GENERAL MEDICAL COUNCIL

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

On:
Friday, 17 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 Eight)

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
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FITNESS TO PRACTISE

THE CHAIRMAN: Mr Stern?

MR STERN: Madam, Dr Donegan forgot her jacket this morning. She left it at home. She feels uncomfortable appearing here without a jacket and so she has gone to purchase one in Manchester and so she is a little late. She is quite content for us to continue, bearing in mind it is Dr Fletcher and obviously she has seen his report, that we carry on in her absence. She hopes to be here in the next 15 minutes, or so.

THE CHAIRMAN: Yes, thank you.

ARCHIBALD PETER FLETCHER, recalled
Examined by MR STERN (continued)

Q Are you ready to carry on, Dr Fletcher?
A As ready as I will ever be, yes.

Q Paragraph 9, please. I am going to take you through this report fairly swiftly, I hope, because obviously the Panel have read it and I just want to ask really whether you have any comments to add in relation to any of the paragraphs, rather than going through them in great detail, if that helps. At paragraph 9 you say that you have looked at the reports and references and you have looked at all the material which forms the basis of giving your report and you have taken into account Part 35 of the Civil Procedure Rules?
A Yes, I have.

Q Thank you. Can we turn to paragraph 12. You say you have read the reports and the major part of the 250 or so references cited by the experts and that, in the light of that, you have assessed carefully Dr Donegan's report and the position as to whether or not in your expert opinion she has fulfilled the requirements of an expert?
A Yes, after doing that it seemed to me that she had in fact performed those functions.

Q As exactly you say in the following paragraphs. I need not trouble you with the rest of that paragraph. Can I just ask you about paragraph 12(*sic*), please. It is a point that was touched on by Dr Elliman - paragraph 13, I beg your pardon. It was a point touched on by Dr Elliman, which is in relation to the use of conclusions or the data within the research material. Could you just give us a little bit more information about that? That may be helpful.
A I think what I was saying here was that in fact the independent expert should in fact not merely look at the abstract, or other things, or the conclusions, but should really take a deeper appraisal of what the publication or the document actually says in itself; in other words, a broader interpretation of what is written there.

Q You say halfway through that paragraph that:

> "The expert opinions which derive from this process may or may not be in agreement with the opinions of the authors"?

A Yes, most certainly. I think that occurs with many appraisals of written material that you do not necessarily agree with what the authors have said and that one's own

opinions may ride over those sometimes.

Q You then go on to say, and this may be the important part, that - (*Pause*) I am on paragraph 13.

THE CHAIRMAN: Are you looking at the right page, Dr Goodman?

DR GOODMAN: Yes, yes.

MR STERN: (*To the witness*) Halfway through paragraph 13 it says:

> "Since these requirements are fundamental principles for all Experts it is not to be expected that an expert will state explicitly on each occasion that opinions differ".

Is that your view?
A Yes, I think that is my view.

Q At paragraph 15 you deal with the reports of Professor Kroll and Dr Conway. The way you put it is that they:

> "… unequivocally focussed upon the benefits, and therefore the safety, of the vaccines and have given absolutely minimal attention to their adverse effects even when they have been clearly included in official literature such as Data Sheets, Package Inserts and Patient Information Leaflets"?

A Yes, indeed. I think that was my impression that, on reading those through, they seemed to be a partial restatement of what comes from the Department of Health in the recommendation for vaccinations for children.

Q Did they in any of their reports, before Dr Donegan wrote her first report, deal with any of the issues that were raised by Dr Donegan in her report? When I say "any" that may be a bit broad, but do you know what I mean? Any of the caveats?
A Could you ask that question again?

Q Yes, of course.
A I am not quite sure that I understand what it is.

Q No, no. Looking at the first reports of Professor Kroll and Dr Conway, you have set out there that they were focused upon the benefits. I think that may be the answer to the question and it may be that I do not need to ask it, but you have said that they have unequivocally focused on the benefits?
A Yes.

Q Did they deal with the other side of the coin, as it were, that was set out in Dr Donegan's report?
A No, I do not think they did. I think my criticism of those first reports was that they exactly did not do that.

Q At paragraph 16 you have given attention to the reports of Dr Donegan and the related references and you say:

> "… I am of the opinion that she has observed the requirements for experts … in respect of published evidence and opinions. Furthermore she has provided a balanced view of the benefits and risks of childhood vaccination which has included consideration of population based reports. It should be emphasised that the sequential nature of reports that has occurred in this case did not demand that Dr Donegan should repeat material already contained in the reports of Professor Kroll and Dr Conway".

That is your view, is it?
A Yes, that is my view indeed.

Q Dealing with the general overview, can I just ask you this before we just touch on one or two points. Having heard the evidence - well, all the evidence of Dr Donegan and most of the evidence of Dr Elliman - has anything changed your view since writing this report? I should ask you that bearing in mind the view of the CPR 35?
A No, I do not think it has. No, I cannot think of anything that has changed my view.

Q You set out at paragraph 17 that in your view:

> "… Dr Donegan has fulfilled the requirements of an expert as quoted above having provided evidence of her attention to the full publication, identification of specific items in the text and the provision of details relating to authors, journals and dates".

Apart from I think the Harrison's 11th Edition, which was photocopied wrongly as we now know, the references are all set out in her report?
A Yes.

Q Then in the second part of paragraph 17 you say:

> "In my opinion Dr Donegan has demonstrated a commendable ability to present a full and carefully considered and balanced report in response to prior reports from the other experts".

You say:

> "This level of ability is all the more remarkable in light of the fact that the reports were produced under severe time constraints".

I think if we add - I do not know if you knew this at the time - that she had not written an expert report before?
A I did not know that at the time, no. Yes, I would reiterate that, I think, that it was a remarkably capable task that she performed.

Q I am asking you more about the overview, rather than the minutiae, because obviously the detail is really a question for Dr Donegan and what she says about the particular points.
A That is exactly what I meant there. My impression from reading it is as I have put it there.

Q Your impression when you read it, did it come through to you as somebody who had allowed her deeply held views on the subject of immunisation to overrule her duty to the court?
A No, I can honestly say it did not. It never crossed my mind that, I must say. Perhaps I should say that I have read many, many other expert reports in the course of my experience and so I have some comparison with which to say and that is what I felt was the case.

Q I had rather assumed, from what you have told us about the work that you have been doing over many years ---
A 30.

Q 30 or so years. I did not want to be too impolite and precise. However, over many years that you had seen many expert reports?
A Yes, of various kinds.

Q Various kinds, of course, yes. The actual type of expert report may not matter, but you have seen a range of them, have you?
A Yes.

Q Over a number of years. Approximately, any idea how many you will have seen? Are we talking ten, 20, hundreds, thousands?
A If we are looking at the documents which are submitted for the consideration for a product licence being granted, then into the thousands certainly.

Q I want to ask you about that you have expressed the view at paragraph 18 about the:

> "… references cited by the Experts had little relevance to an assessment of the benefits and risks of vaccinations for the two individual children but were more concerned with the efficacy in respect of population immunity …"

I think what you were saying there, if I may say so, was that you were saying that was not directly so far the issue for the judge? Is that what you meant, or ---
A I think perhaps I might have taken at the time I was writing that closer attention to the fact that what we were looking at really was the individual benefit risk ratio for two individual children.

Q Yes.
A Therefore from my point of view - my point of view of my own expertise as the safety of medicinal products - is that I was anxious to see that there was evidence of

safety that would be there in respect of the children's individual requirements.

Q Could you just help us with the benefit risk ratio point? Just explain that a little more for - I do not know if everyone is familiar with that, but just explain a little bit more what is meant by that?
A What I meant by that was that there are two things in opposition here. One is the risk of the disease itself and there is also, on the other side, the risk of an adverse effect arising from the administration of one or other of the vaccines. This is a common concept in any form of medicinal product therapy that you have to balance the benefits that you are going to gain from administering the product in comparison to the problems of the disease.

MR STERN: Let me just pause a moment, please. (*Pause*) It is paragraph 19 I am looking at:

Q Dr Fletcher:

> "It is indisputable that over the past 100 years the profound influence of improved social conditions and the quality of health care has been responsible for a major reduction in morbidity and mortality …",

and you say:

> "The extent to which national vaccination programmes have contributed to this reduction is difficult to assess".

Just explain that. Why do you say that?
A Because the two things coincided in time. The two things were happening together, and to separate the influence of preventative therapies such as vaccines in the same time that social conditions and health care and nutrition were also improving may be - well, perhaps they may be impossible to separate from one another.

Q Paragraph 20, I think you have just touched on this:

> "… an evaluation of the risks of the infectious diseases themselves",

and then you say at the end of paragraph 20:

> "When annual mortality of the childhood diseases approaches single figures the greater the safety of vaccines have to be if their risks are not to exceed their benefits"?

A Yes.

Q Could you just help us with this. We have not touched on it in this case, but I would just like to ask you briefly about it, multiple vaccinations. Does that have any impact on this, in your view?
A Yes, I think it does very definitely. The term "multiple vaccines" I presume

means where you have them together as a combination product and so are injected at the same time. You could also say that multiple vaccines could be separate ones given on the same day.

Q Yes, either or both of those?
A There may be a difference.

Q Pardon?
A There could be a difference in that because of ---

Q Let us deal with the latter, because we have not primarily dealt with the former. So the latter, which is a number of single vaccinations?
A Right. This is something I have not been entirely sure myself about what the case is about, as to whether in fact we are talking exclusively about single vaccines of which some are not available at the moment and so you have to give them as a combination product.

Q Yes, I am sorry. I think that is probably my mistake. Yes, thank you. Looking at them multiple as in together then, yes?
A As a combination product?

Q A combination, yes.
A Yes, I think that is very difficult to evaluate at the moment because we do not have that much information on that sort of thing. That is one of my problems.

Q So that is the point you are making, I think is it?
A Yes, it is.

Q That there is insufficient information?
A Yes.

Q I see, all right. Paragraph 22, I think that is a point that has already been dealt with - the herd immunity point.
A Yes.

MS GOULDING: I am afraid I am getting quite distracted.

MR STERN: I think, if I may say so, that I know Dr Goodman is just trying to arrange his thoughts, because that is difficult when one is dealing with a subject that is quite difficult and detailed, but it is obviously important to listen to the evidence first of all before seeking to try and find ways in which one might like to ask questions about it that actually - I do not want to say undermine, or even assist it, whichever it is. I do not know what the position is. I cannot tell. However it is important, obviously, that one evaluates the evidence fairly by listening to it and obviously if there are points that one wants to make about it Dr Fletcher is here to answer them.

THE LEGAL ASSESSOR: Yes. I wonder if I might say something about this, because this is not the first time this subject has been raised and perhaps I could give a little advice to the Panel.

MR STERN: Thank you.

THE LEGAL ASSESSOR: It is perfectly possible, of course, for some people to be able to listen to cross-examination and the evidence and at the same time look at some other document which arises out of cross-examination. With other people it is not possible, and there is a danger in any event of being distracted by what you have to read and therefore not listening. So I would advise the Panel that it is important to listen not only to the cross-examination, but the points that are being made and the answers to them, and if as is almost certain it puts into any of their minds the wish to look for some other document, then they can make a quick note of that and look at it later. However it is very important, justice being seen to be done as well as being done, that every panellist appears to be listening carefully to the cross-examination, or examination in-chief, and the particular document which is being examined.

THE CHAIRMAN: Yes, thank you. That is very helpful. Please continue.

MR STERN: (*To the witness*) Paragraph 27 is what I was going to look at next. You deal with the published references and the amount of them and you make this point:

> "If such selection is not to be permitted then the reader should be advised to read the articles in their entirety".

How does one write a report without actually selecting various parts from the research?
A I do not think that is possible and particularly in the circumstances in which this was being done.

Q You make the point after that sentence:

"Since Dr …" ---

(After a pause)

THE CHAIRMAN: Dr Goodman has asked if you could take the points a little bit more slowly.

MR STERN: Of course. Of course. I thought I would take them at a bit of a speed because I thought everybody had read this.

THE CHAIRMAN: We have read this.

MR STERN: You have read it, yes. However, obviously if I am going too fast then I am sorry:

Q *(To the witness)* At the middle of paragraph 27 ---

DR GOODMAN: Excuse me, could we just hold on while I consider what Dr Fletcher has just said on the previous paragraph, because ---

MR STERN: We have not looked at the previous paragraph.

DR GOODMAN: No. I have to say, Chairman, I am ---

THE CHAIRMAN: We have skipped the previous paragraph.

DR GOODMAN: I have to say, Chairman, I am finding that Mr Stern is proceeding so quickly that after an issue has been considered based on my previous reading of Dr Fletcher's reports, which include a lot of issues raised in other parts of his reports and in parts of Dr Donegan's report and Dr Elliman's, that the points he is making he is running on rather quickly for my consideration of each point.

MR STERN: Certainly. I do not know whether Dr Goodman would like me to go back over anything?

DR GOODMAN: I have got 22 and I am trying to absorb Dr Fletcher's answer to 22 - paragraph 22.

MR STERN: Yes. I think that actually paragraph 22 the reason I skipped over that is because it is a repeat of an earlier point and so I did not want to repeat the points. That is the reason I was ---

THE CHAIRMAN: Of course, we will have full opportunity to ask questions.

THE LEGAL ASSESSOR: I was going to say, because I have not seen anything wrong with your cross-examination.

MR STERN: Examination in-chief.

THE LEGAL ASSESSOR: I am sorry, examination in-chief, nor have I seen anything wrong with anyone's examination in this case. You are entitled in fact to examine at whatever speed you like, but obviously you want the Panel to get the points that you are making. Of course, as the Chairman has just said, if any panellist is not satisfied with or does not follow the answer which is given, then that panellist can ask the witness himself at the end of the evidence to clear up that particular point. However, if you would take it slower because Dr Goodman has ---

MR STERN: Yes, of course, if Dr Goodman is having difficulty I will slow down. What I propose is that I go through it, I hope at a pace that is manageable for everyone and comfortable for everyone, and then if anyone wants to have a break, read the report again, then come back and ask Dr Fletcher questions, that may assist both Dr Goodman or indeed anyone else.

THE CHAIRMAN: Thank you. Please proceed.

