

**GENERAL MEDICAL COUNCIL**

**FITNESS TO PRACTISE PANEL**

**(applying the General Medical Council's Preliminary Proceedings  
and Professional Conduct Committee (Procedure Rules) 1988)**

On:  
Monday, 20 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 Nine)**

Panel Members:

Mrs S Hewitt (Chairman)

Mr J Brown

Ms J Goulding

Dr M Goodman

Mr R Grey QC (Legal Assessor)

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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.

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A THE CHAIRMAN: Good morning. Mr Stern?

MR STERN: You may or may not know that the video link that was proposed is not working, but I think we have set it up by telephone and the witness is ready, once she is called, to give evidence.

B THE CHAIRMAN: Who is the witness?

MR STERN: Mrs Rosalind Eaton.

*(By telephone connection)*

ROSALIND EATON, affirmed

Examined by MR STERN

C Q Is that Rosalind Eaton??  
A Yes, that is correct.

D Q You cannot see us here but you are in front of a Panel, or you are giving evidence before a Panel of the General Medical Council. My name is Ian Stern and I am representing Dr Donegan. Mr Kark, who may ask questions after I finish, represents the General Medical Council, and the Panel may then have some questions as well.

A Okay, I understand.

Q First of all, I think you live in London?

A Yes, I do.

E Q Can you tell us, please, do you know Dr Donegan?

A Yes. I first met Dr Donegan in 2003 after my first son was born, and I have therefore known her about four years.

Q How did you come to meet her, please?

F A I was concerned about vaccinating my newborn baby and I wanted to find someone who potentially had another view. I was recommended to Dr Donegan by I think a lady from the Homeopathic Hospital in London.

Q Before we move on any further, can I just ask you what you do?

A Me personally?

G Q Yes, personally, as your work?

A Currently I am on maternity leave because I have an eight-week old baby, but I work as a pharmaceutical investment analyst in the City. I buy and sell pharmaceutical shares on behalf of pension funds.

Q Do you have any qualifications, if you do not mind my asking?

H A My first degree was in medical biochemistry and then I did a postgraduate in finance, and then I ended up in the City analysing pharmaceutical shares.

Q Does that involve you in any way of having some understanding of vaccinations?

A A Yes, to an extent that I have an understanding of how the pharmaceutical industry conducts its clinical trials and undertake that in order to get pharmaceuticals on to the market. I understand the process that they go through. I also understand to an extent the science that they use.

Q The clinical trials that they use, did those have any effect on your mind?

B A Yes. What concerned me was the sort of gold standard of the double blinded placebo controlled clinical trials that the pharmaceutical industry talks endlessly about in getting traditional medicine through, but they do not seem to have to conduct these trials for vaccination, which I was a bit concerned about. I understand why they do not do it, because obviously they are not going to inject children with meningitis and then expose them to it to see how it works, but I still did not think that it would carry the same scientific clout doing it that way, because that is how they do all the other medicines that they try to get approved.

C Q You went to see Dr Donegan, did you, as a result of the recommendation?

A Yes.

Q Approximately how long ago was that, please?

D A I have seen her probably three or four times in the past four years. The first time, as I have said, was roughly four years ago, and the last time was when I was roughly three months pregnant and my son is now eight weeks old, so about six, seven or eight months ago.

Q What was the reason that you first went to see her, the specific reason that you first went to see her?

E A I first went to see her when my oldest son was eight weeks old. I was worried about the vaccination programme that it was being suggested I undertook for him as an eight-week old baby. I heard all the views of my GP and various other professionals like that. I was unhappy with the idea of vaccinating such a young baby with what I found quite an aggressive programme, so I wanted somebody who had researched an alternative, complementary view and could give me the full side of the story, because the GPs that I asked seemed to just say that this was the process I should go through rather than explaining why, what the potential positives and negatives were, so I wanted somebody who had experience of that and had researched it, and that was when I went to see Dr Donegan.

Q Just tell us then, please, what her approach was when you went to see her?

G A As I think I said in my letter, was a breath of fresh air to speak to someone who had researched the whole area of vaccination in such depth and could give me what I considered to be a much more balanced view of what was actually happening and how the immune system worked, how it should work, how it works with vaccinations, how the body would naturally cope with certain ailments, and the whole process. Because I was able to spend an hour or so with her, I was able to go through the research that she had undertaken and really understand the whole process, rather than just being told by my GP, "This is what you do at eight weeks and *this* is what you do at twelve weeks". It was a sort of very balanced, in my opinion, hour of just going through what I considered to be the facts.

H

A

Q Did she make any attempt to influence your decision about vaccinations?

A No, not at all. At one level, I actually wanted to find somebody who would say to me, "Don't do it" or "Do it". I was quite anxious about the vaccination process and, in a way, wanted somebody to tell me what to do, as you often do in that situation, but she really did not do that, and that is why I remember the structure of the meeting, because basically what she was doing was providing me with information that she made very clear to me, that vaccinating a child or not is my parental responsibility, not hers or anybody else's, and she gave me tools from which I could make the decision myself, in conjunction with the information that I had had from all the other doctors and people I had asked; so it was quite the opposite. As I also said in my letter, I think what she made very clear to me was that if you do not want to vaccinate your child but you are terrified about the outcomes of polio or meningitis, then that fear and terror is in itself a very negative influence and can be damaging, so there was no attempt to influence me at all – just to present a series of information and data that I could make my own decision on.

B

C

MR STERN: Thank you, Mrs Eaton. You may be asked questions by Mr Kark.

Cross-examined by MR KARK

D

Q Mrs Eaton, you said that you wanted to find someone who had another view. What did you mean by that – what view?

A What I meant was, I mean the doctors, my GPs and everything, had just said "Do the vaccination programme" without necessarily explaining to me why. I wanted somebody that would explain to me why I should do it or why I should not do it, or just be able to give me more information and more data. The GPs would take two or three minutes with me, because that is all the time that they had in a baby clinic, but I wanted to be able to go through the data correctly and I wanted to find someone who had actually studied the data, because I found that most doctors had not had the time to research the data that seemed to be available.

E

Q How did you come across Dr Donegan? How did you find her?

A I basically rang up as many people as I could to find somebody who could actually help me with another view, as it were. I wanted them to spend more time with me than I was able to be given by the GP. I started by ringing up the Homeopathic Hospital in London, where I understand doctors use homeopathy as well, and I thought that there might be some form of homeopathic way of vaccinating. That was my initial thought process. Through that, I think one lady that I spoke to said, "You need to speak to a lady called Dr Donegan", or she might have said to me, "You need to speak to somebody" who recommended Dr Donegan. It was one of those trails, as it were.

F

G

Q You said that she went through the research, or I think you said "I was able to go through the research"?

A Yes.

H

Q How did that work? Did she talk you through it? Did she show you the research?

A This is the research that Dr Donegan had undertaken. She talked me through it and I was able to look through the papers, and then I took the papers home. They are referenced, which made me feel reasonably confident, because obviously referencing is rather important from a scientific point of view, as I have understood from my job. So, I

**A** checked a couple of the references that I could get over the internet.

**Q** How many pages did she give you to take away?

**A** Are you talking about papers that have been published in the BMJ and things like that?

**B** **Q** Yes. I just want to know what the sort of range was, how many bits of research she pointed you to?

**A** I think all the pieces that she had written, the references were on the bottom of them, so probably I had access to, if I had wanted to look them up or access to the papers, several – probably a hundred or so I would guess, but, to be perfectly honest, I have not counted them and I do not have the piece of paper that she gave me here with me, so I cannot give you a correct answer to that.

**C** **Q** Was the material that she gave you material that she had written herself?

**A** Yes, which was cross referenced.

**Q** How many pages was that, not the cross-referenced stuff but the actual pages that she gave to you?

**D** **A** I could not give you an exact answer. I do not know the exact number of pages, I am sorry.

**Q** Are we talking about one or two or 20 or 40? Can you give us any idea?

**A** It was more than two and less than 100. I have read every single word several times. I cannot give you the exact answer; more than two and less than 100, but certainly a manageable amount to read.

**E** **Q** Did she provide a conclusion in relation to each vaccine?

**A** No.

**Q** What were the papers?

**F** **A** As I said, this is based on what I read a couple of years ago, and I think I re-read them two years ago when my second son was born. From memory, it was just basically her factual information – for example, the death rate from measles from the 1800s, then the graph falling and then when vaccinations were introduced, things like that; the background of the vaccines, when they were introduced, et cetera. I cannot remember them being definitive conclusions as such. There certainly was not a conclusion in the way that I felt, “Oh! gosh, I should vaccinate against polio but not against measles” or anything like that.

**G** **Q** Having read what you she had provided you with, what did you actually decide to do, may we ask?

**A** I did not decide to do anything on the basis of what I had read from Dr Donegan. I decided to do what I did on the basis of an awful lot of other information as well as Dr Donegan’s.

**H** MR KARK: Thank you very much.

A

Re-examined by MR STERN

Q I have one more question, if I may, Mrs Eaton. Was the material that you read balanced or not balanced, in your view?

A I personally found it very balanced.

B

MR STERN: Those are all my questions, but the Panel may have some.

Questioned by THE PANEL

DR GOODMAN: Mrs Eaton, my first question concerns your background as a city analyst with regard to the pharmaceutical industry, which you mentioned to us. You mentioned that the pharmaceutical industry uses controlled trials with placebo?

C

A Yes.

Q You mentioned that such controlled trials could not be done with childhood immunisations. Am I correct?

A That is what I understand, yes.

D

Q To your knowledge, are there in the pharmaceutical industry any other instances where pharmaceutical products cannot be subject to these placebo trials for similar sorts of reasons, such as because babies are involved and that sort of thing?

A I was just trying to recall that earlier and probably not on the drugs that I had to analyse, because mainly my analysis goes towards companies like Glaxo and Astra, who are doing pretty standard respiratory and sort of oncology type drugs. I mean even with oncology my understanding is they are double blind placebo controlled, because they are usually put into cancer patients in the very late stages of their disease. The only other thing I can think of, but I do not have anything to do with it, is HIV. I am not sure how the clinical trials are undertaken then, because since I have been doing this job I have not had to analyse drugs for HIV.

E

Q My next question is regarding the advice you asked for or you were given by your GP and you say that your GP said your child should be vaccinated.

A Yes.

F

Q Did you ask your GP for the reasons underlying that advice?

A Yes, I did. What I asked him was that I explained that I was nervous, I asked what the side effects were, how many of his patients he has had with side effects and also why we needed to do this. I think at the time it was a three-in-one, or I think four years ago they were doing three-in-one and then two others at eight weeks. He just basically sort of said, "We have always done it", was his reply, and he had seen very few side effects himself, apart from the high temperatures and then, you know, advised to take Calpol.

G

Q So, you did not seem satisfied with the way he gave you his explanation?

A I am sorry, did you say was I satisfied with his explanation?

H

Q Were you satisfied with the way he replied to you?

A No, I was not, because I wanted a bit more - I really wanted someone to give me a bit more understanding of the immunology and how the immune system dealt with the

**A** vaccines and also what a baby's immune system was actually like.

**Q** When Dr Donegan explained to you the immune system, were you given to believe by Dr Donegan that her explanation was scientifically based?

**B** **A** Basically yes, I was, but also I did not just listen to Dr Donegan. I actually went and spoke to a couple of other people who had an understanding of immunology far greater than my own and they all sort of said the same thing, which gave me confidence. If they had all said something totally different, I think I would have been a bit bewildered.

**Q** Can you recall who these other people were? What professional background they had?

**C** **A** One lady is a consultant obstetrician, who worked in the Health Service for 20 years and is now - she is still a doctor, but she works independently and so she is not employed by the NHS any more. That is one lady that was of exactly the same view. There was another lady who is not in the Health Service *per se*, but has done a lot of work with medicine, but not traditional medicine as it were.

**Q** Did Dr Donegan assure you that her view of the immune system was scientifically based, or did you just take that for granted?

**D** **A** To be perfectly honest I cannot remember how I assessed that information because, as I said, my initial meeting was four years ago. Dr Donegan was not in any way forcing information at me, or to me. It was very much, "This is what I have done. Use it as a tool to make a decision, if you choose to". It was not that, "You have to", or, "You do not have to". It was just more information that I took on board, but there was no, "I am right and everybody else is wrong", or anything like that. I did not feel like that at all.

**E** **Q** You quoted Dr Donegan as saying to you that, if you were very worried and fearful about your children getting some of the diseases like polio, the fear could be damaging?

**F** **A** I think what I was trying to express was that, you know, she was not saying, "You must not vaccinate your children", or, "You must vaccinate your children against X, but not Y". It was not that. I think what I took away from it was that, you know, obviously every parent is terrified of their child getting meningitis, which I feel that obviously that would be horrendous, but if you decide not to vaccinate but there is going to be this constant underlying worry or concern that your child might get meningitis and that you are going to be worried about it, then you should vaccinate, as it were. That is what I felt. She never used those words, but that is the inference I took. You know, "Do not not vaccinate and then spend the next ten years in a state of fear because you have not".

**G** **Q** However, she did not use the words that you told us a few minutes ago that fear can be damaging?

**H** **A** I am trying to recall a conversation we had four years ago. That is my interpretation, or my memory, of the meeting. That is what I took away thinking, "Gosh, I had not thought about it like that but, yes, if you are terrified of meningitis, or you are terrified of polio, no parent should really put themselves in that situation". That is the memory I took away. I cannot remember those exact words. As I said, my first meeting was four years ago.

**Q** You do not recall whether Dr Donegan told you, or implied, that this sort of fear

**A** could damage an immune system?

A No, no, no. I do not think it was that, no. The child's immune system? No, no, no. No, that is not what I am trying to convey at all. I just meant a parental anxiety.

**B** Q One last question. When you phoned the homeopathic hospital in London, who did you ask to speak to and do you know what sort of person you were put through to and by whom?

A I asked to speak to or I just asked if there was anybody there - if they had a vaccination department, or if they had anybody that could help me understand the vaccination process for an eight week old. I cannot honestly remember the person I was put through to, but the reason I called the homeopathic hospital was because I understood that some of the people practising there are qualified doctors who have homeopathic experience as well, rather than just being homeopaths, and I wanted someone that had a medical background as well to explain the vaccination process to me. That is why I started - because I felt uncomfortable with the process and my GP was not giving me the sort of information I felt I needed, I then tried to find other forms of information, or other, sorry, places that would provide it for me.

**C** Q Do you happen to recall ---

A I could not tell you if I spoke to a doctor or a homeopath, but I did ask to be put through to someone who could potentially help me.

**D** Q You asked the switchboard, or a helpline, or do you not remember?

A I rang the homeopathic hospital telephone number and asked to speak to somebody who could help on vaccinations and I was put through to somebody. I cannot remember at all if they were a qualified doctor, a homeopath, or who I spoke to.

**E** DR GOODMAN: Thank you very much. That is very helpful.

THE CHAIRMAN: Mrs Eaton, I have just a couple of points to clarify. When you went to your GP in the first instance, were you given any written information?

A The written information I had was from what I was given I think when you leave hospital and also from the health visitor - the NHS pack that I think is given to every mother.

**F** Q Did that refer to vaccination?

A Yes, I am sorry, it was the vaccination pack that they give you. It was the vaccination protocol for the first 18 months I think it is, or something like that.

**G** Q Can you remember where that came from? Was it a Government leaflet, or a GP leaflet?

A I think it was a Government leaflet. I think so. I think it is the standard one that was given to all mothers by the health visitor.

**H** Q The second point I want clarified is when you had completed your consultation with Dr Donegan, you said you spoke to at least two other people and you said that gave you confidence. What did you mean?

A Well just about the sort of information that Dr Donegan had given me was scientifically based and correct, that is what I meant, and because other people with

**A** medical experience said similar things that is what gave me confidence.

THE CHAIRMAN: Thank you.

Mr Stern?

**B** MR STERN: No, thank you very much, Mrs Eaton. I think that is all the questions.

THE CHAIRMAN: Do you have any points, Mr Kark?

MR KARK: No, thank you.

MR STERN: Thank you very much. I am sorry that we could not get to see you.

**C** THE WITNESS: Thank you.

*(The conference call was terminated)*

**D** MR STERN: Madam, there are just a few documents that need to be given to you. I know Mr Kark asked that you be given two documents that were in Dr Fletcher's report and they have been copied for you.

THE CHAIRMAN: Can you just identify what it is, please?

MR STERN: One is the article by Dr Holgate that he referred to. *(Same handed to the Panel)*

**E** THE CHAIRMAN: Okay, then that becomes D25.

MR STERN: The other one is the article by L and R Ball and R Pratt. *(Same handed to the Panel)*

THE CHAIRMAN: That becomes D26.

**F** MR STERN: The next matter is that you will recall that you were provided with part of Dr Elliman's instructions from Field Fisher Waterhouse. We have in fact done a full copy. Mr Kark knows about this and is content that you should have the full copy and so I will provide you with a full copy of that now. *(Same handed to the Panel)*

**G** THE CHAIRMAN: Thank you very much. That becomes D27.

MR STERN: Thank you very much. D27. The next matter is ---

THE CHAIRMAN: Just before we move on, what shall we do with these? Would you like us to read them now, or do you want to take us to points in it?

**H** MR STERN: It may be that I can take you to points in them during submissions, or you can read them at a later time. You do not need to read them now.

A

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

THE CHAIRMAN: Yes, it has no letterhead.

MR STERN: No, that is because it is a copy.

B

THE LEGAL ASSESSOR: However, it is from Field Fisher Waterhouse?

MR STERN: It is from Field Fisher Waterhouse, the solicitors to the Council.

C

The next matter, madam, is this. You will recall that during the course of the cross-examination of Dr Fletcher it emerged that Dr Elliman had in fact undertaken some training - witness training, or expert witness training. He has drafted a very short note in relation to that and I think Mr Kark has copies.

D

MR KARK: I do have copies and can provide them to you. I am slightly concerned, because I do not suppose he - well it may have been better, and this is no criticism of Mr Stern because he did not get this I do not think until Mr Elliman was either leaving or about to leave, but it may have been better if he had been asked questions about it and given fuller information. So, could I ask you just to bear that caveat in mind when you receive it.

E

THE LEGAL ASSESSOR: I wonder if I could just say something about this, because I have been provided with it and I read it and I am bound to say I do not entirely understand it and it may be I only would be able to understand it by either I or one of you, after you know what is troubling me, asking questions of Dr Elliman himself. I do not know whether I am right in saying that it seems that for the purposes of these proceedings the fact is that to the best of his memory he has not undertaken any formal training as an expert witness. I am not absolutely sure how he identifies an expert witness, but he would say that the witnesses in this case, leaving aside Dr Donegan who is obviously a witness as to facts as well, are what he describes as expert witnesses. If you are not following what I say, perhaps it would be better if you handed it, if that is what is agreed, to the Panel and then I can deal with the matter, because otherwise the Panel will not follow what I am trying to saying.

F

MR STERN: Yes, it is only very short.

THE LEGAL ASSESSOR: I am sorry, Mr Kark. I was trying to speak without letting, for the moment, the Panel know the detail.

G

MR KARK: I understand that. I think the Panel will have to see it. If there is going to be criticism of Dr Elliman based upon it then the Panel better know what Dr Elliman has actually said, but as I say there is that caveat that he has not had the opportunity. Again I do not mean this as a criticism, but he has not had the opportunity of really explaining it or being asked any detailed questions about it, but I gather it may form the basis of some criticism of him.

H

THE CHAIRMAN: This, just to identify it, becomes C8.

**A** MR KARK: No, I think it is a "D" actually. It is an exhibit the defence want to put in. The Council are not putting it in.

MR STERN: I do not mind.

THE CHAIRMAN: We do not mind what it is called, as long as it has got a number.

**B** MR KARK: I think it should be D28.

MR STERN: Is Mr Kark saying it is not relevant?

MR KARK: I am not putting it in as an exhibit.

**C** MR STERN: That is not exactly the point.

THE CHAIRMAN: Let us call it D28.

