

GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL

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

On:
Wednesday, 15 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 Six)

Panel Members:

Mrs S Hewitt (Chairman)

Mr J Brown

Ms J Goulding

Dr M Goodman

Mr R Grey QC (Legal Assessor)

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

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

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

INDEX

Page

PRELIMINARY MATTERS re Dr Goodman's
declaration of interest

1

FITNESS TO PRACTISE

DONEGAN, Jayne Lavinia Mary, affirmed
Examined by MR STERN

4

A THE CHAIRMAN: Good morning. Mr Kark, do you have an application?

MR KARK: I am afraid we are going to ask for a little time. You have surprised us coming in absolutely on time. We should have got a message to you. As you probably saw as you came down the corridor, we were speaking to the Legal Assessor and I am afraid there is something that we still need to clear up with him, so I am very sorry to delay matters this morning. Being realistic, I think that it will probably take us 15 minutes or so, and perhaps we could then pass a message to you if we are ready.

B

THE CHAIRMAN: Very well. In that case, we will go back upstairs.

MR KARK: We can liaise with your Secretary. Many apologies.

C

(The Panel adjourned for a short time)

THE CHAIRMAN: We have a list of points that I understand you want to put to Dr Goodman. I agreed that they are agreed between the two of you. It is a question of who is going to put them.

D

MR KARK: Madam, so that it is clear on the transcript, can I just explain what has been going on behind the scenes? This has arisen because on Monday, when we last met, when Dr Goodman began to ask his questions of Dr Elliman – I am looking at the transcript on page 65 – he said:

“I suppose I ought to declare two interests, one being an expert witness in court proceedings myself from time to time and also being involved at the moment in preparing reports as a GMC expert witness, although I have not actually appeared before the GMC yet in this particular case”.

E

Then he said, “I am declaring a couple of interests”.

F

Having had a little time to mull over that, I think that both counsel would like a little further information from Dr Goodman, and I am sorry if it is slightly embarrassing to have to ask a Panel member in open session, but we think that it has to be in open session and has to be on the transcript. We have therefore put together a list of questions – and I have to apologise for my writing – which Dr Goodman has seen, and I am very happy to ask the questions unless you, madam Chairman, think that you or the Legal Assessor should.

G

THE CHAIRMAN: I am content for you to ask the questions. I just wonder whether we ought to identify this document.

MR KARK: No, I do not think so. I am not going to ask for it to be exhibited. It was simply prepared in order to put Dr Goodman on notice, as it were, of the sorts of areas that we were going to ask about, so that he was not taken by surprise.

H

THE CHAIRMAN: We had a brief discussion to decide whether it should be me or the Legal Assessor, but we are content that you should ask the questions.

A MR KARK: Thank you very much. I will do it through the Chair, if I may. The first question is: what reports has Dr Goodman been asked to write for the GMC?

DR GOODMAN: I have been asked to write one report by the GMC and one report by the Medical Protection Society in defending a doctor whose hearing has been listed by the GMC Fitness to Practise Panel.

B MR KARK: The second question is: on what subjects were they written, and I think we can take it that that was in the doctor's specialist field, as it were?

C DR GOODMAN: Broadly, yes. The first, about which I have been asked by the GMC and which is at an investigation stage at the moment, is the fitness to practise of a consultant gastroenterologist in his field of gastroenterology. The second is from the Medical Protection Society in a case that is listed to do with the procedure codes used in invoicing by a consultant gastroenterologist in private practice. That is the dispute in the second case.

MR KARK: Thank you. I think we are probably more interested in the GMC case perhaps than the MPS case. Can we ask when Dr Goodman was instructed?

D DR GOODMAN: I was instructed by the GMC in June of this year.

MR KARK: Had Dr Goodman ever previously been instructed by the GMC to write such a report?

DR GOODMAN: No.

E MR KARK: Has Dr Goodman ever given evidence in either FTP proceedings or any other tribunal or court proceedings?

DR GOODMAN: Yes, I have given evidence once in the Family Division of the High Court; about five or six times in lower courts; quite a number of times as a witness to fact or as a professional witness in coroners' courts; and once as an expert in a police disciplinary tribunal.

F MR KARK: Never in an FTP?

DR GOODMAN: Never in any GMC proceedings.

G MR KARK: I think the sixth question is probably redundant, or I expect that Dr Goodman does not know the answer to it. Dr Goodman has said that the case in which he is instructed by the GMC is still at an investigation stage. Obviously there is a possibility, presumably, of Dr Goodman giving evidence in that case, if it is referred?

DR GOODMAN: It has been specified in my instructions that there is that possibility.

H MR KARK: You have answered the seventh question, which is: is it before an FTP? Does Dr Goodman feel that he has any bias in either way as a result of him having been instructed by the General Medical Council?

A DR GOODMAN: I presume Mr Kark means in this case?

MR KARK: Yes, absolutely.

B DR GOODMAN: As a matter of information, when the GMC instructed me or asked me to receive instructions in June, I informed them that I was a panellist, and then the solicitor in the GMC case consulted somebody more senior in her department and came back to me with the answer that they wished me to continue on the case but advised me to declare my position as a panellist on that case, as a result of which certainly when I was questioning Dr Elliman – and I have declared professional experience when questioning other expert witnesses in the context of how the witness responds to the question – I felt that Dr Elliman and the Panel should be aware of my experience, but, especially as I am aware that this case hinges on the concept of an expert witness and aware that Dr Elliman had made statements about that in his report and was questioned about it, I felt that he and the Panel should be aware that I had that experience and expertise, which is not necessary in all medical members, as I said; but I do not feel that I have any bias.

C

MR KARK: Thank you. Finally, does Dr Goodman have any special knowledge/interest in the giving of evidence in relation to expert evidence?

D DR GOODMAN: First of all, the background. I engaged in medico-legal work from when I was appointed an NHS consultant in 1977, but I stopped taking new cases in 1997 when I became an elected officer at the BMA, because of conflicts of interests there and time constraints, and took no new cases, did not have any cases after about 1999. I went back into medico-legal practice in 2005 and was trained for that by Bond Solon before I took any cases. In between those two time frames, the Woolf report came in. So, my expertise is what comes of being an expert witness. As I said, I have had the training of Bond Solon; I went on a Sweet & Maxwell training day last year; and, over and above that, when the Woolf reforms were coming in, when they were at consultation stage, I was the Deputy Chairman and Chairman of the General Purposes Sub-Committee of the Central Consultants and Specialist Committee of the BMA, which is the consultant division of the BMA, and it was within my portfolio, which was quality and standards, to lead the BMA consultants' discussion with Lord Woolf in that consultation. So, to that extent, I came to experience issues with regard to experts and expert evidence. I think that answers your question.

E

F

There are two other issues that you may wish to be aware of, which have come up in Dr Elliman's evidence. One is that I was on the Editorial Board of the British National Formulary from 2002 to 2006. The second is that I was a member of a Cochrane group, which was referred to, in the early to mid-1990s, but not since then. I hope that answers Mr Kark's questions.

G

MR KARK: Yes. I do not have anything else to ask. Thank you very much.

THE CHAIRMAN: Mr Stern?

H MR STERN: I have no questions. Thank you.

THE CHAIRMAN: Any observations?

A MR STERN: I have no observations personally, but may I just take a minute or two to discuss it with Dr Donegan. I have already asked Dr Donegan, but I just want to confirm her view as to what ...*(inaudible – off microphone)*... and I hope Dr Goodman will allow me just to make the point that there is no question of a suggested or actual bias.

THE CHAIRMAN: Do you want to withdraw with Dr Donegan while we stay here?

B MR STERN: Yes, I am quite happy to do that. I hope that it will take no more than a few minutes.

THE CHAIRMAN: Do the Panel members or the Legal Assessor have any questions?
(No response)

C MR STERN: Will you excuse us for a minute or two?

(Mr Stern and Dr Donegan withdrew for a short time)

MR STERN: I am grateful for the time, madam. It is, as I already understood the position to be, that there is no difficulty at all, and I have no further observations or submissions to make. Perhaps we can continue with the case.

D THE CHAIRMAN: Very well. Are you going to call Dr Donegan.

MR STERN: Yes, please.

JAYNE LAVINIA MARY DONEGAN, affirmed
Examined by MR STERN

E Q Dr Donegan, I am sure that the Chairman will afford you any opportunity, should you wish to, to have a break at any time. Can we start, please, by you first of all turning up the curriculum vitae, which has been copied in the bundle C1, divider B? We can see your name there. What is your full name, please?

A My name is Jayne Lavinia Mary Donegan.

F Q Can you just help us, please? Your qualifications are set out there. You qualified in 1983 from where?

A From St Mary's Hospital Medical School, University of London.

Q I think that is now Imperial College, is it?

G A Yes.

Q We can see your other qualifications. Just help us very briefly with what they are?

A Would you like me to read them?

Q Yes.

H A I have the Diploma of the Royal College of Obstetricians and Gynaecologists of London; I have the Diploma of Child Health, which at that time was from the Royal College of Physicians of London; I have the examination of the Member of the Royal College of General Practitioners of London; I have the Diploma of the Faculty of Family

A Planning and Reproductive Medicine of London; and I am a Member of the Faculty of Homeopathy of London.

Q Having completed your initial qualification in order to practise as a doctor, I think you then undertook GP training, did you?

A Yes, I did.

B

Q Just tell us a little bit about that, where that was?

A Before I started my official GP training, I did six months of accident and emergency and six months of orthopaedic surgery at the Royal Hampshire County Hospital in Winchester. Then I started my GP training with a month in general practice in Andover, which is near to Winchester. Then I continued with my GP training scheme in Winchester, which included paediatrics and neonatal intensive care, obstetrics and gynaecology, general medicine and medicine for the elderly, and a placement where I did six months of ear, nose and throat and ophthalmology.

C

Q Then bring us a little more into modern times. I think in 1990 were you appointed as a partner in the general practice that we can see set out in that *curriculum vitae*, the Hearne Hill Group Practice?

A No. I became a partner in a practice in Queen's Park in north London.

D

Q I think you were a partner but then you stopped in 1991?

A With the birth of my first child.

Q Then did you go on to what was then called, I think, the GP Retainer Scheme?

A I did.

E

Q Help the Panel with that because not everyone maybe familiar with it?

A The GP Retainer Scheme is set up as a part-time sort of protected-type of employment for people who have domestic responsibilities. I originally worked in Willesden Green in north London and then from 1995 I worked at the Hearne Hill Group Practice in south London.

F

Q Was that under the retainer scheme?

A It was.

Q Did that change after a period of time?

A After a period of time the retainer scheme changed and the maximum time you were allowed to stay on it was reduced, so in 2001 I came off the retainer scheme and just carried on doing the same work but as a permanent locum.

G

Q I think that you then worked at that practice beginning in 1995 right through until 2007?

A Yes.

Q Do you still work there?

H

A My last day there was 28 June 2007; I, unfortunately, became a victim of NHS cuts.

A

Q So the locum work ceased?

A Yes.

Q How many partners are there at that practice?

A There are approximately six because some of them are not full-time, some are varying degrees of part-time.

B

Q How many sessions were you doing at that practice?

A Two.

Q Two sessions a week?

A Yes.

C

Q In addition to which you told us about having a child in 1991. Did you have another child?

A In 1993.

Q So you have two children?

A Yes, I do.

D

Q In addition to your mainstream general practice you have also included in the CV that you are a homeopath?

A I am.

Q Again, help with what that is for people who do not know the detail of it?

A Well, I am a medically qualified (obviously) homeopath and homeopathy is a form of complementary medicine.

E

Q I want to ask you, please, to look at the second part of the first page, which is under the subheading "Research interests". You have put there:

"Vaccination and disease ecology. All my medical training led me to term firmly support UK vaccination programme, including extensive counselling of parents in the aftermath of the whooping cough scares of the 70s and 80s. This all changed with research that I started in 1994 as a result of worries about the information supplied by the Department of Health to doctors regarding the Measles Rubella campaign of that year".

F

G

Over the page is a part that we have already, I think, looked at in relation to evidence given by Dr Elliman:

"Since 1994 I have been investigating and collating data on changes in disease patterns from an historic and modern perspective, taking particular account of the effect of social changes, the impact of changes ideas of disease causation, the introduction of vaccinations since the nineteenth century and innovations in medical practice, such as antibiotics in the twentieth century, along with migration patterns of population. I use basic data from the Office for National

H

A

Studies, Centres for Disease Control and refereed medical journals.

The addition of this information to what I previously knew has led me to seriously question the benefits of universal vaccination. I have extensive general practice and personal experience of the course of healthy disease in people, particularly children, treated with conventional and complementary medical approaches.

B

I provide information for vaccination awareness organisations, such as The Informed Parent and write articles for them.

C

I provide a telephone helpline for parents to discuss vaccination issues in the light of my research and experience. I also help to support parents who feel their child has been damaged by vaccines in terms of choices regarding future vaccinations and any amelioration that may be possible in terms of their current symptoms.

I write papers on vaccination topics, which are published by parent information groups, also newspaper articles on vaccination”.

D

The you say you are used as a resource and quoted by journalist. I think then you talk about various other aspects of the media, in the course of which, I think as Dr Elliman has told us, you came to discuss various matters on the radio with him on at least one occasion?

A That is correct.

E

Q 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?

F

Q 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?

G

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.

H

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

A 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.

B **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?

C **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".

D **Q** Is your advice, as it were, to the parent to educate themselves rather than to give them specific recommendations?

A Yes. I am actually quite careful because I am quite careful and I am quite circumspect in that I specifically do not – I do not tell people not to vaccinate and I do not tell people to vaccinate. In fact, some times when they ask me I say, "Look, if I said to you 'don't vaccinate' that would be the same as the Department of Health saying 'do vaccinate'. I think you need to make the decision based on your own information and what is best for you and your family".

E MR STERN: Can I turn now to look at how it was that you came to be involved in this High Court case? Madam, there is some more correspondence that relates to this particular issue and I will ask that be handed to you now. (*Same handed*)

THE CHAIRMAN: D22.

F MR STERN: They do not have page numbers but they are in chronological order.

G (*To the witness*) Can we look at it because it is in chronological order, the two letters that you already have are repeated but one can see how this came about and one can see the time of which you had to do this report. We can see that the first letter in this bundle is 21 May 2002 (dated on the top right). It is written to you. We have, as you will see, blocked out, I hope, all the references to the relevant names. This is from Andrew & Andrew Solicitors who are writing further to telephone conversations you had with the name of the solicitor at Battens Solicitors, which is the other firm.

H "We understand that Ms Weatherill has spoken to you in relation to preparing a report on the issue of the children's vaccinations.

We act on behalf of a mother who has been brought to court to force

A

her 11 year old child, the childhood vaccinations she has to date not received any. Our client does not wish to give her these.

We have been partially linked with Ms Weatherill's case with similar circumstances, which is how we have come by your details.

B

We have left a message on the answer machine ... and now sent this letter.

We would require a report to be filed at the court on 31 May 2002. We would also require your attendance at the Winchester County Court on 8 and 9 July and for a copy of your CV and an estimate of fee".

C

Can I just ask you, please, how it was that you came to be contacted in this way, if you know?

A Yes. In the previous year I had been contacted by the mother, not of the child that Andrew & Andrews are representing...

Q The other one?

D

A The other one. She had rang me up on, I think, probably about three occasions, quite long phone calls, saying that she was in this position whereby she had a child who was unvaccinated and the father of the child, with whom neither she nor the child lived, wanted to have the child vaccinated and was taking legal proceedings. Discussing the whole situation I said to her that at the time I thought it highly unlikely that the Court would find in favour of someone who did not want to vaccinate their children. She said she was asking whether I would consider helping her case, or being an expert witness. At that time I said that I thought it highly unlikely that I would be considered as an expert witness by the Court because although the amount of information I had about childhood vaccinations, I thought, was of a level with an expert/expert knowledge; I thought that the very fact that I was a GP and not a professor of immunology or hospital consultant or whatever would not be in their favour and so I advised her to try and find someone who was more prestigious.

E

F

Q Do we take it from that, that you had not acted as an expert before?

A No. I had never acted...

Q Had you ever written an expert report before that?

A No.

G

Q Had you ever seen an expert report before that, to the best of your recollection?

A No, I had not.

Q You were telling us you recommended some other people?

A Yes.

H

Q What happened then?

A In later, I think it was in 2000 – it is a long time ago but it was some time in 2002.

A

Q Do not worry about the exact dates?

A She came back to me again asking me. She said that they had been told by the Legal Aid Board that they could not have anybody from another country, it had to be someone from the United Kingdom. They also had been told that it had to be someone who was medically qualified from the United Kingdom, not some other branch of healthcare. So she came back again asking me if I would do it. I was very reluctant because apart from anything else I had quite a punishing schedule in terms of what I needed to do myself with my own personal circumstances.

B

Q Sorry to interrupt you, but so that the Panel understand what you are saying. You were acting as a General Practitioner for two sessions a week, you were running a homeopathic clinic, I think?

A One day.

C

Q One day a week. Also your children, what were your commitments in relation to that?

A Apart from the commitments that every mother has running a house and looking after children, I am the sole carer, I also home-educate them.

D

Q You had a schedule with that as well?

A Yes.

Q All right. Carry on, I thought you better explain that allusion to that point. Yes?

A I did not really expect to hear anything more, so when I was first called by Mrs Leanne Weatherill to say they thought they would use me as an expert I was really quite surprised.

E

Q Can we look then at the letter that follows on, which is a letter from you in handwritten-form, which I think was faxed probably?

A Yes.

Q You had better read it because your writing is not the best...

A Doctor's writing. I will point out that a lot of these letters have no name and address on the top. That is because in order to save my headed paper I chopped a piece off and I stick it on the top, fax it and then peel it off and put it on the next one. If you wonder why all these letters do not have headings on them it is because the heading got taken off in my home copies.

F

Q I had not noticed, but thank you for that?

G

A It says:

“Attention Jolene Harris.

Page 1 of 3.

Re: Childhood immunology.

H

Thank you for your letter of 21 May 2002. I spoke to one of your colleagues after you had gone this evening. To follow is a CV as

A requested
2 pages”.

Q The next letter of 24 May, addressed to you from Andrew & Andrew:

B “We enclose with this letter the papers in relation to (one of the children). We have not as yet managed to have the draft letter of instructions approved by the (other firm solicitors or the mother’s name) but we will fax you this once we are in receipt of the same.

C In the meantime we enclose herewith the file papers in advance of the letter. We would also be grateful if you could confirm that you could prepare a report by 31 May”,

then the same point about giving evidence in July is made. The next letter is 24 May:

“We are instructed to act on behalf of”

- then it sets out the mother’s name and also Battens there -

D “We are pleased to that you are able to assist with the preparation of a report for the use in pending court proceedings in the Winchester High Court relating to a specific issue application over the Vaccination of the above named children.

THE REPRESENTATIVES

E This is a joint instruction on behalf of both Respondents in the two separate proceedings.”

In fact, those proceedings were joined, as we know:

“The representatives are:

F 1. We are instructed by”

- the mother and then it sets out who also is representing who -

“NATURE OF INSTRUCTIONS

G 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” I think that should say -

H “independence, that there are no unrecorded discussions or correspondence with any of persons involved in the case.

A

In the unlikely event that you provide any document to the Legal Representatives instructed by any other parties, please send a copy to us and we will provide copy documents to all parties. We will also disclose any document that you provide us to other parties.

B

If you need further information, please contact us. We shall endeavour to provide such information after consultation with the other legal advisors involved."

Then the background is set out and then it says, "YOUR INSTRUCTIONS". The background is that which we already know. The mother is refusing to immunise the children:

C

"... stating that the side effects were a great concern to them. Both set of proceedings were issued separately and were not aware of the others existence until the matter was referred to the High Court. Directions were then set and the proceedings were partially linked."

The fathers obviously had the different view.

D

"YOUR INSTRUCTIONS

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

E

1. What are the comparable risk between the children having the childhood immunisations and not.

2. Whether there is anything in any of the children's medical history which indicates that that child should not be given any or any combination of the immunisations listed in the report of Dr Conway's report dated 4 August 2001. (Trial Bundle page 104-114)

F

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

G

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

- I am not sure what that means -

H

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

6. When answering the questions you should bear in mind that the

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

Is that your writing in the lower part?

A It is. I have added the extra instructions that were given in the Battens letter.

B **Q** We do not need to struggle with that because it is typed up in another document that we will come to. The timetable is as has already been indicated, that they wanted it by 31 May. The hearing dates are given to you and then also some point about the personal circumstances of the individual child. If you require any further information to contact them, and:

C "It is a condition of your appointment that if the court or the parties require you should hold discussions with the other expert instructed in the same field of expertise in order to identify areas of agreement and dispute where there is disagreement between the parties."