MR STERN: Thank you:

Q *(To the witness)* Paragraph 27 is what we were looking at and you were making the point and I will just repeat it:

> "… 130 published references … large volume of such publications a considerable measure of selection is mandatory",

and you dealt with that. You say:

> "If such selection is not to be permitted, then the reader should be advised to read the articles in their entirety. Since Dr Donegan had been requested to respond to a report that extolled the benefits, it was reasonable for her not to repeat that view but to draw attention to hazards of vaccination as set out in the letter of instruction from Battens."

I think that is a point that you have already made but it is a slight gloss on it, if I may say so?
A Yes.

Q Just pause there. (*Short pause*) If everyone is happy, I will move to paragraph 32. Having dealt with the social conditions, you now deal with immunization. You say:

> "There is absolutely no doubt that over the past hundred years childhood vaccination has, globally, dramatically reduced morbidity and mortality from the common infectious diseases"?

A Yes, I think that is a general statement that is acceptable, in my mind.

Q For the rest of that paragraph – I was not going to go through it – you deal with the figures that show the reduction in the disease?
A Yes.

MR STERN: Madam, as you can see, Dr Donegan has just arrived. We will carry on. For Dr Donegan's reference, we are at page 10 of Dr Fletcher's report, paragraph 32, which we have just completed.
Q So again, I think you expand ---

THE LEGAL ASSESSOR: Mr Stern, I am sorry, it has occurred to me, because I was rather taken by surprise, that there is another point that I should mention in relation to what we were talking about a little earlier, if Dr Goodman in particular is troubled. Am I right in saying that effectively what you have decided to do with this witness is precisely what Mr Kark decided to do with Dr Elliman when examining him in-chief, because the Panel would have read Dr Fletcher's report in the same way as they would have read Dr Elliman's, and you were therefore going to just take him through it briefly and leave it to Mr Kark to ask any questions on any subject about which they were not satisfied and then for the Panel to do the same if they wished to do so?

MR STERN: I know that it was a long time ago, but I think Mr Kark mentioned this right at the outset, that we together had discussed the case, and in order to assist the Panel with what we felt was obviously quite complex information, we felt that it would be helpful for you to have all the expert reports in advance because obviously trying to cross-reference

everything is an enormous task, and that Mr Kark would then take the report of Dr Elliman as having been read and would just point to various points in his report as he went through it in-chief, saving, we thought, about two or three days; and you can see from the cross-examination that that must have been about right. Likewise, in this evidence-in-chief I am not going through any of the specific points for the same reason. That is the way we have done it. I hope that the Panel approve. I see by the nods in the main that that meets with your approval.

THE LEGAL ASSESSOR: Thank you.

MR STERN: Thank you for again drawing that to my attention.
Q I do not need to ask you any more about the figures. In paragraph 33, at the foot of that page, you are dealing with the risk benefit or benefit risk balance of vaccination. You say:

> "When mortality due to the disease is as low as 20 (out of an annual birth rate of more than 500,000) …"

But I think you have looked that up again, have you?
A Yes, there are more than that; there are probably somewhere in the middle six hundred thousands at the moment.

Q "… then, clearly, that due to the vaccine must be less than 20. This implies a precarious balance between the benefits and risks for the individual child." I think that is your point, that the balance of the risk is set out by those figures?
A Yes, that is the view that I came to from past personal experience that when you get down to those sorts of numbers, it becomes quite difficult to do the balancing act.

Q I am now going to turn to paragraph 35, which is about adverse reactions or suspected adverse reactions to medicinal products and the question, which we have touched on a number of times, between temporal and causal relationship. Do you have anything to say about that which might help the Panel?
A That is a very difficult question to answer, because we could probably discuss this for several days if we wanted to. It is a major problem that has always existed ever since the early 1970s when the Medicines Act was first put into action. To distinguish between what is a purely temporal association between an adverse effect and its cause has probably created more arguments among people sitting for this thing. I should say perhaps that I have not included it here, but this point has been actually addressed in my chapter in the *Textbook of Pharmaceutical Medicine*, which really I think this is a generally accepted point, it is not a sort of referential thing; but there are really three methods that have been used by the pharmaceutical industry in the development of new products. One is a use of baize theorem, which is a very complicated way of assessing prior and post risks, which essentially has been abandoned by the pharmaceutical industry because it is impractically complicated. There is another, numerical system by Benichou and Danan, which is used sometimes, and the other one that most companies seem to fall back on nowadays is what is called inspired guesswork; and they seem to work much the same.

Q Turning to page 12, if everyone is comfortable with that, I am going to look at

diphtheria just very briefly, as it were, because, as I say, the individual points are there and you have set them out. Actually, on reflection, I think we can just turn to your paragraph 44, because you have set out your reasons earlier and there is no point in going through them again.

A Exactly.

Q In short, you say:

> "My careful appraisal of this short topic is that although some errors are apparent I am unable to support a view that Dr Donegan had distorted a reasoned picture of diphtheria vaccination taking into account that she was responding to a prior report which necessitated a measure of selection."

You then deal with the various points but, as I say, I am not going to ask you about those because ultimately they are a matter for Dr Donegan's evidence.

A Exactly.

Q I just want to ask you a little bit about paragraph 45, where you say:

> "The DTP … vaccine has probably been (and still is) the subject of more controversy than any other. As the Principal Medical Officer and the Medical Assessor to the Committee on Safety of Medicines, I had overhead responsibility for the assessment, evaluation and regulatory action demanded by DTP vaccine associated adverse effect reports…"

You then say that you were promoted. Is there any information that you have about that which will help the Panel or not?

A I would like to reiterate the fact that it is a continuing problem to decide whether or not the various neurological adverse effects that have been observed are temporally associated with the administration of pertussis vaccine, or vaccines which contain pertussis vaccine. The origin of this problem was probably somewhere about 1975 or 1976. The Committee on Safety of Medicines considered it on several occasions and the job was handed over to a particular senior medical officer who continued to spend, I think, about two or three years in doing this, scrutinized a large number of individual patient reports rather than going through epidemiological type studies, which I think the committee had decided were probably not appropriate in this particular circumstance. That was a committee decision. At that time the overall impression given to the Medicines Division and the Committee was that there probably was a causal relationship here but that perhaps the evidence available was insufficient to put that in solid terms, and it was left as a need to put further warnings in the official literature that was available to doctors. In those days it was not available to patients, but it was clearly instructions to doctors as to how to deal with that situation.

Q You touch on that in paragraph 50, referring to Dr Holgate. Just help the Panel with who he is or was?

A He *was*. I am afraid he is not with us any longer. Dr Holgate was an extremely able principal medical officer and he was in charge of the biological section, which of

course included many other substances apart from vaccines, but he then had overall responsibility, through the biological subcommittee, to take this under his wing. I did not personally have anything to do with this, apart from being the medical assessor to the main committee itself, so what his committee decided passed through me on the way through. I think he was a man who was not in fact in any way involved with any, shall we say, inappropriate connections, and he had a very straightforward and honest view of what was happening. I think the chapter that he wrote in the book *Iatrogenic Diseases* does paint a fairly accurate and balanced picture of the situation. I mention it because it is a reference that has not appeared in any of the other experts' listings.

Q One of the few, probably. I think you deal with that over the page, the other part of paragraph 50, where you quote a bit from his book, and indeed you have given the reference there?
A Yes.

Q Paragraph 52, please. I do not want to go into this in any enormous detail. Dealing with thiomersal, can you just help us with that, please? You say that Dr Elliman criticises Dr Donegan – and indeed I think she was cross-examined about it yesterday – for citing a publication that he has been unable to locate, which refers to renal toxic effects of thiomersal. You say that, whether or not this particular reference can be found, there is a paper which clearly states nephrotoxicity for the substance?
A Yes.

Q Just explain what that means?
A I did not want to go into any detail about this. I merely re-looked at this particular paper because, in fact, it did actually address the matter of renal toxicity. I think probably the calculations that can be made from that paper do not stand up to much criticism, but the fact is that for probably the last 10 years the role of thiomersal as a toxic component has been widely debated, and I think it is still a source of considerable disagreement. We could go deeper into that. I am not an expert on thiomersal, so I will leave it at that.

Q Just dealing with that paper though – and it has obviously been disclosed to the other side and the reference is there – in your view, that paper clearly states, does it, nephrotoxicity for the substance?
A Yes, it seems to me so.

Q Then I think you deal with what is called the *Simpsonwood Retreat* at paragraph 53. I will not ask you anything about it. It is on the website. I think you have given the reference there. Then I think we can turn to page 18, paragraph 58, the reference of Nilson, which Dr Elliman criticises Dr Donegan for not including. As we know, he states that it relates to 2000 patients?
A Yes.

Q What is your view of that paper? You have read it, have you?
A Yes. I think I would need some more time to go back over that, as it is not held in my memory exactly, but the point of my criticism there was that I had rather read the paper that I think is at the following tab number to the letter which was done. It is the letter which refers to, I think, about 9,500 patients which were divided into four separate sub-groups, which does give 2000. I had the second paper, which does not mention that

A but deals with a further subset of 699. Is that right?

Q Six hundred and sixty nine, I think.
A Yes.

Q That was the point?
A That was the sole purpose of my comment.
B Q Can I just go back, please? I asked you the question but I am not sure that we have an answer. What is nephrotoxicity?
A Kidney toxicity.

Q That is what it means, is it?
A Yes.

C Q Paragraph 59. Dealing with it in general terms, in the middle of the paragraph you say, "A major problem with all spontaneous systems is under reporting." Can you just help us with what you mean by under reporting? What is that?
A Again this is another topic that could be discussed at great, great length.

Q Well, shortly please.
A The yellow card system in this country originated somewhere around 1972. I
D forget the man who actually thought it up, but Professor William Inman was the person who really introduced the yellow card system, which is one form of spontaneous adverse event reporting. Even Bill Inman himself agreed that it was a rather poor thing and was the best that could be done at the time – perhaps at any time really – in that there was always going to be a rather large and probably unquantifiable measure of under reporting going on, that not every doctor would participate and that many doctors would find differences in what they considered to be a reportable episode and what was not, and that
E has continued right up to the present time. The purpose of my two papers that I refer to there was to ---

Q They are your papers?
A They are both mine, yes. They were both an attempt to make that quantification by using new data which had become available through a system that coincidentally in the same study had active reporting and spontaneous reporting, so you could thereby
F compare the rate of active reporting with the spontaneous reporting and thereby calculate a factor that could be used to correct the amount of under reporting. There may be some other papers, but I am not sure that I know where they are. That showed that, in fact, the degree of under reporting is very considerable.

Q You say:

G
> "…and in efficient national systems averages out at a generally accepted figure of about 90%."

A Yes. It is a very rough figure but it is one that people just use, because you have to use some figure to say, "Well, perhaps we ought to multiple everything by ten in order to get somewhere nearer the real figures". In fact, it may have been much higher than
H that.

A

Q So the point in relation to this is that when it is said that there are rare adverse events or rare suspected adverse events, is it possible to say how rare it is, if there is under reporting?
A Not with any degree of accuracy, but an indication that perhaps the number that you have is much smaller than it should be and you can use these figures as a sort of guideline as to where you are.

B

Q I think the mathematical formula says 90 per cent but it could be anywhere between?
A Yes, wildly different.

Q That is very fair. Thank you. On page 19 are the individual comments that you make about those and I am not going to ask you about them. At paragraph 61 you indicate that you are unable to support a view that Dr Donegan distorted a reasoned picture of pertussis vaccination?

C

A Yes. May I say that at this time I made these comments because I thought that they were relevant, but now, thinking about them, I feel that they are not directly in my sort of expert field? They were necessary, I thought, in order to sort of address myself to these things.

D

Q You tell us what you feel is your expert field then?
A I think it is the matter of medicinal product safety, is what I think it is, and these obviously impact on that but they do not seem to me to be quite what I was thinking about at that time.

Q You deal with polio over the page and you deal with HiB; then you deal with meningococcus C at page 22, again the individual points?

E

A Yes.

Q Measles, mumps and rubella at page 23. I am leaving out the table because it is there for you to see and it there is not much point in repeating the same thing that is there. Just dealing with measles, mumps and rubella, you deal at paragraph 64 with the temporal association of the MMR vaccination, and you say it should be emphasised other vaccines, and that these observed adverse effects, although the matter of causality remains unresolved, as you say?

F

A Yes.

Q In paragraph 67 you say that Dr Donegan has cited 23 references ---
A Can I go back again?

G

Q Yes, please do.
A I am sorry about this, but I would like to make it clear to everyone here that in fact I have been very closely involved in the whole of the MMR litigation, in which I had been an expert up until the time at which legal aid was withdrawn from that. Consequently, I have been told by the court that the disclosure provided by the defendant licence holders is strictly confidential, and there is much of that which should also be covered by commercial-in-confidence requirements; and, as I am a signature to the Official Secrets Act, I am also held by that.

H

A

Q I would not want to be part of breaching that, that is for sure.
A I thought I ought to say that.

Q No, no, it is in your report. I am sure it is in your report. I think you say it there. I cannot remember the exact paragraph, but I am fairly sure that you made that point. At paragraph 67, you are dealing with the:

B

> "23 references which are, in general, unremarkable but provide published information relevant to vaccination against measles that seems to be evenly balanced".

You say:

C

> "Four of the references are predominantly concerned with measles in developing countries and are of doubtful relevance in this case but do support the possible value of vitamin A supplementation in deprived societies. Four further papers are concerned with measles in certain religious communities which are believed to have very low or zero levels of vaccination. These are small poorly recorded communities which are probably of limited relevance",

D

you say. Then you talk about a paper called *Ronne*, which I think you had not come across before, had you?
A No, I had not indeed. It was something completely new to me, that was, and I mentioned it because it did contain some rather interesting and I think unconfirmed findings.

E

Q Going over the page, please, to paragraph 70, you deal with criticism from the earlier page that Dr Elliman deals with and I need not ask you about that. Paragraph 71. This is, I think, part of cell mediated immunity point, is it not?
A (*No verbal response*)

Q

F

> "The facts are that vaccine derived measles virus is, in some individuals, retained in the vaccinees intestine and other tissues and may be associated, directly or indirectly, with the development of an autoimmune disorder and, as a consequence, does have the characteristics of the wild type virus"?

