that you must have realised when you cited research that it was important to reflect the research itself accurately?
A When I cited the research I was citing the findings having taken into account the methods of the research and as I was asked to give an opinion I was giving an opinion.

Q I understand that. I will ask the question a third time and then move on. Did you think it was important to reflect the research accurately?
A I would like you to distinguish between the data presented in the research and the opinions of the authors who wrote the research and made conclusions because they are different.

Q They are not always different.
A No, but they are not the same entities. One is data, I cannot always say fact, but one is found fact from what they have researched; and the other is deductions and opinions that they have made on the basis of what they have produced in their research and they are different in my opinion.

Q We will probably come to that as we go through your report. You also understood, I expect, that certainly the lay readers, by which I mean the fathers and the mothers, and probably the judge, were unlikely, very unlikely, to read all of the research material?
A I did not know how much they would read.

Q When you provided your first report when did the parties get the research material?
A Just at about the time ... well, as you can see, how late I was instructed.

Q Yes.
A I only finished within days or a week before the actual case because of the lateness of my instructions.

Q Yes.
A So it certainly was not a long time.

Q When your report was served, I think it was actually originally served without the background research, was it not?
A I sent off the report on 14 June and the papers were gathered and collated sometime along then before and after.

Q Did you seriously expect the fathers and the mothers to sit down and read through the two files, some of which is extremely complicated, the two files of research?

A I thought that if there were some particular point that they were particularly interested in or maybe not agreeing with or agreeing, they might look it up, but I did not expect them to read through the whole lot. I expected the other experts to.

Q Can we have at look then, please, at your instructions which we have in the separate bundle D22. We have got them in the GMC's bundle as well. It is unpaginated, but if we go to 24 May letter from Andrew and Andrew which is about four or five pages in.

A Sorry, are you referring to the bundle that we produced yesterday?

Q Yes?

A Or what is in the ---

Q D22. Yes, the fourth letter from Andrew and Andrew dated 24 May 2002.

A Which date, excuse me?

Q Four pages in, 24 May 2002.

A Yes.

Q If you go to the second page you will find your instructions:

"We would be obliged if you would please consider the case and prepare a report for use in the proceedings. In particular we would ask you to answer the following questions:

1. What are the comparable risks between the children having the childhood immunisations and not?"

Yes?

A Yes.

Q Let us just stop there for a moment. You were asked in your report to identify the risks between the children receiving the vaccinations and the child not receiving vaccination. Yes?

A Yes.

Q Either way:

"2. Whether there is anything in any of the children's medical history which indicates that that child should not be given any or any combination of the immunisations ...

3. What are the risks and the after effects of the immunisations as listed in the report ... ?"

So you understood ... sorry, I will pause for a moment. It is the fourth page in. It should be the fourth page in of the defence ---

MR STERN: D22.

MR KARK: D22. *(To the witness)* Let me start that again.

"3. What are the risks and the after effects of the immunisations as listed in the report of Dr Conway?"

In other words, you were being asked to consider the immunisations that these children were likely to receive if the court ordered that they should receive them. Yes?
A That is correct.

Q Yes. Not different types of vaccine, not vaccines from other parts of the world, the vaccinations that they would receive in this country. Yes?
A That is what that part of the instruction says.

Q Do not worry, we will come to the other parts of the instructions.

"4. Whether the current age of the children or child indicates that that child should not [be] given any or any combination of the said immunisations.

5. If you recommend that the child should be immunised the timing and sequence in which the immunisations should be given."

Again, it was open to you to form the view that they should have the immunisation or they should not have the immunisation. Yes?
A That is correct.

Q It is left open to you by your instructions. Yes?
A Yes, that is correct.

Q Thank you. I know it is tempting to nod but we have got to try and keep in mind the transcript.

Q

"6. When answering the questions you should bear in mind that the court will base its decision taking each child's welfare as being of paramount importance."

Can we go, please, to the letter at about three or four pages on from Battens, solicitors, dated 29 May 2002:

"In addition to the instructions provided by Messrs Andrew and Andrew we would ask you to:

1. Comment on any known side effects of the proposed immunisations, if so what the side effects are and the effect these would have on the children's health/abilities."

Again dealing with the vaccinations they are going to receive in this country, if so ordered. Yes?

A

A Yes.

Q

"2. Any medical research that you are aware of that deals with any of the individual immunisations and the said effects of the same worldwide."

B

How did you read that?
A I read it as "any medical research that you were aware of that deals with any of the individual immunisations and the said effects of the same worldwide".

Q When you read the words "any of the individual immunisations", what did you understand those words to mean?
C A I understood those words to mean individual immunisations such as each of the separate immunisations that there are.

Q That the children would be ---
A That would be in the schedule.

Q Yes, exactly.
D A That they could ---

Q Exactly. It is the immunisations that they are going to receive in this country if the judge so orders and the effect of those worldwide?
A Could I add something?

Q Yes.
E A I would obviously not consider immunisations that were not in the schedule, for example yellow fever or typhoid, but I took that to mean the immunisations such as whooping cough, diphtheria and so on *per se*.

Q Yes, and how effective they would be if the children went abroad?
A Well, here they said "... the said effects of the same worldwide".

F

Q Yes.
A I did not take it to mean when the children went abroad.

Q How did you take it?
A I took it to mean the effects of these individual immunisations on a worldwide, as they occur, basis.

G

Q However, still dealing with the immunisations that are current in this country at the time? Do you see the point I am exploring with you?
A I see the point you are making and I am trying to make the point, obviously not so eloquently, that I was looking at obviously not immunisation against diseases that are not immunised in the schedule, but I was looking at the immunisations against those diseases.

H

Q I just want to stay with this for a moment, because it may be quite important that we understand what was going through your mind.

A Yes.

Q All the way through, your instructions had been dealing with the immunisations that the children were likely to receive in this country, yes? On Dr Conway's schedule?
A The initial instructions said that until, as I said, they came to the second part of Battens where they asked for experience worldwide.

B

Q Well, I just want to concentrate on this. Did you think that you were being asked to deal with all vaccines given everywhere in the world, or did you think you were being asked to deal with immunisations given in this country?
A The very wording "individual" would mean not just the actual set immunisations in this country, because many of those did not come individually.

C Q No, all right.
A They only come combined.

Q I understand that, but if we were to insert the words, "... with any of the individual or combined immunisations and the said effects of the same worldwide", is that how you understood it?
A Well trying not to be too splitting hairs, but it would still say "individual" and
D "combined". So, you know, in this country there are many immunisations we have and it has become more so that are not available singularly, but they have said "individual" and so in that respect that is what I took it to mean.

Q You understood that this report was being written so that a judge could decide whether these children should receive the vaccinations which were in the schedule provided by Dr Conway and Professor Kroll, yes?
E A Yes.

Q Not any other sort of vaccination available elsewhere in the world?
A Not any vaccination against any other diseases, apart from the ones in the schedule as specified by Professor Kroll and Dr Conway.

Q However, not the type of vaccination used anywhere else, because that would not
F help the judge, would it? The judge needed to know what would be the effect of these vaccinations, not vaccinations used in Africa, Oman or anywhere else, but these vaccinations. You understood that, did you not?
A I understood that they asked for me to discuss the said effects of the individual immunisations, which I took to mean against those diseases, worldwide.

G Q I will move on:

> "Please comment on your experience at 'ground level' with the children and the effects of immunisation that you have had experience of".

H Can we go, please, to the transcript of your evidence and you will need to have this fairly available to you. Could we go to page 9?
A Of the transcript?

Q Of the transcript.
A Internal?

Q I am using the page numbers, as Mr Stern did, in the bottom middle of the page.

THE CHAIRMAN: Which transcript, Mr Kark? Which day?

MR KARK: There is only one.

THE CHAIRMAN: Do you mean the original report?

MR KARK: The original transcript, yes. I am not going to be referring at all to your daily transcripts and so when I refer to "the transcript" ---

THE CHAIRMAN: This is the original text of the report?

MR KARK: Yes, Dr Donegan's evidence before the High Court.

THE CHAIRMAN: Just to clarify, it is not Dr Donegan's evidence to the High Court?

MR KARK: Yes.

THE CHAIRMAN: It is?

MR KARK: Yes. So, whenever I refer to "the transcript" I mean the transcript of the Dr Donegan's evidence before the High Court.

THE CHAIRMAN: Yes, which is C7.

MR KARK: *(To the witness)* You were being asked in general terms about your attitude to immunisation and you said this in the middle of the page. It is line 11 of page 9 at the bottom:

> "I think that if a parent does not vaccinate and is terrified every time their child becomes ill, that they are going to die or be disabled with one of the diseases against which you can vaccinate, this emotional terror will have such a bad effect on the child's immune system that they are likely to have the worst possible outcome of the disease that they have got ... So in that case I would advise them to vaccinate".

If we go to page 12, you continue with that theme at line 10 where you say:

> "No, I don't have a recommendation ..."

I am sorry, it is line 8 first of all:

> "No, I don't have a recommendation ..."

A I am sorry, I am looking at page 11.

Q Page 12.
A You want page 12?

B Q I am sorry, page 12, line 8:

> "No, I don't have a recommendation. I give parents information".

That is what you told the Panel yesterday, yes?
A Yes.

C Q Yes:

> "One of the few times I actually recommend is when I recommend that, if they are really terrified about the diseases, they should vaccinate",

yes?
D A Yes.

Q All right. Does that give us a view as to the line that you take that in general terms parents should not have their children vaccinated, but there are exceptional circumstances (that being one) where they should?
A I would not say that in general I think parents should not vaccinate their children. I think they should make informed choices. However, yes, that is one of the times where I
E do come aside from saying, "Make an informed choice", and will actually say, "Well, I think maybe you might be better off vaccinating and being happy, rather than not vaccinating and being terrified".

Q You say that you think parents should make an informed choice, but the fact is that you yourself - and I think you have made this clear in your report - are against the national vaccination process, are you not?
F A I think my concern is for child health safety.

Q Is the answer to that "Yes"?
A I think that would be too simple an answer.

G Q I see. I want to turn to the process of copying the research - the two files of material.

THE CHAIRMAN: It has just been pointed out that it would have been fairer to read the next sentence at 11 and 12 on page 12 of the transcript.

MR KARK: I am sorry, madam.

H

THE CHAIRMAN: 11, 12 and 13.

MR KARK: I can read all of it, if you want? Is that what is being suggested by the Legal Assessor?

THE CHAIRMAN: To be fair, yes.

MR KARK: Right, okay. I will start at the top of page 11.

THE LEGAL ASSESSOR: Just to be clear, I was not suggesting you were being unfair for a moment.

THE CHAIRMAN: Those are my words.

THE LEGAL ASSESSOR: I just thought it would be better to read the whole of the answer, because she goes on to say:

> "Otherwise, I do not recommend that parents vaccinate or do not vaccinate".

MR KARK: Yes.

THE LEGAL ASSESSOR:

> "I discuss the pros and cons, and they make up their own mind".

MR KARK: (*To the witness*) Yes, that is what you have been saying absolutely.

THE LEGAL ASSESSOR: Could I make it clear that I was not suggesting that you should do this, because everyone can read it for themselves.

MR KARK: Yes, quite. Thank you.

MR STERN: I think there is a danger if I may say so, to coin a phrase, in selectively quoting, but obviously we cannot all have the whole of the transcript in our mind. Doing the best that we can, however, I am sure Mr Kark will try and be fair about it.

MR KARK: Thank you, Mr Stern. Let us move on:

Q (*To the witness*) I want to deal with the process of copying the research.
A Yes.

MR KARK: Can I just ask, by the way, I have not had a chance to ask Mr Stern, has that document turned up? The overleaf list of ...?

MR STERN: There is not one in the solicitor's file for that date. There is one much later on for November, but not at the time. No, I said I had not seen it and I have caused enquiries to be made and the file - the whole file - is here if you want to see it?

MR KARK: No, no, of course not.

MR STERN: There it is.

MR KARK: Thank you:

Q So let us ask you, Dr Donegan. Did you copy some of your own research, or not?
A No, the research that could be found by the solicitor's assistant, or clerk, off the Internet, or the library, because the solicitors were not in London, was copied by them. What they could not find, which was some of my books and some papers that were not available to the general sort of public without memberships to various organisations on the Internet, they asked me for and they arranged that I would take it to an office facility and that they would copy it.

Q Is that what happened?
A That is what happened.

Q How did the solicitor know which parts of the research to copy because, for instance, you see in your report - and we will look at it in due course - you simply give a reference to a whole book?
A Yes. No, I agree. With papers it is easy, because there is a set way of referencing, and I must admit and I apologise for my being a novice in actually citing the books. Even when I asked them to photocopy the books, I did not realise at that time that I should get them to photocopy the front inside sheet of the book, as well as the pages, so you know which edition.

Q So you know the edition, yes.
A I am sorry, this is things that have come.

Q No, it is not a criticism of that.
A I am a lot more on the ball in terms of those things now.

Q So when we come to copies of books that have been copied, was that you standing next to a solicitor saying, "Well, copy those two pages", or did you just tell them what to copy?
A The books were not done by the solicitor. The books that they could get hold of, like they got hold of the Harrison's, that was done by the solicitor and I said, "Pertussis chapter, diphtheria chapter, haemophilus Hib chapter", and the same for the other books like McKeown I said, "The section on diphtheria and section on measles".

Q Then you got the copy back, did you?
A They came back and I sent them off fairly rapidly.

Q I understand. So what the solicitor has copied comes back to you, first of all?
A No, what the solicitor had copied I did not see at all until I got to the court.

Q So, these bundles that we have here you did not see until you got to court?
A No, I did not have that bundle. When I got to court I still had my own.

MR STERN: It is page 3 of the transcript.

THE WITNESS: I still had my own bundles in a box. I did not have the folder that everyone else had.

MR KARK: *(To the witness)* When we look through these references, we see comments against a number of them?
A Yes.

Q Are those yours?
A Those are ones that have been copied that are my own that have been taken to the office services shop.

Q So where we see underlining, or your comments, those are documents that you have copied and sent to the solicitors for inclusion?
A By now there were the ones that I had, there were the ones that have come - there are ones that I have then subsequent to that lined in court and after that, and in the multiple processes of copying to bring this case to where it is today a lot of the references, for example if you look at I think some of the Harrison's 15th edition I think have got editions on them, that is because they have been written on by me in time and then through this enormous copying process for everyone to have copies.

Q I appreciate that you had not written an expert report before. We all understand that. But you were aware, I expect, broadly, of the principles of *Good Medical Practice*. Yes?
A Yes.

Q I am not suggesting you should know every line of every paragraph, nor be able to quote it, but can we just go, please, to Dr Elliman's bundle? It is file 5, tab 1, and it is page 16 of *Good Medical Practice*. This is the edition published in May 2001, as we can see on page 1. So page 16 and it is paragraph 51. Let us read the heading:

> "Writing reports, giving evidence and signing documents
>
> 51. You must be honest and trustworthy when writing reports, completing or signing forms, or providing evidence in litigation or other formal inquiries. This means that you must take reasonable steps to verify any statement before you sign a document. You must not write or sign documents which are false or misleading because they omit relevant information. If you have agreed to prepare a report, complete or sign a document or provide evidence, you must do so without unreasonable delay."

You understood, did you not, when you wrote your report that you must not write or sign anything which was false or misleading because it omitted relevant information?
A I did.

Q Can we then turn, please, to your report? I am going to start at page 11. It is fair to say, is it not, that your whole report was designed to persuade the judge not to order vaccinations?
A I think it would be fair to say that my report was written in an attempt to balance the data; the opinions that had been brought forward by the two other experts.

Q You say to balance what they had said. Dr Conway had dealt both with the benefits but also the known side effects of the vaccinations, had he not?
A He had dealt with some of the side effects.

Q You see, I am going to suggest that the aim that I suggest you had, which was to persuade the judge not to order vaccinations, coloured almost every page that you wrote and that in some areas you misquoted or left material out which was quite subtle. In other ways it was more blatant. Now let us start, please, on page 11. The very first comment that you make that I want to ask you about is the words at the bottom of the second paragraph:

> "Early treatment of diphtheria with antibiotics tends to render people susceptible to further attacks when the antibiotics are stopped."

Now your reference for that was Harrison's Principles of Internal Medicine, 11th Edition, and I am not, I promise you, going to spend any time on the 11th/15th Edition argument. We now have the 11th Edition. I just want to ask you, before we turn to it, what you were seeking to convey to the reader by those words, that:

> "Early treatment of diphtheria with antibiotics tends to render people susceptible to further attacks when the antibiotics are stopped."

What were you intending to convey to the reader?
A I was intending to convey to the reader the words that I have written there. With each of these diseases I have given some description of the disease, its natural history, what was happening to it before the vaccinations were introduced, what has been happening after the vaccinations were introduced, where I could find the documented side effects of the vaccine and vaccination recommendations.

Q If one reads that on its own there is nothing to indicate, is there, what the time limit is on the susceptibility to further attacks?
A No.

Q If we turn to the actual reference, which is tab 1 of your first bundle, so it is file 2. It is the correct 11th Edition you have given us and there is a big "2" at the bottom of the page. Do you have it?
A I have the (*indicating*) ---

Q You have it separately, do you?
A Yes.

Q It is slightly difficult to read because the copy is not very good, but do you see the words "Clinical manifestations" on the left-hand side?
A I do, yes.

Q Can we just go about six or seven lines up:

> "Early therapy of diphtheria with antibiotics may lead to recurrence of the disease

A

> if exposure to fresh infections occurs shortly after discontinuation of treatment, suggesting that the development of antitoxic immunity is suppressed in these cases. Full immunisation with diphtheria toxoid does not prevent nasopharyngeal carriage of the organism but significantly reduces the case fatality ratio. It also ameliorates the symptoms of active disease."

B I just want to go back to the words:

> "May lead to recurrence of the disease if exposure to fresh infections occurs shortly after discontinuance of treatment."

Now it is a minor point but can I just ask, do you think it relevant to mention, when you wrote the words:

C

> "Early treatment of diphtheria with antibiotics tends to render people susceptible to further attacks when the antibiotics are stopped."

Do you think to mention that there was a temporal limit to that? In other words, shortly after that?

A Forgive my saying so but I cannot, in my heart of hearts, see where this particular D additional omission shows that I am clouding my trying to persuade people not to vaccinate. I was discussing, as you would, when you are not vaccinating somebody what happens when you get the disease and I was also discussing some facets to do with the immunity that one gets or does not get from diphtheria, and I cannot see what is misleading or omitting about not putting shortly. I am talking about what happens with treatment of diphtheria in the early stage with antibiotics. Does it make a difference, in your opinion, to saying whether it is shorter or longer, because ---

E

MR KARK: My opinion does not count at all.

A I am sorry, it is the Panel who have to decide.

MR STERN: I am sorry to interrupt. As Mr Kark rightly says, his opinion does not matter at all and I do not mean any discourtesy by that. Cases work on evidence, and forgive me for going back to basics, to use an expression. When one looks at what F Dr Elliman said it is not a complaint that Dr Elliman made in his evidence or in his report, so what I am a little concerned about is the case is complex enough as it is, just trying to look at the 90 pages of Dr Elliman's report dealing with the points that he makes, Dr Donegan has dealt with those. We now are having an entirely different point which was not referred to by Dr Elliman, according to the transcript as I see it. So I just want to G exercise a note of caution about this, that we are not, as it were, going off into the highways and byways of another whole series of another points that Dr Donegan has not had advance notice of them. I am not saying she cannot deal with them, of course she can deal with them and she has dealt with them, but one needs to be very careful which is why I hope it was helpful in setting out that schedule in the first place. Certainly, it was for our purposes initially so we could have some grasp of what the points actually were, because the report is rather long and detailed. I do not make complaint about it but one H just has to be a little bit careful and exercise a note of caution about that.

THE CHAIRMAN: Mr Kark.

MR KARK: You will be advised in due course, I expect, by the Legal Assessor that the expert evidence is there to help you but not to rule you. This case is not decided by experts, it is decided by you as a panel. This particular point has arisen because we did not have the 11th Edition until these proceedings started and I simply wanted to query with the witness, and I am sure she is able to do it, indeed, Dr Donegan has already dealt with it in her own way, whether she thought that was an omission or not. (*To the witness*) So let me just ask you: do you think that was an omission or not?

A No, I do not.

MR KARK: All right. Let us move on to the next paragraph.

THE CHAIRMAN: Legal Assessor.

THE LEGAL ASSESSOR: I wonder if I might just mention an issue which has been troubling me, and it is probably entirely my fault, but when you were cross-examining Dr Donegan using, for example, words such as "subtle" or "blatant" I want to be clear in my mind, are you suggesting that as a result of the genuine views which she holds about vaccinations that in some cases the misleading was deliberate?

MR KARK: That has not been alleged. That is not in the heads of charge.

THE LEGAL ASSESSOR: No. That is why I wanted to be clear about that.

MR KARK: No. (*To the witness*) Let me turn to the third paragraph on that page:

> "Diphtheria increased in prevalence and malignancy in the middle of the nineteenth century and declined before the introduction of the antitoxin",

- and I will not read the next line -

> "By the 1940s when a national immunisation campaign began, the death rate in children had dropped by two thirds and continued to drop."

We have your reference, which I think is at tab 2 of your bundle. I just want your assistance, please, as to how these two sections of that book came to be copied.

A The process?

Q Yes.

A The McKeown book was one of the books that I had to take down, along with the papers I mentioned, to the office services shop to get them to copy it, and you can see some of the instructions written on it - because I had asked them to do sections - "see p 47", which is why 47 is also there.

Q So this is "p 98 + see p 47"?

A No, "see [page]" full stop, because 47 is what is behind because it also discusses diphtheria.

Q How did that little section of the graph on page 99 come to be copied?

A Well that is how it was copied.

Q I understand that. How did it come to be copied like that, because, in fact, page 99 is on the opposite page to 98, and we know from Dr Elliman's bundle that page 99 - I think this is the only time we are going to have to do this, if we turn to tab 6 of Dr Elliman's bundle and it is file 5. That graph that we see produced in your research is at the top of the page 99 but, of course, page 99 reads on:

> "With due regard for this reservation it seems probable that immunization had more effect on the control of this disease than of any other, with the exceptions of poliomyelitis and, possibly, smallpox ... Evidence for England and Wales in 1961-3 indicated that the risk of an attack of diphtheria was about six times greater, and the risk of a fatal attack ten times greater, in those not immunized than in those immunized."

You presumably read those words?
A Yes, I have read all of the book.

Q Did you think it was relevant to have that page copied in full?
A It should have been copied in full because each section was supposed to have the disease copied in full and that is why on this one I added "and page 47" because it was not continuing onto it. It was an earlier one at the beginning of the chapter on infectious diseases.

Q So the copying of only half of page 99 was an error?
A It was, yes, it was not up to me.

Q It was an error by the solicitor, was it?
A No, the solicitor did not copy these. It was the office services that I used.

Q You had asked them to copy page 99, but they only copied ---
A I asked them to copy for each disease the section and this one has a note saying, "and see p 47," because it is not obvious that it is the next part of it because it is prior.

Q Yes, I am just interested in page 99 at the moment.
A Yes.

MR STERN: Again, if it helps, because I am sure that Mr Kark will not take an adverse point, if he looks at number 2 in the references it does have page 99 there.

MR KARK: Yes, thank you.

THE CHAIRMAN: Is it worth just clarifying what office services are? Is it some sort of administration?