Over the page is the next letter of 28 May:

D "We refer to the aforementioned matter and enclose for your use a copy of the report of Professor Kroll which has now been filed ... We await your comments regarding the observations made by Dr Kroll which of course will be the basis of our cross-examination in court."

Then you can see the copy is enclosed.

E **A** Yes.

Q Over the page, 29 May 2002. This is the typed up version of the manuscript instructions that you have written on the bottom of the other one so that you have it all on one sheet, I suppose?

A Yes.

F **Q** It refers to the letter of Andrew & Andrew:

"We act on behalf of ... the mother of ... in connection with this matter.

We would reiterate that this is a joint instructions ...

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

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

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

A

worldwide.

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

B

In respect of the remainder of Andrew and Andrew solicitors letter we concur with the same and would be grateful if you would prepare the report as required."

This is dated 29 May 2002. The copy in the bundle that the Committee have already seen I think is a copy letter, which is why "worldwide" is written manuscript. This is obviously the final version, as it were, and this is the one that came to you?

C

A Yes.

Q Next page, 5 June:

"We refer to our letter of 29th May and enclose for your use a copy of the report, compiled by Dr Stephen Conway, which is referred to by Professor Kroll in his report."

D

We are now 5 June and is it the position that you had only just got the reports by this stage?

A Yes.

Q Or certainly Dr Conway's?

A It had just arrived.

E

Q Over the page is your manuscript response. I should just ask you this: you did have a computer, I think, at this time?

A I had a computer but - yes, I have a computer. I have a computer which is what I did the report on. I used it as a word processor.

F

Q Did you have access to the internet via that computer?

A No.

Q Or e-mail or anything like that?

A No.

G

Q We will come back to look at it obviously in due course, but how did you carry out your research?

A I carried out my research by using the larger number of papers that I already had that I had been amalgamating through time and the references that I had called for at other times. I also conducted some searches through the British Medical Association library and I used them to send me photocopies of articles that I wanted. I faxed them what I wanted and they would send them to me by return of post.

H

Q Did you actually go to that library and do research ---

A No, I did it from ---

A

Q How does it work then?

A I ring them up and then I fax them, in those days, with what I wanted.

Q Then they would send it to you?

A Then they would send me and bill me later.

B

Q Back to this manuscript letter, if you will, please. 7 June, a letter from you to the solicitors:

“Please send me the form of words you wish me to use at the end of my report.”

C

You will have seen Dr Conway’s report and Professor Kroll’s report at this point?

A Yes.

Q Did you have any idea of what should have been put at the end of the report, if anything?

A No, I had no idea.

D

Q Then you say, “Do I need to reiterate ...” This is about the medical notes of the children?

A Yes, the medical history.

Q Yes, the medical history of the children and whether you need to do that. The next letter is 10 June 2002 from the solicitors saying:

E

“We refer to the report that you are providing in respect of this matter ...

We enclose the form of words that is used at the end of the report by Stephen Conway and Professor Kroll for your information. We would suggest you use something along these lines.”

F

Then there is a point about double spacing that we need not perhaps worry about. Then it has:

“Enc. Dr Conway’s report

G

P.S We enclose the report from Dr Conway that has now been provided to us by Messrs Lester Aldridge Solicitors. This is similar to the report from Messrs Andrew and Andrew which was submitted on their own case however they do not appear to have the side effects of the vaccinations from page 10 onwards.”

This is now 10 June?

H

A Yes.

Q You were just getting the second, I think, report of Dr Conway, or one of the

A reports from Dr Conway ---

A Yes, I was.

Q It does not actually make it clear which one. We will go through the chronology in any event of his reports. 13 June is the next letter:

B "We write further to previous correspondence to enquire whether you have been able to complete your report on the above.

... if you can forward us a copy so that we might arrange for the same to be sent to all interested parties."

C That is essentially what that says. Over the page is a letter typed by you. You say, "You should receive my report by Monday 17 June". I think at the top we can see it says "16 May", but, in fact, it obviously is June, is it not?

A Yes.

Q We can see it has been crossed out at the top. Is that your handwriting at the top?

D A Yes. That is subsequent handwriting, when I was trying to chronologise my letters. You can see where I have written 16 May, in the letter it is "17 June". What I mean is that the typing at the top says, underneath the address, says "16 May". It is obvious from what I have written in the letter anyway that it is the wrong month.

Q It is obvious that it could not be 16 May because you had not been instructed by then?

A No.

E Q Are you saying you altered that later on?

A I altered ---

Q It is the June later on?

A The June at the top I altered later on and across the top where you see a lot of dates is me going through subsequent to this case, getting my letters in the right chronological order where I can see it at the top.

F Q At the time it read 16 May?

A It read 16 May.

Q Thank you.

G "You should receive my report by Monday 17 June 2002. It was sent first class on Friday 14 June. To follow is a list of contents.

My report is fully referenced. If a copy of all the references is wanted, someone will have to come and photocopy them for me as it will take too long to do it myself. I will bring them to court if necessary. However, most of them are from standard textbooks or widely circulated journals such as the British Medical Journal, the Lancet, Pediatrics, Journal of Infectious Diseases etc. I would expect

H

A the other experts to have ready access to them. Indeed, I would surprised if they had written their reports without taking such information into account.”

Was that your view?

A Yes.

B **Q** Then you set out the hours and the court attendance and all of that. Over the page, 17 June 2002, is a response:

“I refer to your letter of the 16th May, (I suspect June) which I received on the 17th June 2002 regarding this matter and note your position.

C The court attendance is on the 8th and 9th July 2002 ... estimated that it will be 2 days for the expert’s report/evidence to be heard.”

Next page, 19 June:

D “We write further to previous correspondence in this matter regarding the report you have kindly prepared for us.”

So this is after they have received it, 19 June, Dr Donegan?

A Yes.

E **Q** “We have safely received it and have served it on all interested parties. Thank you for all the effort you have put in.

We note what you have said about the references you have used. However, having discussed this matter with Leading Counsel we believe that it will be necessary to have a copy of all the references.”

F As we know, and the Panel knows because they have looked at the transcript, the mothers were represented both by leading and junior counsel and, of course, the two solicitors that we know of. There may have been two juniors in fact, I do not know?

A There were two juniors.

G **Q** I think one for each of the solicitors?

A Yes.

Q And leading counsel in this matter.

H “... we believe that it will be necessary to have a copy of all the references. Consequently, could you please let us know how they are held? I.e. are they gathered in a single pile which could be sent to us, if necessary by courier, for copying, or are they spread over an assortment of media, in which case would we be able to obtain them

A

e.g. by downloading them from the internet?

Leading Counsel has already enquired whether you would be able to draft an addendum report on GP practice regarding vaccinations, that is, what are the procedures for informing parents of when a vaccination is required, is there any follow-up in the event a parent ignores it, how are GPs remunerated for giving vaccines ...”

B

and if necessary get additional funding.

“In addition, when the expert reports were ordered the Judge asked that, if possible, the experts should meet in order to discuss points of agreement and points of disagreement. Leading Counsel has also suggested that the experts prepare and agree a risk assessment in respect of both children ...”

C

Next is 20 June, the next letter. This is all to do with the references and the copying of them. You set out how to get the references. First of all:

D

“All the journals are available from the British Medical Association Library ... They will need a BMA membership number. You may use mine. They will send it to your address if requested but I think that they will bill me - so I will require funds ...

Available on-line”

E

- and you set out the various references there -

“The textbooks are:

‘Harrison’s Textbook of Internal Medicine’ 11th Ed - whole section for each disease

‘The Role of Medicine’ by Thomas Mckeown”

F

- the book that I think Dr Elliman produced from his clothing suitcase, and various other books there -

“The textbooks will be available in any medical library although there may not be a 1971 edition of Patterson’s.”

G

A Yes.

Q

“I do not have any e-mail addresses or web site addresses because I am not on-line. If you want me to collate all my references and have them ready + the textbooks for someone to copy it will take me one to one and a half hours.

H

To draft an addendum ...”

A that is an addendum which we need not perhaps worry about. Then you say:

“I am more available for meetings in London than in the provinces. The only day that I currently have any time available before the hearing is Wednesday July 3rd ...”

B Over the page, 25 June 2002:

“We write further to previous correspondence and your telephone call of this morning, regarding the proposed meeting of experts, to confirm it will take place on Wednesday 3rd July ... We have contacted Professor Kroll and asked him to confirm exactly where he proposes to hold the meeting ...

C In the meantime, we enclose a copy of Professor Kroll’s Curriculum Vitae for your information. We also enclose a copy of the agenda ... for agreement/disagreement ...

... we are unsure whether Dr Conway will be attending as he is currently in Genoa ... Professor Kroll and Dr Conway largely agree and that you represent the opposing viewpoint, it is to be hoped that the meeting will still be of use.

D ... any additional information you require, we shall contact you.”

E Over the page, 1 July, Professor Kroll has booked a room in the Academic Department of the Obstetrics and Gynaecology department. Perhaps we can take this letter a little more shortly. Half way down:

“We have now been informed that Dr Conway will be attending the meeting as he will have returned from Genoa by then.”

In fact, he did not attend, did he?

F **A** No, he did not.

Q “With regard to your queries about Court times”, and then set out - did you know what time court began or anything like that?

A No, that is why I had to ask.

G **Q** “... you may like to arrive a little earlier in order to meet everybody and discuss any queries you may have ...

H In the interim, whilst we have been able to find a number of the references you have quoted in your report, there are still some we have not. Consequently, would it be possible for you to post us the copies you used so that we may copy the same? We shall, of course, return them to you and pay the cost of postage. We have located all

A

those references referred to overleaf but have been unable to locate the remainder.”

Over the page to 2 July, we are coming to the end of these correspondence letters:

B

“Having discussed the matter further with my principal ... she has decided that, bearing in mind the lateness of the day, it would probably be easier if, as you suggested in your letter of 16th May, you bring those references we have not found to Court with you. In the interim, we shall write to the other experts with a list of what we do have and enquire whether there is anything else they particularly want to see.”

C

Experts meeting for the following day:

“I would be grateful if you could fax and post the ‘completed’ agenda to me so that I may pass the same on to Leading Counsel as soon as possible.

D

I confirm that it will be quite acceptable for you to arrive at Court at around 9.30 ... able to meet Counsel beforehand.”

Can I ask, did you have any conference with leading or junior counsel, or indeed the solicitors, prior to your giving evidence at all?

A No, I did not.

E

Q Were you given any instructions or information in relation to what we have looked at with Dr Elliman, the Part 35 of the Civil Procedure Rules or anything like that?

A No, I was not.

Q Were you given any feedback at all in the intervening period between the dates of your report and the dates in which you gave evidence that there was something not right with your reports? Any information from leading counsel at all?

A No.

F

Q Were you asked to prepare an addendum that there was a difference between the conclusions in the papers and the points that you were making in your report? Did leading counsel, via the solicitors, ever indicate that something might be wrong with that?

A No, they did not.

G

Q Did Professor Kroll indicate anything at the meeting of 3 July that there might be something wrong with this?

A No, he did not.

H

Q The letter that we looked at was 2 July just a moment or two ago. The next letter you will see is 12 November. Just so that the Panel have the chronology before we move on, as it were, so it is clear. You will recall from the transcripts, if I may say so, madam - if Dr Donegan will forgive me for turning away from her for a moment - just so that you have the chronology, which I hope will be helpful to you. You will recall - well, you may

A not actually because you do not have it. Doctor, let me just help you, with my learned friend's permission. On 8 July, Dr Conway gave evidence?

A He did.

Q The case was then adjourned until Dr Donegan's evidence in December?

A That is correct.

B **Q** Just so you have, I hope helpfully, the chronology. That is why the next letter is in November because, as we will see when we look at the history of the reports and the chronology of the reports, there were further reports exchanged. You will remember, I hope, the document that I produced pretty early on which shows the chronology of the reports but, as I say, let us finish with the correspondence and come back to the report, if we may. 12 November 2002:

C "I acknowledge safe receipt of your letter of the 11th November which I received on the 12th November 2002 regarding this matter."

I can then go to the third paragraph, which begins "In respect of Dr Conway's report..." That is the report in which he responded to your report, I think?

A Yes, it is.

D **Q** That reads:

"...I believe this is 52 pages but merely responds to your first report. It is not that you will have to raise a full report merely to pick out the main contentions."

E That is all I need to refer you to there. The next letter is 13 November. Perhaps we can just deal with a few of the points that emerge from this, because obviously it is in manuscript. If there is any error, just let me know, because you can obviously read your handwriting better than I can. It is dated 13 November to the solicitor. The third line down says, "As you know, I am still awaiting nine hundred odd pounds from Andrew & Andrew", so the first point is a money point. It goes on in paragraph 2:

F "Regarding the 52 page report, if the above maths(*sic*) are sorted I can endeavour to reply a(*sic*) two weeks..." -

Well, you had better read it, because I am afraid your writing ---

A "In".

G **Q** Sorry?

A It says:

"If the above matters are sorted out, I can endeavour to reply in two weeks for a report that I receive on Nov 18th. However, it will be cutting it very fine as I have other commitments also. It would have helped if the Dr Conway report had been produced sooner, instead of at the last minute. I know that my original report was produced very late in the day, but that was only because I was engaged very late in

H

A the day.”

Q Can I ask you to pause there for a moment? When we look at Dr Conway’s response, we will see that it has typed at the foot of the page the date 7 December 2002. We are going to look at it, but do you know why you did not receive it until 18 November?

B **A** No, I do not.

Q Carrying on then, please, with point 3, I just want to look at the lower half of that point, could you just read that bit, please?

A Yes.

C “In the order in which you have furnished them, I cannot give my references to an outside firm to get them copied as they are not numbered as they appear in the text. It would require me to stand with the person doing the copying and hand each one to them myself.

I have no time to do this Thursday or Friday, so the options...”

D **Q** I think the options do not really matter. This is all technical in relation to copying, which I need not trouble you with, unless there is anything in there that you want to mention about that letter?

A No, it was just the problems of sorting out the administrative details to do with the references.

Q The next letter is dated 14 November.

E **A** Would you like me to read it?

Q I think it would be helpful, if you would.

A It says:

“Re References

F I was at the BMA Library today...” –

This was the day I went in, because I had a large number of references that I needed then –

G “...and I happened to look properly at the copyright declaration form that I was signing (copy to follow) and I noticed that it says that I am to use the copies for research (as I do) or private study and that ‘I will not supply a copy of it to any other person’. (Please see below).

I questioned the librarian regarding copies of these papers as they are references and the judge (I presume) has ordered a set to be presented(*sic*) for the other side.”

H **Q** I think it says “prepared”, does it not?

A Sorry, “prepared”, yes, you are right.

A “They said that, as far as they were aware, I should not supply copies of anything copied from them but that those requiring them should request the copies themselves or else I would be in breach of copyright law (and my signed declaration)”.

Q So you were concerned about both the declaration and the copyright law?

B **A** Yes.

Q A little further down – I think I can read it – it says:

“As you are the lawyers, would you please clarify this point as a matter of greatest urgency.”

C I think that is what it says?

A Yes, that is correct.

Q Over the page, they then respond to it on 15 November. The second paragraph reads:

D “The references are indeed for your own use as their purpose is to supplement your report and for use at Court in a case in which you are an expert witness. There is, therefore, no infringement of the Copyright Law and you can happily proceed with the copying.”

I think “happily” is not necessarily the right word, but anyway that is what they were saying. The next page, 19 November 2002, a letter from Andrew & Andrew, the second paragraph:

E “We shall be forwarding to you in tonight’s post a copy of Dr Conway’s report. The 62 page report is in two parts. Part one deals with the research material that you used and simply suggests that either you’ve take(*sic*) it out of context or that you failed to include the following paragraph.”

F So the solicitors were obviously aware of the tenor of Dr Conway’s report?

A Yes.

Q But again, as I say, despite that, did you have any contact with the solicitors or leading counsel or junior counsel between 19 November and the early part of December when you gave evidence?

G **A** No, I did not.

Q Halfway down that letter, it says:

“The second part, which starts at page 52, are questions which have been raised by the parties, which he” (Dr Conway) “has been asked to answer.”

H I need not trouble you with that. The next letter is dated 26 November. It says:

A

“We have now received from” (the solicitors for the other side) “the paginated medical references, which have been sent by Dr Conway. I enclose copies of the same (there are 218 pages) for your use.

B

I further enclose an agenda for discussion between the experts (yourself, Professor Kroll and Dr Conway) to find points of agreement and disagreement which have been commented on by Dr Conway. Perhaps you could also deal with this matter.”

The next letter is 3 December. I think it is really only the... Well, if you could just read what it says, obviously it says “Urgent”?

A Yes. It says:

C

“The requested reply to Dr Conway’s statement of November 2002 will be ready some time on Wednesday 4th December, probably early, i.e. before 9 a.m. Please advise whether you wish it to be sent by post or courier.”

D

Q I do not think I need trouble you with the rest. It is about postage. The next letter is dated 5 December, which thanks you for your report:

“Thank you for your report, which has now been filed together with the addition which is in response to Professor Kroll’s.”

That is the two-page addendum?

A Yes.

E

Q It continues:

“We can confirm that the hearing will take place in Winchester 9 December 2002 ... The report of Professor Kroll is for your attention in readiness for the hearing on Monday 9 December 2002. We apologise that you appear to be missing the final two pages and we enclose these for your attention.”

F

THE CHAIRMAN: The Legal Assessor is pointing to the previous letter of 26 November from Battens to Dr Donegan, which includes at the bottom a reference to an agenda. It would be helpful if you have that for us.

G

MR STERN: I do not know whether I have it. It says, “agenda for discussion between the experts”. I think that is the agenda for the discussion that took place on 3 July.

THE CHAIRMAN: Yes. Have you got that?

MR STERN: I think we do have it actually. I am not sure that it is disclosable. That is my only slight concern. Looking at the CPR rules, the CPR rules say that ---

H

THE CHAIRMAN: It is a point about confidentiality?

A MR STERN: Yes, but I can check that. There is no difficulty about you having it, if anyone wants it. Can we come back to that, if we may?

THE CHAIRMAN: Yes.

B MR STERN: Dr Donegan, I am helpfully reminded about the time in which you had to work on Professor Kroll's report.

A Yes. Professor Kroll's report arrived on 4 December. I was working all day and I had to go to a postgraduate meeting that evening. When I got back home at 11 o'clock at night, I had to then work on the answer to Professor Kroll's addendum, which I then faxed to Andrew & Andrew at about 6 in the morning of the 5th, which then was not distributed to anyone apart from Andrew & Andrew at court.

C Q I am sorry, I missed that?

A It was not in the end distributed by ---

Q The addendum?

A That I had spent all that time doing, was not actually distributed at court, so nobody had it apart from Andrew & Andrew.

D Q It may be that the Panel do not have it. I think the Panel do have the addendum. Nobody has referred to it yet, but I do not know if the Panel actually do have it. I know that when it was originally served it was in a separate bundle.

THE CHAIRMAN: We do have it.

MR KARK: It is page 135 and following.

E MR STERN: Thank you very much.

Q So that was never before the court, as far as you know, that addendum?

A No. Well, I mentioned it when I was there and there was a bit of scuffling and then Andrew & Andrew said that they had their copy but they had not realised that they were supposed to distribute it.

F Q It may not matter very much. Can we now turn to look at the chronology of reports, as it were? I think that will be fairly clear from the matters that we have just gone through, the correspondence. I just want to briefly look, if we can please, at the various reports and for you to help the Panel as to ---

G THE CHAIRMAN: Mr Stern, can I just check with Dr Donegan, are you comfortable to carry on?

A I am fine now, thank you.

Q We are an hour into it.

A Yes, I am fine, thank you.

H MR STERN: The first report, as we can see – if you have that schedule to hand, madam, that is the one that I am going to look at, the one that I have prepared, which I hope will help you – is the report dated 4 August, as you will remember. I am not going to go

A through it in any detail because of the way in which Mr Kark has put the matter, but I do need to just draw your attention to one matter in relation to it, in general terms. It is in your bundle C4 and it is in B1. (*Document handed to the witness*) Dr Donegan has all of them there, thank you, do not worry. (*Further document handed to the witness*) What is that? Is that the chronology?

A Yes.

B Q Do you not have one there?

A No.

C Q Thank you, that is very helpful. This report by Dr Conway, which I think is actually dated 4 August 2001, if you look at the foot of the page, you can see where they have tried to block out the name and just below it says, "4 August 01", so if anyone wants to write that on, it confirms the schedule that I have already looked at anyway. This is on Child B from Dr Conway and he sets out that he serves on various committees, including the Joint Committee on Vaccination and Immunization. He initially says that he has been asked to deal with the benefits of MMR, and at the foot of that page he says that, further to that, he has been asked to give a medical opinion with regard to all the immunizations that are missed. Now just help us, please, with this: looking through that, what I am interested in are your views insofar as they affected anything that you did in due course in relation to your report. Does that make sense?

