GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL

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

On: Tuesday, 21 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 Ten)

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

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

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

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

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THE CHAIRMAN: Good morning.

Yes, Mr Stern?

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MR STERN: Madam, the adjournment overnight sometimes produces a shortening of submissions and other times I am afraid not. I am afraid I do want to go into the second report a little more than I hinted at yesterday, but obviously that was because I had not heard Mr Kark's submissions on them and so my initial preparation for my speech was not taking that into account.

Dr Donegan's responses in cross-examination to the second report, just to give you it generally, can be seen at Day 7, 74-82. I am not going to ask you to turn it up, but I am just giving you that reference so that you have got the overall picture.

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There is very little criticism of her. Dr Elliman's criticisms are in my submission unfair, because one can see that Dr Donegan was responding to Dr Conway's report and indeed that was precisely what she was instructed to do by the solicitors. If you look at the points that she makes where there is criticism, she was responding to the particular points that Dr Conway was making. Interestingly Dr Elliman does not adopt many, if any, of the points made by Dr Conway in relation to his report in that second report that you have been referred to.

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Now my learned friend, Mr Kark, in appreciating possibly that his case was perhaps less tenable on the second report, actually for the first time in his closing speech to you yesterday said:

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"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 ...",

and then he went on to explain the blue pencil test.

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Now, that is the first time that he has suggested that. Of course in opening, and indeed in cross-examination, the case was that the reports on every page were coloured in the way that he described it. So it is altering, at least in part, the case at the conclusion. I say altering the case, rather than just reflection of a different report, because the allegation as it is set out, as I say, relates to the reports and that is the way Mr Kark opened it and that is the way he dealt with it in cross-examination. So, he is now as it were saying, "Well in fact half of my case you can jettison, because in fact I can see that possibly that is not quite so misleading".

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If we look at the points that he made in relation to that, please, first of all page 77 of Dr Donegan's report. Forgive me, can I give you the reference to the part that I just quoted. You may have yesterday's transcript, but if you ---

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THE CHAIRMAN: Yes, it has come through.

MR STERN: Yes. You will appreciate that the references I am giving you are taken from my e-mail version and, therefore, I do not have the letters and the page numbers may be one or so out. Doing the best I can, it is D9, page 38. It is right, I am told. Thank you. It is Day 9, 38, at B, for your particular reference I see from that page.

В

Dealing then with page 77 of the report, and I am just dealing with the matters that Mr Kark raised in cross-examination, you will appreciate. It is the point about:

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

and then the example given by Dr Donegan is the USA there as giving an example obviously of a country where it has not virtually disappeared.

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The criticism and the way Mr Kark put it in his address to you was:

"For what it is worth, Dr Elliman's view was that it has in Finland and Sweden".

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Dr Donegan did not say that all countries where there has been a high vaccine uptake. She was giving an example of the very point she was making. To say there "Finland and Sweden" would not make sense, because the whole purpose is that she is showing that there are countries where there is a high vaccine uptake and, indeed, she points out a particular country.

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You will remember that in relation to that there was a criticism by Dr Elliman in relation to the second sentence which reads:

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"The USA gave up its efforts to eradicate measles in 1968 ..."

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I say you will remember, you may remember, and Dr Elliman rejected that proposition until the paper that is actually referenced in that particular paragraph was shown to him. He had not looked and has not looked at the references in the second report at all. When that paper was shown to him again, although I did not mention this yesterday, this is another withdrawal by him of a point.

One would have thought that it would not have been difficult to have looked that up and to have made certain comments about it. That would have been a fair way of dealing with the point, rather in what I submit is an unfair way that he did deal with it. The way he put it was:

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"Dr Donegan's claims on this point are inaccurate".

That is at the foot of his paragraph at page 49. Well, obviously he had to withdraw that when the paper was shown to him. Obviously if you reference a paper, one would have thought that Dr Elliman would take the trouble to look it up and to actually check it.

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Page 83 of Dr Donegan's report. Mr Kark made great reference in his closing address to you at Day 9, page 38, on the reference that I have. It relates to, as you can see at letter E

and further down, that Mr Kark says:

"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 ... that it was on the same page".

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Well, that is not much of an admission. It is there:

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

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and then he put the question that he asked her there, but he did not refer you to her evidence in-chief which in my submission in fairness you need to look at. It is Day 6, page 75, at H. It is G into H, as you can probably see at the foot of the page. Day 6, page 75, G into H. There is the point being made at G:

"This is the Professor Stewart point in the *Lancet*. The criticism is that you failed to use"

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- and it says "Mallis and Bennett" -

"which is a paper that apparently follows on.

Again, let me ask you: did Dr Conway or Professor Kroll refer to that paper to the best of your recollection?

A To the best of my knowledge they did not.

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- Q Did you see that paper?
- A Not then, I have now.
- Q I am talking about the time when you wrote this report?
- A No. I had not read it for this report.

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- Q If you had seen it would you have included it?
- A Yes, I would have included it well I might have included it had I seen it. As I said, part of what I was trying to do was produce a report that was not several volumes long".

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It is not fair, in my submission, to criticise somebody for not including a report if they have not seen it, unless you are saying alternatively that no reasonable expert could possibly have missed such a paper and one cannot say that because we have all three experts that did not include that paper. So, again I am not clear as to what the criticism actually is in relation to that.

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Page 87, paragraph 1.26 there, the point being made by Dr Donegan is:

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"The 'controls' in these studies are not unvaccinated, they have been given tetanus, diphtheria and polio vaccinations, these vaccinations

are associated with numerous adverse reactions and may indeed be the course of 'idiopathic' childhood neurological illnesses themselves".

В

Mr Kark's criticism is he says, "Well, that is putting it too high. "... may indeed be ..." is putting it too high", but the reference that he referred to (and indeed it is in the body of the answer at day 9, page 39, at letter C) the authors of the report you may think are making precisely the same point where they say:

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

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Well what is the point, as Dr Elliman would say, in the juxtaposition of those two propositions if indeed you are not seeking to draw some inference from it? So all she is saying is that, from the juxtaposition of those, she is translating it into, "...may indeed be ...", which is her opinion. Perfectly proper, in my submission, and nothing wrong with that.

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Page 107, please. This is the cell mediated immunity point. Can we look, please, at Dr Donegan's evidence in-chief at Day 6, page 80, at H. At the foot of the page, H, it says:

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"This refers to the cell mediated immunity point, I think that we have already... For whatever reason we are not pursuing, as I understand it?

A Yes.

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Q Do you want to say anything about it?

A No. I think this particular time Dr Elliman is bringing up his calculated, or their calculated vaccine efficacy rate.

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Q Yes. What would you say about that? Should you have put that in? What were you discussing in your report and, indeed, in this about... Well, it is all to do with cell mediated immunity, is it not? As we can see it says it there?"

One of the probably not better questions that I have asked and probably too many in one sentence, but there we are:

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"A I was answering Dr Conway. He was talking about the conclusions of the study in the same way that Dr Elliman was talking about them in his comments on my first report.

So at this stage, all the way through this second paper with Dr Conway, I am answering Dr Conway – he has said something and I am answering it. In my first paper I was giving background, natural history, epidemiological data, but here Dr Conway is making a point and I am answering it. I am not summarising a paper.

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Q Were you dealing with vaccine efficacy or cell mediated immunity?

A Cell mediated immunity".

So, again, it is in my submission a poor point.

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Page 112, please, of Dr Donegan's report. This is the point at the foot of the page. This is the:

"... insulin diabetes mellitus and pancreatitis has been reported to occur after measles ... and MMR vaccine at an incidence of 1 per 250 000 doses".

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There is no question that that is accurate, but if we look please at what Dr Donegan says in-chief about this at Day 6, page 82, at A. It is at the top of the page actually. There is paragraph 1.86 which we are dealing with at the top as you can see:

"... and Dr Elliman deals with it on my page 58, probably your 59",

I say, and then a quote:

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"... which you have included in relation to a paper and his criticism is:

'What she doesn't state is that the authors went on to say that the number of cases of diabetes expected without vaccination was 'far in excess' of the number that occurred after vaccination ...'",

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and then the conclusion.

Then looking at Dr Conway's report, as you can see it carries on at letter C, and then what Dr Conway was setting out:

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"Complications of mumps vaccines ...state that the only two adverse events associated with mumps vaccine meeting stringent criteria for causality are aseptic meningitis and parotitis. The risk of the former has been removed with the presently used mumps vaccine strain. The authors conclude 'it is important to place the risks of vaccination in the context of the risks of the disease'."

