

GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL

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

On:
Tuesday, 7 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 One)

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.

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A THE CHAIRMAN: Good morning, everybody. As you are aware, the GMC has reformed its Fitness to Practise procedures. The changes took effect on 1 November 2004. The transitional arrangements for cases such as this are that the Committee will now be called a Fitness to Practise Panel but will operate under the old Preliminary Proceedings Committee and Professional Conduct Committee (Procedure Rules) 1988.

B The Fitness to Practise Panel will convene today in order to consider the case of Dr Jane Lavinia Mary Donegan. Dr Donegan is present at today's hearing and is represented by Mr Stern QC, instructed by Clifford Miller, Solicitors. Mr Kark, counsel, instructed by Field Fisher Waterhouse, Solicitors, represents the GMC. The Legal Assessor is Mr Grey QC. I am. Sheila Hewitt and I am a lay chairman of today's Panel.

MR KARK: Before we begin by reading the charges---

C THE CHAIRMAN: I understand there are some amendments.

MR KARK: There are. Also, may I introduce Mr Sandesh Singh, who is sitting behind Mr Stern, who is assisting him as his junior.

MR STERN: Would it assist if I introduced everybody?

D THE CHAIRMAN: Yes.

(Introductions by Mr Stern)

THE CHAIRMAN: Mr Kark, you want to identify a small amendment to the charges?

E MR KARK: Yes. Could I also mention that sitting next to my instructing solicitor is Dr Elliman, who is the GMC expert, and I am going to ask that he be allowed to remain in the proceedings throughout because he is an expert witness and he will, in due course be giving evidence and I do not suppose there is any objection to that.

F So far as the heads of charge are concerned, could I just take you to head of charge 7? It is really more of a typo than an amendment. You will see that the heads allege that Dr Donegan's actions in head 6 were "misleading", "(b) in direct contravention of your duty as an expert witness", and then it should be "(c) unprofessional" and "(d) likely to bring the profession into disrepute". So it is just a renumbering, please, of those four heads. Your power to amend under the old rules came under Rule 24 and you can make any amendment provided you are satisfied that no injustice could be caused. I do not think there is any objection to the amendment.

G THE CHAIRMAN: The Panel has no objection to it. Any objection, Mr Stern? Any observations on that?

MR STERN: None, madam. Indeed, the version I am working from is November 2006 which has it correct.

H THE CHAIRMAN: In that case I would ask our Panel Secretary to read out the charges and ask you, please, Dr Donegan, to stand while that is being done.

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THE PANEL SECRETARY: The Panel will inquire into the following allegation against Dr Jane Lavinia Mary Donegan, MB BS 1983 London.

That, being registered under the Medical Act,

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1. At the material times in 2002 you were a registered medical practitioner. You qualified in 1983 from St Mary's Hospital Medical School and you practised as a General Practitioner from 1990;

2. In 2002 you were instructed 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;

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3. You produced reports signed on 14 June 2002 and 4 December 2002 which purported to be independent medico legal reports which you knew would be read by the litigants and their legal advisers, any other experts instructed in the case and by the Judge trying the action;

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4. At the conclusion of each report you declared:

"I, Dr Jayne LM Donegan, declare that this is an independent medico legal report based on my opinion, knowledge and research on the diseases, their vaccines and taking into account the particular cases of the children involved. I understand that the court will use it in coming to a decision as to what is in the best interests of the children involved. I have indicated my sources extensively. The facts and opinions expressed in this report are true and accurate to the best of my knowledge. I confirm that any fees paid to me are independent of the outcome of the case."

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5. You were aware that the provision of your reports might affect the outcome of the litigation;

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6. In the reports that you provided you,

a. Gave false and/or misleading impressions of the research which you relied upon,

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b. Quoted selectively from research, reports and publications and omitted relevant information,

c. Allowed your deeply held views on the subject of immunisation to overrule your duty to the court and to the litigants,

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

7. Your actions in head 6 above were,

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- a. Misleading,
- b. In direct contravention of your duty as an expert witness; unprofessional,

B

- c. Likely to bring the profession into disrepute;'

And that in relation to the facts alleged you have been guilty of serious professional misconduct.

THE CHAIRMAN: Please take a seat, Dr Donegan. Mr Stern, are any of these admitted?

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MR STERN: Yes. Let me assist, if I can. Head 1 is admitted. Head 2 is admitted. Head 3, to the extent that reports signed on 14 June and 4 December 2002, which were independent medico-legal reports, etcetera, is admitted; the words "purported to be" are not admitted. In other words, there is no issue that the reports were prepared by the doctor.

THE CHAIRMAN: Admitted in part?

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MR STERN: Yes. Head 4, admitted; head 5, admitted; heads 6 and 7, in their entirety, not admitted; and serious professional misconduct, not admitted. In other words, the facts of the reports and the declaration that were attached to them are admitted.

THE CHAIRMAN: Thank you. In each case we find head 1 admitted and found proved; head 2 admitted and found proved; head 3 admitted and found proved, only in so far as you produce reports signed on 14th June 2002 and 4th December 2002; head 4 admitted in its entirety; head 5 admitted in its entirety; and both heads 4 and 5 found proved.

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MR KARK: I think my understanding is, so far as head 3 is concerned, it is also accepted that the doctor knew that the reports would be read by the litigants and their legal advisers, and any other experts instructed in the case and by the judge trying the action. The issue, understandably, is with the words "purported to be." If one just puts brackets around that, you will know where the battleground, as it were, is.

F

Madam, before I begin opening the case, I wonder if we could raise the issue of timing briefly, just so we are all in a position of knowledge. I understand next Tuesday the Panel is not sitting, or that is the suggestion.

THE CHAIRMAN: That is a suggestion. I would like to hold that in reserve, because there may be time spent reading papers or drafting.

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MR KARK: Very well.

THE CHAIRMAN: I would like to hold on to that, if you do not mind.

MR KARK: Very well. I also understand there may be a suggestion we should have slightly different hours on Friday to cater for various people's religious beliefs. I think Mr Stern and I were wondering if, on Friday, in order not to lose too much time, we could start a little earlier and carry on through part of lunch and sit, say, nine o'clock to one

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A o'clock, or nine o'clock to 1.30 with a break in between. I do not know if that seems attractive. We have a lot to do in this case and obviously we are keen not to lose too much time.

B THE CHAIRMAN: Indeed, yes. We will certainly be accommodating Dr Donegan's requirements to be back in London by the evening. It would be sensible to use the time on Friday to best effect. Certainly, the Panel would be amenable to starting early on that day. Shall we take that as read?

MR KARK: Certainly.

THE CHAIRMAN: We will revisit it on Thursday evening.

C MR KARK: Could I then ask, before I begin to open, for the bundles to be handed out. Before that happens, let me explain what you are going to get. I think it is going to look rather disconcerting, if I may say so, when you first receive the pile of paper that you are about to receive.

D The first bundle that you will receive will contain Dr Donegan's two reports and various indices to her reference material. That is the first file. The second and third files are the two files that she produced, effectively, in the family proceedings, about which you know very little, but I hope by the end of this morning you will know rather more. Those contain the references that she produced with her report for the purposes of those proceedings. Although they are two very bulky files, and you will have to have reference to them, you are not going to be asked, I do not think, by either side, to read those references in full.

E The fourth bundle you will receive contains the report, first of all, of the GMC expert, Dr Elliman, and it also holds the reports of Dr Conway and Professor Kroll, both of whom made reports, not for these proceedings, but for the proceedings in the Family Court. That is Elliman, the GMC expert, and Conway and Kroll.

F Then the fifth bundle you are going to receive contains Dr Elliman's references which were provided and support, as it were, his report. I am afraid there are going to be five files to cope with. It may well be that you are going to need to slightly rearrange the tables in front of you. You have these, what I think are called plastic desk tidies. I suspect you are going to have to remove your desk tidies and possibly even your water to cater for the files. As you can see, Mr Stern has sensibly brought up some boxes and I have got my files in front of me. Can I ask then that the files be handed out. First of all, bundle 1. Could I ask you to receive Dr Donegan's reports.

