

1 MR PARKER: I think Mr Rennie's points may still be outstanding, but the
2 detailed points raised by Mr Hindle and Mr Murray I believe I have attended
3 to.

4 CHAIR: We will tidy all of that up now.

5 MR PARKER: Yes, I will have to do that with him.

6

7 MR PARKER CALLS –

8

9 **DONALD MORGAN EVANS** (Sworn)

10

11 Q: Is it right your name is Donald Morgan Evans.

12 A: That's correct.

13 Q: And Professor Evans you have prepared a brief of evidence which has
14 been already the subject of some discussion and you have that in front of
15 you?

16 A: Yes, I do.

17 Q: Can we just go through that please for the purpose of the edits which
18 I've just been addressing to the Chair, please. Ma'am, for this purpose I'll
19 have to take him back to para 17.

20 CHAIR: Yes, that's fine.

21 Q: Para 17, please, in the middle of p5. Now do you agree to the deletion
22 of the second line?

23 A: Yes.

24 Q: Third, fourth lines as well?

25 A: Yes.

26 Q: And (2,000) on the fourth line?

1 A: Yes.

2 CHAIR: Can they be pleased crossed out now and initialled.

3 MR PARKER: that's my purpose ma'am, is he should do that as we go
4 through.

5 CHAIR: Madam Registrar, if you could please just see that it is crossed
6 out.

7 REGISTRAR: That has been done already.

8 MR PARKER: And professor, would you then go down to the second para
9 numbered 18 which is at the bottom of the page and delete the whole of the
10 first sentence. And the last two words on that page, please, "some reports"
11 and substitute the word "evidence". If you turn over to the next page, the
12 first line, instead of "have" it should be "has". I think that's just where we
13 got to.

14 CHAIR: It's just grammar.

15 MR PARKER: And then down that page please to paragraph 20 and the
16 words in the first line of that paragraph "forgoing article" say
17 "evidence" in place of that please. The deletion of paragraph 21 do you
18 agree.

19 PROFESSOR EVANS: Yes.

20 CHAIR: I had paragraph 19 circled is that no longer a concern.

21 MR PARKER: That was a question mark in the mind of myself and Mr
22 Hindle you might remember when my episode this morning if I can put it
23 that way came to an end I think there was an exchange there were Mr Hindle
24 raised it and you suggested perhaps it would stay in. I'm not quite sure.

25 CHAIR: We'll leave that one for now we'll just keep going through.

26 MR PARKER: Turning over the page to paragraph 22 and on the
27 second last line of the bold words and the third last line the words

1 “inaccuracies of reporting and” delete those words. Then if you turn to
2 paragraph 28 on page 8 there's a date mentioned on the last line there. Is
3 that the correct date 19 July.

4 PROFESSOR EVANS: Not it's not. I believe it's the 21st of June.

5 MR PARKER: Will you make that alteration please an initial it.

6 PROFESSOR EVANS: That's correct 21st June.

7 MR PARKER: Would you go down to paragraph 30 first line and
8 substitute for the words “an appeal” the words “a request” and then still
9 there on that page last line instead of the word “appeal” substitute “this type
10 of approach”. Turning over same paragraph on page 9 delete the words “this
11 right” those two words.

12 PROFESSOR EVANS: Just those two words.

13 MR PARKER: Delete those and there will be substitution.

14 CHAIR: Well actually my view is this is an argumentative passage
15 which is really better by way of submission. This is a submission that you
16 may wish to make in Sept Mr Parker we don't need to hear from this
17 evidence what is pure argument by saying the Commissioner is reiterating
18 this on the news etc.

19 MR PARKER: Well we're going to delete that reference to the news
20 because there was a direct conversation between the commissioner and this
21 witness on Thursday of this week.

22 CHAIR: Well we have heard from the commissioner. We don't need to
23 have this witness then tell us what the commissioner has said. I don't think
24 we're going to be helped by that I think the passage would be best removed.
25 You've said the commissioner could rule, you've said researchers were told
26 of this mode of request by the Ethics Committee, that should be enough.

1 MR PARKER: Ma'am if you've heard on this point I'm not going to
2 press it. Do you mean the whole of that paragraph.

3 CHAIR: The whole of that sentence and then what you can then have is
4 it was not the place of the Ethics Committee to make such a request if that's
5 what you intended because that makes sense.

6 MR PARKER: If we go further down that paragraph there's a sentence
7 "this was not arranged by the Ministry of Health". If you could make a full
8 step after the word health and delete the words as reported by the meeting.
9 And if you could go to paragraph 32 and delete the first three sentences.
10 And then in the next sentence for the word "they" substitute the words "the
11 Registers". And paragraph 33 please delete the word "publicity
12 surrounding" and insert the words "issues".

13 CHAIR: Where does that appear in paragraph 33.

14 MR PARKER: It is important to balance the publicity surrounding, first
15 line. And then on page 13 paragraph 39 second sentence should be deleted.
16 Page 15 paragraph 44 delete the first line and the first two words of the
17 second line and insert the words "I refer". Paragraph 46 please on page 16
18 delete the first two lines and the first word of the third line and after Skegg
19 insert "in his evidence (B/2407 line 3-8) intimated" so the word "claimed" is
20 deleted. Ma'am those are the edits that have been proposed on my friends
21 and been agreed upon.

22 CHAIR: And there is still the issue that Mr Rennie has raised generally
23 about responding to the news media which I think the worst parts have been
24 taken out of the brief, certainly in terms of where any others are intertwined
25 in the brief we can deal with that by just disregarding it we don't need to go
26 through an editing process. I don't see any reason to admit the NEWSTEL
27 new agency report in exhibit 1 so that should go out.

1 MR PARKER: Yes I regard that as out.

2 CHAIR: If a line could be drawn through exhibit 1 of Professor Evan's
3 evidence and everything else looks to be alright. So if you would just get
4 him to confirm the brief.

5 MR PARKER: Have you made those edits.

6 PROFESSOR EVANS: I have signed the brief yes.

7 MR PARKER: And you confirm it as your evidence.

8 PROFESSOR EVANS: Yes.

9 MR PARKER: Thank you. Now ma'am I'll just take him through who
10 he is and why he's here because that was an issue that was raised a little
11 earlier as to his capacity to be here representing the Regional Ethics
12 Committees, raised by Mr Rennie, quite properly.

13 CHAIR: Yes, thank you very much.

14 MR PARKER: Professor, in your brief, I think it's para 14, you say you
15 are here as a representative and delegate of the Regional Ethics Committees
16 of NZ. Can you tell us, first of all, who are those bodies and how they are
17 constituted?

18 A: There are 13 Regional Ethics Committees in NZ, all of them are
19 involved, for example, in the multi-centre study, which is one of the studies
20 that has been discussed in evidence here. Two of them are in Auckland,
21 they do not duplicate each others work. At a meeting of the Chairpersons of
22 all of those committees, except for Auckland X who was substituted by her
23 Deputy because of illness, at a meeting of all those Chairpersons 2 days ago
24 I was delegated to speak on their behalf on these issues. They were fully
25 discussed at that meeting.

26 Q: And when you talk about these issues, what is it specifically that you're
27 referring to?

1 A: the great concern that the committees feel that some of the evidence
2 that has been given in the hearing here has been misleading and inaccurate,
3 and that it gives a false impression of the role and the character of the
4 activity of Ethics Committees in NZ and that it could be damaging to that
5 important work.

6 Q: Ma'am, I don't know whether this has come up in evidence before, as to
7 the status of Regional Ethics Committees, whether I need to take Professor
8 through that because Ethics Committees have been discussed in evidence, it
9 seems, at some length.

10
11 CHAIR: No, we can raise that. Certainly one of the concerns we had was
12 the need to go to every Regional Ethics Committee, that was why we were
13 querying whether or not for a study which was nationwide why you couldn't
14 get approval from one Ethics Committee. But we can explore that with
15 Professor Evans.

16 MR PARKER: Well ma'am, there are just a couple of matters I'd like to
17 just deal with with the Professor before I leave him to cross-examination.

18 CHAIR: Are these extras to his brief?

19 MR PARKER: Just very minor matters before I sit down. Professor in
20 para 31 of your brief you give us a rundown of the membership of the
21 Otago Ethics Committee, of which you are the Chair. Is that complete that
22 list of members?

23 A: No, it is not complete. The reason I listed the particular expertise that
24 is in that para was to show how well equipped that committee was, in fact, to
25 understand the nature of the multi-centre study that it was reviewing.
26 However, there is one omission there that I think it would be valuable to
27 correct now, and that is that that committee also has as one of its members a

1 biostatistician from the Department of Prevention and Social Medicine,
2 which is fact the department where each of these research trials is going to
3 be run, who is an expert in the design of epidemiological studies and is
4 constantly consulted on that basis.

5
6 CHAIR: Can I just ask you, why do you say each of these research trials.
7 What makes you think they are research trials?

8 A: Well, research studies. Well, the multi-centre study which we were
9 asked to review was so described by the researchers.

10 Q: that's Doctors Cox and Richardson.

11 A: Dr Charlotte Paul, Dr Cox and I forget the name of the third researcher
12 in that group. Mostly Dr Cox and Professor Charlotte Paul. Ann
13 Richardson, I don't think is part of that study, but I stand to be corrected on
14 that. I'm sorry, yes, she is. They are the three. Dr Brian Cox, Dr Ann
15 Richardson and Associate Professor Charlotte Paul.

16 Q: Have you got a letter there which you've received from them?

17 A: Yes.

18 Q: Could we see that letter, please?

19 A: Yes.

20
21 MR HINDLE: Ma'am, if it's of any help I have a number of letters that I
22 was going to produce through this witness which may be these that you are
23 about to be shown, so I've got some copies. I just have to find out the date
24 of it basically.

25 A: 30th June.

26 MR HINDLE: No, I don't have that one. I beg your pardon, a letter from
27 the researchers to you, yes, I do have that.

1 A: That's correct, yes.

2 MR HINDLE: I'm happy to get to it.

3 CHAIR: Yes, I wouldn't mind just having a look at this letter now, please.

4 MR HINDLE: Let me produce it then at this point, would that be helpful.

5 CHAIR: No, no, don't worry, because I just want to ask him a question.

6 You can actually produce them all later. I might just leave these questions

7 until later.

8 WITNESS: I also have my letter of response to that letter, which was

9 written the next day on receipt of that letter.

10 CHAIR: No, I wanted to look because you see this letter is described as an

11 audit of aspects of the National Cervical Screening Programme.

12 WITNESS: If you look at the last para I think you will see, or somewhere

13 there she says "this is cancer research".

14 CHAIR: Well, in terms of finding out about whether or not the programme

15 is effectively reducing the rate of cervical cancer it probably could be

16 described as cancer research, but the whole purpose of this programme has

17 been that the Ministry of Health has sought to engage external qualified

18 experts to do what is an external audit of the performance of the National

19 Cervical Screening Programme, and it is of some concern to the committee

20 that when the Ministry of Health, which at the time it engaged the audit was

21 responsible for the National Cervical Screening Programme finds that its

22 attempt to have an external audit of that programme undertaken stymied by

23 the inability to get access to information which is necessary for that audit to

24 be carried out.

25 A: Well, the Ethics Committee certainly has not wanted to stymie access to

26 that information. It has wanted to protect the interests of research

27 participants, or the participants in a programme of evaluation and in fact the

1 [inaudible] guidelines to which Professor Skegg appealed cover both of
2 those things – cover evaluation programmes as well as research – has
3 wanted to protect the participants’ interests in that study and try to improve
4 the protocol in order to both facilitate their interests and the study.

5 Q: So I take it that the interests of participants in a National Cervical
6 Screening Programme – i.e. the women who choose to be part of that
7 programme because they see it as a means of preventing cervical cancer,
8 their interests are better protected if that programme is not subject to an
9 external audit than if it is?

10 A: Not at all, but you did describe them, ma'am, as choosing to be
11 involved, and that is exactly the point at issue.

12 Q: Well the point is they have chosen to remain on the Cervical Screening
13 Register, they are in the programme. Part of any programme these days, or
14 part of any service these days, it's normally accepted that there is quality
15 assurance of the programme which can include an external audit. Now on
16 that basis, to say that persons acting for the Ministry of Health who want to
17 conduct an external audit cannot get access to information which they need
18 in order to carry out the audit, and to say that that is for the benefit of the
19 participants is really to say, well, it is of greater benefit to these participants
20 if their privacy is protected and they participate in a programme which is not
21 subject to an external audit.

22 A: No, we were told that there were women in the study who would not
23 benefit from being in the study.

24 Q: Well, how can it be said that an external audit of a programme for the
25 purposes of quality assurance is not going to benefit those persons who are
26 part of the programme?

1 A: Well, those persons who are already suffering from invasive cancer
2 would not be helped by it any more than they would have been in the
3 Gisborne study, and that was declared explicitly in the research protocols
4 that were submitted to the committees. And this is where the difficulty
5 arises in epidemiological studies or programme evaluations of this kind.
6 There is a difference in emphasis between the interests of those carrying out
7 the audit and the responsibilities of the Ethics Committee and in fact that
8 tension is spelled out very clearly in the gold standard guidelines for ethical
9 review of this kind of activity which Professor Skegg, and we owe him a
10 debt for this, was as he said in his evidence, part of the writing team for
11 those guidelines. Those guidelines make it very clear that ethical review is
12 required in these cases.

13 Q: So is what you are saying then is that it would be better if women at
14 the time in which they chose to stay on the Register rather than opt off it and
15 so participate in the programme if at that stage their consent to all aspects of
16 the programme including external audit of the programme were obtained.

17 A: We have proposed that and that was in fact not welcome by one of
18 the researchers because it was said they might refuse. Now it seems to an
19 ethics –

20 Q: No I'm talking about the time you decide to be on the programme.

21 A: I agree, that's my point. I think if the Registers were properly set up
22 and that was canvassed then that would be the solution to this problem. You
23 see what is happening is not that the records of these women are to be
24 investigated but they are to be sought out and interviewed.

25 Q: Well there can be a staged process can there not whereby you don't
26 interview the women but you instead look the incidence of cancer on the
27 Cancer Registry, you compare that to the National Cervical Screening

1 Register and look at past smear test history. You then may go back to
2 clinical notes and interview the care givers.

3 A: We have already authorised access to some information so that part of
4 this research is going ahead. What we were worried about was the direct
5 approach to women whose names appeared on the Register without them
6 having been asked whether they would be willing to be approached by
7 researchers by telephone.

8 MR HINDLE: There's a chain of letters in this topic ma'am and it
9 might help if I took him through them and then you might want to come
10 back to it.

11 CHAIR: Alright I'll leave it at this point then. Mr Parker do you need
12 continue.

13 MR PARKER: No I don't Professor Evans has covered one of the
14 points I was to raise so I'm content to leave him to be xxnd.

15 CHAIR: Does anyone have any applications to xxn Professor Evans.

16 MR MURRAY: I just had one matters, the ministerial correspondence
17 referred to at paragraphs 27, 28 and 29 which are not produced with this
18 brief and I don't think they're in evidence but may be correspondence that
19 my friend Mr Hindle has.

20 MR HINDLE: I'd be happy to let my friend Mr Murray go after me if
21 he wanted to because I think I do have some but perhaps not all of them so
22 I'm happy if it would suit my friend to have a look at them after I've
23 produced them through the witness and then I'd be happy if he wanted to
24 have his opportunity to examine at that point.

25 MR MURRAY: It's a very narrow point.

26 CHAIR: Anyone else. What do you want to cover Ms Bunkle?

1 MS BUNKLE: I want to go over mainly the statements in 34 and a
2 series of statements there and to refer to the review of records that was
3 conducted in Cartwright both during the course of the inquiry which lead to
4 the recall of term of reference 3 patients in somewhat similar circumstances.

5 CHAIR: OK what I think we will do is allow Mr Hindle to go first and
6 then see what comes after that.

7 MR RENNIE: Ma'am I confer with Mr Hindle and I think he will
8 cover the matter I'm interested in.

9 MR CORKILL: I'm in a similar position I think.

10 CHAIR CONTINUES XXN OF WITNESS

11 CHAIR: Just before you start Mr Hindle, one thing Professor Evans you
12 did say to me that you consider that it wouldn't be of benefit, an external
13 audit of the programme wouldn't be of benefit to those women who already
14 had cancer is that how you see it.

15 A: That is what we were told in the protocol.

16 Q: Right because it would seem to me that if a clinical audit of their
17 cases were done and it was found out that there had been any
18 mismanagement or mishandling of their cases as medical cases they would
19 have a claim for medical misadventure under the Accident Compensation
20 legislation and they would have the possibility if their clinical audit
21 suggested there had been gross negligence of bringing a claim for punitive
22 damages in the Courts.

23 A: I would accept that I'm simply recounting to you what we were told
24 and I think health benefits are what the people had in mind.

25 Q: Well do you not consider that for a woman who has cancer it might
26 well be of interest to her to know whether or not in the lead up to that she
27 had received the best of care or inferior care or somewhere in btw.

1 A: I most certainly do and the Ethics Committees on both of these
2 occasions thought these pieces of research very very important, that was
3 never in question and certainly the lead committee and the other committees
4 have bent over backwards since the initial application to try and expedite
5 this matter and have made it clear to the researchers that they regard this as
6 a very important study. We have gone to very considerable lengths to try to
7 expedite the matter.

8 Q: We have heard from Dr Cox, we understand that finally the contract
9 was signed for the study in May 1999, it had been initiated from the Ministry
10 originally in the end of 96. It's certainly clear to us that the Ministry wants
11 the study done, Dr Cox and Dr Richardson want the study done, you tell me
12 the Ethics Committee also realise the importance of the study and want it
13 done and it is of interest that although the contract was signed in May 1999
14 as at August 2000 it still hasn't been done.

15 A: That is very interesting I agree. Ethics Committees were not asked to
16 consider the protocol until late Nov 1999. That's almost half that time. The
17 protocols had to be considered by 12 of the 13 committees. They came
18 pretty well right on Christmas so the last committee to look at it looked at it
19 at the end of December. That of course had hit the holiday time, I was away
20 in Europe, but as lead committee all of the comments from the various
21 committees were collated by my administrator, a subsequent committee had
22 been set up of three members of my committee, one of them was an
23 oncologist who had devoted his whole life to treating cancer, the second was
24 a health and disability patient advocate who was a very well respected and
25 robust defender of women's interests and women's rights and third was a
26 maori member. They were very carefully chosen. By the time all of the
27 replies came in from the committees and they collated them, it was nearly

1 the end of Jan because of the holiday period and the combined response was
2 sent back to the researchers in the middle of Feb. I had little control over
3 that because I was in Europe at the time.

4
5 MR HINDLE XXN WITNESS

6 MR HINDLE: Good afternoon Mr Evans.

7 A: Good afternoon.

8 Q: Paragraph 31 of your brief first if we may. You've said there in the
9 third sentence that the lead Ethics Committee Otago includes a celebrated
10 cancer specialist could I have his name please?

11 A: Yes Professor David Holloway.

12 Q: Is he not a pediatrician?

13 A: He was a pediatric oncologist.

14 Q: What cancer work is he celebrated for do you say?

15 A: Treatment of pediatric cancer.

16 Q: So does he know anything at all about gynecological cancer?

17 A: I'm sure he does know a lot about gynecological cancer but I can't
18 speak for him.

19 Q: Does he practice only in pediatric oncology?

20 A: Yes he did practice only in pediatric oncology.

21 Q: And now does he practice only in pediatric oncology.

22 A: No he has retired.

23 Q: See I had the impression from the way you'd put it that we were to
24 assume that he was a celebrated cancer specialist.

25 A: Well yes.

26 Q: And you feel that's an appropriate description of someone whose in
27 fact a pediatrician.

1 A: A pediatric oncologist.

2 Q: Very well. How many people are there on an Ethics Committee
3 generally.

4 A: There are 12 on my committee including a general surgeon more than
5 half of whose work is removing malignant tumors from patients.

6 Q: So how many Ethics Committees in the country did we say around
7 12.

8 A: 13.

9 Q: So that gives us what, a total of about 150 odd people on Ethics
10 Committees altogether.

11 A: The size of them varies I think some of the less busy committees have
12 smaller numbers of members than 12.

13 Q: But you'd accept the total number of people that make up the cohort
14 of Ethics Committee members in NZ comes to something like, what ,130 or
15 so?

16 A: That's correct, yes.

17 Q: Now an Ethics Committee is a collection of individuals, is it not?

18 A: Of course.

19 Q: It has no separate corporate existence, it's not like a company or an
20 incorporated society is it?

21 A: No, it is not.

22 Q: It's a committee of individuals that comes together to consider
23 applications or approval to do various research projects?

24 A: that and innovative treatments and some service delivery issues.

25 Q: Now I take it, then, that being a group of individuals with no separate
26 corporate status, when it has to resolve issues do Ethics Committees look for
27 consensus?

1 A: Yes, all the decisions are consensus decisions.

2 Q: Are you telling me that out of 130 odd people who have to deal with
3 research applications they all get dealt with on the basis of unanimous
4 consent?

5 A: Yes, they do.

6 Q: Really?

7 A: Really.

8 Q: How many research applications are in a year?

9 A: It varies. The very busy committees have between 150 and 200
10 protocols to review.

11 Q: so how many protocols are we talking about each year?

12 A: It's very difficult to say in total because of course numbers of those are
13 multi-centre studies, so they are looked at by numbers of committees. But I
14 would estimate probably about 400 protocols.