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Then a little at G:

"Q He goes on:

'Virtual disappearance of mumps related complications in countries which have achieved high coverage with mumps containing vaccines is unequivocal...'",

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So, the conclusions are already in Dr Conway's paper and it is frankly not fair and

misleading to suggest that Dr Donegan should include them, or repeat them again, when they are already dealt with in his report and she is merely responding and adding to the point that he has made.

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Dr Elliman seems to take no account in his report of the response factor, if I may say so, and what Mr Kark said at Day 9, page 40, in relation to those points that I have just drawn to your attention, letter F, he said:

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

Mr Kark in dealing with Dr Conway's and Professor Kroll's report said this:

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"It may be ..."

This is a point I referred to yesterday, but I just want to come back to it. He said:

"It may be that the writers"

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- that is Conway and Kroll -

"thought it unnecessary to do so"

- that is to say quoting research -

"because all the research supported, in general terms, vaccination".

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That is, if I may say so, not a good or a fair point. First of all, it is speculative. Second of all - and I know that Dr Goodman will know this, but I will draw it to your attention if I may for the others - the CPR 35, which is in your defence bundle. Forgive me, I am flagging on the voice front. Divider 2 I think is where it should be, but it may be in a different divider. I would like you just to turn this up, if you would not mind.

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DR GOODMAN: Divider 2 of ...?

MR STERN: I think it is divider 2 of the defence bundle.

THE LEGAL ASSESSOR: It is D3.

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MR STERN: D3, is it? Thank you, Mr Grey.

THE LEGAL ASSESSOR: It is both D2 and D3.

MR STERN: Yes, but the D2 is the 2002 one, I think, or at least it should be. Yes, it is. The other one - we put the other one in because that will be referable to 2005, therefore Dr Elliman's report, so that you would have both as it were. This one is the one that is applicable, or would have been applicable, to Dr Donegan's, Professor Kroll's and Dr Conway's report.

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You will remember that Part 35 is set out in a fairly limited fashion, but is expanded upon - well, let me take you through it because it will be fairer. 35.1 on the first page:

"Expert evidence shall be restricted to that which is reasonably required ...

OVERRIDING DUTY TO THE COURT"

- at 35.3 -

- "(1) It is the duty of an expert to help the court on matters within his expertise.
- (2) This duty overrides any obligation to the person from whom he has received instructions or by whom he is paid".

Then we can see over the page various other details, but looking please if you would at 35.10 you will see:

"CONTENTS OF REPORT

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"(1) An expert's report must comply with the requirements set out in the relevant practice direction",

and then it sets out what should be at the end of the report and then:

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"(3) The expert's report must state the substance of all material instructions, whether written or oral ...",

and then it deals with that point.

Then 35.12 is dealing with the discussion of experts and perhaps it would be convenient if I looked at this now, but it is a point I am going to make later:

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"(4) The content of the discussion between the experts shall not be referred to at the trial unless the parties agree",

and then the practice direction is at the end of that and it is the practice direction that really gives the detail as is so often the case. 1.3 of the practice direction:

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"An expert should assist the court by providing objective, unbiased opinion on matters ..."

I beg your pardon. It does not have a page number, but it is the practice direction at the back of that. It is, I think, the last four pages in:

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"1.3 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".

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Then:

- "1.5 An expert should consider all material facts, including those which might detract ...
- 1.5 An expert should make it clear:
- (a) when a question or issue falls outside his expertise; and
- (b) when he is not able to reach a definite opinion ..."

Then moving to the "FORM AND CONTENT OF EXPERT'S REPORTS":

- "2.1 An expert's report should be addressed to the court and not to the party ...
- 2.2 An expert's report must ...",

and then:

"(2) give details of any literature or other material which the expert has relied on in making the report".

So Mr Kark's point, if I may say so, is directly contrary to the CPR 35, which is that Dr Conway and Professor Kroll could not of their own volition decide - and I am sure they would not be arrogant enough to do that - that these matters should not be included in the report. The CPR 35 makes it clear that it must be.

Over the page at little subparagraph (4):

"[The expert needs to] make clear which of the facts stated in the report are within the expert's own knowledge",

and the range of opinion, etc. You have looked at this before. So it would not be right to say, and it cannot be right to say, that Dr Conway and Professor Kroll could just not include research.

Can I, while I am dealing with Part 35, just make this point. You have been referred on a number of occasions to paragraph 51 of *Good Medical Practice*. That, in my submission, is where matters I am afraid have gone slightly wrong in this case because, although there is of course nothing wrong with referring to paragraph 51, the duties of an expert in civil cases (as I know at least one of you will know) are set out in the CPR 35. That is where it comes from. Had Dr Elliman set that out in his report, we would not be in the position we are in now of this trail of misunderstanding that I am afraid has crept in both through Mr Kark's submissions to you and the evidence that you have heard, because the duties of an expert are set out in the CPR 35. If there is a breach of that, well, then it is perfectly permissible to say, "There is a breach of CPR 35 and therefore you have breached your duty to the court in civil cases", whatever it is you have done.

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If this Panel finds that there is a breach of CPR 35 and finds the consequences in relation to that, then of course it is entitled to look at paragraph 51 to see whether or not that might amount to serious professional misconduct in this hearing, or indeed impairment of fitness to practise under the new rules. However, the duties of an expert are not set out under paragraph 51 - they are just not - and so where you have been referred to that that may be relevant, but it is not at the stage at which you first have to consider the matter.

That is why it is important that these matters were drawn to your attention through the cross-examination of Dr Elliman. Indeed obviously Field Fisher Waterhouse thought they were important, because they provided him with a copy of them in their letter of instructions, and yet there is no reference in his report to Part 35, but he then says, "These are my views as to what an expert's duties are in civil cases", or "claims". I cannot remember exactly how he puts it, but that is essentially it.

That is where I am afraid matters have gone off the rails a bit. So we are now right at the end of the case where you have as it were been sent off on the rails on CPR 35, because that was never set out and should have been, which is why I said - and I believe it may with some agreement - that the central point about the CPR is whether there is an independent report. That is really the essence of what should have been the way it was charged, although it is not, and why I have tried to help by setting out, as I see it, the way I see the case in order to try and help, because I think everyone will agree (including Mr Kark) that these are not necessarily the most, if I can use the expression, happily worded sets of factual heads.

So coming back, if I may please, to the point. I am sorry to deflect from it, but I was dealing with the point made by Mr Kark that it was unnecessary, or they may have thought it was unnecessary, because all the research supported in general terms the vaccination. That, if I may say so, is an inaccurate assessment of the papers - the research - and this is I am afraid where lawyers and doctors tend to differ, because lawyers have a very simple approach to life in many ways. Lawyers take the view that, "There is one point in this and I am just going to deal with the one point, or the number of points that there are, and try and summarise it in one way". They are always looking for the narrow point. They are always looking for the conclusion of a paper and the conclusion of the paper is what ultimately lawyers I suppose go for.

However scientists, as I understand it, and those who look at science research, have of course an entirely different approach. The conclusions of those papers, that is to say the opinions of the authors doing the research (which is I say in parenthesis mainly funded by pharmaceutical companies) tentatively - tentatively - support vaccination. That is no more than that. None of the conclusions say, "This is the position". They all say, "This may be the position", or, "Possibly this", or, "It looks like this", or, "It may or may not be the other". They are tentative in almost every single case.

Science, as I say, in my submission, is very different. Research is changing. It has being updated and reviewed all the time. Interestingly, if one throws oneself back to 2002 looking at what Dr Donegan was actually saying in her report about thiomersal she was the only one making comments about thiomersal. Indeed, in 2004 thiomersal was removed from the DTP vaccination. I am not suggesting that she got it right or, indeed,

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there is any acceptance of the conclusion that there is a causal relationship between thiomersal and anything else at the moment but it is, nevertheless, although not accepted and proved, there are and were genuine concerns which ultimately led to the removal of thiomersal from the vaccination.

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It is the data that needs to be looked at and, if I may coin a phrase, the jury are very much out on the interpretation of the data that you have looked at in this case. One only has to have the merest squint at it to realise that. In addition to which, I will not repeat the point but you will remember the Cochrane collaboration point and, indeed, Dr Fletcher dealt with this in his response which you may have found extremely interesting. D8/53, I think it is at the foot of the page, he is being asked about a particular point there, SSPE, half way through his last answer:

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"I am sorry, but many of these reports have figures in which really carry such a measure of uncertainty about them that it is extremely difficult to draw any conclusions from them. They are guesswork, as much as anything else, and I cannot really know whether these figures are right or wrong."