MR KARK: *(To the witness)* Can you help us?
A You know there are these shops where you can use them for your office address and they do photocopying, collating and punching and so on and so forth, and they often have photocopying machines and they do clerical work like this. I said to the solicitors

that there was no way I could, with the time scales, get of all of this photocopying done. I had my references but I could not do the rest. So they looked up in Yellow Pages and they found one in my neighbourhood and I took all these documents down to them and left them there for a day and then collected them and sent them off by courier.

Q Can I go to the bottom of the next paragraph starting "In the USA." It is the last two lines.

MR KARK: Should I pause again? Can I say this that I do not entirely take the Stern line. I think it is sometimes better for Panellists to wait until they have heard the whole of the cross-examination, if I may say so, and then ask questions at the end if there is anything remaining because sometimes things will actually naturally get cleared up, if I have not missed some major hole, of course.

THE CHAIRMAN: I will direct the Panel to store up their questions for their opportunity.

MR KARK: *(To the witness)* Let me then take you to the last two lines of that paragraph:

> "Most cases are in adults, as in the former Soviet Union where most of the cases are in vaccinated adults, not unvaccinated children."

Now what impression were you seeking to convey with that, please? What was the point of putting that in?
A Well I was making the point that social and other factors are very important, as I have made all the way through my report, in (a) being infected with the disease when you come in contact to it; and (b) the clinical cause of the disease if you do become infected by it.

So having set the case for what had happened amongst people in crowded living conditions with poor personal and community hygiene and so on, it was to show that in the former Soviet Union, where I had not expanded on the fact that they had had massive population disruption and war and ethnic movements and so on and so forth, but it was to show that when these social situations pertain, being vaccinated does not necessarily protect you as in the case of the former Soviet Union.

Q What was the relevance of that to the two children in the UK that you had been asked to advise upon?
A Because in the UK there had not been great population movement and ethnic movement and war and poor social circumstances and unemployment and poor nutrition and electricity cuts in vast parts of the country. So from that point of view, the children in this country would ... nor was I aware that the children were living in crowded conditions with poor personal and community hygiene. So that was relevant to the children in this case because these cases where diphtheria has been occurring, for example, in the West occur in those social conditions and in the outbreak in the former Soviet Union were occurring also with the adverse social situations. So when they pertained the vaccine was not always effective.

Q That is what I wanted to come to. First of all, the position in the Soviet Union was

not entirely relevant to the two young girls in this case, was it?
A Well the fact that the position ... the situation in this country is different was relevant because that is where they had ---

Q It was better.
A Yes, so where they had the outbreak there were very poor social conditions and here, in the case of the children I was being asked to describe, we do not have these poor social conditions. So I thought it was very relevant.

Q You see one would probably come away from reading this and I think you just said with the view that certainly in the former Soviet Union vaccination programme was ineffective. Is that what you were saying?
A I was saying when the social conditions changed the vaccine basically did not save the people that it was intended to.

Q Can we go to reference one in your bundle and in fact the reference I am using at the moment is one from the 15th?
A This is Harrison's 15th, yes.

Q Yes, it is. Thank you. Page 91(a), is this where this reference to Russia came from?
A No, there is a vast quantity of documents which I did not present here but I presented another one of them in my second report. But, I mean, the outbreak in the former Soviet Union was described on a week by week and month by month basis in journals either the British Medical Journal and the news and update world update items.

Q It was also described in McKeown?
A No, not the one in the former Soviet Union because ---

Q Sorry, I mean Harrison?
A Because the McKeown is 78 to 79 in the 15th edition ...

Q Yes.
A ... which I had not used.

Q Page 910, we have got it, I think, in our bundle. Do you see the second paragraph down, "A massive diphtheria epidemic." Do you have that?
A Wait a minute, I have got, "The majority of cases." Massive, yes, I have got it.

Q

> "A massive diphtheria epidemic ... occurred recently in the states of the former Soviet Union and accounted for [over] 80% of diphtheria cases reported worldwide during that interval. The epidemic began in 1990 with 1436 cases ... [and] peaked in 1995 with 50,425 cases ... and waned by 1998 with 2720 cases ... as the result of a mass immunization program."

Then again, if you think I am missing anything out, please tell me. If you go to the next paragraph:

"A majority of cases throughout this epidemic occurred in persons [over] 15 years old, and adults from 40 to 49 years old had very high incidence and death rates. In 1994, case-fatality rates varied from 2.8% in the Russian Federation to 23% in Lithuania and Turkmenistan. Factors that facilitated the spread of this epidemic included large-scale population movements ...",

such as we have just been referring to.

A Yes.

Q

"... socioeconomic instability, deteriorating health infrastructure, delayed implementation of aggressive control measures in response to the epidemic, inadequate information for physicians and the public, and frequent shortages of supplies for prevention and treatment of the disease. The most important risk factor for diphtheria in the Republic of Georgia was lack of vaccination ...",

and then it goes on.

A Yes.

Q Do you want me to read on?

A Please do.

Q Sorry?

A Yes, to the end of the paragraph.

Q

"... household diphtheria exposure, exposure to skin lesions, the presence of tonsils, a history of eczema, preceding fever with myalgia, sharing a bed, sharing glasses and cups, and taking a bath less often than weekly were also significant risk factors. Although small numbers of imported cases from this epidemic occurred in western European countries, none resulted in secondary transmission of diphtheria, notwithstanding a high proportion of susceptible adults in countries with imported cases. Inadequate primary immunization of children in the states of the former Soviet Union in the years preceding the epidemic, along with failure to maintain adequate immunity in adults by booster immunization, may have synergistically facilitated transmission of diphtheria and emergence of the massive epidemic in this region."

In other words, my lay reading of that and your help please, it was the lack of vaccination?

A In terms of, for example, what are the purposes of the reports for the children in this case what is also, apart from as you pointed out, large scale population movements and so on that I have been talking about, they noted that although small numbers of imported cases from this epidemic occurred in Western Europe, none resulted in secondary transmission of diphtheria notwithstanding a high proportion, actually the same proportion, as occurred in the former Soviet Union and to some extent susceptible adults

in countries.

Now here you see, (and this was the conclusion or the comment) a lot of the authors in the particular Journal of Infectious Diseases that a lot of the comments in here come from, they say that inadequate primary immunisation of children in the former Soviet Union in the years preceding the epidemic along with failure to maintain adult boosters, but basically you have an epidemic in that country which had the large scale population movements, there was war, there was socio-economic instability and deteriorating health infrastructure and when they look at the difference between the former Soviet Union and Europe, where the cases did not spread, the only factor they look at is the fact that in Europe there was adequate primary immunisation of children and they do not mention the fact that obviously in Europe there was not large scale population movements socio economic instability and deteriorating health infrastructure.

So they are saying that is the reason logistically, but what I am saying is that that is what is always taken. They will say, "Well, look at the two immunisation rates. That is what was the cause". They ignore the fact that the whole social situation in Europe where the spread did not occur, even though there was this same waning immunity in adults. I am not saying that is the reason, I am saying it is not given any space here.

Q No.
A Obviously as a layman or lay person it seems that it is an obvious other factor in which the former Soviet Union differs from Western Europe.

Q Dr Donegan, when the lay reader, when the fathers or the mothers or indeed the judge, read just these two lines this is how you deal with this report and I am not suggesting you should write the whole report out into your report, but all they are going to read is most cases are in adults as in the former Soviet Union where most of the cases were in vaccinated adults not unvaccinated children?
A That was the case.

Q They are not going to glean from that, are they, that the authors of the report, their own view from the research, was that the prime cause of the epidemic was the lack of vaccination?
A Not from this, no.

Q Let me move on. The next paragraph:

"The fact that there are so few cases ..."

MR KARK: I am sorry, I am going to pause for a moment. I am just concerned that there is a Panel member who is so close to Mr Stern and his junior. There is quite a lot of discussion going on and I wonder if ---

MR STERN: There is not a lot of discussion at all. I just made one point.

If Mr Kark is suggesting that the test is that the mothers and fathers had to understand it then he should have brought them, that is the first thing.

A

The second thing is this is a particularly poor point, if I may say so with respect to my learned friend, because each of them were represented by at least two counsel and by solicitors and, therefore, the purpose of having an array of experts and lawyers is so that they can be explained in relatively straight forward terms to the client. That is the purpose of having all those people.

B

So to say, "Well would the fathers have understood it?" is, quite frankly, not to me a fair way of putting it. That is why I turned to Mr Singh because I like to reflect on whether I seek to object and I did not get an opportunity to get his response because Mr Kark called us to order. I am not intending that anything that I say should be heard by any Panel member, Mr Brown or anyone else.

MR KARK: I am sure it is not intended.

C

THE CHAIRMAN: Can Mr Singh move a bit closer to you?

MR STERN: As you know, we had a lot of papers ... yes, that would probably be helpful.

MR KARK: Mr Stern is perfectly entitled to make the point that I am making a bad point,

D

but hopefully he will do it in his speech. Meanwhile, I am going to move on with my cross-examination and hopefully without too much interruption and unless I am putting something that is irrelevant or unfair. If you think that this is ---

MR STERN: That is precisely the point, I will continue to interrupt because it is my job to make sure that Dr Donegan is protected from unfair comments. That is why I am interrupting. I will not interrupt, I can absolutely assure my learned friend that I will not

E

interrupt if I do not consider it to be unfair. He must take his course, he can cross-examine for as long as he wishes on any matter that he wishes as long as it is fair.

MR KARK: Dr Donegan, when I started cross-examining I asked (and this is relevant to the objection) whether you understood that the fathers would read your report and take it seriously and you answered yes.

F

A I did.

Q You also understood that the fathers could abandon their application potentially on the basis of you report and you answered yes?

A I answered that I am not an expert in legal proceedings ...

G

Q Quite right?

A ... but I presume that people can at any point decide to abandon their course of action.

Q I am going to move on.

H

"The fact that there are so few cases of diphtheria reported in this country is more likely to be due to a trend towards decreased virulence of the organism and better resistance of the host."

Can we turn to tab 6 of Dr Elliman's bundle, please?
A This is:

> "Diphtheria-tetanus toxoids-pertussis vaccination does not increase the risk of hospitalization with an infectious illness"?

Is that the right one? I do not think it is. Oh, I am sorry, that is tab 16.

Q It is tab 6.
A Yes, it did not look right.

Q I just want to know where - I am sorry, just give me a moment. I just want to see if you can help us as to where you got this quote from?
A It is not a quote.

Q Ah.
A It is an opinion ...

Q All right.
A ... which you will see because I have said on the last line:

> "... because other diseases that have been vaccinated against have not disappeared in such a satisfactory fashion despite very high vaccination rates e.g. whooping cough, measles and mumps".

Q However, do you accept that your words:

> "The fact that there are so few cases of diphtheria reported in this country is more likely to be due to a trend towards decreased virulence of the organism ...",

do you want to reflect upon that and change it?
A Certainly the factors that decide whether someone is going to be infected are to do with the infecting organism factors and the host factors; host factors and infecting agent factors both being influenced by the environment. In the case of diphtheria, the cases that normally are serious are the ones that have this particular thing call the tox gene that makes it more likely that the toxin, which causes the most serious forms of diphtheria, are present. That certainly depends that, if the tox gene is not present, then that type of diphtheria is generally less virulent - I am sorry, diphtheria organism - if it does not have the tox gene that causes it to express toxin.

Q When you were asked about that in the High Court - and if anybody wants to check it it is page 45. This is the High Court proceedings transcript at page 45. Mr Cohen asked you:

> "Dr Donegan, will you agree with me that there is no scientific evidence that the virulence of diphtheria has been reduced?
> A There is comparative evidence.

Q There is what?
A Comparative evidence.

Q I was not asking that. Will you agree with me that there is no scientific evidence that there is a decrease in the virulence of diphtheria?
A Yes".

Is that still your answer?
A No, that is what I said in the High Court.

Q Ah. Why did you say it?
A I have been told that one is in charge of the words that come out of one's mouth, but I can certainly tell you that standing in the witness box and being questioned in the way I was being questioned things can come out of your mouth in terms of a "Yes" or "No" answer that are not what you meant, or not what I meant. I cannot speak for other people.

Q So, are you saying that there is scientific evidence to show that there is a decrease in the virulence of the organism?
A There is scientific evidence to show that the diphtheria organism that carries the tox gene that produces the toxin is more virulent in terms of its effects on the human than is the one that does not carry it.

Q That did not come to your mind when you were answering questions in the High Court?
A Not at all.

Q All right. Can we turn to page 12, please. In fact, we are only going to turn to page 12 to deal with this in passing. You mentioned thiomersals and, in particular, this is the quote where you say that:

"It also mentions that the thiomersal in the vaccine can cause kidney damage".

I am actually going to come back to thiomersal and try to deal with it as a whole, as it were, all right?
A Right.

Q So, I am not ignoring thiomersal. I am going to come back to it. Can I ask you to go on, please, to page 15. Again, it is a similar point to the one that we have just been dealing with. I think it is about the fourth paragraph down where you say:

"It is undoubtedly the case that whooping cough became a milder disease in this country over the course of the first half of the twentieth century".

You were asked about this, if we still have the transcript, at page 56, where at line 11 you are asked:

"... but you could accept -----
A Yes.

Q ----- that basically whooping cough has remained the same, broadly speaking, disease. It is just that we have become better at dealing with it over the last 100 years?
A Yes.

Q I just wonder why, then, on page 173, your page 8, in the middle of the paragraph ... you felt it appropriate to say with such complete certainty that it is undoubtedly the case that whooping cough became a milder disease over the last century. It has not become a milder disease. We have just become better at dealing with it, have we not? Is that what you meant to say?
A Yes".

Then over the page, just to complete it, you say:

"I would like to make a point ... I think we have become better at dealing with it, both from the point of view of medical treatment and being better, generally, nourished - social conditions".

Do you stand by that now, or not?
A Having a milder disease is not the same as saying that the virulence of the organism has decreased. A milder disease is the disease that you see and the treatment will certainly reduce mortality from complications, but what I said here, "... being better, generally, nourished - social conditions", is what I meant when I was making the point that milder disease. I did not say decreased virulence of organism. I said milder disease ...

Q All right.
A ... in terms of clinical symptoms.

Q When you say it has become a milder disease, what you mean certainly is that the treatment has got better so people suffer less?
A No, I mean that there are people who get whooping cough who do not get it for so long, or so unpleasantly, which is what I said here when I said, "... from the point of view of ... being better, generally, nourished - social conditions". I do not mean in that case that the treatment has got better. I mean that the person does not get such a severe disease.

Q Can we turn to page 18, please, and you are dealing here with the advantage, I think, of getting the natural infection?
A Yes.

Q Again, I just want to understand what you are suggesting:

"During natural infection with pertussis IgG"

- immunoglobin G -

> "IgM and IgA antibodies are produced. These IgA secretory antibodies are very important as they specifically stop the bacterium from sticking to the hairs and multiplying. Vaccinations against pertussis does not produce this IgA antibody which is so important against protecting against further infection".

Now, can I just understand. First of all, do you accept now that the vaccine does in fact produce both IgG and IgM?
A Oh, definitely, yes.

Q It does.
A Actually, I do not know if the pertussis one does produce IgM.

Q Well, I am going to suggest that it does.
A I do not know if it does produce the IgM. Certainly the live vaccines, like measles, mumps and rubella do, but this does not actually cause an infection - a sub clinical infection - like the live vaccines do and so I cannot tell you.

Q What you are actually advocating here, just so that we understand it, is that the child is better off getting the infection? Getting whooping cough?
A Yes.

Q Suffering that disease and then they will be better protected against receiving it next time round?
A When they come in contact with it and small children and babies they are less likely to pass it on to them.

Q So to follow this logic, rather than having the vaccination, which I suggest is about 94/95 per cent effective?
A I do not think we will get into, unless you want to get into, discussions of efficacy with the whooping vaccine?

Q You do not think it is very efficacious?
A I would not say 94 per cent. I think we discussed, or there were discussions about that in Dr Elliman's testimony and so I will not argue with you on the figures, but ---

Q All right. However what you are suggesting is that, rather than getting the vaccine to protect you against whooping cough, you are better off getting whooping cough - the child is better getting the whooping cough - suffering the disease and then they probably will not get it again?
A When you say protecting you against whooping cough, as you have yourself said in the figures you have given, it is not 100 per cent and we need boosters and they are considering an adolescent booster at the moment. So, yes, if you do not vaccinate against the disease, then the other side of the coin is that you are likely to get the disease. Some diseases you are unlikely to get and some diseases you are likely to get, but it must be said that whooping cough is very common in circulating in vaccinated children. That is why

they had to introduce the pre-school pertussis booster. So, you know, it is not stopping the disease and there is no reason to think that it is very nice to have whooping cough, but with all these diseases they come in different grades of severity which depend on the state of the health of the person who gets it and how they are treated. So, for example, when you are talking about these diseases, I am not living in some magic world where you say, "Oh, well do not vaccinate and you are not going to get the diseases". Every parent who decides not to vaccinate has to be sitting there deciding that they are going to nurture their child's health and be prepared to nurse them appropriately through these diseases if and when they acquire them.

Q Yes. Can we move on to the next paragraph and the line beginning:

> "Because of continuing increases in pertussis notification ...",

and I think should that be deaths?
A It should be deaths, yes.

Q Which is obviously a significant difference?
A A very significant difference, yes.

Q Yes:

"... especially in young babies, an 'accelerated' schedule of vaccination was introduced ...

> Despite vaccination rates of 94% in under twos the incidence of pertussis has been increasing since 1995. Between 1995 and 1997, 10 of the 12 deaths from whooping cough were in babies under 2 months of age. As with a number of recent reports from the UK, USA and Australia, there seems to be ... increasing numbers of deaths in very young children and a 'waning' ..." ---

MR STERN: "... there seems to be a trend ..."

MR KARK: Yes, I am sorry:

Q *(To the witness)*:

> "... seems to be a trend towards increasing numbers of deaths in very young children and a 'waning' of vaccine effectiveness in 1-4 year olds".

Again, are you saying here in effect, or should the reader glean from this, that the vaccine is ineffective?
A It is waning in its effectiveness, and the age group that the vaccine is really most necessary to protect are the under one year olds and they are having increasing problems even though the starting of vaccination age was moved down to two months.

Q Can we just have a look, please, at your tab 23, which is this reference I think, and

starting with the summary and I am going to start about five lines up from the bottom where I think this comes from:

> "While overall levels of pertussis notifications have declined in recent times, vaccination efficacy wanes with increasing age, and pertussis remains a significant cause of mortality and severe morbidity in the very young. This could be reduced by timely booster vaccination and increased recognition of mild disease in older cases followed by early antibiotic therapy for the very young household contacts".

You are absolutely right, of course, to talk about the waning of vaccine effectiveness and you are entitled of course to cite this report. Did you think it would be relevant to also cite what the author's conclusion was?

A That it could be reduced by timely booster vaccinations?

Q Yes?

A The court was being expected to decide whether the children involved should have whooping cough vaccination, or not, and so it is necessary to look at the efficacy of the vaccination. As I have said before, if you have wild, natural - no, wild whooping cough, you will have better immunity subsequently and then you will be less likely to pass it on to the small babies who have not got any immunity.

Q However, in citing this particular piece of research, did you think it was relevant to balance it, as it were, given that you were being asked remember to write your report both in terms of efficacy and not of the vaccines? You were asked to keep an open mind, were you not?

A Efficacy and side effects.

Q Yes.

MR STERN: I am sorry to interrupt, but I am afraid I must do because this is the point that I was making before. Dr Elliman's criticism was, you may recall, that there was no real trend. His criticism was not that she did not cite the conclusion, so if that is a new point now being made then in my submission that is not fair. The point that Dr Elliman has made in his report, which is obviously the one that we have gone on, is at page 16, it is dealing with page 18, paragraph 2, where he says, "The reference ... does not give a real indication of any trends in mortality, as it only covers 1995-7". That was his point.

MR KARK: You as a Panel are going to have to decide, stepping back from all of this, as to whether there is material in these reports which is potentially misleading and obviously Dr Elliman's evidence helps you. However, just by way of example, if one of your Panel members were to find a part of this report misleading, or potentially misleading, that Dr Elliman had not cited, is it being suggested that because Dr Elliman has not mentioned it you could not rely on it? The expert is there to assist you and that is all, and you will all as panellists have received that legal warning that the case is not decided by experts.

THE CHAIRMAN: I do not think that was Mr Stern's point. I think we are at the stage

of cross-examination and so any new points which might arise now, which they have not been put on notice about, might be perceived to be unfair. I think that is the point that you are making?

MR STERN: There are two points, madam. The first is cases operate on the basis of evidence. The fact that Dr Elliman is an expert is, if I may say, for this purpose irrelevant. Cases work on the basis of evidence. Mr Kark and I cross-examine on the basis of the evidence that we have. I cross-examined Dr Elliman on the basis of material that is available to me and whether you approve of the way I do it is another matter, but that is the basis of the cross-examination.

Dr Donegan is cross-examined by Mr Kark on the basis of the evidence. It is not Mr Kark who can suddenly say, "Why did you not put the conclusion in", because that implies a criticism that is not based on the evidence. That is the point that I make. So it must be on the evidence which is really, I am afraid, so basic and trite that I am sorry to even have to make this point to you.

The second is this, in relation to the point that is being made about could the Panel actually find something in the documentation that Dr Elliman had not found. Of course, it can look at that but it would be unfair if at the end of all the evidence during the course of your deliberations you suddenly thought of something that no-one had spoken to. So whilst I partially agree with Mr Kark about that latter point I do not entirely.

THE LEGAL ASSESSOR: I wonder if I could just say something. First of all, of course, Mr Stern is perfectly entitled to make the objection he has done and, no doubt, the Panel will listen to it, but could I just say that at the moment I cannot see anything wrong with Mr Kark's cross-examination. If I did think so then I would advise the Panel accordingly. Indeed, I did interpose a little bit earlier because I thought that, perhaps, Mr Kark should remind the Panel of the next couple of sentences. What he is really doing after all, perhaps, is giving Dr Donegan the opportunity to answer a point which the Panel themselves might think of in retirement which had not been dealt with, so it could be said, in another sense, to be fair to raise this point. If Mr Kark goes way outside the suggestions which have been made against Donegan and the points are entirely new then I would certainly interrupt to give certain advice to the Panel, and I will do but I do not see that that is happening at the moment.

MR KARK: Can I agree with Mr Stern to this extent: it is important that if panellists do find other areas of the report that they are concerned about that they should give Dr Donegan the opportunity to deal with them. I entirely agree with that. It is important that Dr Donegan does have the opportunity of dealing with any area of the report about which any panellist is concerned.

So I agree with Mr Stern, with respect, that it would be wrong for a panellist much later in the proceedings, once all the evidence has finished, to alight upon something and, as it were, rely on that when the doctor and no other witnesses have had an opportunity of dealing with it. So to that limited extent I think we agree.

Let me move on. (*To the witness*) Could you go to the bottom, please, of page 18? Do you see the last two lines:

A

"The high prevalence of vaccination is also associated with a drift towards a higher incidence of disease caused by the 1,2 serotype which is more likely to be associated with complications and admission to hospital. Despite this apparent failure of infant vaccination to protect the most vulnerable from the disease, the response to these problems is to add another pertussis vaccination to the
B programme and since October 2001 children have had pertussis added to their pre-school boosters."

Can we just look at your tab 23, please? It is the one, in fact, we already have open. I have a large "137" in the bottom right-hand corner, but the printed page number is page 405 at the top. Do you see the heading on the right-hand side of the page, "Severity of illness"?

C A Yes.