MR STERN: I do not mind which reference it has, but I have provided your Legal Assessor with a copy of an authority which relates to ---

**D** THE LEGAL ASSESSOR: I have not read it yet.

MR STERN: Which you have not read. No, I appreciate that. Mr Kark was given it on Friday. It is the case of *Momodou*. It is a criminal case where the Deputy Lord Chief Justice spoke in relation to a number of issues in the case, gave a judgment in relation to a number of issues, one of which was witness training/coaching. The point about it, not necessarily the authority because I will not address you on that until Mr Grey has read it, but I have highlighted the various paragraphs that in my submission are the relevant ones to him to assist him, but obviously he will have the whole authority there because it covers, as I say, a number of issues. The point about it really is whether or not it should have been disclosed. It is not really the level of training, because obviously the details that Dr Elliman has set out here are to say the least rather brief. What they essentially come to is that many years ago he went to a two-day course, or what he thinks was a two-day course, that involved report writing and practice of appearing in court, and it is the practice of appearing in court that is witness training which he distinguishes between expert witness training. I am not quite sure there is a difference but, whether there is or there is not, he is trained in that regard. I can make submissions about that now or at a later stage. The principal point is that that, in my submission, is a matter that should have been disclosed.

**G** MR KARK: I think Mr Stern is going to use this on which to base some criticism of Dr Elliman and I can either deal with it now or in my speech. The short point that I would make is, first of all, there is no training in relation to this case or the facts of this case, as it were. Any failure to disclose depends on whether Dr Elliman knew that he ought to disclose it. As you will see from the letter of instruction that has just been put in – I have not read it again in detail – I cannot recall that there is any instruction to him to disclose any previous expert training. Perhaps he ought to have known that he should, but if he is not asked to do it and the training took place many years ago, you may think that the criticism of him is limited, if not without foundation. That is the short point that is being

**H**

**A** made, I think, by Mr Stern, that he should have disclosed his training.

THE CHAIRMAN: Legal Assessor.

**B** THE LEGAL ASSESSOR: Mr Stern, as it is D8 (*sic*) I will address you. I am trouble about this, because I do not entirely understand it. Part of it in fact seems to be opinion evidence which he is giving, not being an expert. That starts with the words:

“There are two categories of witness in medicine –  
(1) Professional witness to fact  
(2) Expert witness.”

Then just the next sentence for the moment:

**C** “The former...”

that is the professional witness to fact,

“...is something that any doctor may be required to be.”

**D** Of course, when he uses the words “professional witness”, do you understand that means giving evidence for something that happens on a doctor/patient basis? I will give you an example. This is in order to try and understand it. A doctor might see a stabbing in a surgery, for example. He might then have to be a witness as to fact. Any doctor, of course, and any other member of the public may be required to be a witness as to fact. I was wondering is the word “professional” included in (1) in order to exclude that situation or does it include any incident where a doctor is a witness to something?

**E** MR STERN: I think if one looks a little further down...

THE LEGAL ASSESSOR: I was going to. I was trying to take this in stages to try and understand it.

**F** MR STERN: It may be that this last sentence in this paragraph explains what it is Dr Elliman meant. He says:

“I undertook this because it is useful for all doctors to do, but particularly because of my involvement at the time with child protection issues.”

**G** I assume that relates to giving evidence as a paediatrician.

THE LEGAL ASSESSOR: Going on with his third line:

“It was many years ago but I think it was a two day course.”

**H** Pausing there, you do not know who ran this course.

MR STERN: As Mr Kark said, this is what we received at the end of Friday and we did

A not know anything about it until such time as it emerged when Mr Kark thought, as you will recall, that Dr Elliman had in fact been trained by Bond Solon, but had confused it with Dr Goodman.

THE LEGAL ASSESSOR: He goes on to say:

B "...a two day course that involved report writing and practice of appearing in court. I undertook this..."

Then he says:

"To the best of my memory I have not undertaken any formal training as an expert witness."

C If he went on a course that involved report writing, if he is writing a report for litigation or writing a report, is that not as an expert witness?

MR STERN: Yes. In my submission, it is a semantic distinction.

THE LEGAL ASSESSOR: That is why I cannot see the difference.

D MR STERN: He did not go on it because he fancied just going along and might be a witness in the odd case if he saw a car accident. He has gone along because he is a doctor and might need to give expert evidence in due course. Whether he has or he has not, I do respectfully understand the point you are making. Mr Kark will make his submissions and I will make my submissions. Obviously you will no doubt listen to those and draw your own conclusions and accept or reject the point. If I may say so, the details of the course may be important for each of those arguments, but we do not have those.

E Ultimately, the issue is one of disclosure. It may also be the way in which this is written is also relevant to how the Panel approaches training.

THE LEGAL ASSESSOR: Is it agreed that perhaps in this case Dr Elliman and Dr Donegan are in precisely the same position that neither of them has undertaken any formal training as an expert witness? *(Pause)*

F What troubles me is that this is going before the Panel. It is something that they are going to take into account. Dr Donegan was cross-examined on the question of whether she had undertaken any training. In this case she is definitely what one might call a lay witness in one sense, in the sense that she is the only one who can speak as to her intentions, which are quite important, as to whether she allowed her deeply held views to affect her report writing. She can also give evidence in relation to that as an expert witness, in the same way that Dr Elliman can. It is important to be able to understand whether there is any criticism of Dr Donegan for not having undertaken any formal training, or whether there is any difference between her and Dr Elliman so far as their expertise is concerned in that regard.

G H MR STERN: My reservation is that Mr Kark did not cross-examine Dr Donegan on the issue.

A MR BROWN: It was Dr Fletcher.

B MR KARK: I do not want to spend too long on this if possible, but if the simple issue is that this training should have been disclosed and it has not been, that is one thing. If it is going to be suggested that this fundamentally undermines in some way the evidence that Dr Elliman gave, that is quite another. If that is going to be suggested, then Dr Elliman ought to have the opportunity of dealing with it and I would have to apply to recall him, either recalling him live or recalling him by way of video link. I do not think it is fair, with respect, for there to be a fundamental attack upon Dr Elliman's evidence on the basis that many years ago he undertook a course and for him not to be able to answer it. If the simple point is that he should have disclosed it, frankly I think I can answer that without having to go to the extent of recalling Dr Elliman. I am concerned that the attack is more fundamental than that.

C THE CHAIRMAN: Mr Stern, can you help with that?

D MR STERN: I hope I have made it clear that the point is, as I said earlier, that in my submission that should have been disclosed. Where you are a witness who is coming along to give evidence specifically about expert evidence and the role of an expert, one might have thought that you would disclose the training that you personally had had. That is the point I want to make. I hope that that clears up the issue. That is the simple point. The non-disclosure, as I think I said before, is the issue.

THE LEGAL ASSESSOR: It has been disclosed now and you do not wish to have Dr Elliman recalled to question him on it.

E MR STERN: I personally do not, but if anybody else feels that they want to have him back, then they can. I think Mr Kark was saying that the evidence was irrelevant, so he probably does not want Dr Elliman back. In my submission, the point is for you to decide whether it is relevant and, secondly, if it is relevant, what weight to attach to it.  
(Pause)

F THE LEGAL ASSESSOR: I am sorry. You will have seen us talking and wondering what we are talking about. There are notes coming from Dr Goodman making a point which, as he has it at the forefront of his mind, are questions which should be asked by him.

THE CHAIRMAN: They are more observations than questions.

G THE LEGAL ASSESSOR: If they are observations, it makes it even more important that they should be mentioned in open court.

THE CHAIRMAN: Dr Goodman, would you mind making those points and if you want to put a question to Mr Stern or Mr Kark, by all means do so.

H DR GOODMAN: Thank you, Chairman. They were just observations from my own experience and background and unrelated observations. The first observation was that the BMA, when it used to be allowed before the monopolies people came in to recommend professional fees for court or have a list of agreed fees – I think it is still in the list – had

A two different fees. One was for an expert witness, which is what we all know. One was for when a doctor appears as a witness to fact, often subpoenaed, in relation to a fact that arises from his or her medical practice. The BMA has negotiated with the Court Service a fee for that, which the BMA calls a professional witness fee.

MR STERN: That is absolutely right.

B DR GOODMAN: The only second issue I was concerned about with the debate was an observation that if the courts now and in 2002 strongly recommended that all expert witnesses have training, I personally could not see the logic as to where that training had to be disclosed, because it would have occurred to me that they say, "You must have training and you must disclose it", but they say you must have training ideally. That was just my observation.

C MR STERN: I have not seen the document or the court decision which you are referring to which says that the courts have insisted on training.

DR GOODMAN: Strongly recommended, with respect.

D MR STERN: I have not seen a court document to that effect. I think if one looks at the authority that I have provided to Mr Grey, and indeed there is another one we have here, although I do not need to burden you with it, a first instance decision by a High Court Judge, indicating that disclosure is relevant. I am not sure that they are necessarily mutually inconsistent. When you have training does not mean to say that therefore the corollary is that you should not disclose it.

DR GOODMAN: It would not be my position to dispute that with Mr Stern.

E MR STERN: I am grateful to have an opportunity to deal with it.

F THE CHAIRMAN: We have got to the point where you do not want Dr Elliman to be recalled. I do not think we require him to be recalled. We will receive D28 as it stands and we will give it the weight that we think in our deliberations. Obviously you can address us whichever way you like.

G MR STERN: I will not address you until such time as Mr Grey has had an opportunity of looking at *Momodou*. It may be that even Mr Kark and I can discuss such matters as we need to and we can help you, I hope, by reducing what is rather a large judgment to something slightly more pithy in relation to just this particular point. If we cannot, then we will have to give you more. I hope we will be able to help you in that regard.

H THE CHAIRMAN: Is there any other matter within the last three documents previous to D28 that you want us to pay particular attention to?

MR STERN: No. I think we are coming to the end of all those points. I think that is it. If you are going to take a coffee break, you might like to read the letter of instruction in full. It is D27. I am not saying that you should not read anything else. I am merely saying that if, in relation to my submissions, at some point I might invite you to look at this letter. I do not think it will take you very long to read it. You have obviously got

**A** Mr Kark first anyway, unless he does not want to make a final speech.

THE CHAIRMAN: Mr Kark.

MR KARK: If, as I suspect, we are about to take a break before we launch into speeches, I wonder if that is the close of Mr Stern's case and I think it is...

**B** MR STERN: I was just checking to see if I had missed something. There are so many bits and pieces. No, that is it.

**C** MR KARK: So that is the close of Mr Stern's case. Could I draw your attention to the heads of charge? There are two amendments that we are going to seek and I do not think they are challenged now. It may be helpful and pertinent to that now before we do take a break. Head of charge 3, first of all. You will recall that there was a partial admission and it was partial because of the words "purported to be independent". Having spoken to Mr Stern and the Legal Assessor, we all think that, given that paragraph 3 is otherwise simply a factual allegation that she wrote two reports, it would be far simpler if we took out the words "purported to be independent" and inserted the word instead "were" so that it reads:

**D** "You produced reports signed on 14 June 2002 and 4 December 2002 which were medico legal reports..."

It removes the issue at that stage in head of charge 3 of whether they were purporting to be independent or not. Later on you will have to make that decision in any event.

**E** Before you turn to Mr Stern, there is one further short suggestion of amendment. That is at 6(d), which reads at the moment that in the reports that she provided Dr Donegan failed to present an objective, independent and unbiased view. I have been tasked about the word "view" and I think it would be far more helpful if that were to read "report", because any view is liable to be subjective or is bound to be subjective. So:

"Failed to present an objective, independent and unbiased report;"

**F** You have the power to allow those amendments, provided there is no injustice.

**G** THE LEGAL ASSESSOR: Mr Kark, I am sorry to raise it. It is a small point. Last week I initiated this or certainly went along with the suggestion that there might be an amendment. It was not until after I had spoken to both Counsel this morning that one matter occurred to me in relation to that amendment. I want to make sure that you are satisfied with the English which results from this. I had forgotten that, when looking at (d), you had to go back to the beginning of (6) and include the words:

"In the reports that you provided you,

d. Failed to present an objective, independent and unbiased report;"

**H** Does that make sense or not? If not, what can we do about it?

**A** MR KARK: You are quite right. It is always a problem with amending. Can I have a think about that?

THE LEGAL ASSESSOR: It may be that that is why the word "view" was used in the first place.

**B** MR KARK: Can I think during the break and then we can see if we can get that right.

THE CHAIRMAN: Ms Goulding has an observation or question.

MS GOULDING: Just a suggestion that it might say, "Failed to be objective, independent and unbiased".

**C** MR KARK: That is very helpful and perhaps we can have a think about it.

THE CHAIRMAN: Mr Stern, do you want to come back on any of those?

MR STERN: Not at the moment. Perhaps we can think about the various views that have been expressed and consider that.

**D** THE CHAIRMAN: Given the fact that we would like to read these, shall we say half-past-eleven?

*(The Panel adjourned for a short time)*

THE CHAIRMAN: Mr Kark, are we going to look at the drafting of these?

**E** MR KARK: Just dealing with 6d, I think the suggestion was a good one. Either we could amend it to "In the reports you provided you were not objective, independent and unbiased" or "you failed to be..." – which I think was the suggestion – "...objective, independent and unbiased" and then take the word "view" off the end.

THE CHAIRMAN: Put a full stop after "unbiased" and take out "report"?

**F** MR KARK: Yes. In other words, ignore my earlier suggestion of "report" and insert those words at the beginning.

THE LEGAL ASSESSOR: The words "objective, independent and unbiased" as it were stand or fall together because of the use of the word "and". I cannot see circumstances where it would not be all or ---

**G** MR KARK: No, I think that must be right.

THE LEGAL ASSESSOR: Depending on other findings that would either be as a result of objective, independent and unbiased ---

**H** MR KARK: It rather follows, one would have thought, with respect, from (a), (b) and (c).

THE LEGAL ASSESSOR: Yes, exactly. Thank you very much.

A MR STERN: We have discussed this particular amendment and indeed tried to help you and ourselves to understand the way it is set out and, in doing so, this seems, if I may say so, a sensible point to try to clarify at least one aspect of it, so I do not oppose that application.

THE CHAIRMAN: ...*(inaudible – off microphone)*...

B MR STERN: I do not oppose that one either.

THE CHAIRMAN: In that case, it becomes a purely factual statement. Given that, are you going to admit it in its entirety now?

C MR STERN: I think I have already admitted all the factual parts, as I made clear, and Mr Kark has now deleted the part that was unadmitted.

THE CHAIRMAN: Indeed, in which case we will mark it as being found proved.

MR STERN: That is precisely so.

THE CHAIRMAN: That is 3 in its entirety?

D MR STERN: Yes.

THE CHAIRMAN: Thank you. Would it help if I just read it into the transcript, to say that 6d will now read, “failed to be objective, independent and unbiased”?

MR STERN: Yes.

E THE CHAIRMAN: Mr Kark.

MR KARK: I think we can all recognise that this has not been the easiest case, in the sense that the amount of material that you have all had to grapple with has been very large indeed. I may make some references to the research, but I am going to try not to do that too much.

F  
G You must not lose sight, of course, of what this case is all about, and I repeat what I said at the beginning of the case, which I know you all now readily appreciate, namely that this is not a case about the efficacy of vaccines; it is not about whether any side effects are causally related or not to those vaccines. The fact that the efficacy of vaccines is almost universally supported by the quoted research in their conclusions is not seriously challenged, I do not think, either. The case is not about the experts or the relative qualities of Dr Elliman or Dr Fletcher. The case is about Dr Donegan’s two reports and whether or not in those reports she gave misleading impressions of the research that she purported to rely on and whether she omitted relevant information as set out in the heads of charge.

H It is not said by the GMC that the whole of what Dr Donegan wrote in her reports was wrong or unsupported. A good amount of what she wrote was not misleading. Some of what she said was no doubt supported by research. But there were parts of her reports that

A the GMC say were thoroughly misleading and would have left the reader with quite the wrong impression of what the research that she was quoting actually said.

B Before I turn specifically to those issues, it is important, in my submission, that it is admitted that when she produced the reports that she did she knew, as is set out in head of charge 3, that those reports would be read by the litigants and their legal advisers and any other experts instructed in the case and by the judge trying the action.

C The fact that there had been previous reports from Dr Conway and Professor Kroll does not absolve her from her duties both under *Good Medical Practice* and under the Civil Procedure Rules. The reports that had preceded hers were very short and they cited no research in support of vaccination. It may be that the writers thought it unnecessary to do so, because all the research supported, in general terms, vaccination. It was not until Dr Donegan wrote her report, taking a contrary line, that any research was mentioned, so it was crucial that she cited that research accurately.

D Consider who was going to read her reports. It was not just Dr Conway and Professor Kroll. It is important, in my submission on behalf of the GMC, that both the fathers and the mothers of these two young girls were going to read the reports. It can be inferred that they would have read the reports which affected such an important issue in their children's lives, in their lives, with considerable care, and it was an important issue to both of them because the fathers were actually taking the mothers to court as a result of it. So they would be expected, as Dr Donegan agreed in her evidence, to take her report seriously.

E Mr Stern thought that I was taking a very poor point when I put to Dr Donegan that the fathers would read her reports and might take the view that they ought to abandon their action, because he said that they had their own lawyers and, as he put it, an array of experts. It is right that they did have Dr Conway. They did not have Professor Kroll, because he was for CAFCASS, not for the fathers. It is true that they had lawyers representing their interests, but lawyers of course ultimately act upon their clients' instructions.

F The point that I was seeking to make – and it is for you to decide whether it is a good point or a bad point – was that if the fathers took Dr Donegan's first report at face value and some of the dire warnings contained therein, they could easily have taken the view that they as parents were not prepared to subject their children to the level of risk that was being set out. Whether their lawyers sought to dissuade them from taking a certain course or advise them against it is, frankly, irrelevant. What is more, the lawyers themselves might have been misled by the reports, in our submission, into giving certain advice to their clients, now that the research on the face of was properly revealed by Dr Donegan's report. The point that I was therefore seeking to make was to underline the importance of properly reflecting what the research actually said. It is also relevant to head of charge 5, which again has been admitted, that Dr Donegan was aware that the provision of her reports might affect the outcome of litigation.

H Let me then try to assist you as to how you might like to approach head of charge 6, which is, of course, central to your function. All the experts probably made mistakes in their reports. Dr Elliman no doubt gave the wrong references by way of example. Dr Fletcher

A had missed certain of the references that Dr Elliman had given, so he got things wrong in that way. But what is alleged against Dr Donegan is different. It is that she gave false and/or misleading impressions of the research that she relied on. If your view is that any misleading happened in a minor sense only, then you would want to apply what lawyers call the *de minimis* rule. You would say to yourselves, “Those minor misinterpretations are so trivial that they could not be described as giving a false impression of the research on that particular issue”. If, on the other hand, you found that in certain respects a substantially false impression was given of the research in a particular aspect, then you would be entitled to say that you were sure that a false or misleading impression had been given.

B  
C As I have said, much of what Dr Donegan wrote may be correct and accurate, and there are two sides to the argument, and she was entitled to put the other side. However, what she was not entitled to do was to leave the reader with the impression that a particular piece of research said one thing when in fact it said the opposite. She was entitled to quote selectively from research reports and publications. Indeed it was necessary that she should do so, but she was not entitled, in my submission, to leave out relevant information that would put an entirely different gloss or sense on that quoted.

D Head of charge 6c alleges that she allowed her deeply held views on the subject of immunisation to overrule her duty to the court and to the litigants. It would appear that she does not immunise patients herself, although it would appear that other partners in her practice do. She writes at the top of page 10 of her report that her view had changed. She said:

E “So I had been telling parents that there were side effects associated with vaccines but they would basically protect their children against the diseases, but now it seemed that this was not actually the case.”

F We know that she did in fact in this case advise that in any single one of the nine possible vaccinations that the children should receive – and, of course, their boosters et cetera – neither of the children should be vaccinated with any of them. She says that when parents ask her, she does not dictate to them but advises them to do their own research. You have heard from Mrs Eaton this morning what her experience was, bearing in mind that that experience in fact came in the year following the incidents that you are considering and the reports that she had written; and we do not know, because unfortunately Mrs Eaton was not here, in fact what she was given, although it seems to have been some of the writings by Dr Donegan herself.

G Dr Donegan told you that she does not hold her views superficially. If she does have deeply held views on the issue of vaccination, that in itself is not a criticism of her. Indeed it may be thought to be laudable, but the issue for you is whether she allowed those deeply held views on the subject of immunisation to overrule her duty to the court and to the litigants. If you find 6a and 6b proved – in other words that she had given a substantially misleading impression of the research that she had read, and that she had omitted relevant information – then you may think that (c) follows almost as a logical extension, because why else would she do it other than that she allowed her deeply held views to overrule her duty to the court.

