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INQUIRY RESUMES AT 10:03 AM
MONDAY 17 JULY 2000

DR CLINTON TEAGUE (On former oath)

MR GRIEVE CONTINUES XXN OF CLINTON TEAGUE

MR GRIEVE: Dr Teague you will remember that prior to the weekend I was asking you about the cytology review panel results of the four patient one smears and you referred to the question of an error by one degree would not be regarded as a false negative. Do you remember talking about that?

A: Not in this setting sir but I did in the High Court yes.

Q: So maybe my memory is playing tricks with me I thought it had been mentioned but irrespective of that for example you recall saying that in respect of I think the first slide he got it mildly wrong.

A: That's correct yes.

Q: Now that was a situation where a slide which was high grade had been read by Dr Bottrill as being low grade.

A: That's correct.

Q: Although that degree of error may not have been sufficient to track the label false negative, nevertheless, the difference in that call gives rise to a difference in clinical management doesn't it.

A: Yes it does.

Q: So that although maybe not for the purposes of pathology description, correct use of the term false negative or whatever, there is that difference for the woman concerned isn't there?

A: Absolutely.

1 Q: Low grade the recommendation depending on whether it was a first
2 or subsequent low grade the recommendation would be what, repeat in six
3 months?

4 A: Initially for the first one it would be a repeat and then for the second
5 one it would be referral for assessment.

6 Q: Whereas if it was high grade

7 A: It would be referral for assessment.

8 Q: Would it not be referral for colposcopy?

9 A: That's what I mean by assessment sir.

10 Q: And that's irrespective of whether it's high grade CIN II or CIN III
11 isn't it?

12 A: Absolutely, the Bethesda system doesn't really distinguish between
13 those two.

14 Q: Now for the purpose of looking at changes to professional practices
15 for the future, I just want to explore this concept of what is meant by a false
16 negative. I suppose from a lay perspective, simplistically it could be
17 regarded as simply an error couldn't it, a reading error?

18 A: You mean it's a negative reading error yes.

19 Q: Well it's the calling of a slide ...

20 A: You said false negative so it must refer to something that was under
21 called rather over called is the point I'm making.

22 Q: So that we have a slide which has some abnormalities which is under
23 called to some degree.

24 A: Absolutely.

25 Q: Now would you accept that the phrase of false negative however
26 covers a range of errors?

1 A: It covers a range of errors and it covers a range of methods of trying
2 to assess this particular event.

3 Q: So what I'm suggesting to you is that the phrase false negative of
4 itself doesn't say anything about the qualitative degree of error does it?

5 A: If you were talking about a false negative rate you should define
6 quantitatively how your going to actually use it or apply it.

7 Q: You mean in terms of recommending clinical treatment?

8 A: No in terms of if you are talking about a false negative at the outset
9 you've got to be able to define what you mean by a false negative because as
10 we know and as we've seen there are a enormous range of ways of looking
11 at false negatives.

12 Q: Well perhaps let me approach it this way. At the lower end of the
13 scale in terms of the degree of error, a false negative could encompass a
14 slide which would fit into that corpus of slides that has recognised
15 characteristics which generally give rise to the false negative occurring in
16 the first place. I have in mind the sort of literature that Dr McGoogan
17 referred to when she said there's been studies to see if there can be defined
18 characteristics of slides which were shown to have been false negatives.

19 A: Yes, I think we've certainly covered that in the High Court. There are
20 certain characteristics of smears which are found to crop up more frequently
21 in a false negative analysis, and the factors are, the common ones, scant
22 abnormal cells, small abnormal cells, cells in clumps.

23 Q: Or sparsely seen across the smear?

24 A: Absolutely. But they tend to be weighted towards that end, false
25 negatives.

26 Q: Yes, its not absolute of course.

27 A: Absolutely.

1 Q: And if you had a, for example, slide that was reviewed by your cytology
2 review panel and it turned out that there was a false negative, someone
3 looking at the results of the review panel – as you did in Patient One’s case –
4 without looking at the smear under the microscope yourself, you wouldn't
5 know the nature of that false negative, would you?

6 A: No, that’s not recorded. Unless there is some variability in the panel
7 members. As there was, I think, in one of the slides.

8 Q: Well, the review panel as I understand it, the laboratories that do the
9 reviewing, report according to the Bethesda Coding system, don’t they?

10 A: That’s correct, and with the ability to put a comment on the end of it.

11 Q: But by and large, you will get (as we got as an example in Patient One’s
12 case) five results and one was able to look at them and note that there were
13 differences but nevertheless note a consensus?

14 A: By consensus do you mean unanimous?

15 Q: A broad consensus, the majority view.

16 A: The majority view, yes.

17 Q: And what I’m suggesting, and it may be that that was – I don’t know,
18 I’m going to ask you about it, but I suggest to you that certainly in that
19 example, and it was the only example we have of the cytology review panel
20 in action, in evidence in this inquiry, I suggest to you that from the results
21 which you reviewed, there was nothing to tell you about what I call the
22 qualitative nature or degree of the false negative error?

23 A: Only to the extent that the degree of consensus, or the degree of majority
24 view, that is as a measurement of that I think.

25 Q: so that from that, though, without specific detail, one can only make
26 inferences about the nature of the abnormality that wasn’t reported correctly.
27 Correct?

1 A: When you say “nature”, are you referring to the sort of characteristics of
2 a false negative slide?

3 Q: Yes.

4 A: No. that is not assessed directly.

5 Q: That’s what I mean. Now I started off at the bottom end of the
6 continuum of degree of error, with the classic false negative type smear.

7 A: Yes.

8 Q: Although she’s yet to give evidence, I take it you've seen Dr Farnsworth’s
9 report, have you?

10 A: Yes, I've seen the report.

11 Q: And you’ll recall, and she mentions it in her brief of evidence as well,
12 the comments about the unusual nature of the abnormalities her laboratory
13 was seeing.

14 A: I recall the comment. Could I please see the brief.

15 Q: It’s para 22 I think.

16 CHAIR: There are also photographs of the abnormalities as well at the
17 back of the brief.

18 A: Yes, I see that.

19 MR GRIEVE: so what she's saying there really is that she was seeing
20 abnormalities of a significant order, wasn’t she?

21 A: Yes, and she’s pointing out that the type of abnormalities that she was
22 seeing was the type that was more predominant many years ago where we
23 quite frequently saw keratinising dysplasias, whereas nowadays we see more
24 non-keratinising dysplasias. Whether that’s in fact due to screening or in
25 fact is a change in real pattern of the disease I don’t think I know.

26 Q: It’s a little unclear, and there was an issue taken earlier in Dr
27 McGoogan’s evidence about it because at this stage, because she hasn’t

1 given evidence, we don't know whether those appearances that she
2 described in para 22 were false negative slides, you see. But on the
3 assumption that they were, then in terms of the qualitative assessment of
4 error, if you encountered, in a smear which was false negative, a degree of
5 abnormality such as is referred to by Dr Farnsworth, that would be
6 something of importance to note wouldn't it?