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Then he has dealt with a particular part of whether that should be included and I am not dealing with that for the moment but I will come back to it. So there is a sense in which these figures are far from settled and it is not really the appropriate approach to take a lawyer's approach saying: that is what that conclusion of that report says, therefore you should just look at the conclusion and ignore everything else. Of course, Dr Donegan said that had she been told by anyone to put in that the conclusions of the papers are at variance with my recommendations, or whatever it, some other phrase then she would have had no objection to doing that.

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Can I deal with Dr Fletcher because my learned friend said that he did not really help the case of Dr Donegan. That, if I may say so, is a somewhat startling suggestion, therefore I need to look at what Dr Fletcher said. He had, first of all, what you may think to be an incredibly impressive curriculum vitae. He is someone who has spent decades dealing in the safety of medicine and, therefore, having reports put before him day in day out from experts and evaluating those expert reports. Admittedly they are not reports. He is someone unassociated with that, although he has seen 30 expert reports in a recent case. He is unassociated with anyone in this case. He did not know and does not know Dr Conway and Professor Kroll. He had heard of Dr Elliman but did not know him. He had never met Dr Donegan before he was instructed in this case. He is not someone who is associated with anyone in this case. He has no bias or axe to grind. He was asked about expert training and I know Dr Goodman made a point about this expert training, that the courts now and in 2002 strongly recommended it. I have not found a document which suggests that and I do not believe anyone this side of the hearing room has but if there is a document obviously we will consider it. The only reason I raise it is because if there is a criticism of Dr Fletcher by virtue of the cross-examination that was made that he had not had training and, therefore, somehow that undermines or weakens his evidence I do not accept that. In my respectful submission, that is not right.

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Indeed, your learned Legal Assessor has the case of Momodou, judgment given on 2

February 2005 where the Lord Chief Justice, the Deputy Chief Justice of England and Wales, Mrs Justice Dobbs and Sir Michael Wright, a retired High Court judge, gave judgement in relation to witness training. I will just draw your attention to one or two matters in relation to this because it was raised. You will appreciate this was a criminal case but the principle, in my submission, remains the same. The facts of the case do not really matter but there were a number of issues in this case. Group 4, the security company, were to be witnesses in the case and Group 4 subsequently arranged witness training for its employees. My learned friend has it, it is paragraph 39. If there is anything that anybody wants me to read out as well I, of course, will. Paragraph 40:

"As soon as these arrangements were discovered, advice was sought from counsel for the Crown, Mr Nigel Rumfitt QC. His advice was unequivocal. In the context of a criminal trial the proposed training was wrong, and might constitute a contempt of court both by Group 4 and by Bond Solon, the company chosen for training purposes. The programme of training was to be stopped immediately. By then however sixteen potential witnesses for the prosecution had received training. Their names were provided to the defence and in due course to the jury."

Then there was a copy of a case study provided by Bond Solon for training purposes and paragraph 42 I am going to, half way down:

"Even if the discussion and training began by focusing on the case study, the focus would inevitably move to evidence to be given by witnesses for the prosecution in what was then the shortly forthcoming trial. This case study would have been entirely inappropriate basis for any form of witness coaching or training in the present case."

Obviously this is a group of people getting training together and that was an additional factor here that the court very much disapproved of for obvious reasons. Then there are various matters in relation to the training itself that I need not trouble you with. It begins at paragraph 61: "Witness training (coaching) Bond Solon", is the sub-heading. It says this:

"There is a dramatic distinction between witness training or coaching, and witness familiarisation. Training or coaching for witnesses in criminal proceedings (whether for prosecution or defence) is not permitted. This is the logical consequence of well-known principle that discussions between witnesses should not take place, and that the statements and proofs of one witness should not be disclosed to any other witness. ... The witness should give his or her own evidence, so far as practicable uninfluenced by what anyone else has said, whether in formal discussions or informal conversations. The rule reduces, indeed hopefully avoids any possibility, that one witness may tailor his evidence in the light of what anyone else said, and equally, avoids any unfounded perception that he may have done so. These risks are inherent in witness

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training. Even if the training takes place one-to-one with someone completely remote from the facts of the case itself, the witness may come, even unconsciously, to appreciate which aspects of his evidence are perhaps not quite consistent with what others are saying, or indeed not quite what is required of him. An honest witness may alter the emphasis of his evidence to accommodate what he thinks may be a different, more accurate, or simply better remembered perception of events. A dishonest witness will very rapidly calculate how his testimony may be "improved". These dangers are present in one-to-one witness training. Where however the witness is jointly trained...",

and then it deals with jointly trained which is obviously an additional factor and the court said:

"...They may collude deliberately. They may be inadvertently contaminated. Whether deliberately or inadvertently, the evidence may no longer be their own. ... So we repeat, witness training for criminal trials is prohibited."

D | Then at paragraph 62:

"This principle does not preclude pre-trial arrangements to familiarise witness with the layout of the court, the likely sequence of events when the witness is giving evidence, and a balanced appraisal of the different responsibilities of the various participants."

There is witness support in almost every Crown Court and they take the witnesses round and say this is witness box; the dock; the barrister will be there; he will be wearing a wig there; he will be wearing a wig there; the judge will be up there. These are volunteers who have absolutely nothing to do with the case and are not interested in training witnesses. They are familiarising them; making witnesses feel more at ease basically. That is what it comes to. So that is the state of authority as I understand it. Mr Kark may want me to read something.

MR KARK: It is just the last seven lines or so of paragraph 62 starting "Equally."

MR STERN: Yes, of course. Thank you:

"Equally, the principle does not prohibit training of expert and similar witnesses in, for example, the technique of giving comprehensive evidence of a specialist kind to a jury, both during evidence-in-chief and in cross-examination, and, another example, developing the ability to resist the inevitable pressure of going further in evidence than matters covered by the witnesses' specific expertise. The critical feature of training of this kind is that it should not be arranged in the context of nor related to any forthcoming trial, and it can therefore have no impact whatever on it."

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That is expert witness training which obviously is in a different category. I am not suggesting that it is. That is relating to the technique of giving comprehensive evidence of a specialist kind but that is different.

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Dr Fletcher read the major part of 250 references, he told you. His view was that Dr Donegan had fulfilled her role as an expert witness. He set that out both in his report and, indeed, he adopted it in his evidence. If I give you the relevant paragraph, it is paragraph 17 of his report which he adopted and, indeed, he dealt with it at the end of the report as well repeating it, as you will recall. His overall conclusions, which are page 31. You will find his evidence on D8/1, if you want the reference for that as all well and onwards, obviously, and I just refer you to the same part where he dealt with paragraph 17 at D8/3. He adopted the part of his report where he says:

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

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

He said that he did not know she had not written an expert report before. He said:

"A I did not know that at the time, no. Yes, I would reiterate that, I think, that it was a remarkably capable task that she performed."

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Bearing in mind that she had very little time to do that but I am going to come to that. So I am not going to go through Dr Fletcher's report in detail because you have it there and, indeed, that is the reference to the evidence that I have given you but I do commend his evidence to you. Mr Kark did not challenge his view that overall his opinion was that the report was balanced. He did not challenge that although he did ask him about certain errors and points that were made by Dr Donegan in her report which she had already accepted were errors.

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So, in my submission, when you look at all of that evidence that you have in relation to the reports taken either individually or together they do present an independent report, is the way I am going to paraphrase it. If you think that is right or might be right then, in my submission, that would be the end of all the allegations because the issue as to what we are going to look at now, the second issue - the deeply held views point - does not even come into play if you think it is right or might be right that the report is independent.

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So only if you are sure that the reports are not independent, in my submission, would you need to even consider "deeply held views on immunisation". This is, I am afraid, another term that has never been analysed or, indeed, you have not been assisted as to what it is that you are supposed to understand by that and, therefore, nor has Dr Donegan. Does it mean deeply held views in relation to anti-vaccination? Does it mean deeply held views of immunisation concerning the safety of vaccination of children? Does it means deeply held views on the subject of immunisation relating to the safety of scientific research

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material? Which deeply held views are we referring to?

One can see how vague the position is because you will remember just when Dr Donegan was being asked questions by the Panel Dr Goodman asked her about whether she had any views on the British state, because it is really difficult to understand what it is that one is talking about in deeply held views. Is one talking about, and I think this is what Dr Goodman meant behind it, is there some sort of irrational, almost semi-religious view of vaccination? Is that really what the GMC meant? We do not know because it has never been set out clearly. So one has to go, as I say in the way that Dr Goodman has, from the extreme, as it were, to the very limited view. Where we are on that parallel and where we are on that line I do not know because it has never been actually set out.