Q I was not going to read at all but I think I had better in the circumstances:

"Information was available from the enhanced database on hospital admission and the occurrence and nature of any complications. Of the 1177 cases",

D - *that* is your underlining, is it?

A It is.

Q

"Of the 1177 cases where the information was recorded, 787 ... were admitted to hospital. Multivariable analysis with the likelihood of hospital admission as the
E dependent variable demonstrated a protective effect of vaccination independent of age group, serotype and the use of preventative therapy."

This is what I wanted to ask you:

"Unvaccinated patients were 1.5 times more likely to be admitted to hospital than vaccinated children. The results of the GLIM model are shown at Table 3. There
F were no regional or gender differences associated with admission to hospital.

Pertussis in vaccinated cases produced a milder illness as judged by complications reported on the enhanced surveillance form. In addition to the reduced risk of hospital admission ... patients who had received any pertussis vaccination doses
G were less likely to have complications."

Then over the page, the last few lines. Again, please read anything else that you want to:

"Unvaccinated children are 1.82 times as likely as vaccinated children to exhibit complications."

H Just to complete this, over the page again, because this is what you are relying on, we can see it is underlined, the very bottom of the left-hand paragraph:

A

> "However, the proportion due to serotype 1,3 decreased steadily over the 3 years studied, with a concomitant increase in the proportions of serotype 1,2 infections and this trend over time was significant ... In addition, during the study period and for each of the individual years, serotype 1,2 was more severe illness as evidenced by rates of admission to hospital and by the documented notation of complications on the enhanced surveillance data form. This increased severity of serotype 1,2 was not related to differences in proportions fully vaccinated, partially vaccinated or to differences in the age distribution of cases with differing serotypes."

B

Can I just pause there for a moment for your comment? Going back to what you wrote in your report, bottom of page 18 again, just to get this into our mind.
A Yes.

C Q

> "The high prevalence of vaccination is also associated with a drift towards a higher incidence of disease caused by the 1,2 serotype which is more likely to be associated with complications and admission to hospital. Despite this apparent failure of infant vaccination to protect the most vulnerable from the disease, the response to these problems is to add another pertussis vaccination to the programme ..."

D

Doctor, I want to ask you this: if the reader of this went away with the impression that, overall, the vaccination programme was ineffective or that vaccination led to a higher instance of complications over all, that would be wrong, would it not?
A That would be wrong. I have said here that the vaccination, as you will read on the last page, 410 of that paper, in the conclusions:

E

> "At a time of continued high vaccination coverage, the proportion of cases due to serotype 1,2 is increasing independently of the vaccination status or age distribution of cases."

That is what I was making the point of, the selection pressure of the vaccination, a bit like with the mumps one that we discussed the possibility of, seems to be associated with causing an increased prevalence in this particular serotype. Now it said in the body of the paper that if you were vaccinated you were less likely to have complications and it said that, as it says here:

F

> "The prevalence of this particular type was independent of the vaccination status",

G

- but, of course, the whooping cough organism that is circulating is not the same as what everybody has. This is increasing the amount of this particular sort and, of course, people who were dying are, in a lot of cases, babies below the age of vaccinatable (*sic*) age anyway, so for them there is no option whether they want to be vaccinated or not because they are younger than the vaccination age.

H Q They are too young.
A Yes. So in terms of protecting the most vulnerable, the fact that increased amounts of this serotype are being selected for - it is describing it here - are making the

most vulnerable, which are the ones who are too small to be vaccinated, if you wanted to vaccinate them ...

Q I understand that.
A ... susceptible to that.

Q When you refer to:

> "Despite this apparent failure of infant vaccination to protect the most vulnerable from the disease, the response to these problems is to add another pertussis vaccination",

- the reader can easily come away with the impression that, overall, the programme has failed and that would be wrong, would it not?
A Well, it would be an opinion.

Q Yes. If they came away with that impression of the vaccination programme in this country that would be the wrong impression, would it not?
A The reason I put it though is because to me that is a form of failure in the vaccination programme.

Q Let me just deal with the notes and then I am sure you will be grateful for a break, unless you would like one now?
A No, I am quite happy to carry on to the next break.

Q I should have said this at the beginning, if at any stage you decide to you would like to break then, obviously, we will stop.
A Thank you.

Q Can we just go on to the large paragraph at the bottom of page 19:

> "Does the vaccine cause brain damage?"

Then you refer to the NCES study and you talk about the study, this is six lines down:

> "The study did not look at the number of children in the 'event' or 'control' group who had been vaccinated against pertussis compared with those who had not, but only at the numbers who had been vaccinated against pertussis in the seven days before the neurological event."

You have accepted that is an error.
A That is an error, and I accept that that is wrong.

Q In the context of this, what do you say now about the use of the word "damage", brain damage?
A In the context of this and the specific meaning of the word "damage" it would have been more appropriate, I think, to write "illness".

Q Again, I know Mr Stern is not going to like this point, but if you were the father of

one of these two daughters or, indeed, the mother of one of these two daughters and you read those words, speaking about the vaccine potentially causing brain damage, nobody wants to have neurological illness either but there is, potentially, a significant difference between the two, is there not?
A One is permanent if it is damage, yes.

Q Over the page, page 20, and the middle paragraph:

"A similar case-control study in the United States found an association between pertussis vaccination and neurological damage."

Again, we should correct that, should we not, to "illness"?
A Yes, I did not make the distinction.

Q I think Dr Fletcher in his report accuses Dr Elliman of splitting hairs, but you accept that there is a difference between "damage" and "illness"?
A I accept it.

MR KARK: Would that be a convenient moment?

THE CHAIRMAN: We will break now and return at half past eleven. (*To the witness*) You are still under oath.

(*The Panel adjourned for a short time*)

THE CHAIRMAN: Mr Kark, please continue.

MR KARK: Dr Donegan, we are on page 20 of your report. Right at the bottom you deal with the report by Dr Michel Odent and I just want to ask you very shortly about this. First of all, do you accept what Dr Elliman says about the different weight to be attached to different research?
A I do.

Q You have retrospective studies, you have prospective studies, you have perspective double-blind studies, placebo controlled, et cetera, et cetera, and there is a pecking order to those different types of research.
A That is correct.

Q You agree?
A Yes.

Q Do you also accept that in this short paragraph, where you refer to the study of Dr Michel Odent and the further retrospective study from a general practice in Oxfordshire and then the larger prospective forward-looking study of 9,404 children in Avon which failed to show an association, and I accept that you mentioned it, but do you accept that at no point have you made clear the differing weights between them?
A I have not written a hierarchy of evidence. I have on that one written that it is larger and that it is prospective.

Q You have. Do we take it - and I think you said this yesterday and I am sorry if I have forgotten - that you did not know about the second study that Dr Elliman produced?
A The Neilson study?

Q Yes.
A No, I had not seen the Neilson study.

Q Can I just ask how you set about your research for this report? Did you do research specifically for the report or were you, essentially, reliant on the research that you already had available to you?
A I relied on the research I had available to me and I pulled a lot more papers while I was doing this so that I could follow up some of the references in the papers that I had available to me to produce this report.

Q I think the Neilson report is at tab 14 of Dr Elliman's bundle. I do not want to go into great detail in it. It was in, I think, a *Paediatric Medical Journal* in 1998. Did you do a search of any sort for the link between asthma and pertussis?
A No, I used the papers I had and I got further papers that were referred to by them but not this one.

Q All right. Let me move on. The next paragraph but one, in other words the one starting with, "The Swedes abandoned", three lines down:

> "The Japanese raised the vaccination age to two years in 1975 after a number of reports of severe reactions and deaths. This reduced the total number of deaths in infants younger than one year."

Do you accept that the effect of that could be misleading?
A I accept that the effect of that would be misleading.

Q Let me move on. Just before we leave pertussis, I think, in fact, so far as the older child was concerned, the licence would not have extended to her, would it?
A No.

Q Did you mention that in your report?
A I did not mention it because Dr Conway, I think, had said ...

Q Had already mentioned it.
A ... he thought it was a good idea that she should have it anyway, so far as I remember.

Q Did you think it relevant to deal with the licence? This is not a criticism.
A I did not think it relevant because I was not advising vaccination. Had I been advising it for those two particular children I would have mentioned that she was outside of the age range for which the vaccine was licensed.

Q Was that not a reason for putting it into saying, "Well, that is another reason why she should not have a vaccination"?

A No, I did not put it in.

Q Let me move on. Can we go to page 27, please, the top paragraph. We are dealing with tetanus and you say what you have been talking about, just to make it clear, on the previous page is the fact that immunity can result from the ingestion of tetanus spores in somebody who has not been vaccinated. Is that right?

B A Yes, well the point at the beginning of that paragraph is that tetanus is a disease not regarded as being able to cause subsequent immunity. The actual disease caused by the toxin. So then I was leading onto discussing this observation that had been found in places.

Q You go on to deal with why that is relevant. You say:

C "The lack of this gut based immunity may explain the occurrence of tetanus disease in fully immunised people with adequate levels of neutralising antibody."

Then you cite three reports.

A Yes.

Q

D "The non occurrence of tetanus disease in unvaccinated individuals - such as everybody before vaccination was introduced, bearing in mind that the ubiquity of the tetanus spores – in whom it is present."

Now as Dr Elliman has pointed out, all of those authors who you are relying on for the first few lines of this comment were, in fact, supportive, were they not, of immunisation?

E A They were.

Q It is tabs 31, 32 and 33 and I am going to be selective, but if you think I should make reference to other parts then please tell me. Tab 31 on the left-hand side of the article:

F "In developed countries, neonatal tetanus had been abolished before the development of passive immunization against tetanus. In Finland the last case of neonatal tetanus was reported in 1915 and the systematic immunization of babies against tetanus was started in 1957. In the general, immunization program has prevented tetanus among children and young adults.

G There are a few case reports of patients who have contracted tetanus despite adequate immunization and/or a protective level of antibody. Usually in such cases the disease is mild, short-lasting or modified in its clinical picture."

Is that saying that it is mild, short-lasting and modified because the person has actually previously been immunised?

A That is what it is saying.

H

Q Can we go to tab 32:

"Tetanus is a rare disease in the United States"

A Sorry, could I just, while you are on that paper ---

Q Thirty-one?
A Yes, I would like you to read the last ---

Q What page?
A The last ... it is actually page 195 with a circle round it.

Q Sorry, which part?
A "There is an entity."

Q On the right-hand side?
A Yes, it is the beginning of the second paragraph.

Q

"There is an entity called 'subacute tetanus' in areas in which tetanus is endemic, and in some people might have naturally acquired immunity. Its prognosis is favourable, in spite of a short incubation period.

A That is it.

Q Yes?
A Yes, thank you.

Q

"There is an entity called 'sub-acute tetanus' in areas in which tetanus is endemic."

A This is what I was talking about when I was talking about ... well, when I was discussing the basis of gut based immunity. I am just mentioning that you have read in the paper that the paper says that tetanus in vaccinated people is generally milder and I am just pointing out that also there are cases when there are cases of tetanus in unvaccinated people which might have acquired natural immunity that are also milder.

Q Is that relevant to the UK?
A Well the tetanus as a disease has gone down remarkably, but we still do not know to what extent some of that is due to other forms of immunity as in all the people who did not die of tetanus when certainly the tetanus spores, which are everywhere, but were more prevalent because of using horses and so on as forms of transport. They were more prevalent and the people who did not get tetanus disease and die then because otherwise everyone would have died.

Q Yes. Shall we turn to tab 32? Again I am going to be selective.

"Tetanus is a rare disease in the United States as a result of nearly universal active immunization. Although tetanus remains a significant threat in developing

countries, the incidence in the United States is one-twentieth of the incidence before widespread immunization. During 1987 and 1988, only 101 cases of tetanus were reported ... However, the potential exists for an increasing incidence of tetanus due to the inadequate booster immunization in the elderly, the growing population immunocompromised hosts, and the urban epidemic of IV drug abuse. In spite of modern medical care, tetanus is fatal in roughly 20% of cases in the United States."

Then I am going to go to the next report, unless you want to refer to anything else?
A I would point to the next paragraph, three lines down. Would you like to read it?

Q Please, you read it.
A

"A history of immunization and of protective level of anti-tetanus antibody should not lead physicians away from the diagnosis of tetanus in a patient with an otherwise classic clinical presentation."

Q This diagnosis of delay in therapy can have catastrophic consequences.
A Yes.

Q Because, it is obvious, tetanus is an extremely serious disease if you get it?
A If you get it, it is extremely serious, yes.

Q It is very difficult to treat?
A It is, yes. Treatment is supportive.

Q Tab 33, it is a single page. *Shimoni*:

"Immunisation with alum absorbed tetanus toxoid is one of the most highly effective preventive measures in medical practice. The estimated failure rate is extremely low. We report a case of severe generalised tetanus in a patient who had been immunised fully."

It is absolutely right, of course, to point out that there are cases of tetanus in people who have been immunised fully, but just this, in referring to these three pieces of research, did you think it would be fair to a reader to indicate to him or her that the author's conclusion really of all of these reports was that vaccination for tetanus was one of the most highly effective preventative measures? Did you think that would put it into context?
A I could have put that there apart from, I think, that that point is taken out of context there. But, yes, I wrote myself that, if you look down on my page 27, under the actual vaccine when I am actually discussing the vaccine as opposed to discussing the natural history of tetanus disease, I have said:

"It has been available since the Second World War and appears to have contributed substantially to reduced mortality from the disease."

Q Yes, I accept that.
A So under the vaccine, under the tetanus vaccine, I have written that. Where I was

writing before about the natural history of the disease and ... because you see when we vaccinate with tetanus toxoid we are doing something different to what having the disease does. We are actually creating antibodies that would not happen from having tetanus, the disease. So I was pointing out or I was introducing the fact that it is a very interesting observation that people do seem to have the ability to make these antibodies and they do not know if it is gut based, they are just presuming that or hypothesising it. But under the vaccine, which is where I am talking about the vaccine, I say it has been available since the second world war and appears to have contributed substantially to reduced mortality from the disease, which I think the authors in the five to seven and other authors were saying.

Q Let me move on. Page 29, please, the very top of the page:

> "Vaccination of 11 healthy subjects with tetanus toxoid produced a lowering of the T-lymphocyte helper/suppressor ratio such as might be seen in patients with the acquired immunodeficiency syndrome (AIDS)."

What effect, when you wrote those words, did you think they would have on the reader? Fathers, mothers, lawyers, judge?

A Well when you say what effect, I think they would take it at face value and here I am documenting side effects of the tetanus. You will see on the previous page, 27, I have used the package insert.

Q Yes.

A I must say there has been some confusion about these package inserts and when I was producing the references, I did not produce any package inserts because I thought that they are so ubiquitous in the vaccine packets I did not think I was going to have to produce them. So that is why you see them actually written out in full here and not produced. Certainly Dr Conway and Professor Kroll, I do not think, picked up anything untoward in their opinion about what I had said in the package inserts or mentioned that they had not been able to find them. So here I am discussing these side effects that have ... and this was a side effect where it was not a study looking at the safety of tetanus vaccines.

In terms of this, should I have cited all the authors' conclusions I would have prefaced my whole report with a comment, I think, that I put somewhere in my transcript when I was discussing that in the absence of open, well researched, long enough, big enough (that is not how I have put it, I think I put it better) trials and studies into the safety of vaccination and also the efficacy of vaccination. In order to find out information about vaccination that does not just end with a conclusion that nonetheless the vaccination are safe and efficacious, it is necessary to sift through what is available in referreed medical journals, the methods and the results rather than just looking at the conclusions. So here, this was not a vaccine safety study, it was a study that was looking at a way of screening blood so that people who had Aids would not be having their blood products put into the public domain, so to speak, and they happened to notice that it was not a very good test looking at this lymphocyte helper suppressor ratio because you got this same lowering after tetanus vaccination.

Now this was an interesting and unusual (well to me) finding because to my knowledge

A I do not think blood has been taken from babies that have had tetanus vaccinations to see what happens to their lymphocyte helper suppressor ratios. So I put it in, along with the side effects that I was discussing, with the vaccine.

Q Your quote comes from tab 35, I think.
A That is correct.

B Q If we read tab 35, the actual research, I think this is a letter to the New England Journal of Medicine, it is really quite difficult to read, but if we go to the right-hand side of the page,

> "ABNORMAL T-LYMPHOCYTE SUBPOPULATIONS IN HEALTHY SUBJECTS AFTER TETANUS BOOSTER IMMUNIZATIONS."

C and we go about two-thirds of the way down, I think we see the lowest ratio. It is towards the right-hand side of the page. It is the last four lines on the right:

> "The lowest ratio, which is shown in Figure 1, appeared between Day 3 and Day 14 after vaccination and returned to normal subsequently."

D I want to try to avoid getting too bogged down in the science, but is it fair to say that from this research, first of all it appears to have been a temporary effect only?
A In terms of the T cell ratio it is a temporary effect. I do not know whether they looked at any other symptoms of the people other than the T cell ratios, that is what they mention return to normal.

Q There was no evidence, in fact, that it did any harm either.
E A I do not know what they were looking at in terms of harm. They state here that the ratio went back to normal. I do not know if they were giving people questionnaires about their general health.

Q Did you think it was relevant in your report in dealing with this piece of research to make it clear that the lowering of the T-lymphocyte helper/suppressor ratio, such as might be seen in patients with Aids, was a temporary effect only?
F A I think I have mentioned before about the size constraints of this paper. Certainly if I were doing it again I could probably have expanded on what I put there and introduced my rationale for putting it in and also explained that I have put eleven healthy subjects and I did not explain that they were 20 to 50 years old and I did not explain that I did not know what effect would be had on the T-lymphocytes on babies and children that were
G being injected and whether the recovery by 14 days of the lymphocyte ratio would be that seen in babies or children who were vaccinated. I could have put it like that. I could also put the significance of the ratio in terms of making the children or the people in this study more susceptible to infection if their lymphocyte ratios were not normal.

Q Dr Donegan, I accept you could have done all sorts of things.
A Yes.

H Q I just want to look at these three lines and to see whether you left the reader of your report with a fair impression of the research.

A

"Vaccination of 11 healthy subjects with tetanus toxoid produced a lowering of the T-lymphocyte helper/suppressor ratio such as might be seen in patients with the acquired immunodeficiency syndrome (AIDS)."

Now it would not have taken you more than a line to say that it is right to point out that this effect was temporary up to two weeks.

B

A I accept that point.

Q Thank you. I expect you also accept the point that seeing those words in connection with a vaccine that might have a significant effect on the reader.

A I cannot say about that.

C

Q Can you not? If you put mention of the word Aids into a report as being linked to the effect of a vaccine, can you not see that the reader is likely to take that seriously?

A Well in this report I was discussing diseases like paralytic polio as well which I think would cause people to have reactions to discussing it. So I think a lot of the diseases in their most severe form in the most vulnerable populations would have ... I mean, I have discussed that with tetanus you can die, you know, so I do not think that is more severe than ---

D

Q Do you agree on reflection that you should have made it clear that the effect, even on the basis of the research, was said to be temporary only?

A I have already accepted that point, I think. Have I?

Q We can move on then.

A Yes.

E

Q At the bottom of that page you deal with thiomersal and I am going to come back to find that.

Turn to page 34. There is this paragraph, the first paragraph, which takes up about the first half of the page:

F

"As the World Health Organisation struggles to achieve its aim of worldwide eradication of polio it is notable that epidemics of paralytic poliomyelitis have occurred in highly vaccinated populations and, tragically, immediately <u>after</u> a polio vaccination has occurred. Indeed, as India struggles to meet the polio deadline, several cases have been reported of children contracting polio even after receiving up to a dozen doses ..."

G

Then you deal with the Oman outbreak, where the highest attack rate was in the region of the highest coverage rate, and a polio outbreak in Israel in a highly vaccinated population with inactivated polio vaccine. Can you just help us with what relevance did any of this have to two young girls in the UK?

H

A I thought we discussed or we addressed this before when discussing my instructions regarding worldwide experience?

Q I can repeat that cross-examination if you want, but you were being asked to assist the judge and the litigants in this action in relation to vaccinations that these children were going to receive in the UK, not in Israel, not in Oman, or anywhere else. Why if you were keen to restrict your report, as you have told us you were, did you insert this at all? How was it going to help anybody?
A Because I was asked to give worldwide - I cannot remember whether the word was experience, or whatever, but the worldwide was there, of the vaccines.

Q So you read that, did you, as being invited to write a report really covering the use of old vaccines in any other part of the world?
A Well, these vaccines are not all old vaccines. The oral polio vaccine is the oral polio vaccine.

Q Is that used in the UK?
A The eIPV is not one that has been used in this country.

Q No.
A However, the oral polio vaccines used in the other campaigns to the best of my knowledge is the same as the oral polio vaccine used in the UK.

Q However the occurrences in India, in Oman and in Israel, do you agree, had absolutely no relevance to what was going to happen to these two girls in the UK?
A I think you would have to ask the solicitors why they asked me to write on that experience.

Q They are not here.
A No, but I was acting on the instructions that I had.

Q I am going to suggest to you that you may have misread those instructions, or misinterpreted them?
A I take your point but, when I was writing this report, that was what I had in my mind that I had taken from my reading of the instructions from the solicitors.

Q Let us move to SV40:

> "In 1961, inactivated polio vaccines ... was found to contain live SV40 ... a monkey virus that is more resistant [than] the poliovirus to chemical denaturation (inactivation)".

Can you help us, please, with what is the relevance of SV40 to what was going to happen to these girls if they received the vaccine?
A The SV40 is an example of a live monkey virus which was present in polio vaccine that had not been inactivated. The polio vaccine - there was inactivated polio vaccine available in this country when this case was going on, but what was in the schedule was oral polio vaccine. The same caveat pertains in that, whatever you do when you are cleaning up the vaccine that does not kill the polio virus, leaves the possibility of another not desired virus persisting.

Q What evidence was there of any undesirable virus in the vaccine that was going to

be used in 2002?
A We always use the vaccines that are going to be in our knowledge the best and the most safe but, as you will see from the history of blood transfusion, you can only look for things with what you have got available at the time and organisms that you have not been looking for manage to get through the process of cleaning, or I cannot think of a better word.

Q Is the answer to the question none? There was no evidence of any contamination of the modern vaccine?
A I do not have any papers that show it.

Q No, right. Let us get back to what you were saying about SV40. When did it stop being used?
A What, the SV40?

Q Yes?
A The vaccines were cleaned up in the early 1960s to the extent of they did not remove all the SV40, but they removed it to below a certain level. A certain level of contaminants were allowed. So, it was not that the vaccines were guaranteed as being pure or completely free of impurities. The levels were below a certain level.

Q Can we read on in your report to see how you put it, please, and this is halfway down the paragraph:

> "An increased incidence of tumours of the nervous system has been reported in one study in children of mothers vaccinated during pregnancy. SV40 has now re-emerged as a potentially tumour causing virus and has been found in a variety of childhood neural tumours in a distribution that mirrors the range of tumours induced in animals who are injected with the virus. The virus has also been found in lymphomas ... Not many tumours have so far been investigated for the presence of this virus so it is likely that more will emerge in time. SV40 has been found in people far too young to have been immunised with the documented contaminated vaccines so it is possible that it is still being transmitted through the vaccine or, having been incorporated in the human genome, vertical transmission is occurring from parents immunised with the contaminated vaccine to their children".