7 A: It may well be.

8

9 CHAIR: Dr Teague, can you give any explanation as a pathologist for why
10 the cytological appearances that Dr Farnsworth notes resemble those that
11 would be seen in classic cytology textbooks in the 50s and 60s?

12 A: Those appearances were common in earlier days. The appearances that
13 were noted from the early days of cytology – and they refer to mostly
14 keratinising squamous displeases – those are mature cells which are towards
15 the process of producing keratin and they have different cytoplasmic
16 colouration. As I say, nowadays we see a higher proportion of non-
17 keratinising displeases.

18 Q: What is the explanation for that?

19 A: Well there is a possible explanation is that we have screened out the
20 keratinising dysplasias and are left with the other forms of dysplasia.

21 Q: When you say “screened out”, what do you mean?

22 A: Have been identified and treated so that we don't see as many. The
23 other explanation is that there is a true change in the disease and it may be
24 related to different aetiological or other factors. And I don't think that
25 that's particularly resolved in the literature

1 Q: When you say “screened out”, does that mean that in other areas,
2 because the screening has been successful, you have caught the condition at
3 an earlier stage?

4 A: Yes. No, not particularly, but I think because they were the cells that
5 were classically described and so those were the ones that pathologists were
6 more familiar with and as time’s gone on we’re looking at different sorts of
7 cells now.

8

9 PROFESSOR DUGGAN: Dr Teague, in Dr Farnsworth’s exhibit she
10 includes some photographs.

11 A: I haven't seen them.

12 Q: In Exhibit 1. There's a plate A, I think she's using this to illustrate what
13 Papanicolaou described -

14 A: Right.

15 Q: - as normal cells -

16 A: Yes.

17 Q: - in a Pap smear. And then, over the page, are some of the dysplastic
18 cells that Papanicolaou described. Which one of these cells would
19 correspond to the keratinising dysplasia?

20 A: Sorry which one?

21 Q: Which one would correspond to the keratinising dysplasia that you
22 describe?

23 A: I think that the ones with the orange cytoplasm are the ones that the
24 keratinizing dysplasia, so the orange.

25 Q: So that's the top left corner?

26 A: Yes that's correct, and also the ones at the bottom.

1 Q: In the series of illustrations that she includes that represent examples
2 of false negatives, true positives, do any of these represent keratinizing
3 dysplasia or is it possible for you to tell?

4 A: I don't like commenting on photomicrographs to be honest. I would
5 rather comment on slides if I had to. Certainly some of these, I see some
6 neoplastic dysplasias . I don't see obvious keratinizing dysplasias. I think
7 the question is problem better put to Dr Farnsworth who actually made the
8 statement.

9

10 MR GRIEVE CONTINUES XXN

11 MR GRIEVE: Just so I get it clear, I'm not absolutely sure what is
12 meant by keratinizing dysplasia would you just mind explaining that.

13 A: The dysplasia is in the more mature cells present in the cervix. They
14 mature from the bottom upwards and as they get towards the top layer of the
15 cervix, the cytoplasm changes in colour so it goes the orange colour in the
16 cells and indeed if the cervix is subject to prolonged irritation or
17 occasionally has a reaction to underlying dysplasias, we can actually see true
18 keratinisation occur in the cervix which is the change that occurs in the cells
19 of your skin and makes your skin as compared with the squamous mucous of
20 your mouth where it's pink because it doesn't form that top hard horny
21 layer.

22 Q: So is the significance of it that the lesion has been present for longer?

23 A: No I don't think so. It's dysplasia in a different layer of cells. I don't
24 believe it equates to duration but sir I really not am quite sure what Dr
25 Farnsworth is referring to in this paragraph to be honest.

26 Q: Well I suppose we will have to ask her of course but what she appears
27 to be saying as I understand it as a lay person is that when they took on this

1 re-read they expected to see if they were going to see any false negatives
2 that they would be generally of the type of false negative that you mentioned
3 earlier that form that characteristic class whereas they saw these significant
4 abnormalities that were obvious to be seen. That's how I read it.

5 A: Yes she's expressing some surprise about the type of changes that she
6 is seeing but in that paragraph isn't expressing it as false negative so I
7 believe just the presence of them.

8

9 CHAIR INTERJECTS AND XXN WITNESS

10 CHAIR: Dr Teague to get back to the ACL Review as part of that
11 review does that entail the reviewers not only reviewing the slide to see
12 whether or not they read it as normal, abnormality etc. in terms of the
13 Bethesda code but also for the reviewers to comment on the nature of the
14 abnormality present in the way that Dr Farnsworth has done in paragraph
15 22, is that part of the ACL Review or does it not go that extra step?

16 A: No it was never intended to go into that step which I believe is
17 probably the next step on.

18 Q: Yes.

19

20 MR GRIEVE CONTINUES XXN OF WITNESS

21 MR GRIEVE: Well that's precisely the point that I was coming to you
22 see because depending on one's view of them, if for example, and I'll just
23 put in hypothetically for a moment, I don't want you to get concerned that
24 I'm back to patient one smears, but if for example some of the four patient
25 one smears were of the character described by Dr Farnsworth in paragraph
26 22, that fact would not have come through on the cytology review panel
27 report would it?

1 A: No the details of that certainly would not come through on that report.

2

3 CHAIR INTERJECTS

4 CHAIR: Who wrote the guidelines for the ACL reviews?

5 A: I think that that was derived by consensus meetings really.

6 Q: Did you have any hand in those guidelines.

7 A: Yes I did. We believe it was a novel and new process at the time. It
8 was. I think it's unique in the world and I believe that we have had inquiries
9 from both the United Kingdom, from Australia and from the United States
10 trying to follow up on this to see whether they could immitate it because it
11 involved many of the principals that should be involved in review of cases
12 for medico-legal purposes. We were always just a little bit cautious about it
13 because it hadn't been put to the test and I believe that this case probably is
14 the first major test of it as a review process.

15

16 PROFESSOR DUGGAN INTERJECTS

17 PROFESSOR DUGGAN: What principals are you referring to Dr
18 Teague?

19 A: The principals I am referring to is that in a review like this it should
20 be done blind, it should be done by more than one laboratory and it should
21 be done if possible where the reviewing laboratory doesn't know which
22 particular slides are the ones that are in question.

23 Q: When you developed these, these are guidelines for the review of
24 smears in the context of litigation?

25 A: It was set up as a review panel. What had happened was that in
26 Australia there had been a case where a slide subject to litigation had been
27 reviewed by I believe an academic unit by one pathologist who knew the

1 history and then I believe there were difficulties finding the slide. We
2 believed that a fair review process would involve proper handling of the
3 slides, mixing them with slides that were not in question and to be done by
4 multiple independent reviewers.

5 Q: Where these principals modeled on any principals used elsewhere?

6 A: We had no pre-existing model to base it on but it does conform to
7 recommendations such as have come out by the College of American
8 Pathologists, recent recommendations for review of slides.