So the most I can do is to say: well, these are the views that she has expressed to you and, in my submission, when you look at them they are remarkably sane; they are remarkably mature and they are remarkably considered. There is no criticism of her that she holds deeply held views and it would be an outrage if any of us were to be attacked for holding deeply held views because we are all entitled to hold deep views, or not superficial views or whatever it is. We are entitled to hold those views. That is why I submitted right at the outset of my submissions that it is the GMC's case that the non-independence of the report only comes about because of the deeply held views. Otherwise there is no point in putting them there. That is really why they say that it is misleading and indirect contravention of your duties as an expert witness, unprofessional and likely to bring the profession into disrepute. So it is only if you have done so in a blinkered way, as is set out here, that it could be any of those things.

So can I just perhaps draw your attention to one or two references of Dr Donegan where she spoke about this and then just give you the other references for you to see later on if you wish to. D6/7E, this is examination-in-chief:

"Could you help us, really in a nutshell, with what your views are in relation to universal vaccination because it maybe different in relation to individual vaccination; but universal vaccination and what your general views are and why?

A Well, regarding universal vaccination. Universal vaccination is based on a "one size fits all" approach. I think that there are cases where people need to have more of their own personal sensitivities or constitution looked at and I do not think it is necessarily the approach for everyone. When you ask about universal vaccination do you want me to discuss the effect of vaccinations on health and disease?"

I pause just to point out perhaps the point out that Dr Donegan is making there, is it deeply held views on immunisation for an individual? Or is it deeply held views of immunisation in terms of universal vaccination? Because there is a considerable difference because Dr Donegan's views, if I can summarise them, you may recall, what she said was that essentially she considered it with the individual and some individuals decide to vaccination and some do not but she does not actually recommend anything to the individual. You heard from Mrs Eaton in that regard. Universal vaccination, is it her view as to whether everybody should be vaccinated? Or whether a particular individual

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should be? Again, these are matters that really should have been set out clearly and I do repeat the submission I made yesterday: if there is any doubt as to the meaning of that the most favourable interpretation should be given, as always in any case where the burden of proof is on the other side, if there is any doubt about it then the benefit of that doubt is given to that person who faces the allegations. That is axiomatic.

So there is the answer at E, it carries on at F:

"We are going to look in a little more detail at that, but I want you, if you could, to help the Panel because not everyone is medically qualified. One or two sentences as to your views and one or two sentences as to why you hold those views?

A On vaccination?

Q Yes?

A Well, vaccination is, generally amongst medical circles and wider than that, claimed as the reason for the major fall in mortality (which is death) and morbidity (which is illness) for many major childhood diseases in the 20th century, which was also the view that I had always espoused because that is what I had been taught at medical school.

Q What is your view now?

A Now I think that it is not the universal, in a way, panacea. I do not think it is so efficacious as has been supposed. I think that there are problems with vaccinations that are not well really looked into. I think for individual children in their individual families it is some times not the best option.

Q Are you against people being vaccinated at all?
A I am not "against" things. My interest in the whole

vaccination issue is because

I am concerned about child health safety.

Q When you see patients at your general practice surgery do you say to them, "You must not get vaccinated", or words to that effect?

A No.

Q In general terms how do you approach patients who come to

discuss vaccinations with you?

A When they come along and say they specifically want to discuss vaccinations,

I say "Well, there is a lot of information available from the Department of Health, which you need to read thoroughly before you make your decision, but I think that there is also other information that you need to look at as well. When you have looked at a wide variety of information then I think it is really important that you make the choice that you think is best for you, your children and your family".

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That is, in my submission, a commendable approach and one that you heard from a highly intelligent lady, Mrs Eaton, and particularly somebody who is involved and aware of the issues. That is why we particularly asked her to give evidence, although obviously there are other patients that Dr Donegan has seen, but she is someone who knows about the pharmaceutical industry, she is someone who is clearly knowledgeable about science and, therefore, she understood the reason why she wanted to look more deeply into the vaccination issues and she gave evidence before you and she made it absolutely clear that she received, in her view, a balanced, fair approach from Dr Donegan which supports the way Dr Donegan puts it in her evidence.

Can I just turn to page 92/H, please. This is, again, in my submission an important point at the foot of the page:

"A Well, I have not cited, obviously, anti-vaccination people, because you would regard them."

He did not let you finish but he said, "Well, I can only go on what you have cited". You say, "I have cited ---" and he says:

"Do you agree that not one of the authors takes a different – not takes the same view as you do about vaccination against diphtheria?"

A I would agree, yes."

Can I ask you, when you say "anti-vaccination people", are there a series of — well, I think what Dr Elliman was saying in relation to one of the papers, that this was a well-known anti-vaccination group, or something like that I think he said?

A There are many books actually written by medical doctors and others in this country and the United States and Australia who seriously question vaccination, and they bring up a lot of history, proofs, medical papers, to support their arguments. I did not use any of those publications because I thought that the court would not regard them, so I did not use them. I just used what was available in refereed medical journals.

- Q But you were aware of those?
- A I was aware of them, yes.
- Q You presumably had copies of them, or at least could have access to copies of them?
- A Yes, but I did not think that the court would regard those as satisfactory support or references for my recommendations."

There is an irony, in my submission, because the criticism is that she draws up a report in which the reference material that she provides, attached and referenced in her report, has conclusions which ultimately do not accord with hers. That is essentially what it comes down to. Yet she could have relied on a whole series of papers according to this evidence

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which she could have then referenced and attached to her report and then let Dr Conway and Professor Kroll criticise it to their heart's content. That she did not feel was the appropriate course and that shows, in my submission, a degree of discretion and judgment about science and the papers and the way in which one should approach these things.

THE LEGAL ASSESSOR: Just to help you.

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MR STERN: Have I missed something out?

THE LEGAL ASSESSOR: She is actually asked about it at the bottom of the page after the one you have just been referring to, D6/94, at H.

MR STERN: Oh:

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"Q Do you have 'deeply held views'?",

thank you:

The views I have on immunisation and all my medical practice, I would say, are not superficially held.

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THE LEGAL ASSESSOR: Yes.

MR STERN: Yes, and then she deals with the heads of charge I think at that point.

As I say, there is no criticism that she holds not superficial/deeply held views. The question is whether they are such that they blinker her view, but in relation to the specific matter we do not know. Thank you.

Day 7 is the reference I was giving you. Day 7, page 9, D-F. It is more of the same, if you have turned it up. This is I think cross-examination. Yes:

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

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Q You say that you think parents should make an informed choice, but the fact is that you yourself - and I think you have made this clear in your report - are against the national vaccination process, are you not?

I think my concern is for child health safety.

rather than not vaccinating and being terrified'.

Is the answer to that 'Yes'?

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A I think that would be too simple an answer".

Precisely. It is again, if I may say so, the sort of lawyers' approach, "Please give us a 'yes' or a 'no' to what you say about vaccination", which is a massive subject and obviously not one that you can give a "yes" or a "no" to.

The next reference is page 10, C-D, and I will just give you the remaining ones because they are very much on the same vein if that helps: Day 7, 25G-26B; Day 7, 90D-E, and probably up to 91E, actually; and Day 7, 96D-97A. As I say, they are pretty much along the same theme if you see what I mean. The central point is that she tries to give information, more than anything else.

The next ---

THE LEGAL ASSESSOR: I am sorry to interrupt you again, but I wanted to make sure what these references refer to. When you deal with D7, I think you said was it 90 you started at, or ...?

MR STERN: I started at 9.

D THE LEGAL ASSESSOR: No, I mean the later on ones.

MR STERN: Oh, I beg your pardon. 25G-26B.

THE LEGAL ASSESSOR: During the course of Dr Goodman's questioning, she dealt with the question of precisely what she meant by homeopathy and gave quite a detailed explanation during the course of which her views that she held seemed to come out from her very well expressed. Do those references include that reference? I think they do, but I

MR STERN: I am afraid those references have not been done by me, but by Mr Singh. It is page 88, thank you very much. It is page 88, where Dr Goodman's questions begin at C and the reference to homeopathy I think is at letter E.

THE LEGAL ASSESSOR: Yes, and goes on.

MR STERN: Yes, and goes on over the page.

THE LEGAL ASSESSOR: Yes, thank you very much.

MR STERN: So, can I include that in the list of references as well. Again, I am grateful to the learned Legal Assessor.

The next point that I just want to draw to your attention, please, is from the document D24. These are the notes of the meeting I think taken by Professor Kroll when Dr Conway did not attend, but there was the meeting between Professor Kroll and Dr Donegan on 3 July. Just reading the heading, it says:

"We agreed that the purpose of this meeting was to establish, in the

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light of our respective reports, points of agreement and disagreement regarding vaccination of these two children against the diseases listed below. We also identified the issue of vaccine preservatives as one of which we both had possibly relevant opinions",

and that is thiomersal:

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"We acknowledged that the Court will base its decision on what is in the best interests of each child and hope that one consideration must be the reaching of a decision that minimises the animosity between the opposing parties".