D

A Yes.

Q First of all, are there any references in this report at all?

A No, there are none.

E Q Second of all, in relation to this report, did it, in your view, present one particular point of view only?

A It presented the point of view that the vaccinations should be recommended for all the children – that all the vaccination should be recommended for the children.

Q Leaving aside the recommendations, because obviously the recommendations are not in issue...

F A No.

Q ...the issue that I am asking you about is what your view so far as the reasoning or otherwise of the report in your mind was?

A In my mind, the information presented here gave one side of a view, which was that all the illnesses are very severe and all the vaccinations are safe and effective, without qualification.

G Q In fact, if one looks – we need not go through it in any great detail – I think on a number of occasions Dr Conway sets out that the only effective therapy is prevention by vaccination?

A Yes.

H Q Was that something that you agreed with?

A No, I did not.

A Q I am not sure, I cannot quite recall, but I think this dealt with the complications to some extent?

A Of vaccinations or the illness?

Q Of the illness.

A He dealt with complications of all the illnesses.

B Q He dealt with the contraindications, I think, or at least some of them?

A He mentioned some contraindications.

Q That is the first report. The next report, dealing with it chronologically, is dated 19 May 2002, which is Professor Kroll's first report. That is out of order in your file. It is the same bundle but C2. For some reason, the 19th and 20th May ran the wrong way.

C This is the report on Child B?

A Yes.

Q Just in very brief overview, were there any references to this paper, this research?

A No, apart from some references specifically to do with the MMR vaccine.

Q Yes, that is right, specifically to do with the MMR, which is dealt with in his Appendix 1, I think?

D A Yes.

Q Apart from that, anything else? (*No verbal reply*) Were there any other pieces of research referred to apart from the MMR?

A No, apart from regarding the MMR controversy, so to speak, there were no references.

E Q So, again your view in relation to those which affected your mind, or may have affected your mind, in relation to the writing of your report?

A Well, I read again in this report and it seemed to me that there was one particular opinion being given, and it was not balanced by any other opinion.

F Q That was your view, all right. The next report is that also of Professor Kroll. It is in fact in the divider before, which is 20 May, which I think is almost identical but deals with Child A?

A Yes.

Q If I may say so, with no disrespect at all, it is a bit of a cut-and-paste but with specific references once or twice to Child A?

G A Yes, and slightly different vaccination recommendations based on the different child.

Q And obviously the opinion based on the medical record will be different, but just so that we can clear this particular point out of the way, in relation to the medical records for both Child A and Child B – and I think you made this clear in your report – there was no medical reason from their past medical history that precluded them from having vaccination?

H A There was none that I found in their medical records.

A Q I think that is all from Professor Kroll before the first hearing. The next will be Dr Conway's report on 27 May, which is at B2 in the same file. This is essentially dealing with medical history of this particular child and Dr Conway's conclusions, you agree with in your report, that the medical history indicates that there was no basis for not giving vaccinations?

A That is correct.

B Q Again I do not think there is any research there or anything in relation to that. 28 May is the next one, which I believe you will find in divider B3. In the third paragraph down on the first page:

C "I have been asked to provide a detailed written report for purposes of the Court detailing the need for childhood immunisations, any risks appertaining thereto, nature of the disease to protect against any complications that might arise".

Then we have another report that deals with that. Again, any research there that you have seen?

A No. There were no references provided or mentioned in this report.

D Q Looking at this report, if you were looking at it afresh is there anything in that report that would indicate how it was that Dr Conway came to his conclusions at all?

A No, there was nothing.

Q Anything else you want to say about that particular report or can we move on?

A Please move on.

E MR STERN: Those are all the reports prior to your first report and that may be a good time to take a break because I am going to turn to the first report and look at Dr Elliman's criticisms in relation to that.

THE CHAIRMAN: We will return at midday.

F MR KARK: Before we break can I ask one matter? I did not want to interrupt Mr Stern when he was on his feet, but back in D22 (which was the file of correspondence), it is not paginated but there is a letter dated 1 July 2002 from Battens where they talk about having been able to find a number of references but some they have not been able to find. Then over the page, "We have located all those references referred to overleaf"; is there an overleaf?

G MR STERN: I have looked for it but I have not found it. I think this is a matter that my learned friend and I can discuss and we need not delay you, madam.

THE CHAIRMAN: Dr Donegan, you are under oath so you are not allowed to discuss the case with your team.

H *(The Panel adjourned for a short time)*

THE CHAIRMAN: Mr Stern, please continue.

A

MR STERN: (*To the witness*) We are going to start to look at your first report, which has typed "14 May 2002" but we know it was 14 June 2002 and we can see that date in the final page of your report. I want to ask you, first of all, before we look at the detail (because we have spent a lot of time looking at the minutiae of various words and their meaning an dictionary definitions and various things like that), I want to stand back from the report for a moment, if we can. Can you help, please, to give the Panel some idea; in relation in this case to the sequential nature of the reports, did that play any effect in the writing of your report?

B

A Yes. The solicitors sent me Dr Conway and Professor Kroll's report and they asked me to comment on them and I thought I was answering them, so I knew that what Dr Conway and Professor Kroll had before them, had written, was going to be before the Court and so I was not reiterating what they had said.

C

Q In relation to your reports, again who did you think the reports were going to? I mean you knew they were going to the Court?

A I knew that they were going to the Court and they were going to be used by the Court to make a decision, but they were going to the other experts (Dr Conway and Professor Kroll) in the same way as theirs had come to me.

D

Q So far as the format of your report is concerned, where did you get the idea as to how to set it out?

A Well, I had never, as you ascertained before, written or read an expert report before and so I looked at the format of Dr Conway's and Professor Kroll's reports for an idea of how to produce mine.

E

Q Standing back from the detail for a moment, what was it that you had in your mind as to what you were trying to achieve, generally, in relation to this report?

A Right. Well, when I saw Dr Conway and Professor Kroll's reports and I knew that I had to write a report, I must say I felt quite overwhelmed because of what I saw as the enormity of the task ahead of me because, in my opinion, there was one case which that been set and it seemed to me that it was a very large task to try to balance this out and that is why, in a way, I had to go right back to basics and produce the format that I did with the way I did it because I thought that was the only way that the Court could see a balanced picture.

F

MR STERN: Can we now look at the points, please, in the report to some extent?

Looking at your report, please, on the first page we can see is Child A and B. As you can see you set out there your name and qualifications and special interests in vaccinations.

G

You have set out your instructions, I need not repeat those because they are reported from the letters that you have already looked at this morning. Indeed, if you look just below the points of instructions at paragraph eight:

"My report and opinion are based on information relating to the cases of both children provided to me by Battens Solicitors ... including the medical records and medical reports by Professor Kroll ... and Dr Conway".

H

Then you set out the other information that we are already aware of because it features in

A your CV and I will not repeat all that again.

I appreciate that when we look at the points that we are looking at, we are looking or highlighting the specific points of criticism, but if there are other points that you particularly want to draw attention to I can do that in due course, but if there is anything that you particularly want to draw attention to as we go through please feel free to do so.

B It will help if we have Dr Donegan's report and Dr Elliman's reports side by side because we are going to look at those.

If there is a difficulty I would prefer to deal with it now, madam, than at a later stage because this is a very important part of the case, as you will appreciate, and Dr Donegan is entitled to have full attention to her evidence so if there is a difficulty or there is a question that anybody wants to ask then I will welcome to deal with it at this stage.

C THE CHAIRMAN: As you can appreciate there is a lot of paperwork here and some of us might take the opportunity to re-organise our desks; that is what is happening.

D MR STERN: If anybody needs a break to do that then of course we will take that break, but I do think that it is important that Dr Donegan is allowed to, as it were, give that evidence that she needs to give.

(*To the witness*) Page 11 of your report. I am going to try and do these, if we can, without looking at the research papers insofar as that is possible. If it is not possible, then you must tell us. I hope we have been through it and I hope that some of us will at least remember partially what they say, if not the precise detail. We can deal with the first point at the foot of page eight of Dr Elliman's report. I think we can take this rather shortly. This is the 11th edition point. The references show the 11th edition, but the copy that was made was the 15th edition?

E A That is correct.

Q Indeed we have seen that in the transcript, you explaining that, indeed, to the Court at that point?

F A Yes.

Q We can look at it in due course but in any event that is there. The material actually states what it is that you say it is, so it is not inaccurate. Was it any fault of yours that the photocopy was the 15th edition?

G A Well, the only fault that was mine was that I did not photocopy my editions. I handed it over to the solicitors to get those references and copy them so they copied up the wrong edition.

Q Let me ask you because I will deal with it once and for all in relation to the 11th edition. We have heard that is a 1987 rather than a later textbook. Can you help the Panel, please, in relation to that and why it is that you use an older version?

H A I often find with relation to diseases for which we vaccinate against that the later the edition is, the less there is of practical day-to-day advice on how you treat these diseases, apart from vaccination. So I like using older textbooks because I find that they have often more, for example, practical ground-based advice.

A

Q Let me ask you this: in relation to the 11th edition to, if I may as it were, echo a question that Mr Kark asked; is that difficult for a medical practitioner to find, the 11th edition?

A Well, most libraries keep back copies of their textbooks. Medical libraries keep back copies of medical textbooks.

B

Q I think that the British Library is pretty near Great Ormond Street?

A It is.

Q That is the first point. I am going to move on but if there is anything you want to say about any of these points please let us know.

C

The second point is page 11. It is the third paragraph down, the final sentence, which reads:

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

D

Dr Elliman’s criticism is that that implies that the fall in death rate was unaffected by introduction of the vaccine. Did you intend such an implication?

A No. I was describing the disease.

Q Can we move on to the third point, please, which we will find at Dr Elliman’s page nine in the lower section of it and page 11 of your report, the fourth paragraph:

E

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

Again this, according to Dr Elliman, implies that the diphtheria vaccine does not protect, or it does so in a limited manner. What do you say about that?

A I think that it is the case in the former Soviet Union that most cases occurred in adults.

F

Q I can just stop you there because Dr Elliman does agree that that is true. If you look at page 9, he actually agrees that that is right?

A Oh yes.

G

Q He says:

“It is true that most cases of diphtheria in the outbreak in the Newly independent States were in adults.”

So your point is accurate but I think he says that there is an impression from that that the diphtheria vaccine does not work. What do you say about what?

H

A I think that I have stated faithfully the case as it occurred.

Q In this particular section, are you just describing the disease or are you doing more

A than that, in your view?

A In this particular section, as in all the sections, I start off describing the disease and it is what I call ecology, how it has changed in this century, before I go on to the vaccine. When I say "this century", I mean the 20th Century.

B **Q** I think that is something that you said precisely to the court. We will obviously look at that in due course. I think you said that to the court at this hearing?

A Yes.

Q The fourth point, please, in relation to diphtheria comes at the foot of page 11. A comment made by you:

C "The fact there are so few cases of diphtheria reported in this country is more likely to be due to a trend towards decreased virulence of the organism and better resistance of the host - humans - because other diseases that have been vaccinated against have not disappeared in such a satisfactory fashion ..."

D That is the point made by you. Dr Elliman's comment, at page 11, half way down, he says, "Dr Donegan provides no reference". Well, that is right, is it not? There is no reference?

A That is correct.

THE CHAIRMAN: "Evidence".

E MR STERN: "Provides no evidence", thank you, "or even a reasoned argument to support this assertion". Then it says, "It is possible you are basing this on ref 2", and then he quotes that. He says, "Ultimately it cannot be supported by the evidence", and not logical I think, if I paraphrase what he is saying. Can you help, please, with what you say about that?

A The paragraph continues:

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

I have provided the graphs for whooping cough and measles further on in the report.

G **Q** Pause a moment. I think that is at page 13?

A 16 I have for whooping cough.

Q Yes, sorry, diphtheria at 13?

A Diphtheria at 13. 16 for whooping cough. I think it is 50 something for measles. That is what I was drawing on when I was - the picture in the graph is what I was drawing on when I was making that supposition or proposal or hypothesis.

H **Q** Just to paraphrase what you are saying, the supporting evidence that you were relying on was the graphs?

A Yes.

A

Q Is that ---

A Yes, the end of the paragraph, the graphs for whooping cough and measles - there is not a graph for mumps - but that is what I was relying on.

B

Q So far as a "reasoned argument", what do you say about that?

A I dealt with it fairly shortly, but I have not made an argument there but I have at the end discussed factors affecting immunity, of my report.

Q That is the end of your report, but in this particular part is there any argument there?

A No, I just ---

C

Q Your opinion?

A Well, I put my hypothesis. I have said there is the fact that there are few cases and I have said about the graphs, the decreased incidence of deaths from whooping cough and measles and I have not made an argument.

D

Q In a sentence or two, what is the argument from those graphs?

A From the graphs it must be, I think, admitted that it is possible that when you look at the decrease in death rates, mortality rates, before the vaccination had begun, that there must have been some other factors than vaccination that were associated with these reductions in mortality or death.

E

Q Anything else in relation to that that you want to expand on?

A Well, living conditions have improved considerably through the 20th Century from certainly the 19th Century in terms of Local Authority Housing Acts, Sanitation Acts, clean water. Certainly, in the 1940s there were some big changes in the United Kingdom, for example, the 1941 Education Act which made education compulsory between the ages of 5 and 15. I am not talking about the education necessarily improving the health, but the provision of free school meals for people who could not afford them. In 1944, pre-school milk was brought in and in 1948 the NHS was introduced, which I would like to think had some part of an effect on the reduction in mortality in the 20th Century.

F

Q I think by comparison you say, "Other diseases that have been vaccinated against have not disappeared in such a satisfactory fashion". That is the point you are making?

A That is correct.

G

Q I see. The next point I think is at page 12 of your report. Again, I think we can deal with this relatively shortly. If one looks at page 12, three quarters of the way down, this is the point about the absorbed diphtheria vaccine for adults. It reads:

"Listed side effects for the single, low dose, adult diphtheria vaccine ... are local pain at the injection site, redness and swelling. It also mentions that the thiomersal in the vaccine can cause kidney damage."

H

As we know, Dr Elliman said he could not find any document, having spoken to a number

A of his colleagues, that indicated that. In fact, the way he put it is he is:

“... unaware of any document produced by the Department of Health or its predecessors, that has ever indicated that a vaccine may have caused kidney damage because of the thiomersal that it contains.”

B Obviously that document has been produced and you rely on that document, as I understand it?

A I do.

Q Is there anything else that you want to say about that particular document?

A I would say that it is true that it is an adult - it is an insert from an adult diphtheria vaccine. I did state then, and more so now, it is very difficult to actually find information out about specific vaccines because so many are injected in combination. The only difference between the low dose adult diphtheria vaccine and the one that you give children is that the actual diphtheria content, the toxoid content, is about six to seven times - or certainly a lot higher in the children's vaccines than it is in the adult one. That is the only difference.

Q I think Dr Elliman said it was six or seven times the adult ---

A Yes, the children's one is much more potent than the adult one, not in terms of the thiomersal, because that is standard, but the diphtheria content is considerably higher in the children's version. That is the only difference.

Q Higher in the children's?

A It is higher in the children's than the adult.

Q I see Dr Elliman nodding, just check that we get it right as we go through. Pertussis, please, unless there is anything else you want to say about diphtheria? I will not keep asking you if there is anything else you want to say, but you can take it as read that if there is anything, then you should do so.

F Can we turn to page 15 in your report, there being nothing on page 14? Three quarters of the way down page 15. I hope the point as I indicated as I went through to try and underline the point so that I could do it in a more swift way - I am grateful. The last paragraph, last lines or so:

“In 1978 and 1982 there were over 65,000 notified cases of whooping cough but no concomitant rise in the number of deaths.”

G This caused a flurry of activity in relation to dictionaries. I think you have brought your own here - when I say your own, a version which you have been able to have access to whilst you are away from home. Perhaps you could just be given this. (*Same handed*) First of all, if you could just say what it is, what dictionary?

A This is the Chambers Dictionary.

Q Which year?

A 1999.

A

Q Could you just read out the definition of concomitant as it appears there?

A "Concomitant. Adjective. Meaning accompanying, conjoined, occurring along with, because of, or in proportion to something else."

Q Which of those meanings did you mean in relation to your report and using that word at page 15?

B

A I meant the "in proportion to".

Q I think if that is indeed the meaning, Dr Elliman has no comment about it, I think that is my recollection. Can we go to page 15 of Dr Elliman's report? I do not know if anyone wants to see that dictionary? No. Sorry, page 18 of Dr Donegan's report, page 15 of Dr Elliman's report. Again, I think this is a straightforward point. It is at the top of the page. This is another Harrison's 11th Edition point. The document is there and I understand there is no dispute that it actually says it, and I am not going to ask you why you used the 11th Edition because you have already explained that.

C

Can we move to the next point, please, which is on the same page of your report, page 18, but now in the middle, and Dr Elliman's report page 15, half way down. The point that Dr Elliman dealt with in relation to this, half way through the middle paragraph:

D

"Because of continuing increases in pertussis notification in the UK, especially in young babies, an 'accelerated' schedule of vaccination"

- which we know was introduced in 1990 -

"(vaccination at 2m, 3m 4m instead of the previous 3m, 5m, 10m) to try to reduce the incidence of the disease."

E

First of all, could you just help there, please? Dr Elliman's point is that there are no sources to that but the material is contrary to the assertions. What is your view? Do you mean "notification"?

A No, actually I meant deaths.

F

Q Do you accept that that is an error in relation to the word "notification"?

A I accept that is a valid criticism.

Q If the word is changed to "deaths", is that accurate?

A Yes.

G

Q Next, please, if we can, over the page, page 16 of Dr Elliman's report and again page 18 of your report. I think this is just a matter of opinion between you, really. The last three lines of the second paragraph:

"As with a number of recent reports from the UK, USA and Australia, there seems to be a trend towards increasing number of deaths in very young and children and a 'waning' of vaccine effectiveness in 1-4 year olds."

H

So far as the "waning of vaccine effectiveness in 1-4 year olds", there is no criticism in

A relation to that; Dr Elliman agreed. What he complains about is he says there seems to be no real trend and also protection is "very high". First of all, so far as there - or what seems to be a trend, did there seem to you to be a trend? Is that the way you interpreted it?

A The way I interpreted the information was that there did seem to me to be a trend and that is what I wrote.

B **Q** What about the efficacy rate?

A The efficacy rate is reducing and certainly in the aftermath of that the pre-school whooping cough vaccine was introduced.

C **Q** Let me just ask you this before you deal with the efficacy rate point. I think this is not the only time that Dr Elliman criticises you for not including the efficacy rate, so we might be able to deal with it, as it were, globally. What is your point about not including the efficacy rate of the vaccine, as Dr Elliman has included it?

A I find in my opinion the way of assessing the efficacy of the vaccines is actually quite a crude instrument for doing it and it does not take into account many factors. I find often that the efficacy rates are not so meaningful as they could be if they were based on better premises.

D **Q** In relation to your report that you were doing here, why did you leave out the efficacy rate? Leaving that aside, was there any other reason?

A No, I was looking at the trend as I saw it. I was discussing the reasons for the - I was discussing what was happening to whooping cough and the susceptibility of children in this country to whooping cough at that time.

E **Q** I should just go back to Dr Elliman's report at page 16. If one looks about five lines down, in relation to this question of a trend, he says, "The reference", which is the reference that deals with the question of a trend, "does not give a real indication of any trends ..." That is the way he puts it.

A Yes.

Q I think you have put as "seems" to be a trend.

A Yes.

F **Q** That is the difference between them. Can we look, then, please, at the fifth point, which is at page 18 in your report? Essentially, what this comes to is you not mentioning that the vaccine may have had an effect. I think you have already dealt with that in general terms. It is true that you do not mention it?

A Yes.

G **Q** At this point anyway. This is the point, three quarters of the way down page 16, where you are saying:

"The incidence of pertussis death and disease was falling before the vaccine was introduced in the 50s. On the previous page of her report, there is a graph showing that indeed, the deaths were falling, but there seems to be a temporal relationship between introduction of the vaccine, its uptake and the incidence of disease. This suggests

H

A the vaccine may have had an effect, yet Dr Donegan does not mention this.”

What do you say about that?

B **A** I certainly think that whatever effect the vaccine had was quite dwarfed by the effect that the other factors that had reduced the rate of deaths and deaths are obviously the most severe incidence of the actual disease. When the deaths go down, the notifications have usually gone down concomitantly - sorry, proportionately.