G THE CHAIRMAN: Which we will mark C1. They contain both her reports? *(Same handed to the Panel)*

MR KARK: Yes. Then can I ask you to have files two and three, which are Dr Donegan's reference files.

THE CHAIRMAN: That will be C2 and C3. *(Same handed to the Panel)*

H MR KARK: I will be making some reference, during the course of my opening, certainly, to some research in those two files that you have just received. *(Pause)* It may be that when we take a break, we will be able to find some boxes or something so that you can have these rather more conveniently, because at the moment I think it is going to be

A difficult for you all to cope, frankly.

MR KARK: We are ready now for four, which contains the reports of Dr Elliman, the GMC expert witness, Dr Conway and Professor Kroll.

THE CHAIRMAN: That will be C4. *(Same handed to the Panel)*

B MR KARK: Then finally, bundle five, which contains Dr Elliman's references.

THE CHAIRMAN: That will be C5. *(Same handed to the Panel)*

MR KARK: I am afraid it is one of those cases where, try as everybody might, we just have not been able to cut the paper work down to less than that, and I suspect you might receive a bit more.

C Now, the plan of action, as it were, is that - I know Mr Stern is content with, and this is really a lawyer's suggestion as to how we approach this case - first of all, I should open the case to you. In other words, tell you in broad detail what the case is about and introduce you to some of the documents that are reports. Then, when I finish my opening, we were going to suggest to you that it would then be sensible, before you hear from Dr Elliman, for you to take the opportunity of reading both reports from Dr Donegan, also the report from Dr Elliman, and also, and this is a matter entirely for Mr Stern, his report from his expert witness, which I have not handed out to you.

D Now, there are, of course, different time estimates as to how long that might take you. I personally think that could take you the better part of the day. Having said that, once you have read it, of course listening to Dr Elliman's evidence is going to be that much easier and I think you will be able to follow it much better. Obviously that is simply a suggestion, but we both think that would be a sensible approach to take in this case. That does not mean that we are going to ask you to read the reports, but also cross-reference all the reference material, because that would take you many days, and we hope it would not be a necessary thing for you to do. That is going to be the suggestion.

E Let me start by telling you something about the background to this case. Dr Donegan qualified at St Mary's Hospital Medical School in 1983. She is a general practitioner and a homeopath. She obtained the Diploma of the Royal College of Obstetricians and Gynaecologists in 1986; a Diploma in Child Health in 1987; and she became a Member of the Royal College of General Practitioners in 1988.

F In May of 2002, she was commissioned by two separate firms of solicitors to write a report for use in family proceedings in the family division of the High Court in London. Those proceedings concerned dispute between the fathers of two girls aged three and nine. The first girl, the three-year-old, was born in October of 1998, and the nine-year-old was born in October of 1992. As you will see, both of the children obviously have been anonymised throughout the reports as, indeed, have the names of the parents. I am not even going to give you the full birth date, because that is potentially where they could be identified.

G In any event, that dispute between the fathers of the two girls and their mothers centred around whether the girls should receive the normal course of vaccination for children in this country. Each girl lived alone with her mother and the two families appear to have been unknown to each other. The fathers made application under section 8 of the Children Act for a court order that their two children, who are unvaccinated, receive

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A vaccinations appropriate for their age and in accordance with what was generally accepted to be the national policy.

Section 8 of the Children Act provides that the family division may make a specific issue order, which means an order giving directions for the purposes of determining a specific question which has arisen, or which may arise in connection with any aspect of parental responsibility for a child. In all such applications, the court had to determine what was in the child's best interest. It was the children's welfare that was the court's paramount consideration.

B The two cases were, because of the similarity of the issues arising, listed to be heard together. The mothers of the two girls did not want their children vaccinated, so they resisted the applications. There were, no doubt, strong feelings on both sides. Both sides instructed doctors to write expert reports.

C It seems, according to what Donegan said in her first report, that having been once a supporter of the National Childhood Vaccination Programme, she had a change of mind and heart in around 1994 during the national measles and rubella campaign. It is accepted that Dr Donegan holds the views that she does about vaccinations of children genuinely and very firmly.

D This case is not about whether she is right or wrong about the views that she holds, it is about whether the reports she wrote complied with her duties as an expert witness. The case involves two reports, which she wrote in respect of those proceedings. Those proceedings, as you have heard, were in 2002. Can I give you a very brief explanation as to why there has been such considerable delay and why you are now, in 2007, dealing with an old rules case?

E The judgment in the Family Court proceedings was handed down in June of 2003 and there was an appeal which was heard in July of 2004. These proceedings have been considerably delayed in part by difficulties in obtaining the original material. Let me make it quite clear: there is no suggestion that Dr Donegan had any part to play. It was simply the fact that there were a number of consents that had to be sought from the Family judge and also from the parties.

F Another factor in the decision was the judgment in the Court of Appeal in the case of Professor Meadow. Now, the Panel will know that, in that case, one of the issues was whether expert witnesses giving evidence in court had immunity in respect to their testimony from disciplinary hearing before professional regulatory bodies. If there was no such immunity, whether, nevertheless, any such regulatory body would have to have the matter referred to it by the trial judge. As you know, that case has been decided and the Court of Appeal held that if the conduct of an expert witness was such as to raise a question whether the witness was fit to practise in his or her particular field, then the regulatory body would be entitled to investigate the matter for the protection of the public.

G When instructed as an expert witness for the purposes of court proceedings, a doctor has a high duty to perform. Expert evidence will normally be received with a good deal of credence and will often be accorded significant weight. In this particular case, the issue was plainly an important one to the litigants. Both they and the judge trying the issue were entitled to a clear and honest assessment, as far as possible, on the merits and demerits of vaccinating the two children.

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A The duties of an expert witness in court proceedings are to be found in a number of different sources, but the first and most basic duty so far as a doctor is concerned, is set out in paragraph in 51 of Good Medical Practice, 2001 edition. I am not going to ask you to turn that up. Let me quote to you:

B “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. If you have agreed to prepare and write a report, complete or sign a document or provide evidence, you must do so without unreasonable delay.”

C There had also been, by 2002, a number of judicial pronouncements upon the duties of expert witnesses in court. The most pertinent of those was a case which is commonly referred to as *The Ikarian Reefer* case. In that case, Mr Justice Cresswell stated the duties to be as follows:

D “(i) Expert evidence presented to the court should be, and should be seen to be, the independent product of the expert uninfluenced as to the form or content by the exigencies of litigation;
(ii) An expert should provide independent assistance to the court by way of an objective unbiased opinion in relation to matters within his expertise. An expert witness should never assume the role of an advocate;
(iii) An expert witness should state the facts or assumptions upon which his evidence is based. He should not omit to consider material facts which could detract from his concluded opinion;
E (iv) An expert witness should make it clear when a particular question falls outside his expertise;
(v) If an expert's opinion is not properly researched because he considers that insufficient data are available then this must be stated with an indication that the opinion is no more than a provisional one.
F In cases where an expert witness who has prepared a report could not assert that the report contained the truth, the whole truth and nothing but the truth without some qualification then that qualification should be stated in the report.”

G Finally, so far as the duties of an expert witness in 2002 are concerned, there is Rule 35(3) of the Civil Procedure Rules, which provide:

“(1) It is the duty of an expert to help the court on the 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.”

H All of that might be encapsulated in the simple rule that you must not mislead the parties of the Court by mis-stating things or by omitting relevant material that should be there. You must make your report a balanced one and you must not mislead.

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The GMC's case is that unfortunately Dr Donegan fell foul of the basic principles set out in Good Medical Practice. She wrote reports which were misleading in that they gave misleading impressions in relation to the research that she cited. She quoted selectively from the research and she left out relevant material which would have given a different or a more balanced perspective.

B

On occasion she left out material that was so relevant that it would have made it clear that the conclusions of the research material she was purporting to rely on were, in fact, directly contrary to those conclusions which she claimed to support the mothers' case. In other parts of her report misdescription of the findings of research is more subtle, but the overall impression would, nevertheless, in our submission, have been misleading.