**A** Remember her instructions, and remember also her duty under *Good Medical Practice*. Each time I make a reference to *Good Medical Practice* I will give you the reference but I am not going to ask you to turn up each one unless it is specifically relevant, and I know that most of you will remember this well in any event, but in Dr Elliman's reference 1, paragraph 51, the rule is stated in this way:

**B** "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."

**C** You have also Dr Donegan's instructions, which are part of the defence exhibits. At D2, on the fifth page, I am just going to read to you the extract from the Civil Procedure Rules in May 2002. Paragraph 1.1 reads:

**D** "It is the duty of an expert to help the court on matters within his own expertise. This duty is paramount and overrides any obligation to the person from whom the expert has received instructions or by whom he is paid. Expert evidence should be the independent product of the expert, uninfluenced by the pressures of litigation."

Paragraph 1.3:

**E** "An expert should assist the court by providing objective, unbiased opinion on matters within his expertise and should not assume the role of an advocate."

This is D2, about the fifth page in of the CPR rules. Finally, 1.4:

"An expert should consider all material facts, including those which might detract from his opinion."

**F** Then there were her instructions, which you have as another defence exhibit, D22. You have the letter dated 24 May from Andrew & Andrew. It is the fourth page in. On the second page of that letter, her instructions are set out under the heading "Your instructions":

**G** "Please consider the case and prepare a report for use in the proceedings. In particular, we would ask you to answer the following questions:

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

**H** So she is specifically being asked to provide, as it were, point and counterpoint, both sides of the argument.

**A** There was also the letter from Battens, solicitors, dated 29 May. In addition to the instructions provided by Andrew & Andrew, she is asked to comment on any known side effects of the proposed immunisations. I am obviously not going to read all of them out, but then you will see this:

**B** “Any medical research that you are aware of that deals with any of the individual immunisations and the said effects of the same worldwide.”

**C** You will, I expect, have to consider how that was intended and how it was in fact understood by Dr Donegan, but at the end of the day, whether quoting from domestic research or international research, the impression in the report had to be accurate. Equally, whether or not there had been other reports, her report had to be accurate as an entity.

Those rules and her instructions make it clear that she was being asked to consider both sides of the question and that she had a duty not to leave out relevant information that would assist the parties and the judge by putting them into a position of knowledge.

**D** As she agreed when she gave evidence, Dr Donegan did not know that there would be any further reports after hers. When I refer to Dr Donegan’s evidence, I am going to give you a reference number just for your note, but I am not on each occasion going to turn them all up. I am relying on day 7, page 2. What Dr Donegan cannot and does not say, as I understand it, is, “I accept that what I wrote was misleading, but I knew that it would be corrected by others”. She had a duty to ensure that her report was not misleading, whatever had gone before and whatever was to come thereafter, and it was important that her report accurately reflected the material.

**E** Dr Elliman’s evidence was there to help you, but, as I have said earlier in these proceedings, you are not governed by any of the expert evidence in the case. Mr Stern tested his independence as an expert witness, and this morning you have received a further document, which I suppose is intended to in some way undermine him. Just on that, I will say what I said earlier: there is no evidence that that training has in any way affected his evidence. He is not here to answer questions about it. But if the attack is, **F** “Well, that should have been disclosed”, you have to go to his letter of instruction. There is no duty revealed to him to disclose such training and, if he should have done or if he should not have done, you may think that it is a genuinely technical point that is being taken.

**G** I am not suggesting Mr Stern is not entitled to test his independence as an expert witness, but you may think that he had no particular axe to grind on behalf of Professor Kroll or Dr Conway. Dr Elliman plainly does hold a view about the efficacy of vaccines and you may think he was extremely knowledgeable about the background research. You will have to assess it and see how far he did help you.

**H** Dr Fletcher, it is matter for you, but you may think that he did not in fact help Dr Donegan’s case at all, nor more importantly did he really give any evidence that could conceivably assist you except to give you a bird’s eye view of how a lay reader, in other words one not expert in this particular field, might have been misled by what Dr Donegan

**A** had written. He was no expert - and he readily confessed that he was no expert - in the field of immunology and vaccination. Indeed this was the first time he seemed to have come across some parts of the research and, indeed, he had not even read all of the research even where parts of it were very pertinent to the complaint against Dr Donegan.

**B** He claims - and I do not want to be too unfair to him, but he does claim - somewhat blithely in his report that in his view Dr Donegan wrote a balanced report. You may think, with respect to him, that his opinion does not help you a great deal. However, I do not resile from what I said that this is not a case about experts. It is a case about two expert reports. So I would respectfully submit to you that you should not be subverted into worrying too much about Dr Elliman, or Dr Fletcher. Concentrate on the reports.

**C** In terms of areas of Dr Donegan's report which I submit were plainly misleading, I am not going to refer to anything like all those that Dr Elliman referred to and there may be areas which I rely on which you do not think are particularly important. Equally, I may rely on areas of Dr - I am sorry, there may be areas of Dr Donegan's report which I do not refer to that you actually think are misleading. Provided Dr Donegan had an opportunity of dealing with those then you are entitled to rely on those in forming your conclusion, and so what you make of the reports is frankly up to you as a Panel and what follows are merely examples which I submit support the various heads of charge.

**D** As I go through it might help you, although it is entirely up to you, if you make a mark or a note as it were as to which quote I am referring to. I will ask you to have at least Dr Donegan's report available to you, and I am going to start at page 11 of the first report and I am using obviously the pagination in the bottom right-hand corner on each page. I will pause for a moment. (*Pause*)

**E** The first quote that I refer to is at the bottom of the first paragraph beginning:

“Early treatment of diphtheria with antibiotics tends to render people susceptible to further attacks when the antibiotics are stopped,

and I will refer to that as quote 1.

**F** Mr Stern was unhappy at reliance upon this because when we got the 11th Edition, when it was actually finally produced to Dr Elliman during the course of his evidence, as it turns out even the 11th Edition makes it clear that it would have been perhaps more helpful if it could have been made obvious that the further attacks referred to were shortly after the antibiotics being stopped. So that is by no means the most major complaint that we can make about this report, but it is of note that even in fact referring to the 11th Edition, which Dr Donegan was referring to, on one view she did not even quite get that right.

**G** Quote 2 is the paragraph thereafter:

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

**H**

**A** and then at the end:

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

**B** That you may think - and again I am not going to ask you to go right back to where the references are, but that you may think - does in fact give, or is capable of giving, the wrong impression. It is unfortunate that the copy document at tab 2 of Dr Donegan's references, which was the whole of page 98 and then the top half of page 99, stops halfway down the page, as it were, when the rest of the same quote is talking about the efficacy of vaccines.

**C** Let me turn to the third matter on that page, where at the end of the next paragraph Dr Donegan writes:

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

**D** Again to the lay eye, without having to go or without going to the background research, that is misleading in dealing with the Russian experience, because it does not reflect in any sense the article to which Dr Donegan must in fact have been referring which reveals that in terms of the epidemic in Russia it waned as a result of the mass immunisation programme and the reader would not get that impression at all. The reference for that, if anybody in due course wants to turn it up, I think it is tab 3 of Donegan - Dr Donegan. If I refer to Dr Donegan as Donegan, I am sure she will not take it as being discourteous to her.

**E** Quote 4 on the same page:

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

**F** Well, you will have to consider that. Dr Elliman says that there is no evidence that the organism is any less virulent, but it is accepted that modern medicine has meant that our treatment of it has got better.

**G** Dr Donegan there has in fact stopped halfway through the author's quote, which is at Elliman tab 6. Although she has not cited the research upon which she appears to have been relying, you may think it comes from the same text as before, which was the 11th Edition, her tab 2. In fact, if she had completed the text it would have given a different impression. Once again, whilst Dr Donegan is entitled to make the point that she does, it is wrong in our submission to half quote.

**H** I am going to deal with the issue of thiomersals separately. If we turn over the page, we can see halfway down the paragraph starting:

“Listed side effects for the single, low dose, adult diphtheria

A vaccine”,

etc:

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

I am going to deal with that, as I did in cross-examination, as a separate issue.

B There you have on the first page of her substantial points on diphtheria three, if not four, areas where the reader is likely to have been misled as to what the research was actually saying.

Let me ask you to turn to pertussis and could you go to page 18 of the report, please. Would you just give me a moment while I get hold of the relevant transcript? *(Pause)*

C Quote 1 that I would ask you to look at is halfway down the page starting with the words:

“Despite vaccination rates of 94% in under twos the incidence of pertussis has been increasing since 1995. Between 1995 and 1997, 10 of the 12 deaths from whooping cough were in babies under 2 months of age. As with a number of recent reports from the UK, USA and Australia, there seems to be a trend towards increasing numbers of deaths in very young children and a ‘waning’ of vaccine effectiveness in 1-4 year olds”.

D That comes from Dr Donegan’s tab 23 and one has to put that together with the words at the bottom of page 18:

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

F I asked her about this at page 30 of Day 7 and can I just remind you of her answer. I am obviously going to be selective before I am accused of being so. I am obviously going to be selective about the quotes that I use. Day 7, page 30, at D:

G “Doctor, I want to ask you this: if the reader of this went away with the impression that, overall, the vaccination programme was ineffective or that vaccination led to a higher instance of complications over all, that would be wrong, would it not?

A That would be wrong”.

and then she goes on:

H “I have said here that the vaccination, as you will read on the last page, 410 of that paper, in the conclusions ...”

A

and then she completes the quote and makes it clear the point that she was trying to make. However if you read that section of her report, particularly as the lay reader would have done, then they would have come away in my submission with completely the wrong idea as to the effectiveness of that vaccination.

B

Can I take you to quote 3, page 19, and my quote 3 is against the paragraph starting:

“Does the vaccine cause brain damage?”

C

This is derived from the NCES study, which we know was in itself subject to considerable criticism, but it has been misquoted by Dr Donegan as she accepts in two respects. First of all, Dr Donegan speaks on a number of occasions in this paragraph about brain damage. Dr Fletcher complained in his report, and indeed when he gave evidence when he was re-examined by Mr Stern, that Dr Elliman was splitting hairs when he pointed out the difference between illness and damage. To a doctor, the difference is significant. To a parent, it may be significant too. One would not want either damage or neurological illness, of course, but one is undoubtedly more serious than the other.

D

There is then the second matter, which is in relation to whether that study did indeed look at children who had been vaccinated more than seven days before the neurological event. The point of that, of course, is that reading Dr Donegan's report one might have thought that in fact the incidence of neurological illness, or as she put it brain damage, would be even higher because the NCES study was only looking at seven days prior to the event to see whether the children had been vaccinated, but again that was an error and Dr Donegan said at Day 7, page 31, when I asked her:

E

“You have accepted that is an error.

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

Q In the context of this, what do you say now about the use of the word ‘damage’, brain damage?

A In the context of this and the specific meaning of the word ‘damage’ it would have been more appropriate, I think, to write ‘illness’”.

F

It may be said that all of that is reflective when Dr Donegan gave evidence to you and frankly admitted that parts of her report were misleading. That is Dr Donegan now. Frankly, it does not matter whether it is now, whether it is reflective or not. It reveals her view of what she wrote was wrong. That at this stage is the substance of what you have to decide. Was it misleading? How serious that is may be an issue that you will have to consider, should you find the facts proved, later on in the case. The simply question that you have to ask yourselves is: was what she wrote misleading?

G

H

Quote four is a more subtle complaint. That is at the bottom of page 20. It refers to the Michel Odent retrospective study and the fact that Dr Donegan has failed to distinguish with the assistance of the Judge and the parties the differences in weight that should be ascribed to various reports. Let me say straightaway that if that were the only allegation that were being made against Dr Donegan, you might think it is extremely unlikely that

A she would be here and that we would have spent two and a half to three weeks, as it will be, deciding these issues.

Nevertheless, it is, you may think, unfortunate that when writing her reports she did not make it clear what the difference in weight that should be ascribed to the reports was. The Odent study was retrospective, non-blind and looked at 346 children. The Oxford study, to which she referred over the page, was also retrospective, came from a single Oxford practice, linking 1934 patients, again not blind.

B

There were then two further prospective studies, the Avon study, looking at 9444 children and a further Nilson study looking at nine and a half thousand children, both finding that there was no causal link between pertussis and asthma related illness.

C

Dr Donegan is entitled to mention the first two studies, but to the untutored eye, certainly, it may occur that they have equal weight to the other one. She failed to mention the Nilson study at all, but setting that to one side, reading this report, what impression would one have unless put in the picture? When she gave evidence Dr Donegan accepted what Dr Elliman had said about the different weight to be attached to different research. That is at D7/32. The hierarchy, in our submission, is important for a lay reader to understand, because otherwise there is the obvious danger that they will give all numbers of research the same weight.

D

The fifth quote is in relation to the Japanese experience, which is also at page 21. You will recall these words halfway down page 21 in the main paragraph starting "The Swedes..."

E

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

At D7/33 letter E I asked Dr Donegan specifically about that passage:

"Q Do you accept that the effect of that could be misleading?"

A I accept that the effect of that would be misleading."

F

There is one final point to be made about the pertussis vaccine and that is this: Dr Donegan agreed that the licensing vaccine did not cover child B because of her age. Dr Donegan had not mentioned that in her report. You may think that she had become somewhat blinkered, missing a valid point against vaccination in the welter of research that generally supported it, but where she was trying to find contraindications, as it were. You may think that her deeply held view, if you find that there was one, was getting in the way of an unbiased scientific approach which would in fact have helped the court.

G

Let me turn to the issue of tetanus and page 29 right at the top. This, on behalf of the GMC, I would submit, was substantially misleading. This is in relation to tetanus:

H

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

A (AIDS).”

You may think that the reader of this, particularly the lay reader, would take that very seriously. This was a piece of research that, it would appear, Dr Donegan was referring to. She gives at the bottom of the page a 1984 piece of research and she gives the reference.

B Unless one went to the research itself, take the mothers of these two girls first of all, would their resolve to refuse to allow their children to be vaccinated with tetanus not be considerably hardened by reading that paragraph? What would the effect on the fathers have been? You may think they might even be shocked into reversing their view on tetanus. It was a very irresponsible comment to have made.

C If one goes to the research, it becomes clear that the effect to which she referred was temporary only. At page D7/37 of the evidence I asked her about that. I said:

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

A I accept that point.

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

A I cannot say about that.

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

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

It is not good enough, lest this be suggested, that Dr Donegan has included the research, because she cannot have expected certainly the lay readers – and by that I include the Judge – to have read, nor indeed understood, the detailed research that she was quoting. Obviously one would expect the experts, if they are instructed to do so, to make due inquiry, as it were, but the fact that she is copying the research and citing the research does not absolve her, in our submission, from the duty to ensure that what she wrote in her report was accurate. You may think that that paragraph may have had a considerable impression on the reader if left uncorrected.

F Dr Fletcher said that that was one that had slipped through his attention, but he agreed that it was important to mention the total effect, but, as he put it, it did not strike him as being terribly awful. That is a very nice expression. Perhaps it was not terribly awful. This is D8/46. It was certainly, in my submission, misleading.

Let me turn to polio and page 34, skipping over thiomersal again. The first whole paragraph on that page starting with:

H “As the World Health Organisation struggles to achieve its aim of worldwide eradication of polio it is notable that epidemics of

A paralytic poliomyelitis have occurred in highly vaccinated populations and, tragically, immediate after a polio vaccination has occurred.”

B The whole of that paragraph, you may think, is close, certainly, to being irrelevant to considerations in the UK. She wrote it, says Dr Donegan at D7/40, because of her instructions to give a worldwide perspective. If that is how she took her instructions, it would also have been helpful to make it clear that the experiences which she refers to in India and Israel in fact would have nothing to do with the vaccinations that these two children were likely to receive in the UK.

C The next example, my quote two, is on the same page. It refers to the mention of SV40 or simian virus. This is in one sense a piece of scaremongering because, being realistic – I do not want to over-egg the pudding – I was going to say the fear of God, but it would certainly cause any caring parent considerable concern and would trouble any lay reader.

D In truth, it is completely irrelevant, because the contaminated vaccine has not been used since, apparently, 1967, which she nowhere makes clear and the quote underlined at the top of page 35 is only half a quote. If you will give me a moment I am going to find the actual reference on this occasion. It is at tab 51 if anyone wants to follow it. The quote that she underlines is:

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

E That may be right of itself, as it were, but can I just complete the sentence for Dr Donegan.

“It thus remains possible that a later 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 postwar generation.”

F Quite apart from not completing that report, it is nowhere made clear, in our submission, that contamination was not relevant to the vaccination that these children would receive.

At page 36 it may be thought that she repeats the error, because in her conclusion just above the references she says this:

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

H There was no evidence that the new vaccine was in fact contaminated or had ever done any child any harm.

**A** She was cross-examined about this at some length I am afraid at D7/42. I asked her about the sentence that she underlined. I have said page 23 because I was using the pagination in the top right hand corner. It should be page 35, if anyone wants to correct their transcript at D7/42. I said:

**B** “Q This is the sentence that you underlined on page 23 of your report. So you stop there, but in fact the sentence carries on:”

She said later on:

“A I am sorry. I was giving another view of the vaccine, or the vaccines and the diseases, which had not been brought to the attention of the court by the other experts.

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

A Yes.

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

**D** A Yes.

Q You were not just asked to do one because there were a couple of reports that had been pro vaccination. You were not being asked to write a report that just dwelt on the disadvantages, were you?

A I should have at the beginning of my paper said:

**E** ‘The advantages of the vaccination having been presented by Dr Conway and Professor Kroll, I will now attempt to give a balancing view’.”

just before she agrees at page 44 that she thinks it is a good idea to quote full sentences.

**F** There are two points there: so far as this is concerned, she was not quoting full sentence. In our submission, she was giving a misleading impression to the reader.

**G** Could I turn to HiB on page 39 of her report? I do not want to spend too much time, if any, on the difference between a temporal link and a causal link. I expect I could spend the rest of the day, if I understood it properly, trying to deal with that issue. It is obviously a technical issue. However, what Dr Donegan does do, in my submission, is she does not make it clear anywhere in her report where she does talk about reactions – she never makes it clear – that there is no causal link. Again, the lay reader simply is not going to understand that.

An example of this is on page 39 where she writes in relation to the Hib vaccine, about a third of the way down the page:

**H** “Other reaction reported to the Vaccine Adverse (E)vent Reporting System (VAERS) in the USA are Guillain-Barre Syndrome – a

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

B Or one, might want to conclude, or by none of them, because there was no causal link established, but that is never made clear.

C Can I turn to page 45 of Dr Donegan’s report? This is dealing with meningococcus. The heading of the paragraph is, “In 1997 the Department of Health was said to be resisting pressure to introduce blanket meningitis vaccination for university students”. This report, as you know – and I am not going to keep going back to it – was taken from *Pulse* magazine. You may think that this information had only the very slightest relevance, if any, to the issues that Mr Justice Sumner had to decide, because the vaccine mentioned in the press articles was a different vaccine from the one that was later introduced and a different vaccine from the one that these girls would have received. That was certainly not made clear. Indeed, the impression from Dr Donegan’s report was that that report was about the relevant vaccine, because she starts her next paragraph with the words, “The vaccine was nonetheless introduced...”

D The second quote, which is about four lines up from the bottom, reads:

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

E It may be accurate, but there is a cynical gloss, you may think, imposed by the words “it was decided” and it would have been simpler simply to reveal perhaps what the research actually made clear, that there was no evidence of a causal link to any of the deaths; and some of the deaths certainly could be entirely excluded, one would have thought, having looked at it, as vaccine having been the cause.

F Could I ask you to go to page 49, please? I am so sorry, could you go back to page 46? My reference was wrong. First of all, the paragraph starting “By the summer of 2000...” reads:

“By the summer of 2000 the CSM advised that further side effects should added to the product information of the vaccine in relation to older children and teenagers.”

G Then she reveals the various supposed side effects:

“Neck stiffness and photophobia have also been reported and convulsions at a rate of one report per 100,000 doses.”

H Just concentrating on that for a moment, she dealt with this in her evidence at page 50. I asked her about tab 76 of her own research. Tab 76 is headed “Current Problems in Pharmacovigilance Prepublication Copy” under the heading “Safety of meningococcal group C conjugate vaccines”. This was the quote where Dr Donegan was taking that

A 100,000 figure from:

“Seizures have been reported very rarely, with approximately one report per 100,000 doses distributed. Some of the reported seizures may have been faints, febrile convulsions, or coincidental. A causal association between seizures and the meningococcal C conjugate vaccines has not been established. The CSM has recommended that a statement to reflect this information...” –

B

one would have thought all of it –

“...should be added to the product information.

C

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

Having quoted those words to Dr Donegan, I asked her on page 50 of her evidence on day 7:

D

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

She said, “Yes, I could have included those last words”.