Q Over the page - I think it is the same page, actually. Page 19, sorry, it is page 19. Again, I think we can deal with it shortly because the point is, three quarters of the way down page 19:

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

Obviously the inference that you draw from that:

D “This means that a child could have had a serious neurological reaction ...”

I accepted on your behalf, you may remember, very early on when Dr Elliman was dealing with it in-chief, that you accepted that that was an error?

E **A** It is an error.

Q We understand that report was 200 pages long. I do not know if you had a copy of the 200 pages or not?

A I have a report of the 200 - I have a copy of the 200 page report but that was an error and ...

F **Q** It obviously follows that the point that you make in relation to it that follows it is an error?

A Yes.

Q In any event, Dr Elliman says that your conclusion, nevertheless, in relation to this at page 19, is accurate. Is there anything more you want to say about that?

G **A** No, that is correct.

Q Page 20 of your report, please. This is again a matter of wording. Halfway down:

“A similar case study in the US found an association between pertussis vaccination and neurological damage.”

H I think the point is that it is not “damage”. I think Dr Elliman has called it “acute neurological illness” but I think when one looks at the text of the paper it is actually, “serious neurological illness” rather than “acute”?

A A Yes.

Q You have called it "damage". What do you want to say about that? He says that it is not damage but illness.

A Dr Elliman is correct. "Damage" has a certain connotation and I used "damage" when I should have put "illness".

B Q How did that mistake come about?

A I think it came about through either a clerical error or the pressures under which I was writing this report. It is a genuine mistake. I was not trying to misquote.

Q In fact, if we look beyond the next paragraph, we can see this:

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

So you have put in, as it were, the other side of the coin?

D A I did.

Q The next point, please, which begins at the bottom of page 20 and goes over to page 21. This is the reference to Odent, and over the page there is another study and then the final sentence says:

E "A larger prospective (looking forward) study of 9444 children in Avon failed to show an association."

So you were dealing here with an association, and I think what Dr Elliman is saying essentially about this is that you gave a little more line space to the other studies than you did to the Avon?

A Yes.

F Q That is one point that he makes. The other thing is the Neilson report. First of all, in relation to the studies, you have put both sides, as I see it, in there. Is that right?

A I did. I put "studies..." ---

MR STERN: (*To Mr Kark*) I hope you are not going to comment about leading!

G MR KARK: To say "as I see it" and the pose a question is going a bit too far.

THE WITNESS: Shall I...?

MR STERN: No, I am trying to save time, and Mr Kark is right. Let me just ask you this: in relation to that, the studies in relation to vaccination and associations, you say:

H "Vaccinated children were over five times more likely to suffer from asthma and twice as likely to have had ear infection than unvaccinated ones."

A You then deal with another study, which is a retrospective study, showing that children vaccinated against pertussis were 75 per cent more likely to develop asthma, hay fever and eczema later in life, and then you put:

“A larger prospective (looking forward) study of 9444 children failed to show an association?”

B A Yes.

Q The Neilson paper, which you are criticised by Dr Elliman for not referring to. First of all, did Dr Conway or Professor Kroll refer to that paper, to the best of your recollection?

A To the best of my recollection, they did not.

C Q Did you know of that paper?

A No, I did not.

Q Had you known of it, would you have included it?

A I would have, but it must be said that, to some extent, when I was preparing this report I had an 11-page report from Dr Conway and a slightly larger one from Professor Kroll and I was severely aware of the fact that my report seemed to be getting very, very large and I was constrained to some extent in what I wrote down because I was trying to keep the size of what I was producing for the court in some way manageable.

D

Q Page 22 of your report is the graph, which Dr Elliman at page 18, three-quarters of the way down... I do not think this is on your chart, madam. I think this is an additional point that I may have omitted from the chart that I gave you with the points, so forgive me.

E

THE CHAIRMAN: Would you like us to insert that?

MR STERN: I would not like you to, but I had better deal with it. It is an additional point that I think I probably missed when I was doing that schedule.

Q Page 18. It is in the penultimate paragraph. I think it can be dealt with quite shortly. It is not a complicated one. It is this: Dr Elliman says that you used the graphs for the prevalence of pertussis and meningococcal disease to suggest that pertussis vaccine increases the risk of invasive bacterial infection, and that this is a very poor standard of evidence and that in any case, looking at the data, the prevalence of meningococcal disease does not mirror vaccination uptake, and then he refers to another study that you obviously have not referred to. Do you want to say anything about this graph on page 22? First of all, do you agree with Dr Elliman that it is a poor standard of evidence?

F

G

A I agree that it could be a lot better, but it must be said that when I am looking at evidence to do with vaccination and its efficacy and side effects, I learnt one thing at medical school and training as a GP and since then a lot of what I have been researching has been leading me to think otherwise, and I do not take what other people say at face value, especially not when it goes so much in the face of what I have previously been taught, which is why I spent a long time at the Office for National Statistics, getting the information out of the books themselves. So, it must be said that in a lot of literature discussing the effects or side effects or associated effects of vaccination, there is a point

H

A made about the question whether or not there is an increased risk of invasive bacterial infection that ---

Q Can I just interrupt you? I do apologise, but I have not pointed out to the Panel which paragraph it is in your report, and that would obviously help them. It is page 21 and the second paragraph down. Forgive me, Dr Donegan, for interrupting, but they need to be able to follow your point. Carry on.

B
A I was just going to say that this is a point that has been raised and, as I have from the Office for National Statistics a CD-ROM of all the deaths from 1900 to 1999, I thought I would actually just look at deaths from invasive meningococcal disease in 0-4 year olds as this natural experiment did take place when the vaccination coverage rate went down, and there is a change. I mean this is not causal. It is just for me an interesting occurrence that this graph should be of this shape. I mean I do not do experiments at home on mice and things. This is just a way of looking independently with the data that I have.

C

Q Do you say anywhere in that paragraph that it is causal?

A No.

D
Q Can we move to the next point then, please, which is the final one in relation to pertussis? It is page 21 of your report, and again I think we can take this shortly. It is in the third paragraph down. It is the Japanese study. You say:

“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.”

E On reflection, the word “this” – your view now, please?

A On reflection, I certainly would not have put “this”, and I also would not have put “the total number of deaths in infants younger than one year” because actually it is a reduction in deaths of infants acknowledged as being due to whooping cough vaccine, and I do not say causally; I just say acknowledged by the Vaccine Compensation Board in Japan.

F
Q Was that in your mind at the time that you wrote the report?

A That was in my mind at the time when I wrote the report.

Q Can we move to tetanus, please? It begins at page 25 but there is nothing in relation to that page or 26, so we can turn to page 27. It is at the top of the page, page 27, Dr Elliman’s report page 20:

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

H Dr Elliman’s comment or criticism is that you failed to mention that all authors state that this is a rare occurrence and are very supportive of immunization. In your view, was it necessary for you to mention one or either or both of those points at this stage in your report?

A

A At this stage in my report, it really is taken out of context because I was discussing, as I do with my format, I was giving an account of the disease and I had mentioned that actually having tetanus the disease is not an infection but is caused by toxin and it does not make you produce any antibodies or be immune to subsequent meeting the tetanus bacillus; and I was describing this phenomenon of people who had not been vaccinated developing some kind of natural immunity, for which there were

B

various theories, and therefore I was mentioning that this lack of gut-based immunity, such as it may be, may explain the occurrence of tetanus in fully immunized people, and I was not actually discussing the ...

Q Rarity or otherwise of it?

A No.

C

Q Let me just ask you about this: the fact that the authors state that this is a rare occurrence, is that an opinion or a factual comment in relation to the authors?

A The authors stating that it is a rare occurrence is factual, because it is a rare occurrence. The authors stating that they are very supportive of immunization is an opinion.

D

Q Can I refer you, please, to a little further down on the same page, underneath the sub-heading "The Vaccine", which is the next bit, three lines down? You say:

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

E

A Correct.

Q The next point, please, in relation to tetanus. We can find Dr Elliman on the same page, page 20, and in fact the same page of yours right at the foot of the page:

"Some people develop nerve damage causing either muscle weakness or altered sensations."

F

I think Dr Elliman's point is that the word "rarely" is excluded by you from the paper. If I can just refresh people's memories without going to the document, unless anyone wants to, I think the patient leaflet had "a few"?

A Yes.

G

Q In relation to the other side of the leaflet – was that for the doctors...?

A For the health professionals, it said "rarely" and on the side for the patients it said, "a few", and I put "some".

Q Do you consider that to be a fair criticism by him?

A I do not want to get the dictionary out again but I think that for me, when I am writing it, "some" is very similar to "a few".

H

Q Let us not waste time on that. Let us move to the next point, please. Page 21 of Dr Elliman's report at the top of the page and page 29 of your report, also at the top of the

A page. This says:

“The vaccination of 11 healthy subjects with tetanus toxoid produced a lowering of the T-lymphocyte helper/suppressor ratio such as might be seen in patients with AIDS.”

B Just help us, because that is a little technical, as to what that means?

A Well, T-lymphocytes are some of the lymphocytes that are used in producing immunity and protection of the body from infection. When somebody has AIDS, they do not die of AIDS; they die of infections caused by the fact that they cannot keep themselves immune from these infections. This was not a study that was looking at vaccine safety. When you are looking for side effects of vaccines, you have to look and see studies that give you information where you can find it, so this was something that was done on adults aged 20 to 50, because they were looking to see if they could find a test that they could use to screen out people who had AIDS in order not to pass it on through the blood transfusion system and they found out that this was not a good screening test because it happened in these people after having tetanus toxoid vaccination, so I brought it in because it is not something that we test in babies. These were adults, and we do not look at T-lymphocytes in babies, so we do not know what happens to them.

D **Q** I think Dr Elliman’s point is that the changes in the research paper, changes to the patient, were seen apparently to be temporary and that no adverse effects were reported and that you should have included that?

A Certainly it says in the paper that by 14 days they had returned to normal. I do not know about adverse effects because, from what I can see, they were just looking at the T-lymphocytes, and certainly these were adults and healthy adults; and as we do not know – I am not aware of any – research that has looked at the lowering or not lowering of T-lymphocytes after babies and children are given tetanus vaccination, I certainly would not be able to say whether that was the case in terms of returning to normal within 14 days because, to the best of my knowledge, it has not been looked at.

Q In relation to your comment, were you commenting on the phenomenon or were you commenting on relying on this particular research for these particular children, if you see what I mean?

F **A** I was relying on this phenomenon as this is something that has been associated with the tetanus vaccine, along with the previous information about the neurological problems that I got from the data sheet or the package insert. I was giving a list of those.

G **Q** The last point in relation to tetanus we can see at page 29, which is under the sub-heading “Vaccination Recommendation”, the first paragraph, last sentence, which says:

“In a severe and tetanus prone wound, tetanus immunoglobulin may be given intramuscularly and intravenously in established cases of tetanus to produce immediately raised levels of antibodies.”

H I think Dr Elliman says that that is true but that it may be too late. I do not quite know what that means. The point that he is making is that it is better to have prophylaxis rather than wait until you actually get tetanus and then sort it out. What do you say about that?

A A Well, yes. There are two separate issues here. One is the tetanus prone wound and the other one is having established tetanus. Tetanus prone wounds are much more common than cases of established tetanus, and "tetanus prone" just means "prone".

B Q Were you making a particular point here or were you just setting out the factual position, because he agreed that it was factually accurate, or he does in his report? Were you making a point or were you just setting out the facts?

A I was making the point that this is what one would do if one had severe tetanus prone wound or one had established cases of tetanus, because for people who were not going to vaccinate their children, this is obviously something that they would need to take into account.

C Q So if you are not vaccinated, you need to know that that is what the medical procedure will be?

A Yes.

Q I have put it perhaps not very scientifically, but that is basically it?

A Yes.

D Q I am sorry, I just need to understand this. Were you making any point that it is better to have treatment rather than prophylaxis or not?

A No. I was making the point that this is what someone would need to think about in their calculation of what they were going to do in terms their vaccination choices.

Q Polio. Page 31 in your report, 22 in Dr Elliman's. If we get to the bottom of the page 30 we can see:

E "The incidence of the disease continued at moderate rates through the early 20th century to the 1940s ... enormous increases in the incidence of paralytic disease occurred, which were thought to be due to excessive hygiene meaning children not coming into contact with the virus ... It also coincided with the widespread use of antibiotics, which were initially all injected intramuscularly and massive vaccination campaigns".

F Then we have this whole problem with the punctuation and the dates are not very helpful?

A It could have been better.

G Q It could have been better set out, but that is a format point, which I am not sure Dr Elliman is taking but Mr Kark did. Can we look at page 32 at the graph? Could you explain this so we can have a definitive version of how these arrows all fit together?

A Okay. The beginning of the arrow, the blunt end, is when the vaccination started to be used, but it was not countrywide. By the time you get to the point of the arrow the vaccination is now available countrywide so it does not finish there, it carries on.

Q I think we realise that?

H A That is where I put, "Diphtheria vaccination introduced" and then the tetanus vaccination was introduced, you can see, from the early 40s when it was introduced to the member of the armed forces. Then in '51 it was introduced to selected areas of the

A country. Then in 1961 it was nationwide, that is where the arrow stops. Pertussis was introduced over that time scale as well until it was available in the triple vaccination.

Q Dr Elliman's point, I think, is a short one. He says that from the figures the incidence of polio rose rapidly in 1947/48, which I think we can see. He says that does not coincide – he puts it another way. He says, "This coincides with the introduction of none of these vaccines". What do you say about that?

B **A** Well the vaccines were not introduced countrywide at those times and although I have put the vaccines on this sheet, it is also – I have put it coincided with the widespread use of antibiotics. For the antibiotic use I do not have any data that is similar to describing when vaccination campaigns came into being, so I cannot put those on there.

Q Leaving that aside, what do you say about the introduction of the vaccination? I think, as I understand you, you are saying it did not come in, in one day?

C **A** No. It came in over time. It is intramuscular injections and I think that Dr Elliman agreed certainly that when polio was circulating, that intramuscular injections were associated with provocation of poliomyelitis; it is a well-known phenomenon.

Q I can give the reference. D2/17D. Mr Kark says:

D "If you are looking at the effect of a vaccine upon the population and the number of people who thereafter, in fact, get the disease, what sort of period of time would one normally be looking?

E **A** I think I should be specific because this is a very particular instance that I think Dr Donegan is referring to and that is that when wild polio was fairly common. Someone who had had an intramuscular injection stood a risk of getting polio in that limb within the usual incubation period. So a couple of months of that happening. So undoubtedly there were cases and there is no contest that they were due to having an intramuscular injection and then having polio disease on top of that".

Is that the point you are referring to?

F **A** Yes. I am.

Q I am told the next paragraph as well:

G "So in answer to your question if a person is given diphtheria immunisation and there was thought to be a connection between that immunisation and getting polio, then you would expect it within a couple of months".

That is the rest of the answer?

A Yes.

H **Q** Can we go to the next point, please, back to page 31 because we have been looking at the graph. It is page 22 of Dr Elliman and going over to 23. The point is, I think – again I think we can deal with it shortly. You say in the middle of page 31 that there is a requirement for the laboratory diagnosis of polio, that is the point. Dr Elliman

A says, no, you do not. He says that is incorrect. We produced that piece of paper where we can show poliomyelitis, the notification disease. Do you want to say anything about that?

A Certainly if you had a person who had paralysis that was compatible with poliomyelitis, you would not worry about getting a laboratory diagnosis before you notified it although subsequent to that you would nonetheless want to do tests to find out if it were that or some other virus like Coxsackie or whatever. But as less than one per cent of cases of polio are paralytic, if you had a patient who had a non-paralytic form of poliomyelitis, there is no way you would be able to notify it without doing a laboratory test because it would be completely non-specific.

B

Q Is that what you meant? I think Dr Elliman said he had no idea how you would analyse it, how you would test for it?

A Yes.

C

Q I am helpfully given the part. He was asked how he would assess that. He said, "As I said it would be clinical diagnosis. I have no idea how you would arrive at a diagnosis of non-paralytic polio, but for paralytic polio it would be clinical"?

A Yes.

D

Q In your role as a general practitioner, how would you go about if a patient came into you and you suspected that they might have polio, obviously not paralytic-type because that would be obvious?

A Well, this is the subject of my anecdote that I put in my evidence because I was wondering – it is a notifiable disease (polio, both paralytic and non-paralytic) – so I was wondering how many children I see with summer diarrhoea who might possibly have diarrhoea from polio, especially bearing in mind that one of the bonus side effects of the oral polio vaccine was that it would circulate in the community, we were told, and thereby provide additional immunity, which is why I rang up the Department for Public Health (which would now be the Health Protection Agency) and asked what tests I should be doing because it was a notifiable disease, but I did not a satisfactory answer.

E

MR STERN: I think that ends that point. I am happy to carry on or break as you wish, madam.

F

THE CHAIRMAN: I think we will break now for lunch and come back at two. Since we lost an hour this morning, my Panel and I were minded to continue to 5.30.

MR STERN: Certainly. As far as I am concerned that is perfectly acceptable, but subject to see how Dr Donegan feels.

G

THE CHAIRMAN: Yes. I mean if she starts flagging we will bear that in mind, but just to catch up.

(The Panel adjourned for lunch)

THE CHAIRMAN: Mr Stern, please continue.

H

MR STERN: *(To the witness)* Dr Donegan, can we move please to page 34 in your report, 23 in Dr Elliman's report:

A

“As the World Health Organisation struggles to achieve its aim of worldwide eradication of polio, it is notable that epidemics of paralytic poliomyelitis have occurred in highly vaccinated populations and tragically immediately after a polio vaccination has occurred”.

B

Is there a word missing there?

A It should say “polio vaccination campaign”.

Q Then there is various research papers that you deal with and make various comments about it. Let us look at what Dr Elliman says about it at page 23. He says that the implication is that the vaccine is “ineffective”. He says, in fact, this is not the case. Then he deals with various points from the paper and we have looked through those in a degree of detail.

C

“Dr Donegan does refer to the greater susceptibility in young adults previously immunised with OPV but does not mention the reason for this and that the dose of the particular strain of the vaccine has subsequently been increased. Therefore it is not relevant to the UK”.

D

What do you say about that, please?

A Well, they are separate points. One is documenting outbreaks of paralytic polio that have occurred after or along with vaccination campaigns. The other one is to do with this particular type of inactivated polio vaccine called EIPV.

E

Q First of all, can I ask why it was that you were dealing with countries far and wide, as it were? Was that related to your instructions or did you think that this was particularly relevant to the children in the United Kingdom?

A Well, if you remember from the supplementary instructions from the other solicitor asked me to discuss, I think, the words were, “worldwide”.

Q The exact words do not matter, but you were asked to look at it worldwide?

A So I did.

F

Q That is why I was asking. Was that the reason you put these in or some other reason?

A Well I was putting them in for two reasons. One because I was asked to give worldwide experience and the other one was to do with the risk that occurs with oral polio vaccine, that cases of paralytic polio can occur after administration of oral polio vaccine.

G

Q What about Dr Elliman’s comment that it is not relevant to the United Kingdom because a higher potency vaccine is used?

A His comment about the higher potency vaccine is to do with this EIPV, not the previous – I do not think – comments about the outbreaks. The point I was bringing along with the inactivated polio vaccine and the “E” variety is that it is a different potency to the United Kingdom one because we did not have one in the United Kingdom that was on the schedule. There was inactivated polio vaccine available, but it was an illustration of one of the problems that can occur with that vaccine because, having spoken before about the

H

A different types of antibodies produced by vaccination, when I was making the point about not producing the mucosal one called IGA, which the oral polio one does do, the inactivated ones, whether they are this type or the type we use here also do not produce the mucosal antibody.

B Q In relation to Israel, which is one of the studies there, is the vaccine similar or the same as the United Kingdom?

A That particular one, the EIPV, that is why it has got the "E" in front of it because it is designating a different sort of inactivated polio vaccine; a different one that has been changed.

Q That is one that is not used in the United Kingdom?

A It is not used in the United Kingdom, to the best of my knowledge.

C Q What was the relevance of it, if it had any relevance, to the United Kingdom in a sentence?

A Well, I was giving it as part of worldwide experience.

D Q The next point, I think, is at page 34-35. This is the SV40 point. The paragraph begins, "In 1961 the inactivated polio vaccines". Then it goes through and deals with SV40 from the inactivated polio vaccines given in 1961. Then over the page, at page 35, it talks about people far too young to have been immunised with a, "documented contaminated vaccine". "Possible that it is still being transmitted". "It thus remains possible that the late adverse effect of the polio vaccination programme is emerging. Dr Elliman's criticism at page 24. He says it is not clear, to him any way, that this is something that even if it were true only applies to the polio vaccine produced many years ago. What do you say about that, do you think it was clear or not when you wrote it - that is really the question?

E A Yes. I did preface that paragraph, which is rather long, within 1961.