15 Q: So we are talking about 400 protocols being considered amongst 130
16 people, and you are telling me that every time a committee makes a decision
17 it's a unanimous consensus?

18 A: I'm telling you it's a consensus, so we don't vote. The question of
19 unanimous decisions isn't what arises. A consensus is reached in the
20 committee and if in multi-centre studies there are disagreements between
21 committees, as there often are, then the multi-centre process has it that the
22 Chairs will discuss those difficulties between themselves until consensus is
23 reached.

24 Q: Well let's just look at this word "consensus" and let's think about it in
25 the context of the Cox/Richardson study which we were talking about earlier
26 on. Is it the case that every single member of your committee, the Otago
27 committee, shares exactly the same view about that protocol?

1 A: Do you mean the national study?

2 Q: I mean the national study.

3 A: there was a full discussion on that committee with various points of
4 view about various issues being raised. When it came to the point of
5 deciding whether approval should be given or not and what messages should
6 be communicated to the researchers, there was agreement.

7 Q: Well, agreement, does that mean to say that every single person on that
8 committee supported the decision or were there some who would have
9 dissented from it?

10 A: Every single – nobody dissented. Every single person supported the
11 response to the researchers.

12 Q: specifically the response that required them to go to have the Cancer
13 Registry asked for the consent of women in the first instance?

14 A: The response had 16 points which were raised, some of them manifold
15 points about various issues about ways in which the protocol could be
16 improved.

17 Q: I'm only asking you about one of them, I'm asking you whether your
18 committee, every single person on it, agreed that the project should not
19 proceed but on the basis that the Cancer Register write to the women in the
20 first instance?

21 A: It was a consensus decision, the letter sent from the Committee –

22 Q: No, no, I asked you whether everyone on the committee agreed. Now
23 did they or didn't they?

24 A: Well, the letter was sent.

25 Q: No, no.

26 A: And –

27 Q: Sorry, my question –

1 MR PARKER: Ma'am, this question's been asked and answered already.
2 Why we have to persist with it, I don't know.

3 CHAIR: I haven't heard it answered. I would like to hear a yes or no
4 answer. There can be an explanation. If the answer's given in a letter fine,
5 but I'd like to know just simply was the answer yes or no.

6 A: Everybody agreed on the Otago committee about the Otago
7 committee's reservations about the study. The letter which went to the
8 researchers, however, was a composite letter which included not only the
9 Otago committee's responses but all the other committees responses too.
10 That was not the subject of discussion by the Otago committee.

11 MR HINDLE: I do want to get this clear because I was only asking you
12 about the Otago committee and I was asking you whether all of them
13 members of the Otago committee agreed that the Cox/Richardson study
14 should not proceed save on the basis that the Cancer Register write to the
15 women in the first instance?

16 A: Yes, that wasn't expressed in that way, and I have the letter where
17 which went to the researchers –

18 Q: Look, sorry, I don't want to ask you about letters or anything like that, I
19 just want you to tell me yes or no, did everyone on your committee agree
20 that the study should only proceed on the basis that the Cancer Registry
21 write to the women in the first instance?

22 A: Yes, it was a decision of the committee in the way all our other
23 decisions are made, there was no disagreement at all.

24
25 CHAIR: Can I ask you why you are making decisions about who could
26 have access to the Cancer Registry, which is a public register?

1 A: We didn't make a decision about that. We said to the researchers that
2 the research protocol would be improved if the letter of invitation to be part
3 of this study went out on the Cancer Registry letterhead. That was what we
4 asked for. Because the people who would get the letter would know that the
5 Cancer Registry were entitled to have the information that these people had
6 suffered from cancer. Other people not responsible for their care would not
7 be entitled to have it and so we thought it better that the Registry letter be
8 used. That was the proposal that was put to the researchers.

9 Q: But why do you say that other people would not be entitled to have it?
10 What makes you think that other people cannot get access to information on
11 the Cancer Registry?

12 A: Well, because it is confidential information.

13 Q: Well I've looked at the Cancer Registry Act and I've asked the staff
14 about this. There is nothing in the Cancer Registry Act which makes the
15 information private or confidential. The Cancer Registry is part of the
16 Ministry of Health, which is a public agency, which is subject to the Official
17 Information Act. Anyone in this room can make a request under the
18 Official Information Act for information on the Cancer Registry. whether
19 or not information is released by the Cancer Registry depends very much on
20 how they apply the provisions of the Official Information Act.

21 A: Our worry was with the identifiable information, that was the worry of
22 the committee.

23 Q: That's what I mean, identifiable information.

24 A: And that is what we sought guidance on on more than one occasion.

25 MR HINDLE: That's the subject of the correspondence that I shall be
26 going through. That might be an appropriate time.

27 CHAIR: yes, well we will adjourn until 3.55.

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AFTERNOON ADJOURNMENT 3.37 TO RESUME AT 3.55PM

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INQUIRY RESUMES AT 4:00 P.M.

MR HINDLE CONTINUES XXN OF WITNESS

MR HINDLE: Professor when we left off we were talking about the way in which Ethics Committees make their decisions and consensus do you recall that? In your evidence you say that you're here as a representative and delegate of the regional ethics committees of New Zealand. How did you set about getting that authority?

A: I didn't seek about getting it at all it was bestowed upon me I have to say and it was bestowed upon me in a meeting of all those chair persons two days ago.

Q: And what they bestowed upon you was as I understood your evidence in chief to be some sort of right to talk about the role or Ethics Committees in New Zealand is that right.

A: No. They wanted me to rebut what they thought were false representations of the nature of Ethics Committees and of their work and the manner in which they had carried out that work.

Q: Did each of those chairs, do you know did they each canvass and get the full agreement of every member of their individual committees before they bestowed that authority on you.

A: I can't tell you that I do not know.

Q: But you'd agree wouldn't you that a chair who purports to act in something like this without having the agreement of the committee which he or she is a chair of would have no authority to give you that.

A: Well I am speaking certainly on behalf of the chairs of the Ethics Committees.

1 Q: So we're just left guessing what the Ethics Committees themselves
2 think are we?

3 A: I'm not guessing anything I've told you what authority I was given to
4 come here.

5 Q: But you've talked to the chairs of Ethics Committees about it 2 days
6 ago. It's inconceivable that they could have had a vote of each of their
7 committees in that period of time.

8 A: They have not and I haven't pretended that they had.

9
10 CHAIR INTERJECTS AND XXN WITNESS

11 CHAIR: Well you had said earlier on for example of the decisions on
12 research that your Ethics Committee made decisions on a consensus basis.

13 A: Yes.

14 Q: Do other Ethics Committees make decisions on a consensus basis.

15 A: All of them.

16 Q: Well if they tend to make decisions on a consensus basis on issues
17 before them seeking approval for research, when it comes to an issue such as
18 this, would you not expect in order to be properly appointed to represent all
19 Ethics Committees that the members of all Ethics Committees ought to have
20 had the opportunity to participate in the decision making process and for a
21 consensus decision to be reached by all Ethics Committees as to whether or
22 not it was appropriate for you to appear.

23 A: That would have been ideal, there was simply not time to achieve
24 that.

25
26 MR HINDLE CONTINUES XXN OF WITNESS

1 MR HINDLE: Now can I take it that in the time available certainly all
2 the members of the various Ethics Committees but perhaps not even the
3 chairs of Ethics Committees have read and approved your statement.

4 A: The chairs of the committees all had a copy of a paper which I had
5 written which forms the substance of this brief.

6 Q: But this brief is different from this paper am I right.

7 A: It is it became different even one half an hour ago.

8 Q: Yes of course but the position is, is it not, that none of the chairs have
9 actually approved the evidence that you have now given to the committee.

10 A: There is nothing in this brief which was not contained in that paper.

11 Q: That paper which was different to the brief before it got changed a
12 few minutes ago in this inquiry.

13 A: Oh there was more in that paper than is now in the brief.

14
15 CHAIR ADDRESSES MR HINDLE

16 CHAIR: That's not fair to the Professor. The brief hasn't been changed.
17 Portions of it have been struck out, not accepted as admissible evidence and
18 he has added some to make sense. It's not fair to suggest that's a change.

19
20 MR HINDLE CONTINUES XXN OF WITNESS

21 MR HINDLE: I wasn't really focussing on the changes that have
22 occurred in the inquiry room but I really just wanted to know whether and to
23 what extent the chairs of the Ethics Committees have approved the statement
24 that you have given.

25 A: Well they have seen the paper which I wrote which became the basis
26 of this brief which contains more than in is in this brief and they were happy
27 for me to speak through all of that.

1 Q: Well I'm bound to suggest that you're really giving your personal
2 opinions to this inquiry and that you're authority to represent all of the
3 Ethics Committees of New Zealand is not at all clear.

4 A: I certainly have the authority to represent the chairpersons of all of
5 the Ethics Committees.

6 Q: Now at paragraph 18 of your brief you've described as profoundly
7 disturbing to the committees that Professor Skegg's evidence has not been
8 balanced by evidence from an Ethics Committee or an ethicist and I take it
9 you're referring to the list of matters in paragraph 16 from a-I when you are
10 talking about the matters from Professor Skegg's evidence that need to be
11 balanced is that right?

12 A: That's correct.

13 Q: Did you have drawn to your attention the following passage from the
14 notes of evidence when Professor Skegg was giving evidence that's at page
15 B/2399 where he was asked "so I take it that your not suggesting that we do
16 away with Ethics Committees altogether" and he answered "oh certainly
17 not". He was asked "do you see that there is a need for that kind of
18 involvement in these processes" and his answer was "yes I've been a strong
19 supporter of the concept of Ethics Committees I was one of the people who
20 advocated for the establishment of the bio ethics centre at Otago University.
21 I'm strongly in favour of having Ethics Committees. I think they're
22 essential for many reasons but not the least of which is to protect patients
23 from experimental studies which may in some cases carry hazards but
24 equally I think they have a very important role to reassure the public that
25 evaluations of a kind that are being discussed at this inquiry are being
26 carried out in a carefully planned and appropriate way by people who have

1 the appropriate training and with adequate safeguards for confidentiality.”

2 Where you aware of that evidence that Professor Skegg gave.

3 A: Yes I was aware of that evidence.

4 Q: I take it from your earlier evidence today that you don't disagree that
5 it's important to evaluate a programme like the Cervical Screening
6 Programme.

7 A: I think it's extremely important.

8 Q: And it's important to do the evaluation because in the process of
9 evaluation the programme you can find ways to improve it and save lives
10 that's true isn't it?

11 A: Of course.

12 Q: And I should ask you are you aware that all of the experts that have
13 given evidence to the inquiry so far, Professor Skegg, Dr Medley, Dr
14 McGoogan, Dr Cox, Dr Peters have all agreed that the sort of clinical audit
15 of cases of cervical cancer is the gold standard by which you can set about
16 evaluating the programme.

17 A: I'm not aware of the evidence all of those persons have given but that
18 would certainly be my view too

19 Q: You'd accept then that if you delay doing an evaluation like that, in a
20 sense you are costing lives just as Professor Skegg said.

21 A: Oh I agree with him.

22 Q: Now you come to this debate without any medical training is this
23 correct.

24 A: That is correct.

25 Q: You come to the debate without any clinical experience is that
26 correct.

27 A: That is correct.

1 Q: And is it fair to say that you come to the debate with less knowledge
2 about the screening programmes than people like for example Professor
3 Skegg and Dr McGoogan, Dr Medley and others I've mentioned.

4 A: It would be ardent foolishness of me to disagree with that.

5 Q: Am I right to think that you come to the debate with a very firmly
6 held personal view about the importance of informed consent.

7 A: I certainly have strong views about the importance of informed
8 consent and especially as they I think direct the activities of Ethics
9 Committees in New Zealand following the Cartwright Inquiry where it
10 became an absolutely central issue.

11 Q: Now you received the application for the national evaluation that's the
12 Cox and Richardson study in Nov 99 is that correct?

13 A: That's correct.

14 Q: And you gave conditional approval asking that the initial approach by
15 the researchers be to the women should go on Cancer Register letter head is
16 that correct.

17 A: That was one of the conditions.

18 Q: All right well I'd like to show you this document. Madam Registrar.

19 A: Let me say that this document doesn't simply express the decision of
20 the Otago Ethics Committee. This is the response in the multi centre
21 research of which the Otago Ethics Committee is the lead committee to the
22 researchers.

23
24 CHAIR: Could I just follow this line up before Mr Hindle goes on. Why is
25 it necessary – this is the audit being done for the Ministry of Health – to go
26 to so many Ethics Committees. Why can't you just deal with one
27 committee?

1 A: well it is standard practice now in NZ that we have a multi-centre
2 process where patients are going to be entered into a study in various parts
3 or the country. The Ethics Committee nearest to where the patients are
4 found is the committee responsible for protecting the welfare of those
5 patients. Very often, of course, there are quite important differences
6 between one area and another, and sometimes what would be acceptable in
7 one area wouldn't be acceptable in another area.

8 Q: But what impact does that make on statistical research? We have
9 heard a lot of evidence from epidemiologists and public health experts that if
10 there is insufficient data it biases a study, that there needs to be a
11 considerable amount of information before a study can go ahead. For
12 example, with the Cervical Screening Register, before it became opt-off,
13 there was considered to be insufficient data and data which might not be
14 spread over the entire population and that it would, therefore, not reflect an
15 accurate picture. You are aware of those sort of difficulties?

16 A: I am perfectly aware of those difficulties.

17 Q: Well how, then, can any study be carried out when you've got a
18 situation where an Ethics Committee in the northern part of the country may
19 say no, and another Ethics Committee in the southern part of the country
20 may say yes to a study which is intended to be nationwide?

21 A: Well, the point is that each of those committees might want to make
22 amendments to the protocol which would make them more acceptable to the
23 population in their area, and that was the whole point of the letter sent to the
24 researchers; it was an entirely constructive letter, aiming to improve the
25 protocol so that not only would the very worthy objectives of the study be
26 achieved, but the risks of harm to the participants would be minimised.
27 That was the point of the letter.

1 Q: But NZ would be a country of a population of about 4M people. We
2 heard from Dr Wayne I think that one could compare NZ with NSW in terms
3 of population. Surely matters could be handled in such a way that one
4 Ethics Committee could deal with a proposal which was intended on a
5 nationwide basis, there isn't that much difference between people who live at
6 one end of the country from those who live at another?

7 A: Well, there can be considerable differences. There can be differences
8 in the patterns and incidence of disease in various parts of the country. It
9 could be in many research studies that we have, for example, there are
10 different ethnic mixes in various parts of the country and all of these we
11 have to be sensitive to.

12 Q: But that shows an even greater need to ensure that all that information
13 is available for a study.

14 A: Well, yes, of course, but our hope was that this study could go ahead in
15 the most acceptable way to the participants in the study. You see the
16 objective of the study is a worthy one and it was one which spoke for itself,
17 there was never any question on any of these committees that this study
18 would not be allowed to go ahead. What was proposed was that it go ahead
19 in the best possible manner, and the best possible manner was a manner in
20 which the interests of the research participants were best protected. The
21 gold standard guidelines on epidemiological research, which Professor
22 Skegg was party to and indeed partly created, emphasise that there are other
23 kinds of risk to research subjects than simply physical harms.

24 Q: Yes, but you are talking about research. This is an external audit for
25 quality assurance purposes to see whether or not this programme, which has
26 been in place since 1991 and which has never been comprehensively
27 evaluated, is actually functioning effectively.

1 A: Yes, well the CIOMS?? Guidelines actually cover programme
2 evaluation as well as research.

3 Yes, Mr Hindle.
4

5 MR HINDLE: Just while on that subject, my friends will correct me if I'm
6 wrong, I don't have the reference I'm afraid, but I have it in my mind that
7 we've heard evidence that there was a statistical report or a study of some
8 sort which covered the whole of NZ except for Wellington because the
9 Wellington Area Health Board or the Wellington Ethics Committee wouldn't
10 allow the release of the data. Do you think that's acceptable?

11 A: I think it's a pity if that happens, but I would need to know what the
12 reasons were that they refused.

13 Q: Let's come back to this letter. Is that a letter that you wrote –

14 A: Can I follow up that last point.

15 Q: Just, of course.

16 A: I don't want to leave it in mid-air. Ethics Committees function on the
17 basis of the Helsinki Declaration. That is a declaration of the World
18 Medical Association about the proper conduct of research involving human
19 subjects. The Kyonz? document which concerns epidemiological research,
20 that is non-clinical research, actually declares that it too is based on the
21 Helsinki Declaration. And that makes it clear that it is the interests of
22 research participants that Ethics Committees are there to protect first and
23 foremost, and says –

24 MR HINDLE: I'm not arguing with you about -

25 A: And says unambiguously that the interests of research participants must
26 not be sacrificed for the sake of science and society. So if there is a good
27 reason for thinking that a particular group of patients in a study are

1 threatened unacceptably, then that is a good reason for saying that sadly the
2 gain in terms of benefits for the population as a whole is not an ethical one
3 to achieve in this manner.

4
5 CHAIR: Pause there Professor Evans, I would like Professor Evans to be
6 shown Glackin volume 6, tab 26.

7 MR HINDLE: Thank you ma'am, that's exactly what I was thinking of.

8 CHAIR: Just take this slowly.

9 MR PARKER: Ma'am, is there another copy of this, it's just that I've not
10 seen all that.

11 CHAIR: Yes.

12 MR PARKER: I've got one, thanks.

13
14 CHAIR: Now Professor Evans you will see there, this is the first statistical
15 report of the National Cervical Screening Programme, do you see that?

16 A: Yes.

17 Q: It's not a piece of research in most people's minds. Perhaps you could
18 say whether you consider a statistical report to be a piece of research or not?

19 A: I think that whether I say yes or no isn't significant in that the
20 CIOMS/guideline say that the same thing will apply to either.

21 Q: Yes, well we'll go to those guidelines if you've got them in a moment,
22 but look at this report. If you go to p4, you have the introduction of the
23 report, it tells you the goal of the programme is to reduce the incidence and
24 mortality rates of cervical cancer, it says the programme began in 1989 and
25 1990 in two Area Health Boards, and that all Area Health Boards have now
26 entered the programme with the last Area Health Board, Wellington,
27 beginning enrollments in January 1992. Do you see that?

1 A: Yes.

2 Q: And you will see at the end of that para where it says “this was the first
3 statistical report of the National Cervical Screening Register covering the
4 implementation phase of the programme. Unfortunately the Wellington
5 Area Health Board was unable to provide information necessary for this
6 report and results from women in the Wellington Area Health Board are not
7 included” And we have received evidence from Dr Cox, which appears in
8 his brief of evidence at p93, because he was one of the persons who
9 prepared this report, that the data from Wellington was not included because
10 the Wellington Ethics Committee would not release even aggregated data
11 from their regional register because they considered that to be a breach of
12 privacy. Now what comment do you have to make of that?

13 A: Well if that is an accurate account of what happened, I think the
14 Wellington committee made a mistake. If the Registers were set up
15 properly in the first place so that it was possible to abstract this information
16 from the identifiable individuals, whose information it was, and that is
17 managed perfectly well in other disease registers, then precisely the kind of
18 research which the epidemiologists need to do now, or the evaluation,
19 whichever you call it, would be facilitated perfectly. It hasn't happened, and
20 that's where the fault lies.

21 Q: Yes, but the question I'm asking you to comment on this situation
22 whereby anonymised aggregated data was not available for release and
23 therefore was not included in the first statistical report of this national
24 programme.

25 A: Well that's a great pity and I have no problem whatsoever with
26 anonymised data and I think it would be a mistake to have a problem with it.

27 Q: Do you have a copy of the Helsinki Declaration here.

1 A: Yes.

2 Q: And could you take me to that part of it that says that audit and
3 evaluation is included in research.

4 A: No I can't, that isn't in the Helsinki Declaration, that's in the CIOMS
5 guidelines on epidemiological research.

6 Q: Has that been given to the Committee of Inquiry.

7 A: Yes it has though there is a section in the Helsinki Declaration which
8 talks about non-clinical biomedical research and it doesn't mention the word
9 epidemeology.

10 Q: I'm not talking about research or epidemeology I'm talking about
11 quality assurance and external audit or evaluation of a medical programme
12 or a medical treatment. Is that specifically provided for in the Helsinki
13 Declaration and if so can you refer me to where it is?

14 A: No it is not but it is taken up in the CIOMS guidelines which are
15 regarded as the gold standard for epidemeology in which Professor Skegg
16 was involved.

17 Q: Can you tell me where it is to be found?

18 A: Yes. For example on page 12 paragraph 4. There not in proper
19 sequence.

20 Q: I've got that yes. Well as I read this paragraph 4 it's equivocal it's
21 saying some organisations and Government agencies employ
22 epidemiologists who maybe permitted by legislation or employees contracts
23 to have access to data without subjects consent. These epidemiologists must
24 then consider whether it is ethical for them in a given case to use this power
25 of access to personal data. Ethically they may still be expected either to seek
26 the consent of the individuals concerned or to justify their access. It all
27 revolves around epidemiologists employed by Government agencies or other

1 organisations. It doesn't actually say that this is an issue regarding quality
2 assurance and external audits. Paragraph 4 could be aimed at a situation
3 where you have a Government body that actually employs epidemiologists
4 and allows them to do research.