C

Her conclusions in relation to each vaccine that she was asked to consider was that neither child should be immunised with anything, with any vaccine, and the diseases which she considered were as follows: diphtheria; pertussis, known as whooping cough, of course; tetanus; poliomyelitis; haemophilus; influenza type B; meningococcus C; measles; mumps; and Rubella. Ultimately, the GMC's submission is that she failed in her duty to the court and to the litigants to present a balanced report.

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Experts are entitled, of course, to express an opinion, unlike any other witness in a case, and to support that opinion by citing research material. That, of course, is their job, but in doing so they must quote the research accurately and they must not conceal material of which they are aware which could put their conclusions in a different light.

The two other experts who are instructed in the proceedings: Dr Steven Conway ... dealing with him first, he was instructed on behalf of both of the applicant fathers.

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Dr Conway was a consultant in paediatrics and lead physician of about 15 years' standing at St James's Hospital in Leeds which is one of the largest children's hospitals in the UK and he had special interest in infectious diseases and immunology.

Professor Kroll, the Professor of Paediatrics and Molecular and Infectious Diseases at Imperial College School of Paediatrics was instructed on behalf of CAFCAS. CAFCAS is the Children and Family Court Advisory and Support Service and they were acting on behalf of the children themselves.

F

Both of those experts, in broad terms, independently supported vaccination of the children and, therefore, supported the application being made by the fathers. The hearing was, in fact, heard in Winchester before Mr Justice Sumner and judgment was in due course delivered on 13 June 2003. Mr Justice Sumner ruled that it was in the girls' best interests to receive a programme of immunisation in line with the schedules provided by Dr Conway and Professor Kroll.

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The instructions which Dr Donegan received prior to writing her reports appear in your bundle 1. So can I ask you to launch into the documents, bundle 1 is C1. Perhaps I can be forgiven for simply referring to bundles 1, 2, 3, 4 and 5.

H

THE CHAIRMAN: Yes, these are the same numbers.

A MR KARK: Yes, exactly. So bundle 1, you will find the letter of instruction behind tab A. I hope you should find page 1, tab A, is a letter to Dr Jane Donegan and it is from a firm of solicitors starting:

“We are instructed to act on behalf of Miss B who is the mother of child B.”

B Does everybody have that? Then could I ask you to go down to the nature of instructions:

“These instructions are prepared on a joint basis on behalf of both respondents in these proceedings. It is essential both to your role as an independent expert and to the parties' perception of your independence, that there are no unrecorded discussions or correspondence with any of the persons involved in the case.”

C Over the page it gives the background and then another heading, “Your Instructions” and you can see that she was asked to consider four questions:

D “1. Whether there is anything in any of the children's medical history which indicates that that child should not be given any or any combination of the immunisations listed in the report of Dr Conway dated 4 August 2001.

2. Whether the current age of the children or child indicates that that child should not be given any or any combination of the said immunisations.

E 3. If [she did] recommend that the children should be immunised the timing and sequence in which the immunisations should be given.

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

F The first report ---

MR STERN: The third paragraph of the background at?

MR KARK: I am sorry, I cannot hear.

G MR STERN: Can you go back up to the background to the proceedings?

MR KARK: No, certainly. Can we go back up then, please, to the background.

“The background to the current proceedings and your instructions in this matter.

H Both fathers of the children issued applications for specific issue detailing that the children should be given the childhood

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vaccinations.

Both mothers refused stating that the side effects were too great a concern to them.”

THE CHAIRMAN: *(Inaudible - microphone off)*

B

MR KARK: Yes, exactly. I think so.

“Both set of proceedings were issued separately and were not aware of the other's existence until the matter was referred to the High Court. Directions were then set and the proceedings were partially linked.

C

The fathers in the proceedings have already instructed and filed a report from experts and are now endeavouring to do the same with your assistance.”

D

The first report you find behind tab C, you will see at the top of that report a date; 14 May 2002. Could I ask you to ignore that because if you go to the back of the report at page 72, you will see that, in fact, the report was eventually dated and signed off on 14 June 2002 and not May. You will see (I am not going to read it out again) that declaration which is, in fact, cited in full in the heads of charge which Dr Donegan signed.

E

The material that Dr Donegan had received prior to writing her report dated 14 June were the experts' reports of Dr Conway, dated 4 August 2001 in relation to child B, a further report from him, dated 27 May 2001, a report from Dr Conway and child A, dated 28 May 2002, and also the reports from Professor Kroll on child A, dated 20 May 2002 and on child B, dated 19 May 2002. So I will ask you in due course to bear that chronology in mind.

She had received the earlier reports, as I am going to refer to them, of Drs Conway and Kroll and then she was asked to write her report.

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Child B, as I have mentioned, was born in October 92 and so when Dr Donegan was writing her report in June 2002 she was nine years old and she had received no immunisations. Child A was three and she also had not received any immunisations.

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Dr Conway had given a brief overview of the diseases against which immunisation was available and in relation to child B concluded that she should have the full range of immunisations. He also recommended with child A, the three year old, that she should receive the full range of immunisations. Professor Kroll, who you will remember was instructed by CAFCAS, reviewed the medical history of each child and he also concluded that child A should receive the full range of national immunisations, although his view was that vaccines for polio and diphtheria could reasonably be omitted as the risk of acquiring those diseases in the UK, excepting foreign travel, were extremely low.

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So far as child B was concerned, again he recommended the full range of immunisations with a possible omission of diphtheria and polio and a variation of the type of vaccine if

A tetanus and diphtheria were given because of her age. Neither doctor went into any detail as to the research which had been conducted as to the efficacy of the vaccines nor indeed their side effects.

B Dr Donegan's report of 14 June was the first report, therefore, which did go into such detail or at least it purported to do so and her report, as I told you, unequivocally rejected immunisation of any sort for either child.

Dr David Elliman has been instructed by the GMC to consider Dr Donegan's two reports and he is a consultant in community child health, he is a member of the Royal College of Paediatrics and Child Health and a consultant in Community Child Health at Islington PCT in Great Ormond Street Hospital and in due course you will see a full list of his qualifications when you read through his report.

C When Dr Donegan had written her June report, that was passed to Dr Conway and he was asked to write a further report in response. When Dr Donegan wrote her June report it is not known whether she can have been aware that there would have been such response. Indeed, for all she knew, I suppose, was her report might have been accepted as it was. Dr Conway's response, as you will read, was uncompromisingly critical of Dr Donegan's June report and in terms he accused her of confused thinking, making statements which had no scientific basis, he accused her of relying on data and reports which were simply irrelevant to modern medicine and ignoring the conclusions of the reports that she had referred to. He suggested in writing that she had failed to present a full picture and that she had been very selective in the research she had used and that she had left out relevant information. In response to that, Dr Donegan wrote a further report, dated 4 December 2002, again which we are going to invite you to read.

E Dr Elliman has considered both of her reports and it may help you, before you read through those reports, to receive a short summary of his conclusions and his main areas of criticism.

Dr Elliman, as you will see, has ordered his report to follow the layout adopted by Dr Donegan in her reports and so what she did was she dealt with each disease in turn, first of all giving a brief overview of the disease and then dealing with the research.

F Dr Elliman, having reviewed her two reports, sets up five central criticisms of them. He complains that she has been selective in her choice of quotation from the reference material; she has been selective in her choice of reference material; the conclusions that she reaches in her report purporting to be drawn from the reference material frequently do not accord with the actual conclusions reached by the author or researcher; four, in some areas she has misinterpreted or misunderstood reference material to which she has referred; and fifth, the type of source material that she has referred to in her reports is sometimes not appropriate as primary source material and the sort of report she was asked to provide.

G Can I then ask you to take up bundle 4 and can I just introduce you, as it were. I am going to ask you to have, I am afraid, two reports open. First of all, can I just invite you to have a quick look at Dr Elliman's report. You will find that in bundle 4. You will find his CV behind tab 1. I am not going to spend a great deal of time on Dr Elliman's report because I know you are going to read it for yourselves, but you will see how he has approached

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A this case and we start on page 8. The pagination that I would ask you to refer to, I do not know if you have other pagination, but it should be in the middle of each page at the bottom.