What evidence - what scientific evidence - was there to allow you to say that it is possible that it was still being transmitted through the vaccine?
A There is evidence published in a scientific paper by a person called Dr Kops (K-o-p-s). I have the document here. Where the vaccine had been certified as being free of this virus in a case which was being taken by parents who were complaining about - a case brought by parents whose I think child was allegedly damaged by these vaccines it came out that, although from the US Department of whatever it is that the vaccines were free of the virus, internal company memos from Laderle (or [Laid-earl] I do not know how you pronounce the name) had confirmed that there was virus present in vaccines a lot more recently. So, what sometimes happens in cases such as this - I do not mean *this*, I mean

this - is that subsequently it turns out that there is contamination at levels that have been not acknowledged except when legal proceedings take place.

Q Can we just have a look at that. Was the vaccine that you are referring to an IPV or an APV?
A The vaccine that I was referring to was ---

Q The American one?
A I do not know whether that was oral, or inactivated.

Q When was it?
A I have got the paper. I can copy it for you, if you would like to see it, after the break?

Q Yes, we will do that in the break. Can we just look at the paper that you were apparently relying on. I think it is your reference at tab 51 and if we go to the second paragraph:

> "SV40 was characterised as a double stranded DNA virus belonging to the group of papovaviruses",

and then a few lines on:

> "Except for one study, which reported an increased incidence of neural tumours in children of mothers vaccinated during pregnancy, all studies were essentially negative".

That is the Heinonen report, is it not?
A Yes, that is what they are referring to when they say that.

Q Which I think you accepted you did not read?
A No, I used *this* reference, the one that you are reading from.

Q Then over the page, two-thirds of the way down:

> "Even if the identity of the DNA is confirmed as viral in origin, its source would remain unclear as SV40-like DNA has been identified in tumours from those who are far too young to have been immunised with contaminated vaccines. If this cannot be explained by artefact or misidentification then it implies either some other source of human SV40 infection or vertical transmission from immunised subjects. It thus remains possible that a late adverse effect of the polio vaccination programme is emerging, although any risk of cancer ...",

and that is where you stopped, I think, is it not?
A Yes.

Q This is the sentence that you underlined on page 23 of your report. So you stop

there, but in fact the sentence carries on:

> "... although any risk of cancer is likely to be more than outweighed by the benefit of vaccination to the postwar generation".

Can you just help us with why did you decide to not complete the sentence? If you are quoting from a report and those are the exact words that you underlined, why did you think it appropriate to stop after the comma, or before the comma rather?
A That is because whichever paper discusses side effects of a vaccine, a standard conclusion is that it is always better to vaccinate than not to vaccinate.

Q Yes, but you were being asked to consider both sides of the issue, not just one?
A I thought that one side of the issue had already been dealt with by the previous experts, Dr Conway and Professor Kroll, and I was ---

Q Dr Donegan - I am sorry, I did not mean to interrupt.
A I am sorry. I was giving another view of the vaccine, or the vaccines and the diseases, which had not been brought to the attention of the court by the other experts.

Q Dr Donegan, you keep referring to the care with which you followed your instructions in relation to the worldwide issue?
A Yes.

Q You were asked to consider both the benefits and the disadvantages of vaccination, were you not?
A Yes.

Q You were not just asked to do one because there were a couple of reports that had been pro vaccination. You were not being asked to write a report that just dwelt on the disadvantages, were you?
A I should have at the beginning of my paper said:

> "The advantages of the vaccination having been presented by Dr Conway and Professor Kroll, I will now attempt to give a balancing view".

That would have been a more appropriate way for me to have started my report, I think, with the benefit of hindsight.

Q Can I just remind you of the words of *Good Medical Practice:*

> "You must not write or sign documents which are false or misleading because they omit relevant information".

Do you agree, on reflection, that it would have been relevant information to complete the words of that sentence if you were going to quote it?
A I could have completed the sentence.

Q Should you have?

A I do not know. I think that if I had been rewriting this report, as I said, I would have put my proviso at the beginning and I would have made my point about the conclusions.

Q Dr Donegan, even if you had put a proviso at the beginning, do you not accept that it is inappropriate to quote half a sentence which supports one view and not quote the rest which gives the balance?

A I think it is a good idea to quote full sentences.

Q Right, let us move on. Just before we move on to the next area, just staying with that for a moment I am sorry, you accept I think that the vaccination that was going to be given to these young girls, if it was going to be given at all, would not have been by injection, is that right? It would have been what I referred to earlier, showing my age, as the sugar lump?

A It is not clear because the schedule was the oral one, but the inactivated one is available in this country and it might have been an option had the mothers decided that they wanted to go ahead with some part of the vaccination programme that they might have decided that they did not want to have oral and they would prefer to have inactivated.

Q All right. Now this whole paragraph which has been dealing with the problems of SV40, whatever other contaminants there might be you accept, I think, that the SV40 virus in polio vaccine was either eradicated in the 1960s, or brought down to such a level that it was no longer a problem?

A I do not think there is a safe level and there is a lot of controversy regarding whether it has been - how much has been eradicated, or not. I have brought some papers. I can certainly ---

Q Well, try and ---

A So, I cannot say "Yes". I cannot say, "Yes, it has all been decided that it is safe", because there is one view that it is safe and there is a lot of research being carried out by a doctor called Carbone in America as to whether in fact that is the case.

Q The contamination, the sort of contamination to which you are referring ...

A The heavy contamination.

Q ... which occurred in the '60s was stopped in what, about 1966?

A It started being stopped before then.

Q All right. That particular strain of vaccine was no longer used?

A The strain was used, but it was cleaned up.

Q Can we just go to your conclusion at page 36:

> "Due to the rarity of paralytic polio in the UK, USA and other such countries and the fact that almost 100% of cases that do occur are due to the vaccine I do not think that it would benefit either child to put them at such a risk, particularly in view of the, as yet, unknown risk of the contaminants which are still being investigated".

Again, in the context of what you had been writing about SV40 and what you actually knew about that, do you think on reflection that that was an appropriate way to end your conclusions?
A I think that that is very true. It is what I have said to you now, which is that it is still being investigated.

Q Let us move on. At page 38, and this is just a very short point on Hib, two-thirds of the way down:

> "The Handbook of Immunisation against Infectious diseases ... quotes several large field trials in Finland, the USA and the UK as evidence of its efficacy but the trials showing the highest efficacy were for the PRP-OMP and HbOC, neither of which are available in this country".

I am afraid I do not have - certainly HbOC I think used to be used, did it not?
A Dr Elliman I think said that it has been occasionally available, but it is not one of the standard ones in our programme.

Q All right, okay. Can we turn to page 39, then, please. If we go I think it is probably seven lines down in the first paragraph:

> "Other reaction reported to the Vaccine Adverse [Event] Reporting System ... [in] the USA are Guillain-Barre Syndrome ...",

and that is the very unpleasant creeping paralysis, yes?
A Yes.

Q Yes:

> "... - a neurological disease which may eventually cause"

- as you say -

> "paralysis of the respiratory muscles requiring artificial ventilation, transverse myelitis - a paralytic disease mainly involving the legs and death (which may have been caused by the Hib vaccine or by other vaccines that were given at the same time)".

If we go to your tab 56, right-hand side of the page, and it is the third page in, section 279:

> "The conjugate vaccines have been associated with the onset of Guillain-Barre syndrome (GBS). Many cases have been reported in the medical literature and through VAERS. Some of these children received other vaccines concurrently, but several cases occurred when the Hib vaccine was given alone. A 4-year old girl developed progressive weakness of the legs, pain in the legs and feet and gradual inability to walk 10 days after [receiving the] Hib vaccination."

A It describes her very unpleasant condition.

> "Her symptoms gradually improved, and within 3 weeks she could walk with help ... Two cases were reported after PRP-D alone ... and three cases following the HbOC conjugate vaccine were reported."

B Are those the ones that you are saying were not used in the UK?
A Yes.

Q Do you accept that there was no evidence of a causal link?
A I certainly accept that there was no evidence of a causal link.

Q The next paragraph reads:

C

> "The vaccine is only against type B so it only affects infections caused by type B. It is possible that as infections by type B are suppressed there will be a drift towards infections produced by the other types."

Do you accept, I think as Dr Elliman points out, that A and C to F are very rare by comparison with type B?
D A They are at the moment. I agree with that.

Q Did you think it relevant to mention that?
A When you are looking at the natural history of the disease I think it is important. It is the selection pressure that occurs. Nature not being stupid, as I like think to think of it. When certain interventions occur to stop something occurring or kill it off then the ones that are left sometimes move in to fill the gap.

E

Q I understand that, but having mentioned that, did you think it was also relevant to point out that at the present time, the time that you were writing this report, those sorts of infections were very rare?
A I did write that it is possible that there will be a drift, which is to me saying that it is not happening now in many cases.

F Q Can we move on, please, to page 45. Dealing with meningococcus. We need to jump over to your second file. Can we turn to tab 73, please? *This* is the article upon which you were relying, I think. Let me read what you wrote. It is halfway down page 45:

G

> "In 1997 the Department of Health was said to be resisting pressure to introduce blanket meningitis vaccinations for university students, 'The problem is that several hundred thousand students would need to be vaccinated when the incidence of the disease is actually very small'. In 1998, Southampton Local Medical Committee chairman Nigel Watson said that they advised against routine vaccination of 8000 new students as there was, 'No clinical evidence to support it'."

H Then you say:

"The vaccine was nonetheless introduced ..."

Your tab 73, first of all, and you were relying, for this comment, were you, on a news article in *Pulse?*

A That is correct.

Q The first comment in the middle column:

"'Studies have shown that university students are at increased risk of meningitis than other adolescents. The problem is that several hundred thousand students would have to be vaccinated when the incidence of the disease is actually very small', one source told *Pulse*."

Then:

"A National Meningitis Trust spokeswoman said the department had ruled out a vaccination programme because of the limitations of the combined meningococcal A and C vaccine, which is only 80 per cent effective.

'The new meningococcal C conjugate vaccine that will be available from the next two years looks very promising. The trust will be pushing very strongly for everyone up to the age of 20 to be offered it'."

First of all, there is the issue of relying on *Pulse* magazine.

A I accept that point, yes.

Q Secondly, the vaccine that this article was talking about was a different one, was it not?

A It was. It was the old A and C one.

Q When you wrote your report, at page 45, and you wrote the words, "The vaccine was nonetheless introduced in November 1999", do you think it would have been fairer to make it quite clear that it is a different vaccine?

A I think it would have. I think that was unhappy wording.

Q If we go down to the paragraph beginning, "The vaccine was nonetheless introduced", and you discuss the problems, we find, about five lines up from the bottom:

"Twelve deaths were reported to the CSM but it was decided that none of them were due to the vaccine. One reason given for greater reporting of side effects was that nurses were allowed to fill in yellow cards for the first time and it is thought that they may be more open to reporting side effects than doctors."

I just completed it so it is not suggested I have not dealt with the full thing.

"Twelve deaths were reported to the CSM but it was decided that none of them were due to the vaccine."

Why did you use those words, "it was decided that"?

A Because it was. To be more specific I should have said it was decided that none of them were causally linked to the vaccine, if I had been more specific about my words and using the words "causal" and "associated" and so on.

Q Would it have been fairer to say there was no evidence that any of them were due to the vaccine?

B A There was no causal evidence.

Q Shall we have a look at tab 75? Can we look at the bottom of the first page which deals, I think, with the twelve deaths to which you were referring?

A Yes.

Q

C

> "Twelve deaths have been reported to the CSM. Seven of these were from Sudden Infant Death Syndrome. Two were as a result of Meningitis B, a separate infection from Meningitis C, one as a result of Pneumococcal septicaemia, one from bronchiolitis and a patient with congenital heart disease and one from pneumonia with cerebral oedema. None of these deaths can be attributed to Meningitis C vaccine."

D

Again, when you wrote those words, "it was decided that", do you think it would have been more appropriate, on reflection, to reflect what those deaths were really all about?

A There was sudden infant death syndrome and it must be said that the jury is out on what causes sudden infant death syndrome, to the best of my knowledge. Two were as a result of meningitis B. The meningococcal organism lives up, to put it crudely, the nose of about one in six individuals and when there are many cases of meningitis around in the

E area it might be as much as 50 per cent and in places where there are a lot of cases, for example, the universities like Southampton and Cardiff when they had their big outbreaks about 100 per cent of people would have had a meningococcus of one of the groups up their nose, and when people are vaccinated against one type of the meningococcal serotype, or groups, that one will be wiped out, and as there is such a subtle balance between an organism living up your nose and leaving area nose to invade your brain to cause meningitis or leaving your nose to invade your blood stream to cause septicaemia, it

F depends on the integrity of the host's immune system, wiping out one of the groups is not without the bounds of possibility that this upsets the balance and maybe one of the other groups then goes and causes some kind of infection.

So just to say, "Well, they died of meningococcal B disease", is not to discount that there

G may be any link with the vaccine. Looking at these other ones, other organisms that live up your nose as passengers include the pneumococcus and include the haemophilus influenza b. So none of these deaths can be attributed to the vaccine but I do not know how much study they have done apart from looking at the diagnosis.

Q Why did you not just say, "none of these deaths can be attributed to the vaccine"?

A I have become more punctilious now about actually quoting the quotes. I could

H have put "attributed to the vaccine". I suppose in that case I did not put "attributed" because I was making it - you were addressing the question of whether what I was saying was understandable by people who were not doctors and I did not use "attributable to",

A I used, "due to".

Q Let us move on. Can we turn to page 46, please?

"By the summer of 2000",

B - this is the second paragraph down -

"the CSM advised that further side effects should be added to the product information of the vaccine in relation to older children and teenagers: Nausea, vomiting, rash, malaise",

- lymphadenopathy, is it?

C A Yes, lymphadenopathy.

Q Thank you.

"(swollen lymph glands), headache, myalgia and allergic reaction including allergic ones. Neck stiffness and photophobia have also been reported and convulsions at a rate of one report in 100,000 doses."

D

Can we just look, please, at your tab 76? If we go to the penultimate paragraph, do you see, "seizures have been reported"? Is that your convulsions, as it were?

A Seizures, yes.

Q So when you refer to convulsions ---

A I mean seizures, yes. I just made it more lay speak.

E Q

"Seizures have been reported very rarely, with approximately 1 report per 100,000 doses distributed",

- which you say.

F "Some of the reported seizures may have been faints, febrile convulsions, or coincidental. A causal association between seizures and the meningococcal C conjugate vaccines has not been established. The CSM has recommended that a statement to reflect this information should be added to the product information."

G Now we do not know quite what this information means, and I think this was picked up by one of the panellists, perhaps.

A Yes.

Q In other words, should it include the words, "a causal association between seizures and the meningococcal C conjugate vaccines has not been established".

H Then this:

"The vaccines appear to be safe and effective and the risk benefit profiles are

overwhelmingly favourable. The safety of the meningococcal group C vaccines will continue to be intensively monitored. Please report ..."

Again, I absolutely accept that you use the words, "have also been reported". Did you think to include the words that a causal association had not been established?

A For many of these vaccine adverse effects no causal association is established because the appropriate studies of the size or nature to establish causality, as opposed to association, are not done. So it is not possible to establish causality, but that is not the same as saying it is not causal. So they are saying, basically, there is an absence of evidence.

Q Yes, but, of course, in citing the possible side effects did you think it relevant, first of all, to say, "causal association with vaccine has not actually been established"?

A I could have said that for all the other ones, that the CSM advice should be added. I could have added, "it is not causal for nausea, vomiting rash, malaise, headache, myalgia". These things are accepted by the CSM and it does not actually qualify those with saying it is not causal, so far as I know. It just tends to do it for what it regards as these other ones.

Q We can take it that this, I think, is your copy. It has your writing on it?

A Yes, those are my comments.

Q So can we take it you would have read the words at the bottom of the page:

"The vaccines appear to be safe and effective and the risk benefit profiles are overwhelmingly favourable"

A Yes, I have written, commenting on "appear":

"What does that mean [it is] not [very] scientific".

Q Yes. Having quoted from the earlier part of the report did you think in order to balance it, in accordance with your instructions, perhaps, you should have included those last words?

A Yes, I could have included those last words.

Q Let me move on. The next paragraph:

"The Meningococcal C vaccine only has any effect of disease caused by Meningococcal C. As is the case with the Hib vaccine, it is to be expected that as disease with one type declines, there will be a drift to more disease caused by others. This has certainly been seen with the polysaccharide meningococcal C vaccine."

Then this, and I appreciate, I think, you agree you have got this wrong?

A Yes, I have put "disease" instead of "acquisition".

Q There may be more errors than that. Let us have a look at it:

"When used on US forces the incidence of meningococcal C disease was reduced

two to three times but the total meningococcal acquisition rate was essentially the same regardless of vaccine status."

It is tab 77 and it is page 419 at the top right-hand corner. You know the difference between an acquisition rate and the disease, do you not?
A Yes, one is I was talking about organisms crudely living up your nose; that is acquisition.

Q Yes, it means having a virus in one's body but not actually catching the disease.
A Not having ... yes, not having the invasive disease, yes.

Q It should be noted that we read on the left-hand side of the page of the research:

"It should be noted that whereas Group C acquisition rates ..."

so that is clearly talking about acquisition rates.

"were reduced to three times, the total meningococcal acquisition rate (per cent of recruits acquiring a meningococcus during the eight weeks observation) was essentially the same ... Thus, the vaccinated recruits, although protected against Group C ... acquired meningococci of other serogroups."

Then over the page to the right-hand side:

"When the results of all five posts are added together there is a statistically significant reduction in the rate of Group C meningococcal disease among the immunized recruits as compared to that among the nonimmunized recruits. This difference holds true in comparison of those vaccinated to the 20 per cent control group as well as to the 60 per cent control group. The reduction in the attack rate is consistent with a protective effect of 87 per cent against Group C meningococcal disease."

And I will read the next paragraph because it looks as if you have underlined it:

"On the other hand, there was no reduction in disease due to Group B meningococci among the vaccinated recruits. In fact, the attack rate was higher among them although the number of cases of Group B disease was too small to permit statistical analysis."

Just going back to your comment:

"When used on US forces the incidence of meningococcal ... disease,"

we should read there physician, yes, which is important, is it not?
A It is important, yes, it is a misquote. I mean it is an error of the copying.

Q It was reduced to two to three times. Well actually it was reduced, I think, ten times, was it not? If you look at the table, do you remember Dr Elliman took us through this?

A Well it says in the text,

"It should be noticed that whereas Group C acquisition [whatever] were reduced two to three times."

Not my text, their text.

B Q If we look at the table, in fact, as I understand it, it is referring to the attack rate. It is, because the heading makes it clear.

"Cases and attack rates of group B and group C with meningococcal disease according to vaccine status."

C In other words, the people who actually catch the disease. Yes ...
A The invasive disease as opposed to carrying it up their nose. Yes.

Q ... to the acquisition rates. Group C, number of cases one rate 0.07. Non-vaccinated recruits Group C, 38, 0.7. So that is where we get our ten times reduction in the disease?
A Yes.

D Q Do you accept that?
A I do.

Q Did you read this?
A I did.

E Q Forgive me, I do not mean to ask this in a rude way, but did you understand it?
A Yes, it is easier if they give the percentages, but yes, I understand the rate has got a difference.

Q So what happened with your report?
A I discussed what the ... what I have discussed a lot before with removing organisms that are often commensals, the ones that live up your nose without the disease
F is that you can then open up the way for different ones to take their place.

Q I understand that. Perhaps I did not ask you very clearly. If you understood this article, how did you come to write:

G "When used on US forces the incidence of meningococcal disease was reduced two to three times."

because that is wrong, is it not?
A That is wrong because I have put disease instead of acquisition. I think I am not the only person who has made the odd typographical error.

H Q You then go on to say that:

"The <u>total</u> meningococcal acquisition rate was essentially the same regardless of

vaccine status."

Q You mean of different types?
A Of the A, B, C.

Q "Thus, the vaccinated recruits, although protected against group C organisms ..."

A Which I have written. Yes. Sorry.

Q "... acquired meningococci of other serogroups. In fact, the attack rate of group B meningococcal disease was higher among the vaccinated recruits."

THE CHAIRMAN: Mr Kark, we are on that page.

MR KARK: Yes.

THE CHAIRMAN: The table 2 talks about the acquisition rates? Table 4, which shows a ten fold ...

MR KARK: That is cases and attack rates.

THE CHAIRMAN: ... cases attacked.

MR KARK: That is the difference ...

THE WITNESS: That is the disease.

THE CHAIRMAN: That is the difference between. The quotation is from the text reducing two or three times ...

MR KARK: Yes.

THE CHAIRMAN: ... appears to be correct?

THE WITNESS: That is from table 2. Sorry, can I talk to you?

THE CHAIRMAN: Yes.

THE WITNESS: That is table 2. It is what they are discussing underneath it and that is the two to three from table 2.

THE CHAIRMAN: I do not know whether there was a suggestion that that should have been ten times or whether you accept that that is correct.

MR KARK: No, it is one or the other, as it were. If we go to the report, if Dr Donegan is going to be referring to disease, as she does:

"When used on US forces the incidences of meningococcal disease was reduced,"

then it should read "ten times".

THE CHAIRMAN: Yes.

MR KARK: If we leave two to three times then it should read "acquisition" and that is the difference between. *(To the witness)* You accept that, do you not?
A Yes. Yes.

Q All right, let me move on. Could you go on, please, to page 49? This, I think you have already accepted, is unhappily worded?
A Yes, I should have put ... the parenthesis could have been done with being moved so that the final sentence of the paragraph was clearly referring to the first sentence in the paragraph.

Q

> "Measles disease may depress cell mediated immunity for up to three years. The vaccine virus is attenuated but has similar characteristics to the wild virus so it would be expected to have the same characteristics."

Let us just stop there for a moment. This is referring, first of all, to the cell mediated immunity is referring simply to the disease. Yes?
A Yes,

> "Measles disease may depress cell mediated immunity for up to three years,"

is referring simply to the disease.

Q Did this come from the Shaheen?
A Yes, tab 85.

Q When you were cross-examined in the High Court and you can find it at page 107 ---
A Sorry, what page?

Q I think it is 107 in the middle and if we go from the question at line 10 talking about:

> "Q In Guinea-Bissau, children who were tested three years after having had measles have lower general cell immunity than vaccinated children. I am not going to bother about the next two, because they are obviously specific to the area."

And he says a bit further down:

> "Q Then we look back at your report, it comes in a paragraph of some six lines."

A

I think it is this paragraph that he is talking about ...
A Yes.

Q

"... which you no doubt have read many times and which we can read to ourselves. And what you have written is completely misleading in its context, is it not? Here is Shaheen, pointing out the unfortunate outcome for those who have measles rather than being vaccinated, and when we read that paragraph, the whole tenor of it is inverted."

B

You say:

C

"A What they do mention in the conclusion - the summary of conclusions in the paper - is that 40% of the people who have measles were vaccinated."

Q Forgive me - that paragraph of your report casts a gloss which is completely contrary to what Shaheen and colleagues have written?

A Yes.

D

Q Do you think that was appropriate?

A No."

Then further on, again just to complete it, Mr Justice Sumner says:

E

"MR JUSTICE SUMNER: If it is not appropriate, where does it leave your conclusion in the last sentence of your paragraph?

A Well, the last sentence in my paragraph also takes into account the high teeter measles vaccine that Dr Conway said he didn't know the reference of, but I have it in my second bundle. I'm trying to find it now.

F

MR JUSTICE SUMNER: Well, does that conclusion of yours remain now?

A Yes, the conclusion remains."

We will look at that in a moment.

G

Do you accept, I think, now that in fact what you reflected in your report was contrary to the research that Dr Shaheen had come up with?
A No. The question Dr Conway ... Mr Cohen asked me is, which is as this paper is taken, here is Shaheen pointing out the unfortunate outcomes for those who had measles rather than being vaccinated.