5 A: Well I agree that it is general and it seems to include both. It
6 certainly doesn't exclude it and the description here certainly covers each of
7 the studies that have been considered in this hearing but there are comments
8 in here also about programme evaluation.

9 Q: I think paragraph 4 has to be read in context with the entire part of
10 these guidelines which is for bio medical research.

11 A: No with respect ma'am they do not restrict themselves to that.

12 Q: Then perhaps you might help me here. On your view these CIOMS
13 guidelines apply to epidemiologists carrying out external audit of a medical
14 programme.

15 A: Programme evaluations and research.

16 Q: And on the basis of what paragraph 4 page 12 says it would also
17 presumably apply to an internal audit carried out by epidemiologists as well
18 in other words if Dr Cox and Dr Richardson were employed by the Ministry
19 of Health rather than contracted by them so that they were Ministry of
20 Health employees and they were asked to carry out an evaluation of the
21 programme, they would also be covered by paragraph 4 in your approach
22 would they.

23 A: I doubt it the Ministry of Health I think is not a provider of health
24 care services.

25 Q: What has that got to do with it?

1 A: Well, the people who properly can audit, and it's the synaquanon?? of
2 good clinical practice that the practice is audited, are those people who are
3 responsible for providing care to the patients.

4 Q: But don't you understand that the Ministry of Health is responsible
5 for the programme. It is the body that's responsible for the National Cervical
6 Screening Programme .

7 A: I think this quality assurance programme is extremely important and
8 I think if the Registers had been properly set up there wouldn't have been
9 any ethical problems at all.

10 Q: Well what I want to ask you now is this. The Ministry of Health is
11 responsible for the programme. If Dr Cox and Dr Richardson were Ministry
12 employees and they were asked as part of their job as Ministry employees to
13 carry out an evaluation of the programme which required them to gain
14 information from the Cancer Register, from the Screening Register and do
15 everything else that they contemplated doing, would paragraph 4 of the
16 CIOMS guidelines in your view apply to them?

17 A: My own view is that that would not give them automatic access to
18 patient records.

19 Q: You would say that they could still be ethically bound not to do so by
20 paragraph 4.

21 A: The ethical question could still arise and I presume that is why they
22 brought the matter to the Ethics Committee for an opinion and in fact the
23 Ethics Committees were not satisfied with the justification that was offered.

24 Q: Well could you please help me on this. I have here national standard
25 for Ethics Committees which Ms Thorpe provided. Madam Registrar did
26 this come in as an exhibit. Perhaps the witness could be shown this
27 document.

1 A: I have a copy.

2 Q: Well we'll give this document a number. If you would look at the
3 copy that we already have, just confirm that it is the national standard for
4 Ethics Committees.

5 A: That's correct.

6 Q: We'll give that an exhibit number.

7 [Exhibit DME/REC/009]

8 Q: Now page 14 it's set out here those matters not requiring ethical
9 appraisal. Turning over the page it says audit which can be defined as
10 examining practice and outcomes in a particular place to see whether they
11 confirm with expectations with a view to information and improving
12 management rather than adding to general knowledge. Now if the New
13 Zealand national standard for Ethics Committees is saying that that type of
14 audit doesn't require ethical appraisal on your interpretation of the CIOMS
15 guidelines your not actually meeting them.

16 A: Well I think the difficulty here is who is carrying out the audit.
17 Certainly the audit of clinical practice by clinicians and those responsible as
18 health providers is required. That's part of good practice.

19 Q: So what you're saying now is that one ought to read into your
20 national standards for ethics where it says audit which can be defined as
21 examining practice and outcomes in a particular place to see whether they
22 confirm with expectations with a view to inform and improving management
23 rather than adding to general knowledge, one needs to add in the words by
24 persons other than medical clinicians.

25 A: No I wouldn't make it as narrow as that. Health providers. Those
26 responsible for actually providing the care.

27 Q: So they can't do the audit.

1 A: Who can't.

2 Q: The medical clinicians.

3 A: Oh yes it's important for them to be auditing their own practice too.

4 Q: What I'm trying to understand is this. You've referred me to the

5 CIOMS guidelines.

6 A: Yes.

7 Q: You've referred me to paragraph 4. On your interpretation of

8 paragraph 4 you say that that para captures audit and evaluation as well as

9 research?

10 A: Yes, and says so explicitly later on.

11 Q: And these guidelines, the CIOMS/guidelines say that epidemiologists

12 involved in, on your interpretation, audit and evaluation still need to

13 consider whether it's ethical for them in a given case to have access to

14 personal data, is that correct?

15 A: that's what the guidelines say, yes.

16 Q: And it says ethically they may still be expected either to seek the

17 consent of the individuals concerned or to justify their access without

18 consent, is that correct?

19 A: That's what it says, yes.

20 Q: It seems to me that the NZ Standard for Ethics Committees allow audit

21 as defined in 3.3.3, in which case if one relied on the NZ standards it would

22 be quite appropriate for an epidemiologist to have access to personal data so

23 long as he/she was doing so for the purpose of audit as described in 3.3.3.

24 A: With respect ma'am, I think that that is ambiguous in that case, and in

25 fact the guidelines actually quote the CIOMS/guidelines as a reference on

26 the last page.

1 Q: Well, I'm looking at the express wording of 3.3.3. Can you tell me
2 where it says there that an audit of that nature, conducted by an
3 epidemiologist, is nevertheless going to require ethical appraisal?

4 A: Well, an epidemiologist is not a clinician who is providing care to any
5 patient at all.

6 Q: No, we are not talking about care to patients, we are talking about the
7 auditing of a national programme which is the responsibility of the Minister
8 of Health, and we are saying that an epidemiologist hired to carry out an
9 audit as described in 3.3.3 would be recognised, on my interpretation of the
10 national standards, as not requiring the approval of an Ethics Committee.

11 A: Well, we beg to differ on that. However, approval of an Ethics
12 Committee was sought and the approval was not given. Now, of course it is
13 still open –

14 Q: No, I am not asking you about that, I'm asking you about how the NZ
15 standards fit in with your interpretation of the CIOMS/guidelines because
16 they appear to me to be contradictory.

17 A: Well I have suggested a way in which they do fit in and that is where
18 the people carry out this audit are properly authorised people so to do. That
19 is those responsible for providing care to the patients.

20 Q: Where does it say that in this bullet point under 3.3.3?

21 A: You asked me, ma'am, how this could be aligned with the CIOMS
22 document and I am suggesting to you a way in which it can, and a way in
23 which it is normally understood. Clinicians even are not free simply to
24 share any information about a patient with other clinicians except in the
25 context of care for that patient. There are very restrictive rules of the
26 sharing of health information in that sense.

1 Q: Are you saying therefore that any clinician working in the Ministry of
2 Health and the National Cervical Screening Programme is not going to be
3 able to share information of a personal nature about persons on the
4 programme because of ethical considerations?

5 A: Well, with the consent of the patient perfectly well I think. But not
6 otherwise. Not obviously.

7 Q: Do you not see any difference between the Ministry of Health's
8 responsibility for the National Cervical Screening Programme and individual
9 persons who may be on the programme?

10 A: Could you repeat that question?

11 Q: Yes, do you see a difference, or don't you see a difference, between the
12 National Cervical Screening Programme and the individual persons who
13 may be on that programme?

14 A: Well I don't know how to compare a programme with a person. I'm
15 sorry, I don't understand the question.

16 Q: Well you aware of what the programme is set up to do are you not?

17 A: Yes.

18 Q: It is a programme which people enroll on so that they have smear tests
19 on a regular basis as a means of preventing cancer?

20 A: Yes.

21 Q: Now do you not expect that the Ministry who was responsible for the
22 running of that programme would want from time to time to make sure that
23 the programme is running effectively?

24 A: Yes, I think that's correct in the same way that they would want to be
25 sure that the rest of the health service is running appropriately.

26 Q: And do you see those persons working on the programme as being
27 persons similar to a clinician treating a patient or not?

1 A: I do not.

2 Q: and why not?

3 A: Well, for example, if I'm an employee of the Ministry of Health it's
4 quite clear that I do not have the authority to go along to any hospital and
5 demand to see any particular patient's record.

6 Q: I'm actually not sure of the legal position of that.

7 A: I would be amazed if it was the case.

8

9 MR HINDLE: I think the screening programme is the issue, ma'am.

10 CHAIR: Yes, I know. I would be amazed if the Ministry of Health could
11 from time to time check what goes on in hospitals too. Turning to appendix
12 5, you've broken down information there on matters not requiring Ethics
13 Committee appraisal, and again you have audit –

14 A: I'm sorry -

15 Q: Appendix 5, NZ standards. If you look where it says “access to
16 personal health and disability information for the purpose of monitoring the
17 quality of care. Access to personal health and disability information for the
18 purposes of monitoring the quality of care at an institutional level this may
19 go beyond the processes involved in internal clinical audit and may require
20 expertise possessed by members not involved in the health care or disability
21 services team – example expertise in statistical methods, pathological
22 diagnosis or classification. Ethical Committee review is not required for
23 this process as long as all persons involved in the process are operating
24 under the same professional standards as the individual caregiver.” So once
25 again the NZ standards appear to exempt health professionals who are
26 participating in a monitoring exercise of the quality of care.

27 A: it would appear to say that, yes.

1 Q: How does that fit with your view of the CIOMS/guidelines?

2 A: It doesn't fit.

3 Q: Would you agree that there appears to be a contradiction between your
4 view of the CIOMS/guidelines and the national standards for Ethics
5 Committees?

6 A: Oh, I think it doesn't fit with the CIOMS/guidelines, that's where the
7 discrepancy is, not my view of the CIOMS/guidelines.

8 Q: Well at the moment how one reads para 4 is a matter of personal view.
9 You've given your personal view of how it's read as nothing more than a
10 personal view, do you not agree?

11 A: yes, I'm giving my personal view. On the other hand, I can't see any
12 other way in which the CIOMS/guidelines could be read.

13 Q: Can you point to me any passage in the CIOMS/guidelines which deals
14 specifically with evaluation?

15 A: Yes, I've been trying to find that section here. Yes, para 52, p23. They
16 don't run consecutively I'm sorry.

17 Q: Well it's unfortunate that my 52 is way at the top and there are holes
18 from the spiral binding so I can't read it all. Oh, no, I've got it here.

19 A: No, it's at the bottom.

20 Q: I see what's happened, it's all right. From my reading of paragraph 52
21 is it talks about the first part of it research or evaluation of a programme as
22 part of a health care institution, the next part it talks about a Government or
23 hospital dept wanting to examine patient's records to determine safety and
24 efficacy of a facility unit or procedure. It goes on to say if the examination
25 is for research purposes, the proposal should be submitted to the committee
26 that considers the ethical features of research proposals however if it is for
27 the purpose of programme evaluation conducted perhaps, and it says

1 perhaps, by staff of the institution to evaluate a therapeutic programme or it's
2 effects, and then the word is blocked out and it seems to be, it says not need
3 to be submitted to ethical review.

4 A: That's right when it's conducted by the staff of the institution.

5 Q: No it says perhaps it doesn't say only by staff. It says conducted
6 perhaps by the staff which allows the possibility that it could be conducted
7 by persons other than staff.

8 A: And the last paragraph says.

9 Q: The very last. If it is not clear whether the proposal involves
10 epidemiological study or routine practice it should be submitted to an Ethics
11 Committee. Well that's only if it's not clear. Isn't that correct?

12 A: It is not clear in this case because the researchers have actually called
13 the national study a research study.

14 Q: Well then it becomes a semantic argument about how a persons doing
15 a study choose to present it and choose to define it, it's just a matter of if you
16 use the appropriate words, prepare protocols in the appropriate way, you can
17 avoid Ethical Committee approval unless of course it is something that is
18 done completely for research and cannot be dressed up in another way.

19 A: Well the suggestion here is that if there is doubt it's the Ethics
20 Committee that should be canvassed for it's opinion.

21 Q: Yes but if someone doesn't think there's doubt that's the end of it.

22 A: Well, and the responsibility is then there's, but the Ethics Committee
23 difficulty in these cases is that these were submitted to Ethics Committees
24 for ethical approval. They have received ethical evaluation and they are
25 thought to be fault ethically, that is why - the Ethics Committees can only do
26 what they are asked to do. They have been asked to look at these protocols,
27 they do not believe that there is adequate protection of the interests and well

1 being of the patients involved. They have said that conscientiously. Their
2 responsibility is to protect the patients involved, that's what they have been
3 trying to do. They have not been trying to frustrate the research, they have
4 not, as you have heard in one piece of evidence, been hiding behind self
5 created or unnecessary legislation in order to be politically correct. They
6 have had the concern of the research participants at heart. That's what they
7 have been trying to guarantee protection from.

8 Q: Professor Evans there has never been any suggestion that there are
9 research participants. This is an evaluation study which the Ministry of
10 Health is trying to carry out and there has never been one done in New
11 Zealand for the National Cervical Screening Programme. At least use the
12 correct terminology.

13 A: Well if it is an audit it is being called both by the researchers in letters
14 to me. Then all I can say is it was submitted to the committee for ethical
15 evaluation and it has received that and it has been found wanting, not in
16 ways which we believe are irreparable and we were trying to improve the
17 protocols in order both to achieve the research goals or the audit goals which
18 are extremely important, but at the same time not sacrifice the well being of
19 the participants who are involved. That's what the Ethics Committees have
20 been desperately trying to negotiate.

21 Q: And was one of the ways in which you were doing this a suggestion
22 that the Cancer Register write to persons.

23 A: Yes.

24 Q: And on what basis where you asking the Cancer Register to carry out
25 this exercise.

26 A: I can explain that ma'am.

27 Q: Please do.

1 A: In the Cartwright Inquiry were all of this, as you rightly say Ethics
2 Committees as we know have them in New Zealand originated, there was
3 the very unfortunate –

4 Q: I'm not interested in the background. I want to know why it is that
5 you expect the Cancer Registry staff which is a public register, to write to
6 persons who Dr Cox and Richardson want to approach.

7 A: In order to avoid one of the risks of harm that is outlined in CIOMS.

8
9 MR HINDLE ADDRESSES CHAIR

10 MR HINDLE: Ma'am this is in these letters.

11 CHAIR: Right well in that case I've carried as far as I am interested in
12 carrying it with CIOMS.

13
14 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

15 PROFESSOR DUGGAN: Professor Evans perhaps I can ask you
16 this because I have quite a bit of experience myself in my own country with
17 regard to Ethics Committees. Do the Ethics Committees in New Zealand not
18 have a screening process whereby proposals are review to determine where
19 they fall, that is are they research or are they audit and advice given to the
20 applicants in terms of the necessity of proceeding along one or other line.

21 A: They can ask for advice on that and the matters are canvassed by the
22 chairpersons of the committees and an opinion is returned. No such advice
23 was requested in these cases, it was thought straightforwardly that they were
24 proper cases for ethical review and the Ethics Committees did not question
25 that.

26 Q: So despite the fact that the proposal was entitled an evaluation it was
27 considered research.

1 A: I haven't seen that word so far.

2

3 CHAIR INTERJECTS AND XXN WITNESS

4 CHAIR: Well in the letters it's described – the Otago Ethics Committee
5 wrote to Dr Cox saying multi centre audit of aspects of the National Cervical
6 Screening Programme so the Otago Ethics Committee is calling it an audit
7 of aspects of the National Cervical Screening Programme .

8 A: That is the title it has.

9

10 MR HINDLE CONTINUES XXN OF WITNESS

11 MR HINDLE: Just before we do get to that letter two questions arising
12 out of what Madam Chair was asking you. First of all could you find
13 appendix 5 to the national standards for Ethics Committees dated July 1996
14 please.

15 A: Yes.

16 Q: Page 34. That discussion under the heading audit do you see that?

17 A: Yes.

18 Q: Was that ever mentioned when you were considering in your
19 committee the Cox Richardson national evaluation. Was attention ever
20 drawn to that paragraph.

21 A: No it wasn't, it is assumed that the members are aware of these
22 guidelines, they have training and we certainly don't reproduce the
23 guidelines ever time we consider a proposal.

24 Q: With respect to the example of the first statistical report where we
25 saw that the information for the Wellington Area Health Board could not be
26 included by Ethics Committee approval was not obtained, does that not just

1 demonstrate that you can have a different outcome to a research application
2 depending on where in the country you advance it to an Ethics Committee.

3 A: It does demonstrate it and the CIOMS guidelines make it quite clear
4 that that can happen.

5 Q: So are you seriously telling me that if I am a researcher and I apply in
6 Auckland, I could get turned down, but if I'd applied in New Plymouth I
7 might have gone ahead with it.

8 A: Well that's perfectly justifiable in many cases of research
9 applications.

10 Q: In your view.

11 A: Well in can give you an example to demonstrate.

12 Q: Is that your view that that's acceptable.

13 A: Well I wouldn't say it if it wasn't my view but certainly I can give
14 you examples to demonstrate why I say it.

15 Q: Well I shouldn't restrain you from doing so.

16 A: Well I'm very grateful for that. Ethics Committees are asked to
17 approve or refuse approval for research which is carried out on human
18 participants by specified researchers. So it is not just the business of Ethics
19 Committees to look at the protocol to see whether that is acceptable, it is
20 there business also to look at the qualifications and the facilities of the
21 researchers –

22
23 **CHAIR INTERJECTS AND XXN WITNESS**

24 **CHAIR:** Pause there please. This isn't helpful because we don't have
25 time, we're not really interested in what goes on in research, we're really
26 interested with the impact on the evaluation study Mr Hindle and this

1 witness has said as far as he is concerned it's perfectly OK if you get turned
2 down in Auckland but accepted in New Plymouth.

3 A: Ma'am with respect I think you are now misconstruing what I have
4 said. I was asked a very general question about whether a protocol which
5 was thought to be OK in one place could be thought to be not OK in another
6 place and wasn't that odd. I'm saying it's not odd at all. In certain situations
7 that is perfectly proper.

8 Q: Right well we'll just take the case of the statistical report where
9 every Area Health Board region except for Wellington was happy to release
10 the data, Wellington wasn't. You would find that acceptable?

11 A: I have already said I find that unacceptable, it was anonymised
12 information.

13
14 MR HINDLE: I do need to move on ma'am, there's so much one could ask.
15 May I just ask this?

16 CHAIR: Yes.

17 MR HINDLE: If Cox and Richardson had applied to the Auckland
18 committee to do their evaluation it might have gone ahead, mightn't it?

19 A: No, because they did apply to the Auckland Committee. They applied
20 to all of the committees and Otago simply played the role of lead committee.
21 We have simply pooled all of the requests for amendments from all the other
22 committees. We are simply the conduit in the multi-centre process so it is
23 not the case that this decision that has been made, or this letter has been
24 written is a letter that originates simply from the Otago committee. We are
25 simply the conduit of all the information from every other Ethics Committee
26 in NZ.

27

1 CHAIR: Professor Evans do I take it from your information, though, that
2 for the purposes of statistical study which is going to be conducted over, say,
3 nationwide, that in your view, if there were 2 or 3 regions which for reasons
4 relating to those regions considered that the statistical study should not go
5 ahead and information not be released that would be acceptable?

6 A: No, I don't think that. I think it would frustrate the enterprise.

7 Q: That's right. So what happens then, given that there are 14 Ethics
8 Committees and in order to get access to information the approval of each
9 Ethics Committee must be obtained.

10 A: None of the committees have said that it cannot go ahead. What the
11 committees have tried to –

12 Q: No, I'm asking you about the hypothetical case. What happens when
13 there is an evaluation study, over 6 regions, and 2 regions say “no, we're not
14 going to give you the information”.

15 A: Well what happens in the multi-centre process is where there is a
16 disagreement with committees the Chairs get together and discuss the points
17 of disagreement to see whether or not they can be resolved. I do not know a
18 case yet where they have not been resolved.

19
20 MR HINDLE: Except for the Wellington Area Health Board case?

21 A: Well, that was many years ago before the multi-centre process was
22 introduced.

23 Q: I had better come to my letters ma'am.

24 CHAIR: Yes.

25 MR HINDLE: Do you have in front of you a letter written by the
26 administrator of the Otago Ethics Committee concerning the
27 Cox/Richardson national audit?

1 A: Yes, I do.

2 Q: And that administrator is the administrator of the committee of which
3 you are the Chair?

4 A: That is correct.

5 Q: And I will produce that letter at this stage if I may ma'am.

6 CHAIR: Yes.

7 [Exhibit DME/REC/010]

8 MR HINDLE: And there in para 1 we see, do we not, the attitude taken by
9 your committee to the initial approach to the participants?

10 A: By the committees as a whole. This is a letter from all the committees

11 Q: I accept that, and that is the para in which the committees decided that
12 the Cancer Registry staff should first contact the women, is that so?

13

14 MR PARKER: With respect, it's not recording a decision. If you read it,
15 it's a suggestion, it's not a decision.

16 CHAIR: Well the committee will read the letter and come to its own
17 conclusion as what it entails.

18 MR PARKER: I'm sure.

19 WITNESS: We were trying to improve the protocol, which is the common
20 practice. It happens with almost all protocols which are submitted to Ethics
21 Committees.

22

23 MR HINDLE: Well let's just follow the train of correspondence. I show
24 you another letter. Is that letter a letter that was written to you by Dr Cox
25 on the 30th March 2000?