9 Q: Now we have seen that document it's been brought into evidence I
10 think through Professor Skegg and you probably don't need to see if it you
11 are familiar with it however I think you should see it. [Document produced
12 to witness]. Loose exhibit 9, principal 3 at the bottom of the page.

13 A: Absolutely I mean the process conforms to that.

14 Q: Now did your process predate this particular principal development
15 by the College of American pathologists?

16 A: I'm not sure when this was published, ma'am. I suspect it did predate it
17 but I'm not sure. I'd have to look at the publication date.

18 Q: Regardless, there is a commonality in the principles?

19 A: That is right.

20

21 MR GRIEVE: Just for a moment, coming back to this question of
22 keratinisation and your comment that these days it's probably the absence of
23 it may well be because it has been screened out, although I know you gave
24 the other possible explanation that the nature of the disease might have
25 changed over time.

26 A: Yes.

27 Q: But putting to one side that latter possibility –

1 A: I think – I'm not sure whether Dr Farnsworth was referring to this or
2 not. I really honestly am not.

3 Q: I just want to ask you about it because we are, at the moment, in the
4 hypothetical situation because we haven't heard from her.

5 A: Right.

6 Q: But just let's assume that –

7 A: And I think – well, I don't know, the other point that's been made is the
8 photomicrographs here don't show many keratinising dysplasias, so perhaps
9 she's not referring to it.

10 Q: As I say, we'll have to sort that out with her, and we cannot until she
11 gives evidence, but the fact is that she has observed that this was a
12 significant notable feature.

13 A: Right.

14 Q: If we assume that those observations relate to false negatives, then that
15 has some significance doesn't it?

16 A: Yes.

17 Q: And coming back to your comment that the reason for not seeing such
18 dysplasias today might be because they have been screened out, if we put to
19 one side the other possibility – namely changed disease process, the
20 converse of it is that the reason these appearances were noted is that
21 effectively the Tairawhiti population was an unscreened population?

22 A: I think that that is materially wrong, both in fact and it's highly
23 conjectural. There was evidence that there was screening going on here and
24 that people were getting colposcoped. So, you mean, not effectively
25 screened perhaps? But screened is an error, is not correct.

1 Q: Thank you for picking me up on that. But the conclusion might be that
2 the population was not being effectively and adequately screened, mightn't
3 it?

4 A: That's a possible conclusion.

5

6 CHAIR: Why is that a possible conclusion, can you give me reasons for
7 that please?

8 A: Can we just get myself really clear. Can you put the question and I will
9 answer it?

10

11 MR GRIEVE: I put it to you this way: You have said, in connection with
12 observation keratinised smears, that the reason why they are not seen so
13 frequently today may well be because the abnormalities have been earlier –
14 to use your phrase “screened out”, correct?

15 A: Yes, I think the point that I was probably trying to make is that the
16 keratinising dysplasias are the classic ones and are usually more easily
17 detectable and, therefore, are probably picked up more quickly. There is,
18 however, a caveat on that; there are an area where we have atypical or para-
19 keratotic cells, which are a form of keratinising cells in the cervix which
20 may be very difficult to distinguish from dysplastic cells.

21 Q: Now when you talked about the presence of these keratinising
22 dysplasias, the second reason for them being not so readily seen or
23 frequently seen today was that there may have been a change in the course of
24 the disease process – that's the second reason isn't it?

25 A: Yes. That's right.

26 Q: My question was put to you on the basis that we put to one side that
27 second alternative, just assume, if you like, that that has not occurred, that

1 there has been no change in the disease process. I was putting it to you that
2 one inference that could be drawn for the presence of such dysplasias in the
3 Tairawhiti population is that the population could have been inadequately or
4 ineffectively screened, and I think you agreed with that and then Madam
5 Chair said what are the reasons for that. So that's the context.

6 A: I guess if one assumes that these keratinising lesions should have been
7 picked up and if they were present they it would indicate perhaps that there
8 was inadequate screening, but having looked now through these
9 photomicrographs I'm far from convinced that that what Dr Farnsworth is
10 referring to.

11

12 CHAIR: The difficulty is we don't know whether the micrographs fit with
13 para 22. She's referred, in para 22, to the features of keratinisation rarely
14 seen today in practice. She has not said in para 22 that the micrographs
15 shown in exhibit 1 are examples, and so it is actually wrong to connect
16 exhibit – there is nothing in her evidence to connect exhibit 1 with what she
17 says in para 22. It would have been better if, having written para 22, she had
18 included, as a micrograph, an example of this type of slide. But that hasn't
19 happened in her evidence. So we are at a bit of a loss here on that point.
20 One thing I'd like you to deal with for me please Dr Teague, if you could
21 look at Dr McGoogan's exhibit 9, that is an article on the characteristics of
22 false negative cervical smears.

23 A: Yes.

24 Q: And you'll see if you go to the second page, which is p359 in the top
25 corner, there are two graphs given there of the typical false negative slide.
26 Are you familiar with that?

27 A: Yes, I have looked at it.

1 Q: And then over the page there is a graph given there of the typical pattern
2 of a positive.

3 A: True positive I think. The thing that stands out in those two diagrams is
4 the sparsity of the abnormality cells, and that I think was the theme of this
5 paper.

6 Q: Right. And it seems, therefore, that the paper is saying, usually a false
7 negative smear will have sparse abnormal cells on the slide?

8 A: Yes, and I think that work from previous papers had also identified
9 those other factors that I mentioned.

10 Q: and What Dr Farnsworth is saying she found, it seemed to me also, was
11 very obvious abnormal material; in other words, I had interpreted from that
12 that the slides, or some of the slides that she was reading, - and certainly this
13 has to be tidied up when she gives evidence – did not resemble the false
14 negative being discussed in the articles.

15 A: Yes I think that that's probably a fair summary.

16 Q: When the ACL does its review, has it considered going the extra depth
17 and looking at the quality of the false negative slide in other words to see
18 whether it resembles more the false negative shown on page 359 of this
19 article or whether it is a far more obvious type of true positive.

20 A: It was never set up or intended to do that ma'am. I think it was
21 answered the question of really whether this in a normal laboratory situation,
22 should this have been reported as positive or negative, that's all and that was
23 it's entire purpose I believe.

24 Q: If slides have been read as normal when others read them as abnormal
25 and their characteristics do not fit with what is seen now to be the usual false
26 negative, in other words they are more obvious, what does that tell you about
27 the competency of the pathologist doing the first reading.

1 A: I wish I could give you a simple answer to that ma'am. I don't think I
2 can. The reason is in all of these false negative studies, they tend to identify
3 factors which are associated with false negative but not all of the false
4 negatives fall within these characteristics, if you look in the studies
5 generally, there is a higher proportion of slides which show these particular
6 characteristics but not all do and one would have to do a substantive exercise
7 to look at the statistics of what was involved I think to draw a conclusion.

8 Q: Well just taking for the moment what Dr Farnsworth has said in
9 paragraph 22 of her evidence, if that is correct, she hasn't given evidence yet
10 so it hasn't been tested, we don't know whether it is or not, but if it is, what
11 if anything would that indicate to you about the competency of Dr Bottrill in
12 terms of his reading of the slides?