E

At the bottom of paragraph 46, the paragraph beginning “The meningococcal C vaccine...” – and this is my quote 4 and 5, because there are two misquotes here – her evidence in her report about the US forces was simply wrong, and Dr Donegan properly accepts that it was wrong. She understood that there was a difference between the disease and the acquisition rate, but that is not reflected in the way in which she wrote this paragraph. She dealt with this in her evidence, for anybody who wants to look it up, at day 7 page 52. She said:

F

“That is wrong, because I put ‘disease’ instead of ‘acquisition’. I think I am not the only person who has made the odd typographical error.”

No, perhaps not, but there are a series of errors in this paragraph, and let me just go through them. This is four lines down that third paragraph on page 46:

G

“When used on US forces the incidence of meningococcal C disease was reduced two to three times...”

H

Just stopping there for a moment, as I think we made it clear, if the word to be used is “disease”, then it was reduced in fact ten times, according to the research, but she would be right about the acquisition rate being reduced two to three times if that is what she was referring to.

The last line of that paragraph is also wrong. She writes:

A

“In fact, the attack rate of group B meningococcal disease was higher among the vaccinated recruits.”

Again for your note – I am sure you have already got it – it is tab 77, where the paragraph finishes with these words:

B

“The reduction in the attack rate is consistent with a protective effect of 87% against group C meningococcal disease.”

Let me turn, please, to page 49 of Dr Donegan’s report. We spent rather a long time on depressed cell mediated immunity. I do not have to spend very much time on this, I think, because when Dr Donegan gave evidence to the High Court – and this at page 108-112 of the transcript of the High Court case – she accepted that her comments there about depressed cell mediated immunity were inappropriate. To acquaint the effect of the disease with that of the vaccine was inappropriate when the research that she was relying on in fact said the exact opposite. If you want to turn that up, it is tab 85. I am not asking you to do it now. The point from that report was staring out from the first page where we can see at the bottom the conclusions:

C

D

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

The research that Dr Donegan was relying on, in our submission, did not in any way support her contention, as it were.

E

Could you just read on? This is, you may think, a troublesome paragraph, which as a whole gives a very misleading impression. She writes in the third line down:

“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, very risky.”

F

First of all, the high titre vaccines were withdrawn in 1996. They had never been used in the UK, so you may think that this was bordering on the completely irrelevant. Putting all of that into one paragraph with the final line being, “To give a vaccine that has such an effect...” is, in my submission, wholly misleading. Out of interest, when Dr Fletcher gave evidence he admitted that not even he as a doctor really understood what she meant.

G

I am afraid that I have taken that reference off my computer and I know that it is not always quite the same as the transcript, but I think it is around day 8, page 50. In fact, Dr Fletcher did not know if it was the high titre vaccine that was being used in the UK, so you may think that he was a good example of exactly where this report could have misled not just the lay reader but in fact a medical person, albeit not with specialised knowledge of this particular field.

H

**A** When she gave evidence – and I am quoting from page 59 – Dr Donegan said:

“I think I have agreed that unhappily I could have put the sentence in a different way.”

**B** Could I ask you to go to page 54? This is the issue of subacute sclerosing panencephalitis (SSPE). What has happened here again is that Dr Donegan has given half a quotation. It is from the paragraph starting:

“A report in the British Medical Journal from the Communicable Disease Unit at the London School of Hygiene and Tropical Medicine stated that after the 1994 measles rubella campaign there were 530 reactions reported...”

**C** That, of course, should be “suspected reactions”; but, more important:

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

**D** Again it is a matter for you, but you may think that it could appear, indeed would appear, from that paragraph that what in fact Dr Donegan appears to be saying was that the vaccination occurring only a month before the incidence of SSPE is directly relevant to it. I know that you know all these references, but tab 98 makes it quite clear that that is not in fact certainly what the author was saying, and let me complete again the sentence on behalf of Dr Donegan that she did not:

**E** “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.”

**F** Dr Elliman’s evidence, if you recall it, was that there had never, to his knowledge, been a case of SSPE caused directly by a vaccine; it came from wild measles. Reading that paragraph of Dr Donegan’s report, you may think that you would not understand that at all, unless you went back to the research and read it rather carefully.

Let me turn to the issue, please, of mumps, and page 58. At the bottom of that page, two lines up from the bottom, Dr Donegan says:

**G** “In fact, it is thought that having mumps with recognisable parotid swelling has a protective value against getting ovarian cancer in later years. This is clearly desirable.”

**H** No doubt it would be. This again is not the most serious complaint against any particular passage in this report. Of course, Dr Donegan was entitled to mention the 1966 study, as it was, but you may think that again she has over-egged the pudding. “In fact, it is thought that...”, as she phrases it, might be thought to mean “It is currently thought by doctors practising in 2002 that ...” and that there is a scientific basis for it, rather than one report 36 years ago which actually found a causal connection with a possible protective

A value was suggested but the later research did not find any such link, though I accept that the later research was looking at something slightly different. All I am suggesting is that that should have been put in context as to the quality and indeed the age of the research.

Could I ask you to go to page 60? This is in relation to the last couple of lines of the first paragraph at the top:

B “There is a possibility that immunisation against mumps is causing a mutant strain to emerge with limited or no cross protection from the vaccine strain.”

C This again is the good old *Pulse* magazine. Even relying on *Pulse* magazine, it has not been quoted quite accurately. What the article actually says (and if anybody wants to check it is tab 111) is:

“... however, four of our confirmed cases have received two MMR vaccines and the remote possibility of a mutant strain...should be looked into.”

D Well (a) it is a pretty weak report, you may think, and it has not been quite quoted accurately by leaving out the word “remote”.

Can I turn to page 62, please, and this aspect of the report was grossly misleading. You probably do not need much reminder of it, but in the main paragraph in the middle Dr Donegan writes:

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

Therein lies the problem, that very first sentence, because Dr Donegan has missed out part of the report which is essential for its understanding. In fact it appears in her references at tab 115, where she even underlined the relevant sentence which is under word “Background” (so if anybody wants to check it is tab 115):

F “National surveillance of congenital rubella ... started in 1971 ...”

G Those words underlined are the very words that gave the true picture to her words, but she did not unfortunately include them and she did not therefore make it clear that national surveillance did not start until 1971. Dr Fletcher also agreed that that was misleading, Day 8, page 54, and Dr Donegan’s evidence about this appears at page 66. I asked her this at page 66 of Day 7 at F:

“If the reader came away with the understanding that the actual number of cases of congenital rubella had gone up between 1965 and 1990 that would be wrong, would it not?

H A From the data that I was using that was the data that was stated on the paper”.

She did not quite answer the question, you might think. The next question:

A

“Q Let me just repeat the question. If the reader came away with the understanding that the actual number of cases of rubella had gone up between 1965 and 1990 that would be wrong, would it not?

A Yes, it would be wrong, but that is what they would get from reading this because that is what I wrote, because that is what I was reproducing from the table that I was looking at”.

B

I then asked her about the underlining and she said:

“A Yes, that is me.

Q When did you underline it?

A When I was reading it.

C

Q When was that?

A This is originally, not subsequently.

Q So you have underlined the words, under ‘background’:

‘National surveillance of congenital rubella started in 1971’.

D

A Yes”.

The question at the bottom of page 67 of the transcript:

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

E

A Yes”.

Then I carried on dealing with her words, “So the number of cases have gone up”:

“When you later used the phrase, “so the number of cases have gone up”, you meant from 39 babies, did you?

F

A I did. I meant from what was *here* on the table, yes. You are quite correct in the inference that you are taking from what I have written”.

I then asked her:

G

“Q That is misleading, is it not?

A It is, in retrospect, yes”.

You may think that almost of itself that would prove your head of charge 6 (a) but, as I say, there is much else besides. To leave out that crucial factor does leave wholly the wrong impression, because it totally distorts the reality.

H

The second quote on that page is much less significant, but nevertheless relevant. In the same paragraph about six or seven lines down:

A "12 of the affected babies were born in 1996. The mothers of eight of them were born and raised in the UK and would have been eligible for the schoolgirl immunisation programme (ie they had been vaccinated)".

B Well, that again is just an exaggeration. Again Dr Donegan accepted, when she gave evidence at Day 7, page 68, that she should have written "were most probably vaccinated".

I should think I have only got about 20 minutes or more so to go, but I wonder if that would be a convenient moment?

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

C *(The Panel adjourned for lunch)*

THE CHAIRMAN: Mr Kark, please continue.

MR KARK: I will take it that the fact that we are starting a minute early is a compliment to my speech, but it may not be.

D MR STERN: We will probably be finishing a minute early when I start.

THE CHAIRMAN: We have got everyone in the room who should be here, have we?

MR KARK: We are all here, yes.

E THE CHAIRMAN: Yes, thank you.

MR KARK: Can I turn to the next point, which is a short point in relation to page 65. It is under the heading "How vaccines work", and this is the first quote right at the top of the page where Dr Donegan says at the end of that paragraph:

F "Only IgG antibodies are induced and mucosal immunity is not stimulated except in the case of oral polio vaccine".

Again that is inaccurate, Dr Donegan has accepted that that was not as she puts it happily written and she accepted at page 70 of Day 7 of the transcript that she:

G "... omitted the point about the acute stage IgM antibody in some of the vaccines".

H Now, again, let me make it clear. If that fault stood alone in this particular report then of course that is not something that would have brought Dr Donegan before this Panel, but nevertheless it is an omission and on each occasion where there is a relatively minor error of that nature it is invariably, in our submission, on the side of non-vaccination. It is never an error, minor or otherwise, on the side of vaccinating. You will have to consider that issue when you consider whether she was in fact allowing her views on immunisation to overrule her duty.

A

Let me turn, very briefly in fact, to the knotty issue of thiomersals. She mentions thiomersals at various parts of her report, page 12, page 21, page 29 and page 66, but particularly at page 66 she deals with the issue of thiomersal and the effect of mercury on the human body and the fact that in children possible effects on the developing nervous system might lead to impaired mental skills, etc, etc. You will also remember, back on page 12 of her report, the mention of the Department of Health pamphlet mentioning that thiomersals in the vaccine can cause kidney damage.

B

In fact once again she is entitled to mention thiomersals and she is perhaps entitled to mention some concern about thiomersal, but the reality is - and this should have been put in my submission into perspective - that as we heard from Dr Elliman the quantity of thiomersal being used in this country is very low, it is certainly lower - whatever the exact measurements, it is certainly lower - than is used in the USA and, because of the triple vaccine which contains only one measure of thiomersal instead of three, it is lesser still.

C

Out of interest, we read from the material now produced by Dr Fletcher - and this is part of the defence exhibit 26 which was put in this morning. This was a report in fact published in May of 2001. I will just pause so that if anybody wants to find the page they can. It is D26. This is the American experience of thiomersal, in which the conclusion reveals:

D

“Our review revealed no evidence of harm caused by doses of thimerosal”

- as they call them -

E

“in vaccines, except for local hypersensitivity reactions”.

This is page 71, the large 71 at the bottom:

F

“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”.

G

Page 77, the conclusion, a factor that I do not think was in play as it were until this document was produced. I will not read the same seven lines or so from the conclusion because they are repeated, but then this:

H

“The clinical significance of this conclusion is not currently known; EPA guidelines 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”.

A

The reference there to the fact that infants in the first six months of their life might receive thiomersal in America exceeding the EPA recommendations, one has got to ask how relevant that was to two children in this country who had been receiving less thiomersal and were aged three and nine, with the relevant perhaps I can use the word concomitant bodyweight that there would have been? So, again it has got to be put into perspective and it frankly has not been.

B

Can I then turn to the second report and I can do so much more briefly. Can I also say this. You do not have to lump the two reports together, as it were. If you found that in the first report, for instance, there was false or misleading impressions of the research given but not in the second, although this is not something that I would invite you to do, then you would be entitled to say in my submission so far as 6 is concerned, "Well, I will apply what lawyers call the blue pencil test because two reports include the one". You would be entitled to say, "We find that proved so far as report 1 is concerned, but not report 2".

C

However, there is material in my submission in the second report which repeats the errors of the first. Although it is right to say - and one has to bear this in mind whenever looking at the second report - that that was a response as it were to Dr Conway, nevertheless it has still got to apply the same principles and Dr Donegan still had to quote the research accurately and could not obviously misquote it.

D

At page 77, first of all, the very first entry, the very first sentence:

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

E

For what it is worth certainly Dr Elliman's view was that it has in Finland and Sweden, but let me move on to page 83. Just to remind you really, paragraph 1.17 was Dr Donegan's response to Dr Conway dismissing the Stewart paper. Dr Elliman's criticism here is that, if you look at Donegan tab 6 from her original references, there on the right-hand side of the page at the end of the Stewart report is the Malleson report which comes to the opposite conclusion, and Dr Donegan admitted when she gave evidence at page 76 on Day 7 that it was on the same page.

F

I am sorry, would you just give me a moment? I asked her:

"Q Dr Donegan, the question with respect is why would you not bother to read that report? If you had been instructed to write a balanced report, why would you not bother to read that? Is it just because it is on the other side of the argument?"

G

A Well if I had the journal I would have read that report, but this was one of the papers that I had got from the British Medical Association and if I had had the rest of it there, I would have, but I have not read the rest of it."

H

You may think that that does demonstrate a somewhat blinkered approach, that Dr Donegan having been asked to look at both sides of the argument, was looking at one,

A

even when another report, albeit which opposed what you may think is her view, was sitting there on the same page as a report that she was relying upon.

Let me turn to page 87 please. This is just an example of an exaggeration, but an exaggeration which may have had an effect upon the reader, dealing with neurological illnesses purported to have followed DTP immunisations. The report that she was citing said this:

B

*“neurological illnesses reported to have followed DTP immunisation are clinically indistinguishable from idiopathic childhood neurological illnesses...”*

This is chapter 1, paragraph 1.26 at page 87.

C

*“...this immunisation was given at around the same age at which idiopathic neurological illness is typically first recognised...”*

What Dr Donegan has written is:

D

“The ‘controls’ in these studies are not unvaccinated, they have been given tetanus, diphtheria and polio vaccinations, these vaccines are associated with numerous adverse reactions and may indeed be the cause of ‘idiopathic’ childhood neurological illnesses themselves.”

All I would say about that is that, again, Dr Donegan is simply putting it too high and she is slightly exaggerating the suggestion. What impression, you have to ask yourselves, would be left with the reader?

E

Can I ask you to turn to page 107? This is an example, you may think, of Dr Donegan really sticking to her guns, which she would be entitled to do if she was accurately reflecting the results of the report which, according to Dr Elliman’s evidence, she was not. This is going back to the Guinea-Bissau report. It is paragraph 1.68. I asked her about this at page 79:

F

“...Can I just ask you this. Had you gone back to look at this again?

A Yes, I had.

Q You had?

A I had.

G

Q Did you understand that the authors had allowed for that?”

“that” being that 40% of the children with measles had been vaccinated. You will remember that that had actually been allowed for in the conclusion. She said:

H

“A Yes, that they had taken out the other ones and the ratio remained unchanged.

Q Was it relevant to mention that, do you think?

A

A Yes, I could have usefully mentioned it.

Q Should have?

A I do not know. Could have/should have.”

B

That is at page 79 of the transcript. You might have thought the right answer was “should have”.

Could I ask you to turn to page 112? I am just going to check Dr Elliman’s reference. I am not going to ask you to turn it up, but if anybody needs to note it – I am sure they already have – it is page 56 of Dr Elliman’s references. Dr Donegan writes:

C

“The same paper states that insulin dependent diabetes mellitus and pancreatitis has been reported to occur after measles, measles-mumps and MMR vaccine at an incidence of 1 per 250,000 doses.”

I am going to stop there because that is the end of the relevant part. The quote that she was relying on came from page 224 of tab 56 of Dr Elliman. Let me just read it out:

D

“The occurrence of IDDM after measles or measles-mumps or MMR vaccine has been reported from Germany, at an incidence of 1 per 250,000 doses.”

That would seem to be where she is getting it from.

E

“For most of the 20 cases reported, the onset of IDDM was between 3 days and 7 months post-vaccination. However, the numbers of IDDM (not vaccine-related) expected over the same period was far in excess of 20.”

Again, you may have thought that this was a half quote and it was misleading, even if she was answering Dr Conway, because she failed to make it clear that the number of IDDM incidents not vaccine related were in excess of those which were.

F

Those are the central parts of that second report upon which the GMC rely.

G

Can I make a comment about timing, because one of the issues that Dr Donegan has complained of is that she was under pressure of time to complete both her first and second reports. In relation to the first report I think she got an extra two weeks when she asked for it, but no expert can lay the blame for a misleading report on lack of time. It may be mitigation. It might affect your ultimate decision on sanction if you get to that stage, but it cannot excuse, in my submission, leaving out relevant information, particularly where Dr Donegan went to such lengths to include examples from Africa, Russia, Oman and India, most of which, according to Dr Fletcher, are almost entirely irrelevant.

H

So, the plea, “I did not have enough time” – of course, she could have asked for more time, but if you find that these parts of the report that I have drawn to your attention once again were misleading, then lack of time, with respect to Dr Donegan, does not excuse her.

A

Again, you have to weigh up all the evidence that you have heard and you have to bear in mind that really there are no errors, in our submission, which go in the contrary direction.

Again, if you find that her deeply held views on the subject of immunisation did overrule her duty to the court, then lack of time, with great respect, is neither here nor there. The answer to lack of time is, "I cannot produce a proper report in the time available to me."

B

Dr Donegan has admitted on a number of occasions, and I have drawn a number of those to your attention, that her report was in parts misleading. In other areas which she has not admitted I submit on behalf of the GMC that Dr Donegan was in fact leading a misleading or false picture.

C

At this stage in the proceedings you do not have to decide how seriously misleading her actions were. You simply have to decide whether, first of all, 6(a) to (d) are proved. I have made the comment already that if you were to find any errors trivial and unsubstantive, then you would not find, you may think, that she had given a false or misleading impression. Of course, my submission on behalf of the GMC is that there were errors. They were substantial in the sense that they left...

D

If you find (6) or the majority of (6) proved, you will then have to consider 7(a) (b) (c) and (d). If you find, for instance, 6(a) proved, that she gave false and/or misleading impressions of the research which...

THE LEGAL ASSESSOR: It is only if you find the majority of (6) proved. Do you mean that or do you mean if you find any...

E

MR KARK: I should say any. I was about to deal with (a) as an example. If you find, by way of an example, 6(a) proved, that she gave false and/or misleading impressions of the research which she relied upon, you would then have to go on to consider 7(a) (b) (c) or (d). You may think that if you come to the conclusion that parts of her report were misleading to a significant degree, and certainly if you found that her deeply held views on the subject of immunisation had overruled her duties in court, certainly if you found that she failed to be objective, independent and unbiased, then (a) would prove itself, as it were; (b) would also in effect prove itself. She would be in direct contravention of her duty as an expert witness, both under *Good Medical Practice*, but also under the CPR rules. She would, in our submission, have been bound to have been acting unprofessionally.

F

So far as likely to bring the profession into disrepute is concerned, you have to consider the number of people who were going to read these reports and consider them. There were the litigants, their lawyers, the other experts and a Judge who was going to have to read her reports and make a judgment upon them. Her actions once the faults in the reports were recognised were, in my submission, likely to bring the profession into disrepute.

G

At this stage, because we are an old rules case, there is another feature that you have to consider which you have probably grown unused to. That is that, although you are not deciding the issues of serious professional misconduct, you do have to consider whether the facts as found proved are insufficient to be capable of amounting to SPM.

H

A

I know that you will receive a direction from your Legal Assessor in due course, but let me just underline that. You are not deciding at this stage the issue of SPM, but simply whether the facts are capable – that is how I would put it – of amounting to SPM. In my submission, they plainly are one you have decided that any misleading was not of a trivial nature.

B

If you do so decide so that you are sure that she gave a false or misleading impression of research and that she failed to comply with her duties to the court and to litigants, then she will have transgressed *Good Medical Practice* in a significant way. As I say, at this stage you do not decide the issue of SPM, but simply whether the facts as you find them proved are insufficient to be capable of amounting to serious professional misconduct.

C

Those are my submissions.

MR STERN: Madam, can I start by just dealing with two matters? I do not seeking to embarrass any one individual in particular or, indeed, to be critical. It is merely so that these words are heard by Dr Donegan and that the matter is dealt with so that it is clear in her mind that there is no question of any rebounding against her.

D

There have been certain incidents during the course of the hearing, at least it is my experience, and therefore I do wish to deal with two preliminary issues. The first is the role of Counsel and the second is the role of the Panel.