B What he has done, you will see, is he has got a heading first of all, "diphtheria" which was the first disease that Dr Donegan dealt with in her report. He gives a brief overview of diphtheria and its consequences and then he turns to Dr Donegan's report. He starts by dealing with page 11 of Dr Donegan's report and so could I ask you to just put that away, you know at least what it looks like.

C Could you take up Panel bundle 1? Could I ask you to go to tab C which is the June report. I am not going to ask you, although I am going to make fairly frequent references to it, I am not going to ask you to turn up every single page that I refer to which I know will be a relief to everybody. I think it is important that you just know what the report looks like so you can find your way around it.

On page 11 of her report, she claims in the second paragraph on diphtheria – and this is just to give you an example – if you go to the second paragraph on page 11, she claims, as you can see:

D "Susceptibility to the complications of diphtheria generally depend upon the levels of antitoxin in the blood."

That paragraph ends with these words:

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

F You will see there, there is a note, (1). In order to see what that note (1) is, you need to turn the page over. At the end of each section, where Dr Donegan has finished, as it were, dealing with the disease, she gives her references. So note (1), we can see, refers to *Harrison's Principles of Internal Medicine 11th Ed.* In fact, Dr Ellison has looked through the material produced by Dr Donegan and in fact nowhere in that material is that conclusion to be found. The edition of *Harrison* that she chose to refer to was in fact four editions out of date; the most recent edition then at the time of writing her report was in 2002, being edition number 15.

On page 11 in the middle paragraph, Dr Donegan wrote this:

G "Diphtheria increased in prevalence and malignancy in the middle of the nineteenth century and declined before the introduction of the antitoxin. Antitoxin became available in the 1890s and reduced the case fatality rate so that mortality from diphtheria began to fall from that point, in a similar fashion to whooping cough and measles. By the 1940s when the national immunisation campaign began, the death rate in children had dropped by two thirds and continued to drop."

H That was citing a document called "The Role of Medicine". In fact, the fuller quote is in

A Dr Elliman's references. I am only going to do this once but I am going to ask you to turn up Dr Elliman's references, please, so that is bundle 5. Could I ask you to turn up tab 6? In fact, I am not going to ask you to refer to it again, but Dr Donegan's reference which she produced as part of her research material stops at page 98. Could I ask you in the reference material behind tab 6, you will find a page number 98 at the top. Dr Donegan's reference actually stops on page 98 so let me just read out what she provided to the Court.

B You will see under the heading "Diphtheria", second paragraph:

C "It is tempting to attribute the decline of diphtheria deaths between 1895 and 1922 to treatment by antitoxin, and the rapid fall since 1940 to immunization. Nothing in the evidence is seriously inconsistent with this interpretation, and if mortality from the other common infections had increased or remained constant in the same period it could possibly be accepted unreservedly. But the fact that, without prophylaxis or treatment, diseases such as whooping cough and measles also caused far fewer deaths, suggests that other influences may also have been..."

and then we stop. Over the page though, in Dr Elliman's references, he continues:

D "With due regard for this reservation it seems probable that immunization had more effect on the control of this disease than of any other, with the exceptions of poliomyelitis and, possibly, smallpox. This conclusion is supported by the high level of immunity which follows the use of a good antigen. Evidence for England and Wales in 1961 to 1963 indicated that the risk of an attack of diphtheria was about six times greater, and the risk of a fatal attack ten times greater, in those not immunized than in those immunized."

E I am not going to keep switching to the research, but you may think that that would have been a relevant quote for the judge deciding this issue, just by way of example, for him to have.

F On page 12 of Dr Donegan's report she claims, at paragraph 4, that at a Department of Health Review in 1999 – I am not going to ask you to turn it up again, but please do if you wish to – mentioned that the Thiomersal in the vaccine for diphtheria could cause kidney damage. In fact, Dr Elliman has been unable to find such a reference in the Department of Health literature and it was not provided in the references used by Dr Donegan and made available to the Court. Dr Elliman has concluded that that comment was misleading.

G Dr Elliman's conclusion was that the overwhelming weight of the evidence in the material looked at by Dr Donegan suggested first that diphtheria was a very serious disease, secondly that the vaccine was affected, and third that it was safe in healthy children. That was not reflected in her report and she gave a wholly contrary impression.

H Let me turn to whooping cough. Dr Donegan starts at page 14 – you can see the heading "Whooping Cough" – and then could I ask you to turn to page 15? She writes, halfway down the page:

A

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

B

It is undoubtedly the case that whooping cough became a milder disease in this country over the course of the first half of the twentieth century. The death rate had fallen by over 99% before vaccination against pertussis was introduced in the 1950s. The introduction of the vaccine reduced the number of notified cases of whooping cough but peaks continued to occur every three to four years as they always had. Deaths continued their steady decline. This was most clearly seen in the 1970s and 80s when the vaccine coverage fell to less than 40% in 1976 because of health scares. In 1978 and 1982 there were over 65,000 notified cases of whooping cough but no concomitant rise in the number of deaths. Between 30% and 70% of children in outbreaks are vaccinated.”

C

D

That was suggesting that it had become a less serious disease. In fact, according to Dr Elliman, the true picture was that there was a significant rise in the number of deaths, although not as high as one might expect, from the numbers of those catching the disease.

If I can ask you to go to page 18, please, paragraph 2. There she starts off saying, about six lines down:

E

“Because of continuing increases in pertussis notification in the UK, especially in young babies, an ‘accelerated’ schedule of vaccination was introduced...to try to reduce the incidence of the disease.

F

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

G

In fact, the true picture, according to Dr Elliman, was that there was a continuing overall fall in the incidence of disease between 1980 and 1990 and the figure declined to an all time low of 712 notifications in 2000. In other words, the picture was that the vaccine was effective and thus, according to Dr Elliman, Dr Donegan was giving a misleading impression.

H

Dr Donegan was perfectly entitled to put the other side of the argument in order to assist the Court, but she was duty-bound to do so in a fair way, without misleading the Court as to what the various pieces of research actually said.

A

On page 20 of her report, she made this claim about pertussis vaccination – and this is halfway down the page:

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

B

In fact, the survey refers to acute neurological illness and there is a significant difference between the two. “Damage” may be thought to imply a permanent or a long-term effect. Indeed, the authors of the study relied upon by Dr Donegan for that passage concluded by saying this:

“This study did not find any statistically significant increased risk of onset of serious acute neurological illness in the seven days after DPT vaccine exposure for young children.”

C

In relation to the same vaccine, Dr Donegan reviewed, between pages 20 and 21, the evidence of a possible link between the vaccine and links with asthma, and she referred to three reports. One was an uncontrolled case study by a Dr Odent in 1994. He found that vaccinated children were five times more likely to suffer from asthma as non-vaccinated children. The second was an observational study of a general Oxford practice in a GP newspaper which seemed to show that 75% more children who had been vaccinated developed asthma, and the third was a major study of 9,444 children in Avon. That was published in a peer reviewed journal and that failed to find any link.

D

Dr Elliman’s complaint is that Dr Donegan gave scant regard to the last piece of research, which was by far the most persuasive and authoritative and she failed to mention a further, very major, study published in a major mainstream medical journal and that compared almost 10,000 children, a quarter of whom had had diphtheria and tetanus vaccine and the other three-quarters had had one of the three vaccines, diphtheria, tetanus and pertussis vaccines, and there was no difference between the two groups. In Dr Elliman’s opinion, if she was going to cite the earlier research it was inappropriate to leave that important piece of research out.

E

F

On page 21, paragraph 3, you will see this comment about three lines down:

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

G

Can I just ask you to remember those words, “This reduced the total number of deaths”? I am going to ask you to take up Dr Elliman’s report again, so it is bundle 4, tab 1. I am going to ask you, when you find it, to go to page 68 in the middle at the bottom. So this is Dr Elliman’s appendix 4 on infant mortality in Japan. Dr Donegan’s comment, if I can remind you, was that the change in vaccination date to two years in 1975 reduced the total number of deaths in infants younger than a year.