G

A Yes, this is another I think strongly contested point of view at the present moment, but requires I think a great deal more attention in order to sort out how correct or incorrect that view is.

Q Then you deal particularly with a criticism of Dr Elliman about the Dr Cutts's paper, and at the bottom of page(*sic*) 73 you say:

H

> "In the light of this cautious statement"

- in the paper of Dr Cutts I think -

> "I find Dr Elliman's criticism that, 'Dr Donegan's reporting of this article is very selective, giving a message very different from that of the author' is unjustifiably severe"?

A Personal opinion.

Q Yes, certainly. Absolutely. The only reason you have been asked to give personal opinion is because Dr Elliman has been asked to give personal opinions as well. So, 26 is the same of the schedules, 27 is the schedules and ---

THE LEGAL ASSESSOR: Mr Stern, if it helps, on page 26, halfway down on the right, that is where Dr Fletcher as you said mentioned his disclosure of confidentiality.

MR STERN: Oh, yes, thank you very much. Yes, I knew I had seen it. Thank you very much. Thank you for reminding me:

Q (*To the witness*) Page 27 is the rest of mumps and rubella, then the second report you set out what you say in relation to the criticisms and I can turn then to page 30, because you looked at the allegations against Dr Donegan and you say at paragraph 78:

> "The views she has expressed may not be in line with Department of Health recommendations but are commonly voiced in general practice and the general public and are in line …",

and you say they are in line with your opinions?
A Yes.

Q "…commonly voiced in general practice …"? When you say in general practice, do you mean as a GP, or as general practice?
A It is probably not very important but, yes, it is hearsay. I have numerous contacts with various doctors in different areas and this is a feeling which is expressed quite frequently. Certainly I could not give statistical evidence of how often that has occurred, or what the veracity of it is, but it is one that is expressed.

Q So when I think Mr Cohen described it as "a lone voice in the wilderness", do you agree with that?
A No, I do not think I do.

Q No, all right. That is really the point I am dealing with. I want to ask you just about paragraph 79, which is quite an important point in relation to the research material. We have looked at the Cochrane Collaboration, but I would like your view. You say there in the second paragraph(*sic*) of paragraph at 79, dealing with the 250 or so research papers:

> "These publications may claim to be science based but are not science in the sense that physics and chemistry are science. Their

> scientific weakness is not a consequence of ignorance or incompetence but because they are beset by countless variables that prohibit any possibility of precise repeatability. In these circumstances the ascertainment of causality is often beyond experimental reach and temporal association may be the best that is available. It is for these reasons that the cited research is fraught with uncertainty and that the balance of benefits and risks associated with the administration of the appropriate vaccines to these two individual children is an elusive goal".

You then say:

> "My belief is that Dr Donegan has responded to the reports of other experts in the way she has been instructed and, in so far as the sequential exchange has permitted, has provided a fair and comprehensive opinion".

Now, just help us with what you say about the research and why it is not science in the sense of chemistry and physics? What do you mean by that?

A I will start with the chemistry and physics first of all, as I have been in that business myself. Science in that sense is testing hypotheses by what are repeatable experiments. You do the study, you do the experiment, you find the results, you write it up, you hope accurately and comprehensively, and anybody else in the world who is interested in the same thing could go away and do what you say and hopefully get the same results as you did. If they do not do that, then clearly you will have differences between you and you will have to sort this out in some way and that is the way that science progresses. Most studies have got some errors in them and, when those are pointed out, the best thing to do is to go back to the bench again and find out where the discrepancies arose. You cannot do that in clinical medicine, because each time you do repeat a study it is sufficiently different from the previous one to leave a large number of unanswered questions. This is common knowledge. People are different from one another and the biological variability between different human beings is sufficient to make the findings doubtful. I do not say they are completely incompatible, but sufficient doubt for you to say, "Well, I am not sure that I believe that".

Q What about bias of some of the research papers? I do not mean intentional bias obviously, but I am thinking about the bias in the results.

A Even in the hard sciences, as I say, and having been one myself, one tends to look at one's own hypotheses with a sort of possessive interest and you tend to try and keep it going as well as you can. I think this is a natural and perhaps erroneous thing to be doing, but it is inevitable that the authors of papers do tend to defend the contentions that they are putting into them. That may be intentional, but very often it is not intentional and that exists.

Q Can we just then briefly look at your overall conclusions at page 31, paragraph 80, where you say:

> "I have scrutinised all reports that have been provided … During this process"

- paragraph 80 I am on -

> "I have questioned whether or not Dr Donegan has been fair in her reports and responses within the terms of her instructions and whether her medical knowledge and experience qualified her as an expert in this case. My field of expertise relevant to this case is many years of experience in the reporting and evaluation of adverse effects of medicinal products. This experience has included vaccines but has not been specialised in that respect. My opinion is that Dr Donegan has displayed a broad and balanced knowledge of vaccines and immunisation procedures as would be expected of a well qualified general practitioner. I have been unable to identify any intention on her part to mislead the court"

- that is not an allegation and so I can pass over that -

> "and consider that she has been open in her agreement when errors have been pointed out and has been articulate and understanding in her defence of differing opinions",

and then you deal with "the most demanding time scales" which the Panel have heard about. You say:

> "… therefore, my firmly held opinion that Dr Donegan was not selective in her reports or responses in ways that were not imposed upon her by the limitations of her instructions",

and you have been unable to discern any intention to mislead. As I say, that is not an allegation and so I need not ask you any more about that. I think that essentially follows the rest of your conclusions?

A Yes, I would say that certainly ---

Q Anything - I am sorry.

A No, I am sorry. I was just going to say that it certainly is my view.

Q Is there anything you want to add in relation to that?

A I do not think so at this point.

MR STERN: Thank you.

THE CHAIRMAN: Mr Kark?

(*A short discussion took place between Dr Goodman and the Chairman*)

THE CHAIRMAN: Dr Goodman would just like two or three minutes to put his papers in order. I think it is a bit too early to take a break. I was going to say we should, but we will just stay put.

MR KARK: While that is being done, I wonder if I could take the opportunity of just popping outside with Dr Elliman?

THE CHAIRMAN: Yes.

MR KARK: There are one or two questions I would like to ask him as a result of the evidence that has arisen and if I could take a few minutes to do that?

THE CHAIRMAN: Yes, of course.

(*After a pause*)

THE CHAIRMAN: Mr Kark?

MR KARK: We are all ready. Thank you very much.

Cross-examined by MR KARK

Q Dr Fletcher, could I just start by asking you really what you are an expert in?
A I thought I had said that, actually. My expertise derives from about 30 years of really dealing almost exclusively with the safety of medicinal products. I am not an expert, I should say and add to that, in the efficacy of medicinal products, which is a different side of that picture.

Q Yes. What about immunology? Have you ever trained as an immunologist?
A No.

Q Or practised as an immunologist?
A No.

Q Have you actually trained as an expert witness? Have you gone through the Bond Solon training and that sort of thing?
A No, I have not.

Q So, what is your training as an expert witness?
A I do not have one, in that respect, apart from having been asked to be one and having been accepted as being one and having had my reports accepted.

Q I think you said in your report that you have given evidence in three previous cases. Is that right?
A That is not quite correct, is it, because in fact I have not given - well, unless you say writing a report is giving evidence.

Q No, let us split them up. How many reports have you written for court proceedings?
A Three at the moment and I am involved in a fourth one which has had an interim little report done, but not an official one.

Q Could I just ask what the subject of those three reports was?

A Yes, the first one was the matter of the third generation oral contraceptives and the second one was the MMR litigation.

Q Obviously I do not want to know any details about that, but can I ask who you were instructed by?
A I was instructed by Alexander Harris.

Q Who is …?
A That was the firm of solicitors. I got into this in a - do you want to know this? How I got into this?

Q Who were they representing?
A They were representing the claimants. I am sorry, I did not understand that.

Q That is all I wanted to know. So, the claimants in the MMR litigation?
A Yes, Alexander Harris was the firm of solicitors that were representing the claimants at that time.

Q Then the third report?
A Is the one we are on now.

Q Oh, I see. Giving evidence in court proceedings?
A None of them came to that. I am sorry, perhaps I should say that my report in the first one on the third generation oral contraceptive was not required, the second one was accepted and is in from the MMR litigation, but that of course has been terminated by the lack of Legal Aid any further, and we are currently dealing with the other one.

Q So in terms of experience of court proceedings, actually giving evidence in court, is this the first time you have given evidence?
A Yes, it is indeed. Yes.

Q You told the Panel this morning that you have seen many, many, expert reports and you were asked by Mr Stern, "How many?", and you said, "Well, thousands of reports on product licence". How many expert reports for court proceedings have you seen, approximately?
A I can say that I have been supplied with all of the expert reports from both the claimants and from the defendants in the MMR litigation and that amounts to about 30.

Q That was in the case that you were involved with?
A Yes.

Q Yes.
A Well, yes, the second one that I referred to.

Q Yes. Any others?
A I think there was one in the third generation oral contraceptives, but that was quite some time ago and I cannot really remember much about that one.

Q So far as the 30 reports that you were served with, those were no doubt giving a

wide range of views I expect on the MMR issue. You were not being asked to study those reports, as it were. You were being asked to study the subject matter?
A Yes, indeed. In fact, the exchange of those reports was a simultaneous one. In fact, I was sent both the defence reports and the claimants' reports at the same time on a CD-ROM.

Q All right. So far as coming back to vaccinations for a moment, have you ever been in practice yourself where you have given vaccinations?
A No, I could not. I was a pathologist originally and I would not have done that.

Q Yes, quite.
A I have never practised medicine in that sense.

Q No, there is no need in those circumstances.
A No, not on cadavers.

Q Have you ever given patients advice about vaccinations?
A No, because my business has never been with patients.

Q No, all right. Could we just turn to page 4 of your report, please, and you start off on page 4 by saying:

> "It is my understanding that,
>
> a) Both fathers of the two children concerned were clear in their wishes that all recommended vaccines were to be administered at the appropriate times.
>
> b) Both mothers of the children, equally clearly, did not wish any vaccines to be administered.
>
> c) It was the individual childrens'(*sic*) balance of benefits and risks that were the sole concerns at issue. The best interests of the two children were paramount.
>
> d) The potential benefits in respect of population (herd) immunity or infectious disease elimination were not at issue.
>
> With the possible exception of holidays abroad the social and health care standards of the UK were assumed to prevail".

That may be right of course, but it could reasonably be expected that either of these children could travel abroad within the next ten years or so?
A I suppose it was, yes, but that was not what I was led to believe.

Q Can we turn to paragraph 13. In paragraph 13 in the middle - and this has been drawn to your attention I think this morning by Mr Stern - you say:

> "The expert opinions which derive from this process may or may not

> be in agreement with the opinions of the authors. Since these requirements are fundamental principles for all Experts it is not to be expected that an Expert will state explicitly on each occasion that opinions differ".

Now, you no doubt had in mind also when you wrote your report paragraph 51 of *Good Medical Practice*. Can I read it out to you?

A I think I know. Yes, please do.

Q Do you know it?

A Well, I might even have got a copy of it in front of me.

Q Shall I read it?

A Yes, please do so. That would probably be better, actually.

Q That will save you having to dig it out.

A I think I can find it.

Q It says:

> "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",

and I do not think I need to read the rest because it is about how quickly you do it.

A No.

Q However, those words:

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

are very relevant to this case, are they not?

A Yes, I suppose they are.

Q I am sure you accept that, although obviously it would be impossible to reflect the entirety of the research that we have been looking at in this case, what is important is that the writer of an expert report accurately reflects the sense of the research? Do you agree with that?

A I am not sure whether I do, or not. It is a difficult question to answer, that one, and I am not sure whether or not the independent views from their experience of an expert might mean that they give a free opinion of their own.

Q Can I put it another way. What you cannot do is take a small piece of information from one report, or from a report, and ignore the conclusions that that research leads to?

A I think that is up to the opinions of the expert themselves, surely.

A

Q We will have to look at that. You agree, I presume, that you cannot misquote research?
A Yes, I will agree that if there is a precise quotation.

Q You cannot - I am sorry, I will pause.

B (*A short discussion took place between the Chairman and the Legal Assessor*)

THE LEGAL ASSESSOR: I am sorry, Mr Kark. I am getting a little bit concerned as to the question of this witness's expertise.

MR KARK: Yes.

C THE LEGAL ASSESSOR: He is giving an opinion, and has in his report, as to a report given by another doctor. He has now told us that he has never given evidence before.

MR KARK: I agree.

D THE LEGAL ASSESSOR: We know that so far as Dr Donegan is concerned it was the first time that she had made a report, but I assumed from the fact that there was no objection to Dr Fletcher's report going in and you do not seem to be taking the point, although I was not sure when you were examining on expertise, that you seem to be accepting that this witness can give his opinion on someone else's report.

MR KARK: It is a fair point to raise.

E THE LEGAL ASSESSOR: It seems to me you can only do that, or indeed he can only give the evidence, if he is an expert, because it has got nothing to do really - well it has got obviously something to do with clinical expertise, if I can call it that, but he is really giving opinion as opinion.

MR KARK: As an expert.

THE LEGAL ASSESSOR: As an expert.

F MR KARK: Well, sir, that is right. One can deal with it in two ways, I suppose. First of all, one could take a primary objection to the evidence being given at all. Secondly, it could conceivably simply be a matter of the weight that the Panel attaches to any of his evidence if they were to conclude - and it is a matter ultimately for the Panel - that his expert expertise, if it is there at all, is extremely limited.

G THE LEGAL ASSESSOR: He would be, if he was writing a report, bound by the duties which we all know about now in the same way as Dr Donegan is.

MR KARK: Yes.

H THE LEGAL ASSESSOR: So in that sense someone might be considered to be an expert because they know the rules and it might be that their opinion on someone else's

report would be relevant and admissible, but if it is an opinion it seems to be only admissible if he is an expert on that.

MR KARK: Yes.

THE LEGAL ASSESSOR: I am not saying he is not and indeed I have been rather accepting up until now that it is agreed that he is, but I was getting a bit worried when you were cross-examining.

MR KARK: I have to say that so had I, but my questions at the beginning were designed frankly to try to flush out exactly what Dr Fletcher's expertise was.