Q Was it clear to you at least?

A Yes.

F Q Over the page of Dr Elliman's report at page 25. I think this is a general point about the quoting of papers here... Sorry, there is another point, actually, that is not included, I think, in the schedule, which is really Dr Elliman's page 25. In the middle paragraph he says, "By selectively quoting from her reference and omitting these two". So it is the omission of D19 and 20. Did you know about those particular references?

A No.

G Q Did Dr Conway or Professor Kroll include them?

A To the best of my knowledge they did not.

Q If you had known about them, would you have included them?

A I would have included them, having said with my previous rider that in some ways I was trying to contain this report that was getting larger and larger.

H Q Anyway, you did not know about them?

A No.

A

Q Can we look, then, at the final point in relation to this in relation to polio, which I think one has to turn back to page 34. It is about seven lines up from the bottom:

“An increased incidence of tumours of the nervous system has been reported in one study in children in mothers vaccinated during pregnancy.”

B

This is all to do with the 1961 SV40 type thing. Dr Elliman deals with it at the bottom of page 25 of his report. He says he is assuming you are referring to the article by someone called Heinonen, his reference DE21. He says that the paper says:

“There was to evidence of an excess of malignancies in children exposed in utero to attenuated live polio vaccine, to influenza vaccine, or to spontaneous viral infections.”

C

He says:

“This is highly relevant to the situation Dr Donegan was being asked to address, i.e. should the girls have oral polio vaccine. By failing to suggest that the suggested link was only with inactivated vaccine, she may have misled ...”

D

What is your point about that?

A The comment that I made about, “It has been reported in one study in children of mother vaccinated during pregnancy”, Dr Elliman correctly says that I did not give the reference for that. That is because I was quoting from the body of my reference, tab 51, which is ---

E

Q I think this is one of those rare cases where, I am afraid, we are going to have to have a very brief look at the reference. It is your reference 51.

A Yes.

F

Q We better look at it, just so that the point is clear. Sorry to make you go to quite a lot of effort for what is rather a short point. Nevertheless, let me do that, if I may. This is a paper by somebody called Stenton, I think.

A Yes, that is right.

G

Q Is this the paper that you saw - well, you must have done it because is your bundle, it is your reference?

A Yes.

H

Q As I think I have pointed out to Dr Elliman during the course of cross-examination, if one looks at the second paragraph down, about four lines down, it says:

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

A

That was the one study. Is that where you got that line from?

A That is where I got that comment from. If you look, it is reference to - the reference number 4 inside the body of that is in fact Heinonen, which is the one that Dr Elliman has produced, but that is what they put when summarising that study in their paper.

B

Q Sorry, but I just need to ask you this: did you see the actual study that Dr Elliman produced of Heinonen?

A No, I saw this and that is where I got that information from and that was the basis of this sentence that I put here.

C

Q As I understand it, you saw what Stenton said about Heinonen in that one sentence?

A I did.

Q But you did not see the Heinonen paper?

A No, I did not.

D

Q HiB, page 37 of your report and page 27 of Dr Elliman's. It is the third paragraph down:

“The incidence of invasive disease caused by the encapsulated forms (A-F)...”

I think that comes, as we discovered, from the Harrison's 11th Edition?

A It does.

E

Q I think it is agreed that that is where it came from, yes?

A Yes.

Q Is that accurate?

A Yes, it is accurately stated from my reference to Harrison's 11th Edition.

F

Q I think Dr Elliman says there is an implication - I think this is the point that is repeated time and time again - that there is an implication that there may be a link between these events. What do you say about that?

A The incidence of invasive disease has been increasing since that time as noted in Harrison's. That is the time that antibiotics, as I put it, started to be prescribed so liberally and it is also the time that mass vaccination was introduced.

G

Q Is that factual or an opinion by you?

A I do not think anyone will argue that that is - well, that is when mass vaccination was introduced and that is when antibiotics became available and became prescribed more widely.

H

Q Page 38 of your report. This is three quarters of the way down and it is at the foot of page 27 of Dr Elliman, going into, I think, over the page. This again I think is a short point. The PRP-OMP and HbOC, I think he says there is no reference for that, but also

A there is no evidence to support it. No, that is his point at the top of page 28. What do you say about that?

A Certainly they have not been available in this country. I think Dr Elliman said that the HbOC had been available sometimes.

B **Q** I think you have written that “neither of those are available in this country”. Where did you get that information from?

A It would have been from looking it up in the British National Formulary.

Q He says there is no reference there, but why did you not just put “BNF” or whatever it is?

C **A** I do not know, I put it there because I thought that it was just generally well known, or common knowledge maybe, not amongst the court but amongst the other experts who were presenting reports also.

Q I am not sure anyone has picked you up on that. Anyway, let us move on. Page 39 of your report and over to page 40 at the top of page 40:

D “It was thought to be due to possible problems with vaccine efficacy but is difficult to test because of lack of information on antibody levels in these children after their primary cause due to lack of long-term studies.”

If we just go back to page 39, we can see, about eight lines up from the bottom, you are dealing with the introduction of the vaccine and you say:

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

F and then you give the figures and you put the reference there. Dr Elliman’s point I think is in fact dealt with on page 30, second paragraph down. Having quoted quite a lot of material, looking at the bottom of the first paragraph first of all, he says:

G “There was indeed been.”

- I think it should be “There has indeed been” -

“a rise in all age groups towards the end of the period considered, but the rates are still less than before the introduction of the vaccine.

H ... Dr Donegan correctly says that there has recently been a rise in Hib disease ... she discusses why this might be so. As Dr Donegan points out herself ... ‘*antibody levels are not the same as immunity*’,

A so looking for antibody levels are only part of the answer.”

He says there were other figures that were available to you. Did you have those figures?

A No, I used the report as reported from this meeting, where these figures were produced.

B **Q** If you would have had the report would you have included that - or those figures, rather?

A Yes, if I had had the report I would have included it.

Q Again, I think the ultimate point is - I think it may be the first one we have come across - is this question of *Pulse*?

A Yes.

C **Q** Perhaps you could just help us generally so we do not have to go there on each occasion. *Pulse*, use of, what do you say about that?

A *Pulse* is a very useful GP newspaper. It is a sort of newspaper/publication that in its sections often gives reports of medical conferences, medical proceedings such as this particular one that were presented at the International Network of Paediatric Surveillance in York. These are meetings that many GPs and people like myself cannot attend because we do not have the time or ability to get there, perhaps. Often, they give us notification of what is happening before sometimes the Government even tells us and, often, they have interviews with some of the people who write the papers and it is very interesting to hear what they say.

D **Q** Yes, I think Dr Elliman did refer to the fact that this one did refer to - Dr Donegan's reference is 59, last one in the first bundle. We can see that in fact you have - I assume it is you - have underlined various parts of this article ...

A Yes, that is me.

Q ... where the figures are reproduced in your report?

A Yes.

F **Q** This is from something that has actually been presented, is it?

A Yes, and it says in the report that these are unpublished results, and that was in May 2002.

Q Pause a moment. Let me just direct the Panel's attention to that part that you have just read. It says, in the second paragraph down:

G “The unpublished results of the Public Health Laboratory Service study, which will go to the Government's Joint Committee on Vaccination.”

The figures were not in fact published anyway?

A Not those figures, not at the time I was writing my first report.

H **Q** I think the other point in relation to HiB is also the same sort of point, it is in relation to *Pulse*. I think you have already dealt with that and I am not going to ask you

A about that again. Can we go to meningococcus C, page 42? Nothing on page 41, so if we go to 42, three quarters of the way down; page 31 of Dr Elliman's report. Three paragraphs down, you are dealing with the research. You say:

B "Looking at possible reasons for a weakening of people's immune systems over the last ten years or so which would make them more susceptible to invasive disease it is certainly the case that children are having a much larger number of vaccines and at an earlier age than in the past. It may be this is affecting their immune systems such that they are less able to cope with everyday pathogens."

Yes?

A Yes.

C **Q** Dr Elliman's comment is essentially that you should have mentioned about improved surveillance as well. I think that is, I hope, paraphrasing it, the top of page 32?

A Yes.

Q Having put his quote in. Indeed, he is quoting from Dr Ramsay at the top of page 32 of his report and says:

D *"Although the number of cases had increased, Dr Ramsay said surveillance had greatly improved over the last few years, perhaps accounting for part of the rise."*

Did you feel that you needed to put in that particular point?

E **A** What I was introducing here was the concept of why somebody would get invasive meningococcal disease when there are organisms like the meningococcus, as also HiB, the pneumococcus and various other microbes that live in people's bottom noses, or nasopharynx, the back of their throat. As harmonious passengers they are called commensals, although they do stimulate a certain amount of immunity, antibodies, while they sit there. For an organism that lives in so many people's nose to actually cause meningitis or septicaemia, it means that it has to leave the nose and invade the brain to cause meningitis, or it has to invade the blood system to cause septicaemia. The factors that are to do with why that would happen are, in my opinion, to do with the integrity of the immune system. I was addressing the question of how people's immune systems might have changed.

F **Q** I see, rather than the actual numbers itself. Is that what you mean? As opposed to what?

G **A** There may be more sensitive reporting, but there is also - the number has gone up, even if it would have gone up with less sensitive reporting, such that it was one of the impetuses for introducing universal meningococcal C vaccination.

Q I see. In any event, the paper only says it *perhaps* accounts for part of the rise?

A Yes.

H **Q** Can we look, please, of page 32 of Dr Elliman's report and page 44 of your report? Again, I think this is a relatively short point. Second paragraph, three lines down:

A

“In a separate Government funded trial (no numbers mentioned, no follow-up mentioned) 99% achieved putative protective antibodies.”

Dr Elliman’s criticism is that it is *Pulse* I think?

B

A Yes. I am sorry; can you just tell me where I am again?

Q Yes, page 44 in your report.

A Yes.

Q Second paragraph down.

A Yes.

C

Q Third line, “In a separate Government”.

A Thank you.

Q I should just say, if one looks at the end of that paragraph, there is a number “8” there, which if one turns the reference, we can see your list of references there and we can see on a number of occasions the word *Pulse* present there?

D

A Yes.

Q So it is all set out there and obviously that is, I think, a magazine or a newspaper that is fairly well known, is it?

A Yes.

E

Q I mean within the medical world, obviously?

A Yes.

DR GOODMAN: This is not 8 ...

A It is GMC 67.

MR STERN: As I explained before the numbers, I am afraid ...

A 67.

F

MR STERN: ... somebody thought they were being helpful in renumbering everything. That is why the internal numbering in the references of Dr Donegan’s report do not match the numbering that you have in the GMC bundles.

G

THE CHAIRMAN: Number 8 is *Pulse* of May 1999.

MR STERN: That is exactly right. That is why you have to look at the internal numbering in order to be able to see where that is set out.

DR GOODMAN: But I am not clear which internal numbering it is.

H

THE CHAIRMAN: Page 47 ---

MR STERN: If one goes back to page 44 of the report, second paragraph down, you will

A see at the end of that paragraph in brackets it says "8".

DR GOODMAN: Where is this in the bundle that we have been given?

MR STERN: Mr Kark tells me it is 67.

B MR KARK: It is 67.

DR GOODMAN: Thank you very much.

MR STERN: I have not dealt with the article itself because Dr Elliman's criticism is only that it is in *Pulse*, so unless anybody wants me particularly to deal with it with Dr Donegan, I was not proposing to.

C THE CHAIRMAN: Dr Goodman, do you want it traced? Do you want it to be brought up and discussed, 67?

DR GOODMAN: I am having problems finding the word "putative". I am not sure whether Dr Elliman actually raised it. It is page 44, paragraph 2.

D MR STERN: It is page 32 of his report.

DR GOODMAN: Yes, but Dr Donegan underlines the word "putative" in "putative protective antibodies" and I am having a problem finding the word "putative" and where that comes from.

THE CHAIRMAN: Is that a direct quote?

E MR STERN: It does not seem to be in quotes in my copy anyway.

THE WITNESS: No, it is not in quotes.

DR GOODMAN: So those are Dr Donegan's words, Chairman.

F MR STERN: Well, it is not in quotes, so I think one can take it that as it is not a direct quote... Normally, direct quotes are in quotation marks.

DR GOODMAN: So it is an opinion, the word "putative"?

G MR STERN: I do not know. As I say, that is not something that I have addressed because it was not Dr Elliman's criticism, but we can look at it, if you wish to.

DR GOODMAN: No, that is fine.

MR STERN: I can look at it and come back to it, if you prefer.

Q Do you have a view on it, Dr Donegan? Do you want to look at it?

H A I am quite happy to look at "putative".

THE CHAIRMAN: Let us do it now.

A MR STERN: Let us look at it. It is divider 67.

DR GOODMAN: I am sorry, Chairman, I have found it and it is quote.

THE CHAIRMAN: Thank you.

B MR STERN: Can we leave it then?

DR GOODMAN: Yes.

MR STERN: I think we can take it that Dr Elliman, having spent four and a half months on this report, will not have missed much.

C Q Can we turn to the next point, please? Page 45 of your report, the second paragraph down, page 32 of Dr Elliman's report. The second paragraph down is headed "Safety" and it says:

"The control group in one of the three trials of this vaccine was of children who were vaccinated with Hepatitis B which is problematic as it is not without its own side-effects such that it has been removed from the schoolgirl vaccination programme in France due to an association with multiple sclerosis."

D Dr Elliman's point at page 32 is that although you do not quote evidence for it, it was indeed removed from the school programme for both adolescent boys and girls. Did you mean anything in particular by putting "schoolgirls" as opposed to "school children"?

E A No, that was just a mistake; "school child". I was probably thinking about the rubella schoolgirl programme, so it is "school child".

Q What he says is that you failed to mention that it was greeted with what he describes as widespread concern, but I do not think that is actually a quote from the paper. The paper does not actually say that. Anyway, he says that your account is therefore incomplete because you did not put in. What do you say about that?

F A Well, I have said that there was an association with multiple sclerosis. I have not said "causal" specifically, because no one ---

Q I am sorry to interrupt you. He is on a completely different one. He is saying ---

A Oh! he is saying that I should have put the widespread concern...?

G Q Yes, that other people have widespread concern that the vaccination programme is being ceased?

A Well, that is an opinion really. It is not to do with the fact that it was removed and it was removed because of that association.

Q Let us move to the next point, please. This is again Dr Elliman's page 33 and in fact your page 45, still on the same page. In the middle paragraph you say:

H "In 1996 the Department of Health was said to be resisting pressure to introduce blanket meningitis vaccinations for university students."

A Then you have this:

“The problem is that several hundred thousand students would need to be vaccinated when the incidence of the disease is actually very small.”

B You quote also somebody from a Local Medical Committee who said, “No clinical evidence to support”, that is to say, routine vaccination. What was your point in relation to that paragraph?

A My point in relation to that paragraph was addressing the feasibility or desirability or practicality of vaccinating against meningococcal C disease when it is so rare, and I wrote down what they said about several hundred thousand students needing to be vaccinated when the incidence of the disease is actually very small.

C **Q** Dr Elliman’s criticism – it may be that he is on a different point here – is, first of all, he corrects the missing zero of the hundred thousand. He says:

“She does not point out that the reference she used contains the following paragraph:

D ‘Seizures have been reported very rarely, with approximately...’ –

So it is the rareness?

A No, this is a different point, I think. That is not the one with the... On this paragraph this is different.

E **Q** I am sorry, you are absolutely right, it is the one just above it. Thank you very much. It is point 3. That is my mistake.

“Dr Donegan fails to mention that this refers to reluctance to use the then current polysaccharide A&C vaccine rather than the conjugate vaccine under development.”

F So he is saying that you failed to mention that it relates to one vaccine as opposed to two?

A It was a different vaccine from the meningococcal C vaccine, which was introduced in 1999, but I was not addressing the type of meningococcal vaccine. I was addressing the clinical need or otherwise to vaccinate against a disease of which the incidence is actually very small.

G **Q** I think actually Dr Elliman said that he did not really pursue it – day 4, page 12E. That reference may be slightly different because obviously you will appreciate that the email reference... Is it the next point? It may be that my note has gone awry on that. I can address you later on what Dr Elliman said about it, if you would like. I just thought that it might be helpful if you had it at the same time, but we will move on. Page 46 of your report, page 33 of Dr Elliman’s report. This is the last sentence of the second paragraph, “Neck stiffness and photophobia have also been reported and convulsions a rate of one report per 100,00 doses”. I am sorry, this is the point that I had started dealing with before?

H **A** Yes.

A Q Dr Elliman's criticism is that selective quoting from this source could be misleading, that you failed to distinguish temporal and causal. What do you say about that?

A Could I just address the zeros, or are they addressed?

Q I should ignore that point really.

B A Because it is wherever I have put the commas.

Q Do not worry about that.

A Okay, thank you. I reported what was present in the reference that I used, and what I have reported was sufficient for the Committee on Safety of Medicines to recommend an addition to the side effects listed on the data sheet.

C Q As I say, Dr Elliman says that you should have included what he has said should be included in his report at page 33, that seizures have been reported very rarely. Well, that bit is in, I think, is it not? That is the hundred thousand point?

A Well, I put "a hundred thousand" apart from my typo.

Q He says:

D "A causal association between seizures and the meningococcal C vaccines has not been established."

A Yes, but, as I said, they added it to the... I mean it was sufficient for them to add it to the package insert or data sheet.

E Q Then page 46, lower down on that page of your report (page 34 of Dr Elliman's report) – and I think this is the last one in relation to this – I think again we can deal with this because if one looks three lines down on the third or fourth paragraph, the fourth paragraph says:

"This has certainly been seen with the polysaccharide meningococcal C vaccine. When used on US forces, the incidence of meningococcal C disease was reduced two to three times but the total meningococcal acquisition rate was essentially the same regardless of vaccine status."

F I suggested to Dr Elliman that if you deleted the word "disease" or altered it to "acquisition", that would make sense, and he agreed that it did. Could you just help in relation to that? What did you mean?

G A It should have said "When used on US forces, the incidence of meningococcal C acquisition was reduced" because you can see from the rest of the sentence that I was talking about acquisition rate, but I have put "disease" instead of "acquisition".

Q So is that an error?

A Yes, it is an error.

H Q Let us move, please, to measles. It begins on page 48. The first point is at page 49 of your report, at the top of the page, page 35 of Dr Elliman's report. It has to do with

A the contraindication of severe egg allergy. Dr Elliman said in his report that it was incorrect, but in his evidence he withdrew the point, so we can move on. The second ---

DR ELLIMAN: Could you read it out, please? I am sorry.

B MR STERN: As I have been asked across the room, this is the egg allergy point. It is the second line down, a short point. I have read you that particular bit, Dr Elliman, if you would like me to answer you. It is:

“Yes. Would it help if I say that is a point that I would not wish to pursue? I think it would not be useful.”

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

C MR KARK: I am not taking the point.

MR STERN: Thank you very much. There we are, we will move on, if we may.

Q The second point, please, page 49, also in the report, the second paragraph down:

D “Measles disease may depress cell mediated immunity for up to three years.”

Then this is the cell mediated immunity point that I think is, at least according to Dr Elliman, complicated, and I certainly would not wish to disagree with that. Let us look at that paragraph overall, please:

E “The vaccine virus is attenuated but has similar characteristics to the wild virus so it would be expected to have the same characteristics. Indeed a high titre measles vaccine ... used in populations in Africa caused higher death rates in girls from other infectious diseases compared to boys or unvaccinated girls. To give a vaccine that has such an effect on the immune system at the same time and in the same needle as two other live viruses is, in my opinion, risky.”

F Could you just help us with this, please, so that we can try to understand it? What Dr Elliman is saying is that the conclusion of the paper that you quote, that reduced general cell immunity may contribute to the higher long-term mortality in children who have had measles compared with recipients of standard measles vaccine and to the higher child mortality in the rainy season in west Africa and that this shows that the measles vaccine does not have the same characteristics of the disease or at least not to the same degree... It is not actually a criticism. I think it is just that your reasoning is faulty. I am not sure that I have understood the track by which we have got to the reason and then the reasoning, but anyway if you could just help us with what this is all about in a sentence or two – very, very simply, if you would, please, for me?

G **A** Right. Measles the disease has been found to depress cell mediated immunity in this particular paper for up to three years, and then I follow by saying that the vaccine virus is attenuated but has similar characteristics to the wild virus, so it would be expected to have the same characteristics. In the paper that I have quoted, which is the one showing depressed measles immunity for up to three years, it says that the cell mediated

H

A immunity was lower in measles cases than in vaccinated controls. Forty per cent of the cases of measles had been vaccinated. As Dr Elliman pointed out, when the 40 per cent were taken out, there was still a difference; and, as Dr Elliman himself points out in his wording... Which page is it on?