H

Q Yes.
A He said that 40 per cent of the people who had measles were also vaccinated and the decrease in cell mediated immunity is greater in the people who were vaccinated and

had not had measles, but there is still a decrease in cell mediated immunity than those who have been ... the degree of decrease of cell mediated immunity is greater in the people who have had measles whether they have been vaccinated or not, but there is also a decrease in a degree of decrease in cell mediated immunity in those who have been vaccinated in the results on the front page.

Q Shall we have a look ...
A Yes.

Q ... at tab 85.
A Yes, please.

Q First of all, the abstract, but we will go into more detail of it. "To investigate whether children," sorry have you got it?
A Yes, I have.

Q

"To investigate whether children who have had measles have reduced general cell mediated immunity three years later compared with vaccinated children who have not had measles."

It then deals with the subjects with the 391 children living in Bissau during a measles epidemic and still live there. There were 131 primary cases, 139 secondary cases from the epidemic, and 121 vaccinated controls with no history of measles. Conclusion at the bottom:

"Reduced general cell mediated immunity may contribute to the higher long-term mortality in children who have had measles compared with recipients of standard measles vaccine and to the higher child mortality in the rainy season in West Africa."

A Yes.

Q I am going to go over the page ---
A Could I just go back to the results ...
Q Yes.
A ... on that front page where it says that 31 ... the way they are testing cell mediated immunity is with a set of various antigens and they talk about anergy. Ergon is work in Greek and anergy is basically not work, so the cell mediated immunity is not working, simplified in this context, and 31 per cent were anergic who had had measles and these are vaccinated and non-vaccinated compared to 17 per cent who had been vaccinated.

Q Can we go two pages on, please, to page 76? I am looking at the last four lines of that page.

"For children exposed to measles infection at home."

Do you have that?

A Yes.

Q

"The clinical vaccine efficacy was 87% (range 77-93%) for children under 3 years of age. However, measles vaccination coverage was high in the study area therefore a substantial proportion of the cases in this study had received vaccine before contracting measles."

That is what you were relying on. Yes?
A Yes, I am saying in the measles cases 40 per cent of those were vaccinated, so it is not a straight comparison of those who had measles and were not vaccinated and those who were vaccinated and did not get measles.

Q Can we go to page 80, just to try and finish this, right at the bottom:

"Primary cases had an intermediate risk of anergy, but this was not significantly different from that of controls or secondary cases,"

Then the last three lines:

"This did not change when six controls were excluded who had received the high dose Edmonston-Zagreb vaccine and not standard Schwarz vaccine. Overall, 109 of the 270 cases were clinical vaccine failures."

Yes?
A Yes.

Q

"When these children were excluded the adjusted odds ratio for all cases was unchanged."

A Yes.

Q I just want to go back to what you wrote:

"Measles disease may depress cell mediated immunity for up to three years"

which is right, of course.
A From this paper, yes.

Q

"The vaccine virus is attenuated but has similar characteristics to the wild virus so it would be expected to have the same characteristics."

On reflection do you think it would be fairer to reflect the fact that there was not evidence that, in fact, those who received the vaccine virus had cell mediated immunity as a result?
A Well may I take you through something in this paper?

A

Q Yes.
A As I said, to test cell mediated immunity they were looking at anergy, ie not responding to something an antigen that was being administered to them. If you look on page 75 of the GMC numbering, in the second paragraph from the bottom, it says: "Anergy," do you all have that?

B

Q "Anergy or loss."
A I just want make sure all the members of the Panel have found it.

Q It is three lines down in the ---
A Has Dr Goodman found it? Page 75.

C MR GOODMAN: Page 75?

MR KARK: Page 75, the second paragraph up from the bottom.

THE WITNESS: Well it is one paragraph up and third line down:

"Anergy or loss of delayed type."

D

MR KARK: Yes.
A Everybody got that? So they are defining anergy or loss of cell mediated immunity as a loss of delayed type hypersensitivity on skin testing with antigens such as tuberculin. And they confirm on page 77, second paragraph down ...

Q Yes.
E A ... the last full line describes the antigens and one of those is tuberculin. So I am just using this to demonstrate the fact that our response to tuberculin is a sign of a working amount of ... a cell mediated immunity working in the patient. Yes.

Q Yes.
A Yes. Is that okay? I know that the medical members of the Panel will know that.

F Q They may well follow that better than I will. I am sure Mr Stern is following it word for word.
A If we go to tab 84, which is the immunisation against infectious diseases handbook produced by the Department of Health and we find that at page 69 of the GMC numbering.

G

Q Which is 139 of the article for anybody who does not have the GMC numbering, yes?
A If you then turn the page sideways and look at the top left, paragraph 22.4.14. Has everybody got that?

Q Yes.
H A It says:

"Measles virus inhibits the response to tuberculin"

- which we found from that paper -

> "so that a false negative tuberculin test"

- meaning a tuberculin test that does not produce a response -

> "may be found for up to a month following MMR vaccine".

So I think that demonstrates that the measles component of the MMR vaccine can reduce cell mediated immunity response as tested by tuberculin testing, which is the point that I made when I was making the conclusion in that paragraph.

Q Let us have a look at how this continues and then we will break. Perhaps I can just finish this paragraph. You say this:

> "Indeed a high titre measles vaccine ... used in populations in Africa caused higher death rates in girls from other infectious diseases compared to boys or unvaccinated girls".

Let us just stop there for a moment. The high titre measles vaccine referred to there used in Africa, was that one used in the UK?

A No, it is not.

Q It was withdrawn in Africa in I think 1996, we heard?

A It was withdrawn after the discovery of the unfortunate deaths.

Q Yes. Let us read what you then say:

> "To give a vaccine that has such an effect on the immune system at the same time and in the same needle as two other live viruses is, in my opinion, risky".

What did you mean by, "To give a vaccine that has such an effect on the immune system ..."?

A I mean a vaccine that reduces cell mediated immunity to an extent is dangerous, because cell mediated immunity is a very important part of our immune system for dealing with viruses. So to give something with that effect in the same needle as two other live viruses, at a time when the body would then need to deal with the two other live viruses, is in my opinion risky.

Q Why does it follow, or what is the relevance of a high titre measles virus in Africa causing deaths immediately before that sentence?

A I think I have agreed that unhappily I could have put the sentence in a different way. A high titre measles vaccine would obviously be expected to intensify - well it was given to intensify the antibody response and, if there were adverse effect, it could be expected in the case of a live virus (which the measles vaccine is) to intensify the adverse response which unfortunately in this case it did.

Q You see, Dr Donegan, the judge and the parties are going to read:

> "Indeed a high titre measles vaccine ... used in populations in Africa caused higher death rates in girls from other infectious diseases ...",

and so that is related to the depressed cell mediated immunity, is it not?
A Well, it is related to an effect on the immune system.

Q Yes:

> "... compared to boys or unvaccinated girls",

and so comparing to unvaccinated girls, yes, that was the effect?
A Yes.

Q Yes:

> "To give a vaccine that has such an effect on the immune system ...",

the reader might well link those two, might not he or she?
A I was talking about the effect of the vaccines on the immune system.

Q You were talking about or you were using an example of a vaccine that had not been used in Africa since 1996 and had never been used in the UK?
A But a vaccine with the measles virus that had an effect such as, which has been shown, to decrease cell mediated immunity. It did not say in the paper, "Regarding six specific differences in mortality after the high titre measles immunisation in rural Senegal", or the other papers that were used to show this. I mean, I think really when you are reading this paragraph you should look at my statement two where I discuss it again when Dr Conway has made a comment.

Q Should we not ignore the sentence in the middle, because the sentence in the middle in reality had nothing to do at all with what these two children were going to receive, did it?
A Except that, as with a lot of these examples, I was giving examples of the experience of the vaccine in countries other than the UK.

Q No, of a different vaccine? It is a different vaccine you are referring to, is it not?
A Yes.

Q It is not the one used in the UK at all?
A No.

MR KARK: No.

Would that be a convenient moment?

THE CHAIRMAN: Yes, we will break for lunch and return at two o'clock.

Dr Donegan, may I just remind you that you are still under oath and you must not discuss the case with your legal team.

THE WITNESS: Yes.

(The Panel adjourned for lunch)

THE CHAIRMAN: Please continue.

MR KARK: *(To the witness)* Could you turn to page 53 of your report, please, and it is just to point out the heading which is "DOCUMENTED SIDE EFFECTS OF THE MMR VACCINE", and then you list them underneath as "Common", "Occasional", "Rare". Then over the page, "Optic neuritis", at the top of page 54, is that under the heading "Rare", as it were?

Q Yes, it is continued from the previous page.

Q Yes, and then underneath that "Subacute sclerosing panencephalitis"?

A Yes.

Q Is that also ---

A That is from the - this is from the "MMRII Aventis Pasteur MSD Ltd 2000, Priorix MMR vaccine ...", the package insert. That is what I have listed "Common", "Occasional", "Rare" from and it finishes at the end of, "(I do not know their source for this estimation)".

Q Then can we look at the next paragraph which starts, "A report in the British Medical Journal ..." Do you have that?

A I do, yes.

Q

> "A report in the British medical Journal from the Communicable Disease Unit at the London School of Hygiene and Tropical Medicine"

- and this should be reference tab 98 -

> "stated that after the 1994 measles rubella campaign there were 530 severe reactions reported, one per 13200 vaccinations and higher than the one per million usually quoted".

What did you intend to convey to the reader with that paragraph, please, or that line?

A That subsequent to the vaccination of the children in the measles rubella campaign there were 530 severe reactions reported to the Committee on Safety of Medicines.

Q Again I think you accept that there was no causality shown, as it were?

A When there is causality I say it, because it is quite rare to actually have the sufficient evidence to prove causality.

A

Q Yes. The report to which you were referring I think is tab 98, and you may want to turn that up, and again I am going to suggest that you have left out something which is small but potentially important. The report we can see starts at page 138 and the middle paragraph reads:

B

> "By the end of October 1995, Britain's Committee on Safety of Medicines had received 1202 reports describing 2735 suspected adverse reactions to the vaccines administered in the campaign, among which 530 were serious, though none was fatal".

So these are suspected adverse reactions, which makes it clearer perhaps that they were suspected to be reactions to the vaccine. Do you agree with that?

C A Well, yes, you would not report a reaction if you did not suspect that it was something to do with the vaccine.

Q No.

A That is why or that is the basis on which you notify reactions to the Committee on Safety of Medicines.

D Q Yes, but what you wrote was "... there were 530 severe reactions reported". Do you think again that the lay reader of that, whether it is the parents or the judge, might take it that those were 530 severe reactions to the vaccination?

A They might think that.

Q Would it have been fairer, do you think, just to make sure that everything was clear, if you had used the word "suspected"?

E A As I say, I wrote that there were 530 severe reactions reported. I did not say they were causal. I did not say they were caused by the vaccine.

Q I see:

F

> "One report of SSPE occurred one month after vaccination. The child had a history of natural measles infection some years earlier ... A report from a review by expert committees on serious adverse events associated with measles and rubella vaccine concluded that there was a causal relationship established for: Measles:"

That last line in fact relates to what follows, does it not?

G A Yes.

Q So let us just go back to, "One report of SSPE ...", which is a very serious condition, is it not?

A It is a very serious condition.

Q Yes:

H

> "... occurred one month after vaccination. The child had a history of natural measles infection some years earlier".

Can we just look at the sentence that in fact you would appear to have read and were writing out into your report. It is at page 1 of 4 at tab 98, where we can see three lines up from the bottom of the main paragraph:

> "The one report of subacute sclerosing panencephalitis occurred one month after vaccination in a child with a history of wild measles infection some years earlier; thus it is unlikely that the vaccine was responsible".

Was there a reason why again you did not finish the sentence?
A Well, as I said, if I had said, "There was one report of SSPE one month after vaccination ...", I think that would have been misleading, but I put that, "The child had a history of natural measles infection some years earlier", and so I thought I was balancing it there.

Q That might be taken to be quite the opposite, you see? If you say that, "There is a report of SSPE occurring a month after vaccination", and then you say, "Well, the child had a history of natural measles infection some years earlier", it might be thought that you are saying, "Well that was years ago, but the vaccination was only last month". You did not mean to convey that impression?
A No, because Dr Conway addressed I think the issue of SSPE and certainly SSPE is known to come on many years later, so in fact the fact that it came on one month after vaccination is against it being caused by the vaccination.

Q However, Dr Donegan, to the reader of this report, I just want to ask you again, why did you not simply finish off the sentence that you were reading from, "... thus it is unlikely that the vaccine was responsible"?
A I could have put this for all the side effects that are listed there because, apart from the ones that are regarded as causal, it is not known whether they are caused by the vaccine or not. You know, I did not every single time I put down an associated side effect which might be common, occasional, or rare put down, "However, it might not have been the vaccine", and, "However, it might not have been the vaccine".

Q Yes, but the author from whom you are quoting has said, " ... it is unlikely that the vaccine was responsible". Do you think on reflection that it would have been a better balance to have included those words so that the lay reader, without having to go to the research, would understand that?
A Well even going to the research, as I said, I said, "SSPE one month after vaccination", and that, "The child had a history of natural measles infection some years earlier".

Q You agree that you did not conclude the sentence as it was written in the report?
A I agree. Yes, I agree with that. I take your point.

Q However, you do not agree that that would have been fairer?
A I think I had put both parts of the sentence, the vaccination and the natural measles, in that sentence.

Q Can I ask you to turn to page 58, please. Right at the bottom of that page, three lines down, you say:

> "There may be swelling of the ovaries in girls but it does not result in sterility ... In fact it is thought that having mumps with recognisable parotid swelling has a protective value against getting ovarian cancer in later years".

You were essentially putting that forward on the basis of a single study in 1966?
A I think it was 1965 but, yes, in the 1960s.

Q You are right, 1965. Did you think, first of all, that that was a sufficient basis for that comment?
A With many of these infectious diseases, people who are quite happy for their children or themselves to have the diseases do this on the basis of the fact that they think that having the diseases helps their child's immune system mature and that there is some benefit to be derived in terms of future health from having had the disease. You will see that with the attitude of the parents from the Steiner community in Gloucestershire, saying they thought their children in their opinion had undergone a certain amount of maturation and so on. So there is one way of looking at infectious disease as being all gloom, but there are some people who actually are happy for their children to have the infectious diseases because they think that they derive some benefit from them. So, I was putting down this as an interesting example of an observation.

Q Indeed you included again I think in your conclusions, do you not, at page 60:

> "Mumps is generally a mild illness",

and this is under "Vaccination Recommendation":

> "Those most at risk of complications are post pubertal males. In females there may be a distinct benefit in having clinical ...",

and then "mumps" it should be:

> "... in terms of a protective effect against ovarian cancer".

It is just this short point that the research upon which you were relying was both limited and old, was it not?
A There are limitations, but I think it is unwise to discard research just because it is old. Most of the vaccines that we use commonly were licensed on the basis of old research in terms of their safety and efficacy.

Q I think we heard from Dr Elliman that there was another report.
A He produced the one on the women in China.

Q Yes, and you say there were differences?
A I said they were a very different population and it was looking at subclinical mumps. Well, clinical and subclinical. You would not know because it was just looking

at the evidence from the serum that antibodies that the person had had mumps, either clinical or subclinical, and West was quite clear about clinical mumps.

Q I understand that, but was that a piece of research you had actually come across or not?
A No.

Q What research had you made?
A The mumps paper that I had here was on the basis of the mumps information that I had already required.

Q When you sat down to write your report did you think that you ought to see if there was anything post-1965?
A Certainly, I looked at Dr Conway's report and I looked at Professor Kroll's report and they had made a lot of statements that had no references, so I did not know at that point that I was going to need a reference for every single thing that I said because they had not. In fact, I was doing the best I could in terms of trying to make it more clear by actually producing some references.

Q Dr Donegan, what is the fact of Dr Conway and Professor Kroll not producing research got to do with your report? If you produce a piece of research and you decide to base a comment in your expert report upon it you might be expected to do a simple check to see if there was any report since 1965.
A This being my first expert report that I had done - what I had done on what I had received - that being what I thought, particularly with Dr Conway, having been a medical expert many times in the past, I thought that is what the format needed to be. So I was doing my best in terms of trying to provide more information because I knew I was providing a different view to the other two experts and a view that maybe was not current among the views that the court would have come across previously.

Q Did you not - and this may apply to other areas of your report, but just concentrating on this for a moment. When you went back through your papers and you found this report from 1965 did you not think to yourself, "I am writing a balanced report. I wonder if there is anything to the contrary. I had better find it"?
A I was working, as you know, to a very tight time-scale and I was trying to amass as much as I could together to produce this document to the best of my ability at the time.

Q Yes. The answer to the question is? Did you think to yourself, "Before I rely on a piece of research that I have in my bundles from 1965 I ought to do a quick search to see if it is up-to-date"?
A I might have or I might have not. I certainly must say that while I was doing this report a lot of things went through my mind, some which I had the time to act on and some of which I did not.

Q If you are saying, "I did not have time to write a fair and balanced report because I was under too much pressure", if that was going through your mind at the time why on earth did you not say, "I cannot do this in time"?
A I was under an enormous time pressure and I had been instructed to do this report and I was not aware that I could ask for more time. All I had was the solicitors on my

side saying, "Have you got the report ready yet?" As you know, when they first engaged me they wanted it by 31 May, which I then had to move to 14 June.

I think what I have written here is fair and in terms of making it better, embellishing it more, I was not doing an "every single detail", I was not doing a PhD thesis on it, I was trying to present a reasonable report that the court would be able to use and the other experts would be able to use as a basis for their evidence and discussion in the court.

Q Just since we are dealing with this, do you accept that, in fact, your report was not, in itself, balanced in the sense that you were not putting - where there was a piece of research that plainly controverted what you were saying - you were not putting that piece of research in?
A I think that when I gave the view of the disease and what was happening before vaccination and after vaccination that I was giving a reasonably broad description of what I was asked to describe.

Q Of both the benefits and the disadvantages ...
A Well, yes.

Q ... of vaccination?
A For example, tetanus I say, "since the vaccination was introduced" - I cannot remember what my last words were, but, "it has been responsible for a large fall in the number of deaths".

Q Let us move, please, to page 62. I will read the paragraph over. This is in the middle:

> "In the <u>five</u> years before the rubella vaccine was introduced in 1970 there were only 39 babies born with congenital rubella. In the <u>ten</u> years after 1970 there were 454 case. Even assuming that the 14 year old vaccinated in 1970 did not start to have babies until they were 24 (unlikely), in the ten years after 1980 there were still 333 affected babies. So the number of cases have gone up."

Now you dealt with this in-chief with Mr Stern. If the reader came away with the understanding that the actual number of cases of congenital rubella had gone up between 1965 and 1990 that would be wrong, would it not?
A From the data that I was using that was the data that was stated on the paper.

Q Let me just repeat the question. If the reader came away with the understanding that the actual number of cases of rubella had gone up between 1965 and 1990 that would be wrong, would it not?
A Yes, it would be wrong, but that is what they would get from reading this because that is what I wrote, because that is what I was reproducing from the table that I was looking at.

Q Shall we just have a look at the table, which is your research at tab 115. Dr Donegan, sometimes people underline things if they consider those words to be of particular importance, and we can see on the left-hand side of this page, under "background", somebody, I think, has underlined ---

A Yes, that is me.

Q That is you, is it?
A Yes.

Q When did you underline it?
A When I was reading it.

Q When was that?
A This is originally, not subsequently.

Q So you have underlined the words, under "background":

"National surveillance of congenital rubella started in 1971."
A Yes.

Q

"with passive reporting by audiologists, paediatricians and microbiologists of cases in Scotland, Wales and England. With the success of the rubella vaccination programme the number of reported cases declined dramatically."

Then it sets out the figures.

The words, "national surveillance of congenital rubella started in 1971" are important, are they not?
A Yes, they are.

Q Why?
A As we established subsequently, surveillance is going to pick up more cases, although it is - yes.

Q Why did you underline those words?
A So that I could see that national surveillance of congenital rubella started in 1971.

Q Why did you start this paragraph in your report:

"In the <u>five</u> years before rubella vaccine was introduced in 1970 there were only 39 babies born with congenital rubella",

- when you knew that, in fact, national surveillance did not start until 1970?
A Although the babies with congenital rubella would still be reported they would not be looked for specifically, because otherwise there would not be any figures there at all from 1964 to 1969.

Q There is a huge difference there, is there not? Where there is national surveillance it would make a significant difference to the figures, would it not?
A Yes.

Q Why on earth did you not reflect that in your report?
A I think I have already agreed in my examination in-chief that this was badly phrased and I should have expanded on it and I would have had to put the point differently. I should have not made the point that I had made, I should have made a different point about notifications and the difference between spontaneous, passive and active and their reliability or otherwise.

Q Let us concentrate on the point you did make. Having underlined those words, so realising the significance of them, you then decided to put into your report:

> "In the five years before the rubella vaccine was introduced in 1970 there were only 39 babies born with congenital rubella."

When you later used the phrase, "so the number of cases have gone up", you meant from 39 babies, did you?
A I did. I meant from what was *here* on the table, yes. You are quite correct in the inference that you are taking from what I have written.

Q That is misleading, is it not?
A It is, in retrospect, yes.

Q A little further down the same paragraph, after the words, "so the number of cases have gone up":

> "It was only in the ten years after 1990 that the number of cases went down to 46 ... of whom the majority were born to mothers from abroad or who acquired the disease abroad. 12 of the affected babies were born in 1996. The mothers of eight of them were born and raised in the UK and would have been eligible for the schoolgirl immunisation programme."

Then this:

> "(ie they had been vaccinated ..."

How did you come to that conclusion, from the fact that the girls have been eligible for immunisation?
A Because to the best of my knowledge most people are vaccinated against rubella in the schoolgirl vaccination programme.

Q Most people might be but how did you come to say "ie", in other words meaning, "they had been vaccinated"? Do you agree that is simply wrong?
A I could have said, "they were most probably vaccinated", or, "that means they would have been vaccinated", rather than, "they had been vaccinated", because that is very definite without actual documented ---

Q Yes, the words should have been, "they may have been vaccinated", or even, "they were likely to have been vaccinated".
A Yes, rather than, "they had been", because that is stating a definite fact which I was not actually aware of.

Q The bottom of that page:

"Vaccinating 12 to 15 month olds with rubella ... and again preschool almost guarantees that their antibodies to rubella will have worn off by the time they are likely to become pregnant."

Do you accept that was something that made a statement?
A Yes.

Q So that is one page where we have three separate areas where you agree you could have phrased things rather better.
A Yes. I had modified my discussion on the antibodies wearing off by page 63, in the second paragraph, where I say:

"In fact there are likely to be more cases occurring as vaccination is now given at a younger age so it is likely to wear off sooner - even with two doses."

Q How does that make it better?
A What I am saying is I could have been more circumspect with what I wrote at the bottom of that page, and I have already become more circumspect.

Q I see. You are using the words, "likely to"?
A Yes.

Q All right. Then you end the next page, just since you have drawn attention to page 63, these words:

"I do not think it is in the best interests of a child to be vaccinated under such circumstances, especially when other more useful altruistic procedures such as blood and organ donation are not forced upon adults."

A Yes.

Q That reflects what I think we have referred to the charges as your "deeply held view", does it not?
A When you say "deeply held view", I do not hold my views superficially, I investigate things before I say what my view is. So I would not like to say that my views were superficial.