So far as Counsel is concerned – I am talking about defence Counsel at the moment – he or she has the task and privilege of representing an individual to the best of his or her ability. Of course, Counsel has a discretion as to how to approach that. If, and I say if, one of your number felt a degree of hostility to certain parts of the cross-examination of Dr Elliman – as I say, it may be that I am wrong, but I suspect certain adverse reactions – I would say two things.

E

First of all, Mr Kark is equally as experienced as me. Mr Grey is probably twice as experienced as both of us put together. Madam, I know you are extremely experienced in this Panel. I know that any one of the three of you – I do not mean to exclude anyone else – would have interrupted, checked me or made some comment in relation to that if that were the case. I am grateful to the learned Legal Assessor who has indicated in private to me – I do not know if he is constrained to say otherwise in the hearing...

F

THE LEGAL ASSESSOR: Mr Stern, as you have mentioned this, had I thought that there was anything wrong in either yours or Mr Kark's conduct, in the cross-examination or any part of the case I would most certainly have intervened. Not only do I happen to know both of you well enough and know your reputations well enough over many years to be quite sure that that would not happen in either of your case. It most certainly has not happened in this case.

G

MR STERN: I am very grateful. The point I want to make is not so much for me. The point I do want to ensure is that if there is any hostility it is not directed to Dr Donegan.

H

The second is the role of the Panel or, indeed, any tribunal of fact, because it is important

**A** that any tribunal listen to and have an open mind as to the evidence and to draw any conclusions that they may, either accepting or rejecting the evidence once they have heard it and, as it were, not to seek to actively undermine that evidence during the course of it being given. It exhibits, I am sure wrongly, a closed mind which, of course, could be considered from the doctor's perspective to be rather unfair.

**B** Having said that, as I say, I do not want to embarrass anybody and I am not seeking a response of any kind. I want to now turn to deal with the case, if I may.

Can we look at the heads of charge, please? These are extremely tortuous, if I may say so, and, with great respect to the General Medical Council, they are far from clearly drafted, and I am afraid the result of that is a little muddled thinking not least of all in the final submissions of my learned friend.

**C** Can I start by submitting first of all in relation to these heads of charge that it is easier to say what it is that they do not actually allege? If we look at that, I hope that that will give you some perspective on what it is that the case as put by the General Medical Council actually is. First of all, there is no allegation that Dr Donegan acted dishonestly. There is no allegation that Dr Donegan intended to mislead anyone or that the reports were deliberately or designed to be misleading. That is not the allegation in this case. It is not alleged that her views were anything but genuine; it is not alleged that there was anything misleading in her evidence; there is no criticism that she holds deep views; it is not alleged that she simply made errors and that those errors somehow give a misleading impression. That, of course, would be an allegation of performance rather than conduct.

**D** So one has to say: clearing away the decks as to what it is not, what is it that the General Medical Council allege in this case? The allegation, in my submission, is that in  
**E** Dr Donegan's reports she failed to present an objective, independent and unbiased – it was originally "view" but it obviously must be "report" or "reports", as a result of her deeply held but genuine views on the subject of immunisation. I do not know if you have managed to get that down, but that is essentially as I see it, when one condenses the allegations down, what the General Medical Council is saying. It is not just that there are a few errors, because every single expert in this case has made errors, every single expert in this case has admitted to misleading to some extent, and every single expert in this case  
**F** has agreed that, with hindsight, thing might have been put differently. That is not what brings a doctor before her professional body. The central allegation is that the reports are, as I say, not objective, independent and unbiased, as a result of her deeply held views on the subject of immunisation.

**G** Of course, having set that out, that probably actually raises more questions than provides answers, as I hope to show when we go through. Head 6a and 6b are merely, in my submission, the means by which head 6d comes about. The allegation is not that "at paragraph 6 you did *this*, at paragraph 7 you did *that*, at page 15 you did *this*", but the allegation is, "In the reports you gave false and/or misleading impressions" (whatever that may mean) "of the research which you relied upon, quoted selectively from research, reports and publications and omitted relevant information" – well, that is clear enough – and "(d) failed to provide an objective, independent and unbiased report". That is really what it is about, and (a) and (b), as I say, are the means by which you come to 6d. That is  
**H** my submission as to how this reads and, in fairness, how it should be looked at.

**A** The central allegation, as Mr Kark has said certainly in opening, although in his closing he has reduced his allegation almost to 6a – he has ended up almost relying just on 6a, that there are false or misleading impressions and has not addressed you overall on 6d, that is to say, that the report is – I am going to call it “not independent”, forgive me, but if I paraphrase in that way rather than repeating all the words, that is essentially what it comes down to.

**B** So the central allegation relates to the false or misleading impressions of the research that she relied on and the quoting selectively et cetera as a result of her deeply held views on the subject of immunisation. It is not just an objective test of whether, viewed now today in 2007, it is misleading. The allegation is that she gave false et cetera, that she quoted selectively et cetera; in other words, that she did that at the time in 2002 when she wrote the report. In my submission, it is not appropriate or correct for Mr Kark to say “Oh well, it does not matter that you can now look at the position in 2007 and forget about whether or not she actually did that in 2002”. That cannot be right. There is no retrospective view of any kind of allegation. If that were the allegation, then it should have been stated objectively – “your report is misleading”. That would be the allegation, but it is not. The crux, as I say, of the case is that of head 6d, which is governed by 6c.

**C**

**D** Indeed, if one looks at head 7, it says “Your actions”; it does not say “your report is misleading”. It says, “Your actions in head 6 above were misleading” – in other words, the actions of quoting selectively et cetera, and I will not repeat the same thing over and over again. It is the actions of doing that which actually led to the failure to provide an objective, independent and unbiased report, and those actions come about directly, causally, if I may be so bold as to say, not temporally, as a result of her deeply held views on the subject of immunisation. So it is critical that you need to look to see whether the reports, as this is alleged at head 6, are independent, as I am going to call it overall, and, secondly, whether or not those reports, if they are not independent, were directly as a result of her deeply held views.

**E**

**F** Now it is in fact the way that Mr Kark put the case to Dr Donegan when he cross-examined her. I am going to take you to a number of references during the course of my submissions to you. I can see already that the heads are beginning to drop at the thought of it, but I am afraid it is quite important. Can I just promise you one other thing, so that there is, as it were, a snippet of hope? In relation to the points that Dr Elliman makes, when I go through those I will do it extremely quickly. Dr Goodman will be able to follow it in due course afterwards because Mr Singh has very kindly prepared a schedule of the transcript references of examination-in-chief, cross-examination and re-examination for each of the points, so you will have those there and you will be able to see exactly what it is that Dr Donegan said on any of those points at any time. I hope that will be helpful to you. I am sure it will be. You do not look convinced that it will be helpful.

**G**

THE CHAIRMAN: I am sure it will be.

**H** MR STERN: Can I ask you, please, to look particularly at days 6 and 7? I am going to ask you to look at day 7 first of all, page 13B. At day 7, page 13B, very early on in cross-examination, Mr Kark, who has a duty to put his case perfectly properly, says:

A

Q You see, I am going to suggest that the aim that I suggest you had, which was to persuade the judge not to order vaccinations, coloured almost every page that you wrote and that in some areas you misquoted or left material out which was quite subtle.”

I do not think we have got a misquote actually, but nevertheless...

B

“In other ways it was more blatant.”

Then he says, “Now let us start, please, at page 11.”

If you look at page 85C on the same day, in the conclusion of his cross-examination, you will see this:

C

“Q Do you accept that you quoted selectively from research, reports and publications and omitted relevant information? Before you answer let me just remind you of two occasions where you actually stop halfway through a sentence. Do you accept that you quoted selectively from research and omitted relevant information?”

A I think quoting is, by its nature, selective.

D

Q It may be, but do you accept that you omitted relevant information?

A I think it would be hard to write a report and not omit some relevant information at some point, and I think that, certainly, that is one of the reasons I had to write the report the way it was because that is what had happened with the other two reports. They certainly did not make misleading impressions of the research because they did not quote any, apart from in the MMR addendum of Professor Kroll.

E

Q Dr Donegan, on a number of occasions you left relevant parts of information out, did you not?

A There are places where I have left out.

F

Q I am going to put this to you, because it is in the heads of charge. I do suggest to you that you did allow your deeply held feelings on the subject of immunisation to overrule your duty to the court.

A I disagree.”

G

So that is the central allegation in the case as put forward by Mr Kark. I think we can probably add another one of those points to the list of what the case is not about, because today, for the first time, rather than a colouring of every page, as Mr Kark put to Dr Donegan, he said, “Much of what she wrote was correct and accurate”. He also said, “A good amount of what she wrote was not misleading”. So that is where we are at the end of the case.

H

We are not talking about errors or matters that in hindsight could be construed as misleading, or that matters might in hindsight have been put more clearly. There is not, I

A submit, a single expert report, lawyer's advice, lawyer's submission, or any other document that you care to name, that could not be construed as misleading in certain respects, could not be construed – and I will show you in relation to Dr Elliman when I come to it, because, in my submission, every single word of the matters that Mr Kark has said about Dr Donegan can be said of Dr Elliman in his report when we come to it... As I say, if that were the case, each and every expert who had given evidence has accepted that  
B to a greater or lesser degree. So the central point is that because of Dr Donegan's deeply held view on the subject of immunisation, she was so blinkered that you can be sure that it caused her to overrule her duty to the court, namely to provide an independent report. That, in my submission, is the central allegation.

If you agree – and I submit it is clear that that is the way the case has been put and indeed the distilling of the allegations – there are, in my submission, three issues that you need to  
C look at. The first is this: are you sure, on all the evidence, the selection of quotes or the omission of other quotes or the false and/or misleading impressions of research, Dr Donegan failed to provide an independent report? It will be my submission that her reports were anything but that. Only if you are sure of that do you go on to consider whether you are sure that the reason for that were her deeply held views on the subject of immunisation, again whatever that may mean, and we will have to look at that. If your view is that the report was not an independent report and that was or might have been  
D because of the shortage of time and those other points that I am going to come to, then in my submission that would not have been made out.

It is only if you are sure of those two issues and those two propositions that you would then go on to look at head of charge 7. As I say, I am sorry to spend quite a bit of time but it is so unclear and the words are so difficult to work out precisely, and one has to have a clarity of thought about what the allegations really are because otherwise it is at the end of  
E the day very unclear what any finding may mean.

The highest that Mr Kark puts it on behalf of the General Medical Council is that Dr Donegan's report gave false impressions or misleading impressions. What we are not talking about here is a series of wholesale falsities that one may have come across in other cases. That is not what we are talking about. We are talking about misleading  
F impressions on the subjective evidence of a paediatrician, Dr Elliman, who was called as an expert and told you that to him they created misleading impressions. In the opening that Mr Kark made before you, on virtually every point he told you "Dr Elliman says *this*" and "Dr Elliman says *that*", and in his closing after two and a half weeks, Mr Kark said, "The case is not really about Dr Elliman, the case is not really about the experts, and it is really a matter for you" because he is now inviting you to look at it from a father's point of view, not an expert's point of view.  
G

One therefore wonders why it was that we were treated to five or six days of Dr Elliman's evidence if you are to be told that you can ignore all of that and that really what you need to look at is the evidence from the perspective of a father who has never been called but look at it from a man on the street and speculate, please, if you will, about what it is that that person may or may not have gained an impression of. The case, I am afraid to say, with great respect to my learned friend, is not thought through with any clarity.  
H

So the position that we are in now is we have an expert who gave evidence as to what

A misleading impressions are from an expert's point of view because, as you know, madam, he would not have been able to give evidence unless it were expert evidence because he is giving opinions. He could only give opinion evidence on the basis that he was an expert. Otherwise, none of us are able to give opinion evidence. Now Mr Kark says, "Well we do not actually need any of that, because it is the father who you have got to look at it from".

B It is a total shifting of position, it is unattractive and it is unfair in my submission, because what was one has to do is to start from the basis that a case that has taken something like three years to get here, the case is set out, Dr Donegan has the evidence that she knows she has to meet and she and her lawyers worked towards meeting that evidence and then suddenly it moves in a completely different way.

C Impressions are, of course, of themselves entirely subjective. You are asked, when each of you may have different impressions, to come to conclusions in relation to this. It is the result as I say of muddled thinking, because I asked Dr Elliman in cross-examination and questioned him about this, "Are you giving evidence as an expert, or are you giving evidence of impressions?", and he said he was giving evidence as an expert. It is somewhat strange that the General Medical Council seek to rely on Dr Elliman as the evidence that they put forward and nobody else - not Dr Conway, not Professor Kroll, no evidence from the fathers, nobody else - and yet the submissions that are made to you are impressions from a witness who is not here. It is entirely speculative and I have no doubt

D you will be warned about the dangers of speculation.

E There are errors in the reports, or probably only the first report actually, of Dr Donegan. She has accepted those. There are two instances where she has accepted that in hindsight the answers could or would be misleading and I am going to take you to those in due course, but that is not the issue in my submission. The issue is did she fail to provide an independent report? That is the basis upon which the heads of charge are drafted. That is the basis upon which she was brought here; that the reports, etc, etc. I will not repeat it.

F Now the General Medical Council relies on Dr Elliman's evidence, or at least they did when I wrote this speech, to support this assertion. His evidence is central to the case, because you have his report and it is evidence which the GMC have at one stage invited you to rely upon. So, I do have to address you about his evidence - about him as an expert and about his evidence - because you have to evaluate him as an expert and you have to evaluate his evidence.

G The first point that I want to address you on is this. Is he someone who has genuinely come to help you, the Panel, as an expert, or is he someone who himself holds such deeply held views on immunisation that he has become an advocate of the cause, rather than an independent voice of assistance in the case? That is what an expert does. An expert comes along and is supposed to assist you, the Panel, in an objective format.

H If one looks at his involvement in immunisation he has, as Mr Kark has already said, been involved for some considerable time in the pro-vaccination lobby. I use that expression, because it is an expression that I garner from his evidence where he said when he looked at a particular document that his first reaction was that, "This is a well-known anti-vaccination lobby, or vaccination group". It is clearly how he sees things. He speaks in the media in favour of immunisations, he told you, and indeed somewhat extraordinarily you may think he had in fact spoken about the very subject matter of this case; that is to

A say vaccinations in the case involved, not necessarily on Dr Donegan.

He said in cross-examination that he thinks that parents who do not have their children vaccinated are making the wrong decision. Well, he could not have been clearer. That is his view. There is no caveat. There is no plus, or minus. That is his view. It is the wrong decision, although he said he understood their reasons and he would not be in favour of compulsion.

B His views - his views - on vaccination were not set out in his report, unlike Dr Donegan who did set out her views on vaccination.

C Secondly, his appearance of independence in my submission is significantly compromised by his personal association, or associations, with almost every witness in this case. It is a situation which quite frankly is almost unique. It may be unique to your experience, madam, I know not.

D However, of course where there is a small world of people then inevitably it is sometimes difficult to find experts, but part of the reason that Field Fisher Waterhouse in asking Dr Elliman for his contacts with these various people is because they knew (doing their job properly) that contact between an expert and other individuals is obviously going to compromise the independence of the expert. That is why presumably in their letter of instruction they asked him to include in his report that very point.

E It turns out that what I do submit are the briefest of details in his report, which are open at the very least to misinterpretation and some may even say verging on the disingenuous. At page 3 of his report, he sets out in three-and-a-half lines his contact with Professor Kroll and Dr Conway:

“Both Professor Kroll and Dr Conway have also, at various times, sat on ...”,

and he mentions an association which is a:

F “... standing committee on Immunisation, Vaccination and Infectious Diseases”.

Then this is it. It is one line, his connections:

“My time on the committee has overlapped with theirs”.

G That is it.

H In cross-examination, because he had not told us before, it turned out that Professor Kroll had been on the committee for three years, I believe from 2004 to 2007, and they were still on the committee together. Dr Conway, for about one year they were on the committee together about three years ago. He said that the duration that they sat on the committee together he did not see as relevant, but then he said, “... my mistake, perhaps”, which was at Day 2, page 52H -53C.

**A** It is interesting, you may think, that in the entirety of his report, as he set out over - I know we have got different page numbers, but it is about 90 pages. In the entirety of that report he makes not the singlest(*sic*) criticism of Dr Conway, or Professor Kroll. You may say, "Well, he was not asked to", but that is I am afraid not the position.

If you look at page 4 of D27, the letter of instructions, at point 8 and 9:

**B** "8. Where you agree and/or disagree with the conclusions of Dr Conway, and why.

9. Where you agree and/or disagree with the conclusions of Professor Kroll, and why".

**C** He has not actually included any comments about them and one can see why, because inevitably he would have been led to the criticism of Dr Conway and Professor Kroll in their initial reports, because those initial reports fall foul of many of the criticisms he makes of Dr Donegan, if not more.

**D** Continuing with this particular point about the appearance of independence, I am not saying that he is actually biased. I am not saying that. I do not know that. However, I am saying that the appearance of bias are matters that he should have considered very carefully before giving a report in this case and those limited details are troubling to say the least.

**E** He has given no reference to his having sat on the General Medical Council I think Health Committee, I think he said, maybe as a Specialist Adviser, and again he apologised for that. He has given a number of expert reports. That does not feature either in his statement. I think he said about two dozen over six years. He gave no reference to the witness training and, as you know, that only emerged quite by chance when Mr Kark cross-examined Mr Fletcher and asked him whether he had had any training.

**F** The difficulty about training is really this. I do not want to as it were trespass on those who have already had training, but the difficulty about training - and I know that there are at least two views about this - is that inevitably the purpose of training a witness is to give that witness an appearance over and above that which they might ordinarily have so that when they come before the Committee, or Panel, or court, or wherever it is, then they give a better impression of themselves than might otherwise be the case. That is really the point of it.

**G** In many ways expert training is not in the same category, because one can understand that experts not only have a duty but also have a need to assist the court; to assist the court in ensuring that their reports are written in a certain way. Of course Dr Goodman knows much more about this than me, but Dr Donegan had none of that assistance as we know.

**H** However it is a point that one would have thought - and I make the point and I repeat the point that I made before - that, if you were going to come to court and give evidence about the propriety of expert evidence, that is a matter that ought to be disclosed and it has not been.

A There is no reference in his report to the CPR 35, although you can see that in the letter of instruction Dr Elliman had it specifically drawn to his attention. If you remember, I think it is in the part that my learned friend referred you to. It is page 6.

B It may not matter, as I put to Dr Elliman at the time, but it is misleading to say to a Panel who may not know that there are specific rules in civil cases for experts that, "In my opinion, these are the rules for experts in civil claims", which is what he has put in his report, whereas in fact there are very clear rules and guidance set out there and were in 2002, they have been amended in 2005 and I think they may even have been amended in 2007, I cannot remember, but there are very specific rules.

C Quite frankly, if I may say so, the heads of charge should have set out that, "The rules of an expert in 2002 were the CPR 35 and you have breached 1, 2, 3 and 4", or whichever one it is that it is said that they are, and the only one that is relevant is that of providing an independent report because all the rest are not in the CPR 35 which is why I draw it to your attention.

D The third point, if I may, in relation to Dr Elliman. For a witness who spent four-and-a-half months preparing his report, he had a number of conferences - I cannot remember how many now he said he had, but he had a number of conferences with counsel - and he has fully supportive and extremely experienced solicitors in this area of work, he still managed after all that period of time to make a number of important errors and mistakes. I am going to go through those, madam, and I do not know if you would like a break beforehand?

THE CHAIRMAN: We have been going for an hour. Would you appreciate a break?

E MR STERN: I am quite happy to carry on, but I am on my feet and I appreciate others may want a break.

THE CHAIRMAN: Shall we go on until half-past-three?

F MR STERN: Page 8 of - well let me tell you the relevance of this, first of all, because it is not part of my case just to criticise Dr Elliman for no reason at all. That is not the purpose of this. The purpose is that first of all he is a witness - the witness - that the General Medical Council rely on and so his evidence is critical to the case and his credibility is obviously very important.

G Secondly, in relation to his evidence, it is my submission and will be my submission that Dr Donegan has made errors and has made mistakes as has been pointed out and accepted by her, but they are no more than errors, but her report remains overall independent.

The third factor is this. How easy is it to make a number of mistakes and to give misleading impressions even when you are spending four-and-a-half months preparing a report?