Q Page 36. Well, I think he agrees with all that?

B **A** Yes, he says "not to the same degree". The high titre measles vaccine... He does not argue with that, that there was a higher death rate in girls from infectious diseases compared with boys or unvaccinated girls. I am not saying that that vaccine is in use in the UK. I am saying that to give a vaccine that has an effect on cell mediated immunity at the same time and in the same needle as two other live viruses is, in my opinion, risky.

C **Q** Let us just try to break it down, because it may be that it is not as happily worded as it could be. In that paragraph you refer to a high titre measles vaccine used in populations in Africa, so I think you limit it to Africa. Is that right?

A Yes. I probably should have put that in something like parentheses in terms of grammar, rather than ---

Q Can I just help, please, because the last sentence says, "To give a vaccine that has such an effect..." To what were you referring by "such an effect"?

D **A** The beginning – the effect on cell mediated immunity.

Q That measles disease may depress cell mediated immunity for up to three years?

A Yes.

Q That is what you were referring to?

A Yes.

E **Q** Looking at Dr Elliman's report, I do not think he disagrees that measles disease depresses cell mediated immunity. That is at the top of his page 36?

A Yes, so it is unhappily worded. I could have been more clear.

F **Q** Do not worry. Page 52, please, of your report, pages 36 and 37 of Dr Elliman, the bottom of page 37 and over to the top of page 37. In the last sentence of the middle paragraph you say, "Despite the purported success of this campaign..." and Dr Elliman in his report said, "'Despite' is not an appropriate word in this context", and again, unless he wishes to say anything, he agreed with the quibbling when I cross-examined him about it:

"Q You do not think that is a little bit quibbling?

G **A** You could argue that, yes. Yes, is the answer to your question."

The reference for that is day 4, page 23B. Can we move on? I need not ask you about that. In the last paragraph on page 53, going over to the top of page 53 – and it is the bottom of page 37 going over to the top of page 38 of Dr Elliman's report – you say:

"The Department of Health's Immunisation Handbook 1996 states that, 'Before 1988, more than half the acute measles deaths occurred in previously healthy children who had not been immunised'. This is very misleading. Its source is a paper by C Miller ... There were 270

H

A

deaths of which 126 (47%) were in people with severe pre-existing conditions such as cerebral palsy, mental retardation..."

I do not think that one uses that expression any more, but anyway there is a variety of pre-existing conditions set out by you, which I think come from Dr Miller's paper?

A Which is one of Dr Elliman's references; I am not sure which tab.

B

Q I cannot remember now, I am sorry. It does not matter. Let us leave it for the moment unless anybody wants to refer to it. Let us try to deal with the point that is being made here, I think it is D30 actually. I am not going to ask you to turn it up unless anybody wants it turned up.

C

"Social conditions not examined. No attempt made to establish vaccination history. As with most outbreaks above half or more of those with measles had been vaccinated. Rather misleading to imply that all the cases of measles were unvaccinated. Also most people would agree that there is a gradient between such severe medical conditions and health".

Right. That is the paragraph...

D

DR GOODMAN: Excuse me, Chairman. Can we have time to absorb that before we continue?

MR STERN: The criticism of Dr Elliman at page 37 is:

E

"Dr Donegan argues that the children may have had more subtle problems affecting their immune system. This is pure supposition for which there is no evidence".

Can you help with what exactly you meant by it and whether you were referring to more subtle problems?

A No. I was referring to the remark in the *Immunisation Against Infectious Diseases* handbook, which is my tab 84.

F

Q 84 in the second bundle? 127 at bottom right-hand corner?

A Yes.

Q I think we can follow this point through. The top left-hand corner says:

G

"Before 1988 more than half the acute measles' deaths occurred in previously healthy children who had not been immunised".

Is that the point you are referring to?

A Yes.

H

Q While we have got this paper out, page 71, in the bibliography section on the right-hand side the second paper down is *Deaths from Measles*?

A That is correct.

A

Q That is Dr Miller's paper that you are assuming I think – maybe it is a bit higher than assuming?

A It is the source for that quote.

B

Q Then you looked at Dr Miller's paper?

A I did.

Q You have set out your view there as to why it is misleading?

A Yes. I think it is a leap of... I think it is an assumption on the basis of the writers of the handbook to say that all the people, apart from the ones with pre-existing conditions, such as cerebral palsy, mental retardation, Down's Syndrome, various congenital abnormalities, immunodeficiency, immunosuppression or emphatic leukaemia were healthy; that is one point about that statement in the handbook.

C

Q Can you explain that? Why do you say that is a leap?

A Well, as it points out in the paper "severe pre-existing conditions". It did not mention "moderate" or "mild pre-existing conditions" so they themselves regard these as severe and...

D

Q Can I make sure that I have understood this. They have those people with severe pre-existing conditions...

A And they are half...

Q ..and everybody else without as being healthy. Is that what you are saying?

A Well they have no – well, they have, yes. They have in their conclusion of that paper.

E

Q I am trying to understand your criticism of it in this paragraph here. Is that what you are saying?

A Well I am saying that to say that healthy children die of measles because from this paper half of the people who died of measles were healthy, based on the fact that half of them did not have these sever pre-existing conditions is not accurate.

F

Q I see?

A The other point about the paper is that the Department of Health handbook says "were healthy and unimmunised" and this paper makes the specific point – in the right-hand column at the end of the first paragraph it says, "No attempt was made to establish further clinical details, vaccination history or social class", so the paper has no information of immunisation status.

G

Q That is what you are discussing at that point within your report?

A Yes.

Q In relation to that handbook and that point in 1988 that you drew the Panel's attention to, have you sought to find out exactly what the specific reference was for that?

A Well, I have because the statement in the handbook says, "before 1988", and as the Panel will see from the reference it was looking at deaths from 1970 to 1983 so there were still five more years. As you will see from the handbook, there are not little

H

A numbers next to the comments; you have to guess at the back from the bibliography which ones were relevant. I wanted to find out the source of information for (A) the extra five years and (B) the immunisation status. I wrote to Dr Salisbury, who is the person at the Department of Health who is the – he’s not an immunisation co-ordinator, he is the... What is he? Dr Elliman will know. He is the immunisation person at the Department of Health and he is the person listed in the book for queries to do with this.

B I wrote to him on several occasions, three times over several months, and I rang his secretary on many more occasions and I also spoke to some members of his team. I have actually got some copies of the letters submitted here...

Q We do not need to go that far. Did you get an answer?

A He did not answer me over those times. I then wrote to the then Minister for Health Mr Milburn to ask the same question and he did not answer me either. So from...

C **Q** He was so briefly there he may not have got it?

A I have never been answered by the Department of Health about what was the extra information, if any, that they used to make that statement.

Q You have asked, you have made the inquiry?

A I tried hard, yes.

D **Q** Page 54, which is commented upon by Dr Elliman at the bottom of page 37 going over to the top of page 38.

“A report in the *BMJ* ... stated that after the 1994 measles rubella campaign there were 530 severe reactions reported, one per 13200 vaccinations and higher than one per million usually quoted”.

E Dr Elliman’s point at the top of page 38 is that it is “suspected adverse reactions”. Do you see any difference between “suspected” or “reported” in your mind?

A Well, in order to report the reactions one has to suspect them first and then report them, so all the reported reactions are obviously suspected. I have made no comments about causality or whatever because they are...

F **Q** That is why I am asking you about that particular point?

A I am just saying that they were reported, because they were, and the author is giving a summary to that effect.

Q The next point is the following sentence:

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

I think Dr Elliman says that the case of SSPE was unlikely due to the vaccine, “again not mentioned by Dr Donegan”. Help us with that. Is that accurate by him?

H **A** Well, I have put that there is a report of SSPE one month after vaccination and I have put in that the child had a history of natural measles because it is known that this can occur after natural measles, that is why I put it in. Certainly the experts (Dr Conway and Professor Kroll) would know that a child who had natural measles, that could be a

A reason for the SSPE, but it was reported.

Q I do not think that Dr Conway commented on this. In your mind, "one report of SSPE appeared one month after vaccination", so you are making the point about the vaccination. The second sentence, "the child had a history of natural measles infection some years earlier". What was the purpose of putting both of those points together?

B **A** Because one is the reported incidence and the other one is sort of the corollary to say, well, they had had natural measles so that could have been the reason.

Q I do not want to put words in your mouth, but are you dealing with both sides of it then?

A Yes. I am saying that after vaccination, but also one month after vaccination is a shorter timescale than you would expect SSPE to occur.

C **Q** Can we deal with the next point, please. Page 55 of your report and page 38 of Dr Elliman's. The ITP point. This is one where you say:

"A study in France concluded that there was sufficient evidence of a clear temporal relationship between MMR vaccination and the occurrence of ITP to make a causal relationship highly plausible".

D Dr Elliman says:

"...a condition in which the number of platelets – this leads to a tendency to bruise easily... MMR vaccine is causally related to ITP".

I think he has put it higher than you?

E **A** He has.

Q His criticism is that you failed to point out that the reference notes that measles and rubella diseases cause ITP more than the MMR vaccine. What do you say about that? Do you need to put that in, in your view at this particular point when you were dealing with it or did you need to put it in at all?

F **A** Well, if you see which section this particular item was listed under on page 53, it is under, "Documented side effects of the MMR vaccine" so.

Q It maybe obvious but you had better conclude that point?

A So I was documenting side effects, which are documented, which is....

G **Q** Next point, I think, is page 38, last paragraph in Dr Elliman's report and the foot of page 55. You are describing the Avon longitudinal study:

"27 children were hospitalised for febrile convulsion after the MMR vaccination compared with an expected background rate of 16. Cases peaked two weeks after vaccination with 14 admissions compared with an expected four".

H Dr Elliman's criticism is that you used the latter figure. He says if you were presenting a balanced view, you would have used either formal comparison or both. In fact – let me

A quote it accurately otherwise I will be... He said, "Sorry. I am in error. I did not realise that".

All the figures are in the report, so Dr Elliman is in error in relation to those figures. They are all there. Yes? So I need not ask you about that.

B Page 56 of your report, foot of page 39. This is a dates' point. I am not really sure there is much in this. This is in relation to autism. Not described as a disease, you say, until the fifties. He says, in fact it was described in 43. I cannot remember the exact reference, I am sure we can find it. I think the effect of it was that it was not widely described until the fifties; I think that is what Dr Elliman accepted. Dr Elliman accepted that at D4/37A:

C "Q I think, to be fair, it was first described in 1943, but would you agree not widely described until the 50s?
A Yes, all right, yes".

I am not going to ask you about that.

Mumps. The foot of page 58 is where mumps begins. Page 41 Dr Elliman. Your comment is:

D "In fact it is thought that having mumps with recognised parotid swelling is a protective value against getting ovarian cancer in later years".

That is the point that you were making. Dr Elliman says,

E "This is based on one paper and based on patients remembering whether or not they had mumps".

We explored that in sufficient detail and I am not going to go back over that with you because I think that the study, when you look at it, actually balanced out the remembering...

F A Of both groups. So they should both be expected to remember and forget at the same rate.

Q Exactly. "In fact there is a study that comes to the opposite conclusion". Although his reference is wrong, it is DE36 rather than 34, did you know about that other study?

A No. I had not seen the other study.

G Q You have now looked at it, I think?
A I have.

Q And is that Gangarosa and Galaska?

A No. I think it is Chan or Chen.

H Q It is the Chen one, yes. The point that you put in there:

"In fact it is thought that having mumps with recognised parotid

A swelling is a protective value against getting ovarian cancer in later years”,

we have looked at that. I think it is a quote from the reference, your reference is 106?

A Yes.

B **Q** I am not going to look it up again but we have been through it...

A I was going to say that the study that Dr Elliman has produced, while correcting for the fact that people might have recall problems, because it is done on a serological analysis, is therefore looking at serological evidence of mumps, which means that people who had clinical and sub-clinical disease would be included and the West paper was looking at clinical mumps. He said clinical mumps, which with parotid (that is where you get the swelling *here*), according to his study was associated with a reduced incidence of ovarian cancer. The other study, as well as looking at a different population (because China has a very low incidence of ovarian carcinoma) was not looking at clinical mumps; it was looking at clinical and sub-clinical mumps because it was based on the antibodies, not on confirmation of clinical symptoms.

C

Q All right.

A So it was not directly comparable.

D

Q So the paper that he is referring to, DE36, is that the one you mean is not directly comparable?

A No.

Q Do you mean no or yes?

A No, it is not directly comparable.

E

Q Page 42 at the top of Dr Elliman's report and page 59 of your report at the foot. This is in relation to Leeds and Bradford:

“... there were increases nine times and 30 times the incidence between 2002 and 2001. One third of those affected were aged over 15, just the time when boys are likely to be made infertile.”

F

His criticism is that:

“The rise in this age group is for these reasons”

G

- that is to say that they might not have received the vaccine -

“and is not due to poor efficacy of the vaccine, although it is accepted that the mumps vaccine is the least effective of the three components.”

H

Then he gives his opinion as to what the answer is, although that I think is not in relation to what your report says, but is his own opinion, as it were. Just help us, what do you say about that? Do you deal with efficacy in relation to this or ...

A No, I am just dealing with the incidence of mumps in an undesirable age group.

A

Q Then the third point at page 60, top right-hand corner of your report, page 42 of Dr Elliman's. He says - it is a quote from *Pulse* and the quote is, there is

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

B

He says, "... no evidence to support this assumption". Do you want to look at the *Pulse* article or not?

MR KARK: It is 111, I think.

C

MR STERN: Thank you very much. I think it is, if I could just draw your attention, is it the right-hand side, about three quarters of the way down that begins, "The population among who". Is that the part?

A It is the last page.

Q You better tell me the bit that is relevant.

A It is the last page, middle paragraph, middle column.

D

Q Just pause a moment and let us get that. Does it have a 173 in the bottom right-hand corner?

A It does.

Q Middle column?

A Middle column. It is not the penultimate paragraph, it starts in the middle.

E

Q "Does this outbreak say anything about" ---

A It says, "The mumps virus identified ..."

Q I see.

A It is about three lines up from the penultimate paragraph.

F

Q "The mumps virus identified"?

A "... from several of our Stockport cases has been identified as G6 genotype.

G

Although this differs from the A genotype of Jeryl Lynn, the advice from the Public Health Laboratory Service is that cross-protection between strains should be sufficient. However, four of our confirmed cases had received two MMR vaccines and the remote possibility of a mutant strain (with limited or no cross-protection to the vaccine strain) selected out under pressure of immunisation should be looked into."

H

Q Just going back to the first page of that report, if we can, please. We can see on the right-hand side that it is a book from David Baxter, who is a district immunisation co-ordinator and consultant in communicable disease control at Stepping Hill Hospital, Stockport. Is that the same position that Dr Elliman holds, obviously not precisely the

A same because they are doing different jobs, but I think it is, is it?

MR KARK: I am trying to discourage Dr Elliman from having a conversation with Mr Stern across the ---

B MR STERN: I was not looking to have a conversation with him. I was merely asking a question. Do you know or not?

A I do not know if he still is but he certainly used to be the vaccine nation or immunisation co-ordinator for Merton and Sutton.

Q In any event, a similar sort of position. Did you have any reason to think this Dr Baxter might not be accurate in this *Pulse* report?

A I thought, bearing in mind his provenance, that he would be accurate.

C Q Just explain, if you will, please, how that quote - for those who are not medically in tune like me - how that actually relates to the point that you are making at the bottom of the first paragraph on page 60, if you would. This is the mumps causing the mutant strain. Just tell us, in a sentence or two, how that fits together.

D A Nature is very resourceful and so are microbes. This is a similar condition - it is a similar occurrence as antibiotic resistance. As we use a lot of antibiotics the bacteria can become resistant by modifying themselves and the ones that survive reproducing. It is possible when you vaccinate - this is what they are talking about a mutant strain - that a strain which normally might not have been very prevalent but now is having a survival advantage because it has not been addressed by the vaccine, might become more prevalent, if that is simple enough.

E Q At the risk of getting this wrong again, is this connected to Crowley and Afzal?

A Yes.

THE CHAIRMAN: Are you going on to rubella?

MR STERN: I am in a minute.

F THE CHAIRMAN: Shall we pause now?

MR STERN: I have not finished this particular point. I think Crowley and Afzal is corrected with this?

A Yes, it is.

G Q We have produced that paper ---

A It is in one of these D ...

Q Yes, it is a D thing. Do we need it?

A The Panel might like to look at it again to refresh their memories.

H Q D13 and that will conclude mumps. This is, I think if we just look at the summary - I think I have already looked at this with Dr Elliman - the summary, the last few lines:

A "These findings raise the possibility of emergence of a mutant strain under the selective pressure of immunisation, with limited or no cross protection induced by the vaccine strain."

A Yes.

B Q Is there anything else in the paper that you want to refer to?

A Just the "Introduction". Can I read it?

Q Of course.

A It says:

C "Since only one serotype of mumps virus is described, infection or vaccination with any mumps strain can be expected to produce lifelong protection against subsequent reinfection; and therefore the Jeryl Lynn strain of mumps used in most vaccines worldwide should provide protection against all strains of mumps. In spite of good vaccination coverage in most developed countries, occurrence of mumps outbreaks is reported periodically. These outbreaks are usually attributed either to the presence of pockets of unvaccinated children, or to primary vaccine failure in persons who do not seroconvert after vaccination, or to waning of vaccine-induced immunity. The possible role of different strains or genotypes of mumps virus in reinfection is not usually considered."

D

Q In a sentence - for the likes of me and others - what is the significance of that that you are drawing our attention to?

E A The possible emergence of a mutant strain which is not covered by the virus in the vaccine.

Q Looking at the summary, does that add any more?

A No, it was just some of the process.

F Q More scientific?

A Sorry.

Q But it comes to the same thing?

A Yes.

G MR STERN: Do not apologise. It is just important that we understand what you are saying about that and make sure we are not missing something. Thank you.

THE CHAIRMAN: We will return at twenty-to four.

(The Panel adjourned for a short time)

H THE CHAIRMAN: Mr Stern?

MR STERN: Rubella, please. First point, page 60 of your report at the foot of the page,

A and page 43 of Dr Elliman's report. Again, I think this is one we can deal with rather swiftly. This is another Harrison's 11th Edition point, is it not?

A It is.

Q Let us move to the next, please. Page 62 of your report, in the middle paragraph:

B "In the five years before the rubella vaccine was introduced in 1970 there were only 39 babies born with congenital rubella. In the ten years after 1970 there were 454 cases. Even assuming..."

- and we will leave out that sentence -

C "... in the ten years after 1980 there were still 333 affected babies. So the number of cases have gone up."

What did you mean by "the number of cases have gone up"? In which way? From where?

A From the table that I was quoting from, the cases had gone up from 39 to 454 and then started coming down to 333.

D **Q** I think that is 1970, 39. Dr Elliman makes the point that you had misunderstood the BPSU report and that the cases only went up because there was not reporting before, I think is generally what he is saying?

A Yes.

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

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

Q Let us move to the third point, which is Dr Elliman, page 44, bottom of page 62:

"Vaccinating 12 to 15 months old with rubella (in the MMR vaccine) and again preschool almost guarantees..."

F - it is the "almost guarantees" I think -

"...that their antibodies to rubella will have worn off by the time they are likely to become pregnant."

G I think Dr Elliman's point at page 44 is:

"The authors do agree that they cannot be certain how long immunity lasts and it is important to monitor the situation. However, Dr Donegan's statement 'almost guarantees' is not in keeping with the evidence."

H What do you say about that?

A I think, on reflection, I could have been more circumspect. I have on the next page in ---

A

Q Thank you, I was trying to work out what my reference meant.

A In the second paragraph ...

Q Thank you.

A ... be more circumspect.

B

Q Yes, I think in relation to exactly the same point you have used the word "likely" at page 63, over the page, second paragraph down, second sentence:

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

C

Is that the same point?

A Yes.

Q So you have, as you say, perhaps put it in one way "almost guarantees" and then "likely" in the next bit. Which would you prefer, bearing in mind - now, on reflection?

A I think that "likely" is preferable.

D

Q Can we deal with "HOW VACCINES WORK", which begins at 64? The bottom right-hand corner is "HOW VACCINES WORKED". This, again, I think needs a little explanation. Page 45 of Dr Elliman at the top, just help us, please, it says:

"Vaccines are intended to induce protective antibody formation by mimicking natural infection. However, the antibodies produced by vaccination (IgG) are only the final stages of a long series of protective measures by which a child deals with infections."

E

In this paragraph and over the page, we see IgG and IgA. I think there is also an IgM as well, is there not?

A Yes. The IgM is an acute phase antibody that is produced during acute initial infection.

F

Q Is that relevant to how vaccines work or not? You have not included IgM.