Q For what it is worth, it is not intended as a criticism.
A It is one of the heads of charges, I think, so I would not like to ...

Q It is within a factual content, you are right, but it is not a criticism that you hold the view deeply. Can we just finish with this report? Could we go over to page 65?

"In the vaccination process",

- this is the top of the page -

A

> "except in the case of oral polio vaccine, all these initial stages are missed and the attenuated organism or toxin is injected directly into the child, bypassing all the first stage defences and presenting itself 'naked' to the immune system, the very immature immune system. It is not surprising that problems occur. Only IgG antibodies are induced and mucosal immunity is not stimulated except in the case of oral polio vaccine."

B

Again, do you agree that that is inaccurate?
A I agree that I, while making the point about the mucosal antibody, omitted the point about the acute stage IgM antibody in some of the vaccines.

Q Such as measles, I think?
C A The live vaccines, yes. Measles, mumps, rubella.

Q If we turn over the page to page 66, we come to the issue of thiomersal. I just want to take you, if we can, through an overview of what you said about thiomersal in your report. We will have to come back to page 66, but can we go back, first of all, to page 12 and we will see, two thirds of the way down the page, just above "Vaccination Recommendation":

D

> "Listed side effects for the single, low dose, adult diphtheria vaccine (Adsorbed Diphtheria Vaccine for Adults, Secretary of State for Health, Department of Health rev 1999), are local pain at the injection site, redness and swelling. It also mentions that the thiomersal in the vaccine can cause kidney damage",

- and we will come back to that.

E

Page 21, please. This is dealing with, I think, pertussis, "A Swedish trial", do you see, about seven lines up from the bottom?
A Yes.

Q

F

> "A Swedish trial of one and two component acellular pertussis vaccines in 1986-87 compared vaccine to placebo. It concluded that side effects of the new vaccine were mild. The placebo was the 'vehicle', the liquid which 'carries' the vaccine. It contained thiomersal (a mercury containing compound), formalin and aluminium phosphate."

G

Just to finish that off, you say:

> "The side effects of the new vaccine compared to this 'placebo' were indeed minimal but, when looking at the data, the incidence of floppiness, vomiting, inconsolable crying for more than one hour, fever and drowsiness that occurred after the 'vehicle' alone was substantial. The addition of the whooping cough component did not cause much more. It is certainly worrying that the 'vehicle' in which the vaccine is delivered seems to be so toxic."

H

A

Were you referring primarily to the thiomersal there?
A No, I was referring to the thiomersal, formalin and aluminium.

Q All three.
A Yes, because one would not know which part of it it was.

B Q Could you turn, please, to page 29? The last paragraph:

> "In view of the above and the side effects associated with the tetanus vaccine, including the fact that it is only available in a vehicle containing thiomersal (a mercury compound), aluminium hydroxide and formaldehyde I would think that a reasonable alternative approach to the vaccine would be the promotion of a healthy immune system in the child combined with scrupulous wound toilet."

C

Then we come back to page 66, under the heading, "additives". You write:

> "Ethyl mercury in thiomersal has been used in vaccines for 60 years. The 1999 product information for the adult diphtheria vaccine ... states that it can cause kidney damage."

D When you said *it* can cause kidney damage, you meant the ---
A The thiomersal.

Q In vaccine?
A In the diphtheria vaccine. Well, yes, thiomersal in vaccine, yes.

Q

E

> "In May 2002, pregnant women, babies and children under the age of 16 years were advised to stop using shark, marlin and sword fish as a precautionary measure because high levels of mercury that have been found in these fish. The risk was said to be highest in babies in utero as mercury can damage the developing nervous system."

F Et cetera.

> "The letter from the Deputy Chief Medical Officer said that mercury in surface water was being changed by bacteria into the more toxic form of methyl mercury."

G

You say:

> "Ethyl mercury is injected into babies in many of the childhood vaccines."

That is?
A That is thiomersal.

H

Q Thiomersal.
A Yes.

Q

> "Could this be one of the reasons for the marked prevalence of dyslexia among children today? Concerns about using such a toxic ingredient in vaccines were dismissed for years but after official US data raised the possibility of a link with developmental delay in 1989, USA has moved to a thiomersal free vaccine schedule. By 2001, steps were eventually being taken to remove it from the vaccines in the UK (but only after all the old stocks had been used up)."

First of all, I am sorry to have taken so long to do all that. Could you turn to what you said at the High Court at page 50 and I am going to read out from line four because Conway said what, in fact, Dr Elliman has told us now. So it may not be unreasonable to rely on it.

The question is this:

> "You heard what Dr Conway said, that by American standards - and probably America is the most safety-conscious and litigious country in the world, and we have half the dose that they have ..."

You say, I think it should be "except".
A Yes, except.

Q

> "Except they are withdrawing thiomersal from all their vaccines. And he, [that is Dr Conway] in 14 years of running a clinic, has not once seen a thiomersal reaction."

You say:

> "He - reporting of side effects or reactions after vaccinations is not very full. It is actually very hard to get someone to ascribe a side effect to the vaccine that happens soon after vaccination, let alone something that happens quite a long time after.
>
> Q That is a roundabout way of saying that you know of no example of where it has been proved that damage has been caused by thiomersal in vaccine in this country?
>
> A Yes."

So that is just to remind you of what you said previously.
A Yes.

Q First of all, that is right, is it not?
A It is correct. I do not know about Dr Conway and his thiomersal reactions because I do not quite know what he would be expecting to find.

Q I agree we can set that to one side. There is, as I think you accept, no example where it has been proved that damage has been caused by thiomersal in this country?
A I think we have accepted that it is very hard to prove causality.

Q Yes. Shall we just go very briefly to the document that you produced upon which you rely for the comment that the thiomersal in vaccine can cause kidney damage? It is, I think, exhibit D6 and this is for the absorbed diphtheria vaccine for adults. If we go down below:

> "Precautions before use. Do you have any type of infection?
> Do you think you may be allergic or sensitive to any of the ingredients in the vaccine which are listed above, in particular thiomersal, which can cause kidney damage? If the answer is YES to any of these questions, you should tell your doctor."

Now I think Dr Elliman was drawing a distinction between thiomersal causing kidney damage which, of course, it is accepted it can, and thiomersal in vaccine. I think you accept, well let us see, do you accept that the amount of thiomersal in vaccine in this country was something like half that used in the US?
A The amount of thiomersal used in vaccines in this country was less than in the United States. I think ... did Dr Elliman not do a calculation based on the mercury in the vaccines and find out that for some weights of babies it was more than the recommended? I cannot remember from the transcript.

Q At some point we are going to have to review the transcripts, but I am afraid I cannot on my feet remember that.

Do you also accept that, while you are entitled to rely on the leaflet that you have relied on, it might also have been appropriate to mention at least in passing, in fact, that there is no evidence that thiomersal in vaccines in this country have ever caused such damage?
A Well the marketing authorisation holder of this is the Secretary of State for Health, the Department of Health, Waterloo Road, said, to the best of my knowledge, these package inserts are reviewed by ... I do not know what it is called now, but it used to be the Medical Standards Agency and I cannot see why they would put a rider in here about thiomersal if they were not talking about the thiomersal that would be at a concentration present in the vaccine because this is after all a package insert for a vaccine.

Q The package insert, as you rely on it, also makes it clear that it is referring to people who are allergic or sensitive to thiomersal?
A Yes, but I do not know how we find out whether people are allergic or sensitive before we vaccinate them.

Q Just finishing off your first report, could we go, please, to page 70 and we see the heading, "The best interest of the child," and I hope Mr Stern does not get excited about this, this is not something that Dr Elliman picked up, but I am going to ask you about it. It is something you said in your report:

> "THE BEST INTERESTS OF THE CHILD

A

The court will base its decision taking each child's welfare as being of paramount importance.

In terms of what is in the best interests of the child; it is in the best interests of the child to have their and their families' immune system supported rather than compromised by the enormous stress that is brought upon a family by having to undergo a court procedure and all that this entails. It is all the more unfortunate in a case such as vaccination which, in this country, is not mandatory."

B

Then this:

"It is always in the best interests of the child for the parents to make an informed decision themselves as to whether or not to vaccinate their child or not. In the event that the parents are not able to agree, I think that it is in child's best interests that the difficult decision is made by ..."

C

and then you set it out.

A Well would you like to continue reading it, please?

Q Yes, I can certainly.

D

"By the parent who has:

(A) day-to-day care of the child in terms of feeding, clothing," et cetera.

A "And nurturing them to support their global well-being ..." Shall I finish it?

E

Q Yes, certainly.

A

"And their physical, emotional, intellectual and spiritual development; and

(b) To nurse and support the child through the diseases that they contract, whether they be diseases for which there are vaccinations available or those for which there are not. The parent with care will have to bear the immediate and long term consequences of the effect on the child's health if the child catches the disease or if they suffer the side effects of the vaccine.

F

The Children Act recognises that the care giver needs both practical resources and a feeling of being valued if they are to give of their best. It also enshrines the principle that young people's wishes must be elicited and taken seriously."

G

Q How did you form the view that those comments form part of your expertise?

A Because I was asked to ... I was told that the evidence I gave would be used by the court and the best interests of the child were to be met and I know the best interests of the child comes from the Children Act.

H

Q Let us turn to your second report and I am going to be rather briefer, I hope, in relation to that. Can we go to page 77, please, first of all?

A Yes.

A

Q

"The measles, mumps and rubella have not virtually disappeared from countries with high MMR vaccine uptake."

B For what it is worth, do you accept that so far as Sweden and Finland are concerned that comment is wrong?
A I would accept that at the moment they have good control, but if you read the rider at the end of the paper that Dr Elliman presented they have expressed ... they have not been too over-confident and they are hoping that this will be the case, but they realise that the mathematical modelling that they used might not be accurate. They hope it will.

C Q Well that is, I think, for the future, is it not? The point is at this stage in 2002, measles, mumps and rubella had indeed virtually disappeared from Sweden and Finland?
A Well it is also true that when you vaccinate children you are not vaccinating them necessarily for today, you are vaccinating them for the future.

Q Could you just try and answer the question? At the time when you were writing your report is it fair to say that measles, mumps and rubella had virtually disappeared
D from those two countries which had a high MMR vaccine uptake? Do you accept that or not?
A From those two countries I actually cannot remember what date it is that the paper that Dr Elliman showed was. I presume it was the dates that I would have been writing in.

Q Page 83, please, in your report. This is going back to Professor Stewart's paper and I think it is going back to your first bundle I am sorry to say and it is your reference 6
E and the point that it is made, if we look at the very last page of that tab (and we know the point very well now I think) is that you made no reference in the Malleson report. Can we take it you read the Malleson report?
A I had not. No, I said yesterday I had not. I have got it now. I said yesterday that I had not.

F Q If we look at the last page of that tab 6.
A Dr Elliman's tab 6 or my tab 6?

Q No, it is your tab 6. Is the underlining on the left-hand side of the page yours?
A Yes.

G Q You had not read the Malleson report which is on the right-hand side of the page?
A No, I had not.

Q Why did you not cast your eye at least over what was right there in front of you?
A Well because it has only got one column of it.

Q I do not want to spend too long on this, but if you are trying to write a balanced
H report and you see something on the right-hand side of the page when you are referring to the left-hand side of the page, and the summary which you can read says:

A

"188 children with pertussis were admitted to Derbyshire's Children Hospital over a period of ten years. Fewer immunised children were admitted than would be expected if immunisation were effective. Immunisation seemed to decrease the risk of complications and the time spent in hospital. It is suggested that pertussis immunisation is valuable and it should perhaps be introduced at an earlier age than is now recommended."

B

If you are writing at that point in your report about pertussis, why would not you think to yourself well I had better read that report?

A Yes, I have read it now.

Q Yes.

A In working out their vaccination efficacy they used an estimated vaccination coverage of 75 per cent because they do not actually have the data on which children were vaccinated.

C

Q Dr Donegan, the question with respect is why would you not bother to read that report? If you had been instructed to write a balanced report, why would you not bother to read that? Is it just because it is on the other side of the argument?

A Well if I had the journal I would have read that report, but this was one of the papers that I had got from the British Medical Association and if I had had the rest of it there, I would have, but I have not read the rest of it.

D

Q Could I ask you to go to page 87, please, of your second report and Dr Conway has written at the top.

E

"Neurological illnesses reported to have followed DTP immunisations are clinically indistinguishable from idiopathic childhood neurological illnesses ... This immunisation was given at around the same edge in which idiopathic neurological illness is typically first recognised."

In other words the fact that there may appear to be a temporal link with DTP immunisation, it also happens that at the same time children are likely to start exhibiting those problems?

F

A Yes.

Q That is what is being said?

A Yes.

G

Q In lay terms:

"The 'controls' in these studies are not unvaccinated, they have been given tetanus, diphtheria and polio vaccinations, these vaccines are associated with numerous adverse reactions and may indeed be the cause of 'idiopathic' childhood neurological illnesses themselves."

H

Again, causally would you agree is there any evidence to support that?

A Well as you can see, I specifically said "associated" and "may".

Q Yes.
A And not ... if it had been causal I would have written causal.

Q You say "may indeed" actually, which I suppose might be slightly different. "May indeed be a cause of these neurological illnesses." What impression would that leave the reader with, do you think?
A Well it might leave the reader the impression that the studies of the safety of the whooping cough part of the vaccine are not very reliable unless they are as the control group they have an unvaccinated set of children.

Q Let us move on page 89: 1.29. This, I think, is the same error that you have conceded previously.
A To do with my first statement, yes.

Q Yes. Had you thought perhaps about going back after receiving Dr Conway's report, which I suppose might have taken you something by surprise in a sense? It was a very critical report, was it not?
A I was quite surprised by some of his language.

Q Yes. Did it actually cause you at any stage to pause and review and perhaps re-read some of the material such as this that you had previously been relying on?
A Well, when I answered Dr Conway's report I answered all his points in my second report and so obviously I reassessed them when I was doing that.

Q Well, that is why I asked you. If you had reassessed the material, how had you made the same mistake twice?
A (*Pause*) I am just reading Dr Conway's page that I was replying to, if you would not mind?

Q Well, let us find it. It is Dr Conway in section B4 in file 4. It is page 22 and then:

> "d) Miller et al. Pertussis immunisation and serious acute neurological illnesses in children ..
>
> In the introduction to their paper Miller et al discuss the NCES study. "An even smaller number of children had evidence of persistent neurological deficits a year later, and it was therefore still less certain whether or not the vaccine could cause permanent brain damage ... it seems safe however to conclude that if this occurred at all it was 'a very rare event'" and attribution of a cause in individual cases was regarded as 'precarious'".

Perhaps we can all read the rest through for ourselves, if we need to. Are you saying that that did cause you to go back and have another look at the NCES study?
A I am saying that Dr Conway, who was quite scathing in his criticism of much of what I wrote in my first report did not himself point out that I had said "within seven days of the onset of symptoms" despite his obviously careful reading of my first report. Therefore, it is not something that I addressed when I was answering his criticism.

A

Q I understand that, but you did just say that it caused you to review your research and I am just wondering are you saying that you re-read the study and got it wrong again, or did you not read it again?
A No, he criticised me and in his particular paper he is talking about one of the many papers discussing this NCES study, the paper by Dr Miller, (a different Miller to the measles Miller), and that is what he is discussing. So, even when I went back to look at his criticism, I went back to the Dr Miller paper, not to the original study.

B

Q All right. Could I ask you, please, to go forward to page 95. You are dealing just above 1.42 with the issue of is it the Shields et al study?
A Yes.

Q You say on page 94:

C

> "Certainly the graphs in figure 2 page 803 show the percentage of onset of epilepsy as being highest at the major times of vaccine - administration one to eight months, lowest level at 12 to 14 months and then rising again to a smaller peak ..."

Then over the page you quote, I think:

D

> "The authors then go on to conclude that, 'no association between the occurrence of epilepsy and immunisation was observed', and that, 'In the present study, 350 children had bacterial meningitis or aseptic meningoencephalits. It is reassuring to find no association between pertussis immunisation and the occurrence of these neurological illnesses'",

E

and then you say:

> "This is not what might be deduced by looking at the graphs".

I for one am not even going to attempt to launch myself into these graphs, as Mr Stern bravely did yesterday, but in effect are you saying that their analysis - their understanding - of the graphs is wrong?

F

A It differs from mine.

Q I am sorry?
A It differs from mine.

G

Q Could you go to page 107, please. Again we have already covered this in your first report ...
A Thankfully.

Q ... and so I want to try and avoid rehashing as it were the old ground, but I think you repeat at the bottom of this paragraph that - well, perhaps we ought to read 1.68 in full:

H

> "C1.51 Dr Conway states that I have not given the full picture in my

> statement regarding cell-mediated immunity after measles disease [cf] measles vaccine ... Reading the study reveals that 40% of measles 'cases' had been vaccinated against measles and were described as, 'clinical vaccine failures'",

and again you have dealt with that already this morning. You then say this towards the end of the paragraph:

> "The substantial proportion of cases who had had measles preclude a conclusion that, 'reduced general cell mediated immunity may contribute to the higher long term mortality in children who have had measles compared with recipients of the standard measles vaccine', because 40% of children with measles had been vaccinated".

Can I just ask you this. Had you gone back to look at this again?
A Yes, I had.

Q You had?
A I had.

Q Did you understand that the authors had allowed for that?
A Yes, that they had taken out the other ones and the ratio remained unchanged.

Q Was it relevant to mention that, do you think?
A Yes, I could have usefully mentioned it.

Q Should have?
A I do not know. Could have/should have.

Q Just over the page, please, 108, at the bottom of the page:

> "1.72 C1.53 Dr Conway states that giving a second booster of measles vaccine in the present vaccination schedule, problems associated with waning maternal antibodies is overcome. This statement is speculative, unreferenced and unsupported by any data".

I suppose it may depend which angle, as it were, you are coming from, but you are not suggesting, or are you, that the second booster of measles is an ineffective vaccination?
A He was making the point - my point in my paper, the first one, was that the antibodies produced by vaccination in mothers who have babies that crossed the placenta are not such good quality, or so long lasting, as the ones produced by natural disease.

Q Yes.
A Dr Conway here is saying that the second booster dose of measles in the present vaccine schedule ...

Q Overcome that problem?
A ... overcome that problem, but he has not referenced it. I think Dr Elliman mentioned it when he was giving evidence, but I have not seen any evidence or papers to

say that the second booster dose of measles is going to overcome this problem in the babies of mothers who have derived their measles immunity from vaccination.

Q Do you agree that it may not overcome the maternal antibody problem, but it will provide the same protection, as it were?
A That was not the point that Dr Conway was making. He was criticising my comment, or I think he was criticising - in fact I would have to look at his C1.53, actually. That might make it clearer.

Q It is around page 46, I think?
A Yes. I must admit that some of the forthrightness in my language in my second report was engendered by the forthrightness of Dr Conway's language in his report criticising my first statement.

Q Well one of things you have not been criticised for is that, as it were. Dr Conway writes:

> "1.53 Page 36, paragraph 4. Dr Donegan's argument that maternal antibodies following natural infection are superior to those produced by vaccination is recognised. Dr Donegan does not present the counter argument i.e. by giving a second booster dose of measles vaccine as in the present vaccination schedule problems associated with waning maternal antibodies is overcome".

A So, he is not making the point about the second dose of measles MMR protecting children from measles. He is making the point that that is going to overcome the problem with waning maternal antibodies, but he has not produced a reference or anything to show this. Dr Elliman mentioned it too, but I have not still seen any evidence to do with this.

Q Let me move on to page 112, please, of your report. This is actually dealing with C1.63 of Dr Conway which talks about mumps being a safe vaccine:

> "Complications of mumps vaccines. Medical Virology 1995 ... state that the only two adverse events ..."

I am sorry, this is page 50 of Dr Conway if anybody is looking for it:

> "... state that the only two adverse events associated with mumps vaccine meeting stringent criteria for causality are aseptic meningitis and parotitis. The risk of the former has been removed with the presently used mumps vaccine strain. The authors conclude 'it is important to place the risks of vaccination in the context of the risks of the disease'. Virtual disappearance of mumps related complications in countries which should have achieved high coverage with mumps containing vaccines is unequivocal evidence of the overall benefit to the population of mumps immunisation".

So, that is just to put into context what you are answering. You say:

"The same paper states that insulin dependent diabetes mellitus and pancreatitis has been reported to occur after measles, measles-mumps and MMR vaccine at an incidence of 1 per 250 000 doses".

I think this comes from Dr Elliman's reference at tab 56. If we go to page 224 in the body of the text, so it is tab 56 of Dr Elliman, I think this is the report you were quoting from. Is that right?

A Yes, it is Dr Conway's reference that he quoted from and then that I went and looked at.

Q In fact, Dr Elliman has now reproduced it?

A He has reproduced it, yes.

Q So, we know we are looking at the right document. If we look on the left-hand side of the page we see:

"Diabetes

Cases of Insulin Dependent Diabetes Mellitus (IDDM) and pancreatitis have been reported after natural mumps infection and clusters of diabetes mellitus have been shown to occur after epidemics of mumps.

The occurrence of IDDM"

- in other words, insulin dependent diabetes mellitus -

"after measles or measles-mumps or MMR vaccine has been reported from Germany, at an incidence of 1 per 250 000 doses".

So that is where this is coming from, is it?

A Yes.

Q Can we just read on:

"For most of the 20 cases reported, the onset of IDDM was between 3 days and 7 months post-vaccination. However, the numbers of IDDM (not vaccine-related) expected over the same period was far in excess of 20".

Did you think it was relevant to include that part of the quote?

A Dr Conway had cited this paper in 1.63, saying that it is a safe vaccine, and he cited this paper to say that only aseptic meningitis and parotitis were causally linked to it. He did not mention any of the other events that had been brought up too as the suggestion that they might have been associated with it.

Q No, but I am concentrating on your report for a moment.

A So, I was answering Dr Conway.

Q Maybe you were, but you are answering Dr Conway by saying:

> "The same paper states that insulin dependent diabetes mellitus and pancreatitis has been reported to occur after measles, measles-mumps and MMR vaccine at an incidence of 1 per 250 000 doses",

and then you stop. However, what is important surely to know is that the numbers of IDDM not vaccine-related were in excess of that?
A Yes, but it is sometimes - it is not very well-known how many expected cases we ought to be having.

Q Does it matter if the research that you are relying on says, "Well, if you do not have the vaccine you get more IDDM"?
A Well, this does not say that. This just says the background. It is not discussing after mumps.

Q

> "However, the numbers of IDDM (not vaccine-related) expected over the same period was far in excess of 20".

Did you not think, just on reflection, that in order to balance up the quote you were giving that that ought to have been put in?
A I thought that the person who brought up this paper was Dr Conway to say that the mumps vaccine is safe, apart from the two things he mentioned, and he certainly left quite a lot out of this paper himself. He also had finished his paragraph by quoting their conclusion that it was a - what was it about? Yes, the unequivocal benefits of the mumps vaccination programme. So, Dr Conway had added all those things. I was just adding some other things/events that had been mentioned in the paper that he had omitted.

Bec's fifth take

Q You can put your second report ---

Q You can put your second report away. In the transcript, we have all read it and I can give you the page numbers if you want, you accept that, I think with two exceptions, all of the authors who you cited in your very extensive research had concluded, by recommending, in effect, vaccination?
A Could you just direct me to the number?

Q It is 35, first of all. This is dealing, first of all, with diphtheria, page 35 at 16.