26 A: Yes, it is.

27 Q: And you received it?

1 A: Yes.

2 Q: I will produce it while I'm thinking about it.

3 [Exhibit DME/REC/011]

4 Q: And do you see there in para 1 Dr Cox deals with this question about
5 the Cancer Registry making an initial approach and he says that "under the
6 Health Information Privacy Code consent is not required to access
7 information from the Register", that's the Cancer Register for research; do
8 you see that?

9 A: I do.

10 Q: And then at the end of that para he gives some practical suggestions for
11 why they didn't want to go through the Cancer Register, do you see that?

12 A: Is that still in para a)

13 Q: Para a) where it says "the method we propose, where the women's
14 medical advisers are asked first whether they judge it would be appropriate
15 for us to approach the women directly, allows the doctor to discuss the issue
16 with women if necessary and avoids us causing undue distress".

17 A: Right.

18 Q: That was what Dr Cox suggested wasn't it?

19 A: Yes.

20

21 CHAIR: Could I just ask here. I am still confused about this. Who was the
22 body that first started things off by saying that the Cancer Register
23 information couldn't be obtained?

24

25 MR HINDLE: Can I get there ma'am, it is going to emerge.

26 CHAIR: Yes, all right.

1 MR HINDLE: I would like to show you another letter. You now have a
2 letter dated the 13th June 2000 written to you by all of the researchers in the
3 national evaluation – i.e. Doctors Paul, Cox and Richardson.

4 A: That is correct.

5 Q: And you received that letter?

6 A: Yes.

7 Q: Just going to the first para, it says there “we've had Ethics Committee
8 approval for the aspect of the audit involving women with pre-invasive
9 disease to proceed but we have not received approval for the party which
10 requires the release of the information to us from the Cancer Registry.” I'm
11 curious. Why is the pre-invasive disease study proceeding and the post-
12 invasive disease one not?

13 A: Well, I think I'm struggling to remember all the details here, but I think
14 that there were possible benefits – I mean health benefits – for the pre-
15 invasive cancer patients and we did not want to hold that up, and there it
16 could be regarded, if you like, as part of the good clinical practice in caring
17 for these patients. That was the difference.

18 Q: And then in the second para they talk there about what they believe is
19 the ethical obligation on those offering a public health programme to
20 evaluate it, with which I take it you would agree?

21 A: Absolutely.

22 Q: Now if we go to your brief of evidence –
23

24 CHAIR: Am I going to find out who's responsible for thinking the Cancer
25 Registry is –

26 MR HINDLE: I'm getting there in the next step. If you go to para 27 of
27 your evidence, in that evidence you say that the committees tried strenuously

1 to resolve the problem by asking the Minister of Health to seek a declarative
2 judgment from the High Court through the Minister of Health about the
3 meaning of rule 11 of the Health Information Privacy Code. Do you recall
4 – well, that's obviously your evidence.

5 A: I recall it very well, yes.

6 Q: And the application arose out of the letter – sorry, the letter to the
7 Minister arose out of the letters we've just been looking at, didn't it?

8 A: It did.

9 Q: And so I take it that you took the view that because of rule 11 of the
10 Health Information Privacy Code the Cancer Registry was not entitled to
11 release the information to those studying the matter?

12 A: We didn't know, and it's not my view, it was the committee's view, and
13 I was asked by the committee to write to the Minister to seek clarification on
14 that.

15 Q: But we know from your consensus approach to committee decisions
16 that you agreed with that view didn't you?

17 A: Yes, I did, I wrote the letter.

18
19 CHAIR: What was the response, are you coming to that?

20 MR HINDLE: Oh yes, we need to give an exhibit number to the 13 June
21 letter.

22 [DME/REC/012]

23 Q: Can I show you a final document in the chain.

24 A: Penultimate document I think isn't it?

25 Q: Now is that a letter that you wrote, a copy of a letter that you wrote to
26 the Hon the Minister of Health on 21st June 2000?

27 A: Yes, it is.

1 Q: And it's clear that in the meantime you've had a response from the
2 Associate Minister, Ruth Dyson?

3 A: Yes, I have a copy of that here.

4 Q: You refer to it in the third para, and I notice that your letter says that
5 you presented the letter to the Otago Ethics Committee but the committee
6 found the response to be unhelpful in that it simply reiterated rule 11 2c) and
7 claimed this presented a clear process thus rendering a declaratory judgment
8 unnecessary. So can I take it that the Minister felt it was clear that under
9 rule 112C you could go ahead your committee didn't agree.

10 A: That wasn't clear from the letter.

11
12 CHAIR ADDRESSES MR HINDLE

13 CHAIR: Have we got the letter. Would should have the letter from the
14 Minister.

15 MR HINDLE: I don't have the letter but –

16 A: I can provide you with a copy of all these letters.

17 CHAIR: Thank you.

18 A: I've been going to bed with them for weeks. I also have a copy of the
19 Minister's reply to my second letter.

20
21 MR HINDLE CONTINUES XXN OF WITNESS

22 MR HINDLE: If you just hand them to Madam Registrar at this stage.
23 While we are looking at those letters let me ask you this. Do you accept that
24 the person charged with the responsibility of managing the information on
25 the Cancer Register is the Director-General of Health.

26 A: Yes I take your word for it.

1 Q: Do you accept then the person who has the legal responsibility to
2 consider what obligations exist if you are going to release information off
3 the Cancer Register is the Ministry of Health .

4 A: Yes.

5 Q: I'm going to ask Madam Registrar to show you a copy of rule 11 of
6 the Health Information Privacy Code.

7
8 CHAIR ADDRESSES MR HINDLE

9 CHAIR: Well I've got it here and I think the important thing to do
10 before we start going to rule 11 is to try to get things right because the
11 Health Information Privacy Code makes it quite clear on page 53 that public
12 hospitals the Ministry of Health and a number of other public bodies are
13 subject to the Official Information Act. It says when a request is made for
14 official information and that includes the Cancer Register which is not about
15 the requester, so you're asking for someone else's information, a public
16 sector agency must consider the application under the Official Information
17 Act. One of the purposes of the Official Information Act is to protect
18 Official Information to the extent consistent with the public interest in the
19 preservation of personal privacy. Accordingly one of the permitted reasons
20 for withholding information is privacy. Section 92A provides for
21 information to be withheld if it is necessary to protect the privacy of a
22 natural person. If 92A applies the agency must also consider whether in the
23 particular circumstances the need to withhold is outweighed by other
24 considerations which render it desirable in the public interest to make the
25 information available. If an agency refuses to release information in a
26 response to an Official Information Act request it must give it's reasons in
27 appropriate relevant terms to that Act. Example I consider it necessary to

1 refuse the request under s92A of the Official Information Act to protect the
2 privacy of the person concerned and I do not consider any other public
3 interest consideration outweighs that interest in this case. The Privacy Act
4 should not be cited as the reason for refusing a request under the Official
5 Information Act even if privacy itself is the reason for withholding the
6 information and the other point is that if you do get refused under s92A you
7 can then go and lay a complaint with the Ombudsman who can look into the
8 matter. When the Ombudsman looks into the matter he is obliged to consult
9 with the Privacy Commissioner under s29B. That is the legal position as I
10 understand it, that's what set out in the Health Information Privacy Code.
11 There is no point in going on about privacy principals because it's not the
12 correct legal situation.

13 MR HINDLE: I wasn't going to ma'am. I was going to ask –

14 CHAIR: You really want to ask Professor Evans whether he was aware
15 of that and whether his committee has ever given any consideration to it.
16 You can look at my copy which I've underlined. You can read that to
17 yourself and you will there see it set out in that booklet.

18
19 WITNESS ADDRESSES CHAIR

20 A: Ma'am do you have a copy of my letter to the researchers dated June
21 14?

22 CHAIR: No I don't.

23 MR PARKER: I have a copy of it.

24 A: In that letter I pointed out to the researchers this was a recourse which
25 they had and up until two days ago and I spoke with the Privacy
26 Commissioner they had not taken advantage of that recourse. I accept and
27 the Ethics Committee accepts that even if it is ethically undesirable and that

1 is what we were asked to rule on. We could be overruled of course and
2 permission could be given to access that information. That would not be an
3 ideal situation but it is again a situation which CIOMS allows for and this
4 was proposed to the researchers and they did not take that route.

5 CHAIR: Well I think your suggesting they go to the Privacy
6 Commissioner, you're not suggesting the Official Information Act but no-
7 one would expect you to be suggesting the correct legal.

8 A: No the law is a mystery to me I have to say.

9
10 MR HINDLE CONTINUES XXN OF WITNESS

11 MR HINDLE: If you thought it was legal to release the information
12 would you have regarded it as ethical?

13 A: No not necessarily.

14 Q: You see those two as distinct.

15 A: I certainly do.

16
17 CHAIR INTERJECTS AND XXN WITNESS

18 CHAIR: So even if Dr Cox and Richardson could legally have got
19 access to the information they required from the Cancer Register you would
20 consider it unethical for them to do so.

21 A: Yes were they could have ameliorated the risk of harm to the patients
22 concerned and that is set out very clear in the CIOMS guidelines.

23 Q: Well what if someone else applied for the information and got it on
24 their behalf who wasn't a clinician and then handed it to them, what impact
25 would that have.

26 A: Well that would also be unethical that would be a breach of
27 confidentiality I suspect.

1 Q: No once official information is released it's released, there is actually
2 a protection, there is no breach of confidentiality –

3 A: That would be a regrettable loophole I think in the legislation.

4 Q: Well that is the legislation that parliament has seen fit to draft. It
5 favors release of public information.

6 A: Well so be it and my judgment of that ethically is that it's rather
7 shabby.

8
9 MR HINDLE CONTINUES XXN OF WITNESS

10 MR HINDLE: Would you put an exhibit number on the letter dated 21
11 June 2000 that you wrote to the Ministry of Health .

12 [Exhibit DME/REC/013 produced]

13
14 CHAIR INTERJECTS AND XXN WITNESS

15 CHAIR: Before we go any further could I just deal with one further
16 point. This is a question upon which I would like your ethical judgment
17 Professor Evans. I would like you to look at this document which is
18 produced by the National Cervical Screening Programme , it is described as
19 an information sheet for women having smear tests and you'll see that
20 written down the bottom, Matcham volume 2 tab 5. Now if you look at that
21 form if you just turn it sideways and look at the little blue line down the right
22 hand side you'll see it says information sheet for women having smear tests.

23 A: Yes.

24 Q: If you turn it back up you'll see the first heading in the left hand
25 column what is the national cervical screening Register.

26 A: Yes.

1 Q: You see it tells you what it is a record of all cervical smear and tissue
2 test results of women who have enrolled.

3 A: Yes.

4 Q: Under the heading your safety net it sets out a number of things, if
5 you read those paying particular attention to the one at the bottom which
6 says helping evaluate the effectiveness of the National Cervical Screening
7 Programme. Now given that a woman when she is given this information
8 sheet for having smear tests is told what the Screening Register is, what it
9 will do for her in terms of reminding her when to have her next test if she
10 has an abnormal smear result and it says at the end, help evaluate the
11 effectiveness of the screening programme would you consider that if a
12 woman having been given this and she decides to have her name put on the
13 Register, well actually she has a choice to opting off, is consenting to an
14 evaluation of the programme?

15 A: Certainly yes.

16 Q: So if women are given these information sheets when they have their
17 smear tests on your interpretation of that statement you would consider that
18 they were consenting to an evaluation of the programme taking place?

19 A: Yes.

20 Q: And therefore consenting to persons carrying out the evaluation
21 having access to the National Cervical Screening Register.

22 A: No.

23 Q: Why not?

24 A: Access to data that is included there, but the patient certainly isn't told
25 here that their name, that their identity will be divulged to those researchers.
26 You see, abstracted information from these registers is a perfect way to do
27 this kind of evaluation, it's the best way because it both protects the

1 participants and provides all the information we want, and if the Registers
2 had been properly set up that is precisely what would have been happening.

3 Q: What do you mean if the Registers had been properly set up?

4 A: Well, if all of the data was on them and was uniquely identified so that
5 the Cancer Registry and the Cervical Screening Register could be linked, all
6 of the information which these research or audit teams want would have
7 been available for them and the privacy of individuals would have been
8 protected and there would no need to override their consent. This has been
9 proposed to access any information which identified them.

10 Q: Well I don't understand how having the two registers linked of its own
11 would help. You'd have to be using some national health index number.

12 A: No, you could encrypt a number, and that's not very difficult at all, and
13 that key could be held by the Register and not revealed to anybody so that all
14 the data would be there for the researchers but they wouldn't know which
15 patients they were talking about. In the same way that I have heard some
16 witnesses in this hearing referred to by number. I don't know who they are
17 but I do know what has been said by them.

18 Q: The fact is that every counsel and party in this room knows who they
19 are, their names are suppressed for publication.

20 A: Yes, but I do. But that's just an illustration of encryption and that
21 could happen on registers and it happens on other registers.

22 Q: Well how, then, would the persons making the evaluation know whose
23 medical records to look at?

24 A: they wouldn't, and they don't –

25 Q: How, then, could they make an evaluation?

26 A: Oh, they would have all of the information that they're currently
27 seeking; they would be able to compare all of the smear results and the

1 health status of the person concerned. Now those who are concerned in the
2 earlier part there, the safety net with treating the women, of course we'd
3 know the identity of the person concerned and name concerned, and they
4 need to because they are caring for her.

5 Q: yes but one of the points of carrying out this exercise to see whether or
6 not there has been under-reporting of smears, if there has been false
7 negatives, and it's all very well to say, "well look at the smear history", but
8 in order to be able to evaluate whether or not the smear tests have been read
9 properly you would do a comparison between the two registers first of all to
10 see if there were any unusual patterns such as 3 normal smear tests fairly
11 close to an incidence of cervix cancer –

12 A: Precisely.

13 Q: And then you would want to go and locate the actual smear tests that
14 were done and have them re-read to see whether or not they had been
15 misread. How would you be able to do it?

16 A: And all of that can be done anonymously in the way I proposed.

17 Q: Well how would you know which laboratory to go to and which slides
18 to get to re-read?

19 A: Well if the matter is set up properly then that number can be attached to
20 all of the data relating to that patient.

21 Q: So you would then have control over the laboratory –

22 A: Just as easily as the national insurance number – I'm sorry?

23 Q: You'd have to have control over the laboratory and how it categorised
24 its slides?

25 A: Well you certainly would want co-ordination and I've heard that
26 appealed for earlier today between the different people involved in
27 screening. You would want proper co-ordination, yes.

1 Q: And how would you get it? How could you go to a laboratory that is a
2 separate legal entity and say to it, “we don’t want to release patients names,
3 we've got these two registers set up in such a way with encrypted
4 information that we’re able to compare the Cancer Registry data with the
5 Screening Register data and we can see there patterns which suggest to us
6 further examination is made of smear tests but all we’ll have is an encrypted
7 number to identify the woman concerned”, how are you going to require a
8 laboratory to also adopt that number for her?

9 A: Well, you contract the laboratory to do the work and you give them the
10 encryption and those slides can be as easily identified with a number as they
11 can with a name.

12
13 MR HINDLE: the fact is Professor Evans that you just don’t understand
14 that what Professor Skegg has to do is go right the way back to GP notes in
15 order to do his study properly – you don’t understand that, do you?

16 A: If the Registers had been set up properly I think we would have been in
17 a very different situation.

18 Q: So what, they would have all of the GP’s notes on them, is that what
19 you're saying?

20 A: No, I’m not saying that

21 Q: We will leave it at that. Coming back to this question of the letters, I
22 just want to round that out. The bottom line here is that you were engaging
23 in a legal debate with the Ministry of Health about what was/was not the
24 legal position under the Cancer Registry Act for release of information from
25 that register.

26 A: It wasn’t a debate, I was asking for clarification.

1 Q: But you weren't accepting the Ministry's point of view because they'd
2 made that perfectly to you, hadn't they?

3 A: No, they hadn't at all. The committee didn't feel that anything had been
4 clarified.

5 Q: Well just let me ask you this: What right did you think you had to
6 engage in a legal debate with a person who has given statutory custodianship
7 of the information at issue?

8 A: We didn't engage in a legal debate.

9 Q: what is this letter of the 21st June, what did you mean when you said
10 that the committee found the Minister's response, the Associate Minister's
11 response to be unhelpful and that it simply reiterated rule 11 2c) and claimed
12 that it presented a clear process thus rendering a declaratory judgment
13 unnecessary. What was that sentence meaning?

14 A: It was certainly not a debate of the legal position.

15 Q: We will leave the committee to consider that in due course.

16 A: I hope so.

17
18 CHAIR: Professor Evans I would just like to tidy something up with you.
19 My understanding from Dr Cox was that he couldn't get access to
20 information on the Cancer Register without having the informed consent of
21 the women. That was the attitude the Ethics Committee adopted, is that
22 correct?

23 A: We thought it would be much – well, I'm sorry, you're talking about the
24 Tairawhiti study?

25 Q: No, Dr Cox's evaluation of the programme.

26 A: Well could you repeat that.

1 Q: My understanding from Dr Cox's evidence was that he couldn't get
2 information from the Cancer Register because the Ethics Committee had
3 required him to obtain the consent of the women concerned and he couldn't
4 get that consent because he didn't know who they were until he got access to
5 the Cancer Register.

6 A: The national study which we were considering in that multi-centre
7 study –

8 Q: The audit.

9 A: Well, the au –

10 Q: that's how your letter describes it.

11 A: Well, the audit was an audit which involved approaching the women
12 directly to ask if they would be willing to be interviewed. It wasn't a
13 question of getting to their records.

14 Q: Well my understanding of the audit was the first thing they wanted to
15 do was to go to the Cancer Register to find out first of all who were the
16 women who they would need to audit.

17 A: that is why we said the better approach would be for the letter of
18 invitation to go out on Cancer Registry letterhead.

19 Q: But my understanding, and I want you to correct me if I'm wrong or
20 not, is that the Ethics Committee had stated that Dr Cox could not get the
21 personal information identifying women with cervix cancer or high
22 incidence of abnormalities from the Cancer Register.

23 A: We never put it that way. The letter that we wrote to him said it would
24 be preferable if this was done.

25 Q: Yes, well was that the import of the letter?

26 A: As it has turned out, that is I think how it has turned out.

27 Q: that is how it's turned out.

1 A: Because the researchers refused to consider that as a possible approach.
2 Q: As getting the Cancer Register to write to the women?
3 A: Yes.
4 Q: Were you aware of whether the Cancer Register was willing to do that
5 or not?
6 A: No, we weren't, and if the Cancer Registry had refused that would have
7 been a different situation. I would be surprised if it did.
8 Q: So I'm right in understanding that Dr Cox couldn't get access to the
9 personal information about women on the Cancer Register as far as the
10 Ethics Committee was concerned?
11 A: Well presumably I believe the custodians of the Register can't give
12 access unless there is ethical committee approval –
13 Q: that is another matter for them.
14 A: Yes, I agree.
15 Q: I'm asking you what is the attitude of the Ethics Committee.
16 A: Well the committee didn't think it the best way to do it, and so they
17 were not satisfied and were trying desperately –
18 Q: Does that mean they were saying yes or no?
19 A: well they certainly have not given full approval until they were satisfied
20 on that.
21 Q: Do you interpret it as a no?
22 A: We don't think we're at the end of the negotiation. We have never said
23 no. We think that the matter is still open.
24 Q: But as matters stand, Dr Cox cannot get access to the Cancer Register?
25 A: Ethical approval hasn't been given for that, no.
26 Thank you.
27

1 MR HINDLE: I had better move on. I think you appreciate that in the case
2 of the Tairawhiti study all that Professor Skegg wants to do is look back at
3 clinical records and look at the information on the registers do you
4 understand that?

5 A: I understand that.

6 Q: And in the case of the national study they want to do that but they
7 also want to interview some of the women.

8 A: Correct.

9 Q: Do you understand that in neither study do they want to take any
10 more samples from anyone.

11 A: I understand that.

12 Q: Do you understand that in neither study do they want to conduct any
13 new medical tests or surgical procedures.

14 A: I understand that.

15 Q: Do you understand that in neither case do they wish to withhold
16 treatment from anyone?

17 A: I understand that.

18 Q: Do you understand that in neither case do they wish to offer anyone
19 any unproven medicine or new treatment.

20 A: I understand that.

21 Q: It's just a look back exercise do you understand that.

22 A: I understand that.

23 Q: Now at paragraph 24 of your brief you refer to the two studies and
24 then you talk about the first question an Ethics Committee asks and you say
25 that the origin of this emphasis is the Nuremberg Code set up as a response
26 to the atrocities committed by the Nazis during the second world war on
27 Jewish patients is that right?

1 A: Not only Jewish patients.

2 Q: At paragraph 34 you go on to say or to provide as an example of the
3 sorts of concerns that irrelevant to your decision you refer to the unfortunate
4 experiment at National Women's Hospital where Professor Green was
5 amongst other things withholding treatment from some patients as part of
6 his study.

7 A: Correct.

8 Q: You're not seriously suggesting are you that what Professor Skegg
9 wants to do is anything like what the Nazis did during wartime Germany or
10 what Professor Green did in the unfortunate experiment.