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So, that was obviously the way in which they approached it between Professor Kroll, in any event, and Dr Donegan.

Looking then at the notes taken:

"Diphtheria",

and you can see "K" is obviously Kroll and "D" Donegan:

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"K and D agree that the chance of either child acquiring disease is low in the UK at present. We agree that this may change. We disagree on the ratio of risk to benefit of vaccination, K believing the benefit substantially to outweigh any risk, and D believing the risk to outweigh the benefit. However we agree that in numerical terms, both risk and benefit are small.

We disagree on the advisability of vaccinating against tetanus, K

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Tetanus

believing the benefit of vaccination to be substantial and D believing it not to be.

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Pertussis

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We agree that if the children are not vaccinated it is highly likely that they will get pertussis. We disagree on whether that matters. K, but not D, believes the illness to be serious, with risks to the children's health that far exceed the risk of vaccination.

Polio

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As for Diphtheria, K and D agree that the chance of either child acquiring disease is low in the UK at present. We agree that this may change. We disagree on the ratio of risk to benefit of vaccination., K believing the benefit substantially to outweigh any risk, and D believing the risk to outweigh the benefit. However we

agree that in numerical terms, both risk and benefit are small.

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We **agree** that [one child] is past the age where vaccination is advisable. We **disagree** on the advisability of vaccinating [obviously the younger child] K, but not D, regarding it as advisable.

[Meningitis]

We **agree** that both children have passed the first period (under 2 years of age) of greatest risk from meningococcal disease, and **agree** that the second period of greatest risk lies ahead of them, between the ages of 14-19",

and then again they disagree on the advisability of vaccinating. I will not read the whole sentence out again because it is pretty much the same one each time:

"Measles

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We **agree**, as for pertussis, that if the children are not vaccinated it is highly likely that they will get measles. We **disagree** on whether that matters".

and then again:

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"K, but not D, believes the illness to be serious, with risks to the children's health ...

Mumps

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We agree, as for pertussis, that if the children are not vaccinated it is highly likely that they will get mumps. We agree that this is a less severe disease than measles, but disagree on the advisability of vaccination",

and then again the point made there that it:

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"...is highly desirable to prevent an infection with significant morbidity, while D believes it is positively good to get natural mumps infection.

Rubella

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We agree that the disease poses no significant immediate risk to either child, and agree that the issue is protection of unborn children",

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because there is an additional factor in relation to vaccinating for rubella because you are not vaccinating in order to assist the health of the individual, in the sense that you are vaccinating to protect unborn children and therefore vaccinating to protect mothers getting it. I think I have put it generally, but that is I think what it is.

It says:

"We **agree** that the disease poses no significant immediate risk to either child, and agree that the issue is protection of unborn children. Where we **disagree** is that D believes it is preferable for the children to acquire natural rubella infection to protect their future children from possible congenital rubella, mistrusting the quality of vaccine-induced immunity. K does not agree with this".

You will remember actually that we looked at what Dr Donegan said in her report, in that it should be delayed and they should make their own minds up a bit later I think. Again I am paraphrasing, but that is what it comes to:

"MMR

We **disagree** on the matter of whether, if proposing vaccinating against measles, mumps and rubella, the components should be given in the combined MMR vaccine or given as separate injections. K believes MMR should be used, while in D's opinion, if you are going to vaccinate, the components should be given individually".

You will remember, of course, this was 2002:

"Vaccine additive: Thiomersal ...

We **agree** that it is desirable to avoid administering vaccines containing this preservative, noting that it is declared policy that these be withdrawn from the infant schedule as soon as is practicable. We **disagree** on the absolute necessity of this, -but not D - believing that the benefits of vaccination enormously outweigh what he believes is a theoretical risk".

So that was the nature of the 3 July meeting, and the reason I draw that to your attention is because you will remember Dr Donegan said in evidence that there was no hint to her that there was this major problem, as there now appears to be, with the GMC, of her report. So one looks at what it is that she went through and the procedures that she went through, and I know that again Dr Goodman will know this but I mention it for the other Panel members, if I may.

Clearly when you are instructed as an expert, then just like Dr Elliman you have conferences with counsel, you have meetings with your solicitor - the solicitor that is instructing you - you may be asked questions, you may be sent e-mails to say, "Please can

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you help us with this bit? Can you do an addendum to your report", or whatever it is, but that sort of thing, and indeed if you remember from the correspondence that Dr Donegan had you will remember leading counsel had asked one or two points.

Now leading counsel would never have put forward Dr Donegan's report, or indeed put her in the witness box, if she had taken the view that the report was misleading. That is obvious and, if I may say so, beyond doubt. If leading counsel, or indeed any one of the other counsel who were instructed, had thought that the report was misleading, then beyond doubt - because you would not want to call a witness who you knew was going to undermine or destroy your case. That would be obviously ridiculous.

So the very simple thing, if leading counsel would think it was appropriate, would be to say, "Well, Dr Donegan, we have looked at these papers and indeed the conclusions appear to be somewhat out of line with the conclusions or the recommendations you are making. What do you say about that?" "Oh, counsel, the position is this. I take the view that the data needs to be looked at, you interpret the data and the conclusions and opinions", or words to that effect. "I see. Could you please just draft a short additional statement setting that out and making that clear for the court?". "No problem, leading counsel". Leading Counsel then gets that, analyses it and says, "Taking that into account and taking all the other points that I wanted you to deal with in your report ...", and that is the whole point of having a conference with your expert so that you know what the position is, because it is very often the lawyers do not understand what the guts of the report are and need to be helped by the expert. That is why you have an expert.

However, for reasons that frankly I cannot understand and are not clear from the papers, this is a case where no conference took place and there was no solicitor input as to what it was that was expected of Dr Donegan, because you have seen the letter of instructions to Dr Elliman. There is nothing like that for Dr Donegan. There is no reference to the CPR 35 and there is a letter from her saying, "Well, what shall I put at the end?"

Now, all of those matters are the responsibility of the legal team. They are not the responsibility of the expert. The expert is not an expert in giving evidence. The expert is an expert in the chosen subject that the witness is giving evidence about. You can be an expert without ever having given evidence before. Every expert has to give evidence for the first time and it is not your expertise in giving evidence that is being sought. It is your expertise in the particular subject matter which you are brought before the court to give an opinion about.

That is why, if you look at the 2005 CPR and the protocol that is attached to it, it sets out clearly that the obligation is on the lawyers to make it clear what the position is. (*Pause*) I am just asking if we can find the exact part, because I just need to - I am not going to ask you to look through it now until we get you the exact bit. Oh, Mr Singh already has it. Thank you. It is in the protocol and it is page 9. It is October 2005. It is the "D" document after the 2002 one.

THE LEGAL ASSESSOR: D3.

MR STERN: Thank you, D3. I will not read it all, but it is set out under the subheading "Instructions". Point 8 and point 9 deals with an expert's acceptance of instructions and

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then 10 is "Withdrawal".

So that was clarified, for obvious reasons in my submission, because I do not know what the level of experience was of these particular firms of solicitors. I have not come across them. I do not know them. Oh, paragraph 7 if you could just make a note of that in the same protocol:

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"Before experts are formally instructed or the court's permission to appoint named experts is sought, the following should be established:

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- (a) that they have the appropriate expertise and experience;
- (b) that they are familiar with the general duties of an expert;
- (c) that they can produce a report, deal with questions and have discussions with other experts ...",

etc:

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- "(d) a description of the work required;
- (e) whether they are available to attend the trial ..."

That is why when you look at the letter from Field Fisher Waterhouse, if I may say so, that complies with that and sets out and you can see an example there of that letter of instruction.

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However, it is the obligation on the lawyers who are the ones who actually understand the court process. The expert is not there to understand the court process. The expert is there to provide his or her opinion on the specialist point that they are giving evidence about. It does not matter whether they have never given evidence before, whether they have never had any training before, or whether they have never written a report before. You can be an expert on the particular subject that you are giving evidence about without any difficulty at all, if the court rules that you are an expert.

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Just while we are on the subject of instructions, because Mr Kark said that Dr Elliman did not need to mention about his witness training because it did not feature in the letter of instruction, and so if I may say so he is relying on the particulars of the letter of instruction, as it were, to give Dr Elliman a basis for such a point, but he was critical of Dr Donegan and does not provide her with the same leniency, if I may say so, in relation to her letters of instruction. He says that that is not relevant. It is precisely relevant and it is a relevant point.