THE LEGAL ASSESSOR: Yes, but we are not dealing here and you have already indicated that you are not saying that Dr Donegan's opinion is wrong, any more than you are saying that Dr Elliman's is right.

MR KARK: Oh, you mean conclusion.

THE LEGAL ASSESSOR: Yes, conclusion, I am sorry. So, I understood that this was really a case of expertise in writing a report in the light of the duties which every doctor knows by inkling.

MR KARK: If the Panel were to take the view that having now heard how Dr Fletcher puts his expertise - and nothing I say, I hope, will be taken by him as being rude in any way. However, if the Panel were to take the view - and they may want to consider this, I do not know, in camera - that while he may be an expert in other areas of medicine he is simply not an expert because (a) he has no real knowledge of immunology it would appear at all, never having studied it, and (b) he has not done any particular expert training in relation to how to give expert evidence, if the Panel were to conclude that he is in those circumstances really unable to assist them as an expert and therefore proffer his opinion, then I would not need to go any further frankly.

THE LEGAL ASSESSOR: But he has written reports, as he has told us.

MR KARK: He may have written reports but ---

THE LEGAL ASSESSOR: He has said that he has written reports on previous occasions and knows the rules by which he is bound, so it may be that Mr Stern effectively will be saying, "He does have some expertise and is in a position to be able to…" and there are some analogies to the *Meadows* case in the sense that we are talking here about expertise or possible expertise outside doctor/patient expertise.

MR KARK: I would say that Dr Elliman, in my submission – and it was never seriously challenged – his expertise I think was challenged on the possible suggestion of bias, as it were, although that was not really pursued, I do not think, by Mr Stern. He, of course, however, is an immunologist and has also done expert training. Let me sit down to see what Mr Stern says.

MR STERN: I wonder if I might intervene in this conversation. If I may say so, with

respect, there was a fundamental misunderstanding, in my submission, with the points that are being made. First of all, this expert report was disclosed to my learned friend Mr Kark before this hearing, sometime before this hearing but I cannot remember exactly when – maybe a week or two. It is somewhat unfortunate that at the end of his evidence-in-chief this matter is now being dealt with. That is my first point, but that does not, if I may say so, go to the specific points raised by the learned Legal Assessor. The issue that one has to determine is what one is looking for in terms of expertise. What is the expert evidence required? Neither, if I may say so with respect, Mr Kark nor the learned Legal Assessor dealt with that issue. This is not a case about expertise of vaccinations. As was just pointed out, the opinion on vaccinations is not in dispute.

The second matter is this: the issue in relation to this case, as Mr Kark has already made clear, is about the writing of expert reports. It is about the objectivity and/or otherwise of expert reports. I submit that Dr Fletcher has a considerable degree of experience and expertise in reviewing expert reports. Whether or not they are for court is, in my submission, irrelevant. They are medical reports that are put before him to objectively actually consider the safety of medicines. Now that is putting both sides, assessing… Well, I will not say more because we will get more from Dr Fletcher if anyone requires it. But those are objective reports in relation to medicinal safety. Therefore, Dr Fletcher is extremely experienced in looking at expert reports in that area. That is the issue with which you are concerned. His sphere of expertise is in medicinal safety and, if I may say so, in expert reports.

The fact that he has no expert training is, in my submission, a point in his favour, not a point against him. I am disturbed to hear for the very first time that Dr Elliman has apparently had expert witness training. I thought that Mr Kark had just said that.

MR KARK: He gave evidence of it.

MR STERN: No, he did not. You can show me in the transcript, if you will, where he mentioned that.

THE LEGAL ASSESSOR: Mr Stern, as far as I am concerned ---

MR STERN: It is not in his report. I am sorry, I must just finish this point because it seems to me that this is…

THE LEGAL ASSESSOR: I think you are right about that.

MR STERN: …extremely disturbing.

THE LEGAL ASSESSOR: Dr Elliman nodded in ---

MR KARK: My recollection is that it was Dr Elliman who had said that he had had the Bond Solon training.

THE LEGAL ASSESSOR: Dr Goodman did.

MR KARK: I do apologise. I am sorry, Mr Stern.

A

THE CHAIRMAN: Yes, it was Dr Goodman.

MR STERN: Are you saying then that Dr Elliman has not had expert training or that he has? If he has, I think that should have been disclosed.

MR KARK: Can I find out at an appropriate break and relay it to Mr Stern?

B

THE CHAIRMAN: It is a question of "yes" or "no", is it not?

MR STERN: If it is "yes", I would like a little more detail, but yes, I appreciate that.

C

THE LEGAL ASSESSOR: Mr Stern, I was going to stop you for this reason: you have very clearly explained what your position is and why you say that this opinion is admissible, and that has satisfied me that I can advise the Panel that it is admissible. The reason you understand why I interposed was as a result of Mr Kark appearing to me to be suggesting that he had no expertise in this regard, otherwise why ask about how many reports et cetera he had written.

MR STERN: I agree.

D

THE LEGAL ASSESSOR: I was also concerned when he asked the question whether he had had expert training. That took me rather by surprise, because there must be many, many experts who give evidence about a report when they have not had any training. But, be that as it may, I am now quite satisfied that I do not have to advise the Panel that this witness has no expertise in this regard and, therefore, his opinion is admissible.

E

MR STERN: Thank you very much. I hope it is accepted that I would not put forward an expert report in this way unless I considered that this person was an expert in the sphere in which I am proposing that he give evidence about or be cross-examined about now.

THE LEGAL ASSESSOR: You may have done it but it would have been wrong, but, of course, as you have indicated, no objection has been raised previously to this report being produced.

F

MR STERN: Exactly.

MR KARK: That is right but, just to finish off this topic, the Panel are still, in my submission, entitled to decide what weight they give to the opinion that is proffered. That is not, as it were, a dead subject.

G

THE LEGAL ASSESSOR: That, of course, is right, and I do not think that Mr Stern ---

MR STERN: That is the nature of evidence, that it has to be evaluated by the Panel. That is why I am calling it before you and the witness is about to be cross-examined and you will make such of it as you will. May I take it then that Mr Kark is not suggesting in any way that Dr Fletcher is not an expert, because I think that needs to be clarified?

H

MR KARK: All I can do is test with Dr Fletcher what his actual expertise is, and I think I

A have done that, and then it is a matter for the Panel and a matter for what weight the Panel will ascribe to the evidence that they are going to hear.

THE CHAIRMAN: Do you want to go over the training point?

MR KARK: The note that I have from Dr Elliman is, "I have had no expert witness training but I have had training as a professional witness". I am not really sure what that training is. I do not know whether Mr Stern wants to take that any further.

B

MR STERN: I am slightly surprised that Mr Kark does not want to take that further, rather than me, because he is under an obligation to ensure that these matters are all disclosed in advance. If there is a distinction – and it seems a semantic distinction, if I may say so – between expert and professional training… I can see Dr Elliman trying to involve himself in it. Perhaps he would just restrain himself for a moment and address any of his remarks through Mr Kark. If there is such a distinction, this can be set out in writing and I can look at it and indicate whether I have any further submissions about it, but it is a matter, in my submission… Well, I will not make any submissions about it; I will do that later.

C

MR KARK: We can do that. I will ask Dr Elliman to set out his specific position.

D

THE CHAIRMAN: Please continue.

MR KARK: I think we were on paragraph 13 of your report, Dr Fletcher. Sorry for that brief interlude. I was asking you whether you agreed that, first of all, you cannot misquote research. I am sure you agree with that?

A Well, no, you cannot put in inverted commas something which is not there; yes. I mean if you are literally meaning the same words quoted, no, you could not do that, I agree.

E

Q Nor should you quote part of a sentence that leaves out the rest of the sentence and the sense of the sentence may be thus changed?

A I do not know how to answer that one really, because I do not know whether that is right or wrong. I really do not know the answer to that one. I think it is done many, many times, otherwise it is very difficult to know where you should end in such a thing.

F

Q Do you agree that you should not quote out of context?

A If you are meaning "quote", again as I have said before, the use of the precise wording that the author has used, yes, I would agree with that; but if it is a paraphrase of that, then I think that would be possible.

G

Q Do you think that if you disagree with the conclusions of an author, you should at least make that clear, in terms of a report that you are relying on?

A I think if you make that clear right from the very beginning as an overall statement, yes, but I do not think you have to repeat it each time you say it or do that, no.

Q Somewhere you have to make it clear that the authors whom you are quoting, or going to quote, do not actually agree with you?

H A I suppose that may well be every single paper that there is there, if there are

fragments of it with which you do not agree, and I would probably say that I do not agree with a large amount that is in the stuff that has been provided here. Well, I suppose if you are going to say that we have to repeat that each time we have said it, okay, I do not object to that, but I would not have thought that it was strictly necessary in a report.

Q If you do not repeat it each time, you at least have to make it clear somewhere in the report?
A Yes, that is what I said.

Q Let us turn to paragraph 15. You say:

> "The reports of both Professor Kroll and Dr Conway are, thus, unequivocally focussed upon the benefits, and therefore the safety, of the vaccines and have given absolutely minimal attention to their adverse effects even when they have been clearly included in official literature such as data sheets, package inserts and patient information leaflets."

You have repeated that evidence this morning. Could I just ask you to take up – I hope it will be made available to you somewhere – our file 4? Behind tab B, you will find tab 3. It is the first 3 that you come to in the report. Could you then go to page 10, the bottom right-hand corner?
A Yes.

Q This is Dr Conway's report of 28 May 2002. Do you see the heading, halfway down, "Potential Adverse Events/Results from Immunization", and then he goes through the adverse events for MMR; over the page, diphtheria, in short form; then tetanus, HiB and pertussis; and over the page, polio, meningococcal C and MMR?
A Yes.

Q Over the page, he says:

> "As with any medication, anaphylaxis may occur but this is extremely rare for all of the above vaccinations".

Do you accept, albeit in short form I accept, that Dr Conway did indeed deal with the adverse effects of these vaccinations – the known adverse effects of these vaccinations?
A I do not agree with that, because in fact what I was referring to were the precise… We have been talking about whether or not you should quote things accurately. I was talking about data sheets, package inserts and patient information leaflets which are agreed through the Committee on Safety of Medicines, through the licensing authority, as the official wording, and this is not that. It is not even describing which MMR it is. There are several different MMRs and I think they are not exactly the same as one another because they do not contain the same strain of measles. Therefore, you would have to do each one I think separately, and that is what I meant. He did not in fact refer precisely to the officially agreed statements of adverse effects.

Q But your wording is that he has given "absolutely minimal attention" to their adverse effects?

A That is an opinion of mine, as I said.

Q Can we go to page 6 of your report, please, and the very top paragraph, starting "balanced view"? You say:

> "It should be emphasised that the sequential nature of reports that has occurred in this case did not demand that Dr Donegan should repeat material already contained in the reports of Professor Kroll and Dr Conway."

I do not want to go through all the reports, obviously, but the position was that the first reports of Professor Kroll and Dr Conway were relatively brief, were they not?
A Extremely brief.

Q They did not set out any of the research as Dr Donegan did in her report?
A Yes.

Q Can you just help us, what are you actually saying in terms of Dr Donegan's duty? Are you saying that she was therefore entitled simply to give one side of the picture because the other side had already been given?
A I do not think I was saying either of those, but I think my understanding of the meaning of that was that having had the sort of Department of Health view put by Professor Kroll and Dr Conway, that was there on paper and Dr Donegan could assume that it did not have to be repeated each time she came to a particular point in her own report.

Q At paragraph 17 you say:

> "My opinion is that Dr Donegan has fulfilled the requirements of an expert as quoted above having provided evidence of her attention to the full publication, identification of specific items in the text and the provision of details relating to authors, journals and dates.
>
> In my opinion, she has demonstrated a commendable ability to present a full and carefully considered and balanced report in response to the prior reports from other experts. This level of ability is all the more remarkable in the light of the fact that the reports were produced under severe time constraints."

You consider Dr Donegan's reports to be balanced, do you?
A Yes, I do, taking into account what I have just said about the fact that the given prior statements from Kroll and Conway were, in fact, a part of that; they had become joined with it.

Q They were not joined with it; they were written prior to it. They were going to be submitted to the court and Dr Donegan's report was going to be submitted to the court?
A So you are saying that in fact she should have repeated what Professor Kroll and Dr Conway said each time she came to any point…

A

Q I am suggesting that she should have written a balanced report, and we will look at that. In reading her report, did you identify any significant errors at all?
A I am not quite sure what you mean by "errors" in that sense. Do you mean that she made factual statements that are incorrect?

Q We have suggested, as you know, that in parts of her report the sense as it was left was misleading, and Dr Donegan has accepted that in evidence.
B A I think that is her opinion on that one.

Q It is not yours?
A I am not giving an opinion on that.

Q Yes, you are; that is what you are here for. When you wrote your report, did you identify any aspects of her report that you considered to be misleading?
C A No, not misleading in that sense, no. I…

Q Sorry, did you want to say something?
A No, it is all right, I will not bother to go on.

Q In paragraph 18 you say:

D

> "A large part of the published references cited by the experts had little relevance to an assessment of the benefits and risks of vaccinations for the two individual children but were more concerned with efficacy in respect of population immunity which was not at issue."

Population immunity, of course, is the sum of individual immunity, is it not?
E A Yes.

Q At the bottom of page 6, paragraph 19 – I just want to make sure that I understand your view on this – you say:

F

> "It is indisputable that over the past 100 years the profound influence of improved social conditions and the quality of health care has been responsible for a major reduction in morbidity and mortality from the common childhood infections. The extent to which national vaccination programmes have contributed to this reduction is difficult to assess."

You are not challenging the suggestion that the national vaccination programme has had an enormous beneficial effect on childhood diseases, are you?
G A I thought I had dealt with that matter when I was referring to you. I thought I had already given an answer to that one.

Q I was just about to take you to paragraph 32, where you say:

H

> "There is absolutely no doubt that over the past hundred years childhood vaccination has, globally, dramatically reduced morbidity

> and mortality from the common infectious diseases. It is equally beyond doubt that vast improvements in social conditions in developed countries…"

et cetera. When you wrote the words, "The extent to which the national vaccination programmes have contributed to this reduction is difficult to assess", how did you mean it? Did you mean precisely in quantity terms?