13 A: The problem really is that this paragraph indicates that there were
14 keratinizing dysplasias present, it doesn't indicate that these slides were false
15 negatives in this paragraph.

16 Q: I see. If the slides that are being spoken of in paragraph 22 were false
17 negatives and we have to tidy that up when she gives evidence, what then
18 would this tell us about the competency of Dr Bottrill in terms of his reading
19 of the slides?

20 A: I think again we would have to look at the statistical analysis of this
21 to see whether they were all in this category, some in this category, mostly in
22 that category, mostly not, I don't know but it would need that sort of further
23 analysis I believe to draw a conclusion.

24 Q: Right so without further information we can't draw a conclusion at
25 the moment.

26 A: Absolutely.

27

1 MR HODSON INTERJECTS AND ADDRESSES PANEL

2 MR HODSON: I'm not sure that Dr Farnsworth will be able to help us
3 because she is not meant to know what the previous calls were.

4 CHAIR: Yes well Mr Hodson we're just dealing with this at the
5 moment, we'll deal with Dr Farnsworth when she gives her evidence and
6 find out what she has to say then.

7

8 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

9 PROFESSOR DUGGAN: Dr Teague in your usual practice do you
10 actually make a comment about the type of dysplasia that's present, that is
11 whether it is caratinising or non-caratinising?

12 A: No we would normally just report in the Bethesda coding system
13 which wouldn't identify a caratinising dysplasia. We have an area in
14 Bethesda where we may make a free comment and if there are funny or
15 unusual features we may well make a free worded comment about it. We
16 don't have a policy of saying if we see a caratinising dysplasia we say so.

17 Q: So it's not routine practice to add a qualitative identifier to the cells.

18 A: No I don't things that's part of Bethesda which we have encouraged
19 laboratories to use.

20

21 MR GRIEVE CONTINUES XXN WITNESS

22 MR GRIEVE: I just want to follow on on the questions of Madam
23 Chair about whether conclusions can be drawn about competence and I want
24 you to assume that Dr Farnsworth's results do relate to false negative smears
25 for the purpose of these questions.

26 A: Yes.

1 Q: You said a few minute again when asked about this caratinising
2 dysplasias that they were easily detectable. Now my question is if you have
3 a smear even a single smear where the abnormality is easily detectable, it
4 is a false negative and read wrongly why do you say that that does not reflect
5 to some degree ... perhaps I'll put it this way, why do you say it is not
6 relevant to the issue of the smear readers competence?

7 A: I didn't say it wasn't relevant but I said it would have to be done by
8 statistical analysis to see if this was a regular and recurrent problem. At one
9 end of the spectrum there are caratinising dysplasia which are easily
10 recognisable. At the end of parakeratosis there is in fact quite extreme
11 difficulty at times distinguishing between parakeratosis and a typical
12 parakeratosis or dysplastic keratosis so that there is an end of this spectrum
13 which is difficult and an end of the spectrum which is easy.

14 Q: Well now still sticking with qualitative evaluation of false negative or
15 error, I think you will probably recall that Dr or is it Professor, I've forgotten
16 which now, but Professors McGoogan said and I can take it from paragraph
17 the paraphrasing she says one incorrect reading doesn't mean that it's
18 negligence. You would agree with that wouldn't you?

19 A: Absolutely.

20 Q: And so when we have identified error the labels that one attaches to
21 that down the spectrum depend on the degree of error don't they.

22 A: They depend on the degree and the multiplicity of those errors.

23 Q: Yes and they range from acceptable and excusable understandable
24 error starting at that point?

25 A: Even at the extreme there has to be as I have indicated a statistical
26 analysis of the numbers of those errors. The higher up the spectrum they are

1 probably the lower the threshold. But there are not well documented these
2 particular levels.

3 Q: I suppose the point is that again if we take this case as an example,
4 we all know with the great advantage of the retrospectoscope that these
5 smears may have provided a window into what was in fact happening,
6 mightn't it. We know now it was happening that is under-reporting in
7 Gisborne ...

8

9 CHAIR ADDRESSES MR GRIEVE

10 CHAIR: Hold on Mr Grieve we don't know, that's the purpose of this
11 inquiry.

12 MR GRIEVE: I put that on the basis of for example Dr Tie's evidence
13 on Friday Madam Chair where there is an acknowledgement there of an
14 unacceptable level of under-reporting. Now that hasn't been found but I'll
15 put it on the basis that there is evidence.

16 CHAIR: Well you can say some people think there has been under-
17 reporting because that's what it is in expert opinion.

18

19 MR GRIEVE CONTINUES XXN

20 MR GRIEVE: Some people think that there has been under-reporting
21 during this relevant period and I'm going to be coming to ask you whether
22 that's your opinion shortly, but what I'm getting at here is if the cytology
23 review panel for example had given some qualitative statement about or
24 made a qualitative assessment of the nature of the errors, that might have
25 alerted somebody to the fact that something was wrong here.

1 A: I think that's drawing a long bow that in one case on four slides that
2 we would have come to that conclusion, but it's possible, but it's
3 hypothetical.

4

5 CHAIR INTERJECTS

6 CHAIR: The simple fact is that the ACL Review doesn't go that far
7 does it?

8 A: It wasn't intended for that process ma'am.

9

10 MR GRIEVE CONTINUES XXN

11 MR GRIEVE: But might it not be helpful in the future for it to do so.

12 A: I believe that in the future we should be putting in place quite a lot of
13 things which have already been the subject of much discussion here.

14 Q: What does that include?

15 A: That includes, particularly, reviews of every case of cancer. It includes
16 the histopathology/cyto correlation statistics. There are a host of things that
17 have been brought out that we need to look at for the future.

18 Q: I noted when I was looking through your exhibits, Dr Teague, since
19 we've come to this point I would like to deal with it now, that, for example,
20 your exhibit p50, which is a meeting of the Advisory Group on 14 February
21 1990, p52, you were expressing concerns there about the need for a
22 histology register.

23 A: Absolutely

24 Q: And the use of the Cancer Register.

25 A: Yes, that's been a common theme I think through a lot of the committee
26 meetings.

1 Q: I noted that it was again mentioned, p68 – reference to the Cancer
2 Register, about a backlog. Page 69 you have a reference to the State of
3 Victoria recording cytology information for many years.

4 A: Yes.

5 Q: Page 72 there is recommendations that appropriate steps be taken to
6 ensure that full registration of cancer in NZ is restored. Actually on that
7 point, why do you use the words “restored” – did we use to have it and was
8 it then lost?

9 A: I think that NZ actually had a very good Cancer Registry from quite
10 early days and I think that it faced a number – well, it’s speculative on my
11 part really, but I believe it faced a number of resource issues and it did get
12 behind with its registrations.

13 Q: Was it voluntary up until 94?

14 A: Yes it was voluntary up until 1994 and the registrations were reasonably
15 complete, I believe, through the public hospital system as it was then, but it
16 was incomplete from the private system. I don’t believe that there was any
17 problem from the private system in supplying the statistics but they did need,
18 and wanted, protection in doing so.