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The purpose really of all these points is to say this. The process seems, for whatever reason, to have let down Dr Donegan. I am not suggesting that it is entirely outwith her duty to look at what is going on. I am not suggesting that. However, the fact is that you will remember the time pressure that she was under. She got I think the report - Mr Kark said she asked for a two week extension. Again that is not entirely a fair point, because

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she had not actually received the report until the end of or the middle of May. The end of May, thank you. So, she asked for a little bit more time to be able to provide the report because it was a necessity. She did not actually have the material. So she got until 14 June, two weeks or just over two weeks, to prepare her report.

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I know Mr Brown asked this question about whether she could have asked for more time, which is a perfectly reasonable question, but of course the court case was looming on 8 July and this report had to be disclosed and served (as again I know those who have been involved in expert evidence will know) in advance so that the others can have a look at it. You cannot just turn up at court and just sort of say, "Here is my expert report".

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So, that put her under enormous time pressure. You will know from the second report that for reasons that are not explained that, although Dr Conway's report is dated 7 September, it was not delivered to her until at least 19 November and you have seen that in the correspondence. She was before the court, I think, on 8 December. I may have got that wrong. It may have been 4 or 5 December, but anyway it was early in December.

THE CHAIRMAN: 10 December.

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THE LEGAL ASSESSOR: The trial was on the 12th, I think.

MR STERN: It was early in December some time. I cannot remember the exact date. 10 December is what the front of the transcript says.

THE CHAIRMAN: She may have been there the day before. I do not know when the trial started.

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MR STERN: She may have been, but I do not - no, I do not think so, because that is the day on which the hearing started I think. She may have been, I do not know.

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So, she has no training and no experience as well. What is the relevance of all these points? It goes to both issues really, but if you think that if you have come to the conclusion that the report is not independent - as I say, I am on to the second point now and I have already made submissions about that and I will not go back over that. If you were sure that the reports were not independent then you would have to consider this question of the deeply held views point, but if you think that it was or may have been as a result of time pressure, etc. etc. the other points that I have just drawn to your attention, then of course you could not be sure that it was as a result of her deeply held views and you would have to reject that. In my submission it would be almost impossible to reject the proposition that errors were as a result of that, which also deals with the first part of

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the case as well.

If you were to find all of that - all of head 6 proved - then obviously you will have to go and look at head 7 and determine what you make of that. That is ultimately a matter for you, because obviously I am addressing you in a vacuum because it depends on what you find.

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Head 7 is again a somewhat tortuous and not an entirely easy head to understand, because it deals with "actions" and "a. misleading". Is that misleading that the report is

misleading, or the actions as I believe it to be relate to the giving of a false and/or misleading impression? Ultimately, a failure to provide an independent report. Your actions in that regard were misleading and in direct contravention of your duty as an expert, unprofessional and likely to bring the profession into disrepute.

So in my submission in relation to both aspects of this case, which I have tried to as it were summarise into two sections, first of all are you sure that the report is not independent? In my submission, it plainly is. Secondly, in relation to deeply held views, holding deeply held views is perfectly acceptable, but is there any evidence at all - and I suggest there is not only no evidence that her deeply held views led to her overruling of her duty to the court, but when you actually look at the reports there is evidence to show that in fact she in one particular regard that I drew to your attention yesterday played down the position.

Those are my submissions, unless anybody has any questions obviously that I am able to deal with?

THE CHAIRMAN: What we will do is take a break and then the Legal Assessor will ---

THE LEGAL ASSESSOR: I wonder if I could deal with one matter, which you mentioned, which to some extent took me by surprise and it may affect the advice I give. That is in relation to the duties of the expert. Mr Kark in his opening set out, I thought fairly and accurately, the duties of an expert witness. He firstly referred to paragraph 51 of *Good Medical Practice* 2001, secondly to Mr Justice Cresswell's judicial pronouncement in *The Ikarian Reefer* case.

MR STERN: If I may just interrupt, 1992 or 1993.

THE LEGAL ASSESSOR: 1993, that was. Thirdly, rule 35 (3) of the Civil Procedure Rules. That would be D2, not D3, at that time. Now when your client gave evidence, Mr Kark put to her paragraph 51 of the *Good Medical Practice* and she agreed with that and agreed she knew that those properly reflected her duties.

MR STERN: Yes.

THE LEGAL ASSESSOR: At no stage I do not think throughout her evidence did anyone ask her about Mr Justice Cresswell's pronouncement, or indeed the Civil Procedure Rules which in a sense the practice direction seemed to arise out of Mr Justice Cresswell's dicta, and I had understood that effectively there was no problem in relation to what an expert's duties were and I was proposing to advise the Panel that Mr Kark had helpfully and accurately set out those duties as set out in *Good Medical Practice, The Ikarian Reefer* case and the Civil Procedure Rules.

I am not quite following your point in relation to the Civil Procedure Rules and the extent to which, indeed, the point is relevant even if it is a good point. So certainly I appreciate that you referred to other parts of the Civil Procedure Rules so that the Panel has heard those and, secondly, certainly referred to D3 in relation to Dr Elliman, which again is perfectly reasonable. Can you help me as to whether it would be wrong for me to and advise the Panel that Mr Kark accurately and helpfully set out what the duties are?

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MR STERN: In general terms I do not dispute anything that Mr Kark said. I agree it was both accurate and fair. I am not suggesting otherwise. The question is though that the heads of charge deal with a duty of upon an expert. That is the central crux of the case. Because it is an allegation at 7(b) that:

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"In direct contravention of your duty as an expert witness."

In order to be able to see whether someone has contravened their duty as an expert

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witness you obviously need to know what that duty is and I cross-examined Dr Elliman, it is one of the first topics that I dealt with, in relation to what he has set out in his report as the basis for the duties of an expert and at that stage we put in, you will recall, the CPR 35 and I expressed it to him that those were, in fact, the rules that an expert needs to abide by. So that is the background, as it were. What I am submitting is that the CPR Rules are the rules that dictate the duties of an expert. I do not think there can be any dispute about that. Whether they are also fairly summarised by Mr Kark in The Ikarian Reefer and paragraph 51 of Good Medical Practice as well is not in dispute. I am not saying they are inaccurate, if you see what I mean. The point is that when one is coming along to give evidence as an expert and saying an expert has fallen below the standard in her duty as an expert in civil cases, which is what you are looking at, then it is important that you know what the duties are, or the Panel know what the duties are and those duties are set out in CPR 35. So I am saying that, and think I said to you in my submissions, that the way it should have been phrased in the heads of charges is "Your duties are set out under CPR 35. You breached your duty in regard to 1, 2, 3 or 4", whatever it is the GMC say and as a result of that you are in direct contravention of your duty as an expert witness, which is unprofessional and likely to bring the profession into disrepute. That would have been clearer because that is where the duties emerge. So I do not think what I am saying is consistent with what Mr Kark says, if that helps.

> "You must be honest and trustworthy when writing reports 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 any documents which are false or misleading because they omit relevant information."

At the top of the page he deals with 51 Good Medical Practice:

THE LEGAL ASSESSOR: You seem to be saying that *Good Medical Practice* does not set out her duties, which I am not sure if I understood you correctly but perhaps if the Panel do not mind if we can go to the transcript of these proceedings, D1/7B, this is where Mr Kark sets out what I understood he was saying accurately were the duties of an expert.

Pausing there. I read from that *Good Medical Practice* says your duty is not to write or sign any document which are false or misleading. The GMC is saying that she fell foul of that and, indeed, fell foul of Mr Justice Creswell's pronouncement and the Civil Procedure Rules, effectively whether she had read them or not. I understand what you are really doing is wanting to draw the Panel's attention to more of Rule 45 than was referred to by Mr Kark.

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MR STERN: Yes, that is why we put in that as well. I have not objected to paragraph 51 and I certainly do not object to it. As I say, I am not questioning the fairness or otherwise of what Mr Kark has done.

THE LEGAL ASSESSOR: Yes, thank you very much. That clarifies it for me.

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MR KARK: Just so it is clear, when I addressed the Panel the basis is that this is not just an expert witness, it is an expert witness who is a doctor and, therefore, must also comply with rule 51 which is why I mentioned it.

THE LEGAL ASSESSOR: Yes.

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THE CHAIRMAN: We will return at 11.45 when the Legal Assessor will give us his advice

(The Panel adjourned for a short time)

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THE CHAIRMAN: Before we receive the legal advice, it is just preliminary point. Mr Stern, you mentioned the business about provision of training for experts and you thought that you had not seen anything substantive. What we have got is a DCA extract relating to the Wolff Report of the 1996 "Access to Justice" paper and it has a section, paragraph 54, which is a sort of recommendation supporting provision of training for experts. It is not mandatory.

MR STERN: Thank you very much.

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THE CHAIRMAN: Shall we pass it to you?