A Yes, I did. I do not know how you can do that. I think that is what I said before, did I not?

Q Paragraph 20:

> "The relative risks of vaccination incurred by individual children can only be judged by an evaluation of the risks of the infectious diseases themselves. The greater the influence of improved social conditions and health care, the more demanding is the need to balance the risks of vaccination. When annual mortality of the childhood diseases approaches single figures, the greater the safety of vaccines has to be if their risks are not to exceed their benefits."

The reason that annual mortality is so low is because so few children catch these diseases because they have been vaccinated?

A I think that is a contentious issue. No, not necessarily entirely at all. They may not be catching the diseases because of other factors, like proximity of living.

Q There are all sorts of other factors that may be relevant, but your paragraph 32 I think makes it clear that you accept that childhood vaccination has, globally, dramatically reduced morbidity and mortality from the common infectious diseases. Do you not agree that at least a very significant reason why annual mortality is so low is because so few children catch these diseases because they have been vaccinated?

A That is a part of the problem, but only a part.

Q Can we go to your paragraph 22, please? You say:

> "It is my opinion that the reports overall and in particular those of Dr Conway and Professor Kroll had neglected to observe limitations imposed as a consequence of the fact that population immunity and disease limitations were not at issue in the legal case. Notwithstanding this limitation, Dr Donegan has been requested to broaden her remit to include medical research on the individual immunisations worldwide in her instructions from Battens, solicitors."

Now D22 is the letter that contains those instructions. Can I just read out the relevant paragraph? It is a letter dated 29 May 2002.

A I am afraid I have not got that.

Q Could D22 be passed to Dr Fletcher? (*Same handed*) If you leaf through those pages, Dr Fletcher, you will come to 29 May 2002, a letter from Battens, solicitors. Do you have that now?

A Yes.

Q Paragraph 2 of that letter states:

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

Do you agree that what those instructions appear to be asking Dr Donegan to do is to deal with the individual immunisations that these children were likely to receive in this country and the said effects of the same worldwide?

A I read the words, but I am afraid that I was in the position that I did not quite understand what they were wanting. Had I received that letter, I am afraid I would have written back to the people and asked what they meant by it, because I did not understand.

Q Can we go to your paragraph 27, please? You say:

> "Dr Donegan has based her report(s) on 130 published references. In the face of a large volume of such publications a considerable measure of selection is mandatory."

Just pausing there for a moment, Dr Donegan was being asked, was she not, to give her opinion on the comparable risks between the children having the childhood immunisations and not? She was being asked to give her opinion on both sides?

A Yes.

Q The comparable risks between the two?

A The comparable risks between getting the disease or getting the vaccine.

Q You say:

> "If such selection is not to be permitted then the reader should be advised to read the articles in their entirety."

You probably accept – I do not know – that although the experts instructed in the case were likely to read the research in its entirety, you have looked through it yourself and it is very unlikely that a lay reader would be able to do that, is it not?

A I am sorry, I do not understand your question.

Q You say:

> "If such selection is not to be permitted then the reader should be advised to read the articles in their entirety."

You mean the core research that was contained in the two bundles produced? Is that what you mean?

A What I meant was that Dr Donegan would have to make a selection from the articles that were being referred to.

Q But you are saying that if such selection is not to be permitted, the reader should

A be advised to reads the articles in their entirety. Can I take it that you agree that to the lay eye, the non-medical eye, certainly some of these reports would be extremely difficult for a lay reader to comprehend?
A Yes, I do agree with that. I think it is quite difficult for professional people to understand some of them too.

Q At the bottom of page 9, paragraph 29, you say this:

B

> "Following further responses from Dr Conway and Professor Kroll, Dr Donegan was, in turn, requested to provide a further report addressing the issues raised.
>
> It is my personal opinion that by this time any hopes of independent, unbiased reports had long passed."

C So you are saying that, in you view, the answer by Dr Conway was biased, that the response by Professor Kroll was biased and that the second report of Dr Donegan ---
A I do not think I was saying that. What I was saying was that a situation had arisen in which A said one thing, B responded to it, C said another thing and then that was responded to, and these were going on backwards and forwards, and that had been done on several occasions, so that the idea that any one of these people was in fact going to give a completely independent and uninfluenced report had gone, because they had all been referring to one another's.

D

Q You say:

> "It is my understanding that at this point Dr Elliman was requested by lawyers acting for the GMC to respond to Dr Donegan's second report."

E

Is that how you understood it, what Dr Elliman's role was?
A That is what I did understand, yes. I did not have documentary evidence from anybody else but that is what my understanding was.

Q Did you read Dr Elliman's report?
A Yes, I did.

F

Q He was not responding to Dr Donegan's second report, was he? He was commenting on both of her reports for the purposes of these proceedings?
A I am sorry, wait a moment. (*Pause*)

G Q Do you see what you have written? It may just be an error, I do not know.
A I do not know whether it is an error or not, but it is probably that I gained that from somewhere else. So, you are saying that I should have said Donegan's first and second report?

Q Well, he was not responding to anything. He was commenting upon the two reports, was he not, as an expert witness?
H A I have used the wrong word perhaps.

A

Q All right.
A We are talking about word definitions again, are we not?

Q Paragraph 33, please:

> "Taking the example of measles, the benefit-risk balance of vaccination for *individual children* is dependent upon the average annual mortality for the disease compared to mortality associated with the vaccine. When the mortality due to the disease is as low as 20 … then, clearly, that due to the vaccine must be less than 20. This implies a precarious balance between the benefits and risks for the *individual child*".

B

C

I just want to understand that. The mortality rate, do you agree, is likely to be higher in those unvaccinated than those vaccinated, because those unvaccinated are more likely to catch the disease?
A I was not actually meaning that. What I was meaning is taking the populations when in fact the whole population, which includes those who have had vaccines and those who have not, have come down to very low-levels. You also have to equate with that correspondingly low levels of adverse reactions. I merely said that if you get - this is only sort of a shot in the dark with 20, because it was a figure that has been published in many, many listings and things and so it has been available in those things. If the overall mortality from the disease gets below that, whether or not you are vaccinated, you do not want to be having a higher mortality from the vaccine itself.

D

Q No. However, just by way of example, if all of those 20 unfortunates who died were unvaccinated, then you would have to take that into account, would you not, when considering whether to vaccinate or not?

E

A I think what I am trying to say is that when the number is as low as that, whether you are vaccinated or not, it becomes extremely difficult statistically to distinguish between the two.

Q Dr Fletcher, with respect, you cannot say "whether vaccinated or not", because that is the issue. The issue is whether these children should be vaccinated and so to say, "Well when you have only got, by way of example, 20 dying as a result of the disease, you have got to consider the risk/benefit so much more carefully". If in fact the mortality rate of those unvaccinated is much higher then that makes, with respect, something of a nonsense of this paragraph, does it not?

F

A I do not see it that way, I am sorry.

Q Do you take the point that I am seeking to put to you?

G

A I am not sure whether I do, or not.

Q You do not see the importance of considering how many of those children have been vaccinated as compared with how many had been unvaccinated?
A I think we are talking at cross-purposes here, are we not? I think what I meant was if in fact let us say this hypothetical situation which I put here, suppose in fact that the vaccine was causing 50 deaths and there are only 20 from the rest of the population,

H

A then I would be very, very doubtful if I wanted to do it.

Q Yes.
A If the death rate from the disease as notified were 500, then I would say that was worthwhile.

Q Let us move on to your paragraph 35:

B

> "A general problem with virtually all suspected adverse reactions to medicinal products, which includes vaccines, is the distinction between a temporal relationship and a causal relationship. With very few exceptions the first reports of a suspected adverse reaction concern temporal associations of the reaction with administration of the product. Long experience has shown that it may be many years before causality can be established and in some cases that objective may be permanently elusive. From the point of view of medicinal product regulation the relevant authorities frequently have to take action, such as issuing warnings and other advice, on the basis of purely temporal relationships. This attitude of 'better safe than sorry' may be entirely justifiable as guidance in medical treatment but may fall short of requirements demanded in law".

C

D What did you mean by that?
A What I meant was that I had been led to believe in one of the previous cases which I have been involved in, which was the third generation oral contraceptives which was taken out under the Consumer Protection Act, that there was a necessity in fact to have a relative risk of greater than two. To precisely come up with an excess risk, is what I am really saying - an excess risk that is two or greater - would be extremely difficult and, if you had to do that before you ever issued a warning through the official literature, I am afraid you would probably never get them in there. That was a legal requirement, so I was told by the lawyers, that we would have to show excess risk of two or greater. What I am saying here is that a regulatory authority would feel itself necessarily required to put in advice and warnings to doctors nowadays, and to patients, if they were of the well considered opinion that really the excess risk may be less than two, but was nevertheless sufficient for that warning to be required.

E

F Q Is the reality nowadays that in terms of the warnings that are issued with various products on occasion certainly that the risk is in fact negligible, or it is very, very low indeed, but nevertheless in order to avoid litigation the warning has to remain?
A Like everything there is a measure - a partial measure - of truth in that, but that is not the way in which officially what it is like in the summary of product characteristics, as it is called in Euro speak, which used to be data sheets, is arrived at. There are various different reasons. In general, the licensing authority would be reticent to include warnings that were clearly aimed solely at avoiding litigation. They would have to be - I have been in this position where I have been actually involved with the writing of data sheets with licence applicants, and those who have had variations to existing licences, and one would be very careful to see that that was not the primary reason. One would wish to see that the warning was related to the judged seriousness of the adverse effects concerned.

G

H

Q Yes, but it does happen, does it not? I am thinking - and I cannot put my hand on it immediately, but it is in the Defence Bundle - of the warning about thiomersal in vaccine. Now just to take that by way of example, there is absolutely no evidence in this country that thiomersal in vaccine has ever caused kidney damage, is there?
A You mean there has not been an adverse effect report to that effect?

Q Yes. Well, no. Answer that first.
A Is that what you mean, I am sorry.

Q Yes.
A You would not know that, because in fact the measure of underreporting is such that you could have no reports at all and yet they could be there. We do not know. That is an unanswerable question, because we do not have the evidence to give you an answer on that one.

Q I see. I will come to underreporting in due course. Can we turn to your paragraph 38, please:

> "Dr Donegan has provided a textbook description of the disease and has commented on page C11 that changes in the virulence of the organism and better resistance has contributed to the virtual elimination of the disease. This is a reasonable and plausible opinion".

What, please, have you read in the research that indicates that there has been a change in the virulence of the organism, as opposed to better health care treating the disease generally?
A I do not think I have said that. I said I think, "This is a reasonable and plausible opinion". I do not think I have said anywhere that I said that virulence had in fact changed. It is certainly a possibility and one which perhaps we should look into and it does still seem to me to be a reasonable and plausible opinion.

Q Dr Fletcher, all sorts of things are possible, but they have to be based, if you are writing an expert report, on some sort of science, do they not? I just want to know on what basis you say that that is a reasonable and plausible opinion that, "… changes in the virulence of the organism and better resistance has contributed to the virtual elimination of the disease". What was that based on?
A That virulence can change.

Q I am sorry?
A I am sorry, that the virulence of any particular organism is not cast in stone. They evolve. They do have mutations themselves.

Q What evidence is there that the organism which we are dealing with here, diphtheria, has diminished? That the virulence has diminished?
A I do not think she said it had. I think you will have to ask Dr Donegan this one, because that is her statement, not mine.

Q We have and I think my recollection is that she agreed that the actual virulence of the organism probably had not changed?
A Probably had not, but ---

MR STERN: Transcript page, please?

MR KARK: I do not have it, I am afraid:

Q *(To the witness)* I just want to know that when you said that that was a reasonable and plausible opinion it was your general view, but based on any scientific research, or not?
A I have no doubt that I could find you, if I were to be given the time, references which do show changing in virulence of organisms.

Q Of diphtheria?
A I do not know. Give me the time and I will have a look to see if I can find out.

Q All right. I just wondered if you checked it yourself, you see, when you read that phrase?
A No, I am sorry, I did not check it at that time.

Q Let us go to paragraph 40:

> "Dr Elliman criticises Dr Donegan's report and her interpretation of references to an outbreak of diphtheria in Georgia and other post-USSR states. It is my view that these references have little, if any, relevance to the present case, firstly because they relate to non-UK countries in which social conditions and standards of health care may not be comparable and secondly are relevant to population, but not individual, immunity and are, therefore, not an issue in the case".

I am sure you understand, Dr Fletcher, that the reason they are an issue in the case is because Dr Donegan chose to include them in her report. That was why Dr Elliman was commenting on them, was it not?
A Yes, I suppose it was.

Q Could we go to page 16 of your report. We better start, I am sorry, at the bottom of page 15 just to make sense of it.

THE CHAIRMAN: What is your estimate of time, Mr Kark, because I just wanted to give Dr Fletcher a break?

MR KARK: Yes, of course. I hope I will finish by shortly before one o'clock. I am sorry, but it is very difficult to tell.

THE CHAIRMAN: Yes.

MR KARK: I would hope I would finish by 12:30.

THE CHAIRMAN: Did you say Dr Fletcher has a problem for Monday and so he could not return on Monday?

THE WITNESS: That is correct. I cannot.

MR KARK: If the worst came to the worst would it be possible to video link Dr Fletcher, or is he away? Can we ask where you will be on Monday, just in case?

THE WITNESS: I will not be at my home, no.

MR KARK: Can we ask which city you will be in?

THE WITNESS: I do not know, because I am - no, I do not have the determination to do that at the moment. That is why I cannot get here.

MR KARK: All right. Well, I will not take it any further.

THE WITNESS: I am sorry, it is a personal matter which I am afraid I cannot ---

MR KARK: No, I am sorry. I did not mean to pry.

MR STERN: Perhaps we can carry on. If it seems as if we may have to go a little beyond one o'clock, Dr Donegan has just sent me a note saying she is happy for us to carry on in her absence. Personally I do not feel that happy about that, but I can understand obviously if Dr Fletcher cannot be here then there is not really much we can do about it. If Mr Kark thinks he will finish by 12:30, let us work to that.

MR KARK: Obviously, I will do my best. I do not want to rush, but I will do my best.