H

You can see in that graph on page 68 that it was reducing on a fairly even line, you may think, from the left-hand side to the right. You can see where the change in age of

A vaccination occurred. It was already dramatically reduced and so to ascribe the change in vaccination age, or rather to ascribe the reduction in the number of deaths to a change in the vaccination age, may have been thought to have been misleading.

B Again, Dr Elliman concluded that the overwhelming weight of evidence in the material provided by Dr Donegan in relation to Pertussis, whooping cough, was that the vaccines in use in the UK were both effective and safe in healthy children. Well that was not the impression given by Dr Donegan.

As a matter of interest, he also concluded that because the licence of the vaccine did not extend to the older child, it would only be appropriate to give it to the younger child. Bear in mind that Dr Elliman is not here, as it were, to comment on the original decision, but it is worth bearing that in mind, and that was not, I think, something picked up in her first report by Dr Donegan.

C I am going to turn to tetanus. You will be glad to know I am slightly more than halfway through my opening. Perhaps we can deal with tetanus and then take a short break.

D Tetanus, we all know, is a disease which can arise from infected cuts or wounds to the skin, and there is a significant instance of mortality from that disease. A vaccine has been available and has been part of the routine immunisation programme since 1961. It is potentially dangerous, tetanus, because of the risk of receiving an apparently inconsequential injury which can become infected if not treated.

E In two, perhaps, subtle ways, Dr Donegan left the impression that the research led her to the conclusion that a safe and reasonable alternative to vaccination was to promote a healthy immune system and careful cleaning of wounds, should they occur. She cited research which demonstrated the occurrence of tetanus in fully immunised individuals, but she failed to mention that the same research declared the instance to be rare. She failed to mention that all three reports which she cited, in fact, were fully supportive of immunisation. Well, she also mentioned that some people, as she put it, developed nerve damage, causing either muscle weakness or altered sensation. Again, she failed to mention that such a reaction was rare. She stated, also, at page 29 of her report, that the vaccination can lower the lymphocyte helper/suppressor ratio, such as might be seen in people with AIDS, but she failed to mention that such a change was temporary and that there was no adverse effect recorded as a consequence.

F Again, she concluded that it was unnecessary for either child to have a tetanus vaccine. Dr Elliman concludes that the research provided by her demonstrates, in reality, that the vaccine was safe and effective, and the risks were small. The alternative, which she suggested, of waiting for an injury and then treating it with an immunoglobulin which is prepared from the human serum, would put the child at risk of receiving other unknown infections and depends, of course, upon recognition of the danger from a wound and prompt effective treatment.

G The conclusion of her advice on tetanus, once again, is not the issue. She is perfectly entitled to come to the eventual recommendation that she did. As with the other vaccinations, it is how she sought to persuade the judges and the parties that the research supported her view when, on a careful reading, in our submission, it did not.

H Now, I am going to move on to poliomyelitis. I wonder if that might be a convenient point to take the break?

A THE CHAIRMAN: We will take a break until quarter past.

(The Panel adjourned for a short time)

THE CHAIRMAN: Mr Kark, please continue.

B MR KARK: We are on to polio. Can I apologise, really. This is, I appreciate, fairly turgid stuff to go through, but it is important to introduce the report to you, so, eventually when you read it and then hear the evidence, it will become much clearer. Apologies if it is heavy-going at the moment.

C Let me turn to polio, which Dr Donegan started dealing with at page 33 of her June report, so again using the bottom right-hand corners. Vaccines against polio have been used in the UK nationally since 1956, and the consequences of the disease are, of course, potentially devastating. The live oral vaccine has been in use since 1962 and, in 2004, that was replaced with inactivated vaccine.

D Again, Dr Donegan sought to persuade the court that the vaccine not only could be ineffective, but also potentially dangerous. She mentioned at page 34 that epidemics of paralytic poliomyelitis had occurred in highly immunised populations. So she was implying that the vaccine was ineffective and she relied on three pieces of research to support that view. In fact, the research upon which she was purporting to rely was supportive of vaccination. One of those pieces of research, produced by an author called Sutter, and others, calculated that the vaccine reduced the risk of paralysis by 91 per cent.

E Well that fact did not get a passing reference in Dr Donegan's report. She relied on various failures of vaccine programmes from around the world, such as in countries like Albania, Namibia and India, which might be thought to be irrelevant to considerations of vaccination in this country. What is more, the research provided explanation for the various failures of the vaccine programmes which had, in the past, occurred in other countries.

She also went on, at page 34, to mention the contamination of the polio vaccine with a virus known as simian virus 40, or SV40. You will find that in the second half of the page, page 34. You will see:

“In 1961, inactivated polio vaccines was found to contain live SV40...a monkey virus.”

F Well, the virus was thought to cause tumours in the recipients. Dr Donegan quoted the research to demonstrate that SV40 has now re-emerged potentially as a tumour-causing virus. That, of course, would be, you might think, very significant to a judge deciding whether to give this vaccine. What Dr Donegan did not mention in her report was that measures were taken back in the 1960s to remove that virus from the vaccine and tests on vaccines stored since 1966 have known it to be free from the simian virus.

G Her comment, at page 35, which she has underlined in the top paragraph on page 35:

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

H It is true, but it is highly misleading to a judge trying to decide in 2002 whether to direct that two young girls should then receive the polio vaccine in relation to which there were no SV40 worries. Again, if left uncorrected, a decision could have been made on what

A was, frankly, a false basis.

Dr Donegan also cited, at page 34, an increased incidence of tumours of the central nervous system having been reported in one study in children of mothers who had been vaccinated. That appears to have been based on an article by a doctor called Heinonen, published in 1973, which suggested that there was a link between the use of the early inactivated polio vaccine. It also said that there was no evidence of an excess of malignancies in children exposed in utero to attenuated live polio vaccine. Dr Donegan did not make it clear that the only suggested link was with the inactivated or killed vaccine.

The final words of the article upon which she seemed to rely, but did not quote to persuade the court not to order the administration of the polio vaccine, in fact, was:

C “Finally, there can be no question that polio immunisation virtually eradicated a crippling and frequently lethal disease.”

Dr Donegan chose not to quote those words and she left the parties to the case to discover them for themselves.

She concluded by saying:

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

E Presumably a reference to SV40, which was dealt with back in the 60s. Although what she writes about the rarity of risk is true, her remark about the unknown risk of contaminants was, in our submission, misleading.

F Let me turn to - I think it is pronounced haemophilus B influenza. Although it is called haemophilus B influenza, I understand it has got nothing to do with influenza at all and simply more appropriately named haemophilus B. There are various types of haemophilus, the most serious of which, type B, can cause meningitis, epiglottitis, or severe croup, and septicaemia. In 1992, the Hib vaccine became part of the national vaccination programme.

G On page 39 of her report, Dr Donegan mentioned that since the vaccine only protects against type B of the disease, it is possible that there would be a drift towards A and C infections. What she did not make equally clear is how rare those infections are, and they are far outweighed by the fall in Hib disease from receipt of the vaccine.

H Although she cites figures at page 40 of her report, which demonstrate that the incidence of the disease had dropped significantly since 1992, she went on to write that this meant that children were being left without natural immunity and invasive disease was therefore occurring in older children. Well there is, according to Dr Elliman, no evidence to support that contention. The reality is that the success of the Hib vaccine has caused a general fall in the prevalence of the disease, and thus a fall in the disease in older people. That arises because of what is known as herd immunity. I am sure you all have some sort of understanding of that. As I understand it, it is the reflection of the effect upon the

A wider population of a large vaccinated population who are therefore immunised from the disease, thus effectively protecting others.

In recommending against either child receiving the Hib vaccine, Dr Donegan cited the risks associated with it and the disruption caused to natural long-lasting immunity. Again, the overwhelming weight of the research provided by Dr Donegan, but not specifically referred to in her report, proves the effectiveness of the vaccine. Dr Elliman, for what it is worth, does agree that because of the age of the children, it was not unreasonable to advise withholding the vaccine. Of course, Dr Donegan is perfectly entitled to make that point, but, again, the way that she goes about persuading the judge was, in our submission, wrong and misleading.