MR STERN: Yes, I would like to have a look at it because I have not seen it and Mr Kark will probably have a copy as well. (Same handed) Any other preliminary points?

MR STERN: No.

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THE CHAIRMAN: I will ask the Legal Assessor to give the Panel his advice, thank you.

THE LEGAL ASSESSOR: Members of the Panel, I have provided you with a copy of the advice which I propose to give and both counsel have seen my advice in advance, so you and they will be able to follow it whilst I am giving it. It may help you to have also at hand the yellow pages, in other words the charges, so you can refer to both what I am saying and the charges as I proceed.

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1. Although you are, as you know, a Fitness to Practice Panel, rather than what used to be called a Professional Conduct Committee, you are applying the old Rules, i.e. the General Medical Council's Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988. That is because the case was referred to the GMC prior to November 2004. I shall come back to those Rules at the end of my advice.

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2. I do not intend, nor is it my duty, to rehearse or summarise any of the evidence, except where I consider it helpful or necessary when advising you on the law or any particular

approach to the evidence.

3. In any event you have the advantage of having been provided with daily transcripts of the evidence to which you can refer if you have need to refresh your memories during the course of your deliberations. You have access to all the documentation produced and relied on by either side and helpful addresses of counsel.

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4. It is my duty to advise you on any aspects of the law which I deem appropriate, even though you will be aware of some of the principles. We are, of course, at what is often called the 'fact-finding' stage. Your first duty is to determine the facts, as far as you can.

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5. Heads 1 to 5, as they now stand, have been formally admitted on behalf of Dr Donegan and, therefore, found proved.

6. So far as heads 6(a) to (d) and 7(a) to (d) are concerned, you have to decide which, if any, of them have been proved to the necessary standard by the GMC based on the oral and documentary evidence produced by both parties and inferences properly drawn from it. You must deal with each charge separately. You must not speculate.

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7. So far as the burden of proof is concerned, the burden of proving each alleged charge rests on the shoulders of the GMC. So far as the standard of proof is concerned, you cannot find any fact proved unless you are sure of it. In other words, the standard of proof is the same as it would be in a criminal court.

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8. You have already found proved in charge 2, on Dr Donegan's admission, that she was instructed (by solicitors) as an expert witness to provide reports on behalf of two mothers engaged in litigation in the Family Division of the High Court on the issue of whether their children should receive various vaccinations contrary to the mothers' wishes. That was, of course, in 2002.

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9. You have also found proved in charge 3, on Dr Donegan's admission, that she produced two medico legal reports, dated 14 June and 4 December 2002, which she potentially knew would be read by the litigants and their legal advisors, any other experts instructed in the case and by the judge trying the action. She clearly believed that they might be read and all would be read by all.

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10. You have also found proved, on Dr Donegan's admission, in charge 4, that she made a declaration at the end of each report in the words set out in that charge, (I will be coming back to that) and, in charge 5, that she was aware that the provision of the reports might affect the outcome of the case.

11. The duties of an expert witness in court proceedings were helpfully and accurately set out by Mr Kark in his opening. Firstly, paragraph 51 of Good Medical Practice 2001, the wording of which you will find set out by Mr Kark in the transcript of these proceedings at page D1/7B of which Dr Donegan agreed she was aware; secondly, by the judicial pronouncement of Cresswell J in National Justice Cia Naviera SA v Prudential Assurance Co Ltd (The Ikarian Reefer) (1993) 2 Lloyd's Rep 68, the wording of which is set out in the transcript at page D1/7C to F; and, thirdly, by Rule 35(3) of the Civil Procedure Rules, 2002 (your exhibit D2), the wording of which Mr Kark set out at page D1/7. Mr Stern

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has also drawn your attention to other parts of Rule 35 both in D2 and D3 which you will take into account.

- 12. Mr Kark also rightly told you that experts are entitled, of course, to express an opinion, unlike any other witness, and to support that opinion by citing research material. They must quote or summarise their research accurately and they must not conceal material which they are aware could put their conclusions in a different light. That is part of the GMC's complaint in this case, in particular that Dr Donegan did not set out in her reports the contrary conclusions of the authors of her cited publications. In her evidence, she accepted this and agreed that it would have been better at least to mention the conclusions at the beginning of her reports, but denied 'concealment' because they were in the publications which she had produced for everyone to read, and gave evidence to explain both before the judge and you.
- 13. It was in relation to this issue and others that it was agreed that the chronology of events was very important.
- 14. The allegations are in relation to the reports, not in relation to her evidence.
- 15. You have already been helpfully provided with more than one chronology, but, because of its importance, I propose to try to help you by putting a little more flesh on the bones of the chronology.
- 16. Dr Donegan pointed out that it was not she who, as it were, started the 'ball rolling', but Dr Conway and Professor Kroll. The chronology, therefore, starts with them.
- When I tell you this chronology I apologise for leaving out both "Dr" and "Professor" as a prefix to each name.

4 August 2001 Conway's first report.

This includes the declaration that he has understood:

"...that my primary duty in written reports and giving evidence is to the court, rather than the party who engage me"

and that he has indicated:

"...the sources of all information I have used".

No references or publications were produced.

19 and 20 May 2002 Kroll's first report (Child B) and second (Child A).

He made no declaration nor produced any publications in either report.

27 and 28 May 2002 Conway's second report (Child B) and third (Child A)

In both reports he made the same declaration as in his first report. No references or publications were produced.

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14 June 2002

Donegan's first report

In which she made the declaration cited in charge 4 which included the words:

"I have indicated my sources extensively".

She indeed produced a large number of unamended references and publications from which she selected quotations or parts of which she summarised when preparing her reports.

3 July 2002

Meeting of experts Kroll and Donegan

Conway was due to attend but did not. In a letter of 25 June 2002, Battens Solicitors had said to Donegan:

"Both Professor Kroll and Dr Conway agree that you represent the opposing viewpoint, it is to be hoped that the meeting will still be of use".

The date at the bottom of every page of the report is 7 September 2002 but did not reach Dr Donegan, it is clear from the correspondence, until after 19 November 2002. It is not clear why that response took so long to reach Dr Donegan.

7 September 2002 (Not Reaching Donegan until after Conway's response to Donegan's first report

19 November 2002)

Same declaration as before. His references reached her on or just after 26 November 2002.

28 November 2002

Kroll's supplementary report

No declaration

5 December 2002

Donegan's second report

Declaration as it appears in charge 4 – which was a response to Conway's latest report – less than a week to go before trial date. (In their letter of 12 November, Battens had indicated to her that:

"It is not that you will have to raise a full report, merely to pick out the main contentions").

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10 December 2002 Donegan gave evidence at the trial

May 2004 GMC started proceedings against Donegan under the 1988 Rules

Over two years after that -

10 September 2006 Dr Elliman's report

Four years after the reports complained of. Dr Elliman was, of course, called before you to identify the particular matters which

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I hope this chronology serves to assist.

17. Turning to charge 6, this is what I would describe as a WHAT, HOW, WHY AND THEREFORE charge in the sense that the GMC is, in effect, saying to Dr Donegan:

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In 6(a) – WHAT you did when writing your reports was give false and/or misleading impressions of the research you relied on.

In 6(b) – HOW you did that was by quoting selectively and omitting the information.

C

In 6(c)—WHY you did it was because you unwittingly allowed (I deliberately add the word "unwittingly" because there is no allegation here of deliberate misleading or dishonestly) your deeply held views to overrule your duty.

In 6(d) – THEREFORE (or as a result) you failed to be objective, independent and unbiased.

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18. Dealing first with 6(a), before you can find that proved, you have to be sure that Dr Donegan gave false and/or misleading impressions of the research which she relied upon. It is for you to decide what "false and/or misleading impressions" means, bearing in mind all that you have heard and particularly that there is no allegation of dishonesty or intent to mislead which may not make your task any easier in trying to determine what is or is not misleading.

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19. Dr Donegan has conceded that parts of her reports could have been better written or were wrong or misleading in hindsight but says that, when she wrote the reports, she believed that the court would read or have its attention drawn to anything relevant that she had omitted from the reports but had included in the publications which she produced. These publications were not concealed from the court.

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20. It may be important for you to decide whether or not you should take the reports and the publications together in deciding the question of false and/or misleading impressions.

21. In this regard Mr Kark several times stressed, whilst identifying particular parts of the report, their effect on the "lay reader".

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22. It may, therefore, be important for you to take into account to whom the reports were directed and for what purpose. In this regard you may get some assistance from the actual declarations which Dr Donegan made in both reports which are set out in charge 4. You will see that charge 4 includes in the declaration stated:

"I understand that the court will use it [the report]in coming to a decision as to what is in the best interests of the children involved. I have indicated my sources extensively".