MR STERN: No, no, I am not suggesting you should. I am just saying that that is an offer, as it were, if necessary.

THE CHAIRMAN: Okay. Well we should have a short break, I think that is only fair, and come back at quarter-past-eleven and then we will do our best to keep to our original timetable.

MR STERN: I will just give you the reference. Mr Kark suggested I think that Dr Donegan said something about the virulence. Let me just give you the reference. It is Day 7, page 23, A to D.

MR KARK: Thank you.

MR STERN: I think it is an error.

THE CHAIRMAN: So we will return at quarter-past-eleven, please.

MR STERN: I am sorry, can I just mention one other matter while we are still live. I will be literally two seconds. If in the break Dr Elliman could set out in writing what I think he called professional training, what that means, where it is, the number of courses

A

and various things like that, and also if Mr Kark could - he criticised Dr Fletcher for not being an immunologist. As I read it Dr Elliman is not an immunologist, he is a paediatrician, but if he has other qualifications that I have not been made aware of then perhaps I could be told about that?

MR KARK: Can I just deal with that, because Dr Elliman quite properly sent me a note after I had sat down saying, "I am not an immunologist. I am a paediatrician with special interest in immunisation", which is what he said when he gave evidence.

B

MR STERN: Yes, which is why I wondered why Dr Fletcher was being criticised.

MR KARK: Yes.

THE CHAIRMAN: Yes, and you will produce the information about the training, but let us not delay our break. We must come back here and start again at quarter-past-eleven.

C

(The Panel adjourned for a short time)

THE CHAIRMAN: Please continue.

MR KARK: Dr Fletcher, could we turn to your paragraph 52, please?

A Yes.

D

Q You start off by saying:

> "Dr Elliman criticises Dr Donegan (under 'diphtheria' section but relevant for DTP) for citing a publication he has been unable to locate …",

E

and I think we have now found that. It was produced by the defence:

> "Whether or not this particular reference can be found a paper by L K Ball et al … An assessment of thimerosal use in childhood vaccines (2001) … clearly states nephrotoxicity for the substance. The thiomersal issue is of importance in the evaluation of any vaccine containing that substance".

F

Can I just ask you, first of all, we are going to look at the report in a moment, but until you had had to consider this case had you yourself done any work on thiomersals in drugs?

A No, none at all.

G

Q So, this was a fresh subject?

A This was really only - I mean it was hardly even that, in fact. It was merely an effort to just check for myself, not having the previous or the other reference, that there was somewhere in the literature and I went into PubMed and found this. Quite honestly, I did no more than that really.

H

Q Can we just have a look at the report.

A Yes.

MR KARK: I presume that the Panel were given - were they given the references as well?

MR STERN: No.

B MR KARK: Ah, I am sorry.

THE WITNESS: I do not want to be awkward, but in fact I am not really sort of in a position to do more than the fact that I would recognise that this was a paper which had that particular statement in.

MR STERN: Which paragraph, I am sorry?

C MR KARK: It is page 71 of the references and it is paragraph 52 of the report.

MR STERN: Thank you.

MR KARK: If Dr Fletcher has his own references, then ---

D MR STERN: Yes, Dr Fletcher has got them. Yes.

MR KARK: All right. The Panel do not need to have this immediately, but the point I think I am going to make is a very short one. If anybody considers that they ought to have this reference paper that Dr Fletcher has referred to, then I am sure that we can get that copied:

E Q Dr Fletcher, it is at page 71 of your references, I think. Is that right?
A It could be, yes. No, it is not in mine.

MR STERN: I think it is in the penultimate divider. *That* is it, is it not?

THE WITNESS: It is not in there.

F MR STERN: Is it not *that* one *there*?

THE WITNESS: I am sorry. I am sorry. I was looking for a different one.

MR KARK: (*To the witness*) It is headed "REVIEW ARTICLE An Assessment of Thimerosal Use in Childhood Vaccines".

G A Yes.

Q Just to make it clear what you were referring to in your report, this is a report by Leslie Ball, Robert Ball and Douglas Pratt and it comes from America, does it not?
A Yes, indeed.

Q Yes. The conclusion of the report was that:

H

> "Our review revealed no evidence of harm caused by doses of thimerosal in vaccines, except for local hypersensitivity reactions. However, some infants may be exposed to cumulative levels of mercury during the first 6 months of life that exceed EPA recommendations. Exposure of infants to mercury in vaccines can be reduced or eliminated by using products formulated without thimerosal as a preservative".

First of all, do you appreciate, or did you appreciate when you included this, that the level of thiomersal, as we call it in this country, is I think something like half that used in the States? Did you know that?

A I did not know that, but I did know there were differences in the levels, yes.

Q If you could just turn to the conclusion, because this is material in fact that the Panel have not had but it may be relevant if they are going to be considering the issue of what was said about thiomersals. It is page 77 of the research.

A (*Pause*) I am sorry, I am taking rather a long time to do this.

Q I am sorry.

A I am sorry, but I have got two page 75s. That is my problem.

Q Do you have page 77?

A Yes, I am there.

Q I will just read out the conclusion and, again, if the Panel want this:

> "Our review revealed no evidence of harm caused by doses of thimerosal found in vaccines, except for local hypersensitivity reactions. At the time of our review, vaccines containing thimerosal as a preservative could expose infants to cumulative mercury at levels that exceed EPA recommendations during the first 6 months of life".

That is what we have just seen earlier in the report:

> "The clinical significance of this conclusion is not currently known; EPA guidelines"

- which is the standard, as it were -

> "contain as much as a 10-fold safety factor and such guidelines are meant to be starting points for the evaluation of mercury exposure. However, reducing exposure to thimerosal from vaccines is merited given the goal of reducing human exposure to mercury from all sources, the feasibility of removing thimerosal as a vaccine preservative, and the desirability of ensuring public confidence in the safety of vaccines".

So the point that it is making first of all is that, although in America there may be an

occasion in a child's life when they exceed EPA recommendations for the ingestion of mercury, the EPA guidelines themselves contain a tenfold safety factor, yes?
A That is what it says, yes.

Q All right. Just to make it clear, this is not research that you had come across before, but you thought it relevant to include it?
A I did, yes, purely because in fact there seemed to be some controversy whether we could find the original paper and I just had a look to see if I could find another one.

Q All right. Also I suppose one has to take into account, but again this really is not your field, that these two children of course were not infants less than six months. A No.

Q One was aged I think three and one was aged nine and so the body weight and all of that is going to be completely different.
A Oh, absolutely. I completely agree with that, yes.

Q Which affects the relevance of thiomersal?
A No, indisputable.

Q Thank you very much. Could we turn to page 18 of your report, please, right at the bottom. No, I am sorry, at the top first of all at paragraph 58. I think you accept now, do you not, that there is a reference? It is Reference 13 in Dr Elliman's bundle where you can get that 2,000 figure from?
A Yes, I do. I think I said that too. It is just an error on my part in not looking at the right tab number.

Q No, that is no problem. Let us go to the bottom of page 18, please:

> "Dr Donegan has drawn attention to this problem in her report …"

The problem is I think encapsulated a few lines above:

> "The number of subjects required in a study for an adverse reaction occurring at a rate of 1 in 1,000 in which there is zero background incidence is 3,600, if the background incidence is the same as the adverse reaction (1 in 1,000) then about 20,000 subjects would be required.
>
> Dr Donegan has drawn attention to this problem in her report … and points out that whereas vaccine efficacy can be established on greatly fewer numbers, rare adverse events need very large numbers and such studies are not available".

It is a point I think that you made when you were giving evidence this morning, when you said that, "Testing a hypothesis requires repeat experiments", and this is in a scientific field. "If there are differences, you have to sort them out. You cannot do that in clinical medicine". I think the point that you are making, and perhaps Dr Donegan was making, is that you would need to do an enormous study really to know what the real

adverse consequences of these vaccines are. Is that the point that is being made?
A Yes. In fact the actual tabulation of those figures are on page 59 of my references, in which I do refer to Professor Graham Smith's original work which shows the various proportions of incidence and relate those to background noise. You very soon reach extremely large numbers if you wish to - have you found that?

Q Yes, I have, but that report ---
A There is a table there on the right-hand side. You have to turn it round.

Q Yes, the report - that report - was in relation to the safety evaluation of new drugs. Is that right?
A It was Professor Graham Smith's comments really on the size of studies that would be needed to conduct in certain circumstances if you wanted to get, shall we say, 10,000 patients into a study. It does not matter what you are doing it for but, depending upon the background noise, you are going to have to increase the numbers rather rapidly.

Q However, in terms of vaccines, of course, there are an enormous number of vaccines given in this country every year, are there not?
A You do not mean an enormous number of different vaccines, but an enormous number of prescriptions?

Q No, vaccines - or immunisations as they are perhaps referred to in this case - are given to children as part of the nationwide programme, are they not?
A Yes, indeed.

Q If we just consider for a moment that an infant I think in the first four months of its life will have three visits and will receive DPT, polio and meningococcus, so that is three different visits and three different - well, actually five different vaccines. Then at 13 months they have an MMR, then between three and five years old they will have their DPT and another MMR. That is happening up and down the country and I think you said that the birth rate was at about 600,000?
A That is I think a generally regarded figure, yes, or somewhere around that.

Q Now obviously not all of those children will be having vaccinations, but perhaps half-a-million children every year are having vaccinations in relation to each of which there is a yellow card reporting system for adverse reactions, is there not?
A Which picks up probably something like five per cent at the greatest number, I would have thought. A very small number are picked up by yellow cards on vaccines. In fact, very small numbers of anything are picked up. Only five per cent of doctors actually contribute to the yellow card system.

Q However, you still have something like half a million children receiving in the first few years of their lives six or seven vaccinations?
A Yes.

Q The numbers are huge, are they not?
A The numbers are available, and one of my problems with this whole thing is that they are not reported like that though.

Q When you say "they are not reported like that…"?
A What I mean to say is that if you - can I expand on this a little bit?

Q Yes.
A The numerous references that have been cited by the various experts here do not in fact contain what I would call a single substantial, authoritative paper which has adequate numbers and durations of active surveillance to give a reasonable picture of what safety is for any of the products. These are available nowadays, as I have tried to show in some other things, but the fact is, you are quite right, we have not conducted the sort of rigorous and possible studies which would be taken from general practitioner research databases, which would in fact access, you are quite right, about 500,000 a year. They are available but they have not been done.

Q But if there were serious events at least temporarily linked, you would expect those serious events to come to light?
A That does not work that way, I am afraid. I am afraid that is not the way it works.

Q Very well.
A There are very good reasons why it does not work that way. One is that many doctors are protective of their own possibility of litigation by reporting what is a serious event when the patient or the parent of the patient may come back and say, "It was your fault for giving that wrong drug", so they do not report it. This is a very well known response. So, actually that does not work that way.

Q Can we turn to page 19 of your report, please? With respect, I am not going to pick you up as it were on every single point where you have agreed with ---
A Well, no, I have done this not with any very great sort of… I mean I do not regard this as my full level of expertise.

Q No, it is not really your field, is it?
A No. I did it because the data had been given to me and it at least showed that I had read through the stuff and done something with it.

Q That is a fair way of putting it. As I was about to say, I am not going to pick you up on every area of Dr Donegan's report with which you agree.
A We have already done that, yes.

Q Otherwise, we will be here for a very long time, but I am going to just pick you up, if I may, on a few points. If we look at your page 19, in the middle of this table is where Dr Donegan was referring to the NCES study and I think she herself accepts that she was in error?
A Yes.

Q You quite properly say:

> "Dr Elliman is correct. JD provides a balanced view and there is no reason to suspect that has misled."

What you presumably meant by that was deliberately misled?

A Yes, that is right. I do not think she had intended to do so. It was probably a…

Q But she accepts that she was wrong and I expect you accept that she was wrong?
A Yes, that is quite right.

Q I am not going to go into the issue particularly with you in relation to the difference between brain damage and neurological illness. You do not suggest, and I do not think Dr Donegan suggests, that she was right to use that term?
A I would not wish to give an opinion on that one particularly.

Q It is not your field? (*No verbal reply*) Could I ask you to turn to your page 20? In the middle it refers to Dr Donegan's page 27 and it is at paragraph 1, where Dr Donegan writes:

> "The lack of this gut based immunity may explain the occurrence of tetanus disease in fully immunized people with adequate levels of neutralising antibody and for the non-occurrence of tetanus disease in unvaccinated individuals such as everybody before vaccination was introduced."

She quotes or mentions three authors there. This is just to take it by way of example. We know that all those three authors supported immunization?
A As my memory goes, that is it, yes.

Q I think you agree that either she should mention at this point that those three authors support immunization, or elsewhere in her report, in a global fashion, she should indicate, "As a matter of fact, I ought to mention that although I cite a huge amount of research, the authors that I cite in fact end up by supporting vaccination"? That should have been somewhere, should it not? I am just using that as an example.
A I do not know about that at all. I can see that there is a point at which you might say that it would be a reasonable thing to do. On the other hand, it may be that the total evaluation of the whole study in her mind was such that it did not really justify that. I am hesitant to say "yes" or "no" to that one.

Q I thought you had agreed earlier – and I was just using this as an example – that, as a generality, if you are going to cite research supporting a particular view, you ought at some point to make it clear?
A I am sorry, perhaps I misunderstood you. If this is the first occasion on which that statement is going to be made, then yes, I suppose that is true, because I did say that.

Q Could I ask you to turn to page 29 pf Dr Donegan's report? I do not think this is an area that… Oh yes, you have. I was going to say that you had not dealt with it, but I think you have. At the top of page 29, Dr Donegan writes:

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

A

Dr Elliman's criticism was that Dr Donegan had not mentioned that the changes were temporary and that there were no adverse effects reported. First of all, when you read those lines in Dr Donegan's report, which presumably you did, this is not your field of speciality, is it?
A No, certainly not.

B

Q I understand that, but what you write is, "JD is providing a balanced view". Can you just tell us why you think that is right, where she has not mentioned that the effects are temporary, which may be thought to be important to the reader, and that there was no evidence that it did any harm? Why do you think that is a balanced view, Dr Fletcher?
A I suppose it could be interpreted in that case that I have made a mistake there and that perhaps it should have been, yes.