H At page 8 of Dr Elliman's report, the first paragraph in the introduction:

"With good treatment, 5-10% of patients die",

A

of diphtheria. One could not think of anything more important in relation to this particular disease. Obviously anyone reading that would say, "Well, what are my chances of dying if I catch this disease and I do not have the vaccination?" "5-10%", says Dr Elliman in his report. Totally unreferenced - the critical part of the whole of that particular disease totally unreferenced - but I drew his attention to two references that he produced which showed the figure to be 3% and 3.1%. I am going to give you all the transcript references for this in a moment. I asked him about the 5% to 10%. He said:

B

"It includes a lot of others."

I do not know what that means. He said:

C

"I did not use these particular references for that one..."

That is the one I drew to his attention,

"...and I did not reference the background material which arguably I should have done in retrospect."

D

(D2/73E to 74B).

The second point on the same page, and this is the Harrison's 11<sup>th</sup> edition point that, in my submission, is clearly misleading. At the foot of page 8 there is the quote from Dr Donegan:

E

*"Early treatment of diphtheria with antibiotics tends to render people susceptible to further attacks when the antibiotics are stopped."* The material provided does not state this. I have checked through the copy of the reference provided by Dr Donegan."

Incidentally, he does not mean the reference because the reference is to Harrison's 11<sup>th</sup> edition. He has checked the copy of the material that has been included, not the reference.

F

"I cannot find the quote she gives, nor can I find any statement along similar lines. The photocopy she provides is identical to the pages from 15<sup>th</sup> edition (2001). This would have been current at the time Dr Donegan wrote her report. If this is correct, it is interesting that the current edition, the one Dr Donegan should have used, no longer has this statement."

G

Could you take up the transcript for D2/68F?

H

"Q Can I ask you this, please: if you look at page 12 of Dr Donegan's report, keeping your finger in page 11, the reference you can see to number one, which is the reference that she draws the reader's attention to, is to Harrison's Principles of Internal Medicine, 11th edition. Yes?"

A Yes.

A

Q Now, the document provided was the 15th edition, was it not?

A If you say so, yes.

Q Well, I am looking at your report.

A Yes.

B

Q It says, "The photocopy she provides is identical to the pages from 15th edition."

A Yes.

Q I am assuming that you worked that one out?

A Yes.

C

Q Are you saying that you did not know that that 11th edition was the one that she intended to refer to?

A What I used was the material provided by Dr Donegan, which was the - as you say, the one we were given, and the reference should have matched that.

D

Q That is not quite the question I am asking you.

A Sorry.

Q It is obvious, is it not, you have got the wrong reference. If you looked at the references - I do not know if you did?

A I did look at the references in detail. I looked through the bundle of references that I was given, which were in support of Dr Donegan's report.

E

Q Why did you not just write: The material that has been provided is the 15th edition, the reference says the 11th edition? Did you look to see whether the 11th edition contained those words?

A I tried to get hold of one, but I could not get hold of one.

F

Q Why did you not put all that in there? In fairness to Dr Donegan, why did you not put that there?

A I had written down what happened, that, 'The photocopy she provides is identical to the pages from 15th edition.'

G

Then he said in the last answer at E:

"Q Well, the material that Dr Donegan is referring to there is the 11th edition, not the 15th edition, is it not? That is what she puts in her report.

A That is what she has put in her report, but I was not provided with that. I was provided with something else. I assumed that what I was provided with was the correct material. I am sorry, I did not check to make sure a mistake had not been made in what I was given."

H

A

At letter F he says:

“I could not find the material.”

At D2/71H – this is going back to this point:

B

“Q Can I just ask - sorry to go back on this, if I may, why it was you did not check the 11th edition when that was clearly her reference?

A Oh, I did try hard, and I could not find it. I was not sure that it was correct. I had assumed that perhaps a mistake had been made and the up-to-date edition had been used, in fact, because that is what I would assume when preparing a current report, that one would use the current edition of things rather than historical versions of things.

C

Q So why did you bother to try to get the 11th edition then, if that is what you assumed?

A I wanted to do the best I could.”

Looking at F on page 72:

D

“Q Do you know any research that disproves that particular point now?”

having been show the 11<sup>th</sup> edition,

E

“A I do not know of any research that disproves the point that if you look at people in the immediate period after they have had an attack of diphtheria, have been treated with antibiotics, then they are more susceptible to get diphtheria.”

The difficulty is that, quite clearly, Mr Kark obviously took the view that this was a piece of material that was not included and had been deliberately made up, because if you look at Mr Kark’s opening at D1/12 E to F, he relied on this very point. Having read out a particular paragraph and the passage in Dr Donegan’s report, Mr Kark deals with having looked at the reference – you may remember he slightly paused when he saw it said 11<sup>th</sup> edition – and then said:

F

“In fact, Dr Ellison...

G

That is either a typographical error or he forgot.

“...has looked through the material produced by Dr Donegan and in fact nowhere in that material is that conclusion to be found. The edition of *Harrison* that she chose to refer to was in fact four editions out of date; the most recent edition then at the time of writing her report was in 2002, being edition number 15.”

H

A The point was put before you and I have no doubt that when you look and listened to that passage that the implication was that the material was entirely made up, the conclusion was made up and that nowhere anywhere is that material true.

B That is not the position and, in my submission, the fair way of dealing with that from the report would have been to have said, "The reference is the 11<sup>th</sup> edition. The copy is the 15<sup>th</sup> edition. I have tried to get the 11<sup>th</sup> edition, but have been unsuccessful. I know of no research that refutes the particular part or sentence that Dr Donegan has asserted." Otherwise, what is the purpose of leaving it in that particular way that Dr Elliman has? The only purpose can be to seek to draw an adverse inference against Dr Donegan of which there is not one to be drawn. You will remember, of course, that Mr Kark did not cross-examine on that point.

C Page 16 of Dr Elliman's report, about five or six lines down:

"What Dr Donegan does not point out is that this is a fall from 95.8% protection to 91.8%. This latter is still a very high degree of protection."

D In fact, that figure is inaccurate, as eventually he conceded. It is not 95.8% to 91.8%. It is 95.8% to 88.9%. (D3/35C). Dr Elliman accepted that he got the figures wrong. (D3/41A). I am not asking you to turn it up, just to reference it if you want to.

Page 35 of Dr Elliman's report, the final paragraph:

"Dr Donegan says that "*severe egg allergy is a contraindication*" to MMR vaccine. This is incorrect."

E I was just about to ask him questions in cross-examination about this. He said it is a point he would not wish to pursue (D4/18E). He did not give a reason, but clearly if it is not being pursued there is no point in me wasting the Panel's time in asking questions about that.

F The point arose, you may recall, during the course of Dr Donegan's evidence in chief. I do ask that you look at D6/57H. I was asking Dr Donegan, taking her through the points and trying to get through them.

G "Q Let us move, please, to measles. It begins on page 48. The first point is at page 49 of your report, at the top of the page, page 35 of Dr Elliman's report. It has to do with the contraindication of severe egg allergy. Dr Elliman said in his report that it was incorrect, but in his evidence he withdrew the point, so we can move on."

Then something that you may have thought was absolutely extraordinary. Dr Elliman called across the room:

H "Could you read it out please? I am sorry."

He shouted across the room. I then read that out. I said:

A

“I am sorry if I have misinterpreted that, but I thought we were not pursuing it.”

Of course, Mr Kark, perfectly properly, got to his feet and said that he was not taking the point. It is an example, in my submission, of the total loss of objectivity of this witness in this case.

B

Page 37 at the end of the first paragraph. The point may not matter very much, but the point that Dr Elliman is making is that he is criticising Dr Donegan:

“ ‘Despite’ is not an appropriate word in this context.”

C

He agreed in cross-examination at D4/23B to C that this was quibbling. I asked in relation to both those two points that I have just made and, indeed, others as well, why it is that an expert who spends four and a half months preparing a report, has meetings with Counsel and no doubt numerous telephone calls and e-mails between him and the solicitors getting that report to the state which is put before you, that just in the face of no reason at all he decides to withdraw those points and accepts that the point he has been making is quibbling. That is not the appropriate basis, in my submission, to bring a professional person before their professional body on the basis of points that are subsequently withdrawn for whatever reason, or not pursued for whatever reason and are agreed to be quibbling.

D

Page 38 please. At the foot of the page, the last four or five lines:

E

“In the article Dr Donegan uses, there are two figures looking at the comparative risk after the vaccine – 27 cases in the first month after the vaccine as opposed to 16 expected and 14 in the first two weeks as opposed to 4 expected. Dr Donegan uses the latter figure. If presenting a balanced view she should use either the former comparison or both.”

F

So it is a criticism that she is not acting in a balanced fashion. Obviously, if one wants to look at it – and I do not mean it facetiously – for somebody reading that it is perfectly easy to understand. It does not require an expert to interpret it. Yet, it is entirely wrong. In cross-examination Dr Elliman accepted that this was an error as both figures were quoted. He said he did not realise. (D4/32F).

G

Appendix 8 in Dr Elliman’s report is pretty important because it deals with the vaccinations, the schedule of vaccinations. It is page 75 for you, I imagine.

“Below is set out the routine immunisation schedule in place in the UK in 2002.”

H

No, it is not. It is 2004. He should have included the 2002 and you will remember he went through and there were a number of editing features.

No doubt if Dr Elliman was sitting where Dr Donegan was and Mr Kark was cross-

A examining he would have said, "There you are. That is absolutely critical." It just goes to show what it was that Dr Elliman had in mind. It is very easy to look at reports, to pick up errors and say, "Look how misleading all of this is."

There are a number of typographical and reference errors. I am not going to draw your attention to those. They are petty, but nevertheless they are present.

B We come to the cell mediated immunity point that he said he did not wish to pursue, if you look at D5/27G.

C "Q Let us look at what is referable to page 107 of Dr Donegan's report, paragraph 1.68. There is a discussion between Dr Conway and Dr Donegan about a particular paper and Dr Donegan quotes parts from the paper and your criticism is that she does not mention that they calculate, that is to say in the paper, the efficacy of the vaccine to be 87 per cent. That is really it, is it not?"

D A Yes. You do not want to pursue this paper because, in fact, I pursued this paper over the weekend – remember it was that complicated paper – and one of the issues was whether you could separate out the children who had been vaccinated and had measles, which is a comment that Dr Donegan makes here, which in fact you can, but unless you want to pursue it, I do not."

E I need no greater invitation than that to leave something aside. That is what happened. Whether it was as a result of reading Dr Fletcher's reports, who comments on cell mediated immunity and makes the comment that, looking at what Dr Elliman says, it seems that he is not terribly – I cannot remember the exact words – confident with the science of it. Whether that was what caused him, having seen Dr Fletcher's report, I do not know, but he did withdraw from it.

Page 9 of the report. I know we are going back, but this is a slightly different point, the paragraph in relation to page 11, paragraph 3:

F "Dr Donegan by her statement that *"By the 1940s when a national immunisation campaign began, the death rate in children had dropped by two thirds and continued to drop."* implies that the fall in death rate from diphtheria was unaffected by the introduction of the vaccine."

G At the foot of that paragraph he says:

"Contrary to Dr Donegan's stated view, this suggests that the vaccine may have had an effect..."

H It is D2/75C. I am not going to ask you to turn it up. I simply give you the reference. He accepted that it was not a stated view, but it was his interpretation, so, again, quite an important qualitative difference between my impression of the evidence that Dr Donegan gives is X, as opposed to her stated view is X.

**A** Page 12 of the report. I think that for this we will also need Dr Donegan's report at page 12 as well. Just to remind you of the point about page 12 of Dr Donegan's report, you can see what it is that is being dealt with there. It is the listed side effects for the single low dose adult diphtheria vaccine, and then there is a reference, "Absorbed Diphtheria Vaccine for Adults, Secretary of State for Health, Department of Health revised 1999". It then sets out the side effects. It also mentions that thiomersal in the vaccine can cause kidney damage. I just remind you, if you look please at page 66 of Dr Donegan's report, keeping your finger as it were in page 12, of a reference to precisely the same document, the 1999 product information for the adult diphtheria vaccine, Secretary of State for Health, Department of Health, which states that it can cause kidney damage – no comment by Dr Elliman when it is set out there.

**B**

**C** In any event, he does make a comment about it in the evidence, and we ought to look, please, at that. Would you turn, please, to day 3, page 11 letter F? You will remember that we produced the patient leaflet at this point. That was only very short, but the point is at 11F:

"Precautions before Use

Do you have any type of infection?

**D** Do you think you may be allergic or sensitive to any of the ingredients in the vaccine which are listed above, in particular to thiomersal, which can cause kidney damage?"

He says:

"Yes, I can see that.

**E** Q Let me ask you first of all how it is that you are not aware of that document?

**F** A I do not know why I was not aware of that document, because I made enquiries of the Department of Health. What I am slightly puzzled by – and you will understand that they have had it for nine months, we have not had it so this is my first sight of it – this is, I think, a patient information leaflet. This is a leaflet that is put in a vaccine pack, not by the Department of Health, put in the pack by the manufacturers."

He said that he was lightly puzzled by the title.

**G** "If I had known it was a patient information leaflet, I would have gone to the manufacturers."

**H** Of course, the point of showing you page 66 is that it does actually say that it is a patient information leaflet. I think someone asked him about that – maybe it was I – later on, and I think he said that he had not married them up. In fact, this is dealt with right the way through to 15G. I will just give you that reference and just point to various parts, but that is the full reference where it is dealt with.

At 13B, he says, "I am aware that thiomersal causes kidney damage". At the foot of the

A page, I interrupted the witness and then he said:

“There is no debate that thiomersal causes kidney damage. There are no articles at all that I am aware of that have made any good evidence of a link between the amount of thiomersal vaccine and kidney damage.”

B He says that he cannot think of an analogy. It is somewhat odd – and I think this is the point that Dr Donegan was making – that if it is on a patient leaflet for a vaccine, one would have thought inferentially, if not overwhelmingly clearly, that the thiomersal in the vaccine is what is being referred to, otherwise what is the point of putting it in the patient leaflet. Dr Elliman is drawing a distinction and saying, “Oh! well, of course, I knew all along that thiomersal causes kidney damage but I had no idea that it might be associated with a vaccine, and I am not aware of any evidence that suggests that”. But Dr Donegan was merely pointing out what was in the patient leaflet, which is accurate.

C Now it is somewhat odd that he could not find that, but again it would have been much easier to have said “I cannot find it” and more appropriate to have said, “I cannot find it”, which is what he says at the bottom of page 12 – perfectly okay – “I am unable to trace it”; but then over the page he says that he is unaware of it, the Department of Health or its predecessors ever indicating that the vaccine may have caused kidney damage because of the thiomersal that it contains. He says:

“As it is not qualified, Dr Donegan’s statement is likely to be read as suggesting that the vaccine may cause kidney damage. Dr Donegan’s statement is therefore misleading”.

E I have to say, with respect to Dr Elliman, that I still do not understand the distinction that he makes. The point that Dr Donegan is making is clear in her report and the document supports it.

F A general point about Dr Elliman’s report, if I may, is – and I am not going to refer to all of them but you will have seen them I think as we went through and also we will when we look at the report again – there are a number of positive references by Dr Donegan to vaccination which he has not included in his report. I will just give you one example: day 3, page 21E. I am not asking you to turn it up now, because you will have seen in the report that he accepts that he has not referred to them, and in fact it speaks for itself, you can see that they are not referred to in his report.

G So, what one has in Dr Elliman’s report, when he overall as an expert is supposed to be evaluating and assessing whether or not the report is overall objective and fair – my words; I cannot remember the way he phrases it but that is essentially what it comes to – one would have thought that he might have drawn attention to the positive points made by Dr Donegan and he has fallen foul of precisely the same point that he criticises Dr Donegan for.

H Can I ask you to look, please, at day 3, page 57D?

THE CHAIRMAN: Mr Stern, it has gone past half-past-three. Would you like a break

A now?

MR STERN: I am fine to carry on. Shall I just finish this point and then we can have a break?

THE CHAIRMAN: Yes, okay.

B MR STERN: I will just finish this point as you have the passage open. It is a short point. It is page 57 letter D-G. This was when we were looking at the Neilson study:

“This is where you thought you said perhaps you did not phrase it as happily. I am paraphrasing what you said. I think that is essentially what you are saying.”

C This is the one with the 2,000 in each group, but actually the report is 669 children. At letter F, “Did you just read the letter?” You will remember that there is the letter and then the research in the following divider.

“Q Did you just read the letter or did you actually read the study which follows on at divider 14?

D A The reason why I say it is perhaps a little misleading...” –

so he accepts that it is a little bit misleading –

“... is because this is one study looking at two aspects.”

Then he explains it. At the foot of that answer:

E “So where I am saying I might have misled people, he is leading them to the second study implying there were 10,000 in total there.”

It is not difficult to mislead when one is writing a report of such magnitude.

F While we are on that – I know that I said I would finish it but there is just one more point in this section and I can make the point very shortly – on page 51, letters B to C there is an omission by Dr Elliman of the word “serious” before “acute neurological illnesses” because he said that he mistakenly encompassed all neurological illnesses.

So that is an acceptance of a further mistake in relation to his report. Thank you.

G THE CHAIRMAN: We will take a break until 4 o'clock.

*(The Panel adjourned for a short time)*

THE CHAIRMAN: I am just taking soundings about possibly a late sitting today, but I appreciate that it is toughest on you, Mr Stern.

H MR STERN: No, I am absolutely fine to carry on for as long as you can bear it.

**A** THE CHAIRMAN: We thought five-thirty-ish, if that helps. We will see how you feel.

MR STERN: I am grateful for the extra break, although of course it will allow Mr Kark to go on endlessly how you were a minute early for his speech!

**B** The points that I was referring you to that Dr Elliman was making, it shows, in my submission, that it is perfectly possible to make errors even when you have a considerable period of time to prepare a report and indeed, so far as Dr Elliman was concerned in this case, a continuing duty to correct any of the errors or omissions that he had made. I draw to your attention page 64 of his report, which has the declaration at the back of his report. You will see that letter F says:

**C** "I will notify those instructing me immediately and confirm in writing if for any reasons my existing report requires any correction or clarification."

That was not done until Dr Elliman gave evidence in 2007. Because there are errors and even one or two points that may be considered in retrospect misleading, that does not mean that the reports overall of Dr Elliman or indeed Dr Donegan are not independent.

**D** I want to look now at Dr Donegan's reports, but I am not going to look at the detail of it just at the moment. I want to just stand back from a few points, if I may. Apart from two points that I am going to ask you to look at, please – day 7 page 33D-E, Mr Kark saying "All right, let me move on", which is the Japanese study, which, you will remember, is page 21 of Dr Donegan's report – in her report it reads:

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

It goes on, although Mr Kark, did not read this:

**F** "In 1981 Japan introduced the acellular vaccine. This is said to be safer than the whole-cell one."

So, in fact, the point that she was making was in relation to Japan when the vaccine in fact was not long gone; it was in 1981 that they introduced the acellular vaccine, which, as we know, is the vaccine that ultimately came to this country.

**G** Looking at day 7 page 33D, Mr Kark reads part of the part that I have just read to you:

"Q Do you accept that the effect of that could be misleading?

A I accept that the effect of that would be misleading."

**H** So she is perfectly open and prepared to accept that that is the position, and you will see what she says about that evidence-in-chief on day 6. I do not need you to turn it up but if you want to just cross-reference the same point, it is day 6, page 40E. The second reference is in day 6, page 69, letter B. We are so familiar with this that I do not even need to trouble you with the detail of it. You will remember that it is the BPSU, I think it

A is, where it says "39 prior to national surveillance". Letter E:

"Q What is your view on that, bearing in mind Dr Elliman has now pointed that out?

A I think certainly if I had had more time in preparing this report, I would have taken that on board and phrased it more clearly."

B That is what she said in-chief. Day 7 is the cross-examination and it is page 67F. There are some preliminary points dealt with just before that, and then it goes on:

"Q Why did you start this paragraph in your report:

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

- when you knew that, in fact, national surveillance did not start until 1970?

D A Although the babies with congenital rubella would still be reported they would not be looked for specifically, because otherwise there would not be any figures there at all from 1964 to 1969.

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

A Yes.

E Q Why on earth did you not reflect that in your report?

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

F Mr Kark then says:

G "Q Let us concentrate on the point you did make. When you later used the phrase that the number of cases had gone up, you meant from 39 babies, did you?

A I did. I meant from what was here on the table, yes, you are quite correct in the inference that you are taking from what I have written.

Q This is misleading, is it not?

H A It is, in retrospect, yes."