11 A: Of course not.

12 Q: As I read your statement am I right to think that the essential message
13 which you were trying to convey is that the paramount or predominant
14 concern for your committee is always patient autonomy and informed
15 consent is that right.

16 A: That is the paramount – well no it's not the paramount concern it is a
17 very important issue. The paramount concern – the first question that a
18 committee has to ask is is this aimless or unnecessary research –

19 Q: Did you say aimless.

20 A: Aimless or unnecessary.

21 Q: Are you described Professor Skegg study as aimless.

22 MR PARKER: He didn't put it in that way. Please don't misconstrue
23 it, he obviously wasn't saying that.

24 Q: I'm sorry you were answering the question. Is this aimless.

25 A: The first question which an Ethics Committee is obliged to ask is is
26 this aimless or unnecessary research.

27 Q: I'm sorry, apologies I did jump in too soon. Go on.

1 A: The Helsinki Declaration says that there should be no unnecessary or
2 aimless research carried out on human participants so the very first thing you
3 look at in an ethical review procedure is the objective of the study that is set
4 out on the first page of the protocol. If you consider that that objective is
5 unnecessary or not worth while then it is unethical to subject any human
6 being to the procedures that are proposed so that's the first question that is
7 asked. It was blindingly obvious to everybody on every one of these
8 committees that this was most worthwhile research that has never been
9 questioned.

10
11 CHAIR INTERJECTS AND XXN WITNESS

12 CHAIR: What I want to know is why do you keep saying it was
13 worthwhile research. It's an audit. An evaluation of the programme.

14 A: It was a worthwhile procedure. I apologise it was a worthwhile
15 procedure. The question that is asked is have the participants in this
16 procedure been adequately informed and have they given a propre consent to
17 be part of the procedure. Ethics Committees are charged above everything
18 else after knowing it is a worthwhile procedure with ensuring that is the case
19 and the whole business on these two studies have devolved on that issue.

20
21 MR HINDLE REPLIES & CONTINUES XXN OF WITNESS

22 MR HINDLE: That view you come to of course untroubled by any
23 clinical experience or medical qualification.

24 A: I'm very troubled by the suffering of these patients if that's the
25 inference but I have no medical qualifications and I have no clinical
26 responsibility any more than you have.

1 Q: This is my last topic let me just ask this. I want you to imagine for the
2 purposes of this question that you are responsible, you are responsible for
3 the health and wellbeing of let's say a group of 100 people. Are you with
4 me?

5 A: I'm with you.

6 Q: 2 die and 8 more become ill with a disease. Are you with me?

7 A: I'm with you.

8 Q: Now you've got reasonable grounds to believe that if you could look
9 at the records of those two and the other 8, then you could prevent other
10 people in the group that you were responsible for from contracting that
11 disease. Do you understand me?

12 A: Yes I understand that.

13 Q: Well let's start with the 2 who died would you need to get the consent
14 of their representatives to look at their records.

15 A: No I wouldn't.

16 Q: And what about the 8 that are ill would you need to get their consent.

17 A: No I wouldn't.

18 Q: Well how in point of principle do you distinguish the position I've
19 just put to you with the position that applies in the case of –

20 A: Because I am the caring physician responsible for the welfare of these
21 people. I have this information. That was the scenario you gave me.

22 Q: I didn't actually suggest that you were the caring physician I said you
23 were responsible but I agree I wasn't clear.

24 A: Well you said imagine you have these patients so I thought you were
25 asking a hypothetical question imagine I was a doctor, that's extremely
26 difficult and I don't usually answer hypothetical questions but I was going
27 along with you to try to help.

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CHAIR INTERJECTS AND XXN WITNESS

CHAIR: Well lets take the same hypothetical but say your not the person caring for these people but you're an epidemiologist who has been brought in because 2 people have died, 8 people are ill and there's a strong possibility others are going to fall ill as well. As the epidemiologist whose trying to see what can be done in a general sense who is not the clinician for each individual in this group would it be permissible to look at the records of the two deceased persons.

A: I don't that would be where an epidemiologist would be involved but clinicians most certainly –

Q: No I asked you on the point from the epidemiologist who is trying to look generally at what is the cause of the disease and to see whether it can be stopped for others, not the clinician of each individual person, would it be permissible for the epidemiologist to look at the records of the 2 deceased persons. Yes or no.

A: It depends –

Q: If you can't say, say so.

A: I can say but I have to qualify my answer first of all. If we are talking about a situation where there is an imminent and serious threat to another person, if that's the situation we're talking about and that's what I took you to be describing, something like the beginning of an epidemic, then of course the health information privacy code says that a doctor is under an obligation to make that information known because of the serious and imminent threat.

Q: I don't want to hear about the health and privacy information code. That's a separate issue. As lawyers we're quite capable of interpreting the

1 code for ourselves. What we want to know is from the ethical stand point.
2 If you would please give us your opinion as chairperson of an ethics
3 committee, would it be ethical.

4 A: I think in that emergency situation it certainly would.

5
6 MR HINDLE CONTINUES XXN OF WITNESS

7 MR HINDLE: What about one that's not quite an emergency but you
8 still know that the longer you leave it the more people are going to die.

9 A: Well it's got to be very difficult to know where to draw the line but
10 that there is a crucial difference between general epidemiological studies in
11 the population and these emergency situations there is no doubt about at all.

12
13 CHAIR INTERJECTS AND XXN WITNESS

14 CHAIR: Well what if we have a situation here where Professor Skegg
15 has been asked to do a study for the purposes of the Committee of Inquiry to
16 find out whether or not there are any – whether under-reporting is a systemic
17 problem within the programme and Professor Skegg is charged with that
18 particular task and that of course if very important because if there is a
19 systemic problem there may be cases of cervical cancer which could have
20 been prevented by the programme that are not. It means the programme is
21 failing in that circumstance do you consider it to be ethical to permit
22 Professor Skegg to carry out an audit of the programme.

23 A: I think there are degrees of goodness and degrees of badness. I think
24 the ideal situation would be that all of the people and we're not talking about
25 a very large number of people here, all of the people consent for their
26 identifiable information to be accessed by Professor Skegg.

1 Q: Just tell me this. How do we find out who they are. We don't know
2 who they are that's the problem.

3 A: But their physicians know who they are.

4 Q: So what are we supposed to do put an advertisement in the paper
5 asking all physicians to come forward and how can they come forward and
6 tell us given their own obligations of confidence to there patients?

7 A: Well there are people who do know who they are, and the approach
8 could made by the custodians of that information.

9 Q: The only way we can find out is by looking at the Cancer Registry?

10 A: That's right, and those who are custodians of that information, and
11 quite justifiably so, could make the approach to the people concerned. And
12 that is precisely what we proposed in the national study, and I suspect that is
13 – although I'm not in the Tairawhiti committee, I presume that is what they
14 had in mind also.

15 Q: And in terms of the ethics of the situation, what happens if half of the
16 women approached refuse, what do you do then when you know that you
17 need to look at the information in order to see whether or not the programme
18 is failing in the rest of the country?

19 A: Well now that is a very difficult situation, but we have to go back to the
20 Helsinki Declaration which says that the interests of the individual
21 participant – they're in a research project but it's taken up by CIOMS in
22 epidemiological studies.

23 Q: Well I don't read CIOMS as doing that, and I don't see how –

24 A: Well it declares it, ma'am.

25 Q: - you can pick up the Helsinki Declaration. Well, we can keep going
26 back to CIOMS again, at the end of the day the committee will form its own
27 view on CIOMS.

1 A: Of course.

2 Q: But my reading of CIOMS is that it is not clear at all that it applies to
3 an audit or an evaluation of a programme, and particularly with Professor
4 Skegg's audit because that is being done for the purposes of a Committee of
5 Inquiry specifically set up to look into under-reporting of the Cervical
6 Screening Programme.

7 A: And I have no doubt that you have the authority to access this
8 information and that he can do so. I think it will be very much better if he
9 did so with the blessing of the women concerned, because I think, as the
10 CIOMS guidelines point out, there are certain losses involved for those
11 women. If it is the case, and I'm not saying that it is, but evidence – you've
12 heard more evidence than I have on this, but if it is the case, and it certainly
13 was in the Cartwright Inquiry, that large numbers of women have received
14 sub-optimal treatment – i.e. they already feel that things which are crucial in
15 their lives are beyond their control, and that was the way it was expressed I
16 believe at Cartwright, it does not seem good to me that those people should
17 now feel that their records and access to them is also beyond their control. I
18 suppose very few of them – I agree with Professor Skegg here, we have
19 talked about these things – of them would refuse. But that is not to say that
20 they should not be asked. That's all I believe that the Tairawhiti committee
21 was recommending. If it went that way, I think it would be a better audit
22 than if it went ahead without it. That's what the Ethics Committee has said.

23 Q: Yes, but are you saying if they are asked what if they say no, what do
24 you do then?

25 A: Well, of course you have the power, I understand, to access those
26 records in any case.

1 Q: I'm not asking you about how the Committee of Inquiry exercises its
2 powers, I'm asking you about your Ethics Committee and what happens
3 when you say consent should be obtained and it becomes clear that consent
4 is not going to be obtained to the extent that it's going to allow the study or
5 the evaluation audit to be carried out in a meaningful way.

6 A: Well then it comes back to my point about there being gradations of
7 goodness and badness, and I would say it would be much better if consent
8 was given by everybody, but the gain is so important that in the event of
9 people having the opportunity to agree to their records being seen, if their
10 refusal to consent is over-ruled, well it is important that the study go ahead.
11 But they have, in fact, been treated with dignity and they have been asked
12 "you have control over this information, would you be willing for us to look
13 at it", that seems to me a desirable procedure.

14 Q: So you are saying, then, that for Doctors Cox/Richardson, also applying
15 the logic of what you say, that you would go to the women concerned once
16 you'd found out their identities, ask for their consent, if it wasn't
17 forthcoming that wouldn't necessarily be the end of the matter because it's
18 the act of going to them and seeking consent that is of crucial importance
19 rather than whether or not they consent?

20 A: that in itself is very important. It wouldn't make it perfectly ethical, but
21 I'm saying it would be less unethical than not bothering to ask in the first
22 place.

23 Q: And just so I can be sure on your view of the CIOMS/guidelines, its
24 para 52 and 4 that you say capture audits and evaluations?

25 A: Excuse me ma'am, I'm getting lost with all this paper here. Para 52
26 ma'am?

27 Q: Yes, 52 and para 4 as well you referred to.

1 A: Yes, that's right, para 4.

2 Q: I noted in your evidence from time to time you said that if the Registers
3 had been set up in the appropriate way these difficulties wouldn't be
4 encountered?

5 A: Yes.

6 Q: but do you agree that in dealing with situations like this one has to deal
7 with them as they present themselves and come to the best possible answer
8 rather than looking at how they might have been handled better in the first
9 place?

10 A: You've got it absolutely right, ma'am, and I think there are some better
11 ways of doing it than the ways that were proposed.

12 Q: Yes, but it's not really very productive at the moment, do you accept, to
13 be focusing on how things might have been done rather than looking at how
14 can they be approached given the way they are?

15 A: It's not for me to decide what recommendations should be made by this
16 Inquiry, but I presume –

17 Q: I'm not asking you about recommendations to be made by the Inquiry,
18 I'm saying to you, you've said a number of times in your evidence, if the
19 registers had been set up in an appropriate way, linking the information with
20 encrypted identification, this problem may not have occurred; is that right?

21 A: I did say that, yes.

22 Q: And I'm just asking you now, when one is approaching issues such as
23 whether or not to have access to personal information do you not think it is
24 appropriate to look at the situation as it presents itself in fact rather than to
25 focus on how it might have been done?

26 A: Yes, that's what the Ethics Committees have done, ma'am.

27 Thank you.

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MR HINDLE: I think I've spent enough time on this, thank you ma'am.

CHAIR: Yes, thank you. Does anyone else have any questions? Yes, Mrs Marshall.

XXN MRS MARSHALL:

Q: I just have one very brief question Professor Evans, and that is, I would like to refer to a letter that has been produced during these discussions, it's a letter from Dr Cox to you of 30th March, and that's been given the number of 11.

A: Yes, I have it.

Q: And under 1a), if I could just read out the last two sentences, entitled "should the Cancer Registry make the initial approach to women".

A: I have the wrong letter I think in my hand.

Q: It would be exhibit 11. Madam Registrar it's the 30th March 2000 to Professor Evans.

A: Now I have it, thank you.

Q: 1a) has the title "Should the Cancer Registry make the initial approach to women"

A: Yes.

Q: And the last two sentences read "the method we propose" – and this is from Dr Cox – "where the woman's medical advisers are asked first whether they judge it would be appropriate for us to approach the women directly allows the doctor to discuss the issue with women if necessary and avoids causing undue distress." The last sentence then states, "we have been using this method in a current study of men with prostate cancer and it has been very well accepted." Professor Evans can you confirm whether the Otago

1 Ethics Committee gave approval to Dr Cox and his colleagues to undertake
2 the prostate study to which he refers here?

3 A: I have no memory of it. I have only been the Chair of this committee
4 and a member of this committee for a year and a half.

5 Thank you.

6
7 CHAIR: Yes, Ms Bunkle.

8
9 XXN MS BUNKLE:

10 Q: In your brief of evidence you variously describe the purpose of Ethics
11 Committees as patient protection or to enhance the safety, health and welfare
12 of patients, is that correct?

13 A: Could you refer me to the section?

14 Q: At various points through your brief you refer to the purposes as patient
15 protection, or you refer to your purposes is enhancing the health or welfare
16 of patients.

17 A: Not all patients but patients who are research subjects.

18
19 CHAIR INTERJECTS AND XXN WITNESS

20 CHAIR: What about patients that are the subject of an audit.

21 A: Or patients who are subject to an audit. I apologise ma'am. I must
22 learn to remember that.

23
24 MS BUNKLE CONTINUES XXN OF WITNESS

25 MS BUNKLE: So as you understand the purpose of an Ethics
26 Committee it is only to do with the welfare of people who might be involved
27 in strictly defiant research situations.

1 A: No I have said the opposite to that in answering questions to the
2 chair.

3 Q: Yes I rather thought you had. So it does have to do with the welfare
4 of patients more extensively defined.

5 A: Well those who are participants in either the audit or the research or
6 whatever but not with future patients or patients in general.

7 Q: Or past patients.

8 A: Well it might.

9 Q: Deceased patients.

10 A: No Ethics Committees aren't usually consulted on research on
11 deceased patients.

12

13 CHAIR INTERJECTS AND XXN WITNESS

14 CHAIR: My understanding I'm sorry to interrupt Ms Bunkle of the
15 Tairawhiti Ethics Committee who I understand you represent today required
16 Professor Skegg to get the consent of the next of kin of persons who had
17 died of cervical cancer. Are you aware of that?

18 A: I am aware of that I cannot comment on it ma'am. I am certainly not
19 here to speak to the decision that that committee made, the reasons it had
20 for making that decision. The reason I was asked to come by all the
21 committees was to rebut some of the things said in evidence about Ethics
22 Committees.

23 Q: Well can I take it if Professor Skegg applied to the Otago Ethics
24 Committee and he wanted to look at the records of persons who had died
25 from cervical cancer would the Otago Ethics Committee require him to get
26 the permission of the next of kin?

1 A: I would have to ask them ma'am they are consensus decisions as
2 counsel has correctly pointed out.

3 Q: Can you say what you would decide?

4 A: I think I would ask what the purpose was for wanting the information.
5 I don't think it's information that should generally be ?? about but I certainly
6 would not be as strict in my requirements there as I would for those yet ??.
7 That is just my personal view.

8 Q: So if he was doing a study to see whether cervical screening
9 programme was working or failing in preventing cervical cancer in those
10 circumstances if he wanted to look at the records of persons who had died
11 from cervical cancer who were part of the screening programme what is
12 your personal view as a member of the Otago Ethics Committee as to
13 whether or not the consent of next of kin should be obtained.

14 A: Well again it would depend on the circumstances. If the person had
15 died this morning or yesterday and the family were grieving in think I would
16 be much more careful than if it had happened some time ago for example.

17 Q: And if it had happened a year ago.

18 A: I think that wouldn't bother me but that is just my view.

19 Q: So you wouldn't see a need for consent if the patient had died a year
20 go

21 A: No but you have asked for my personal view on that.

22
23 MS BUNKLE CONTINUES XXN OF WITNESS

24 MS BUNKLE: Thank you. In paragraph 32 of your brief you say that
25 it's not the Ethics Committee responsibility to facilitate a catch up review to
26 remedy deficiencies in management or treatment. How is patient protection
27 advanced by a catch up review not going ahead?

1 A: Well with respect your quote of my brief is incomplete. What I said
2 was that those committees should not be expected to abandon their
3 responsibility to protect research subjects in order to facilitate such a catch
4 up process.

5
6 CHAIR INTERJECTS AND XXN WITNESS

7 CHAIR: But just pause there because I understand that as you consider
8 that audits and evaluations are also captured by this requirement although
9 here you just say protect research subjects, we should read into that the
10 words subject of audits and evaluations.

11 A: I apologise ma'am I've done it again I apologise.

12 Q: Right so reading that into the sentence please answer Ms Bunkle's
13 question.

14
15 WITNESS ANSWERS AND MS BUNKLE CONTINUES XXN OF
16 WITNESS

17 A: I'm simply saying that your quotation was incomplete. What I'm
18 saying they shouldn't be expected to do is to abandon their responsibility to
19 protect research subjects or those whose records are to be accessed in the
20 course of an audit to abandon their responsibility to protect those subjects in
21 order to facilitate a catch up review that's what I says.

22 Q: Where those research subjects that you don't want to abandon are the
23 same people as patients how can you set the interests of those people as
24 patients against their interests as potential research subjects when they are on
25 in the same person.

26 A: Well I'm sorry ma'am you've misunderstood my point. I am
27 contrasting the interests of patients in general and future patients for

1 example with the interests of these persons who are either involved in a
2 research project or who are involved in an audit. That's the contrast I am
3 making.

4 Q: But don't you understand that if the patients who are involved in the
5 audit they too have the benefit of the audit if it goes ahead.

6 A: Some of them do but as a matter of fact in one of these protocols we
7 were told there was no benefit to them at all and for some of them in the
8 other we were told there was no benefit at all. That's what we were told in
9 the protocols now you have made a very good point about there being some
10 benefits, but not health benefits.

11 12 CHAIR INTERJECTS AND XXN WITNESS

13 CHAIR: It might be of benefit to their peace of mind though to know
14 whether or not the cancer they ultimately got was just a natural incidence of
15 the disease rather than a failing in the programme.

16 A: This might well be and that's a matter for them to tell us.

17 Q: But until the audit is done they're not going to know that's the point.

18 A: When they are asked for their consent they can be told what the point
19 of the audit is and if they think that's a valuable gain for them as in all other
20 proposals to Ethics Committees then they can make a decision in the light of
21 that.

22 Q: Yes but the problem is you see unless we are told for example in
23 Tairawhiti that there are 61 cases of cancer now registered from 97-1000 we
24 are also told that unless the audit goes ahead for all or most of those cases,
25 there is no meaningful benefit overall in the audit going ahead therefore
26 what it really means is that the refusal of a number of people could lead to
27 the audit not going ahead at all.

1 A: Well ma'am I thought I remembered reading in evidence of xxn of
2 Professor Skegg that if he discovered that there was someone who did not
3 consent he would respect that wish.

4 Q: And my understanding is that there needs to be a certain number of
5 people in order for this audit to make sense.

6 A: You're quite right methodologically.

7
8 MS BUNKLE CONTINUES XXN OF WITNESS

9 MS BUNKLE: Professor is it ethical not to protect people as patients
10 because you have decided that they need protection as potential research
11 subjects?

12 A: I'm not quite sure I understand your question.

13 Q: As patients these people could benefit from this catch up audit which
14 has not occurred.

15 A: That was denied in the protocol.

16 Q: You say that it is not your ethical business as an Ethics Committee to
17 consider – to take responsibility for a catch up audit not to occur but I'm
18 saying is it ethical for these patients to be denied the benefit, the protection
19 of a catch up audit because you have decided to protect them as potential
20 research subjects. Which is the ethical decision.

21 A: Well again I'm confused by your question. The protocol which we
22 had said that in the Tairawhiti case, this is the protocol as I have read it, but
23 there was no benefit apart from the benefits Madam Chair has pointed out
24 which were not health benefits but this audit held for them.

25 Q: So for example the catch up audit might have discovered that not all
26 of them had had completed treatment . Is it ethical to withhold the

1 possibility that might be discovered because you believe that in doing so you
2 would turn these very same patients into research subjects.

3 A: Well all I can do is repeat what the protocol said it didn't envisage
4 that as a possibility.

5
6 CHAIR INTERJECTS AND XXN WITNESS

7 CHAIR: No but just deal with the questions as put to you?

8 A: Well we have already permitted one phase of the Otago study to go
9 ahead precisely for that reason.

10 Q: My understanding is that study is looking at certain aspects of
11 abnormalities it's not looking at incidences of cancer or cancer mortality.

12 A: No, no. but it is with a view to treating these women whose treatment
13 may be required.

14 Q: Let's focus on the part of the evaluation that isn't going ahead. It's
15 confusing to introduce aspects of it that are going ahead.