C

Q That it should have been what?
A That a mention that it was a temporary event that T-lymphocyte helper/suppressor ratio should have done, yes. Perhaps it was one that slipped through my attention.

Q It would be quite important to mention that, would it not?
A Yes, I suppose it would. It does not strike me as being so terribly awful, but I suppose it would be.

D

Q Not terribly awful but important to mention it, Dr Fletcher?
A I think that is a matter of opinion, quite honestly; I really do.

Q Are you really not prepared, Dr Fletcher, to agree that it would be important to the reader of this report to understand that that effect potentially upon their children would be temporary and that there was no evidence of any risk of harm?
A Yes, okay, I will agree with that.

E

Q Can we go to page 21 of your report, please? I am sorry, you will have to have both Dr Donegan's report and your report available. In Dr Donegan's report it is page 34. On your page 21, it is the second one down, [D31 (see 35)]. You start by saying:

> In this and the following … criticisms the fact that polio is now almost unknown in the UK has to be taken into account in the individual child benefit risk evaluation. For the individual child the risk of serious illness from the polio virus is essentially zero, so the risk of adverse effects is a dominant factor. Professor Kroll states 'This dreadful infection is mercifully now very rare indeed. No cases have been acquired in the UK for many years'."

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I have mentioned that so that we can put into context your words "see above". Can we look then at Dr Donegan's page 34 and the bottom half of the page, where she starts speaking about the SV40 virus?
A Yes.

Q This goes over the page, finishing with the words that are underlined in Dr Donegan's report:

H

"It thus remains possible that a late adverse effect of the polio vaccination programme is emerging."

There are two points that I want to ask you about here. First of all – and again this is not your field, of course – I do not know if you have come across the SV40 simian virus at all?

A I do know about it, yes, but it is a piece of general knowledge that I have picked up somewhere along the way.

Q What you say so far as Dr Elliman's criticism is concerned is, "see above", in other words that the risk from the polio virus is essentially zero, and I just want to understand this: are you saying that because the risk of the polio virus is essentially zero, it did not really matter what Dr Donegan was saying about the SV40 virus, because the children were not going to get polio anyway? What were you saying about it?

A I am sorry, I do not think I am following quite what you are saying here. I have sort of missed the track on this one a bit.

Q I am so sorry, it is my fault, not yours. On page 21 of your report you refer to D34, and I think you are referring to Dr Elliman's criticism. You say, "If true, applies to vaccines produced many years ago. Not quoted in two more recent studies". I am not sure but I think that is referring to the bottom half of Dr Donegan's report where she talks about the SV40 virus, because that was in vaccines back in the 60s?

A Yes.

Q You have that point, okay. What you say in your report is "see above", and the "see above" is the part that I quoted to you where you speak about the fact that the risk of polio is so low and no cases have been acquired in the UK for many years (quoting Professor Kroll) and I just wonder how you put those two together, as it were. Are you saying that because the risk of getting polio is so low, it does not much matter what Dr Donegan has put in her report, or what?

A I did not mean it in that sense, no.

Q How did you mean it?

A What I really meant was that I thought I had sort of dealt with the whole matter of polio vaccines because it was not going to happen anyway, because we think we all agreed that that was the case. I must say that perhaps I missed something there, but I did not think it was worth spending more time delving into this when we were not going to take any notice of it anyway.

Q You were being asked to comment on Dr Donegan's report and whether it gave a fair and accurate account of the research and whether it was misleading. With respect, where we see these tables of yours where you say "see above" and "Dr Donegan has produced a balanced view" ---

A That was my opinion.

Q So when you read Dr Donegan's report, when she speaks for half a page and a bit about SV40 virus and the fact that it thus remains possible that a late adverse effect of the polio vaccination programme is emerging, you did not find any basis for criticism of those remarks. Is that right?

A No, I do not think I did. I think that is right. I do not think that it did strike me that way at all.

Q With regard to the fact that, in fact, Dr Donegan has quoted half a sentence from her reference, did you note that she had only quoted half a sentence?
A I honestly cannot remember whether or not I did. It was a long time ago and I have not got the… I really do not know whether I did notice that.

Q Let me just conclude the sentence as if Dr Donegan had put it in. The way the sentence actually reads – and if anybody needs to check it, it is reference 51 in Dr Donegan's bundle – is:

> "It thus remains possible that a late adverse effect of the polio vaccination programme is emerging, although any risk of cancer is likely to be more than outweighed by the benefit of vaccination to the post-war generation."

Does that bring back to your mind the fact that Dr Donegan had quoted only half a sentence, or did you not notice that?
A I presume I did not notice it because I must say I cannot really remember on that point.

Q Could we go to page 22 of your report? I just want to ask you again how you meant this to be taken. About seven or eight lines up, your paragraph on the right-hand side starts, "I have read JD's pages 42-47…" Five or six lines up from the bottom, you write:

> "The benefits and risks of MenC vaccination at the population level are certainly questionable and there would appear to be no available information at the individual patient level. DE criticises references to *Pulse*. However, JD is correct in saying that, for the general practitioner, it is frequently the only source of information."

First of all, I do not suppose *Pulse* really is the only source of information for a general practitioner?
A I think we are talking there in general terms, that it is something that you can… I mean you would have to go out of your way to start trying to find something else, which is probably not practical for a busy general practitioner.

Q Of course, Dr Donegan in this case was not acting as a general practitioner, was she? She was acting as an expert in this particular field of medicine, and there is a difference, is there not, between what a… Well, I will ask you that first: do you agree that there is a difference between what a GP can get hold of and what an expert in his or her field should be relying on in a report? Do you accept that there is a difference there?
A I suppose there is a difference, yes.

Q In all the thousands of reports that you have read, which you have told us about, the research reports, have you come across occasions where researchers have relied on an article in the *Pulse* magazine?

A I do not think I have, no.

Q If you were writing an expert report, would you rely on an article in the *Pulse* magazine without going back to the research?
A It would entirely depend on what it said.

Q Is that right?
A Yes, it would seem to me that it is perfectly all right.

Q You would think that it is reasonable, would you, without going back to the core research material, to rely on what is said in an article in *Pulse* magazine?
A That is a different question, is it not? Once again, I am at a loss to know quite where we are going on this and I do not know quite how to answer that problem, because I can see very clearly that a measure of reliance on *Pulse* as a piece of information could be sufficient for what I wanted to know. There could be circumstances in which it was not, in which case I would have to go and have a look. It may be that I was not sufficiently interested to do that because it was not sufficiently important. There are many alternatives to doing this. I do not think that it is a one or other situation there.

Q I do not want to spend too much time on it, but I just want to have your answer whether, writing an expert report for court purposes, you would rely… Taking the MMR issue first, which apparently you have written a report on, did you rely in your report on any articles in *Pulse* magazine?
A No, I did not, but there may be very good reasons why I did not, because it was not relevant to what I was writing.

Q Let me move on. I am sorry, I will pause. Is there a point to be made?

THE CHAIRMAN: The Legal Assessor is making the point that each case depends on its own factors and you might not be able to carry through the same experience.

MR KARK: Yes, I accept that.

MR STERN: While there is a short interlude – I was not going to interrupt – when Mr Kark says "refer back to research", the particular point that he is referring to is not about research but about the newsletter and what it says about numbers. If he is going to make the point about going back to the research, it is only fair, in my submission, that he should put to Dr Fletcher what that research is that has not been referred to.

MR KARK: With respect, I wanted Dr Fletcher's general comment. When I address the Panel in due course, I shall be referring to specific areas of the report, I submit, where Dr Donegan has simply relied on the *Pulse* magazine, but I am not going to go through it now, with respect.

THE CHAIRMAN: Do you want to move on?

MR KARK: Dr Fletcher, could I take you please to page 24 of your report? In paragraph 69 you say:

A

> "Dr Elliman comments upon Dr Donegan's responses concerning the well known observation that measles disease depresses cell mediated immunity and seems to generally agree with her views. The paper concerns a study conducted in Guinea-Bissau and is, thus, of only peripheral relevance to the two children that are the subject of this legal case. On page 36 of his report Dr Elliman quotes from the conclusion of the paper and then states:
>
> 'This shows that measles vaccine does not have the same characteristics as the disease, or at least not to the same degree, thus Dr Donegan's reasoning is faulty'."

B

Then, just to finish your comments, you say:

> "I feel that this uncompromising criticism relating to circumstances largely irrelevant to the case and, revealing Dr Elliman's own uncertainty of disease versus vaccine, is unnecessarily harsh."

C

Can we just turn to page 49 of Dr Donegan's report, please? This is the paragraph, a quarter of the way down the page, that I think you are referring to:

> "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. 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. 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."

D

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I appreciate that this is not your field, which is in a sense why I am asking you. When you read that paragraph, what did you understand Dr Donegan to be saying?
A My interpretation of that would coincide with one of my concerns, that in any circumstances in which you administer by injection more than one live virus, there is, in my view, a possibility of some risk. We have not, I think, got the data on which to base whether or not multiple live viral vaccines carry more risk than others. I have not seen that. It may be that somebody else knows this, but it struck me that that was a reasonable thing to say.

F

Q Did you know whether the high titre vaccine was used still in this country?
A I did not know about that. I took it that that was correct.

G

Q You took it that what was correct?
A I am saying… What is the question? She says that the high titre measles vaccine, the high dose Edmonston-Zagreb strain, is not available here. Is that right?

Q I am just asking you whether you knew whether it was available here or whether it was the vaccine that was used. How did you read the words "To give a vaccine that has

H

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"? How did you understand that?
A I thought I had just said that. I said that I am of the opinion – and it is my, Peter Fletcher's, opinion – that the administration of live viruses, wherever they come from, more than one in the same needle, carries a measure of risk.

Q Did you understand that the high titre measles vaccine is one of the vaccinations given in this country, the same one used in Africa?
A I did not know "yes" or "no" on that question.

Q You would not have known, of course, that the high titre measles vaccine was withdrawn in Africa, I think we heard, in 1996 and had never been used in this country. You would not know that, obviously, because that is not your specialist field?
A No, it is not.

Q Could we go to page 26 of your report, please? About halfway down you are dealing with E37-38 and D54, so Dr Elliman's 37 to 38 and then Dr Donegan's page 54?
A Yes.

Q Dr Elliman's criticism is that Dr Donegan's reference is selective and omits important points. You say:

> "The whole matter of adverse effects associated with the several MMR vaccines is highly controversial. As a past medical expert on the now abandoned MMR litigation, I am bound by the court to strict confidentiality in respect of disclosure by the defendant licence holders."

I am sure that that is right. Can we go, please, to page 54 of Dr Donegan's report? You will see that halfway down she begins, "A report in the British Medical Journal…"?
A Yes.

Q

> "A report in the British Medical Journal from the Communicable Disease Unit at the London School of Hygiene and Tropical Medicine (1996) 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. One report of SSPE"

- which we understand is subacute sclerosing panencephalitis -

> "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:"

A and then:

> "Anaphylaxis …
> Thrombocytopenia …
> Death from the measles vaccines strain …"

I just again want to ask you what your understanding of this was when you first read it: "One report of SSPE occurred one month after vaccination"? Did you go back to the
B research when you wrote your report to see what the research actually said?
A (*Pause*) I honestly do not know at this point whether I did or whether I did not.

Q I think we better have a look at it. It is tab 98 and can I ask that you be handed it. It is Panel Bundle 3.
A I have got it *here*.

C Q Have you got it there?
A Yes. Tab 98?

Q Tab 98, yes. Do you remember that now? Did you read that, or can you not remember, or did you not?
A Oh, Felicity Cutts?

D Q Yes.
A Yes, I read this. Yes.

Q Did you read the passage that Dr Donegan was apparently quoting from? Let us just have a look at the middle paragraph starting, "By the end of October 1995 …"
A Yes.

E Q

> "By the end of October 1995, Britain's Committee on Safety of Medicines had received 1202 reports describing 2735 suspected adverse reactions …",

F and then could I ask you to go about five lines down where do you see that:

> "There were 91 reports of serious neurological reactions (including 61 reports of convulsions); but reported rates of encephalitis, convulsions, and Guillain-Barre syndrome were lower than the background prevalence of those conditions".

G Now obviously you understand what that means, do you?
A What it says is that there were 91, I presume, yellow card reports.

Q I suppose they may have been yellow cards, or not, but ---
A However you need to multiply that by ten, because there were 910, actually, because that is the agreed figure. So we have to say there were actually 910 reports of
H serious neurological reactions, because that takes into account the underreporting.

Q Well say there were 910, but:

> "… reported rates of encephalitis, convulsions, and Guillain-Barre syndrome were lower than the background prevalence of those conditions"?

A I do not understand the sentence, I am afraid.

Q The background prevalence means in the wider population, does it not?
A I am sorry?

Q Does not the background prevalence mean in the wider population, so in other words it was lower in these subjects than it would be in the population generally?
A I cannot comment on that, because I do not know the source of that information. I would need to evaluate.

Q That is what it says.
A You are right that the word "report" has been used twice, but I do not know whether they are comparable with one another. I would need to know where that came from.

Q Let us go to the next sentence, which we can read I think without having to go elsewhere:

> "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".

Dr Donegan has accepted I think - I am afraid I have not got the transcript in front of me - that perhaps those words should have found their way into her report, but you read this yourself. It is rather important, is it not, to include those words - those last words?
A I am sorry, could you say that again. I have lost track of this again, I am afraid. I am sorry about that.

Q No, it is not your fault. Let me just take you back to Dr Donegan's report at page 54.
A Yes, I have got that.

Q She writes:

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

and she stops there. When you read that, did you take it that there was a potential link there between the vaccination and the occurrence of SSPE?
A I think I was probably very, very sceptical about these figures altogether and I am not sure what I thought about that at that time.

A

Q So, you cannot help us?
A I do not think I can on that one, no. I am sorry, but many of these reports have figures in which really carry such a measure of uncertainty about them that it is extremely difficult to draw any conclusions from them. They are guesswork, as much as anything else, and I cannot really know whether these figures are right or wrong.

B

Q Do you agree that, in order to avoid misrepresenting the true position, Dr Donegan should have included at least the full sentence that she was quoting from which concluded with the words, "… thus it is unlikely that the vaccine was responsible"?
A No, I do not think it was necessary to include that.