A accepts that she might have phrased it better, but we are not before the General Medical Council on an analysis word by word on the ability of Dr Donegan to write English and create a report in that regard. That is not the basis on which this case was referred to this Panel and it is not the basis on which the allegation is set out initially.

B You will have noticed, as I said a little while ago, that Mr Kark in his cross-examination of Dr Donegan said on a number of occasions, "It might have been fairer, in retrospect..." This is not the case. We are not analysing here a report that has been made by Dr Donegan and sitting round having a seminar as to whether or not she might have been able to phrase it slightly differently if matters were different, that is to say if she had more time, et cetera. The case is that she is so blinkered by her views that it caused her to just focus on one particular aspect of vaccination. As I see it, that is essentially the case – that she holds genuine views but, blinkered by those views, she created a report that was not independent. I think that summarises or paraphrases the allegation.

C A number of the points made by Dr Elliman – and I can deal with them generally – is that Dr Donegan has omitted the opinion of the writer of the research, and Mr Kark cross-examined time and time again about this, the opinion of the writer of the research and the conclusion that the writer of the research provides in the research, which is essentially, "This is likely, that is likely, this may be the case, that is a possibility, possibly not, possibly there is no connection", et cetera.

D Now Dr Elliman said that it was not necessary to follow conclusions blindly. You come to your own conclusion, and that could be a different conclusion from the author of the report. The criticism of not including conclusions, in my submission, is marginal, if indeed it is real.

E Dr Fletcher did in fact give some evidence about this and had a view about this. He said, and again I am paraphrasing, that essentially you could take the data and pretty much come to any view you wanted to. He did not have a high regard, I think, for the research. Indeed he is supported to some extent by the Cochrane Collaboration, which was produced by Dr Elliman. The Cochrane Collaboration, you will remember, just looking at the MMR, said that there were something like 5,000 pieces of research papers that were initially looked at in relation to MMR and that, once they analysed those 5,000 papers against the criteria that they thought was appropriate for inclusion, non-bias, etc, there were I think something like 31 pieces of research that met that criteria. So, in my submission Dr Fletcher is supported in his assessment of the absence of science from a lot of the research.

G There is another matter that one needs to look at, which Mr Kark has made a point of on a number of occasions, and it seems, if I may say so with respect, not to have a foot in reality. Here Dr Donegan, you will recall, was effectively responding in her view to Dr Conway and Professor Kröll's initial reports. Those were reports which had absolutely no reference at all and provided no indication to the reader as to where their research had come from or where those opinions had come from; whether they were their opinions, or indeed whether they were opinions based on science, or indeed whether they were opinions based on publications generally.

H It was she who produced the references through her solicitors who provided copies of

A them. She did not use, as she told you, non-mainstream papers, but sought to say that the conclusions from Dr Conway and Professor Kroll are not the only opinions or interpretation that can be made from these mainstream papers.

B Mr Kark to some extent supported that in his submissions just a little earlier this afternoon, because he said, although it is entirely speculative without any evidence, "Maybe Dr Conway and Professor Kroll did not rely on any research, because it is part of the national immunisation data, if you like. It is part of the immunisation programme - the vaccination programme - and so they did not need to".

C The reports together with the references - and I frankly do not understand the suggestion that they are somehow disparate, or separated, and that the reports have to be looked at in isolation, because the reports were provided with the research material reference and with the reference papers so that Dr Conway and Professor Kroll, who were to receive these - as well as others of course, but Dr Conway and Professor Kroll who were to receive these - would have all of the research papers and would probably know a large number of them anyway, because Dr Donegan is a GP, I think Professor Kroll is an immunologist and Dr Conway is a paediatrician, but a specialist in this sort of field rather like Dr Elliman.

D It is really, if I may say so, cloud cuckoo land to suggest that by providing the reports and research to these two eminent individuals, who sit on the JCBI, that you are somehow not providing them with all the appropriate material. Dr Conway was instructed on behalf of the fathers. There was leading counsel, possibly two junior counsel, solicitors and they also had Dr Conway. There is no evidence at all - although Mr Kark repeated it time and time again, there is no evidence at all - that the fathers either saw the reports, or indeed were capable of reading. We do not know whether they were literate, we know nothing at all about them and so to suggest that frankly these reports were written for the dads is really to suggest a nonsense.

E It may be that Dr Conway sat in a conference with the fathers, together with leading counsel and junior counsel, and said "Now listen, dad, this is the position. We have got this report from Dr Donegan. We do not think much of it. We think we will be able to answer it. Basically, what she is saying is this". We just do not know, but it is as equally plausible as Mr Kark's suggestion that the fathers sat there scrutinising every word and might have withdrawn their application without speaking to their counsel, or their expert who was provided for specifically on their behalf.

F The test of the clarity or otherwise of an expert report could never be whether a non-expert might be misled. The whole purpose of an expert report is to provide an opinion on a subject which is by definition outside the knowledge and understanding of non-experts. That is why they are entitled to give an opinion.

G One could say that the fathers were completely misled by Dr Conway's report, because he had not given the full information and when those fathers read that report of Dr Conway, or those reports of Dr Conway, they would have thought in the absence of any balancing aspect of vaccinations and would have got the clear impression that there were no risks at all attached to immunisation and that therefore they should proceed full steam ahead.

H So it is, if I may say so, not an appropriate test to say, "Well, what would the fathers have

**A** thought?", because that in my submission cannot be the test of how to evaluate an expert report, because every case - every case - almost without exception on precisely the same material has at least two experts. So how is it that, if there is only one view provided by such a balanced expert report, there is in relation to every case two experts who on precisely the same data provide precisely the opposite opinions?

**B** That, in my submission, is the point about data and the interpretation of it. Dr Conway took one view, Professor Kroll took a second view and Dr Donegan took a third. You will see actually when you look at Professor Kroll and the meeting he had with Dr Donegan that they largely agreed on some of the aspects and, indeed, Professor Kroll did not agree with Dr Conway on all of the aspects in relation to vaccination. So, there is a spectrum of interpretation and that spectrum of interpretation is what allows the expert to give evidence.

**C** As I have already indicated in relation to the particular points that have been taken from Dr Elliman's report in that initial schedule that we provided you with in order to try and help you go through, because one of the things that the heads of charge did not do is to set out any of the specific points and so we, as it were, have had to rely entirely on Dr Elliman's report in order to assess what it is that the GMC were alleging was a misleading or a false impression, because clearly there should have been a schedule attached. In fact if you look at the letter of instruction that Dr Elliman had he was asked to do that, but for reasons I do not understand that was never done. I think it is at page 3:

**D**

"The style and format of your report is essentially a matter for you. At the conference you indicated that it was your intention, subject to Counsel's views, to use 'themes' to structure your report rather than dealing with the concerns in relation to each disease. It was agreed, as you may recall, that this was an extremely helpful suggestion and that such a structure and approach would be valuable in Counsel being able to formulate the particulars and allegations to be brought in the case. Further, you mentioned the possibility of identifying and commenting only the principle(*sic*) examples which support each theme/principle and then producing a comprehensive table which refers, in summary form, to each example of a theme/principle. That table would be annexed to your report".

**E**

**F**

**G** I have to say we only got this letter the week before and so we had already done the table - it was not as a result of this that we did it - in order to try and make sense and help Dr Donegan in preparing for this case, but that never happened and so we are left with this rather woolly document that you have.

What I would say about those heads of charge, just on one further point, is this. They are very woolly and any interpretation on them must be an interpretation which is the most beneficial to the practitioner. It would be quite wrong, in my submission, at this stage to put an interpretation on it which is adverse to the practitioner right at the very end of the case in the absence of any specific interpretation of the particular words.

**H** We have the schedule. Perhaps we can provide you with that now. Dr Donegan's evidence - well, I will wait until you get it and then explain it to you. If I may say so, I am

A extremely grateful to Mr Singh for this document because I think it will save me and you some considerable time and will help you in looking at the particular points.  
(Same handed to the Panel)

THE CHAIRMAN: As this is part of your evidence(*sic*) to the Panel, I do not think it needs a "D" number, does it?

B MR STERN: It is entirely up to you, madam. I do not feel particularly strongly one way or the other, but it is really as I think Mr Kark would call it a working document. You will see what it is. It is points made by Dr Elliman with references to Dr Donegan's evidence. So it is the points that we put in the table and as you can see all the references are there, but what Mr Singh has included is the transcript reference in the far right-hand corner. If you look just above the schedule at the first page you will see that the normal print is examination in-chief, the transcript reference in bold is cross-examination and the italics is re-examination so that you have it all there down on the right-hand side. It is, if I  
C may say so, an extremely useful document and it will mean that ---

THE CHAIRMAN: I cannot see any italics.

D MR STERN: If you remember, there was I think one question in re-examination. It does not have page numbers, but it is under "RUBELLA".

THE CHAIRMAN: Okay, thank you.

MR STERN: There may be another one as well, but I cannot remember. No, that is the only point. Yes, thank you. Yes, that is the only one.

E I am going to look at the points and as I say I am going to look at them very briefly because, as I say, Dr Donegan has dealt with them all in her evidence and there has been no real challenge to it. Can we just look at page - well let us look at diphtheria first at page 11, please, of her report. At page 11, just dealing with the points going through in the first or second paragraph, the last couple of lines, "Early treatment of diphtheria ...", that is the 11th Edition point. I am literally going to be as quick as that on each of these points, but obviously if I am going too fast please stop me.

F The next is the end of the next paragraph:

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

G That is an impression apparently held by Dr Elliman. It is not an impression that was intended. Indeed, if anything, in my submission it gives the impression that is opposite to that which Dr Elliman seeks to draw from it, because what it shows is that immunisation continued - immunisation caused, if you like, or at least appears to have caused, the death rate to continue to fall. So it is a non-point, if I may say so.

H The next paragraph:

A

“Most cases are in adults ...”

It is a true comment, it is accurate, Dr Elliman does not say it is not true and he says, “Well, in this particular case there is again an implication that the vaccine does not work”, but Dr Donegan as you know is setting out here her description of the disease. That is what she says about it in short.

B

The final paragraph there at the foot of the page:

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

C

This is obviously an opinion of Dr Donegan and she accepted that she could have given a slightly fuller version, but nevertheless she says that that was based on the very graphs that she produces in her report and she was going to make that clear, if needs be, if it was not clear to those who looked at it.

Page 12, this is three-quarters of the way down, the adult diphtheria point which comes from the document that you have.

D

That is diphtheria. In my submission, when you look overall in relation to diphtheria - I have only looked at the points that Dr Elliman has raised, but overall - there is nothing in there, in my submission, that can be said to be not an independent view in response to Dr Conway and Professor Kroll.

E

Pertussis, page 15, please. I should just say that, if you were to look at page 14 and the top of page 15, you will see that the description of the disease as set out by Dr Donegan raises no criticism by Dr Elliman and at the top of page 15 it says:

“Babies less than one year old usually have the most severe forms of the disease and it is in this age group that complications and death most often occur”,

F

and then she deals with convulsions, coughing spasm, the lung may collapse and:

“Another complication of the disease is pneumonia, again, more common in babies and a major cause of death”.

G

I do not think one can say that is saying that the disease is anything other than serious.

If one looks - and this is a point not made by Dr Elliman - at the next paragraph:

“In the nineteenth century whooping cough was most definitely a killer disease. ‘Deaths from whooping cough remained at around 10 000 a year from 1847 until the 1900’s and then declined steeply as the health and care of children improved and had reached less than 400 a year by 1950. Immunisation started in the 1950s, deaths continued to fall and notifications fell sharply”.

H

A

So, again, a reference to immunisation and the fall in notifications not referred to by Dr Elliman at all.

The next paragraph:

B

“It is undoubtedly the case that whooping cough became a milder disease ... The death rate had fallen by over 99% before vaccination ... was introduced in the 1950s”,

and then this:

C

“The introduction of the vaccine reduced the number of notified cases of whooping cough but peaks continued to occur every three to four years as they always had. Deaths continued their steady decline”.

Again, that is a perfectly balanced view of the vaccination, not mentioned – not mentioned at all by Dr Elliman.

D

At the end of that paragraph, 78 and 82, 65,000 notified cases of whooping cough, but no concomitant rise. I think, having consulted a number of dictionaries, we can conclude there was absolutely nothing inaccurate or misleading about that. Indeed, Mr Kark did not cross-examine on that point and has not mentioned it at any stage hereafter.

This is the level of point that Dr Elliman is addressing you on, dictionary definitions of words rather than what one would have thought, if you were being told, “Here you are.

E

Here is a report that is obviously misleading. There are ten fundamental points which are wholly inaccurate, false and improperly put forward.” We are not in that territory. We are just talking about some misleading impressions. One cannot help wonder whether it is because the views are of somebody who is “against” vaccination or is cautious about vaccination, rather than somebody who is pro vaccination.

F

It is to some extent an area I do not profess to understand where, for reasons best known to those who are involved, debate appears to be stifled and there appears to be an area where we are all bullied not to discuss it. It is not an area or a concept that is really of much understanding in that regard. It raises, as Dr Elliman accepted, temperatures on both sides. If I may say so, both Dr Donegan and Dr Fletcher, approached this question of vaccinations generally in a very mature and sensible and considered way. Not for them shouting out across the room. There are two sides to the debate and it is about time, one would have thought, that there was a mature approach to it.

G

Page 18 at the top. This is a Harrison’s 11<sup>th</sup> edition point. The middle of the next paragraph. I am not going to deal with every point, but obviously most of them if I can. Halfway down that middle paragraph:

H

“Because of continuing increases in pertussis notification in the UK, especially in young babies, an ‘accelerated’ schedule...”

A that is the one that came in 1990, as you know, etc. Dr Donegan made a mistake. It should not have said "notification"; it should have said "deaths."

The last point on that paragraph:

B "As with a number of recent reports from the UK, USA and Australia, there seems to be a trend."

That is entirely an opinion by Dr Donegan. Dr Elliman disagrees. He says it is not a trend, although if you look at his report at page 16, four lines down he says:

"The reference does not give a real indication of any trends."

C We are again in the splitting of hairs territory, in my submission.

The first sentence of the second paragraph:

*"...the incidence of pertussis death and disease was falling before the vaccine was introduced was introduced in the 1950s."*

D Again, Dr Elliman does not seem to consider any point about that can be properly made unless you put the other side of the coin, that is to say, "By the way the vaccine is effective and works and there is a high rate of efficacy."

E The point that she makes is true. There is no doubt about that. She is just giving a description of it. You can see she is beginning in the 1950s. She goes on in 1978, setting out there some of the points. Of course it is selective. Everything is selective. There is no word that one can choose in any sentence, either spoken or written, which does not involve a selection and therefore the omission of other words. That is the nature of language.

F If I may say so, the criticism is somewhat unfair in any event in relation to that, because, although Dr Elliman has not troubled to mention it, at page 15, as I drew to your attention, in the paragraph in the middle, Dr Donegan said,

"I have already stated immunisation started in the 1950s, deaths continued to fall and notifications fell sharply...",

so why does she need to repeat it again on page 18?

G The point is that one cannot help but resist this conclusion that Dr Elliman holds such deeply held views on vaccination that one is not allowed to criticise or even suggest a point that maybe there is something not quite right with vaccinations. For those of us who are new to the debate, it does seem a somewhat immature approach.

H Page 19, at the foot of the page. If I may say so, the trouble with trying to quell any kind of comment that is adverse to vaccinations is that all it does is create mistrust in the minds of the public in relation to vaccinations. That is the real problem with seeking to quell any dissent. There it is. Page 19. The point that is being made there in the last paragraph

A – you know that there is an error there in relation to a report. This is a report that apparently was 200 pages long, so although Dr Donegan has got the seven days in and that is wrong, Dr Elliman does not criticise her conclusions. Her conclusions are right, but she has made a point which is a bad point just there about the child who had serious neurological reaction. You notice she says “reaction” and not “damage” two or three weeks after the pertussis vaccination. This would not have been included in the figures.

B The point about damage is made at the top of that paragraph and also you will remember Mr Kark made the point in his closing. Over the page at page 20 it is also there as well in the middle paragraph:

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

C The point made is the difference between damage. Dr Donegan accepts that, though interestingly Dr Fletcher said that he could not actually think of an instance other than the psychiatric illness where a neurological illness did not cause neurological damage. That is the reason why he took the view that it was splitting hairs, because scientifically or medically there is not any difference between a neurological illness and neurological damage, because when you have a neurological illness you get neurological damage, according to Dr Fletcher, save for psychiatric cases, or strictly psychiatric cases and even then it may be that those individuals have as well suffered neurological damage, but just unknown.

D

Looking at page 20 again, again not referred to by Dr Elliman, the paragraph below that point that I have just drawn to your attention says:

E “All these studies and reviews of them say that the risks of them say that the risks from the vaccine are small and where the evidence is not regarded as sufficient to either accept or reject a causal association this is taken to mean that the vaccine is safe and that parents should be encouraged to carry on vaccinating their children.”

F That is a perfectly objective proposition which could be taken by either party to be what the present state of the vaccination is.

G Page 21. This is again, in my submission, is really a trivial point. Whether you accept that or not is a matter for you. Here Dr Donegan is setting out a number of studies. She is putting them in one or two lines maximum, each of them. She ends by putting the other study, which is a larger perspective, looking forward study, so in other words a prospective one – I am sure the fathers really understood this – of 944 children in Avon failed to share an association.

Dr Donegan dealt with this at D7/32G. At the foot of the page at 32H:

H “A I have not written a hierarchy of evidence. I have on that one written that it is larger and that it is prospective.”

That obviously means more to others. It means more to Dr Conway than it would to me

A or others.

B There is also, in relation to this particular part, that Dr Elliman criticises Dr Donegan for not mentioning this Nilson research. This is one of a number of criticisms – I cannot remember how many there are, but maybe on three or four occasions – where he complains that she has not referred to particular papers, which he says is a larger study, a better study or a more helpful study or whatever. If she had the study and deliberately did not include it, one could understand the point, but the very nature of preparing these reports, especially in the absence of the Internet and e-mail, is that you are likely to be obtaining the research from the papers you have got and other material that you read, the BMJ and various other articles.

C The point is in any event not a good one, in my submission, because, again not mentioned by Dr Elliman, none of the papers he says should have been referred to by Dr Donegan were referred to by Dr Conway or Professor Kroll. The test, if one wants to look at the test, is this: if the assertion was that no reasonable expert could have failed to have pointed to those particular pieces of research, then that would be a fair point if Dr Conway or Professor Kroll said, “This particular study is so well known I cannot imagine how it is that Dr Donegan has failed to mention it.” It is a poor point, because all three of the individuals, Conway, Kroll and Donegan do not refer to it, so it is not a reasonable or a fair point to make, in my submission.

D Page 21 is the Japanese point. I have already dealt with that. I dealt with that right at the start.

E Page 25 please, moving to tetanus. Again, Dr Donegan sets out there fairly fully the illness that is caused by it and the infection. Looking at the end of the first paragraph:

“Tetanus infection has been reported after trivial or no injury...”

She makes it pretty clear that it does not take much to get it. The next paragraph about halfway down:

F “There may be irritability with muscle twitching and spasms accompanied by a low grade fever. This can progress to ‘lockjaw’ and severe cases may have laryngeal spasm causing difficulty in swallowing saliva, spasm of the respiratory muscle necessitating artificial ventilation and, in some cases, death.”

G Why did Dr Elliman not mention any of that in his report? She has set out what is clearly the severe ramifications of catching tetanus. Catching is the wrong word, of getting tetanus.

Over the page at page 26, the second paragraph down. I am just pointing to the most obvious parts, rather than all of them:

H “Complications contribute significantly to the likelihood of death or disability in tetanus disease.”

**A** Why did he not mention that in determining whether overall there are misleading impressions? Further down, dealing with tetanus disease not being regarded as being regarded as being able to cause subsequent immunity,

**B** “...but studies in isolated communities where people have been vaccinated against tetanus (or anything else) have shown the presence of antibodies to tetanus toxin increases with age. Immunity is thought to have been induced by ingestion of tetanus spores...”

etc. She then explains in detail how it comes about.

At page 27 we have:

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

That is a perfectly fair point, in my submission. It is not inaccurate. I believe Dr Elliman did not say that it is. I think his point is that Dr Donegan failed to mention that all authors state this is a rare occurrence and are very supportive of immunisation.

**D** I am sorry. My note has gone awry.

In the middle of page 27, again the vaccine. The second paragraph:

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

**E** Why is that not a balancing feature in the report when Dr Donegan is setting out that vaccine? You have heard no submissions from Mr Kark or, indeed, Dr Elliman in his expert evidence about this. Why is that not overall, looking at the report, sufficient to say that the report is independent?