16 A: Yes.

17 Q: So Ms Bunkle if you would continue.

18
19 MS BUNKLE: I wonder if we could turn to para 34, in that you say that
20 the issue of consent has arisen partly because at the Cartwright Inquiry it
21 was discovered that doctors had allowed a study of early cell changes in the
22 cervix to proceed without consent. Are you aware that those studies also
23 involved what was then called microinvasion and that we would call high
24 grade abnormalities?

25 A: Yes.

26 Q: Are you aware that as a result of the review of the records conducted by
27 the Cartwright Inquiry more than 100 women with high grade abnormalities

1 were identified as being at risk by that Inquiry and were recalled by the
2 Inquiry?

3 A: Yes.

4 Q: Are you aware that these terms of reference 3 recalled women when the
5 recall was undertaken by the Inquiry demonstrated that some of them needed
6 further treatment?

7 A: Yes.

8 Q: And that they got that treatment as a result of the review that was
9 undertaken of their records?

10 A: Yes.

11 Q: If we applied the very strict definitions that you are asking us to apply
12 to this Inquiry, that review of those patient records by the Cartwright Inquiry
13 could not have gone ahead could it?

14 A: Well what happened at Cartwright was three of the physicians who had
15 responsibility – physicians of various kinds – for the care of these patients
16 and had access to all their data had, as you will know, tried for a very long to
17 bring this difficulty out into the open and felt that their patients had been
18 denied optimal care.

19 Q: At the Inquiry however, the records of the women involved were made
20 available, both to the Inquiry members and to parties at that Inquiry, and as a
21 result those records were reviewed and the result of that review was that the
22 Inquiry recalled patients and lives were saved. That review could not have
23 happened under the strict definitions of consent that you are now trying to
24 apply to the records of women involved in this Inquiry, could it?

25 A: Well I think this Inquiry has exactly the same powers as the Cartwright
26 Inquiry had.

27 Q: Yes, but it didn't face impediments from Ethics Committees.

1 A: Ethics Committees arose out of the Cartwright Inquiry for the specific
2 reason that the women who had been included in that study hadn't been told
3 they were in a study and hadn't been asked to consent to be in that study.
4 Ethics Committees were created out of the Cartwright Inquiry to protect
5 patient participants in research from that kind of abuse. That's why Ethics
6 Committees were created.

7 Q: Thank you for informing me about that, I had nearly forgotten. Can
8 you confirm to me that part of the ethical considerations that arose from the
9 Cartwright Inquiry were that there were women who had not consented not
10 to be treated and that those women were identified as at risk because of a
11 review of their medical records undertaken by the Cartwright Inquiry?

12 A: Yes.

13 Q: do you believe that the Cartwright Inquiry behaved ethically in
14 undertaking that review of the women's records?

15 A: Yes, I believe that it had good reason to believe that these particular
16 women were at risk. And that had been revealed by clinicians.

17 Q: So if this Inquiry undertakes a parallel review of patients records it will
18 also be behaving ethically to protect those women?

19 A: Well, the health status of these women, as I understand it in the
20 Tairawhiti case, is already well known.

21 Q: Are you so certain that that is the case, that all 61 women have been
22 identified to this Inquiry and that this Inquiry is therefore able to ascertain
23 that they don't need further treatment without a review of their records
24 taking place?

25 A: I'm not certain of that at all, and I have to say, as I said a little earlier,
26 that I was not involved in the Tairawhiti decision so I do not have all the
27 information on that.

1 Q: Are you aware that the Cartwright Inquiry took place because of
2 information derived from a study by Doctors MacIndoe, McLean, Jones
3 which involved the review of patient records at National Women's Hospital
4 and its subsequent publication?

5 A: Yes, I'm aware of the 1984 paper and all the people that you have
6 mentioned had part responsibility for the treatment of those patients.

7 Q: But they did not actually have the consent of the women whose records
8 the reviewed in preparing that paper?

9 A: No, but they had access to the information as their clinicians, as
10 clinicians caring for them.

11
12 CHAIR: Hold on a moment, professor, are you seriously suggesting that a
13 medical practitioner, who has care of a patient can if that medical
14 practitioner feels like writing a research paper on cancer, can dip into the
15 patient records, pull out information about the patient and use it for the
16 purpose of the practitioners research paper about cancer?

17 A: A great deal of new knowledge comes to light in the process of
18 clinicians audit of their practice, and they will often, in an anonymised
19 fashion, describe the cases that they have treated.

20 Q: Just to get an understanding of this. In terms of medical ethics, it's
21 perfectly acceptable for a clinician to use the information he/she receives
22 from his/her patients as part of the treatment process for the purposes of that
23 clinician doing their own private research paper to have it published in a
24 medical journal – that is acceptable, yes or no?

25 A: they are not conducting a research trial or a research project, but new
26 knowledge can come out of audit of their own practice. They are not

1 accessing information about those patients that they didn't already have
2 access to.

3 Q: Yes, but they're not using it for the purpose for which the patient's
4 given them the information are they? If I go along to a doctor and reveal
5 certain aspects about myself to the doctor for the purpose of getting
6 treatment, the doctor provides me with the treatment. If then uses the
7 information he has learnt about me and the way in which my body has
8 reacted to the disease in a medical journal, that is not the same purpose for
9 which I gave him the information.

10 A: Well, it is a review of his practice.

11 Q: Are you suggesting that an article in the Medical Journal where a
12 practitioner may write about what he/she has learnt about the disease in a
13 particular patient is not research?

14 A: Well, it isn't research explicitly, no.

15 Q: Well, it's really got nothing to do with auditing my files, has it?

16 A: Well it has, it has to do with auditing your treatment and quite a lot of
17 new medical knowledge comes to light in precisely that way, not always in
18 the context of research trials.

19 Q: I see, so if the Ministry of Health wants to have someone come along to
20 see if their programme is working effectively, that type, what would be an
21 audit to a lay person is treated as research by an Ethics Committee and
22 equally if a doctor chooses to pull out information from patient files and
23 write an article about the disease in a Medical Journal that's an audit of the
24 patient's case, is it?

25 A: No, I'm perfectly happy to call what we've been describing here today
26 audit. I forget to do it sometimes, but I'm perfectly happy to do so.

1 Q: And just so that I can be clear: You are perfectly relaxed about a
2 medical practitioner going into his/her patient's files, extracting information
3 that the practitioner has learnt about the patient, the progress of the disease
4 in the patient, and writing about it in a medical journal?

5 A: The point of access isn't the difficulty.

6 Q: Well, I want to know whether you are comfortable with that happening,
7 without the consent of the patient concerned?

8 A: Well, I think by and large I am comfortable with it, in that the
9 information is already in the possession of the clinician and there is no
10 breach of confidentiality and information is totally anonymised in any
11 publication of a review of a series of cases.

12 Q: But it's not being used for the purpose for which it was given is it. It's
13 being used for a different purpose.

14 A: It is true that the clinical practice is being reported yes.

15 Q: It is being used for a different purpose for which the patient gave the
16 information.

17 A: Insofar as it is a report of what was done, yes that is the case.

18 Q: Thank you Mr Rennie.

19
20 MR RENNIE ADDRESSES CHAIR

21 MR RENNIE: Ma'am I know it's a little irregular but I have the honors
22 to act for Dr McIndoe, Jones and McLean at the 87 Inquiry and with the
23 greatest respect to the witness, his assertion that they had clinical
24 responsibility for the cases they wrote about is utterly untrue. The real point
25 of the study was that they were writing about the cases, Professor Green had
26 clinical responsibility for but I interrupt not to start a debate ma'am but
27 purely to offer a pretty vital factual correction.

1 CHAIR: Yes because what we are really interested in looking at is what
2 is really illustrated here is that if the same ethical rules applied today would
3 the Cartwright Inquiry have ever got off the group.
4

5 WITNESS REPLIES

6 A: Could I answer that ma'am.

7 CHAIR: Yes.

8 A: Well the colposcopist as far as my reading of the unfortunate
9 experiment goes and the general physician and the pathologist were all
10 involved in these cases.
11

12 MS BUNKLE CONTINUES XXN OF WITNESS

13 MS BUNKLE: Are you aware that Professor Green was severally
14 criticised because he did not make available the information from those files
15 or analyse them in a properly established evaluation and audit process.

16 A: Yes I am and I think quite properly. I mean he was condemned quite
17 properly. I have said that audit of practice is a *sena qua non* of good clinical
18 practice.

19 Q: So in your view if he had organised the information that he derived
20 from his clinical practice into a research proposal, that would have been
21 unethical.

22 A: I'm not quite sure what you're asking now.

23 Q: The inquiry decided that part of what made Dr Green's process
24 unethical was that he left his clinical information and did not organise it into
25 a proper audit of his results but you believe that that would make these
26 women research subjects.

1 A: No I don't, I agree with Madam Chair I'm trying hard to learn not to
2 use the word research in this context but you are making it difficult for me.

3 Q: Professor Green called it clinical cartography you might be more
4 comfortable with that description. Are you aware that it was extremely
5 difficult for Dr McIndoe, Jones and McLean to obtain the key clinical
6 information that they needed in order to publish the results which made
7 Cartwright possible because as the responsible clinician Professor Green
8 would not release that information.

9 A: Yes I'm aware of all of those struggles yes.

10
11 CHAIR ADDRESSES MR RENNIE

12 CHAIR: If I could just interrupt here Ms Bunkle, I just want to fix up
13 the point Mr Rennie raised, Mr Rennie I note that from the bar you have told
14 the committee that you acted for –

15 MR RENNIE: Dr McIndoe, Jones and McLean who were the three
16 medical authors of the 1984 ma'am.

17 CHAIR: And in your view they were not acting as clinicians for some
18 of the women they wrote about in that paper.

19 MR RENNIE: It's not merely a matter of view ma'am, it's a matter of
20 record, I obviously haven't come equipped to demonstrate it by reference but
21 that is certainly the position.

22 CHAIR: Well what I'll do is I'll just canvass everyone here to see
23 whether or not they are happy for that information to go into the record by
24 consent and if not then well you'll have the opportunity to show that that
25 was the case and if it can go in by consent we can just take it as so. What's
26 your position Mr Hindle.

27

1 MR HINDLE REPLIES

2 MR HINDLE: Certainly consent I actually think that the full text of
3 that article that research I think was an appendix to the Cartwright Report
4 itself which is a publication.

5 CHAIR: Yes well we're trying to find it but I want to move on. So
6 what's the position of everyone else, Mr Parker are you happy if it goes in by
7 consent.

8 MR PARKER: Yes

9 CHAIR: Everyone else happy, very well we will accept by consent that
10 Dr McIndoe, Jones and McLean were not acting as the clinicians for a part
11 of the women about whom they wrote in the article of what year, 1984
12 which in turn was the catalyst for the Cartwright Inquiry .

13
14 MS BUNKLE CONTINUES XXN OF WITNESS

15 MS BUNKLE: I'll be very quick ma'am. So Dr McIndoe, Jones and
16 McLean undertook a review of patient records in order to publish their
17 results and those results lead to the issue at National Women's becoming
18 public and therefore to the possibilities of the Cartwright Inquiry. Do you
19 agree?

20 A: Yes.

21 Q: Under your definition of patient consent that 84 study which lead to
22 the Cartwright Inquiry could not have gone ahead could it.

23 A: Well there was evidence of very serious damage and this I think does
24 make it rather a different kind of situation. There were clinicians in that
25 hospital who believed that patients were not being properly treated. That is
26 certainly true of the 3 clinicians who have been mentioned.

1 Q: There are doctors in Tairawhiti who are concerned about their
2 patients not being properly treated and concern about some of their patients
3 who have died. Does that materially alter the difference around consent and
4 the legitimacy of a review of patient records.

5 A: What I have said earlier is that I think there are degrees of goodness
6 and there are degrees of badness. I am not opposing this kind of audit into
7 these women's records, I am saying it would be the better if it was done with
8 their consent, that is the point I labored a little earlier and I don't think you
9 would really disagree with that.

10 Q: Madam Chair has said that it is ironic that the study that lead to the
11 Cartwright Inquiry and the establishment of Ethics Committees couldn't
12 have gone ahead under your strict definition of consent. What comment do
13 you have to make on that irony.

14 A: Are you referring to the evidence, the questioning in evidence, I
15 though Madam Chair your point about irony was a different point from that.

16 Q: It was a point made about exactly this situation.

17 A: I thought the irony you referred to was that the very inquiry which
18 looked in to the cervical cancer study also gave rise to Ethics Committees
19 that was the irony you were referring to

20 Q: No that was the irony Sandra cony was referring to.

21
22 **CHAIR REPLIES**

23 **CHAIR:** The irony I was referring to was the fact that the Cartwright
24 Inquiry gave rise to Ethics Committees as they now are that the very type of
25 publication by Dr McIndoe, Jones and McLean which was the catalyst for
26 the Cartwright Inquiry might not now be permitted to go ahead by Ethics
27 Committees because without consent I couldn't see how it could happen.

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MS BUNKLE REPLIES & CONTINUES XXN OF WITNESS

MS BUNKLE: Madam may I read your quotation.

CHAIR: Yes.

MS BUNKLE: Madam Chair said so it's rather ironic that an inquiry that has been the catalyst for the national development of Ethics Committee in their current form may well not have taken place if those very Ethics Committees in their current form had been in place at that time. Will you comment on that irony?

A: Well I think where there is suspicion that there is something nasty in the woodshed occurs, then inquiries such as the Cartwright Inquiry have the powers to look into those matters and it is important that –

CHAIR: No that's not the question that's being asked. Just concentrate on the question.

MR PARKER: The question was comment, it wasn't a question, it came down to will you comment on that and that's what he's doing. He wasn't asked a specific question.

CHAIR: Well Mr Parker I think that it's quite clear what Ms Bunkle wanted him to comment on. She wanted him to comment on the irony that had Ethics Committees in their current form been in place at the time Dr McIndoe, Jones and McLean wrote their article, it's likely they wouldn't have done so because they wouldn't have got consent.

A: Well I said that it's not clear to me that that is the case. I would need – I am almost totally dependent on the unfortunate experiment for my account of what went on at Cartwright and that's why I would not contest anything that has been said by my understanding of the situation there is that much of this clinical information was available to the people who published

1 the 1994 paper, but not on the basis of conducting any kind of research
2 project.

3 Q: And is it your view that under those circumstances their writing that
4 paper was ethical?

5 A: I don't see anything unethical about writing the paper. There was no
6 identification of any of the people concerned in that paper, and it's rather
7 like the clinical practice case I was discussing with Madam Chair some time
8 ago.

9
10 CHAIR: But to write the paper they would need to get access to the
11 personal information of patients who were not their own patients?

12 A: Well, my understanding of it was, but I stand to be corrected, if we
13 mean "by their own patients", the clinician who was responsible for their
14 overall care, which I agree was Associate Professor Herbert Green, that's
15 one matter, but if these people who were conducting examinations of what
16 sort and another on these patients then their involvement with the patients
17 does make a difference.

18
19 MS BUNKLE: So it is your view that their conducting this review of the
20 women's records was ethical, not because they had consent but because they
21 were practising clinicians within National Women's Hospital; is that what
22 made it ethical?

23 A: Yes, properly auditing their practice. There's a responsibility on
24 clinicians so to do.

25 Q: And not because they organised the study into a properly organised
26 research project?

27 A: well, my understanding is it wasn't a project like that.

1 Q: So you would disagree with Judge Cartwright's criticism of the
2 processes in National Women's Hospital because it failed to organise the
3 information gathering into a properly organised research study?

4 A: I certainly would agree with her that there should be proper collation of
5 information in order to proper audit can occur. That is very important and I
6 have never disagreed with that in this case. I think it's extremely important
7 that happens.

8 Q: So if the doctors at Gisborne Hospital volunteered to undertake this
9 review, if it was anybody in their own hospital, that would be ethical without
10 consent. That's the analogy, isn't it?

11 A: Yes, it is, and I did talk about health providers having that access much
12 earlier and in my answer to Madam Chair's questions.

13 Q: So when those providers patently failed to protect their patients, that is
14 not unethical but them reviewing the records without consent, just because
15 they're the women's doctors, is ethical. Is there an irony in that?

16 A: Well, I disagree with the first part. Of course it's unethical not to
17 provide optimal treatment to patients.

18 Q: So how are the women ever to discover that they were not provided
19 with optimal treatment if the doctors in the hospital concerned do not choose
20 to tell them, or choose to audit their results in terms of that they can identify
21 the women and tell them?

22 A: Well I think that it is perfectly possible, as I've described to Madam
23 Chair, to set up audit procedures which could identify those cases.

24
25 CHAIR: Well you can't go back on the past now, we have registers that are
26 set up in the way that they are.

27 A: Yes.

1 Q: It's all very well talking about how they could have been done, you
2 have to go with how they have been done, would you agree?

3 A: Yes, I agree, and we had worked over that, I agree. But I think that we
4 should make the best of a bad job now and I think some ways of doing it are
5 not as good as others, and that's what the Ethics Committees have said.

6
7 MS BUNKLE: Are you aware that the purpose of Ethics Committees as
8 established through the recommendations of the Cartwright Report were to
9 improve the safety, health and welfare of patients, not to obstruct it?

10 A: Well, I'd be amazed if it was to obstruct it, certainly.

11 Q: Are you, therefore, quite confident that you've behaved ethically in
12 obstructing this kind of review?

13 A: I have tried to say that Ethics Committees have not been obstructing
14 this review, they've been trying to improve the character of the Inquiry that
15 these clinicians were wanting to make, and they have struggled very hard to
16 do that. It is true that some evidence has been given which suggest that
17 they, for example in Tairawhiti, are hiding behind privacy legislation in
18 order to obstruct research. That seems to be not only highly implausible but
19 a perverse description of what the Tairawhiti committee have done.

20 Q: It seemed extremely implausible to Associate Professor Green too,
21 thank you.

22
23 CHAIR: Does anyone else have any questions? Mr Murray?

24
25 XXN MR MURRAY:

26 Q: I just have a mundane point, I think. A ministerial letter was to be
27 produced, and if it is that solves my concern.

1 CHAIR: What I will have to check is that all these letters got exhibit
2 numbers. Have they Madam Registrar?

3 MR MURRAY: And Madam Chair, I'm not sure if the status of the
4 National Standards for Ethics Committees, I think there were 4 provided to
5 us.

6 CHAIR: Yes, we should have that produced as well.

7 MR PARKER: It is produced, ma'am. I asked the question just now. It's
8 009.

9 CHAIR: I've just got one more thing I'd like you to do please Professor
10 Evans, and that is just to look at the transcript of evidence. I think the
11 quickest way of dealing with Dr Cox is to if you would just sit and read the
12 transcript of evidence for 26 July, which is B2528, top of the page, line 1,
13 over to 2529, line 15. If someone could please give Mr Parker a copy of
14 that transcript. Perhaps to get the very best appreciation of it, start at the
15 bottom of 2527, questioned by Mr Corkill, starting at line 26. Do you have
16 that Professor Evans?

17 A: Yes, that's where I am starting.

18 Q: If you would just read that all over p2528 down to line 19 of p2529.

19 MR PARKER: Perhaps he should read down to line 23 because it does
20 continue on.

21 CHAIR: Certainly, I've got no objection to that.

22 MR PARKER: I'm obliged.

23 CHAIR: You then get into my questions about the length of time overall
24 that this project has been in the wind.

25 MR PARKER: I was just a bit concerned, there's reference to one legal
26 opinion the Otago committee had, and then I saw further on it referred to
27 another, and I think both should be read.

1 CHAIR: No, no, you are on the wrong page Mr Parker, I've asked Professor
2 Evans to go to p2528.

3 MR PARKER: Oh, I beg your pardon, I thought there was reference to
4 2527 a moment ago and then 2528.

5 CHAIR: No, it's all of 2528 and 2529 down to 19.

6 MR PARKER: I'm grateful, I apologise. Thank you.

7
8 CHAIR CONTINUES XXN OF WITNESS

9 CHAIR: Have you read it?

10 A: Yes.

11 Q: All I want to know from you is whether or not what Dr Cox has told
12 us about what has happened here with the audit vis a vis the Ethics
13 Committee is from your perspective a reasonably accurate summary of what
14 has occurred or is there any part of it where you would differ and if you
15 would differ please tell me which part and then you could say why you
16 would differ.

17 A: There are inaccuracies in it.

18 Q: Yes if you could just please say the lines and the page number where
19 you say there is an inaccuracy and say what you think the position is.

20 A: I'm trying to find the reference to the written consent which I
21 certainly remember reading. First of all let me say about the legal opinions.
22 These legal opinions, and there was not just one there was one legal opinion
23 that the Ethics Committee in Otago had been given, there was another which
24 agreed with it that the Canterbury Ethics Committee had received and this
25 concerned a different study altogether though it was a cancer study, it was an
26 OSH study and I'm not a lawyer but there is a lawyer on the committee and
27 there is also a lawyer on the Canterbury committee and our advice was as is

1 described here. The researcher in that OSH trial also got a legal opinion and
2 the legal opinion was different so the committee wasn't in a position to
3 decide which way to jump. Immediately on the heels of all we had the
4 application for the National Screening project. That is why we sought
5 advice from on high as it were to help to cut this Gordian knot because we
6 didn't know where we stood so that's one inaccuracy the evidence.