> "Do you not think that it would have been appropriate in your report to have said, for example in relation to diphtheria, that, although you have referred to lots of articles, in fact none of the authors agree with the conclusion which you have reached, because all the authors recommend vaccination but you do not? Do you think it would have been appropriate, in the body of your report, to have alerted us to that fact?"

Then, "possibly". I think you now accept that?
A I agree, yes. I would have put it at the beginning.

Q Page 36, since you asked for the quote, at line 7:

"do you not feel that you should be duty bound to say that those authors who you are citing in fact draw exactly the opposite conclusion to the one that you have drawn?"

You said:

"I could have reproduced the whole article each time, which I did in the references ----

Q That is not the question. Do you not think that you should, as an independent expert - if that is how you regard yourself, and you may say you do not",

You say:

"I do.

Q Well, do you not think that it is appropriate for you to state, and it need take no more than one sentence, that: 'The authors to whom I have referred have all drawn a different conclusion to me?'
A It probably would be a useful thing to do."

There are other references I could give you if you want?
A Yes.

Q Do you want them?
A No, no, no. That is fine. Thank you.

Q Did you set out to provide a balanced report?
A I did.

Q I want to have this clear because it may be important to the Panel. You have said on a number of occasions that you thought you were answering Conway and Kroll. I do not mean any disrespect to them, but you thought you were answering Conway and Kroll. Right?
A Yes.

Q You did not think, did you, that that entitled you simply to give one side of the picture?
A When I received Dr Conway and Professor Kroll's report and I looked at what they had written and I saw their recommendations and what they presented to bring those recommendations about, I must admit I thought that my task was really quite overwhelming. Because they had given such a narrow view I felt that I had to start almost from the beginning again to try and give some wider view of the vaccination and its place in these particular diseases, although it must be said that vaccination actually takes its

place in actual people's health because there are many diseases against which we do not vaccinate that we need to ensure health for, that I had to start almost at the beginning and try, and that is why I gave the format that I did.

It was looking at their reports and then trying to think how I could give a view so that the court would have a balanced view on which to make their decisions and so that the two other authors would also have something on which to comment or argue or modify their decisions on the basis of.

Q You accepted, I think, when I started asking you questions that when you wrote your first report you did not know, indeed could not have known, that there would be any reports to follow?
A Well I had seen the two first reports and I knew that the experts, including myself, were going to be examined in court.

Q Yes. I understand that, but you did not know, for instance, that Dr Conway was going to write a response, did you?
A No.

Q You are not saying, are you - and I just want to have this clear - that you felt you could put something into your report which was, in fact, misleading unless corrected? You did not feel you could do that on the basis that, "Well, Conway will be along to correct me"?
A No.

Q On a number of occasions, both, I think, when you were being examined by Mr Stern and when I have been cross-examining you, you have accepted that parts of your report either could have been phrased better or were, frankly, misleading?
A Inaccurate and misleading in some cases. Some were inaccurate, some were misleading, yes.

Q Are you saying all of that is down to the fact that you were under a time pressure to write the report?
A I think it is recognised that it is human to err. Even Dr Conway, when he is making his recommendation for measles, says, "immunisation is effectively prevented by the measles component of the MMR vaccine", which is not what he meant to say. Even Dr Elliman, writing about the rubella, says that mumps is effectively prevented and reproduced the 2004 schedule instead of the 2002.

Q People make mistakes.
A I do not think that either Dr Conway or Dr Elliman were in any way trying to mislead anybody. With the best will in the world people cannot put down exactly what they would have meant to have done if they wanted in the most perfect of worlds.

Q Yes. Do you accept that the effect on the occasions when you have admitted that a paragraph presents a false or misleading impression of research, that that could have been relied on by the court?
A I think overall what I have written, taking into account places where I have, unfortunately, phrased things not as well as I could have but overall there is insufficient

there that is not phrased, unfortunately, and is not inaccurate for it to be an accurate representation of the opinion that I wanted to give to the court.

Q Do you accept this, that in taking the first report, that in the first report particularly you did give false or misleading impressions of the research which you relied upon?
A I think in places I could have phrased things better.

Q Is that another way of saying, "I accept that in parts of my first report I did leave a misleading impression of the research"?
A To say that I gave a misleading impression of the research I presented is too broad.

Q Do you accept that you quoted selectively from research, reports and publications and omitted relevant information? Before you answer let me just remind you of two occasions where you actually stop halfway through a sentence. Do you accept that you quoted selectively from research and omitted relevant information?
A I think quoting is, by its nature, selective.

Q It may be, but do you accept that you omitted relevant information?
A I think it would be hard to write a report and not omit some relevant information at some point, and I think that, certainly, that is one of the reasons I had to write the report the way it was because that is what had happened with the other two reports. They certainly did not make misleading impressions of the research because they did not quote any, apart from in the MMR addendum of Professor Kroll.

Q Dr Donegan, on a number of occasions you left relevant parts of information out, did you not?
A There are places where I have left out.

Q I am going to put this to you, because it is in the heads of charge. I do suggest to you that you did allow your deeply held feelings on the subject of immunisation to overrule your duty to the court.
A I disagree.

MR KARK: Thank you.

THE CHAIRMAN: Dr Donegan, would you like a break now? There will be questions from Mr Stern and from the Panel.
A If we are going to have a break this afternoon I suppose now is a good time to do it.

THE CHAIRMAN: We will return at quarter to four.

(The Panel adjourned for a short time)

THE CHAIRMAN: Just to check where we are, it is re-examination from you, Mr Stern, and then questions from the Panel?

MR STERN: Yes. Your learned Legal Assessor made a suggestion that I am quite content to go along with, that it may be better if you were to ask questions first and then,

obviously, if I have any questions that may deal with some of the points I was going to raise. I have very few anyway. So it may just be quicker to do it in one session.

Can I just say, in addition to that, that I do have copies now of the discussions between Professor Kroll and Dr Donegan and I thought it may be better if they were handed in now just in case you had any questions for Dr Donegan. So, in other words, before she leaves the witness box.

THE CHAIRMAN: This is minutes of a meeting that was held ---

MR STERN: Yes. I will just get it confirmed by Dr Donegan, but my recollection is that Professor Kroll took notes at the time at which this meeting was taking place and then typed them up afterwards. That is my recollection but we will confirm it, obviously, through the witness.

THE CHAIRMAN: That becomes D24. (*Same handed to the Panel*)

MR STERN: Perhaps Dr Donegan can just confirm. I think it is signed at the end by both of them.

THE CHAIRMAN: I think the Legal Assessor may have to change his advice.

MR STERN: I am sorry ---

THE LEGAL ASSESSOR: No, you are quite right that I did suggest that, perhaps, it would be more sensible if all questions were asked first and then you asked questions, which actually, I think, may possibly have been possible under the old rules but not under the new ones, and we are acting under the old rules. I have spoken to the Panel Secretary and thought about this and it has occurred to me that, of course, you now have the right to re-examine from Mr Kark's cross-examination and it might be better for you to do that first, because after the Panel have asked any questions then both of you have the right to ask questions. So I think it would be better. I do not want to get into trouble.

MR STERN: I think the Panel is, strictly speaking, master of its own procedure but we will deal with it whichever way. Did you say D24?

THE CHAIRMAN: D24, yes.

MR STERN: Thank you. I will not go through this now. You can perhaps read it in your quieter moments.

THE CHAIRMAN: That might take us to the end of today, re-examination and our questions.

MR STERN: It may be.

THE CHAIRMAN: Because we would be aiming to finish at just before five, and then there is tomorrow morning.

MR STERN: Shall we see where we finish? I do not think this will take more than two or three minutes to read. I do not ask that you read it now but at any time that you want to.

Re-examined by MR STERN

(*To the witness*) Dr Donegan, just before we move on with any other topic can I just ask, are these the notes then of the meeting between you and Professor Kroll of July 3?
A They are.

Q Signed by you and, indeed, by Professor Kroll?
A Yes.

Q Dr Conway, it has been noted, did not attend on that meeting?
A No, he did not. Is it possible, from my point of view, that the Panel can just read them for three or four minutes so they have read them?

Q Of course.
A Is that all right?

Q It is absolutely all right. In fact, it removes a considerable part of the re-examination I was going to deal with, which was the question of the vaccinations and the recommendations. In fact, they are all here so I need not ask you about those. (*After a pause*)

Can I just ask you, please, is there anything you want to say about *this*?
A No.

Q Thank you. Can I just ask you one question about your report? Page 62, please. Your first report. It is a short point. The middle paragraph, about two thirds of the way down:

"The mothers of eight of them were born and raised in the UK",

- and you say -

"and would have been eligible for the schoolgirl immunisation programme",

- then you say -

"(ie they had been vaccinated ..."
A Yes.

Q I think you were saying they were eligible and that they had been vaccinated?
A No, I was saying, "ie", that is, "that they had been vaccinated".

Q Quite. That they had been vaccinated but you were also saying they were eligible in the same sentence?
A Yes.

Q Were you relying on one or both or other?
A I was saying they were eligible because of being in this country and it is offered universally to schoolgirls.

Q So "they had been vaccinated" was an assumption?
A Yes.

MR STERN: I just wanted to understand that. Thank you.

Questioned by THE PANEL

DR GOODMAN: Good afternoon, Dr Donegan. The first question I have relates to your CV, which I presume is the CV that you submitted with your report to the court. Is that correct?
A It is the CV that I submitted to be sent to the Legal Aid Board to see whether they would accept me as an expert.

Q You state in this that you do general practice, NHS and you do homeopathic practice. Briefly, can you tell us what is homeopathy, the basis of it, but, more particularly, how you practise it and how it affects your practice and your views in preparing this report, if it did?
A Yes. I do NHS general practice work and I do private homeopathic work and when I do my NHS general practice I also use homeopathy in situations there. So it is not just that one is NHS and just conventional medicine and the other one is homeopathic. I do homeopathy in the NHS as well.

Homeopathy - I will leave aside the basis of infinite dilutions and I will say that with homeopathy when you look at a person you do not look at the symptoms as being the problem, you look at the symptoms as being a sign. Rather like if you were driving a car and the oil was low a little red light would come on. To give an example, in conventional medicine we regard the symptom as the problem and therefore we need to get rid of it, which could be compared to looking at the red light on the dashboard and unscrewing the bulb. The oil would still be low.

In homeopathy we regard the symptom as the sign and we regard the symptom as not the problem because we know that if we correct what we regard homeopathically as the imbalance then in the case of the car filling up the tank with oil the light will go out on its own, and in the case of the symptoms, the symptoms will disappear on their own.

So with homeopathy you look at the whole person and their environment and by treating that you expect the symptoms then to go in a particularly prescribed order, depending on whether the remedy you are giving is working in a supportive way, or if you have not got it correct it might be in a suppressive way so you aim for the supportive way.

So the holistic way of looking at children themselves, their parents and their environment forms a large part of how I look at health and disease and in my general practice work when people come to see me, I do not go round prescribing homeopathic remedies to all of them, but whenever people come I look at them from a global homeopathic

perspective, which in a case of many of the patients for whom I do not prescribe any medication, either conventional or homeopathic, but the type of advice that I go through with them is based on a holistic homeopathic approach.

Q Did that approach have any influence on your report or opinions?
A It had a large influence on my report, but I did not write the report from a homeopathic point of view because I had not been asked to do it from that point of view. So in terms of absence of homeopathy in my recommendations or in my references it is because I relied on what was available in text books and medical journals because I thought it would be difficult for the court to start taking on board homeopathy as an alternative way of achieving health.

Q Your other colleagues in general practice who do not use homeopathic medicines, do they have a holistic approach to their patients, do you feel, or is that something that we could discuss another time?
A They have a certain level of a holistic approach because that is what everyone in general practice aims for. The only thing is that I have found, from having a conventional training and a complementary training, is that you cannot practise in complementary ways in which you do not know. So if you are only conventionally trained you practise in the most holistic way you can with that, but you do not actually have access to some of the other ways that you could use because you do not know them.

Q Coming to the regular medications, the ordinary medications you use in general practice and you personally use them, I am sure. I presume (not talking about vaccines just for the minute) that drugs and stuff you would prescribe on the basis of, as far as you are assured, probability of benefit exceeding probability of risk as determined in whatever trials or evidence there is in conventional medicine.
A We have guidelines for what treatment levels are for hypotension and lipids and so on and so forth.

Q In your general practice do you take notice of the science of it, or do you look into it yourself, or have you got enough to do looking into the vaccines?
A One of the problems with a case like this is it makes it look as if I am obsessed with vaccines to my looking at it, but, in fact, I am very interested in a lot of areas and, for example, hormone replacement therapy.

From the reading I had read with the literature to do with that I, from my reading, had seen that it was problematic in terms of heart disease at a time when a lot of my patients were being put on hormone replacement therapy, not particularly because they had bad menopausal symptoms, but because they were told that they had a poor cardiac history in their family. Whereas I, from my reading of the literature, had not seen that and I advised them accordingly.

Subsequent to that, I think it was 2002 or 2003, the Department of Health came out in favour of my view, not that they would have known it was my view, and they advised using hormone replacement therapy because of the problems associated with heart disease only for a short term and preferably not at all. Whereas I had already been advising my patients of that.

A

I have a particular interest also in women and children and the same pertain to the injectable contraceptives which, as far as I could see, I had not seen literature showing it, but I knew that it abolished ovulation and I knew that other conditions that abolish ovulation such as being very thin, make you more prone to osteoporosis. I reasoned that this would be the same with this vaccine and, in fact, I questioned this at a meeting when I was doing my refresher course for my diploma of the Faculty of Family Planning. I put

B

my hand up and asked about the problem with osteoporosis and they said well there is not. I said that it abolishes ovulation so there must some and they said yes, but it is different.

Then a couple of years later we had the guidelines saying that there was a risk with osteoporosis. So I look into a lot of treatments and interventions that I use for my patients and I make up my mind myself and it must be said that the government guidelines might say one thing, but I look at also what I see myself from my own research.

C

Q How much note do you take of statistical probability in the conventional medicine terms, not vaccines and not homeopathic, how much note do you take of the conventional statistical probabilities that are in the trials?

A I look at the conventional statistical probabilities depending on their populations. For example, in terms of some other drugs like treatment of hypotension or high cholesterol, you sometimes see statistics used and the statistics are used correctly, but the

D

populations they are used on is then extrapolated to a population that has not had a history of heart disease and to me that is the wrong use of statistics.

Q Coming onto vaccination now (and I may have missed this) but yesterday Mr Stern asked you if you were against vaccination at all and I was not clear what your answer was.

A My answer is that my interest in vaccination and in all the aspects of the health care that I advise my patients on and actually prescribe or administer myself is from the

E

point of view of safety. So my particular interest in vaccination is to do with child health safety because the whole aim of vaccination and any medical intervention we have is, to my mind, health and people being as healthy as possible with the least possible side effects.

Q It just occurs to me that we are talking about nine completely different vaccines. I appreciate that there are common mechanisms in immunology involved. Do you think

F

the probability of all nine being wrong were inappropriate and I would not wish to get into probabilities because I am not an expert in statistics. Do you think that has a bearing on perceptions of your report?

A Yes, I have not recommended any of the vaccines. It must be said if I had wanted to recommend one or two of them now I could not because they are all together and the

G

ones that you could have separately or in smaller amounts have additives which are now no longer present in the multiple ones.

One of the recommendations to do with vaccination and the way we treat disease is based on the conventional medical view of the germ theory of disease which is widely accepted as promulgated by Pasteur which is that you meet the germ and you get the disease. Although he is supposed to have said on his death bed, "The seed is nothing and the soil

H

is everything." We know from ourselves that if the germ theory of disease were that straight forward and that simple then on a bus when one person had flu, everyone would catch it because it is new each year with new antigens, but that is not the case.

So there is more to health and disease than just meeting a germ and either killing it with an antibiotic or stimulating an immune response with a vaccine.

Q May I suggest a parallel? Is it not the case that every living being, even within the same species, apart from identical twins, has a different genetic tendency to develop the disease from a particular infection?
A I would agree with that and that is one of the problems I have with the one size fits all aspect of mass vaccination.

Q You told us in your general practice that you advise parents to make their own informed decisions looking at the literature?
A Yes.

Q You tell them what the Department of Health view is. How do you advise them, if you advise them, how to approach the literature and how to assess the literature?
A Well they already usually have their leaflets that they have from the Department of Health and there is a very good website that is provided by the Health Protection Agency and there is a lot of information provided by the NHS on vaccination.

There are other websites. In fact, if you just Google vaccination a lot of websites come up and you can read them. I think sometimes when we are talking about science and medical advice we regard ourselves as being the experts and the lay people as not really having any grasp, but I think people make so many important decisions in their lives based on the information they have, I think they are quite capable of reading information that sounds reasonable to them and reading information that does not sound reasonable to them. I just think they need to have more access.

I think it would be better in terms of the Department of Health if there were a wider breadth of information given on health and disease when addressing vaccination. I mean, for example, when trying to increase the levels of MMR vaccine coverage, the Department of Health has advertisements with little babies in nappies sitting on the edge of a cliff with a lion there. I do not think that is a balanced way of presenting the view of those diseases. So, in a way, what you speak to me about is there is an awful lot of, I suppose you might call it, in every war there is propaganda and in the war against microbes it is no different. So I am trying to provide a balance.

Q We have talked about your views which you say your views are always deeply held and I do not think there is any dispute about that. In your CV you mention television and newspaper and magazine articles and appearances, what sort of things do you say in those fora?
A It must be said this CV was written in 2002 and I do not think I have done any since then. There was a quite a rash of interest in vaccination and so on in about 2000 and 2002, but it has gone down a lot since then and I say what I say now, I think that the most important thing is to cultivate the soil, which is a healthy person, just like in organic gardening. If you do not want to cover your vegetables in weed killer and pesticide, what you do is you put a load of good manure in the soil and that makes them more disease resistant and grow better on their own. I think that is what you have to do with your children and yourself.

Q In your evidence and in your reports you talk quite often about The Department of Health. You told us just a few minutes ago about government guidelines?
A Yes.

Q Many of the guidelines come from voluntary Royal Colleges and Societies. Do you have an over all view, a philosophical view, about the State or the British State or something like that?
A No.

Q Coming to your work as an expert witness, of which this was clearly the first case, did anyone suggest to you that you should have any training, if that were possible in the short time scale, or if there were funds for it, or look at any reference literature before going on into court and so on?
A No. One of the things that I think came out when Mr Stern was questioning me was the evolution of how I came to be an expert witness. I think I put across the fact that I was rather reluctant to do it, but I never put across the fact of why I ended up doing it. Why I ended up doing it was because these mothers did not find anybody else who would provide a report for them and so I did it on the basis that otherwise they would be in court and they would have no one presenting a different view to what had already been presented. So in terms of ... I felt it was my moral duty to do it, which is why I did it.

Q You did mentioned, I think earlier this afternoon, that you had provided reports presumably in the course of your general practice for other presumably court tribunals and so on.
A I often act as an advocate for my patients and I have written a lot of not reports but letters to housing departments and a lot of reports for my patients who have been struck off the disability register when they have mental health problems and are the least able to argue a case to put themselves back on again.

When I worked in casualty a long time ago I used to have to write little reports for people who had come in having broken their bone or damaged themselves in road traffic accidents.

Q When you wrote those reports, not this one, were you mindful of the general tone of Rule 51 of Good Medical Practice which I think has been discussed today in writing of the reports?
A I do not know whether Rule 51 was extant in 1983 or four. It might have changed, but whatever the rules were then ... I generally read the little handbook that gets sent out from time to time by the GMC reminding me of good medical practice.

Q In your report, the two reports that we have got, there is underlining that is obviously put in by the word processor and by yourself?
A Yes.

Q Was this your own emphasis? Is that a way of emphasising your points?
A If it is just in my writing then the emphasis is mine. When I am quoting I usually write at the end of it if the emphasis is mine.

Q I do not think it is appropriate for me to go through these 100 and odd pages in detail, but if you remember (and I think you will but you may want to refer to it) those two graphs in Dr Elliman's reference 52. D52. It is my final question actually.
A Yes.

MR STERN: Mine says 53 at the top.

MR GOODMAN: It is the pertussis and neurological disorders.

MR STERN: It is the one that I think has been described as blue blocks on them.

THE WITNESS: With the coloured bits.

MR GOODMAN: Yes.

MR STERN: We gave you this copy, I think, a coloured copy yesterday.

MR GOODMAN: Yes. *(To the witness)* If you look at the top of page 804 at 428 months, you see where the two lines, the dotted line and the continuous line, are apart, but the bars overlap.
A Yes.

Q I think it has been explained to us that the bars are the sort of 95 per cent spread of probability?
A Yes.

Q That the statisticians say that when the bars overlap the difference is not significant and there is what is called a P value there of 0.23, which means that this could have occurred by chance. Have I got this the right way round? 23 per cent of cases or the probability of the difference is 23 per cent. It is not the conventional 0.05 and you had a disagreement that you mentioned to Mr Kark about your view that these lines are apart and you said your interpretation by the expert, I cannot remember whether it was Dr Conway or Dr Elliman's interpretation, differs from yours.
A I think it was the conclusion of the authors differed from mine.

Q Yes, yes. Your conclusion is that the lines being apart represents a real different. Is that correct?
A Well, there is some difference there and so I do not think it is clear from this graph that there is not a difference.

Q No, that there is not a difference, or there is a difference?
A Yes, it is not clear from the graph ...

Q No.
A ... but I would not say it was necessarily reassurance that there was not a difference.

DR GOODMAN: Yes, I see what you mean. Thank you very much.

MR BROWN: Good afternoon, Dr Donegan.
A Good afternoon.

Q We have seen the timetable to which you were operating in preparing these reports and D22 gives us some insight into that.
A Yes.

Q Just turning if we may to D22 and in particular the letter of 24 May 2002 from Andrew & Andrew, which is in effect your commissioning letter if I may so describe it?
A Yes.

Q It does say on the third page under the subheading "THE TIMETABLE" ---
A I am sorry, which date is that?

Q That is a letter dated 24 May 2002.
A Yes.

Q It is page 3 of the letter with the subheading "THE TIMETABLE", yes?
A I am sorry, which date is that? 20 June?

Q Yes, it is 24 May 2002.
A 24 May, yes.

Q It is a letter from Andrew & Andrew Solicitors.
A Yes.

Q It does say:

> "Please advise us immediately if you are unable to meet this deadline".

I wondered, given the pressures to which you have referred, did you ever contemplate exploring whether an extension could be sought?
A Well, in terms of I put next to that "Done → 14 June".

Q Yes.
A They extended it to 14 June. I was not aware that I could say, "Can you please cancel the court case and adjourn it to another time?"

Q No, I just wondered if you had gone into that sort of dialogue with Andrew & Andrew?
A No, I was not aware that anything so august as a court case would be able to be adjourned on the basis I had not finished what I needed to have ready in time.

Q Yes. Putting it another way, had you had more time to prepare your report - and you may have touched on this - would you have been more expansive in what you have said?
A I would have been more expansive with some things and probably more succinct with other things.

MR BROWN: Yes, thank you very much.

THE CHAIRMAN: Except to say that you did seek one extension of time? You did seek that extra two weeks?
A Yes, the extra. They wanted the report by 31 May, but they had not sent me most of the other reports by whatever this was, 24 May, and so that was obviously not going to be made.

THE CHAIRMAN: Ms Goulding?

MS GOULDING: I have no questions, thank you.

THE CHAIRMAN: I have got just a couple of points. We had a question from Mr Kark talking about the nature of your instructions ...
A Yes.