B

C Let me turn to meningococcus C. Meningitis, of course, is a serious illness, caused most commonly by groups B and C meningitides bacteria. Dr Donegan started, at page 41, by correlating the increase in group C meningococcus with a weakening of the immune system as a result of the large number of vaccinations being given and the widespread use of antibiotics. What she does not mention is that the apparent increase may be due to the fact that the detection of the disease is better than it used to be, and that more cases are being recognised as being caused by meningococcus.

D At page 45 of her report, she stated that in 1997 the Department of Health were resisting pressure to introduce blanket immunisation for university students. That was right, in part, as it were. What she failed to mention was that the resistance by the Department of Health was to using one type of vaccine, a polysaccharide vaccine, rather than an improved version which was launched in 1999. Of course, if these girls were to be vaccinated, they were going to be vaccinated with the new vaccine, and the type of vaccine against which there was resistant was, frankly, irrelevant. In fact, in the same article in Pulse magazine, to which she was referring to support her stance, in fact, a National Meningitis Trust spokesman was quoted as saying:

E "The new meningococcal C conjugate vaccine"

- the new vaccine I just referred to -

"that will be available in the next two years looks very promising.
The Trust will be pushing very strongly for everyone up to the age of 20 to be offered it."

F That quote is in Dr Donegan's reference material. Of course, it does not appear anywhere in her report and so it requires a very close reading of all of this reference material, as it were, to glean where the truth lies.

G On page 46 of her report she quoted a number of potential side effects to the meningococcus vaccine. She quotes - and I accept immediately that this may well have been by way of typographical error. If I could ask you just to turn it up, page 46 of her report, bottom right-hand corner. If you go to the second paragraph:

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

H Then she cites the various purported side effects. Then she says this:

A

“Neck stiffness and photophobia have also been reported and convulsions a rate of one report per 10,000 doses.”

In fact, it is with a comma in the wrong place. It should have been 100,000. That may well be a genuine typographical error, bearing in mind where the comma is.

B

In fact, the article from which she quotes reads, if read in full:

“Seizures have been reported very rarely, with approximately one report per 100,000 doses. Some of the seizures reported may have been faints, febrile convulsions or coincidental.”

C

That passage does not find its way into Dr Donegan's report. Again, the complaint is that Dr Donegan has quoted selectively from poor source material in order to support her negative recommendation for the vaccine. Had she quoted the material accurately, it is our submission that it would be very hard for her to come to the same conclusion, or to give the reader of the report the impression which she did.

D

Let me turn to measles. As we all know, I expect, it is an extremely infectious disease, born by airborne droplets. Recovery is normally complete, but five to ten per cent of people with measles may develop complications. The vaccine was first introduced nationally in the UK in 1968 and then, in 1988, it was replaced by the MMR vaccine.

Dr Donegan wrote an adverse report and it concluded that neither child should be vaccinated, as I say repeatedly she was entitled to do, but she was inappropriately selective about the reference material that she chose to quote.

E

As an example, in relation to a report, a piece of research by a Dr Cutts, which Dr Donegan referred to on page 54 of her report, Dr Donegan wrote the report in the BMJ stated that after the 1994 MMR campaign, there were 530 severe reactions reported; ie, it would appear to be saying as a direct consequence of the administration of the vaccine. In fact, the original report by Dr Cutts quoted that there were 2,735 suspected adverse reactions, among which 530 were serious. She also quoted the report by saying that one report of SSPE, which is subacute sclerosing pan-encephalitis, occurred one month after vaccination. Well, that would be very serious if it were due to the vaccine. What Dr Donegan failed to mention was that the reference she was quoting from went on to say that that particular incident was unlikely to be due to the vaccine, and the quote out of context was, therefore, potentially misleading.

F

THE CHAIRMAN: Since you are on that paragraph, should the reference be 18 and not 19 on page 54?

G

MR STERN: Yes.

THE CHAIRMAN: Dr Cutts' report is page 18.

MR KARK: Yes, it is. You are absolutely right. Thank you.

H

MR STERN: There are one or two others, and I think you will be able to mark those as we go through.

A

MR KARK: Thank you. The author of that report, the Cutts' report, concluded:

“The difficulty in attributing causality to events that are temporarily associated with vaccination is well known.”

B

And concluded that:

“Side effects are outweighed by improved disease control.”

Again, those conclusions did not form part of Dr Donegan's report. Dr Donegan also, in Dr Elliman's view, significantly played down the potential harm that could be done by the disease.

C

Let me turn to mumps, a virus spread by airborne droplets. It can cause inflammation to the testes or ovaries, inflammation of the pancreas gland, deafness, and viral encephalitis. Routine use of the live attenuated virus became common in the UK with the introduction of the NMR vaccine in 1988.

Dr Donegan, at page 58, quotes the common complications associated with mumps, including swelling of the ovaries, but states that:

D

“It is thought that having mumps with recognisable parotid swelling has a protective value against getting ovarian cancer in later years.”

You can see that underlined right at the bottom of page 58. This, she describes, as “clearly desirable.” No doubt it would be if that were the effect, but her comment was based on a single report of a study on a test involving 194 women, and it was in 1966.

E

Another report from China in 1992, which Dr Elliman will refer to, concluded that there was no such link, or that it is right to say that that report did not form part of the research material upon which Dr Donegan in fact relied.

She also declared, at page 60, that there is a possibility that immunisation against mumps was causing a mutant strain to emerge with limited or no cross-protection from the vaccine strain. Her citation for that piece of evidence was an article in Pulse magazine, which was not peer reviewed and would be known to a doctor, certainly, to have limited weight. What that article, which was written by a group of doctors in Stockport, actually said was:

F

“The replacement vaccine strain has an estimated efficacy of 90 to 92 per cent and there is a considerable value, therefore, in ensuring that children have two MMR vaccines...however, four of our confirmed cases have received two MMR vaccines and the remote possibility of a mutant strain...should be looked into.”

G

Again, that reference to the remote possibility does not appear.

According to Dr Elliman, there was absolutely no evidence to support Dr Donegan's claim of a mutant strain, and a one-off article in Pulse magazine should not have formed the basis of any advice that she was providing to the litigants or to the judge. Of course, if she was going to quote the article, then it was important to quote it accurately to put into context what the conclusion of that article was. So from her own material the evidence

H

A was, overwhelmingly, that mumps can be a serious disease and that the vaccine was safe to use, although it is accepted it is not necessarily as effective as other vaccines.

B Can I turn to the issue of rubella, which she begins to deal with at the bottom of page 60. Rubella again is a virus spread by airborne droplets. The illness is normally mild and can go unrecognised, but it is dangerous in early pregnancy and may well cause a baby to be born seriously disabled. Once again, Dr Donegan produced a conclusion that was adverse to vaccination, despite the material upon which she was purporting to rely being almost universally in support of it.

C A good example is in the middle of page 62 of her report, where she starts by saying in the five years prior to the vaccine being introduced in 1970, there were only 39 babies born with congenital rubella. She is relying there on a reference which is in her tab 115. This is the last time, if it is of any relief to you, I am going to ask you to turn up the reference. Could I ask you to go - I think this is the first time you have looked at it - Panel bundle 3, which is Dr Donegan's second reference bundle. Could I ask you, first of all, to go to tab 100. It is about halfway through the bundle. If you turn first to tab 100. The only reason I have taken you there is so you can turn on to tab 15 after it. It is actually tab 115. If you can turn to tab 15, which should be headed on the left, "Congenital rubella."

D Now, can I just ask you to bear in mind this is one of those cases you are going to have a finger in several documents. The beginning of that paragraph by Dr Donegan was that in the five years before the rubella vaccine was introduced in 1970, there were only 39 babies born with congenital rubella. If you look at the first page after tab 115, it should be page 178 in the bottom right-hand corner, you can see that there is a table, and you can see under the heading, "Primary source of notification," under "Year of birth," 1964 to 1969, "BPSU," which is the British Paediatric Surveillance Unit, zero notifications. I am not sure that BPSU were actually reporting there. Then "Other," "39," so, "Total," "39." That would appear to be where Dr Donegan has got her figure of 39.