7 CHAIR: The point about written consent shows up at line 26-27 on
8 page 2528.

9 A: That never happened at all we did not ask for written consent from
10 the women with invasive cancer we asked that the letter to invite them to be
11 part of the procedure be sent on the Cancer Registry letterhead. That was
12 the request that we made and that was a willingness to be approached by the
13 researchers.

14 Q: And you'll see there what Dr Cox says about that, continues on over
15 the page.

16 A: Yes the argument was that it wasn't practical to do so. Now then I
17 don't know whether they asked the Cancer Registry whether it was possible
18 to do so. Quite clearly it is not impossible to trace these people because that
19 is precisely what the researchers proposed to do.

20 Q: Well it's one thing if the researchers are going to spend the time doing
21 it, it's another thing to expect the Cancer Registry staff to do it.

22 A: Well ideally we said the letter should go so that's the first stage and
23 that wouldn't have involved research.

24 Q: That would require searching for where the persons where.

25 A: Well presumably they have an address for each of these persons.
26 Now the worry is that of course some of those addresses are no longer
27 accurate so there will be some patients that are not caught by that first letter

1 that goes out. We appreciate that but it does seem to the committee that it
2 would be ethically desirable for as many of these women as possible and we
3 appreciate that some may not be connectable, for as many as are contactable
4 to be contacted to ask whether they would be willing to be approached by a
5 researcher. This is according to the CIOMS guidelines a way of protecting
6 any risk that may attach to those women and loss for example of self-esteem.
7 That is that without their permission strangers have been told that they have
8 suffered from cervical cancer.

9
10 CHAIR ADDRESSES MR MURRAY

11 CHAIR: Mr Murray it would be helpful, we never asked Mr Fraser if
12 the addresses of persons with cancer or cancer mortalities are included on the
13 Cancer Registry. You've actually given us a document which shows what
14 sort of information is on the screening register. We don't have a similar
15 document for what's on the Cancer Register.

16 MR MURRAY: If you just give me a moment madam I actually asked
17 somebody about this I'll just see.

18
19 CHAIR CONTINUES XXN OF WITNESS

20 CHAIR: What else Professor Evans is there anything you want to say
21 about that?

22 A: We were certainly never told by the researchers that the Cancer
23 Register couldn't do it because they didn't have any addresses. The story
24 was that not all the addresses would be accurate. That was the story we
25 were told. Now of course they might not have any addresses but we are
26 dependent on the researchers for that information.

1 Q: And do you agree with Dr Cox when he says you need to approach
2 everybody otherwise you get a biased sample and your results aren't
3 particularly applicable.

4 A: Yes I accept that, that's methodology I accept that.

5 Q: Well I'm just wanting to be clear on – you've told me so far those
6 passages of Dr Cox's evidence that you would wish to correct as being
7 inaccurate. Is there anything else there that you've read to which you take
8 exception.

9 A: No.

10 Q: Thank you.

11 A: Well it says, is it still intend to read not unless the Ethics Committee
12 gives approval. We have proposed two ways in which this matter could be
13 expedited on the part of the researchers. We have been desperately trying on
14 the one side over all this period to cut the Gordian knot as it were and we've
15 failed. We have proposed two possible remedies for them. One is there is a
16 second opinion process available in ethical review. They could have asked
17 the HRC Ethics Committee to pass a second opinion on this review process
18 to see whether it was faulty in any way. They knew that and they have not
19 made such an application and of course if the health research Ethics
20 Committee had pointed out to these committees, and I'm making clear that
21 it's these committees, it's not just one committee, it's not just my committee,
22 mine is simply the lead committee. If the health research Ethics Committee
23 had made it clear that as a matter of fact they were not correct for one or
24 other procedural reason in this decision , that would have been fed back to
25 these committees and the committees would have taken it into account. No
26 such application was made. The other possible route to expedite matters on
27 the researchers part was that they could have gone to the Privacy

1 Commissioner as I canvassed earlier. I informed them of that too and they
2 have not taken that route so it seems to me the Ethics Committee have been
3 trying really hard to resolve this dilemma but the researchers have not taken
4 either of the two recourses that were open to them.

5 Q: Well is the health research council related to this Health Research
6 Council Ethics Committee.

7 A: The Health Research Council Ethics Committee is the second opinion
8 body. It used to be the national Ethics Committee, when that was disbanded
9 last year the second opinion duty was devolved to the HRC Ethics
10 Committee.

11 Q: Right well that is of concern yet again because you see in the Cox
12 exhibits volume 1 if you go to page 52 of exhibit 4, if you firstly go to page
13 46 you will see there that the cervical screening advisory- minutes of the
14 cervical screening advisory committee of April 92. At page 52 there is a
15 discussion about national evaluation and there is discussions in the first
16 paragraph about evaluation whether it's defined in terms of audit or quality
17 control and how it will be more readily funded as an integral part of the
18 programme. If you go to the next paragraph it is said there that the health
19 research council perceives evaluation as an integral part of a programme and
20 the next one down it says one of the criteria for funding by the health
21 research council is that a project breaks new ground evaluation is not
22 original research so I don't know whether they take a different view for
23 ethical reasons but certainly from the purposes of funding they distinguish
24 between evaluation and original research?

25 A: The second opinion body is the Health Research Council Ethics
26 Committee, not the Health Research Council.

27 Q: And the Ethics Committee is part of that body is it, or separate to it?

1 A: It's a committee of the Health Research Council, yes.

2 Q: So it is a committee within that Council?

3 A: Yes.

4
5 MR HINDLE: I know it's late and I wouldn't do this unless I thought it was
6 really necessary. Could you please take your exhibit 10 in your hand.
7 While Madam Registrar is looking for it I think one of the inaccuracies
8 which you attributed to Dr Cox's evidence was that, am I right, you said that
9 there was no requirement by your committee for written consent. Did I
10 understand that properly?

11 A: We certainly didn't make it a requirement. They may have said, in
12 their application, that that's what they were going to seek. What we
13 suggested in our answer to them was that they make their first approach on
14 Cancer Registry letterhead.

15 Q: Yes, but if you just look at item 1 of the letter from the administrator of
16 the conjoined Ethics Committees, and if I take you to the third sentence –
17 actually it might be just after a coma beginning “consent form (for signed
18 consent to the review of her screening history) and the questionnaire”.
19 What's that if not written consent?

20 A: Oh, the consent that I was referring to was the consent to be
21 approached. That's what we were asking about, the consent to be
22 approached by the researchers; in other words, in order for these
23 researchers to be approached at all, it would have to be revealed to them that
24 the people they were telephoned had suffered or were sufferers from cancer.
25 That was the issue that worried the committee, that first approach, that
26 breach of confidentiality. We weren't asking for written consent for them to
27 be approached by researchers. I'm sorry, that's what I was referring to.

1 Q: Look, the document says, “consent form for signed consent to the
2 review of her screening history”. Surely that’s a requirement for written
3 consent to participate in the study?

4 A: We were talking about the consent to be approached with a view to
5 being interviewed.

6 Q: Well, there may be some different that I don’t fully understand.
7

8 CHAIR: Well let me just try to understand this. Are you saying there's a
9 series of consents: you get a woman’s consent to an interview, which may
10 be oral or written, and you get written consent to look at her screening
11 history on the Screening Register; is that what you're saying? Is there any
12 other series of consents that are required?

13 A: Well that does sound terribly complicated, and normally we wouldn't
14 demand that. But we weren't asking for a written consent from the women
15 to be approached, we were asking that the privacy of these women be
16 respected and that the Cancer Registry be asked if they'd be willing to be
17 approached. We wouldn't ask them to write a written consent for that. And
18 that was what I was referring to when I said we were not asking for a written
19 consent.

20 Q: So you were asking for an oral consent to one thing and a written
21 consent to another?

22 A: Well, I think that what Dr Cox is referring to here isn't the access to the
23 Register at all but the approach to these women, that’s what I think he is
24 referring to.

25 Q: No, Dr Cox has made it quite clear to us that he doesn't even know who
26 the women are because until he looks at the Register he has no idea who has
27 cancer and who hasn’t.

1 A: Correct.

2 Q: Therefore, the first thing he has to do is get access to the Register,
3 that's the Cancer Register, and he understands that release of data from the
4 Cancer Register is not possible without the women's consent.

5 A: Well, we were concerned with access to the information in the Register
6 which identified these women, that's what we were referring to when we
7 asked for the Cancer Registry letterhead to be used.

8 Q: That's right.

9 A: We were not asking for a written consent for that. We were saying,
10 "it's the cancer people who should be making the first approach to these
11 patients about being involved in a study, or being approached to be involved
12 in a study."

13 Q: Well Dr Cox says, "initially the Ethics Committee requested that we get
14 written consent from women with invasive cancer to have their names
15 realised from the Cancer Register. We can't do that, we don't know who
16 they are." And then he said, "it would have to be the Cancer Register that
17 would do that on our behalf."

18 A: And that's what we proposed.

19 Q: And at what point were you going to insist on written consent?

20 A: I would have to see the protocol again. That would have been spelled
21 out by the auditors in the application form that they sent to the Ethics
22 Committee, because there is a section there asking them to describe the
23 consent process. I haven't got a copy of that application form here, I don't
24 know whether it's been submitted in evidence.

25 Q: And what were you going to do if the Cancer Registry wasn't going to
26 take on this task of writing to women on the Cancer Register?

1 A: Well then the ideal solution would not have been available and the
2 committee then of course would have reconsidered the matter. It thinks this
3 is a very important study to go ahead, but it thinks it's best to go ahead in the
4 best possible manner. That was the point. But as far as I understand it, that
5 possibility hasn't even been investigated by the researchers. We had in fact
6 discussed another compromise situation when the researchers came to the
7 April meeting of the committee. The compromise was something like this,
8 if I remember rightly, that – and I think it might even be mentioned in
9 evidence – the Cancer Registry letter go out. If there is no reply, then after 7
10 days that that be followed up and the further compromise we proposed in
11 that meeting was that at that point, if consent could not be achieved, then we
12 would consider the possibility of accessing the records without consent but
13 we'd have paid the respect to these women, as far as we possibly could, in
14 treating their records with as much confidentiality as possible. We decided
15 not in fact to recommend that in the end, though that was a proposal floated
16 at the meeting, when between us – the researchers and the committee, we
17 were trying to find some kind of compromise to allow the study to go ahead,
18 and then it occurred to us – and the researchers agreed with this – that the
19 quickest way would be to get a declaratory judgment on whether or not
20 permission could be given immediately, as it were, without this condition
21 being satisfied. We were never given satisfaction about that.

22 Q: Thank you. There are some letters that haven't been produced yet, so
23 they should be produced now. Give them to Madam Registrar and she can
24 read out the numbers. [Letter dated 19 July 2000 - Exhibit DME/REC /014.
25 Letter dated 5 May – Exhibit DME/REC/015. Letter dated 20 June to
26 Professor Paul from Professor Evans – Exhibit DME/REC/016]

1 MR MURRAY ADDRESSES CHAIR

2 MR MURRAY: And the answer to the question about the Cancer
3 Register is it does contain the New Zealand residential address of the
4 women.

5 CHAIR: Thank you. Do you recall if anyone asked the Cancer Register
6 staff if they would write to people in this way?

7 MR MURRAY: I don't recall that but I'm not sure whether I was here.

8 CHAIR: No I can't recall it. Mr Corkill did you inquire of them. I
9 didn't ask Mr Fraser that question.

10
11 WITNESS REPLIES

12 A: I understand not ma'am.

13 CHAIR: What?

14 A: I understand that no such approach was made.

15 CHAIR: No I'm not asking that question.

16 A: Oh I'm sorry.

17
18 MR CORKILL REPLIES

19 MR CORKILL: No.

20 CHAIR: It may be something Mr Murray it would be nice if we just had
21 in an affidavit just simply what the situation is. Do they if asked to write to
22 61 – well I don't know how many women there are concerned really it's just
23 to what degree did the Cancer Register staff take on the responsibility of
24 writing to persons on the Register as part of any study being done to see
25 whether or not they are happy to have their information released.

26 MR MURRAY: I'll check whether there is something in the evidence
27 already from Mr Fraser, if not we might be able to just fix that up with a

1 brief affidavit but it did occur to me listening to the discussion that because
2 Dr Cox and Richardson are proposing to do a study as agents for the
3 Ministry of Health that may be a situation where they could persuade their
4 principal the Ministry to actually start the process by getting the women's
5 consents but that would not necessarily be something the Ministry would
6 take on or other research proposals not commissioned by the Ministry.

7 CHAIR: That's right or even evaluation studies at the moment by the
8 Health Funding Authority or by HSS's or District Health Boards as they're
9 envisaged. You can think of plenty other health providers who might want
10 to do a monitoring exercise who may wish to get access to the Cancer
11 Register.

12 A: Yes.

13 Q: Thank you very well.

14
15 PROFESSOR DUGGAN XXN WITNESS

16 PROFESSOR DUGGAN: Professor Evans can you tell me has there
17 since the establishment of Ethics Committees in New Zealand been a
18 strategic review of the Ethics Committees in terms of their structure and
19 fashion?

20 A: I have only lived ma'am in New Zealand for 2 years and 10 months.
21 I regard it as heaven but I don't know the whole history of this. What does
22 happen is that the national standard is reviewed regularly and that is
23 currently under review. I serve on a working party in the Ministry of Health
24 working on that restructuring.

25 Q: Thank you very much so to the best of your knowledge you don't
26 know if there has been a review.

1 A: I don't think there has been a review of the Ethical Committee
2 structure apart from the review of the national standard which last happened
3 in 1996 but of course that does deal with a great deal of detail about the
4 nature of Ethics Committees like their membership, terms of reference and
5 so on and up until the moment there has been no proposal before the current
6 restructuring - in the current restructuring discussions about changing
7 membership or terms of service or anything of that kind.

8 Q: Has there been a review or evaluation of the performance of Ethics
9 Committees since they've been instituted post the Cartwright Inquiry ?

10 A: Not as such although of course there is an accreditation procedure
11 carried out by the HRC Ethics Committee and an annual report has to be sent
12 every year by each committee to the HRC Ethics Committee and a re-
13 accreditation process occurs every third year.

14 Q: Professor Evans have the researchers in New Zealand been surveyed
15 with regard to their level of satisfaction with the Ethics Committees.

16 A: Well interestingly my associate Professor Paul has done her research
17 on this and published it just a few months ago and it was by and large very
18 favorable, especially with respect to the committee's use of the health
19 information privacy code.

20 MR PARKER: It's enclosed in Professor Evan's evidence.

21 CHAIR: Thank you Mr Parker. Very well no questions. Ms Bunkle?

22
23 MS BUNKLE ADDRESSES CHAIR & CONTINUES XXN OF WITNESS

24 MS BUNKLE: Ma'am I ask your indulgence for one final question.

25 CHAIR: All right one final questions.

26 MS BUNKLE: Professor Evans today August 5th is the 12th anniversary
27 of the publication of the report of the Cartwright Inquiry. Do you think we

1 would have recommended the establishment of Ethics Committees if we had
2 known the result would be to prevent the routine audit of the adequacy of
3 treatment by the relevant health authorities?

4 A: I certainly don't think put in as many words that would have been the
5 case but I do think in the last 12 years many many tens of thousands of
6 research subjects and I think also subjects of audits have been protected and
7 been protected very well by the service of Ethics Committees and I think
8 New Zealand patient research subjects would be in a much worse state
9 without them.

10 Q: Do you think we would have recommended the establishment of the
11 National Cervical Screening Programme if we had have imagined that the
12 outcomes of that programme in terms of patient safety would not have been
13 routinely satisfactorily audited.

14 A: Definitely not and it is just a pity it seems to me that one was set up
15 that wasn't facilitated.

16
17 CHAIR ADDRESSES MR MURRAY

18 CHAIR: Thank you very much Professor Evans. Mr Murray, what is
19 envisaged in respect of Dr Patasi giving evidence. Were you going to lead
20 evidence from her.

21 MR MURRAY: Actually no it was Mr Grieve.

22 CHAIR: I know Mr Grieve wanted her and now he's gone yes.

23 MR MURRAY: So my proposal was simply to call Dr Patasi, refer the
24 panel to where we got to with Dr Peters evidence in the transcript and I
25 mean I can do it two ways, if it's of assistance I can pick up the issues that
26 were left after Dr Peters evidence and lead some evidence but it may be
27 faster if the people that have the concerns possibility Mr Corkill and the

1 panel members simply ask the questions on the topics you defined Madam
2 Chair so we can do that fairly quickly first thing in the morning.

3 CHAIR: Well what I was going to suggest is so that we can have a clear
4 run at the other witnesses tomorrow morning if we had a 15 minute break
5 and then did it. How does everyone feel. The panel is willing to do it.

6 MR MURRAY: I'm happy with that.

7 CHAIR: Everyone else happy? Well we can do it in circumstances
8 where we can record the transcript because of course its always being
9 recorded but the persons typing it up at the moment now want to stop so it
10 will just delay the transcript coming out but if everyone's happy to stay on
11 here we could do that so that we will have a clear run with Dr Boyd, Ms
12 Glackin and whoever else is giving evidence tomorrow. Ok we'll take a
13 break now until 7 and come back.

14
15 INQUIRY RESUMES UNTIL 7:00 P.M.

16
17 INQUIRY RESUMES AT 07:02 P.M.

18
19 MR MURRAY called –

20 KAREN OLIVE POUTASI (Sworn)

21 Q: Dr Poutasi, your full name is Karen Olive Poutasi, correct?

22 A: Correct.

23 Q: And you are a registered medical practitioner and also a Fellow of the
24 Australasian Faculty of Public Health Medicine, is that correct?

25 A: That's correct.

26 Q: That qualifies you as a public health specialist?

27 A: Yes.

1 Q: You also have a MBA with a Science Master in Health Services
2 Administration from Harvard University, is that correct?

3 A: That's correct.

4 Q: And I understand you are appearing voluntarily before the Inquiry,
5 but on the way to the Inquiry you learned that, for legal reasons, your name
6 needed to go into a summons to cover the Inquiry's request for cancer and
7 screening programme register information, are those details correct?

8 A: Absolutely.

9 Q: Now thank you for coming at such short notice and the point at which
10 the Inquiry arrived at where your attendance was raised was in relation to Dr
11 Peters evidence. Dr Peters had given extensive evidence to the Inquiry
12 about the developmental work on the programme since it had been
13 transferred into the Health Funding Authority in 1998, and Madam Chair, at
14 page 3459, is a relevant point to pick up the evidence where there was a
15 question, "Do you think that you will get the support that you need from the
16 Ministry of Health in order to implement all the hard work that you have
17 done in the draft documents you've put before the committee in exhibits 40,
18 42 and 47", to Dr Peters. Over the page, just leaving some of the evidence
19 out, Dr Peters said: "I mean, really all I can say is that I've had, through my
20 manger, a commitment from the Director General that she wants to ensure
21 that it's put right, and that then necessary resources are made available to
22 ensure that things are put right. She doesn't want to leap to solutions in
23 terms of staffing, she wants to consider it carefully. It seems a positive
24 response which could give one confidence and I don't really feel I can
25 comment any further than that, having never worked in the Ministry or
26 experienced those situations". Then there was a question, again I think this
27 was from Mr Corkill: "Tell me, the Ministry in it's new form with the

1 Health Funding Authority as part of it, is it still going to be a policy
2 organisation or will it have an operational role as well.” “I don’t think that's
3 probably finally determined”, says Dr Peters, “I mean, certainly initially it’s
4 going to have an extensive operational role, but I think ultimately how
5 operational it may remain will depend on the extent of devolution that
6 occurs, and I don’t think that’s clear.” So ‘Dr Poutasi, just if I can ask a
7 question about that and then leave it to you to answer others questions but
8 could you just explain what you understand the role of the Ministry will be
9 once this restructuring as at 30 Nov is implemented or whenever the bill
10 goes through and how the Dr Peters team will fit in to the new structure as
11 you understand it.

12 A: Yes after – my understanding and of course this does not pre-empt
13 Government decisions on the legislation that's just been introduced into the
14 house is that the Ministry will have a mixed role in the future. Indeed I think
15 Dr Lambie gave in evidence earlier today the Ministry has in fact had a
16 mixed role although largely a policy role to date because David referred to
17 for argument sake National Radiation Radiation Laboratory. Operational
18 units of the Ministry which we have continued to be responsible for over the
19 past 10 years or so, so we’ve never been a purely policy Ministry we have
20 had in some areas an operation focus which has sat quite comfortably with
21 our role but to take your question where we’re looking to in the future, the
22 Ministry will have a policy role, it will have a funding role, it will have a
23 monitoring role, it will have an operational role and it will have a regulatory
24 role and I would certainly envisage the Cervical Screening Programme
25 sitting very comfortably in that set of roles and indeed we’ve had quite
26 considerable discussion about this to date and I understand the inquiry has

1 been advised that it is envisaged that the Cervical Screening Programme will
2 be a discreet unit of the public health directorate.

3 Q: One of the issues that Dr Peters covered in evidence was that as part
4 of that discreet unit she will take on a contracting role so she will have a
5 direct contracting role with the providers required to fulfill the programme
6 requirements and that will involve an increase in staff. Are you able to
7 comment on the extent to which that's been resolved yet.

8 A: Yes I've read a report from Dr Peters in that regard. We've discussed
9 that report and we will obviously have ongoing discussions and I'm
10 absolutely committed to providing whatever resources are necessary to
11 secure an effective Cervical Screening Programme.