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That was the declaration she made in both her reports.

23. By the time she wrote the reports Dr Donegan knew that the matter was going before a judge at the request of the fathers and that he would decide whether or not the children should be vaccinated. She said that she had seen the expert reports, (Conway and Kroll's) believed that they would present the opposing view and wished to present a balanced view. Accordingly, she knew that the reports and the unamended publications she produced would all go before him and also be seen by the experts, the lawyers and the litigants who would be in a position to assist him.

As, indeed, would she if she gave evidence.

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24. This brings me to 6(b) which you cannot find proved unless you are sure that Dr Donegan quoted selectively from research, reports and publications and omitted relevant information. That is for you to decide.

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25. 6(c) sets out the GMC's allegation as to motive. To make a decision on that you have to be able to identify what her deeply held views were and then go on to decide whether you can be sure that they so blinkered her that she unwittingly allowed them to overrule her duties. Mr Stern identified where in the transcript you can find what Dr Donegan said about her views. You have those references.

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26. 6(d), taking account of your decisions on the previous sub-charges, you have to decide whether you can be sure that her reports failed to be objective, independent and unbiased. Mr Stern submitted that this was the crux of allegation 6, i.e., whether she failed to write independent reports. The words "objective", "independent" and "unbiased" stand or fall together.

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27. If, having dealt with each sub-charge in charge 6, you cannot be sure that any one is proved, you find charges (a) to (d) not proved. You will then find charge 7 also not proved in its entirety because you will see at the beginning of charge 7:

"Your actions in head 6..."

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If you find all or any of the sub-charges in charge 6 proved, then you will go on to decide, dealing with each of the sub-charges in charge 7 separately, if you find any one of them proved in relation to the sub-charge/s you have already found proved in charge 6.

28. I indicated that I would return to the 1988 Rules at the end of my advice. Rule 27(2) states that:

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"On the conclusion of proceedings... the Committee shall consider (i) which, if any, of the remaining facts alleged in the charge and not admitted by the practitioner have been proved to their satisfaction, [charges 6 and 7] (ii) whether such facts as have been so found proved or admitted would be insufficient to support a finding of serious professional misconduct, and shall record their finding."

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29. Applying that Rule to this case, you have already found charges 1 to 5 proved and admitted by Dr Donegan. You, therefore, are only considering charges 6 and 7. If you find that none of the charges alleged in charges 6 and 7 is proved, I advise you that you must find that the facts admitted and found proved in charges 1 to 5 are insufficient to

A support a finding of serious professional misconduct. If, however, you find any part of charges 6 and 7 proved you will go on to consider whether those facts are insufficient to support a finding of serious professional misconduct, using your collective professional judgment and record your finding.

30. Finally, Rule 27(3) states that:

"The Chairman shall announce that finding and, if as respects any charge the Committee have found that none of the facts alleged in the charge has been proved to their satisfaction, or that such facts as have been so proved would be insufficient to support a finding of serious professional misconduct, the Committee shall record and the Chairman shall announce a finding that the practitioner is not guilty of serious professional misconduct in respect of the matters to which that charge relate".

31. That concludes my advice.

THE CHAIRMAN: Any observations from either counsel?

D MR STERN: No, than you.

MR KARK: No.

THE CHAIRMAN: I just wanted to clarify whether either counsel wants the Legal Assessor to give the Panel guidance of the definition of SPM - serious professional misconduct - at that stage in terms of the threshold?

THE LEGAL ASSESSOR: Could I just say that the advice I would give is that it is a matter for them and, as I have said, using their collective professional judgment.

MR KARK: Yes. Only to underline the fact that, of course, the Panel are not deciding at this stage on the issue of SPM, simply incapability amounting to SPM. Whether in those circumstances it would then, therefore, be sensible to direct the Panel on what SPM is it is a matter really for the Panel whether they would be assisted by that advice at this stage. If they have got to consider it, it might be they would be.

THE CHAIRMAN: There is a set of amount of literature, case law and the *Indicative Sanctions Guidance* has some material. I am sorry, Mr Stern, have you anything else?

MR STERN: No, I have nothing. I have nothing to say, unless you particularly want me to address you on it. I know this is an experienced - at least I know some of the Panel are very, very experienced and I do not require anything to be said any more, but if obviously anybody does feel that they wish to it is more a matter for the Panel than for me, as it were.

THE LEGAL ASSESSOR: Yes, but as may well be found, their experience may well include their knowledge of case law and previous pronouncements on the definition of professional misconduct, or serious professional misconduct, and it may be that they want

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to know whether at this stage they can consider that or not.

THE CHAIRMAN: Mr Kark?

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MR KARK: It also just occurs to me that of course the Panel - and I am afraid I do not know how experienced the Panel are, but they may be well used to dealing with the issue of impairment and less used to dealing with the issue of serious professional misconduct. It may be some of the Panel have not actually had to deal with a case alleging serious professional misconduct, but I am afraid I simply do not know.

THE CHAIRMAN: That certainly applies to three out of the four.

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THE LEGAL ASSESSOR: It may be that, if this matter raises and becomes a complication, that we can come back into open court(*sic*) before I give any directions in relation to that. At the moment, particularly because neither counsel has addressed the Panel on this subject, I am content to leave my advice as it is on this subject.

THE CHAIRMAN: Mr Brown, you had a question?

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MR BROWN: Yes, it is a just a point of clarification on paragraph 27 of the advice. I am just trying to get the correlation or identify how the two or the various elements hang together. Sentence 1 seems to suggest that, when we are looking at each sub-charge in charge 6, if we cannot be sure that any one is proved then you go on to find charges (a) to (d) not proved. Is that right?

THE LEGAL ASSESSOR: Yes. If you cannot be sure that any one of the sub-charges in charge 6 is proved, then you find them not proved because you cannot be sure.

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MR BROWN: Ah, yes. I am sorry, yes. Then when you go on to the final, or the next sentence:

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"If you find all or any of the sub-charges in charge 6 proved, then you will go on to decide, dealing with each of the sub-charges in charge 7 ..."

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THE LEGAL ASSESSOR: Yes.

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MR BROWN: I can understand that, but it seemed to me that just reading - and obviously I seem to have taken a wrong impression of sentence 1 - is that if you found one element of the charge unproved then the whole of the charge was dismissed, but that is not what you are saying?

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THE LEGAL ASSESSOR: No, it is quite clear. I am sorry if the wording could be a little bit better, but could I re-read it and perhaps putting the stress in the right places:

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"If, having dealt with each sub-charge in charge 6, you cannot be sure that *any one* is proved ...",

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in other words you cannot be sure in relation to any of them.

MR BROWN: I understand that, yes.

THE LEGAL ASSESSOR: Yes:

"... you find charges a to d not proved",

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and I would say that is obvious:

"You will then find charge 7 also not proved in its entirety",

because that follows from you finding all actions in head 6 not proved. Then:

"However ...",

I could have put:

"... if you find all or any of the sub-charges in charge 6 *proved*, then you *will* go on to decide, dealing with each of the sub-charges in charge 7 separately, if you find any one of them proved in relation to the sub-charge/s you have already found proved in charge 6".

Does that help?

MR BROWN: Yes, it does. I just found, for want of a better word, the first sentence misleading.

E MR KARK: Can I just make a suggestion on that? I am sure it is clear now, but if at the end of that sentence, "You cannot be sure any of them", as opposed to, "any one is", I think it is then clear. I am sorry, clearer.

THE LEGAL ASSESSOR: I am quite content we that, although I deliberately put in the word "one".

F | THE CHAIRMAN: So, it will be "any one of them"?

MR KARK: No, take out the word "one" and so it would read:

"If, having dealt with each sub-charge in charge 6, you cannot be sure that any of them is proved, you find a to d not proved".

MR BROWN: Thank you.

THE CHAIRMAN: Anyone else? No. In that case, the Panel will now go into camera. I understand we have an arrangement of being in touch with you, but it will not be before tomorrow morning and we will notify you around 9:30. I think what we will do is we will notify you at around 9:30 whether we need you to be here at 9:45, because I understand you are about 15 minutes away.

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MR KARK: That is very helpful indeed. We are on a 15 minute leash, as it were.

THE CHAIRMAN: Yes.

MR KARK: That is very helpful.

B THE CHAIRMAN: Is that helpful?

MR STERN: Yes, thank you, madam.

THE CHAIRMAN: Thank you.

STRANGERS THEN, BY DIRECTION FROM THE CHAIR, WITHDREW
AND THE PANEL DELIBERATED IN CAMERA

(The Panel later adjourned until 9.30 am on Wednesday, 22 August 2007)

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