E She then says this, "In the ten years after 1970, there were 454 cases." We can see that, between 1970 and 1979, there were 454 cases. What Dr Donegan has not quoted is the rather important opening words to this paragraph, which you, if you can look on the left-hand side under the heading:

"Background

F National surveillance of congenital rubella started in 1971 with passive reporting by audiologists, paediatricians and microbiologists of cases in Scotland, Wales and England. With the success of the rubella vaccination programme the number of reported cases declined dramatically."

G So there are two matters there. First is that when she is quoting the fact that only 39 babies were born with congenital rubella in the five years prior to 1970, what she has failed to report was that national reporting did not start until 1971, but it is sitting there in the piece of research that she must have used to glean these figures from. Secondly, the second comment in that opening paragraph, "With the success of the rubella vaccination programme the number of cases declined dramatically," well, that did not find its way, unfortunately, into her report.

H She goes on (I am sorry to refer to her as she, Dr Donegan knows I do not mean any

A disrespect) but Dr Donegan goes on to say at page 62 again:

“In the ten years after 1970 there were 454 cases.”

Then there is also:

B “In the ten years after 1980 there were still 333 affected babies.”

So would you look at the next line:

“So the number of cases have gone up.”

C Well that statement, with respect, is wholly misleading. It was directly contrary to the material which she must have read in order to produce that section of her report.

Now I have tried to give you a sort of snapshot, as it were, of some of the complaints that are being made about that first report and in due course we are both going to invite, Mr Stern and myself, you to read through these reports and you will obviously do so in more detail than I have been able to deal with now.

D She concluded her first report with the comments that you have at page 71. Right at the bottom of the page:

“In my opinion it would be in both child A's and child B's best interests, bearing in mind that they are now healthy children in their fourth and tenth years respectively, to be allowed to continue to develop in their current healthy way without being unnecessarily subjected to the unquantified risks of vaccination when they are ...” I think it should be “... when they cannot be regarded as being in a high risk category should they contract the diseases.”

E

And then she ends with that declaration.

As I have already mentioned, Dr Conway, the expert instructed on behalf of the fathers, then writes his report, dated ... I have not got the reference for that.

F

MR STERN: 19 November.

MR KARK: November. Thank you very much, Mr Stern. In November and I have already dealt with the fact that he was highly critical of Dr Donegan's first report.

G

Now the tone of his report in its criticism of Dr Donegan and the way that she had gone about producing her first report I have said was scathing. As you will see, it was in strong terms for one medical professional to write about another and it might cause her to reflect upon what she was doing and upon her duty to the court, but it does not appear to have had that effect.

H

That report was served upon the parties to the proceedings and upon Dr Donegan. In addition to the supplementary report from Dr Conway, following receipt of Dr Donegan's June report, Professor Kroll was also asked to produce a supplementary report which he

A did, dated 28 November 2002. He wrote in his introduction as follows:

“In her report, Dr Donegan advances on a case-by-case basis her general thesis that in the UK today the diseases in question are of little importance, and that the vaccines offered to prevent them would carry unacceptable risks to the two children.

B Dr Conway comprehensively disagrees with this position, and I entirely agree with him.”

C Well he expanded on some of Dr Conway's criticisms. He goes on to accuse Dr Donegan of risking giving a misleading impression of the research and giving a misleading impression through selective quotation. As I say, those are very strong words for a medical professional to use about another. In fact, in relation to the child B, who was by then aged ten, Professor Kroll did not agree that that child, because of her age, should be given the pertussis or the Hib vaccine.

D Those two reports are served upon Dr Donegan and they might have caused another doctor to pause a long time before putting pen to paper. They both accused her of giving a misleading impression in her report. And a more careful expert witness might even have been tempted to review her earlier report and to correct some of the more misleading impressions. In the GMC's submission she did not do that. Instead she stuck to her guns.

E I am going to turn rather more briefly to that second report. It was dated 4 December 2002. You have it behind tab D, but I am not going to ask you again to turn up each section of it. Sorry, tab D, of course, in Panel bundle1, C1.

According to Dr Elliman, who has reviewed that report, she was again economical with her citation of research and she often left out critical information. In fact, the way that that report is structured is specifically (as you will see at page 74, I think it is, bottom right-hand corner) so the second page in of the report, that she was simply responding to Dr Conway's report of 19 November and she says:

F “I shall prefix Dr Conway's paragraph numbers with a 'C' to differentiate them from mine.”

G So what I would respectfully invite you to do when you read through these reports is pay fairly close attention with respect to the dates when they were written, because in order to make sense of this report, you will have needed to have read, albeit, perhaps, briefly, Dr Conway's report which again we will be asking you to do.

Paragraph 1.15 is an example of a statement by Dr Donegan when she refers by way of example to a dramatic increase ... sorry, I will wait for you to find it.

THE CHAIRMAN: Which paragraph is that?

H MR KARK: 1.15, page 82, bottom right-hand corner. She refers to a dramatic increase in notifications of pertussis, or whooping cough, despite high vaccinations in Norway. In

A fact, the paper Dr Donegan referred to reported a system of enhanced surveillance of pertussis and so again, comparing figures with those routinely collected, it was not comparing like with like.

B Paragraph 1.17 she referred again to the reports that she had referred to in her first report by Dr Stewart which refers to the fact that fewer than half the children admitted to hospital with pertussis were below one year old and this figure rose between 1970 to 71, and 74 to 75. What Dr Donegan did not mention was that just five of the 203 children admitted overall had in fact been vaccinated.

In relation to diphtheria at paragraph 1.21, Dr Donegan stated:

C “Here we have a disease that has not disappeared in such a satisfactory fashion despite very high vaccination rates.”

It has not disappeared, but it is right to point out that in the whole period between 1986 to 2001, a period of 15 years, there have only been 22 cases of diphtheria and one death.

D In paragraph 1.26, she suggested that a cause of the control samples of patients in the studies she was referring to developing neurological illness may indeed have been caused, she said, by receiving the tetanus, diphtheria and polio vaccinations, a fact, according to Dr Elliman, there was no evidence once again to support that contention.

E Paragraph 1.33 (I am sorry, I am rather moving through this at a greater speed than the earlier report) leaves the suggestion (paragraph 1.33 starts at page 90 and goes over the page to 91) that there was still thought to be a link between neurological disorders as reactions to the DTP vaccination. The paper which she cites, which was, in fact, written by Drs Pollock and Morris, in fact, ended with these words which she did not quote:

“We cannot rule out the possibility that some vaccines may on rare occasions cause brain damage, but no convincing evidence of this has appeared in our study.”

F Paragraph 1.68 discusses a report by an author called *Shaheen* and others. I will just find it (page 107) and she discusses that report which was published in BMJ in 1996 which revealed that 40 per cent of cases of measles in Guinea-Bissau had been vaccinated. Well that is the sort of statistic that she uses and you will see through both of her reports she uses those statistics fairly regularly. Of course, the higher the uptake of the vaccination, the higher the proportion of children with, for instance, measles who are going to have been vaccinated. In other words, if you have got 100 per cent of a population vaccinated against measles and there are five cases of measles amongst that population, then 100 per cent of those with measles have been vaccinated against it, but it does not mean that the programme is ineffective. What Dr Donegan failed to mention when dealing with that report was the fact that the authors still calculated that the vaccine efficacy was 87 per cent. In other words, still protecting some 87 per cent of those who received the vaccine from the disease.

H A further example is at paragraph 1.86 at page 112 and 113. When she cites in her report that diabetes mellitus and pancreatitis have been reported to occur after the MMR

A vaccines and an incidence of one per 250,000 doses, what she did not report was that the authors said that the total association ... sorry, she did report that the authors were saying that the total association was inconclusive. What she did not say was that they had gone on to say that the number of cases of diabetes expected without vaccination was far in excess of those after vaccination and they concluded the current evidence does not, therefore, suggest association between the mumps vaccine and diabetes, but that again was left out of Dr Donegan's report. Other examples will be given by Dr Elliman when he gives evidence, but it is his view, looking at the whole picture presented by Dr Donegan, that she did not comply with her duty to present an objective picture.