19 Q: I see that in 29 March 1990 – page 76 – the expert group was saying it
20 was impossible for it to adequately perform its task if the Cancer Registry
21 was not adequately functional.

22 A: Absolutely.

23 Q: You were recommending to the Minister then, as a matter of urgency,
24 that the Cancer Registry be resourced with equipment, staff, legislative
25 framework etc.

26 A: Yes.

1 Q: Then I've noted p84, which refers to a meeting of 29 March 1990,
2 there's again a reference there to the Cancer Control programme, and need
3 for an interactive computer with the Cancer Registry.

4 A: Yes.

5 Q: I saw again in May 1990, which appears at p123, there is the discussion
6 about the need for a cytology register, a population register and a National
7 histology register which contains results of biopsies to determine rates of
8 cervical intraepithelial neoplasia. So it seems to me – I'm not going to
9 continue, but at a very early stage the expert group recognised the
10 importance of histology/cytology correlation and having an effective Cancer
11 Registry so that the data between Screening Register and Cancer Registry
12 could be correlated.

13 A: Absolutely. It's fundamental I believe to running the programme.

14 Q: Why did it never happen? Or why did it take so long to happen?

15 A: I'm not sure that it has yet happened, to be honest. The histopathology-
16 cyto correlation is happening and I believe that correlations are available for
17 about 2 years backwards, but have been available to laboratories more
18 recently than that. I can't answer why it didn't happen. I can say that people
19 such as myself and a large number of other people did their very best to try
20 and get this to happen. I believe that there have been, what, resourcing and
21 structural issues which have effectively delayed what she have happened. I
22 think obviously we've seen, in some of the recent evidence, we still have
23 some real problems about getting the correlation with the Cancer Registry
24 and the cervical cancer programme being able to extract that data and
25 analyse those cases.

26 Q: That's because of s74A.

1 A: Yes. I find that extraordinary, and I mean, we've got international
2 experts like Professor McGoogan, we've got Professor Skegg, we've got all
3 of the groups who've looked at this have all said the same thing.

4 Q: It seemed to me, looking at your exhibits, in 1990 you were making it
5 clear how important it was that you be able to correlate the Cancer Register
6 with the Cervical Screening Register and it couldn't happen because of
7 difficulties with the Cancer Register, and then subsequently with the
8 amendment to the Health Act, with s74A, they then become legal hurdles
9 which make it more difficult.

10 A: There was one improvement in the legal hurdles and that was when it
11 made it compulsory for all cancers to be notified to the Cancer Registry.
12 That cleared the path so that there were no concerns for people outside of
13 the State system supplying that information. So that was a step forward.

14 Q: But then you have the lockup in terms of not being able to legally
15 correlate the two sets of information.

16 A: That is right.

17 Q: The officials that you spoke with, as a member of the Advisory Group in
18 1990 when you were asking for the Cancer Register to be updated and
19 emphasising the importance of being able to correlate Cancer Register with
20 Screening Register, did they understand the implications of what you were
21 saying?

22 A: I don't know. I think probably people at the end that we interfaced
23 probably did. I believe it got lost in the upper echelons – I don't know. It
24 wasn't for want of trying to explain the reasons why it was required.

25 Thank you Dr Teague.

26

1 PROFESSOR DUGGAN: Dr Teague I just have one question about the
2 Registry. The expert group's recommendations with reference to the
3 Registry were made in order to establish the policy of the screening
4 programme, is that correct?

5 A: the expert group referred to was an expert group put together to form the
6 policy of the programme, yes.

7 Q: And the policy of the programme was to reduce the incidence and
8 mortality of cancer?

9 A: that was the goal of the programme.

10 Q: But you were impeded because you did not know what those figures
11 were, is that correct?

12 A: Absolutely.

13 Q: And this was the reason why you made all of these recommendations
14 with regard to the Cancer Registry?

15 A: Not only that, but people such as myself and others went on to various
16 other committees, that were attached to the Cancer Registry – or at least
17 examining the Cancer Registry – to try and get this to happen as well.

18 Q: Was it appreciated at that time that a fully functional and robust
19 Registry would be necessary in order to evaluate the success of the screening
20 programme?

21 A: Well, it was appreciated at the level that I worked at. I can't say for
22 other levels. But it was, as you can see, a recurrent and repeated theme.
23 More than that I can't say really.

24 Q: I see Dr Teague that at page 192 this is in a document which begins
25 on page 154 it's the National statement of the National Cervical Screening
26 Programme expert group in August 1990 and at 192 at paragraph 10.1.7 you
27 say another difficulty limits the effectiveness of the register plan for the

1 programme to monitor the proper treatment of women with abnormal
2 smears, histology results need to be linked to the cytology registers, this is
3 not part of the current plan, achieving this link could be done either by
4 including histology results on the cytology registers or by linking in with an
5 updated New Zealand cancer register which has been extended to include
6 dysplasias. Until there is such a histology cytology link up the quality of
7 smear reading in laboratories cannot be evaluated by the Register and more
8 importantly the monitoring of women with abnormal smears would not be as
9 complete as it could be. You then go on to talk about legislation and refer to
10 the fact that as currently designed the Register does not meet the
11 requirements of Registers used in successful overseas programmes. So you
12 knew all of this in August 1990.

13 A: Yes.

14 Q: And no-one was doing anything in response to what you were
15 advocating at that time?

16 A: Well I suppose one of the frustrations is that nobody rejected it,
17 nobody said we're not going to do this. It was really a matter of yes this is
18 something that needs to be done and I guess there were assurances that it
19 would be done it's taken a long long time to happen.

20 Q: If it had been put in place shortly after you recommended it in August
21 1990, do you think we would be here today?

22 A: No I don't think so and I don't think so particularly the one thing that
23 I think was crucial to the particular situation that we may be facing here is
24 the correlation or the assessment of all cases of cervical cancer which I
25 think as I've said in my brief is the gold standard for such a programme.

1 Q: Well you've said that but I understand too that Professor Skegg
2 wanted to go back and do such a study and he has been prevented by the
3 local ethics committee are you aware of that?

4 A: I am aware of that and I just feel that this is déjà vu. It's here we have
5 an internationally recognised expert saying one thing and it's not happening
6 and is being rejected by another group who I don't think are of the same
7 standing as Professor Skegg.

8 Q: In order to carry out such a study would you need to actually
9 interview the women concerned again or would it be a matter of just going
10 back over their existing records?

11 A: I think in the initial phase I think it would be just a matter of going
12 over records.

13 Q: So it would have no direct impact on the women concerned?

14 A: No.

15 Q: Thank you Dr Teague.

16

17 MR GRIEVE XXN CONTINUES

18 MR GRIEVE: I just want to come back if I may to the cytology review
19 panel. Do you not think that it would be helpful for the future if in addition
20 to the analysis that the panel already does, it included a qualitative analysis
21 of the error, assuming it finds error?