Then Dr Donegan deals with listed side effects. At the foot of the page:

**F** “Some people develop nerve damage causing either muscle weakness or altered sensations.”

**G** This is the point I was making. Dr Elliman’s criticism is that where Dr Donegan says “some”, in fact the report says “rare”. He says leaving out the word “rarely” is misleading. In fact, you will remember when we looked at it the patient information leaflet actually says a few patients rather than some and rather than rarely. That is where she got it from. I have to say, in my respectful submission, that is on the quibbling side.

**H** On page 29, at the top of the page, is the T-lymphocyte helper/suppressor ratio that Mr Kark referred you to. The purpose of adducing it in your report, Dr Donegan said, is that in fact what happens is the immune system becomes reduced and therefore you are prone to infection. He draws attention again – and I have already addressed you on this – to the fact that the fathers may see the word “AIDS” and therefore that will cause havoc. I think

**A** Dr Conway did not refer to that particular passage at all. Leaving that aside, Dr Elliman's criticism is not that it was mentioned at all, but that the changes were temporary and the authors did not refer to any adverse effects due to this. That was his criticism, not Mr Kark's. Obviously you must take account of his as well.

**B** Dr Donegan gave evidence about this at day 7, page 38F. I draw it to your attention because Mr Kark made quite a lot of this particular point. You will see that the introduction to it is at letter B. At D, Mr Kark says that he wants to try to avoid getting too bogged down in the science:

"I want to try to avoid getting too bogged down in the science, but is it fair to say that from this research, first of all it appears to have been a temporary effect only?

**C** A In terms of the T cell ratio it is a temporary effect. I do not know whether they looked at any other symptoms of the people other than the T cell ratios, that is what they mention return to normal.

Q There was no evidence, in fact, that it did any harm either.

**D** A I do not know what they were looking at in terms of harm. They state here that the ratio went back to normal. I do not know if they were giving people questionnaires about their general health.

Q Did you think it was relevant in your report in dealing with this piece of research to make it clear that the lowering of the T-lymphocyte helper/suppressor ratio, such as might be seen in patients with Aids, was a temporary effect only?

**E** A I think I have mentioned before about the size constraints of this paper. Certainly if I were doing it again I could probably have expanded on what I put there and introduced my rationale for putting it in and also explained that I have put eleven healthy subjects and I did not explain that they were 20 to 50 years old and I did not explain that I did not know what effect would be had on the T-lymphocytes on babies and children that were being injected and whether the recovery by 14 days of the lymphocyte ratio would be that seen in babies or children who were vaccinated. I could have put it like that. I could also put the significance of the ratio in terms of making the children or the people in this study more susceptible to infection if their lymphocyte ratios were not normal."

**G** Then at the foot of the page:

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

He said:

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

A The answer was, "I accept that point." Further down:

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

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

B There is a danger in being rather simplistic in looking at some of these points and just saying "Oh! well, you should have added the words 'This is temporary'." It is a complicated area, as I think Dr Elliman agreed. What one has to realise is that reports are not your last will and testament. They are reports that set out the main parts. You will remember that when Dr Elliman gave evidence he was taken through in-chief by my learned friend and he picked various points and expanded on them, because that is the nature of expert reports. They are reports but they are not everything that you want to say on the subject. So, it is well known, and obviously Dr Donegan realised, because if you look at the correspondence she knew that her report was to be used as the basis for cross-examination, that is what was said in the letter, so she knew that it was going to be used for cross-examination purposes and she knew that, in turn, she would give evidence and be cross-examined. Obviously, in an adversarial system the system is such that people give their evidence, their evidence is challenged and tested by cross-examination, et cetera. So it is, if I may say so again, a rather simplistic and narrow view of an expert report to say that everything has to be in there and that you have to put every point in relation to it there.

Page 31, please, moving to polio. The second paragraph:

E "The introduction of the vaccine appears to have caused a great reduction in paralytic disease apart from large outbreaks of poliomyelitis in vaccinated children with many deaths which occurred when certain breaches of vaccine from the Cutter laboratories were used."

F She is saying there that the introduction of the vaccine appears to have caused a great reduction in paralytic disease apart from one large outbreak there – again not referred to by Dr Elliman.

G I am going to move on, because there was no cross-examination of Dr Donegan in relation to any of these matters until we get to page 34 of the report. It is the top point, the worldwide point at the top. You can see it there. You have Dr Elliman's report at page 23, which deals with it. His point was really again in relation to the studies referred to at 10, 11, 12 at page 34 of Dr Donegan's report – the reference in her report at 10, 11 and 12, but obviously they have different tab numbers, as you know – and he says, "The implication is the vaccine is ineffective". He then goes through the research papers, saying that Sutter calculated that the vaccine reduced the risk of paralysis by 91 per cent. You will remember that I went through all those papers in detail with him. They are a difference of emphasis, which is so much of the criticism that he makes. They are merely a difference of emphasis, which does not, in my submission, amount to the report being not independent.

H

**A** The next point made by Mr Kark is the next paragraph and over the page, which we have spent a lot of time on, the 1961 SV40. In my submission, when you look overall at that paragraph which goes over the page and you read it in its entirety, it is, in my submission, clear that this is a vaccine that was in 1961 and is no longer in use, and that there is nothing misleading about that whatsoever, in my submission.

**B** You will remember that in relation to the very last point at page 35, the last sentence,

“It thus remains possible that the late adverse effect of the polio vaccination programme is emerging”,

**C** Dr Donegan did not see the full paper – I think it is by Heinan or Heinonen or some such name – but she saw the report of that by I think somebody called Stenton, and the complaint made is that she did not finish that last sentence, and in my submission she did not need to, but what the sentence reads is:

“...although the risk of cancer is likely to be more than outweighed by the benefit of vaccination to the postwar generation.”

**D** Well, that is nothing more than an opinion of the author, which frankly, in my submission, did not need to be included, and it is not right to suggest that it is misleading by leaving out the opinion of the author. I do not ask you to look this up but I just give you the reference. On day 7, 43A-H, Dr Donegan said that, with the benefit of hindsight, she could have completed the sentence. If I may say so, with respect, I do not agree that that was necessary.

**E** HiB: It begins at page 37 of her report. The criticisms are extremely limited. I think Professor Kröll agreed that it was not necessary to immunise the children for HiB. We are going to look at 3 July anyway, so we will come back to that. If you look at page 38, the criticisms at pages 38, 39 and 40 are really no more than Dr Elliman saying that she should also have pointed out the efficacy of the vaccine. Well, that is a point that he makes time and time again. In my submission, it is not necessary, and you have heard her view on that.

**F** Can I just draw your attention to a passage on page 39, please? Halfway down the last paragraph, she says:

**G** “After the introduction of the vaccine in 1992, cases of HiB disease were dramatically reduced, although some of this was thought to be due to significant under reporting of cases after introduction of the vaccine combined with more rigorous case definition with ‘consequent overestimation of the effectiveness of the immunisation programme’. However, after this initial decline, cases in children aged five to eleven months have been rising in England and Wales...”,

**H** and then she sets out the figures. So she does set out that after the introduction of the vaccine cases of HiB disease dramatically reduced; it is putting both sides.

**A** Over the page at page 40, the second paragraph:

“In 1992 before the vaccine was introduced, carriage of HiB was found in 4% of 1500 children tested. This had dropped to 0.7% by 1994 and in 1997 none of 500 children were carrying it.”

**B** So, in my submission, again it is a point in favour of the vaccine.

Meningococcus: Page 45 I think was the first point made by Mr Kark. He did not deal with the second paragraph and I will not either.

**C** “In 1997 the Department of Health was said to be resisting pressure to introduce blanket meningitis vaccinations for university students, ‘The problem is that several hundred thousand students would need to be vaccinated when the incidence of the disease is actually very small’.”

So that is the point that she is making and is dealing with there.

**D** The beginning of the next paragraph begins, “The vaccine was nonetheless introduced in November 1999”. In cross-examination, Dr Donegan accepted that she could have made it clearer that there was a different vaccine. As I say, that was a point brought up by Mr Kark, not in Dr Elliman’s report, but that is there.

Page 46, the penultimate paragraph, is the acquisition/disease point. It is obvious, you may think, that she has made a typographical error, as she has asserted, in the middle of that paragraph:

**E** “When used on US forces, the incidence of meningococcal C disease was reduced two or three times...”

and it then goes on:

**F** “... but the total meningococcal acquisition rate was essentially the same regardless of vaccine status.”

So she is dealing with the acquisition rate but there is a typographical error. Indeed, if one looks at the paper, the reduction for two to three times fits in with the acquisition rate, so that is an error that she has made.

**G** I should just correct the point that Mr Kark made at the bottom of that paragraph, which is an error, if I may say so, about the attack rate of group B meningococcal disease being higher among the vaccinated recruits. It is the end of that same paragraph. He was in error, I think, in saying that that was wrong. It is in Dr Donegan’s references at tab 77. I do not ask you to turn it up. I will give you the reference, if I may. It is page 419. I will just read the relevant paragraph to you. It is just above the discussion heading. It says:

**H** “On the other hand, there was no reduction of disease due to group B meningococci among the vaccinated recruits. In fact, the attack rate

A

was higher among them, although the number of cases of group B disease was too small to permit statistical analysis.”

Just for your reference... Well, you will have it in Mr Singh's reference, so I need not take you to it.

B

Measles, page 48. In the first paragraph, about eight lines down, it says:

“After about five days the rash starts to fade, the temperature drops and the symptoms all resolve. Treatment consists of general measures to keep the child comfortable and well hydrated (lots of drinks). Nursing in a darkened room is helpful if photophobia is troublesome. The most common complication is pneumonia, ear or mastoid infections and conjunctivitis.

C

Most deaths due to measles follow complications such as pneumonia, croup and diarrhoea and are often associated with malnutrition, particularly lack of vitamin A. The *Immunisation against Infectious Diseases Handbook* also states that, ‘complications are also more common and severe (in) poorly nourished and chronically ill children. This is why measles is such a killer in developing countries.’

D

That is a perfectly fair and balanced picture of measles.

E

Page 49, please. Again we are on grammar in the second paragraph down. Dr Donegan has told you that the last sentence of that second paragraph, “To give a vaccine that has such an effect on the immune system at the same time...” et cetera, was a reference to the cell mediated immunity which is depressed, as Dr Elliman agrees at the top of that paragraph, and she says, and you may think it is obvious when you look at it, that “Indeed a high titre measles vaccine used in populations in Africa...” – it does not say “in the UK” – “...caused higher death rates in girls from other infectious diseases compared to boys or unvaccinated girls” ought to be in parenthesis. That is what she said in evidence.

F

Page 54. This again, if I may say so, is a distinction without a difference. Two-thirds of the way down, there is a reference to the BMJ Communicable Disease Unit:

“A report in the British Medical Journal from the Communicable Disease Unit at the London School of Hygiene and Tropical Medicine stated that after the 1994 measles rubella campaign there were 530 severe reactions reported.”

G

Dr Elliman's criticism is that they were suspected. Dr Donegan says – and, quite frankly, you may agree – that there is no real difference between suspected and reported, since in order to report you must suspect first of all. It is, in my submission, again another point of tinkering.

H

The following sentence reads, “One report of SSPE occurred one month after vaccination.” Of course, the point made by Mr Kark in relation to the fathers reading this I am sure would have no idea what SSPE is, so it is pretty clear who Dr Donegan was

**A** writing it for, who she thought was going to be considering it, because otherwise you would never have put in "SSPE". It says it further up, but who is going to know what "subacute sclerosing panencephalitis" means?

**B** In my submission, although a seemingly small point, this is in fact quite an important point. Dr Elliman in his report at page 37... I am sorry, that may not be a correct reference. I will have to come back to you on the reference, but you will remember this because Dr Elliman said that this is... No, I am sorry, I am on the wrong point. Forgive me, my reference is wrong; this is a different point.

**C** The report of SSPE occurred one month after vaccination. That is the point. Then Dr Donegan has put in the next sentence, "The child had a history of natural measles infection some years earlier". She is putting both in, that is to say, the fact of vaccination and the fact of the natural measles, and you may remember that she was asked questions about that and she indicated that, in fact, it would be more likely therefore to be not the vaccination, because SSPE takes some time to actually contract, and therefore it is more likely to be the natural measles, and she has put both in, although she has not made the specific point in relation to that.

**D** I am sorry, the point I was going to draw attention to is over the page at page 55 in the penultimate paragraph:

"A study in France concluded that there is sufficient evidence of a clear temporal relationship between MMR vaccination and the occurrence of [ITP] to make a causal relationship highly plausible".

**E** This is important, in my submission, because Dr Elliman did deal with this at page 38 where in the middle paragraph he said:

"MMR vaccine is causally related to ITP".

Dr Donegan has said that there is:

**F** "... a clear temporal relationship between MMR vaccination and the occurrence of [ITP] to make a causal relationship highly plausible".

**G** So this is a person who the Council say seeks to colour her view at every page, and yet at the very opportunity - the single opportunity - to promote the point that there is in fact a causal relationship between MMR and ITP does Dr Donegan lick her lips and relish and dwell on that causal relationship? No, not at all. What she puts there is, "No, there is a clear temporal relationship", and so more cautious than Dr Elliman. So if she was so blinkered and so coloured by her deeply held views on immunisation, this was a classic opportunity - a prime opportunity - to make the point and drive it home. However, no, the research she had and the papers she produced is faithfully reported by her in her statement that there is "a clear temporal relationship".

**H** Dr Elliman had another paper which showed that in fact that he said it was causal. Whether it is or it is not may not matter, but the point is that this is a classic opportunity and it is extremely telling as to whether or not this is a practitioner who is seeking to

A colour her whole report by putting matters just that are favourable and putting them higher than they might be. So it is an important point, in my submission, that the one opportunity she had to state that there was a causal relationship she does not take.

Page 56, please, and this is again the level of point I am afraid that Dr Elliman has gone to. If you look at the end of the first paragraph it says:

B “Autism, however, was not described as a disease until the 1950s ...”;

C etc, etc. Dr Elliman’s point here is that it was 1943. In fact when he was cross-examined he accepted that it was first described then, but not widespread description until the 1950s. Is that really the subject matter of an expert report before a General Medical Council in relation to a misleading report? He has exercised no discretion, in my submission, of the points to include and not include and, whether that is a criticism of him or not, it does say a lot about his judgment.

Page 58, mumps, the first paragraph, second sentence:

D “The peak age of incidence is five to nine years. One attack of clinical or subclinical mumps confers lasting immunity and second attacks are most unusual”;

and so there is Dr Donegan setting that out.

Over the page at page 59, please, the second paragraph down (and again these are all points not made by Dr Elliman):

E “Mumps meningo-encephalitis is uncommon but is the most important complication seen in childhood. Headache, vomiting and sometimes convulsions are accompanied by neck stiffness and occasionally focal signs of paralysis. Mumps meningitis requires no specific treatment although lumbar puncture provides relief from the intense headache and the outlook is usually excellent. Rarely, deafness can occur”;

and so not exactly holding back on the complications or effects of this disease either.

Just going back to page 58, at the foot of the page:

G “In fact it is thought that having mumps with recognisable parotid swelling has a protective value against getting ovarian cancer in later years”.

This is dealt with by Dr Donegan at Day 7, page 64, at G. Mr Kark is saying just above the answer at letter G:

H “It is just this short point that the research upon which you were relying was both limited and old, was it not?”

A

A There are limitations, but I think it is unwise to discard research just because it is old”,

or people:

B

“Most of the vaccines that we use commonly were licensed on the basis of old research in terms of their safety and efficacy”.

Then Mr Kark says:

“Q I think we heard from Dr Elliman that there was another report.

A He produced the one on the women in China.

C

Q Yes, and you say there were differences?

A I said they were a very different population and it was looking at subclinical mumps. Well, clinical and subclinical. You would not know because it was just looking at the evidence from the serum that antibodies that the person had had mumps, either clinical or subclinical, and West was quite clear about clinical mumps.

D

Q I understand that, but was that a piece of research you had actually come across or not?

A No.

Q What research had you made?

A The mumps paper that I had here was on the basis of the mumps information that I had already required.

E

Q When you sat down to write your report did you think that you ought to see if there was anything post-1965?

A Certainly, I looked at Dr Conway's report and I looked at Professor Kroll's report and they had made a lot of statements that had no references, so I did not know at that point that I was going to need a reference for every single thing that I said because they had not. In fact, I was doing the best I could in terms of trying to make it more clear by actually producing some references”.

F

That is an important point, in my submission:

G

“Q Dr Donegan, what is the fact of Dr Conway and Professor Kroll not producing research got to do with your report? If you produce a piece of research and you decide to base a comment in your expert report upon it you might be expected to do a simple check to see if there was any report since 1965.

A This being my first expert report that I had done - what I had done on what I had received - that being what I thought, particularly with Dr Conway, having been a medical expert many times in the past, I thought that is what the format needed to be. So I was doing my best in terms of trying to provide more information because

H

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I knew I was providing a different view to the other two experts and a view that maybe was not current among the views that the court would have come across previously”.

That is, in my submission, a very fair and thorough approach.

B

She does actually say at 66A:

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

C

So, that is the basis on which she put that forward.

Page 63, please, rubella, the second paragraph down:

D

“To protect unborn babies from rubella syndrome in women who are not immune, it is possible to see that vaccination does not necessarily stop this occurring. In fact there are likely to be more cases occurring as vaccination is now given at a much younger age so it is likely to wear off sooner - even with two doses. It would be far preferable for girls to get rubella disease and have the better quality antibodies associated with natural infection so that in their own pregnancies they will not catch rubella for the first time. When they reach childbearing age they can have their rubella antibodies checked. If they do not have antibodies to rubella at that time, then rubella vaccination could be considered, but this would be at an age when a decision could be made without reference to the court”.

E

F

So, it is not right to say that Dr Donegan did not indicate that vaccination should never be considered in each of these children. She did say there that rubella vaccination could be considered, obviously taking into the account the wishes of the mother, and then it would be at a time when the children would be able to make their own decision, because here was a sensitive case, or at least Dr Donegan treated it sensitively. The other reports, you may think, were not terribly sensitive, when you had fathers who wanted vaccinations and mothers who did not want vaccinations. This was a difficult ethical issue - and I think Dr Elliman said that is what he spoke on the radio about, this difficult ethical issue - as to two parents with different views which had to be handled sensitively and the mothers were entitled to have their views at least explored by the various doubts that there are in the science.

G

H

That is why Dr Donegan, as she told you, was initially reluctant to help or to be an expert, but felt morally under a duty to assist the mothers in preparing this report because otherwise they would have no-one to assist them and to put the other side of the coin. So rather I suppose as she does in her surgery, explaining both sides, she hoped that she would be able to at least put the other side in the absence of that being done by Dr Conway or Professor Kroll. Had they fulfilled their task appropriately under the CPR

**A** 35 then it may be she would not have needed to provide a report at all because, had they included in it all the possible side effects, all the potential adverse reactions and dealt with that matter fully, then Dr Donegan's report would be otiose.

THE CHAIRMAN: Time to stop, or do you want to finish a point?

**B** MR STERN: I have actually dealt with the end of the first report. I am not going to go through any of the points in the second report and so that would be a convenient time to stop if everyone has had enough. I am quite happy to carry on, but if you ---

THE CHAIRMAN: Yes, thank you. It will give your throat a rest as well. We will start again at half-past-nine tomorrow.

**C** MR STERN: I am quite happy to start at nine o'clock, if you would like, to give you a little more time, but only if that is convenient for everyone?

THE CHAIRMAN: I am getting nods from everybody. Yes, nine o'clock then.

**D** THE LEGAL ASSESSOR: I had already prepared my advice, or a draft of my advice, to the Panel over the weekend. I have had to amend that and indeed add things in my mind as a result of your and Mr Kark's addresses to me, and the legal secretary very kindly has agreed to allow me to type those to her. I was thinking of doing it, because now I have heard enough to be able to finalise my draft, if she could do it at nine o'clock in the morning. It may be that it should not take more than half-an-hour, but it is just a possibility that it would. I am only saying that because that is a way ---

THE CHAIRMAN: Is it safer to go for 9:30 then?

**E** THE LEGAL ASSESSOR: Yes, and so you could all come at 9:30.

MR STERN: Yes.

THE CHAIRMAN: Okay, then given that we will go back to 9:30 then.

**F** *(The Panel adjourned until 9:30 am on Tuesday, 21 August 2007)*

**G**

**H**