Q ... and we had a quite a lot of discussion about the worldwide aspect of the report. I am just trying to turn it up. I wondered whether you could give us, or could you help us with, what you would say were common elements of vaccines used in this country, in terms of its generic quality, compared to the worldwide application of these vaccines in the schedule, bearing in mind that you have said high titre measles is used in some parts of Africa, for example, and not in this country?
A Yes.

Q If you could just very briefly give us a feel for how much commonality there is in terms of generic vaccines in the schedule and their worldwide application?
A For example the eIPV - the E inactivated polio vaccine - was one to the best of my knowledge that was a different potency. It was the same type of vaccine, but it was just a different formulation. The high potency one that was used in Africa, that was withdrawn, that was a different type of measles vaccine, but the potency was high. You will see in the paper - the cell mediated immunity paper - that they also mentioned that there was a Schwarz high potency vaccine as well, but the normal one that is used is standard. So, there is some commonality between the vaccines that are different to the ones that we use here to a certain extent.

Q Are those the only two that you can think of?
A At one point the Swedish vaccines and the Japanese vaccines they were using types of acellular whooping cough vaccine that were not introduced here and, when the whooping cough acellular version was introduced here, it was a different one because it had been - these were the trials that were looking at the vaccine and whether it would have enough antigens on it to provide enough of what was regarded as an appropriate antibody response and so they were part of the evolution of the vaccine that we have here; not that that vaccine was in the schedule at the time that the children were coming to court, but an acellular vaccine was available in this country at that time for the parents to use should they have wanted to.

Q So in retrospect, looking at it with the benefit of hindsight, you would say that was still a valuable exercise and worth incorporating in your report?

A I think so, because the rate at which the vaccines change is so fast. I mean every few years now we have a different formulation added, or an extra vaccine added, to the schedule. So it is hard to actually have data that gives you an idea of the impact that the vaccination has on health and immunity just sticking to the ones that are available, because they keep changing in certain ways and certain combinations and certain additives. As you saw in the study that Dr Goodman brought up, I mean one of the things that they did in the second part of the study was I think they took out the aluminium adjuvant and they changed the potency of the whooping cough. So, it is a moving situation all the time. Really if you just wanted to look at just what is available here and you wanted to look at the history of it and the evolution of it, in some cases you would not be able to because the vaccines just keep changing to a certain extent.

Q Thank you. The second question again relates to the instruction that you were given, and the instruction from Andrew & Andrew asked you to answer the question about:

> "What are the comparable risks between the children having the childhood immunisations and not".

A Yes.

Q In your evidence today you have said on a number of occasions that you thought your report was written to balance the opinions of the other two experts, and then more recently just a few minutes ago you said you wanted to give a different view to what was being presented?
A Well, yes, I suppose I should have said a wider view.

Q Yes. Do you think you have followed the instruction?
A Of the comparable list of the children of having the immunisations, or not? Well, as I said, I did not repeat what had already gone ahead and I attempted to give a view that was going to be a broader sort of view. If I could have, or if I had been asked to add alternative health views then that would have been another different sort of view again, but I was not and so I could not add things like that that would have fleshed it out perhaps to an extent. One of the things that happens with vaccination is on the one hand you have people saying, "Vaccination is the only way and the diseases are all very serious", and then on the other hand you have people saying, "The vaccinations have all these side effects and you should not have them", but in the middle is the child, or the adult, and they are going to come across these microbes and they are going to come across these diseases and they are also going to have a lot of infections, or come in contact with the infection causing agents, for which there are no vaccines. What you really need to do is to know how to bring up a healthy child and treat them appropriately when they have their illnesses, particularly in the cases of the sorts of illnesses like the illness due to meningococcal C, or Hib, and/or coming up now with the pneumococcal which is not the subject of this. These microbes are present in a lot of people's bodies, so you never know which red illness with a fever that you are treating, because we do not go swabbing everybody all the time, that might be due to one of these illnesses. So you really need to treat them appropriately, hopefully in ways that are going to bring out the fever and bring out the rash, if it is present, and bring out the mucous, rather than suppressing all the symptoms which from a homeopathic point of view tend to make you more likely to have

internal disease which we would call invasive in the form of ear infections, pneumonias, meningitis, septicaemia. So, from that point of view how you treat a childhood illness when they have it is very important as to whether you are going to have a reasonably good course for the disease, a mild course, or whether you are going to have complications.

THE CHAIRMAN: Thank you. That is very helpful. I understand the Legal Assessor has some points to clarify.

THE LEGAL ASSESSOR: Yes, it is really a question that I think I can ask Mr Stern ...

MR STERN: It is not medical, then.

THE LEGAL ASSESSOR: ... but I will do it at this stage in case you wanted to ask your client. You produced not long ago D24, which is the meeting between Professor Kroll and Dr Donegan on 3 July 2002.

MR STERN: Yes.

THE LEGAL ASSESSOR: I wonder if we could go back to D22. It is the letter which I did ask a question about a couple of days ago. It is the letter dated 25 June, to Dr Donegan, and I asked about whether we had a copy of the agenda.

MR STERN: Yes.

THE LEGAL ASSESSOR: I was thinking of the meeting and not being sure whether it took place or not. Of course now we know, because if we just read that letter Battens say:

> "We write further to previous correspondence and your telephone call of this morning, regarding the proposed meeting of experts, to confirm it will take place on Wednesday 3rd July at 11:00 am",

and we can see it did take place as between Professor Kroll and Dr Donegan on 3 July. Battens go on to say, "We have contacted Professor Kroll ...", and then in the third paragraph:

> "To date, we are unsure whether Dr Conway will be attending as he is currently in Genoa and it is not clear whether he will be back in time. However, given that both Professor Kroll and Dr Conway largely agree"

- that is obviously with each other -

> "and that you represent the opposing viewpoint, it is to be hoped that the meeting will still be of use".

So, the proposal was that all three would be there?

MR STERN: Oh, yes.

THE LEGAL ASSESSOR: However, in the event Dr Conway was not able to attend and that is why he is not there. Is that right?

MR STERN: No, because the next letter of 1 July actually sets out the details of where the meeting was to take place and about three-quarters of the way down it says:

> "... Dr Conway will be attending the meeting as he will have returned from Genoa by then",

but for whatever reason he was not there.

THE LEGAL ASSESSOR: He did not?

MR STERN: No.

THE LEGAL ASSESSOR: No, that is all I wanted to know. Thank you very much.

Now, the other question is to do with the chronology.

MR STERN: Yes, the chronology of reports?

THE LEGAL ASSESSOR: Yes, the chronology of reports.

MR STERN: Yes, may I just try and find mine?

THE LEGAL ASSESSOR: It is the "CHRONOLOGY OF EXPERT REPORTS FOR FAMILY DIVISION HEARING" and you have got the right date for Dr Donegan's first report of 14 June, but then the next one is:

> "Response to 14th June 2002 report by Dr Donegan",

and then in brackets:

> "Report of Dr Conway prepared 7th September 2002]",

and that is on the ---

MR STERN: That is a quote from the ---

THE LEGAL ASSESSOR: It is on every page, I think, that phrase.

MR STERN: It is a quote, yes, from the bit at the bottom.

THE LEGAL ASSESSOR: That is right. However, in the left-hand column it has got "19th November 2002". Where did you get that from?

MR STERN: I think I have taken that from Dr Donegan's report, second report, page 74.

THE LEGAL ASSESSOR: Yes, I see that. It says, "4th December 2002", and then it

says, "Response to report of 19th November ..."

MR STERN: That is right. It is dated 19 November 2002, so I am rather assuming that the report, as and when she got it, was either dated that, or that was the date she got it.

THE LEGAL ASSESSOR: Yes, because the only date we have on it in fact is 7 September.

MR STERN: Yes, but if you look at the correspondence I think you can see that she did not get it until I think 19 November. However, she will correct me if I am wrong.

THE LEGAL ASSESSOR: Well, that was really the point I was getting at that she did not get it.

MR STERN: No, thank you for clarifying that.

THE CHAIRMAN: Mr Stern, you can now do your re-examination and cover any points that arose from our questions.

MR STERN: No, I have no further matters, thank you very much.

THE CHAIRMAN: Mr Kark?

MR KARK: No, thank you.

THE CHAIRMAN: In that case, Dr Donegan, that concludes your evidence and you are free to return to your seat.

THE WITNESS: Thank you.

(The witness withdrew)

THE CHAIRMAN: I will just check now the timetable for the rest of the day and tomorrow?

MR STERN: Yes. Dr Fletcher is here, I propose to call Dr Fletcher and obviously I will do that at a time that is convenient for you and your Panel. If you are happy to start now, I am happy to start now.

THE CHAIRMAN: We do want to finish at five o'clock today. Do you think it is going to take longer? You could do your bit.

MR STERN: It will definitely take longer than five o'clock today, yes.

THE CHAIRMAN: No, I thought you might cover part of it today. You could maybe start?

MR STERN: Yes, that is what I say. I am happy to start, if you want to start now, or if you want to start more afresh, maybe looking at it again overnight, that will obviously

make things a little quicker, or possibly make things a little quicker. I am entirely in your hands, madam, as I say. He does have difficulty on Monday, I should just mention that, but I am pretty sure we will finish him - I have to be careful what I say. I am hopeful we will finish him tomorrow.

THE CHAIRMAN: I am anxious not to let time go by unnecessarily.

MR STERN: No, no. There is a matter that I need to discuss with Mr Kark and the learned Legal Assessor and so we could use the time for that, but I could also do that afterwards. I am just giving you all the options for whatever you would prefer.

THE CHAIRMAN: The general consensus is that we should press on and make a start today.

MR STERN: Dr Fletcher then, thank you.

THE CHAIRMAN: Dr Fletcher's report is D1.

MR STERN: Thank you.

ARCHIBALD PETER FLETCHER, affirmed
Examined by MR STERN

Q Could you just tell us your full name, please?
A My name is (*Pause*) Archibald Peter Fletcher.

Q I am sorry, I did not mean to pry on the "A".
A Yes, the "A". Yes.

Q I know you hesitated for a moment.
A Yes, hidden away.

Q Forgive me. Could you just turn to page 33 of your report, because there we have your "Biographical Notes", as you have described them, in your Appendix 1 to your report, so we can tell the Panel something about you. First of all, as we can see, you were a medical student in London between 1949 and 1955?
A Yes.

Q Just tell us, please, what you did after that?
A After that I did my usual one year at that time of junior house jobs, and at that point I decided that the specialty in medicine that I would like to move into was pathology and ---

Q No comeback from the patients.
A Accordingly, I took two different posts. One, my starting post, was with the Greenwich Group of Hospitals at the Dreadnought's Seamen's Hospital and the Miller General, which was there in those days but I believe it has gone now, in which I got some preliminary training. I then moved as a registrar to the Mayday Hospital in Croydon, where I did a further two years doing many post mortems and doing surgical histology and

A other aspects. That was my basic pathological training.

Q Then I think in 1961 to 1965 we can see that you became a biochemistry student, as you describe it there?
A Yes. As a consequence of the training that I had received in general pathology, I decided that I was much more scientifically inclined than I was to the medical side of it and I applied to Professor Albert Neuberger to see if he would accept me as a PhD student at St Mary's Hospital. He said he would do so on the condition that I went to University College and did the MSc course, which was intended for those students who had got a prior degree to spend one year and sort of get an MSc at the end of it. I did that and was subsequently accepted as a PhD student by Professor Albert Neuberger and he was my supervisor.

C Q Just in very brief terms, what was it that you actually did as part of your PhD?
A Professor Neuberger, in 1938, had done a very remarkable study on hens' egg albumen – this was done at Cambridge – in which he showed, convincingly, that there was a chemical link between the protein part of hens' egg albumen and the carbohydrate part. The war came and Albert went to do many other things during that time. When he ended the war, which I suppose was somewhere round about 1948, he went to St Mary's and decided he would pick up again with the earlier researches he had been doing and I was one of the people who continued that work for the next three or four years. My topic was the structure of hens' egg albumen.

Q I will not ask you any more about that. We can see that you were a Medical Research Council Scholar at that time and then a Medical Research Council Fellow?
A Yes, those were the financial resources that I had available to me during that training period.

E Q I think, as we can see, you also lectured in that period in chemical pathology?
A Yes, the department was called the Department of Chemical Pathology although it had a rather broad research basis which extended outside that specific description.

Q From 1970 to 1973 you were Head of Biochemistry at the American National Red Cross Blood Research Laboratory in Bethesda, Maryland. Just tell us about that, if you will?
A I must say that I crossed the Atlantic for financial reasons and I had been invited before that to become the head of this department, which was in Bethesda, Maryland. I went across there and I was there for three years, really directing the interests in that establishment. I returned to the United Kingdom because we had children at that time as they seemed better, perhaps, catered for in the United Kingdom than where we were in Maryland.

Q Then were you involved in clinical pharmacology at drug companies, or pharmacological companies?
A Yes, Lepetit, which then later became part of the Italian company Pharmitalia. This was sort of an intermediate job when I got back from the United States. Later, after that, I joined Upjohn.

Q Not everyone knows what Upjohn is.

A Upjohn, I think, is called Pharmacia or something else these days.

Q It was a pharmaceutical company?
A Oh yes, a pharmaceutical company. Sorry.

Q You were the medical Director. Thereafter, from 1975 to 1980, just tell us what you did then?
A I was situated in Belgium, it so happens, in Brussels. My job was in fact to look after the whole of what they called the Nordic area with regard to their clinical research operations. It was my task to travel almost---

Q That was the Medical Director in Scandinavia?
A Yes. I was in Brussels but I was working in Scandinavia, so I travelled rather a lot.

Q Sorry, I was asking you about the next bit – I thought the Department of Health had moved?
A No, no, no – not yet.

Q From 1975 to 1980, the Department of Health?
A Yes.

Q Just help us with that. What were you doing there?
A I joined what was then called Medicines Division and then became the Medicine Control Agency and is now the MHRA. I became the Principal Medical Officer there, in which I had responsibility for really the agenda and the running of the Committee on Safety of Medicines. This was, I suppose, the second-most senior position in Medicines Division. Dr John Griffin was the Head of the Division at that time and I reported to him.

Q In general terms, what were you looking at?
A These were to do with the implementation of the Medicines Act of 1968, which involved the licensing of new medicinal products and also the surveillance and conduct of existing products, variations and abridged applications.

Q What was your role in relation to that? What were you actually doing?
A I was responsible for vetting the reports which were provided by the Senior Medical Officers who reported to me, about six or seven of them, and they wrote the documentation from original material supplied by the applicant companies, which were then presented to the Committee. It was up to me to look over that stuff and see that it was suitable for presentation to the Committee and other minor items which occurred. The Committee, I should say, met once a month and they had to get through their agenda each day of each month, and it was my responsibility to see that we kept the business going.

Q Just help us with Senior Medical Officer, Principal Medical Officer – those entries that you have there. What do they relate to?
A These were the positions I had there. They were levels within the Civil Service structure. I cannot remember what they go to.

Q Over the page, please, we can see Senior Principal Medical Officer, Chief Scientific Officer and Under Secretary?
A Yes. In case people think I was thrown out of Medicines Division, I was not. Actually I was, I suppose, because I was promoted to another division as the Senior Principal Medical Officer and the Chief Scientific Officer. In that position I was responsible for all the scientific services for the whole of the National Health Service – which, I must say, I was not prepared to continue so I made my own exit from that.

Q Tell us what you did after that. What was involved in that?
A I went on then to the Toxicology Division after that – actually, I dropped down a grade on that one – where I was then not only responsible...instead of being responsible for medicinal products I was now responsible for non-medicinal products that had toxic implications on the environment and use and I was then involved in a lot of guideline writing and dealing with matters of the writing of directives in the EU and also in the OACD.

Q You have set out there the Department of Health responsibilities as well?
A Yes. I think this is important because in fact it covers some of the things which I carried on with me after that and it sort of gives me the reason for my expertise at the moment. As well as being responsible for the main Committee on the Safety of Medicines itself, I was also Medical Assessor to the Toxicity and Clinical Trials Sub-Committee and the Chemistry, Pharmacy and Standards Sub-Committee. Those reported through me to the main committee. I was also not with the Medicines Division, but with the Toxicology Division I was Secretary to the Mutagenicity Committee. I am sorry, those are out of order because in fact the Grahame-Smith Working Party, which is possibly of some significance for what we are dealing with here, was in fact established under the Medicines Division responsibility and arose as a consequence of the fact that applicants from the pharmaceutical industry were very unhappy at the time it was taking for new products to be registered and they wanted to have some means by which that could be truncated. David Grahame-Smith was the Chairman of the Toxicology and Clinical Trials Sub-Committee. He was given the responsibility to---

Q Forgive me, I am not familiar with him. Who is he?
A He was the Professor of Clinical Pharmacology at Oxford University. As I say, he was the Chairman of the Toxicity and Clinical Trial Sub-Committee. He met fairly regularly and really enunciated the concept that we could truncate matters with applications if pharmaceutical companies agreed to do substantial post-marketing studies in addition to their initial application data. He proposed that studies of at least 10,000 patients should be examined and that they should be actively surveyed for at least six and preferable twelve months, so he was looking at long-term, large-scale safety evaluation studies at that time.

Q Can we move on? Director of Regulatory Affairs in Europe in 1980 and 1982, and then a Consultant in the same thing from 1983 until 1986. Over the page, more of the same. These are all pharmaceutical companies or businesses?
A Yes. After I had left the Toxicology Division, I was taken on as the Director of Regulatory Payers for what was then called American Cyanamid, which is a subsidiary of Dow Chemical.

Q It is a very well-known organisation.
A Then I became a Consultant in Medical Regulatory affairs on my own. I set up my own little business which I called Documenta Biomedica. At that time I was under contract in respect of my work with my own small business with Life Science Research, which is now a part of – what is the name of the place that is in trouble with all the animal rights people now?

Q Huntingdon?
A Huntingdon, that is the name. Huntingdon bought Life Science Research out and they had taken me on to run a group of theirs which was doing normal human volunteer studies on things like consumer products of various kinds. Perhaps I should explain how I got on to the next step at 1987. That was because at the time Life Science Research was actually owned by IMS, which does not really stand for much – it stands for Intercontinental Medical Statistics. I was given the option of staying on with Life Science Research or going to IMS, and I chose to go to IMS, who were seeking my assistance in developing large-scale observational cohort studies and---

Q Can I just interrupt you? Who are IMS? Not everyone knows who they are
A IMS is the largest supplier of data to the pharmaceutical industry. They collect prescription data and a large quantity of other medically based data. They were moving rapidly into the business of actually becoming active in doing studies themselves and having a contract business, which became Post-Marketing Surveillance International Ltd, which I was a director of that one.

Q I think we can see Director of Post-Marketing Surveillance International Ltd, responsibility for 15 safety evaluation studies in the United Kingdom, six in Germany and five in other countries. What does that mean?
A IMS, of course, is a contract organisation for the pharmaceutical industry and we sought companies which in fact were interested in doing these kind of studies, which other people, obviously, were developing. One of the very first studies – actually, it is the subject of one of my references there, "Profile of a large-scale cohort study", which we did in fact for SmithKleine Beecham – it is published so it is no secret about that at the moment – which was extremely successful, on a non-steroidal anti-inflammatory agent. From that point on, we started to get contracts from numerous other large pharmaceutical companies.

Q Over all this period of time, have you had access to and looked at medical reports of the sort that deal with safety or efficacy of medicines?
A Indeed. A large part of my responsibilities were concerned in the matter of – certainly when I was with the Committee of Safety in Medicines, was actually looking through and evaluating thousands, probably, of clinical trials and other clinical studies which were done, evaluating the ways in which those were being assessed. Later, it was a matter of advising companies themselves as to the sort of studies they should be doing and then evaluating their programmes. Yes, a very large number of such documentations.

Q Since 1995 we can see there are a variety of things that you have been doing. Just dealing with the second one, a member of European Pharmacovigilance Research Group with the Chairman Sir Michael Rawlins. Just tell us a little bit about that, please, and who Sir Michael Rawlins is?

A Once again, I went back to running my own little business, which I called Pharma Services International at that time. I had known Michael Rawlins for a long time anyway – we had been sort of quite close friends – and he invited me to join this group, which was set up under the EU, to look into ways in which the further safety evaluation of marketed products could in fact be continued. It was attended by two or three people from each of the EU countries at the time – I think there were 15 of us at that point; I cannot remember how many there were. I was one of the people who was there on the basis that I had had previous experience in the matter of post-marketing surveillance. It is probably of interest that Sir Michael Rawlins ceased to be in that position when he took over as the Chairman of NICE, which he is at the present time.

Q That is the National....
A National Institute of Clinical Excellence.

Q Also a member of the Brockham Group. What is that?
A The Brockham Group was set up by SmithKleine Beecham in order to look into and examine the problems concerned with excess use of antibiotics. It was called the Brockham Group because that is where penicillin had been developed. This was a committee or little group which ran for about a year. We eventually managed to get a very brief paper in *Nature* which did really say that the excesses of antibiotics by the medical profession should be curbed a little as it was probably causing problems.

Q Just help us with the final entries there – Consultant of Theradex Ltd?
A That was a minor job. This is a small oncology – American company that took me on to advise them. They were wanting to move into Europe and they asked would I go and help them out with that. EPIC was the group which was looking after the General Practitioner Research Database, which is of importance because it is the largest computerised general practitioner database which has probably somewhere between six and eight million patients in it. I was taken on by them to advise them on the way in which that could be used in the conduct of large retrospective studies on the patient histories that were available there.

Q Have you, throughout this long and rather glittering career, been involved in research of medicines generally and their safety?
A Yes, indeed. Almost exclusively really, I would say, though there have been other things coming along on the way through. It has really been my area of expertise, I think, exclusively within the field of the safety of medicinal products.

Q I think, as you set out, you are a Fellow of the Faculty of Pharmaceutical Medicine (by distinction). Was that in 2002?
A Yes, I think it was about then.

Q And you are an author of approximately 70 papers and a number of book chapters?
A That is a rough estimate.

Q Of which we can see your most recent, I think, is 2006, is it?
A Yes, indeed. It was not really meant to be there. This was originally done for somebody else but they wanted to know my recent – I am the senior author in the fifth edition here of the chapter on The Safety of Medical Products and I have now been

invited to carry that job on into the sixth edition, which is due next year.

Q Who is that used by, that textbook?
A Those aspiring to be physicians in the pharmaceutical industry largely, but it is used by other people in other areas where pharmaceutical products are of interest.

Q Can I just ask you this? Are you associated in any way with anyone in this case?
A Not at all, no.

Q Did you know or do you know Professor Kroll or Dr Conway?
A No, I do not.

Q Do you know Dr Elliman?
A Only by name but I have not met him.

Q Before you were instructed in relation to this case, had you ever met Dr Donegan?
A No, I had not.

Q Or had any contact with Dr Donegan at all?
A No, I have not.

MR STERN: I am about to turn to the report.

THE CHAIRMAN: A good time to stop, yes. Dr Fletcher, now that you are under oath you cannot discuss the case with the legal team.

THE WITNESS: I understand that.

THE CHAIRMAN: We have been starting earlier – is that something that will suit people?

MR STERN: Yes, please.

THE CHAIRMAN: Nine o'clock tomorrow then.

MR KARK: Just for my own peace of mind, can I take it that I will not be called on to address you tomorrow? I certainly would rather not.

MR STERN: It would be fairer if we addressed you on Monday.

THE CHAIRMAN: Certainly. We will adjourn until nine o'clock tomorrow.

(The Panel adjourned until 9.00 a.m. on Friday, 17 August 2007)