22 A: It certainly could be considered as part of that. This review panel to
23 be honest was really very narrowly focused only on cases where there as
24 likely to be a medico-legal issue involved with it. I believe that we could
25 look at other mechanisms which might well address your concerns sir.

1 Q: So a panel similarly constructed to remove as far as is possible on any
2 rereading a bias, but with the added or wider function, in appropriate case to
3 look at the issue of query competence?

4 A: Yes I'm not sure about query competence but certainly to query is
5 there a problem.

6 Q: Yes but the problem is caused by varying degrees of competence isn't
7 it, or incompetence?

8 A: In it's broadest concept perhaps yes.

9 Q: And taking or recognising that the pathologist role in all this is just
10 part of the whole process?

11 A: In my brief I've actually gone into the different types of review that
12 could and perhaps should be done which may help.

13

14 CHAIR INTERJECTS AND XXN WITNES

15 CHAIR: In terms of the ACL Review though that is something that
16 happens after the event in other words there is a concern that a slide has
17 been under read and this is to check it out.

18 A: Yes.

19 Q: The real concern now is to develop strategies which will ensure or
20 reduce the likelihood of slides being under read.

21 A: Absolutely and I believe that what were talking about, both of us are
22 talking about now, really would be, there should be a panel system of some
23 sort set up to review all of those cases in which cervical cancer occurs and
24 that it should address these very issues that you have raised. I think that
25 should be part of it.

26 Q: Could it be possible for women who have decided to remain on the
27 programme if this evaluation of cancer cases was seen as being part of an

1 evaluation of the programme, as you said it was the gold standard, could it
2 not be seen as part and parcel of an effective screening programme so that a
3 woman who decides to remain on the Register is taken implicitly as
4 consenting to that type of study occurring should she later develop cancer.

5 A: Absolutely but to be effective the analysis should be done on all
6 cases.

7 Q: On all cases right. So that would include women who haven't been
8 screened.

9 A: No, well yes it would, and it would also include those who were not
10 on the programme because after all is the cancer is occurring in people not
11 on the programme we've got a problem then with recruitment or other
12 issues.

13 Q: So what is really needed then is a complete study in the case of all
14 women who have cervical cancer?

15 A: Yes.

16 Q: Thank you Dr Teague.

17

18 MR GRIEVE CONTINUES XXN OF WITNESS

19 MR GRIEVE: But I think a number of experts have said, and it's in the
20 evidence in various reports and so on, with the best will in the world and
21 even with the best system in the world there are still going to be errors aren't
22 they.

23 A: Absolutely, this is the real problem with controlling these type of
24 programmes, it would be easy to control if any error signified incompetence.
25 This would be easy, it's not, there are going to be errors and it's very hard to
26 control.

27

1 CHAIR INTERJECTS AND XXN WITNESS

2 CHAIR: That's because the nature of reading slides is subjective it's not
3 a litmus test is it.

4 A: Absolutely and again another illustration of this, I believe that if it
5 was that simple and straightforward we would have image analysis and
6 computer analysis systems which would be doing it for us now. It's not and
7 we can't and even the computer image analysis systems available still
8 require the human eye to make a subjective assessment at the end.

9

10 MR GRIEVE CONTINUES XXN

11 MR GRIEVE: But for all those reasons given that there is still going to
12 be errors and given the possibility that those errors may conceal a wider
13 problem, there needs to be a mechanism to evaluate those errors doesn't
14 there.

15 A: Yes I mean in terms of cancer that's what we have been suggesting
16 should be put I place.

17 Q: Right but your review of cancer is retrospective isn't it, that would be
18 retrospective.

19 A: Absolutely.

20 Q: What I'm suggesting is that if coming back to it the cytology review
21 panel or something like it, a body like it, was to make a qualitative analysis
22 of the errors (if it found them), then that might help in providing an
23 indication that something should be done in whatever area that slide
24 originated from?

25 A: It may be, but you're getting into then quite subjective areas, and it
26 would be very hard to interpret on small numbers of slides. These are
27 subjective observations.

1

2 CHAIR: And a slide would only go to the ACL review panel in
3 circumstances where a concern had already been raised about the reading of
4 the slides?

5 A: Absolutely, it was only a very narrowly focused review panel for one
6 particular purpose. But it met, I believe, a need which other countries were
7 experiencing problems with. That was the review of slides which were
8 subject to litigation.

9

10 MR GRIEVE: Just take a hypothetical case, but building on the four smears
11 example that we have, if the cytology review panel, having looked at those
12 four smears, had then said in relation to one or two of them, had made the
13 sort of remarks that Dr McGoogan made – namely, obvious abnormalities –
14 that sort of thing in para 22

15 CHAIR: Isn't that Dr Farnsworth?

16 MR GRIEVE: Sorry, Dr Farnsworth. Do you think that would have done
17 anything to alert people to the possible problem?

18 A: It's hypothetical. It's both hypothetical and subjective and it's done on
19 a small number of slides. I believe that I personally would have taken what
20 more notice if it'd seen 4 smears reported as high grade and all reported as
21 normal would be of greater significance than perhaps the subjective
22 assessment of the ease with which the diagnosis was made. I took, to be
23 honest, the proportion of the panel that came to a particular conclusion as
24 indicating the ease of which that diagnosis could be made. In other words, if
25 1 was different to the other 4, then that indicates a slight degree of difficulty.
26 If it was a 2/3 split, clearly it was a difficult slide to interpret.

27

1 CHAIR: Before you could start to come to the sort of conclusions that Mr
2 Grieve is asking you to come to, how many slides would you need to see?
3 For example, if you looked at 50 slides and of those 50 30 had been read as
4 negative when they were quite clearly didn't resemble the usual false
5 negative, what would that mean to you?

6 A: I think it would start warning me that something might be going on. I
7 think that perhaps the difficulty is shown from Professor McGoogan's
8 comments about the standards from the false negative rate on primary
9 screening using re-screening - rapid re-screening as a standard, and for only
10 high grade and worse lesions - accepting that you have to have between 85
11 and 95% to be satisfactory, and given that rapid review would probably only
12 detect approximately half of the actual false negatives, you are actually
13 looking at a false negative rate for high grade in that situation somewhere
14 between 10 and 30%.

15 Q: So of the slides reviewed by the ACL panel, in your view, there was
16 insufficient numbers of those slides reviewed for them to give you any
17 meaningful indication of the general competency of Dr Bottrill?

18 A: I believe so. As God is my judge, if I thought that there was an
19 indication of systematic under-reporting from those slides I would have done
20 something about it.

21 Q: And you had the other laboratory as part of the review that in part had
22 agreed with Dr Bottrill's reading?

23 A: That is right.

24

25 MR GRIEVE: So to summarise that, your view is that, and later on you
26 had the opportunity to look at the slides yourself, your conclusion was that
27 they gave no indication or reason giving rise to any cause for concern?

1 A: I didn't look at them with the purpose of either raising or not raising
2 concern, I did it for a specific purpose, which was to photograph those slides
3 for the case. If you are asking me would I have had concern, I believe one
4 of those slides was a real – in terms of outcome – critical miss and it was a
5 difficult slide for me to photograph because the abnormal cells were
6 relatively sparse in it.