A The point I was making was about IgA and, for the sake of completeness, I could have put the IgM but it was the IgA mucosal antibody that I have mentioned before with reference to whooping cough and polio, oral polio vaccine.

G

Q Dr Elliman does not make any criticism about IgM. I just wanted to deal with that for the sake of completeness, as it were. We can leave that to one side. IgG, what does that do?

A The IgG antibody is the one which higher levels are present after somebody has had natural infection or infection secondary to active immunisation.

H

Q What about IgA?

A The IgA occurs also but not with vaccines.

A

Q So you get IgG and IgA ---

A And in the acute phase ---

Q Sorry, let me finish. Forget about IgA for the moment. You get those two with the natural disease?

A Yes.

B

Q With the vaccine you only get IgG and IgM but there is no need to ---

A Out of the IgA and the IgG you get IgG.

Q That is what I meant. So just help us with what you are actually saying here in relation to this?

C

A I am saying that with vaccination in terms of the long-term period after vaccination, there is only one of the types of antibodies that have been induced by the immunization, so you are not protected in the way that you would be with the mucosal antibody that might be produced from natural infection.

Q Over the page at page 65, it says:

D

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

He does not say which, but I think in his report at page 45 he says that that is not right, that those are not the only antibodies that are induced. What do you say about that?

A He is correct when he points out that IgM is produced.

E

Q What is the point that you are making then in relation to that?

A I was making the point about lack of mucosal antibody. The mucosa is an important first stage barrier for organisms to have to get past or breach when they infect you.

Q Were you dealing with IgM in that paragraph at all, or not?

A No, I was not, but certainly for the sake of completeness I could have put it in.

F

Q Page 66, the bottom right hand corner, of your report; page 45 of Dr Elliman's report. At the top of page 66, this is the thiomersal 1999, and then you have included the same reference, although I think you have expanded on it by calling it “the product information”. This is the one that Dr Elliman could not find, do you remember, at the top of page 66?

G

A Yes, product information.

Q Then we have:

“In May 2002, pregnant women, babies and children under the age of 16 years...”

H

et cetera, but I think the actual point is about six lines down, where you say:

“In children possible effects on the developing nervous system might

A lead to impaired mental skills, such as attention and memory, and physical incoordination in childhood.”

I think we actually do have to look at your reference 117. Just help us with what you were talking about here, because it is sometimes rather difficult when you just take a sentence in the middle of a paragraph to explain what it is that you are talking about. If we look at little further up, we can see:

B

“In May 2002, pregnant women, babies and children under the age of 16 years were advised to stop eating shark, marlin and swordfish as a precautionary measure because high levels of mercury have been found in these fish. The risk was said to be highest in babies *in utero* as mercury can damage the developing nervous system. In children possible effects on the developing nervous system might be impaired...”

C

et cetera. Where did you get that from, please?

A I got that from my reference marked as 1, which is the GMC tab 117, and it is page 3 of 5, and it is the second paragraph after the question, “What are the possible adverse effects of high mercury intakes from food?”

D

Q We can see:

“In children possible effects on the developing nervous system might lead to impaired mental skills, such as attention and memory, and physical incoordination in childhood.”

E Is that the point you are making?

A That is the point I am quoting from the information provided by the public health link from the Department of Health.

Q What were you talking about – the possible effects of what?

A There I am talking about what they have regarded as problematic in terms of the possible effect of eating compounds containing mercury.

F

Q Were you talking about the vaccination there?

A No. I went on to the vaccination about three lines later.

Q I think it begins, “Ethyl mercury is injected into babies in many of the childhood vaccines”?

G

A That is correct.

Q I think Dr Elliman’s comment is that you provide no evidence that they have caused damage to children as a result of vaccination, but was that what you were saying in any event? I think you have already answered it, but were you saying that it was as a result of vaccination?

H

A No, I was then carrying on and asking a question after that. I was hypothesising.

Q I think you were just dealing with what appears to be the high levels of mercury

A found in fish?

A Yes.

Q Just before we get to the second report, can we just go back to the chronology, as it were, so that the Panel have that in mind? The next report in time is Dr Conway's, dated 19 November 2002, which is a response to your report of 14 June – correct?

B A Correct.

Q It is bundle 4, C2. I do not need to look at it in any detail with you but I just want to ask you one or two matters about it.

MR KARK: I think it is B4.

C MR STERN: I said "C4". I am sorry, it is my mistake. It is B4.

THE CHAIRMAN: No, B4.

MR STERN: C4/B4.

Q Just looking at the foot of the page, we can see "Prepared on 7 September 2002". It is in very small type, but I think, as we have seen from the correspondence, you did not receive it until 19 November?

D

A Yes, 19 November.

Q Which is why it features in my schedule as being dated 19 November 2002. This was a response by Dr Conway on a paragraph by paragraph basis?

A Yes.

E Q Thereafter, there was a report by Professor Kroll dated 28 November, which is C4/C3, where essentially he adopts Dr Conway's report and makes further points as well?

A Yes.

Q You have told us about the timing of those. Just in general terms, having received those, they were obviously – well, particularly Dr Conway – critical of your report?

A Yes.

F

Q Did you then prepare this second report, dated 4 December 2002?

A I did.

Q Is there any more that you want to say about Dr Conway's report or Professor Kroll's report before we move on to look at your second report?

G

A No.

Q Let us look then at the second report that you prepared. Dr Elliman's comments begin on page 46 in relation to it. In your report it is pages 73 and 74.

THE CHAIRMAN: This is an administrative point. The numbers in our bundles are one higher than in your list.

H

MR STERN: Yes, they may well be. Do you mean in relation to Dr Elliman's report?

A

THE CHAIRMAN: Yes.

MR STERN: I am sorry about that. You have the paragraph numbers, so that will probably reduce any confusion.

B

Q If we look at paragraph 1.5 of your report... I am sorry, there is actually a comment just before that. I think Dr Elliman makes a comment in relation to 1.3 and 1.4, where you have set out various comments. No, I am sorry, I am going to leave that. Let us just go to 1.5. I do beg your pardon. In essence, what he is saying in relation to this is that the tone of the paper relied on by you is very much in favour of immunization. What do you say?

A Well, here I was answering a specific point raised by Dr Conway, which I answered. The tone is somebody's opinion.

C

Q All right. Next, please, also paragraph 1.5 but over the page at my page 77, probably your page 78, where it says:

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

D

Then you set out a number of examples and ---

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

MR STERN: It is page 77 of Dr Donegan's report, page 49... I have in my schedule a note that says “withdrawn”, but I may be wrong about that. I may have to come back to it.

E

MR KARK: Where is this? Is this on B)?

MR STERN: Yes.

MR KARK: I think the evidence was that so far as Sweden and Finland are concerned, Dr Elliman was saying that the report was still wrong, but so far as the USA giving up its efforts to eradicate measles in 1968, he accepted that.

F

MR STERN: That is right, yes, that is the point. I do not think there is any reference to Finland in B). I think once Dr Elliman saw the particular passage in the Orenstein paper... yes, thank you, so I think I can move on from that.

Q Next, please, page 78 of your report, again 1.7 and 1.8; page 50 of Dr Elliman:

G

“Dr Donegan's quotes are correct, but both articles point out the value of immunisation in preventing diphtheria.”

What do you say about that?

A Sorry, can I just find Dr Elliman's? Which page is it?

H

Q It is 49 for you and me. I do not mean to whinge about this at all, but I wonder if Mr Kark could indicate in due course the letter that shows that we were sent the repaginated version many months ago. None of us over here seems to have it, and that is

A a strange omission if indeed it was sent many months ago, so if Mr Kark could provide the correspondence, I would quite like to see that.

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

B MR STERN: I am sorry, I cannot hear you.

THE CHAIRMAN: There is a blank page, a sort of not typed up page, which has ---

MR STERN: I am not disputing that everyone else has the same page numbers. All I am suggesting is that we on this side do not, and I do not quite understand how we have all managed to miss this new version.

C THE CHAIRMAN: It is page 45 and it is virtually blank except for a few words.

MR STERN: Thank you very much. So that is what accounts for the extra page. As I say, I will do my best. I am on paragraph 1.7 and 1.8 of page 78 of Dr Donegan's report and there is no complaint about the quotes.

D Q But should you have added, according to Dr Elliman, the value of the immunization in preventing diphtheria? That is really it.

A Well, here I am answering Dr Conway.

Q Quite.

E A Who has agreed that the chances – I am reading from Dr Conway; I think I have a different numbering from you; it is Dr Conway, paragraph 1.12 – he agrees that the chance of contracting diphtheria for any individual living in the United Kingdom is low but that there is a real risk nonetheless, and that it can be brought into the UK by a traveller and a non-immune person coming into contact with such a person is susceptible, and he says that it is a significant risk for anyone travelling outside the UK, especially in eastern Europe or Africa, which is why I brought in the quote to answer what he said, which was from the Dittman paper, which is "Importations of diphtheria to other highly industrially developed countries with high rates of adult susceptibility have not led to significant secondary transmission." That is why I brought in that quote.

F Q That is very helpful. Thank you very much. The next point is at page 82 of your second report, paragraph 1.15. This is one where Dr Elliman could not find the reference in the paper and therefore we have no evidence in relation to that, so I will move on to the next one, which is page 83 of your report, paragraph 1.17. This is the Professor Stewart point in the *Lancet*. The criticism is that you failed to use Mallis and Bennett, which is a paper that apparently follows on.

G 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.

H Q Did you see that paper?

A Not then, I have now.

A Q I am talking about the time when you wrote this report?
A No. I had not read it for this report.

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.

B Q In any event, the point is that you had not seen it, as I understand what you are saying.

The next point, please, page 87. 1.26. Second half of that particular passage:

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

Dr Elliman’s criticism is that use of the term “may” could be misleading. What do you say about that?

D A Well I use the term “may” because basically we do not know one way or the other, there is no evidence to show causally whether it does or it does not.

Q Is there any more you want to say about that or is that it? Does it imply “causal” to you if it says “may”?

A No. I mean “causal” is a very specific word and had I been meaning “causal” I would have written “causal” because it is a word that has very significant meaning.

E Q I think, as we have seen, you have used the word “cause” in relation to one or two instances. When you use the word “cause” what do you specifically mean?

A I mean that it has been accepted by some authorities, such as the Institutes of Medicine or it is written on the package insert or it is accepted, for example in that article by Dr Cutts when they say, “This has been accepted as causally related to this vaccine”.

F Q When you say “may” do you mean that there is a causal connection or not?

A No because if there had been a causal connection I would have written “a causal connection”.

G Q Next point, please. Page 90 of your report. Paragraph 1.33. This is in relation to the Pollack/Morris paper, which you are dealing with there at the foot of page 90 of your report. Over the page, half-way down, that top paragraph says:

“However the conclusion was that, *“The neurological disorders reported in the voluntary system as reactions to DTP were too widely divergent to suggest a common aetiological agent. Taken individually, since such disorders are known to occur in unvaccinated children ... none could be attributed to the vaccine”.*

H

A Dr Elliman's criticism is that the summary of the paper says:

"There is no convincing evidence that DTP caused major neurological damage emerged from this large and lengthy study"

Then he says:

B "The paper itself ends, 'We cannot rule out the possibility that some vaccines may on rare occasions cause brain damage, but no convincing evidence of this has appeared during our study' This is important as it implies that if there is a link it is rare and by omitting this may mislead".

C Help us with that. He is saying that you should have put in that it rarely causes brain damage. I think you have put in, "None could with any confidence be attributed to the vaccine". Is there any difference? Have I missed something here?

A Yes. I mean I started saying that the, "neurological disorders were too widely divergent to suggest a common aetiological agent and none could with any confidence be attributed to the vaccine" so...

D **Q** Is there any difference between what he is suggesting and what you have included there?

A Well I suppose there probably is because he thinks there is, but to me I have put in that "with any confidence it could not be attributed to the vaccine" and also that the "present study was small and the findings should be retested in a larger investigation".

E **Q** Did you intend there to be any different meaning from that, which he has set out at the end of the paper?

A I do not... Well, I certainly think I indicated that it was by no means proven.

Q Next, please, page 94 of your second report. Paragraph 1.41. Dr Donegan, if we see what Dr Elliman says first of all. He says you comment on figure two and three in the paper of *Shields*.

F "She fails to mention that apart from febrile convulsions there was no statistically significant change in any of the distributions in spite of the change of pertussis vaccination timings".

Then he says:

G "The simplest explanation is that pertussis vaccination has no effect on these conditions with the exception of febrile convulsions. This will be in keeping with most of the rest of the literature. To say that no effect was seen because of the removal of the adjuvant and reduction in potency does not explain why there was no significant reduction suspected adverse effects at the ages when pertussis was no longer given".

H Looking at page 94 of your report you set out there quite a lot about the graphs. Then over the page at page 95, again half-way down, it says:

A

“The authors go on to conclude that no association between the occurrence of epilepsy and immunisation was observed. In the present study 350 children have bacterial meningitis or aseptic meningoencephalitis. It is reassuring to find no association between pertussis immunisation and the occurrence of these neurological illnesses”.

B

Leaving the last sentence just for a moment, we will come back to it, is there any difference from what Dr Elliman is criticising you for omitting than the conclusions that you have included in that particular paragraph, or any significant difference?

A Well he mentions febrile convulsions and I have not mentioned them, as far I can see, although maybe I did at the beginning.

C

Q You put, “No associated”...

A ..“and immunisation”. They also say:

“in the present study, 350 children had bacterial meningitis or aseptic meningoencephalitis. It is reassuring to find no association between pertussis immunisation and the occurrence of these neurological illnesses.

D

Q It is really the conclusion that I am asking you about. Is there any difference, in your view, between the conclusions that you have set out and his criticism; any meaningful difference?

A Not really.

E

MR STERN: I think actually during the course of giving evidence Dr Elliman changed his criticism. In the last sentence of that passage it says, “This is not what might be deduced from looking at the graphs”, and I think he went on to criticise that point.

We do have some copies of this. Although it is in your bundles already there are copies with particular points on it that will help you understand the point that Dr Donegan was making. Can I ask that they be handed to you now so that I hope that will make life easier. *(Same handed)*

F

THE CHAIRMAN: This becomes D23.

G

MR STERN: *(To the witness)* This is from DE52. Dr Elliman spent a bit of time giving an explanation. I want to deal with this as simply and as shortly as we can please and then just make your point on it. Direct, if you will, the Panel to the particular point you want to make and which page?

A Okay. I would like to start off on Dr Elliman’s page 54 where he says:

“To say that no effect was seen because of removal of the adjuvant and reduction in potency does not explain why there was no significant reduction in the suspected adverse reactions”.

H

this is the important bit,

A

“at the ages when pertussis was no longer given”.

Q Right?

A I put some coloured things on these marks on these graphs because I find it very hard to keep my eye on the ball without some external help.

B

Q Which one would you like to...

A If we look at 803.

Q That is the first page?

C

A The hard line is 1967 to 1968. That is when the whooping cough was given with the diphtheria and tetanus and the IPV (the inactivated polio), which you will see on the graph is the little red bit (that is the pertussis) and the green bit is the diphtheria and tetanus and the inactivated polio vaccine. They were given at periods between four to eight months and 15 to 19 months and that was the hard line on those graphs.

Afterwards, when they looked at cases between 1972 and 73, the pertussis was taken away from the diphtheria and tetanus and inactivated polio vaccine and it was given at different times; it was given between one to three months and nine to eleven months.

D

You would expect if, for example, the epilepsy rates or the febrile seizures or the infantile spasms were occurring due to the whooping cough vaccine at the times that there is a little peak on the epilepsy (one at four to eight months and at 15 to 19 months) that when you remove the whooping cough component then the 72 to 73 line, which is interrupted, would come down then and maybe possibly go up where the little blue blobs are, which is the new post-1972 to 73 time it is given. Dr Elliman is saying so you would expect the dotted line/interrupted line/the dashes to be lower there.

E

My point is that when you look at these graphs, in fact what is still left at the time that the whooping cough used to be given is the diphtheria and tetanus and the inactivated polio vaccine, which I have not proved a causal association with but there have been reports of effects happening after and temporarily related to the diphtheria and tetanus and certainly they contain adjuvants, which are the vehicle that go in it. So if you look at that, you will see it has not come down but I would contend that some of that is because they are still

F

having another vaccine there; if they moved all the vaccines to the new ages then you might have a better idea of what was happening.

If you look at page 804 and remember that there has been this question postulated about increased invasive bacterial infection and whooping cough vaccine, you will see that these graphs are looking at CNS (or central nervous system infections), bacterial meningitis and aseptic meningoencephalitis. You will see on those ones that when the whooping cough vaccine is not given between the four to eight months group in those smaller babies, that in fact the dotted line does come down.

G

Q I think your time is up on that...

A I am sorry about that.

H

As I quoted from the paper – well in fact I did not. It does say in the paper that there was an increased in central nervous system infections, which they thought were due to a

A change in referral patterns. As I say, that was my point with the colours on the graphs and the reason why, to my mind, it might not have come down after the whooping cough times was moved. Sorry to...

Q No. Do not apologise at all. Do I take it you do not accept the criticism by Dr Elliman?

B **A** You do.

Q Can we do 102, please, which is the next point by Dr Elliman. Paragraph 1.56. This is in relation to the Oman study at the top of the page at 102. I certainly am not going to ask you to look at that unless you particularly want to.

C “The authors and Dr Conway ignore the fact that the outbreak occurred, *‘in the face of a model immunisation programme.... The region with the highest attack rate had one of the highest coverage rates whereas the region with the lowest coverage had the lowest attack rate’* could be due to the vaccination campaign causing the outbreak. OPV is a combination”,

D et cetera, et cetera. His point in relation to this paragraph is that quote is accurate and correct,

“However, she seems to be implying there might be an inverse relation between uptake of vaccine and cases of polio and hence her statement that the programme may have caused the outbreak”,

E in fact there is no relationship, he says, between uptake and cases. What do you say about that?

A I was giving examples of this in terms of the worldwide polio where outbreaks of paralytic poliomyelitis have occurred at the time of a vaccination campaign certainly showing – I have not actually quoted this correctly. I quoted it correctly in my first paper but I have not quoted it correctly here. I put, “The region with the lowest coverage had the lowest attack rate”. In fact I quoted it correctly in my first paper, which said, “The region with the lowest coverage had a low attack rate”. The fact that the outbreak occurred at the same time as a vaccination campaign is the case and certainly there was no correlation between the polio vaccine given and the uptake, which should have been because where it was very high people should have been more protected if it was going to work. I presume that the differences are because of the different types of social – environmental positions pertaining in the different areas that were looked at in the study.

G **Q** You say that your point stands?

A Yes.

Q Page 107 is the next point. Middle of paragraph 1.68. 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?

H **A** Yes.

Q Do you want to say anything about it?

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

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?

B 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.

C Q Were you dealing with vaccine efficacy or cell mediated immunity?
A Cell mediated immunity.

D Q The next point is page 111 of your report at the foot of the page. This is the same reference and the same point if one looks at Dr Elliman – I think he has repeated it. It is probably page 59 of his report. It is under the heading “Page 111, 1.84”. I think it is just a repeat of the third point in relation to mumps. This is Dr Baxter, the one we looked at a little earlier, is it not?

A Yes.

E Q The immunisation coordinator, it is the *Pulse* point. You do go on to say, if we look at page 112 of your report, in the top paragraph:

“He later asks what this says about vaccine efficacy and emphasises the need for a two-dose MMR programme, ‘for protection against measles, mumps and rubella’, but this last comment is entirely speculative and I reiterate the observation made throughout this and my previous statement: that vaccination lowers the incidence of the vaccinatable disease at the usual age and leads to increasing incidence in younger and older age groups.”

F That is what you were saying?

A Yes.

G Q Do I understand from that that your view is that vaccination works?
A It has an effect on the incidence of a disease.

Q You put that better than me. Just so we understand, what is the “but”?

H A But it moves it into ages, in my opinion, that are less desirable, particularly in diseases such as whooping cough and measles when it starts occurring in younger, more vulnerable children. It is also very difficult for older people to have, particularly episodes of, for example, clinical measles or mumps. In mumps it is much less desirable – and rubella.

A Q The next point, I think is at the foot of page 112 of your report, paragraph 1.86 and Dr Elliman deals with it on my page 58, probably your 59. Again, this is a quote which you have included in relation to a paper and his criticism is:

B “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. They concluded ‘The current evidence does not therefore suggest an association between mumps vaccine and diabetes’. To omit these points is very misleading.”

I think actually we need to look, do we not, to Dr Conway’s report to see what it was he was saying and you were responding to?

C A Yes.