C

Q You do not think that was necessary?
A No, I do not think that was necessary. No, I do not.

D

Q I see. Page 27 of your report, please, and we are getting towards the end.
A I am sorry, I will just get rid of *this* one before I can get to it. (*Pause*) I am sorry, what page?

Q Page 27 of your report.
A Right.

Q It is page 62 of Dr Donegan's.
A Yes.

E

Q You have dealt with two areas of Dr Elliman's criticisms. The area of Dr Donegan's report I want to ask you about is the main paragraph 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"?

A I am sorry, I am looking at the wrong place again.

F

Q I am sorry, page 62 in the bottom right-hand corner of Dr Donegan's report.
A I am sorry.

Q You are, I think, just coming to terms with the complications that we have faced throughout these proceedings.
A You could say that again, yes. Page 62 of Dr Donegan's report?

G

Q It is page 62 of Dr Donegan's report and it is the big paragraph in the middle, "In the <u>five</u> years before …", do you see that?
A Yes.

Q

H

> "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>

A

> years after 1970 there were 454 [cases]. 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 was still 333 affected babies. So the number of cases have gone up".

Now, you have heard the evidence and you heard Dr Donegan give evidence about this and her cross-examination?

B

A Yes.

Q Do you accept that that was in fact misleading?

A Again, you are catching me out because I need more time to think about what that means. Off-the-cuff I do not know what the answer to that one is. Could you perhaps give me a few more guidance on that?

C

Q Of course. Of course. The point that I am asking you about is that, if you recall, we know that national reporting in relation to the rubella vaccine did not start until 1970, all right?

A Right.

Q What Dr Donegan has written is that:

D

> "In the <u>five</u> years before the rubella vaccine was introduced in 1970"

- so in the five years before national reporting began -

> "there were only 39 babies born with congenital rubella".

That of itself, would you agree, is misleading?

E

A It probably is, yes.

Q It follows that the words at the end of that sort of passage, "So the number of cases have gone up", those words are misleading, are they not?

A We are back again to the reliability of reports, are we not?

F

Q With respect, no, we are not. I think it is quite a simple point. If national reporting did not start until 1970 and Dr Donegan is equating the fact that there were 39 babies between 1965 and 1970 who had rubella, whereas in the ten years after 1980 there were 333 and she is saying the number of cases have gone up, that is simply misleading, is it not?

A I suppose it could be looked at from that point of view, yes. I must say I had not seen it that way myself when I read it but, yes, I suppose you are right.

G

Q If we go to page 29 of your report, this is dealing with Dr Donegan's second report when she deals with the USA official literature in terms of adverse reactions to MMR. You say:

> "For reasons of confidentiality I am constrained from giving details but data in the MMR litigation …"?

H

A Yes.

Q On reflection, I am not going to ask you about that. Yes, page 30, please, and starting with page(*sic*) 77 where you say:

> "It is my personal opinion that the administration of multiple vaccines may be, for a subset of children, a potential risk factor. I am fully aware that is a controversial issue"

B

- I think we can all agree with you on that -

> "but the absence of even a cursory mention by any of the experts is a noteworthy omission.
>
> 78 The views that she has expressed"

C

- meaning Dr Donegan -

> "may not be in line with Department of Health recommendations but are commonly voiced in general practice and the general public and are in line with my opinions".

D

That may be right, but I am sure you would accept that any opinion that you state in an expert report of this nature ought to be based on established research? Do you accept that, or not?
A I do not know. No, I do not think I do, because I think in my own case it is something that I was probably the researching person and I am referring to my own experience and so I do not know that there is anybody else involved in this apart from me.

E

Q Can we just turn finally to the report by Dr Holgate that you have produced.
A Yes.

MR KARK: Again, I am sorry, but the Panel do not have this.

F

THE WITNESS: Oh, do they not?

MR STERN: Do you mean the chapter?

MR KARK: Yes, it is chapter 37 of Dr Holgate's book.

G

THE WITNESS: It is on page 15, is it not, of mine?

MR KARK: I think I am going to ask - we do not need to copy it now, but I think I will ask for this to be copied:

Q (*To the witness*) Is it relevant to your views?
A I suppose it is, yes, because it is a longish chapter and it has got quite a bit in it and there are one or two bits and pieces that - I think the main point that I wanted to bring

H

out was that the whole matter of neurological problems associated with pertussis had been very carefully examined by the main Committee of Safety of Medicines and the subcommittees, that Dr Holgate had written this appraisal of that and also that he had pointed out the need for more substantive and better research to be done in these areas and I thought that was important.

Q Could I just take you to page 17 of the report. (I apologise that the Panel have not got this).
A Page 17 of …?

Q Page 17 of Chapter 37 of Holgate. It is page 17 at the bottom, but it is actually page 883 of the book in the top right-hand corner. I am afraid I do not know which tab number it will be in your file.
A It is 5, is it not?

MR STERN: 4, I think.

THE WITNESS: 4, is it? It is 5 in mine. I am sorry, which was the page number? 883, was it?

MR KARK: (*To the witness*) Yes, page 883, because you talk in your report about risk benefit ratio and I just want to see what Dr Holgate says about that. He writes:

> "The whole question of risk-benefit ratio present with virtually all drugs is brought to the highest pitch in the case of vaccination since the prophylactic agent is usually being given to an otherwise entirely healthy individual and the benefits of proper use are gained not only by that individual but also by the community. The acceptability of certain vaccines has recently been questioned both by the medical profession and also the mass media as a result of publicity about adverse reactions. This has produced two results - the good being a realization that vaccination produces great benefits but needs care and attention in administration, the bad being the decreased use of several good vaccines which have been shown to provide protection".

Then over the page for you:

> "Policy of use must be formulated on hard scientific evidence which, if not already available, must be actively sought. It must recognize the nature of the disease against which protection is being required; often as a result of many years of virtual eradication of a disease a previously valid risk-benefit ratio is attacked without justification as the nature of the disease has been forgotten while the risk has been magnified by media publicity. Such a shift should not be possible if both benefit and risk are closely monitored and all the evidence is constantly updated".

Do you agree with those sentiments?

A Yes, I think I do. I think that is a pretty fair statement.

Q In particular in relation to vaccines, when considering the risk/benefit, the words that he uses:

> "It must recognize the nature of the disease against which protection is being required; often as a result of many years of virtual eradication of a disease a previously valid risk-benefit ratio is attacked without justification as the nature of the disease has been forgotten …",

that is a specific risk in terms of vaccines that one has to guard against when considering ---

A He says so, yes. That is his opinion, yes.

Q Yes, but it is one - I am only taking it because you have produced the report.
A Yes, all right.

MR KARK: Would you just give me a moment? That, I hope, is it. (*Pause*) Yes, thank you very much, Dr Fletcher.

THE CHAIRMAN: Any points by way of re-examination, Mr Stern?

MR STERN: Just one, please.

Re-examined by MR STERN

Q Dr Fletcher, could you turn to page 19 of your report?
A Yes.

Q Three-quarters of the way down there is this point about neurological illness, not neurological damage, and you say:

> "This is unnecessarily critical for a minor terminological distinction".

Could you just help? Is it a minor terminological distinction between neurological illness and neurological damage?

A In my mind it is splitting hairs a bit, I think, definitely, because I suppose my example of a neurological illness which does not imply some measure of cellular damage would be purely psychiatric conditions in which we have behavioural disorders and even those may at some point be traced to DNA or some other damage. In most other neurological conditions, there is damage to some part of the nervous system in the manifestation of the illness.

Q Well that is what I wanted to ask you, because we have not actually defined terms or actually specified meanings of things, but is there a neurological illness that does not cause neurological damage, apart from the psychiatric ones that you have just spoken of?
A I am not an expert in neurological illness, but I do not know of one really. I

A cannot think of an example where there really ---

Q No, all right.
A There may be many in which we do not actually know what the damage is because it has not been discovered, but I would guess that ---

MR STERN: No, I appreciate that. Thank you.

B

THE CHAIRMAN: Dr Fletcher, there may be questions from the Panel.

Questioned by THE PANEL

DR GOODMAN: Hello, Dr Fletcher.
A Hello.

C

Q I certainly can assure you that I have been giving your evidence my full attention, even though my office is sort of all round *there*.
A Yes.

Q Dr Donegan told us that she was a holistic doctor. Could I just for clarification from your CV ask when you personally last treated a patient?
D A Oh, I have actually stood in for a general practitioner on one or two occasions and so I do not quite know, but the last time I really properly treated a patient was probably in 1957.

Q Thank you very much. That is fine. You also mentioned at one stage the Official Secrets Act. Are you able to say how that is relevant to your evidence today and in your report?
E A I do not think it is relevant, really, because I have tried to avoid any contravention of that because I did not want to be taken away to jail today.

Q Okay. Now you may not wish to go to it, but in paragraph 15 you refer to package inserts and patient information leaflets as being, as you put it, "official literature"?
A Yes.

F

Q When you were giving evidence this morning I think to Mr Stern, and it was with reference to paragraph 45 when you were working in the Department of Health about these inserts, you said that, "Some effect was probably causal, but there was actually insufficient evidence in solid terms", and I am quoting you I hope, and you decided in your Department of Health Committee that there was not really any evidence but you better put a warning in the patient insert literature. Am I quoting you correctly?
G A That is pretty clear what I was saying. Perhaps I was making a rather clumsy wording of that, but what I was really meaning is that an accumulation of circumstantial evidence in these things often has to be taken into account as to whether you are going to change the existing wording in a package insert, or whatever it was. The way that is done in the department is in fact by a referral to the Committee first to get their opinion on whether or not in their opinion a change in the form of the words of advice, or whatever it
H is, or even a dosage change or an indication change, is justified.

Q That decision is quote official end quote?
A It becomes official later when, on the advice of the Committee, there would normally take place a more or less friendly discussion with representatives from the licence applicant, or the holder, where you would come to some sort of agreement on the wording which would then be put to the licensing authority for approval, which normally happens. Rubber stamping, that really is.

Q I do not want to take you out of context, that is what we have been about, but you made a comment to Mr Stern this morning which was actually in reference to paragraph 35. The quote I think is that, "Companies fall back on inspired guesswork". Can you remember that quote?
A Yes, I can.

Q Can you explain to us what the relevance of it is?
A This has arisen because of the extreme practical difficulty of I suppose attributing causality, in many circumstances, when you know in your own heart that you do not know that it is causal, but you know you are going to have to do something about it. So in those circumstances you know that, if you were to wait for proof of causality, you may be going some many months or even years down the line before you could say that. So you have to make an assumption, and this is a judgment matter rather than anything else. Is that the answer that you wanted?

Q Yes, that is fine. Yes, that is exactly ---
A I am not sure whether it was right.

Q I mean, we have not got a yellow card with us. In fact, we probably have in the back of the National Formulary.
A Yes, it is in the National Formulary. Yes.

Q However, my recollection when one reports adverse events in yellow cards, clinical trials and whatever is you report the event and then I think the doctor is asked to say, "Do you think this is related, or not? Are you just reporting it temporally?" It is just that to me that would mean that I am reporting a suspected event, or I am reporting a temporally related event that I might not think is suspected. Am I overdoing it?
A No, I cannot remember exactly what the wording on the yellow card is, but there is I think some reminder that, "Do you think this really was caused by the administration of the product that you are talking about?", yes.

Q Yes. Do you get any feel as to whether the reporting doctors have in their view individual adverse events as to whether it might be related or not, or is that not relevant?
A It is a major problem from the point of view that fortunately with most chemical entities which are the subject of adverse event reporting they are pretty rare things and so many, many doctors (whether they be in hospital or whether they be in general practice) probably only ever see one or two in the whole of their careers and so they are not very well-versed in actually knowing what a serious adverse event is. It happens and perhaps three weeks later they think, "Oh, that is funny. I read about that in the BMJ …", or something, "… and so perhaps that was one", and there are quite a large number of yellow cards which are filled in quite a long time after the event as a consequence of that

sudden realisation that, "Perhaps what I saw really was one". So it is a very sort of uncertain system that we have doing that and it has many problems with it, but it is probably the best we have.

DR GOODMAN: Thank you very much. My only other point is that I would personally like to see the Graham Smith paper, but I do not think I would need to see it today. I do not know what other panellists feel?

THE WITNESS: It is very difficult to find, may I say, because it was published by the Department of Health and you have to go back to them and they do not even - it was the report of his Committee and I think it was dated something like 1981, or something. David Graham says himself - I am going to see him very shortly, in fact, but he might have one of his own.

THE CHAIRMAN: It is a request which ---

MR STERN: If it can be obtained by Dr Fletcher before Monday then obviously we will get that, or I ask Dr Fletcher to get it because he knows where to look.

THE CHAIRMAN: Yes, okay. Are there any other questions from the Panel? No, the Panel has no further questions, Dr Fletcher. I do not know if any points arise from that from either counsel?

MR STERN: No, I am grateful to my learned friend, Mr Kark, for completing that within the time.

THE CHAIRMAN: Mr Kark?

MR KARK: No, thank you.

THE CHAIRMAN: In which case, Dr Fletcher, thank you very much for coming to give evidence. That concludes your evidence to the Panel and you are free to leave.

THE WITNESS: Thank you.

(*The witness withdrew*)

THE CHAIRMAN: We are going to adjourn now. Mr Stern, have you any observations?

MR STERN: No, I was just standing to be polite.

THE CHAIRMAN: Do you have any other evidence?

MR STERN: There is a matter that I want to discuss with Mr Kark, but we will deal with that on Monday, if it is relevant.

MR KARK: I am afraid my copy of the Holgate report is marked, so if we could get a copy …

MR STERN: Yes, certainly, we will arrange that.

MR KARK: Thank you very much.

THE CHAIRMAN: Is there anything else that you want to say?

MR STERN: No. If there is anything further on Monday, it will be short and then …

THE CHAIRMAN: Final speeches from Mr Kark?

MR STERN: Yes.

THE CHAIRMAN: I think we are at the rule 27(1)(i) and (j) stage.

MR STERN: I am sure that is right.

THE CHAIRMAN: Thank you very much. We will now adjourn and meet again at 9.30 on Monday, 20 August.

(*The Panel adjourned until 9.30 a.m. on Monday, 20 August 2007*)