7

8 CHAIR: So in that sense was it a slide that resembled more the true false
9 negative shown in the article? That exhibit 9, McGoogan?

10 A: Yes.

11

12 MR GRIEVE: that was slide C, wasn't it?

13 A: Yes.

14 Q: And consistent with what you've said today, do you recall the terms of
15 your letter of 14 August when you reported the outcome of the review to Dr
16 Bottrill?

17 A: If you get it in front of me.

18 Q: We will show it to you. [Witness shown letter]

19 A: Yes, that just, to me, was a letter of summary of those results.

20 Q: And while I'm not going to take you through it now, we don't need to
21 because it speaks for itself, but there would be nothing in there that would
22 have even alerted Dr Bottrill that there might be a problem, would there, or
23 was there?

24 A: I think that the evaluation of this problem requires – this is not an
25 adequate evaluation to answer the question that you're trying to answer with
26 it, I think.

1 Q: Well, all I'm suggesting to you is that there would be nothing in your –
2 consistent with what you've said today about your opinion of the review
3 panel and even your own look at the smears for the purpose of
4 photographing it – letter to alert Dr Bottrill that he might have a problem,
5 was there?

6 CHAIR: In terms of systematic under-reporting, that's what you mean,
7 don't you Mr Grieve?

8 MR GRIEVE: Yes.

9 A: I don't think that this is necessarily an indication of systematic under-
10 reporting.

11 MR GRIEVE: And as it happens, you didn't remind him of your advice to
12 get TELARC accredited?

13 A: No, I didn't in that letter, I thought this was a more formal letter which
14 would clearly be used for other reasons.

15 Q: Now I've got the 4 smears here. I just want you to identify them for me,
16 please.

17

18 CHAIR: Are you going to produce the letter Mr Grieve?

19 MR GRIEVE: Yes, ma'am I am, thank you for reminding me.

20 [CAT/RCPA/016]

21 Q: Just have a look, they've come in the containers from the High Court,
22 but you will know how to deal with the little plastic container with the four
23 smears, all I want you to do is check them and I suppose from the labeling
24 do they appear to you ...

25 A: They appear to be the relevant slides.

26

27 CHAIR INTERJECTS

1 CHAIR: Mr Grieve where are we going to with this. My understanding
2 is the line of questioning before was pathologists have lost their morality.

3 MR GRIEVE: Madam Chair where we're going to is that as I've
4 indicated last night in a discussion with Counsel assisting I'm going to be
5 asking Dr Farnsworth to look at those smears under a microscope.

6 CHAIR: What is the point of that.

7 MR GRIEVE: Because she can be asked to assess them in the context
8 of her categorisation as described in paragraph 22.

9 CHAIR: Well Mr Grieve this is not an inquiry into the ACL panel
10 guidelines, whether the ACL panel did it's job properly or not. We have got
11 Dr Farnsworth's evidence, the Health Funding Authority has had a very
12 expensive study carried out, there is nothing that Dr Farnsworth can say
13 about those four slides that is going to make much difference one way or the
14 other.

15 MR GRIEVE: Well Madam Chair I'm prepared to be heard on that at
16 some appropriate stage but I suggest that rather than take up time with it
17 now I simply get this witness to produce them having identified them so that
18 we can deal with that when the time comes, I'm not going to be asking him
19 any further questions other than to identify them.

20 CHAIR: Alright.

21

22 MR RENNIE INERJECT AND ADDRESSES CHAIR

23 MR RENNIE: Ma'am I do question whether if that's all my friend
24 wants to do to ask Dr Teague to look at some slides and indicate whether he
25 thinks that they are slides that may have come from the High Court, that may
26 have been the slides subject to an inquiry that Dr Teague is not really in a
27 position I suggest to do that. It's a very strange way indeed to try and prove

1 the admission of an exhibit and I would respectfully suggest that if he has no
2 intention of asking the witness about the exhibit and I don't see how he can,
3 because Dr Teague didn't do the review and didn't look at the slides, then
4 that isn't the way to get them in either.

5 CHAIR: Yes.

6 MR GRIEVE: Could I be heard on that Madam Chair?

7

8 MR HODSON ADDRESSES CHAIR

9 MR HODSON: Could I add my bit before my friend has the right to
10 reply. My understanding is that when the rescreening programme was
11 announced the firm of Solicitors instructing my friend was invited at that
12 stage to provide all the smears in their possession and I think they may have
13 and I think they may have had a number to be part of the programme and
14 they declined and it seems very strange indeed to try and have Dr
15 Farnsworth look at it with whatever equipment is here in Gisborne which
16 she won't be familiar with to provide something which may or may not be of
17 any use to you.

18 CHAIR: So these were slides that could have been sent to Sydney for a
19 re-read but that did not occur. Is that right?

20 MR HODSON: I believe so ma'am.

21

22 CHAIR ADDRESSES MR HINDLE

23 CHAIR: Well Mr Hindle I'll hear from you then Mr Grieve.

24 MR GRIEVE: Yes ma'am it is true that my friend and I had a
25 discussion last night. I must say I wasn't entirely prepared for my friend
26 wanting to produce the slides through this witness and I think I'm not doing
27 any justice to our conversation to say that he wanted Dr Farnsworth to look

1 at the slides, that was up to him and now that it comes to it I have to say I do
2 think it's really irrelevant. It's very difficult to see that how anything that
3 could be said about those 4 slides is going to make any difference to your
4 report, that's the bottom line.

5 CHAIR: Yes, Mr Grieve.

6

7 MR GRIEVE ADDRESSES CHAIR

8 MR GRIEVE: I can deal with the technical aspects of it first.

9 CHAIR: Yes.

10 MR GRIEVE: It's been said by Mr Hodson that my instructing
11 Solicitors declined to permit smears to go for rereading. That is not so. My
12 instructing Solicitors acting for a number of the women effected who have
13 given evidence had smears and many of them, with the exception of these
14 ones that were exhibits in the High Court in respect of which I think at the
15 time there was pending an application for retrial and an appeal. It was
16 decided that it was too difficult to get them across for the reread but apart
17 from that, all the other smears in there under their control were included in
18 the reread so that's dealing with that point. Mr Rennie's point as I
19 understand it is well simply from the labeling Dr Teague may be unwilling
20 or unable to identify these four smears as being the smears we're talking
21 about and that may or may not be so. But if it is so, I can make a microscope
22 available to him at a break and have him look at the slides and in that way
23 identify them as being the slides from which he took photomicrographs so
24 that he can look at the material. So those are what I term the technical
25 objections and in my submission they can be met. There is then objection on
26 the basis of admissibility raised by yourself and supported by counsel. The
27 issue as you also mentioned in passing is internal morality. I don't know

1 what Dr Farnsworth will say about these slides but, and I accept immediately
2 that any report by her as to the precise degree of abnormality if she finds any
3 abnormality is of course subject to the problem of bias for obvious reasons I
4 accept that. But, and that's not the purpose for having a look at them, the
5 purpose would be to ask her the question, do any of these slides have the
6 appearances of the type she describes in paragraph 22, that is appearances
7 which should have been readily identifiable. Now depending on her answer
8 to that, that may or may not, depending on her answer, go to the question of
9 whether those appearances should have caused people to do something when
10 they were observed and I would propose, subject to what she says about the
11 appearances, to ask her have you seen those slides in similar circumstances,
12 in your professional experience and opinion what would you have done
13 about it.