B

C Of course, experts do sometimes find that the evidence leads them in one particular direction and, therefore, they are entitled to give a further opinion. What Dr Donegan has done is to present only part of the research and to leave the reader of her report in a position that if they only had her report to read they would be misled as to what the research, in fact, indicated. It is not accepted that the reader has to do their own research, as it were, to discover the true version of events which, in fact, lies behind Dr Donegan's words.

D That is all that I say to you in opening. There will, in due course, be further matters that we seek to put before you. They will be the subject, I think, of argument and we will be discussing those with your Legal Assessor, preliminarily with your Legal Assessor, to see how it is best to resolve the issues that there are between myself and Mr Stern. Of course, whether it is under the new rules or the old rules the standard and the burden of proof remain the same and that is that it is for the GMC to prove each of these heads of charge and to prove them to the standard so that you are sure.

E I think the joint approach is that we would ask you, of course, it is a matter for the Panel, now to take time to read through the reports and I would suggest that you try and do so, as it were, in a chronological way. So can I just take you to those and make a suggestion as to how you might like to read them?

F In panel bundle 4, behind tab B, you will find the preliminary reports of Dr Conway. You will find the first is in August 2001 and behind tab 1, the first page should be page 96 (apologies to Mr Stern because I know that he and I have both been struggling with pagination) but just to let him know the first page behind tab B and then one of panel bundle 4, should be 96. That is the first report that was prepared for these proceedings. Then you have tab 2 behind B and that was also prepared prior to Dr Donegan's report. The date of that, if you want to write it on, I think, is 27 May 2001.

G MR STERN: Sorry, to interrupt but I wonder if I might do so just to be helpful. What I have done is prepared a schedule of the reports because, quite frankly, keeping it in my head has been impossible. I do not know if that would help because you may want to mark on that where each of these reports are. That is the reason I have interrupted Mr Kark to save him writing it on one piece of paper and then transferring them to another list. I hope it is accurate. I think it is.

H THE CHAIRMAN: Mr Kark, you have not seen this?

MR KARK: No, I do not need to see it.

A

MR STERN: You can have a look at it.

MR KARK: I am quite content for Mr Stern to pass that around.

B

MR STERN: It is not contentious in any way, but I will pass a copy to Mr Kark. I was not going to give it at this stage, but as Mr Kark is dealing with the chronology ---

MR KARK: I am very, very happy that you should receive it.

MR STERN: It seems sensible that you should have it at this stage.

THE CHAIRMAN: I do not think we need to give it a D number at this stage..

C

MR STERN: No, I would not have thought.

MR KARK: In fact, it might be sensible at some point to put this into the beginning of the expert report file.

THE CHAIRMAN: Which one?

D

MR KARK: Probably Panel bundle 4, I would have thought. If Mr Stern has got ---

MR STERN: I do not mind where it goes, but I would have thought it would be one of those documents that you might want to leave to the side and refer to as and when we go through various thing because clearly it would be a document that helps you (I hope so) in looking at the chronology of how things developed.

E

MR KARK: Can I make the suggestion that you take that document now and you mark on it, if you want to, first of all, the first Conway report is bundle 4 and then it is tab B1.

The first Kroll report is behind tab C in bundle 4 and then tab 1. The second Kroll report, 19 May Kroll report on child B, is in fact the second one in our bundle for some reason, so actually it is tab 2 of C, and then 20 May Kroll report is behind tab C1.

F

Then we go back to Mr Conway, again in bundle 4, and again back to B and I think you will find that is behind tab 2. Then we have Dr Conway's report on child A behind tab 3.

THE CHAIRMAN: B3?

G

MR KARK: Yes, B3. Then we revert to Dr Donegan's bundle which is bundle 1. Then we move back to Dr Conway and that is the rather chunkier report behind Panel bundle 4 again B4. That is a response, of course, to Dr Donegan's first report.

Then to get to Professor Kroll's response we have to go to tab C of bundle 4. Then we are back to Dr Donegan and, as you will see, she wrote a very, very short two page report to which I have not adverted, but it is simply said for completeness.

H

Now, as I said, perhaps I am just a slow reader, but I know how long it took me to read

A this lot just once, as it were, and I suspect you will need certainly the rest of today and possibly part of tomorrow morning, if you adopt the suggestion that we are making, but I think we both think that would be a sensible approach and then once you have finished the reading we propose to call Dr Elliman.

B MR STERN: May I just help in this regard? As my learned friend has indicated, it would be helpful, I would have thought to you and your Panel, to read the reports so that you have some sort of overview of the points. I do not know whether it is necessary to read it in minute detail in terms of cross-referencing because we are obviously going to go through it on a number of occasions. So what I would invite you to do at this stage is to read them and I would have thought that we will be able to start at the latest tomorrow morning and I was wondering whether or not you might feel that we could start with some evidence later this afternoon.

C I do not know how much of these reports you need to read in depth, if you see what I mean. I think you have got the flavour from Dr Elliman's report; you have got Dr Donegan's reports, Conway and Kroll are really, as it were, makeshift parts of the case because it is Dr Elliman who is the witness who is called on behalf of the GMC. So obviously you have to look at his report and again go through it, I should think at least two or three times before the end of the case. So I merely set out the programme, as it were, in a way that I hope helps with your timing.

D THE CHAIRMAN: You are suggesting that we take stock around 3.30 or four when we could call ---

E MR STERN: Possibly, I do not know how you are going to read. It may be that it would be better to start first thing tomorrow morning with Dr Elliman. I do not know how long it will take you to look through it.

THE CHAIRMAN: I am just looking to the Legal Assessor because he has had the privilege of seeing these. Have you any guidance in terms of timing?

F THE LEGAL ASSESSOR: It is really a matter for you, but I can help to this extent as I have with the reports and I would be inclined to say not before tomorrow morning, but you may well be in a position ... what I am really saying is that, having read it myself, it seems to me that, of course, there is not just one member of the Panel there are more members of the Panel, one may finish at a certain time, others go on and, it seems to me, that they would all have finished reading, if they have done, this afternoon at a time when really it would not be very sensible to keep witnesses back to give evidence.

G MR STERN: It might not be worth starting.

THE CHAIRMAN: Very well, we will then adjourn to read as you have directed us to the chronological order and we will reconvene at ... can I just take soundings from my Panel members?

H DR GOODMAN: Chairman, I am not clear about the position of reading Dr Elliman's report, I was ambiguous in what I heard.

A THE CHAIRMAN: Mr Stern, do you want to give us a bit more?

MR STERN: If it was something I said, I am sorry.

THE CHAIRMAN: My impression of what Mr Stern said is that we must not cross-reference in too great depth ...

B MR STERN: I am not saying you must not.

THE CHAIRMAN: ... because you will be taking us through those.

C MR STERN: I think Mr Kark will go through some of it. The evidence will stand as the evidence-in-chief. I will obviously have to go through it in detail. I am not saying that you should not do that, I am merely saying that I think certain time will be saved in due course because we will be going through it on a number of occasions. It is a matter for you.

D MR KARK: I agree. I do think it will be sensible for you to read Dr Elliman's report in full, not going to all the references necessarily, because then what it will allow me to do is simply concentrate on perhaps two or three examples as we go through each disease to really flesh out, as it were, what he is saying, but it would help, therefore, if you do read the whole of Elliman's report and then, as Mr Stern says, that will ease the way when you actually hear from the witness and it will certainly make my task, I hope, rather shorter than it would otherwise be.

THE CHAIRMAN: Is that clear?

E DR GOODMAN: It is fine with me.

MR STERN: I think the plan was, between us, if you read the report it would stand as the evidence-in-chief and that Mr Kark would then clarify or pick out certain particular points that he wanted to. I think, as he said, two or three examples maybe on each of the vaccinations. I hope that that will, therefore, probably save about two days.

F THE CHAIRMAN: So we will retire to read and we will reconvene at 9.30 tomorrow morning.

(Discussion re housekeeping matters)

G *(The Panel later adjourned until 9.30 am
on Wednesday 8 August 2007)*

H