Q If we look at Dr Conway’s report of 19 November 2002, which you will find at B4 of C4, because the pagination is all changed I am afraid I cannot give you the bottom right-hand corner pagination but the top page numbers are page 50, top right-hand corner. It is the last paragraph, 1.63. At the foot of that page it should read “Mumps is a safe vaccine”, do you have that?

D A Yes.

Q Then the paper that he quotes:

“Complications of mumps vaccines”

(and he sets out the reference)

E “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’.”

F So he has already put the conclusion in?

A Yes. Yes, he has.

Q He goes on:

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

so again he has put that point there, has he not?

A That is his point.

H Q That is his point, yes.

A “...evidence of the overall benefit to the population of mumps immunisation.”

So the criticism by Dr Elliman is that you do not put in the conclusion effectively, I think is what he is saying?

B A I was commenting on what Dr Conway had said when he said the mumps vaccine was safe, and he had not put in all the other factors which I have brought to his attention in this paragraph in my answer to him.

Q Your answer at the bottom of page 112 is:

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

So you are effectively responding to what he is saying in his report there?

A Yes, about the same paper.

D **Q** About the same paper – exactly. I think the same is true of the next point. If we look, please, at page 113 of your report, this is where you are setting out the highest reported incidence in New York, but if we look at what Dr Conway is saying this is a continuation

– your point here is a continuation of Dr Conway’s paper, if you like?

A It is the continuation on my comments on his comments of his paragraph 1.63.

Q Because if you look at 1.87, your response, it says:

E “The same paper”

- that is the one, I think, that Dr Conway was referring you to –

“also considers”

and then various things, and then:

F “Regarding allergic reactions, ‘it is difficult to be precise about the incidence of these reactions...’ It is surprising that such case definitions were not refined during initial safety trials and post marketing surveillance.”

G You are, as I understand it, quoting from the paper that he has put forward?

A I am.

Q Page 116 of your report, paragraph 1.92, page 59 in Dr Elliman’s report for us and page 60 for you, again you are commenting on a report that Dr Conway referred to at the top of that page:

H “that susceptibility to Rubella as measure by the proportion of the female population without antibody to rubella rose...that proportion

A of antenatal women without antibody while falling from 1987, rising to 1993, and sustaining a brief fall in 1994 started to climb again by 1995.”

A Yes.

B **Q** Dr Elliman’s comment is that you are right to sound a note of caution but it cannot be denied the programme has been successful. That does not seem to have taken into account anything that Dr Conway has said about that, which is 1.65, where he sets out on page 51 in the top right-hand corner:

“Dr Donegan quotes figures (unreferenced) to prove that the rubella vaccine is ineffective. We refer the Court to...”

C then he refers to page R30.

“The table clearly shows the fall in incidence of congenital rubella syndrome and infection. The accompanying text states ‘the incidence of congenital rubella is now very low and most affected infants are born to women who came to the United Kingdom as adults and were not covered by the school girl immunisation programme’.”

D So he has set out there---

A His premise.

E **Q** ...his premise, which is that the programme was successful?
A Yes.

Q Next paragraph:

“The story of a child with congenital rubella syndrome born to a mother who had been vaccinated in the school immunisation programme referred to by Dr Donegan cannot be taken at face value.”

F Then he criticises your point?
A Yes.

G **Q** Your response, as we can see at 1.92, you just make further comments about the paper that he has provided?
A Yes. Could I just make one little point?

Q Yes, certainly. You can make a big point, if you like.

A My figures were not unreferenced. My figures from page 62 of my first report quite clearly give the reference which is number 4 in my numbering and it is the GMC 115, so it was referenced for him to look at.

H **Q** Page 117 of your report, paragraph 1.94; Dr Elliman’s 59 for you, probably 60 for

A the Panel. Again looking at Dr Conway, because this is a reply to Dr Conway, although not mentioned by (I do not think) Dr Elliman, page 52 top right-hand corner Dr Conway says:

“Vaccination against measles, mumps and rubella is safe.
Conclusions...”

B – he then quotes a number of papers there –

“Comprehensive analysis of the reported adverse reactions established that serious events causally related to MMR vaccine are rare and greatly outweighed by the risk of natural MMR disease.”

C So he is saying there is a comprehensive analysis of the reported adverse reactions. Your response then, at page 117, is:

“Dr Conway states that MMR vaccine is safe. This is an opinion. He then quotes two studies to back his opinion. I refer the Court to a review presented”

D and then this is the Cochrane review that Dr Elliman produced two pages of and we then produce two further pages of which you have there, so I am not going to go into the detail of it, but you have then quoted from the Cochrane review. What was the purpose of quoting the Cochrane review in relation to what Dr Conway was saying?

A To point out that the person who is the lead person in the vaccine division of the Cochrane review had pointed out how few of these studies were acceptable in terms of providing actual evidence of safety.

E **Q** Yes, because Dr Conway is saying that it is comprehensive analysis that causes adverse reactions etcetera?

A Yes.

Q Dr Elliman’s criticism though of you at page 59/60 is that you used *Pulse*?

A Yes.

F **Q** He then goes on to say that the published report, the Cochrane report, was not actually published then?

A No, it was not.

G **Q** We have looked at the publication. Is there much difference between the Cochrane collaboration full paper, as it is now published, and the *Pulse* article?

A The final conclusion is more circumspect, having said, as Dr Elliman has reproduced in his report:

“We could not identify studies assessing the effectiveness of MMR that fulfilled our inclusion criteria...”

H and then they go on with:

A “...even though the impact of mass immunisation on elimination of diseases has been largely demonstrated”,

But that is not the same as finding studies that assess the effectiveness. Then they say:

“The design and reporting of safety outcomes”

B (which is the point in question)

“in MMR vaccine studies both pre and post marketing are largely inadequate.”

C Having said that, they then go on to say, basically, that immunisation with MMR cannot be separated from its role in preventing the target diseases, but that is not the same as evidence of safety.

Q We looked at the Cochrane collaboration and I am not going to go over that again, Dr Donegan. Page 130 of your report, which is, I think, the final point, paragraph 2.31, and Dr Elliman’s point at his page 60 or 61, he has in fact included precisely the point that I think he dealt with in relation to the first report?

D **A** In the Hib section.

Q It is a complete repeat; he has obviously cut and pasted, I think, the same thing because he says:

“She says”

E - I think that is you –

“she was just being descriptive. Why mention it if it is unimportant? Most people will assume that if mentioned it has some relevance and most will assume a link. If no link is claimed that should be made clear.”

F I think you have, if one looks at page 130, paragraph 2.31, you say, in response to Dr Conway:

“I have not claimed either cause or association, paragraph 3 of my page 25 is entirely descriptive, however, I refer Dr Conway to my reference (1), Harrison’s Principles of Internal Medicine, 11th Ed...”

G In fact, that very point is set out there that you had put in your first report with the specific reference and quote from the 11th edition, is it not?

A Yes.

H **Q** The one that Dr Elliman thinks that he could not find. So that ends the reports and I want to just look very briefly with you, please, at the short part of your evidence in the High Court. Are you all right to carry on, Dr Donegan?

A I am.

A

MR STERN: Is everyone else all right to carry on, may I ask? It is quite tiring.

THE CHAIRMAN: Dr Donegan, are you sure you are okay?

A Thank you for your concern but I would quite like to finish this part, thank you.

B

MR STERN: This is, I think, the less taxing part and I am coming to the end, so it would probably be helpful if everyone could bear with me for a little while if I just try and finish this part and then that will be the end of Dr Donegan's evidence-in-chief.

THE CHAIRMAN: So we should have in front of us C7, which is the High Court transcript?

C

MR STERN: Yes, it may well be. I am going to refer, as I say, to the numbers in the middle of the page, as I indicated the other day before you had read it.

Q Can I just look, please, at the bottom of page 3? This is how it starts: "I have the bundle but I don't have the numbering." As I understand it from this part of the transcript, you did not have even a numbered joint medical bundle?

A No. I had my separate references in a box, because they had not been paginated in any way that was reproducible for me.

D

Q I think that was handed to you as you were giving evidence?

A Yes. It was very hard actually, extremely hard, because I could not refer to anything because I could not find it. Other people had a set of references with numbers but I did not.

E

Q I know the feeling! On page 24 you say:

"Well, unfortunately the person who did a brilliant job of getting some of the references themselves, rather than getting them off me, used the 15th edition of Harrison's, which is 2001, and this is actually the 11th edition of Harrison's, which is 1997, which I can show you."

F

A Yes. It is actually 1987 but we will not worry about that.

Q Had anyone actually spoken to you before you went into court and asked whether or not you had these copies or these documents?

A No.

G

Q Page 5. The reason I am going back is because I am not dealing with it chronologically. I am sure that this is a point known by everyone but I make it just in case it is not. At the foot of the page, you say,

"Generally in general practice it is health visitors who administer vaccinations."

H

I think that in the main doctors do not administer vaccinations in general practice, do they, or do they?

A In the main, they do not.

A Q On page 6, line 7, you were asked about advising parents and you said:

“When parents ask me what they should do about vaccination, I say it is a decision they have to make themselves, but they need to be well informed.”

B I think there are a number of references to this and it is expanded on in a number of different points but, in essence, is that a fair representation of what you were telling the court and what you have told the Panel?

A It is.

Q I want to deal with the question of research. On page 9, line 3, the learned judge put to you:

C “You were saying that it is a very subtle process which is not fully understood as yet.”

You said:

“At the moment ... although it is the subject of ongoing research.”

D To what were you referring at line 7?

A I was referring to the research that is going into what they call PNI, which is psycho-neuro immunology.

Q At page 13, line 11, you are asked:

E “And what weight have you given to the position – particular positions of the mothers in these proceedings and their opposition to vaccination?”

You say:

F “Apart from that at the end of my first statement, I have not given any.”

Is that right?

A That is correct.

G Q You were then asked:

“But you have written it with a view to the interests of these particular children?”

You say:

H “Each time I’ve described the disease and its epidemiology, and its vaccine, that has just been descriptive.”

A Is that what you intended to do with your report, to make it merely descriptive in that regard?

A That was my intention.

Q You go on to say:

B “At the end of each disease and vaccination, I give a recommendation which is specific to the children”?

A That is correct.

Q By way of example, I want to take diphtheria. It begins on page 22 at line 8. At line 19, you say, “It can certainly be very severe and can cause death”?

C A Yes.

Q At page 30, speaking about the Soviet Union socio-economic groups, at the foot of the page Mr Justice Sumner says:

D “Though this is very interesting, I am trying to relate it to – what it appears to say is that the mode of infection in the newly independent states can vary?”

You say:

“I think what it is saying is that social conditions can make a big difference to whether or not you have a diphtheria outbreak, and --- ”

E Then at the top of page 31:

“MR JUSTICE SUMNER: Well, on the basis that it may be that in this country social conditions are ---

A Are good.

F MR JUSTICE SUMNER: --- are better than that ---

A Yes.

MR JUSTICE SUMNER: --- there is less risk of an infection.

A Correct.”

G Does that fairly summarise your view in relation to vaccinations?

A Yes.

Q Page 32, please. In the middle of the page – it may not matter which particular research you are looking at – this is cross-examination by counsel on behalf of the fathers:

H “Q So Dipman and the author of the article you have just been looking at – they both advise, do they not, that it is important to maintain the level of immunisation in the population to stop outbreaks occurring?”

A

A They say that and it must be pointed out, in a lot of these papers, that ---

MR JUSTICE SUMNER: Sorry, I am struggling to keep up with all those more familiar with the papers than I am ... Dipman is the author of ---

B

MR COHEN: Dipman is the author of the article that begins at..." --

et cetera. Over the page, Mr Cohen says:

"And indeed not one author to whom you refer says anything other than that immunisation against diphtheria should be provided routinely?"

C

Your answer is, "I agree. That is what they say". After Mr Justice Sumner has taken a note, you say:

"I would make the point that the facts presented by authors in their papers are sometimes not reflected in their conclusions, and this is particularly the case regarding promotion or otherwise of vaccination as a method for control of these diseases."

D

I think that is the point you are making in relation to conclusions of papers generally. Is that right?

A Yes, that is correct.

E

Q The next bit is:

"You are not suggesting that they authors are, deliberately or otherwise, intellectually dishonest when it comes to the writing of their conclusions? Is there no other explanation?"

You say:

F

"I do not think they are being intellectually dishonest. I think that they are so pro vaccination that they sometimes do not see the wood for the trees."

G

You then agree with counsel, who says:

"Does it occur to you that perhaps they are right and that description could be applied to you?"

and you say:

H

"I agree. However, having said that, it's of no professional or financial benefit to me to hold the views that I hold about vaccination."

A

A I can heartily agree with that.

Q Over the page, the learned judge asks whether he is entitled to regard most of these articles as written by respected academics, and you say “Yes”? (*No verbal reply*)

B

THE CHAIRMAN: Could you say “yes” for the transcript?

A Yes.

MR STERN: Going to page 35, you were asked whether or not the conclusions ought to have been included in your paper. I am summarising what are a number of points made here, but essentially, when it comes to it, you were asked whether or not the conclusions should have been inserted in your paper, and you said “Possibly”. What do you say about that?

C

A Well, when I am researching into vaccination, I have to be very careful about the conclusions. When I am looking at any scientific paper... In fact, I think this was the advice in a paper in the British Medical Journal, I think maybe in 2005, Montori et al, where they said it was guidance for how to read scientific papers, and they say that you should always read the methods and the results before you read the abstract or the conclusion because the conclusions are sometimes not those that an – and I do not know whether they said “objective” or “unbiased” – person would deduce from the data presented, so I always look at the methods and the results rather than the conclusions.

D

Q Let me ask you this: if learned leading counsel for the mothers had said in a conference with you, or at some other stage by way of written advice, “Will you please make a further statement making it clear that the conclusions are contrary to the matters that you have set out in the report”, so that you could do that by way of an addendum to your report, would you have had any objection to that?

E

A No. I mean what I would have liked to have done, if I had been advised that this was the case, I would have written at the beginning of my report what I said in court – that I rely on the data inside – and each time I was quoting from a report, if the conclusions were different from the suppositions that I was making, then I would have reported them each time.

F

Q I think it was you who actually produced all these papers?

A Yes.

Q Not Dr Conway or Professor Kroll?

A No, there were no references from either of their initial reports.

G

Q We have looked at the papers. There were no references by ---

A None from Dr Conway, and there were none from Professor Kroll apart from his section that he did on MMR, but there were no other references.

Q So you actually produced all those papers. I appreciate that thereafter Dr Conway’s response to you produced more papers?

H

A Yes.

Q But, until that point ---

A

A There were no references produced or referred to.

Q On page 36, again Mr Cohen makes the same point, and I think at line 10 you say:

“I could have reproduced the whole article each time, which I did in the references.”

B

I think you are making that point there?

A Yes.

Q Again, perhaps somewhat repetitively, at line 16:

C

“Well, do you not think that it is appropriate for you to state, and it need take no more than one sentence, that: ‘The authors to whom I have referred have all drawn a different conclusion to me?’”

You say:

“It probably would be a useful thing to do.”

A Yes.

D

Q But the important thing is: did you think of that but just decide to reject putting it in?

A No. If I had thought of it, I would have done it.

Q As I said, the important thing is this: if someone had drawn it to your attention, would you have had any objection to putting that in?

E

A None.

Q In fact, at the foot of page 36 you say:

F

“I use the information provided in the paper – several papers – to come to my own conclusions. That is why I cite the papers. I cite the information, and then I draw it together with my conclusion, which I have stated in my conclusions.”

At the foot of the page, the learned judge indicates that he did not actually read the papers, or at least not all of them, I think he says. At the foot of page 38, Mr Cohen says:

G

“But forgive me – sifting through the literature – let us confine ourselves to diphtheria at the moment – you are a lone voice crying in the wilderness at the gates of immunisation, are you not, so far as your authors are referred to – so far as your authors have ---”

and you say:

H

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

A 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?"

B 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?

C 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.

D 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.

E Q I do not think I need to trouble you about any more of that. I think the questioning is in pretty much the same vane for each of the diseases. You were asked about the conclusions and why you did not put them in?

A Yes, Mr Cohen brought up this point every single time.

F Q Can I ask you, please, to look at the allegations brought by the General Medical Council? It is paragraph 3 that I want to ask you about, that you produced reports signed on 14 June and 4 December – well, we know about that – which purported to be independent medico-legal reports. I have to break it down because it is rather lengthy wording. When you prepared those reports, did you intend them to be independent medico-legal reports?

A Yes, I did.

G Q Did you do the best that you could in that regard?

A I did.

Q Obviously, you knew that they were going to be read ---

THE LEGAL ASSESSOR: Would you just give me a moment?

MR STERN: Yes, of course. (*Short pause*)

H THE LEGAL ASSESSOR: (*Following consultation with the Chairman*): Mr Stern, there may be nothing in this at all. I, of course, have the Rule 6 letter to Dr Donegan, informing

A her of possible proceedings. It is dated 13 May 2004. Do you have that?

MR STERN: Somewhere, yes. As I understand it, the Panel do not have it, and if the Panel do not have it ---

B THE LEGAL ASSESSOR: No, the Panel do not have it. I am not going to say to them what it says.

MR STERN: I cannot remember what it does say, but I have to say that it is a matter ---

C THE LEGAL ASSESSOR: I was just looking at paragraph 3 and, as it touches on the very point that you are at the moment examining Dr Donegan on, there may be an obvious explanation for this, but it may be that you would want to look at it and look at paragraph 3.

MR STERN: Can I carry on with this part of the examination, look at it and then decide by tomorrow morning whether there is anything further that I need ---

THE LEGAL ASSESSOR: Whether you need to come back to it, yes.

D MR STERN: Thank you very much.

THE LEGAL ASSESSOR: I raised it deliberately at this stage because it was on this very point.

MR STERN: All right. Thank you.

E Q Paragraph 6, please, Dr Donegan. That alleges that in the reports – so it is just the reports that we are concerned with – that you have provided you (a) gave false impressions and/or misleading impressions, which I think is essentially what it is saying, of the research that you relied on. Did you give false or misleading impressions in relation to the research that you relied on?

A No.

F Q That you quoted selectively from research, reports and publications, and omitted relevant information. Did you do that?

A No.

Q It says about your deeply held views:

G “Allowed your deeply held views on the subject of immunisation to overrule your duty to the court and to the litigants”.

Did you do that – were your reports as a result of your “deeply held views” or not?

A No.

Q Do you have “deeply held views”?

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

A Q I do not know if it is a criticism to hold deep views, but there we are. You, “Failed to present an objective, independent and unbiased view”. I think that is what it comes to, that is essentially the point that is being made is that you did not present an objective, independent and unbiased report. What do you say about that
A I do not agree.

B Q It is said that in relation to the actions of preparing such reports, the actions were “misleading”. Do you consider your reports to be misleading?
A No.

Q Do you consider them to be in direct contravention of your duty as an expert witness – the reports?
A No.

C Q Or unprofessional or likely to bring the profession into disrepute?
A No.

D THE LEGAL ASSESSOR: Mr Stern, I notice when you were – I think I understand why – when you were asking your client about head of charge 6(d), the question you asked was not, “Did you fail to present an objective independent and unbiased view?” It was, “Did you fail to present an objective, independent and unbiased report?” And she answered that question.

MR STERN: I meant to say “a view in the report”.

E THE LEGAL ASSESSOR: I raise that because I am troubled as to whether (there will be no problem if the word “report” was there instead of the word “view”) but I am troubled as to whether a view, which is – let us assume a view formed as a result of independent, unbiased research, if you like; it is possible for that view not to be biased. Once you have formed the view you have a bias in relation thereto, which would apply to all the experts who form a view. It was something, which I was intending to raise, possibly both with you and Mr Kark, in open session before probably you address the tribunal.

F MR STERN: That may be the more appropriate time, if I may say so.

THE LEGAL ASSESSOR: The reason why I raised it at this stage was because I noticed the question you asked was substituting the word “report”.

G MR STERN: If I did, I did not mean to. I meant a view in relation to the report. If I did I am sorry.

THE WITNESS: Should I say “no” again?

MR STERN: Yes. I will sit down now, if I may.

H THE CHAIRMAN: Given the time it seems a good point to break. Does that conclude your evidence?

MR STERN: Yes. I would not have sat down otherwise. I am sorry, I did not make that

A clear.

THE CHAIRMAN: Mr Kark, it will be your go next in the morning.

MR KARK: It will be my go next, yes.

B THE CHAIRMAN: Dr Donegan, you are still under oath. Tomorrow morning Mr Kark will begin his cross-examination and following that there will be re-examination and questions from the Panel. You remain under oath so if you could refrain from discussing the case with your legal team. We will reconvene at 9.30 tomorrow morning.

(The Panel adjourned until 9.30 a.m. on Thursday, 16 August 2007)

C

D

E

F

G

H