12 Q: And are any decisions being made now which would pre-empt any
13 recommendations that the inquiry may make about the programme?

14 A: Absolutely not.

15 Q: There may be other questions so if you could just deal with them as
16 they arise.

18 CHAIR ADDRESSES INQUIRY

19 CHAIR: Thank you Mr Murray. If I could just say to everyone first, Dr
20 Poutasi has come along really to assist us in view of the request Mr Grieve
21 made in terms of concern about the programmes future. There are issues
22 about past performance of the programme which we have already had
23 Ministry of Health officials speak to us about and some of those officials
24 have come back to deal with those matters. I don't consider it appropriate to
25 raise those matters with Dr Poutasi so any questions must be firmly directed
26 to what is going to happen in the future. Does anyone have any questions
27 they want to ask. Yes Mr Corkill.

1 MR CORKILL: Madam Chair just to advise you that counsel have
2 conferred and tried to agree a co-operative approach to dealing with these
3 matters as efficiently and as quickly as possible given the hour.

4
5 MR CORKILL XXN WITNESS

6 MR CORKILL: Dr Poutasi I just want to raise a couple of topics with
7 you briefly to set the scene and they are both future oriented matters but to
8 set the scene for the first of those topics, it's easiest if I take you to a
9 document in Ms Glackin's exhibits at volume 7 tab 35. You'll see there that
10 that tab is a report from the CSAC advisory committee on monitoring and
11 evaluation in Oct 94. Is this a report with which you are familiar?

12 A: No.

13 Q: You'll see if you go to page 13 of the document at the foot of the
14 page there is a section from this advisory committee about the nature of
15 good operational leadership. If you could just read that paragraph through to
16 yourself please. Now you'll see there the advice given by this committee as
17 long ago as 94 was that skills in the fields of medicine, epidemeology, public
18 health, statistics, computing and cytology will be required. In light of that
19 advice are you able to set that there is a good deal of – there is a wide skill
20 mix which is required for strong central leadership of a national programme
21 of this nature. Are you able to accept that proposition?

22 A: Absolutely.

23 Q: And that to the extent that it is needed the Ministry will be in a
24 position of making available those disciplinary for the future leadership of
25 the programme?

26 A: Yes.

1 Q: The other topic I want to discuss with you briefly relates to cancer
2 control as a strategy. Could the witness please be shown a Skegg exhibit
3 008? Just while others are finding it Dr Poutasi you will see it's a medical
4 journal piece and if you go to the second page and look at the right hand
5 column.

6 A: Yes.

7 Q: Now that article which was in the medical journal in December last is
8 of course generally about the need for a national cancer control strategy in
9 this country and in the section that I've drawn to your attention there is a
10 potted history if you like of this issue. I think probably you would agree in
11 general terms it reflects recent history on this issue. Is that yes.

12 A: Yes.

13 Q: And I want you just to now note the last paragraph which refers to the
14 need for a national cancer control strategy which draws on the available
15 expertise of the community management, oncologist, surgeons, GPs, nurses,
16 public health physicians, allied health professionals, non Government
17 organisations and the Ministry and that that is essential to ensure a strategic
18 cost effective approach to address the projected incidence of cancer in and
19 mortality in New Zealand. Now this inquiry has also heard evidence to
20 similar effect from a number of expert witnesses and in particular Professor
21 Skegg and Dr Brian Cox who will be known to you. First of all what is
22 your view regarding the need for a national cancer control strategy of the
23 nature outlined in the final paragraph?

24 A: I'd be fully in agreement and indeed the Government's health strategy
25 signals a significant commitment in that regard. It's a draft strategy,
26 consultation is finished, we'll be reviewing the consultation but there's every

1 evidence that that commitment is there and that this is something that we
2 require.

3 Q: And what sort of timeline do you see for that initiative developing?

4 A: We've been scoping the initiative together with most of the expertise
5 solicited there but in particular with the Cancer Society and we would
6 envisage work beginning on that this calendar year. I might also say that
7 that is a task for the public health directorate within the Ministry of Health
8 and I've signaled that the public health directorate is of course where we
9 envisage the national screening programmes being located.

10 Q: Do you agree that the screening programmes should be part and
11 parcel of an overall cancer control strategy?

12 A: Yes they are indeed part and parcel of an overall screening strategy.
13 To date we've put our effort into of course breast screening and cervical
14 screening and into tobacco control as being the major focus of cancer control
15 in New Zealand to date. We are now looking to go broader and work on a
16 national cancer control strategy that draws together a comprehensive
17 approach to cancer control as distinct from a focus on those three particular
18 aspects.

19 Q: And just finally I wonder if Dr Poutasi could be shown volume 2 of
20 the Marshall exhibits please and I'd like you to go please to exhibit 41 which
21 is if you go to tab 31 and it's actually the last document in the bundle. It's
22 the final document in this material. Exhibit 41 if you go to the very rear of
23 this volume you'll see it's the final letter. It's a letter from the Cancer
24 Society to the Health Funding Authority of 6 March 2000.

25 A: Yes.

1 Q: And just run your eye over the statements at the foot of the page and
2 over, that is paragraphs 1-4. Are those all priorities that you can support as
3 Director General?

4 A: Yes they are. The only difference is that of course we envisage the
5 public health directorate having a major part to play as distinct from a
6 directorate or a particular unit reporting directly to me and that we believe
7 that that will in fact produce an excellent result given it's public health focus.

8 Q: And in particular you can commit to the first of those, the WHO
9 requirement underscoring the importance of monitoring and evaluation for
10 the programme?

11 A: Absolutely and I think in evidence today the Ministry's shown it's
12 commitment to that and I think in evidence before the inquiry you've been
13 briefed on the work that the Health Funding Authority has done to secure all
14 the features of the programme within a particular unit and it's that unit that
15 we envisage transferring lock stock and barrel into the Ministry of Health
16 with no disruption whatsoever.

17 Q: Thank you Dr Poutasi.

18 CHAIR: Thank you Mr Corkill. Does anyone else have any questions?
19 Yes Ms Janes?

20
21 MS JANES XXN WITNESS

22 MS JANES: Just following on from that last question. With the
23 transfer into the Ministry of Health of the public health unit and all of the
24 attendance components of the National Cervical Screening Programme are
25 you able to offer assurances that once the complete restructure of the
26 Ministry of Health and the devolution to the 22 District Health Boards is

1 complete that there will not be a fragmentation of the Cervical Screening
2 Programme.

3 A: Absolutely, we've taken into account a large number of the issues
4 that have been laid before the inquiry and obviously whatever I say is not to
5 pre-empt the outcome of the inquiry but it is very clear to us that
6 fragmentation is to be avoided and planning is proceeding on that basis that
7 we are talking about and an integrated connected programme.

8 Q: I'm sure you've been very well briefed on the evidence that has been
9 put before the inquiry and all of the issues regarding lack of accountability
10 and clear channels of communication and variability of delivery of services
11 and quality so the intention is to ensure all of those things don't occur again
12 despite the fact there are going to be the 22 District Health Boards.

13 A: Yes absolutely I think the programme is in a better space now that it
14 has been through all its history and we intend to build on that to correct
15 whatever requires correction on the advice of the inquiry and to move
16 forward from that position.

17 Q: We've certainly heard from Dr Peters that one of the advantages for a
18 programme would be sustainability in terms of planning and the ability to
19 consolidate and have seen some excellent documents in terms of standards
20 and performance indicators and I assume that in the reformed structure that
21 they are going to have the chance to be implemented and followed up.

22 A: Absolutely, one of the approaches that we are using in the sector
23 change process is the concept of building forward and I believe that applies
24 more appropriately than in this particular position or in this particular
25 circumstance in the sense that the work done to date will be consolidated
26 and built on.

1 Q: One of the problems that we've heard quite a bit about as well is the
2 fact that with health reforms in the last decade there have been a tremendous
3 amount of changes in personnel and resources and that in some ways has
4 hindered the programme because it takes people time to get up to speed and
5 the loss of institutional knowledge. Now obviously you can't assure me that
6 all the people will stay in their current jobs but would it be correct that there
7 is a recognition of the requirement for that institutional knowledge to be
8 retained if at all possible .

9 A: Absolutely and we are doing everything in our power, and in
10 particular I am doing everything in my power to secure institutional memory
11 and the people who are currently involved so that we can move forward
12 from a position of strength.

13 Q: And my friend Mr Corkill briefly touched on the staffing and Dr
14 Peters is giving evidence that she in principal has approval for the expertise
15 and the staff resourcing that she needs into the future. Can you see anything
16 that may possibility come up that may derail the ability to resource the
17 programme adequately in the future.

18 A: No I don't believe so. Obviously New Zealand is a small country and
19 my attention has been drawn to the range of skills that are necessary. Dr
20 Peters and I are keen to secure, and I think she's canvassed this with you,
21 more full time commitment into the programme as distinct from relying on
22 consultancy and we will do our best to do that, admittedly for some
23 particular aspects we will continue to need to rely on consultancy services
24 because of the scarce expertise so with that caveat which is simply a feature
25 of the size of New Zealand as I said I'm committed to building forward
26 whatever resources are necessary to secure an effective Cervical Screening
27 Programme.

1 Q: And one of the other areas that was identified at Dr Peter's brief is
2 the funding issue as to whether it would actually be controlled by the
3 Cervical Screening Programme for both the breast and cervical screening or
4 whether it would be done by a funding directorate. Are you able to give any
5 indication of the outcome of that debate.

6 A: We suspect it will probably be through the Cervical Screening
7 Programme if that is the most effective way of doing it and to date all the
8 evidence seems to be leading us to that direction and that's something we
9 will be talking about.

10 Q: And just if I can very quickly have you shown Dr Peters exhibit 52
11 which is behind the affidavit. It shows the level of funding for the Cervical
12 Screening Programme over the last 3 years and of particular note is the
13 quality monitoring policies audit and the Register line where under the
14 1999/2000 year there was 890,000 with a significant leap to 1.633 million in
15 the current financial year. Is that level of commitment likely to continue
16 particularly for the quality and monitoring and evaluation aspects of the
17 programme?

18 A: If that's what necessary to secure adequate quality and monitoring the
19 answer has to be yes.

20 Q: And there was a 1.4 million special one off funding which has been
21 for one year is there likely to be the resources for similar resources to be
22 applied to the programme as required?

23 A: I'm not sure what the special one off was for but I can certainly
24 provide assurance that whatever resources are necessary to secure an
25 effective programme will be applied.

26 Q: One of the things we've heard a lot about is monitoring and
27 evaluation and how from 1991 onwards an audit has been recommended in

1 retrospect of look back and you've obviously been here through the ethics
2 debate. Do you have any views on how the Ministry could potentially
3 address those issues with regard to the requirement for that audit as both
4 being an ethical responsibility after inviting women to participate in the
5 programme and then ensuing the quality delivery of that programme?

6 A: Well certainly as far as I am concerned we must be able to quality
7 assure the programme and I'm very grateful for today's debate because I've
8 been beset by the legal implications and the ethical implications of being
9 able to audit the programme and I think I'm confident that today's debate
10 will shed quite significant light in that regard but I will continue to do what I
11 can to have us in a position where we can provide for ongoing audit and I
12 believe it's a critical feature of the programme and obviously it is an area
13 where the ethical issues of a population programme seem to come up against
14 the ethical issues of personal delivery of services and I'm sure the answer
15 lies in the middle but we simply have to be able to audit programmes. It is
16 inappropriate to offer programmes where we cannot audit them and say with
17 confidence that they are having the desired effect.

18 Q: And given that this has been termed the gold standard for the
19 programme are you able to comment on a view of how often that should
20 occur in the future? Obviously it would be nice to get the first one done?

21 A: Indeed it would. I'm not really technically competent to be able to
22 answer that. I believe we should take the advice of experts as indeed we did
23 in working through how to evaluate and the process that we should go
24 through.

25
26 CHAIR INTERJECTS AND XXN WITNESS

1 CHAIR: If I could just come in here because one of the things we heard
2 from Dr Cox was when he put his application in in June 97 his evaluation
3 study which he said he thought all the aspects of it was essential, couldn't be
4 done because there wasn't enough funding and so three priority areas were
5 chosen. Do you think ideally in time if expert epidemiologists identify areas
6 which should be evaluated in the programme as a matter of course, that
7 ought to occur.

8 A: Yes I do. I think that we needed to start somewhere and I think we
9 needed to work through the issues to enable us to address the priority areas
10 and once we've done that we need to look at whatever other areas are
11 deemed necessary toward it and that we ought to be looking at those.

12 Q: We've heard, just looking at the audit that the Register is a key
13 management tool as well as being a very good quality assurance measure.
14 Are you able to comment on whether it will be located with the National
15 Cervical Screening Programme or with the Information technology.

16 A: We're talking here about the Cervical Screening Register.

17 Q: The Cervical Screening Register.

18 A: With the programme we've obviously been throughout the year
19 working on the shape of the Ministry of the future. Initially in a consultation
20 document between the Health Funding Authority and the Ministry there was
21 a proposal that it should be located with the National Health Information
22 Service thinking of the Cancer Registry being there. As a result of
23 consulting on that proposal we have determined that it should be with the
24 cervical screening programme in public health.

25
26 CHAIR INTERJECTS AND XXN WITNESS

1 CHAIR: Is there any reason why the information on the Cancer Register
2 in relation to cervical cancer couldn't also be kept on the Screening
3 Register because part of the problem that has arisen with the attempt to have
4 the evaluation study is the fact that there are two registers here and gaining
5 information from each Register, there is a different process in respect of
6 each Register and looking at some of the documents we've seen
7 internationally, the World Health bulletin for example suggests a Register
8 where the incidence of cancer is kept on the same Register so it's really sort
9 of a cervical cancer Register with screening history plus incidence and
10 mortality.

11 A: I think that's a very valid question and it's one that I'll certainly be
12 asked. To date of course the two programmes have evolved in slightly
13 different ways and it's a feature of history that they are separate. The Cancer
14 Register does I understand use the national health index number and so does
15 the Cervical Screening Register so therefore linkage is possible and we
16 ought to be looking at where the Register can develop in the future.

17 Q: I was going to ask that question because it's been one of those things
18 that has been mooted for many years, the linking of the Cancer Register and
19 the Cervical Screening Register. Is that something that's possibility
20 contemplated on the agenda in the future?

21 A: I certainly think it's something that we must be looking at. I can't
22 answer the technical complexities but with information technology
23 developing very very rapidly it ought to be possible.

24 Q: And just one final question in Dr Peter's evidence there was an
25 indication that there are no contracts to be entered into beyond 30 June 2001.
26 Is that I assume to give the Ministry flexibility once it absorbs the Health
27 Funding Authority to be able to – the different contracts?

1 A: I'm not privy to that discussion because we've, in the change process,
2 attempted not to intrude on the Health Funding Authorities contracting
3 capability so it may be an internal decision that that's a sensible period of
4 time, internal to the Health Funding Authority, that that's a sensible period
5 of time. It is not a Ministry requirement.

6 Q: So it's in recognition of being reabsorbed.

7 A: And it may be to keep some flexibility for the programme itself I'm
8 really not in a position to be able to comment.

9 Q: Thank you very much.

10
11 MRS BARRETT XXN WITNESS

12 MRS BARRETT: Good evening Dr Poutasi.

13 A: Evening.

14 Q: I'd just like to ask you a couple of very basic questions and one of
15 them is we heard from Dr Peters that the programme will be based in
16 Auckland. Do you think that the programme will be isolated by being based
17 in Auckland?

18 A: No I don't because I made reference before to the fact that it would
19 be located within the public health directorate so that physically it may in
20 Auckland but there are other public health functions in Auckland and being
21 part and parcel of the directorate means it is not likely to become isolated
22 and indeed we'll be working to make sure that it's not.

23 Q: Do you see in the near future where you would shift it back to
24 Wellington?

25 A: I can't see that in the near future for the very reason that I was asking
26 an earlier question and that is to secure the people who are there. They are
27 currently based in Auckland and we would conceive of that continuing into

1 the future. We do not want to disrupt the institutional memory, we don't
2 want to loose the people who are there and I'm very confident that being
3 part of the public health directorate which has a strong Auckland basis, it
4 will not become isolated.

5 Q: My last question is with the programme being based in Auckland
6 will there be a strong collaboration with the maori directorate for the
7 programme?

8 A: Yes there will be and it doesn't matter so much whether a particular
9 directorate is based. The linkages I can assure you on planning that the
10 Ministry directorates will be very interlinked. They simply must be and our
11 maori directorate will be very linked with the other directorates and indeed
12 each directorate is expected to build it's maori capacity within it's own
13 functional area and to of course take advice and if you like some overview
14 from our maori directorate.

15 Q: Thank you very much.

16
17 PROFESSOR DUGGAN XXN WITNESS

18 PROFESSOR DUGGAN: Are you familiar, you must be familiar
19 with the draft policy and quality standards for the National Cervical
20 Screening Programme.

21 A: I'm familiar but in a very broad way.

22 Q: Well it's Peters 40, it's something we recite everyday. Dr Peters told
23 me in evidence a couple of days ago that the finalisation of these draft
24 documents is her number 1 priority and I explored with her how she was
25 going to do this and she described the consultative process that she is
26 required to go through in order to finalise them. The question I asked her

1 was how long in her opinion should this consultation process take and I'd
2 like to ask you the same question.

3 A: From the point of producing a document like this and if we are
4 looking for significant sector and public input, so if those two preconditions
5 are there, then something like 3-4 months. It requires about – you can
6 manage 2 months but given that a large number of organisations perhaps
7 only meet monthly and if you miss their monthly meeting you don't give
8 adequate time. I'm far more comfortable with something like a 3 month
9 period and 4 months maximum.

10 Q: I appreciate that you're not completely familiar with the entire
11 contents but let me say that the contents in terms of the approach and the
12 creation of process and process standards predominantly is very comparable
13 with other documents from other countries that we have seen. As part of this
14 consultation process do you have any idea what degree of compromise is
15 allowed. That is how much of the document can be diluted?

16 A: Again I'm speaking generically. If this is grounded as I would
17 imagine it is on sound evidence from our experience within New Zealand
18 and effective overseas programmes –

19
20 **CHAIR ADDRESSES MR MURRAY**

21 CHAIR: If you could just pause there, Mr Murray just before we go on,
22 it seems to me that we all know the legal position as consultation is not
23 negotiation, legally you don't have to compromise at all but you have to
24 have an open mind and you have to take into account what people say. I'm
25 concerned that if Dr Poutasi answers the question by attempting to say how
26 much she thinks one could give away in a consultation process it might give
27 rise to complaints later that there has been a closed mind or something like

1 that, I actually have a bit of concern about her pre-empting what is a
2 consultation process. The fact is legally we know you don't have to give
3 away anything if at the end of the process having fairly heard everyone with
4 an open mind, you are still of the view that your standards ought to apply as
5 they are.

6 MR MURRAY: Tired as we are Madam Chair you're sharper than me.
7 That is a genuine concern.

8 CHAIR: Well I think we'll just stop here.

9 PROFESSOR DUGGAN: I think I was told to withdraw my
10 question. I was close to getting an answer though. Apologise for that but I
11 am on a mission. Perhaps I'll say no more. Thank you very much.

12 CHAIR: I've got no questions so thank you very much for coming Dr
13 Poutasi. Is there any re-examination you want to make Mr Murray?

14 MR MURRAY: no perhaps I could just confirm one thing with Dr
15 Poutasi. Dr Poutasi is it the position that in response to the summons you've
16 referred it to the Crown Law Office for advice given the difficult issues that
17 arise from that, but in the meantime you've also asked the people in charge
18 of the two registers to start work on obtaining the information and collating
19 it or correlating it.

20 A: Yes.

21 Q: Pending advice from Crown Law.

22 A: Yes absolutely so that once the advice is through there should be no
23 delay in making the information available to the inquiry.

24 CHAIR: Perhaps I'll just say Mr Murray given that the summons for
25 legal purposes had to have a specific date put on it that we will advance that
26 date to a date yet to be set by us given that the material has to be produced at
27 a hearing, we will just, given that Dr Poutasi has appeared today we'll

1 adjourn any need for her to appear at any subsequent hearing until we should
2 order whatever the date may be.

3 MR MURRAY: Yes I'm grateful I was going to ask for a dispensation
4 from today and we can talk about that in the context of the timing of where
5 we go from here so I'm grateful.

6 CHAIR: Yes and if you could liaise with counsel assisting once you
7 know whether the material can be made available or not etc just so that we
8 can go through the right processes so no-one can complain, we could
9 convene a hearing which may take place in Auckland or Wellington or
10 whatever in some physical setting whereby the material could be produced to
11 me and I'll receive it on behalf of the committee.

12 MR MURRAY: Of course.

13 CHAIR: Thank you very much for coming Dr Poutasi. Thank you very
14 much everyone for staying. It's important as we get down to the very end of
15 the time available to us. Let me say that tomorrow because Dr Duggan in
16 order to catch her flight to Canada on Monday has to leave Gisborne at 2pm.
17 We will sit until 12:30 and I suggest we start again at 8 am and stop
18 whenever we can. If we finish before 12:30 so much the better.

19
20 INQUIRY ADJOURNS AT 7:42 P.M.

21 UNTIL 8:00 A.M. SUNDAY 6 AUGUST 2000

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