14 CHAIR: And putting aside for a moment the relevance to the terms of
15 reference, how could the inquiry form any conclusion on the strength of Dr
16 Farnsworth's evidence on that point in the absence of hearing from those
17 pathologists who looked at the slides when they were part of the ACL
18 review panel. Any finding which says Dr Farnsworth's says, if she saw
19 these slides, it would ring warning bells and she'd be off to the Medical
20 Council and the Minister of Health and anyone else, would be quite wrong
21 without hearing from the pathologists who reviewed the slides because
22 implicitly it would amount to a criticism of them, they are not present.

23 MR GRIEVE: Well Madam Chair with respect I don't accept that that
24 is the position but even if it were, it doesn't render her opinion inadmissible
25 and we are here talking about admissibility and the other factor is, and I will
26 be asking her subject to ruling of course, I will be asking her whether or not

1 the fact that all these slides were from the same woman has a bearing on her
2 opinion?

3 CHAIR: Well, in terms of the admissibility issue, in the absence of being
4 able to carry out this issue to its logical conclusion and ensuring there is a
5 fair process, any evidence of Dr Farnsworth is of no weight. What is the
6 point of hearing evidence when it is quite clear procedurally that there would
7 be a breach of natural justice if the pathologists, who reviewed the slide and
8 who failed to take the steps that we assume hypothetically Dr Farnsworth
9 would say they should have done do not have an opportunity to be heard?

10 MR GRIEVE: Well, Madam Chair, for a start, there is additional
11 information that would be put to Dr Farnsworth and asking that question
12 which wasn't in the possession of the reviewing laboratories performing part
13 of the cytology review panel. So that the sort of information would be that
14 Dr Bottrill was the sole practitioner, a primary screener, those sort of issues.
15 So that those are alerting factors which would not have been known to those
16 people.

17 CHAIR: Well, if they didn't know it, how can you then say they've lost
18 their morality?

19 MR GRIEVE: I didn't say that they've lost – Madam Chair, I'm not saying
20 – I don't accept for a moment – I'm not submitting that the cytology review
21 panel people lost their morality. So that is not an issue as far as I'm
22 concerned.

23 CHAIR: No, but my understanding was the line of the questioning was that
24 they should have seen something which should have set them on the alert
25 and they should have told someone there was a problem. You say that Dr
26 Teague should have told someone that there was a problem. However, if
27 you are now saying that there is information that Dr Farnsworth will have

1 that they didn't have at the time, I can't see how you can therefore make the
2 submission, on reading these slides alarm bells should have rung, they
3 should have done something. Because you're now saying they didn't the sort
4 of information Dr Farnsworth would have. You're not even comparing like
5 with like.

6 MR GRIEVE: Madam Chair, with respect, you are not understanding my
7 argument and I'm obviously not putting it clearly enough for you, and I'll try
8 and recap.

9 CHAIR: Yes.

10 MR GRIEVE: The members of the cytology review panel had, I accept,
11 limited information. I'm not sure whether in fact – I assume they would
12 know that there were some slides in question from one laboratory. They had
13 10 slides, of which 4 were in question, but they wouldn't know which 4 even
14 – only Dr Teague knew that. So that they had no information, apart from the
15 smears, about the background. So there is no suggestion that they should
16 have been alerted. On the other hand, upon receiving the report, Dr Teague
17 had the cytology review panel results, he knew something of Dr Bottrill – as
18 we've heard in evidence, I won't review it again – and at a later stage, I
19 accept some time early in 1997, he had the opportunity of looking at the
20 smears for himself. He says for the limited purpose of taking the
21 photographs. Now Dr Farnsworth has reviewed slides from Tairawhiti and
22 described them in terms of para 22 as to some. It seems to me that it's
23 appropriate to ask her whether or not, upon looking at these smears, any of
24 them could be said to attract a similar description. If so, then she can also be
25 asked, "Well, given that this was a sole pathologist", what I would be doing
26 would be putting to her the facts known to Dr Teague and asking her to say
27 "in those circumstances, what would you have done about it." Now, in my

1 submission, that is permissible and admissible, and that is the basis upon
2 which it is being done. I emphasise again, there is absolutely no criticism
3 nor, in my submission in the circumstances, could there be of the members
4 of the cytology review panel. So it's on that basis that I'm seeking to do
5 this. I submit it goes to this issue of – call it what you will – internal
6 morality or lack thereof, whistleblowing – you can give it all sorts of
7 descriptions.

8

9 MR HODSON: Just one brief comment. At the disciplinary hearing
10 another pathologist, who I think had all the information my friend has
11 referred to, gave evidence and touched on the question – you'll see it in Dr
12 Teague's brief at p231 as part of his evidence. Another pathologist, also
13 with the knowledge of all the material gave evidence at the High Court, and
14 that was for the defence. And I really can't now remember which and who
15 of the plaintiff's witnesses saw them. So we are not only talking about this
16 panel.

17 CHAIR: Did you say Teague 231?

18 MR HODSON: No, it was another pathologist entirely. Dr Thompson is
19 page 231.

20 CHAIR: I don't intend to allow the questioning to continue, Mr Grieve, and
21 I will give you my reasons now. Mr Grieve has applied to be able to put
22 four slides to Dr Teague and for Dr Teague to identify those slides, the
23 purpose of this exercise being that Mr Grieve has indicated that when Dr
24 Farnsworth gives evidence he intends to ask her to look at the slides,
25 depending on the view she takes of the slides and given the knowledge she
26 has of Dr Bottrill's practice, he will then ask her whether or not she would
27 have taken any steps to report any concerns she might have about the slides

1 to the Medical Council or any other appropriate authority. Mr Grieve says
2 that this evidence is both relevant to the terms of reference and admissible.
3 There is an objection from Mr Hodson on behalf of Dr Bottrill and from Mr
4 Rennie on behalf of the Royal College. Mr Hodgson has said that the slides
5 could have been send to Sydney for the purpose of the re-reading. Mr
6 Grieve has responded to that by saying that at the time slides were exhibits
7 in Court and could not be made available. Mr Rennie has said that it is not
8 appropriate to ask Dr Teague to identify the slides from the labeling. Mr
9 Grieve has said that he could have a microscope available to Dr Teague to
10 enable him to do so. I have found that I will not allow this line of
11 questioning to proceed. The reasons I do so are that Mr Grieve has said that
12 the line of questioning is relevant to the terms of reference because it goes to
13 the question of the internal morality of pathologists as to what steps they
14 would take and when they would take those steps to report concerns they
15 might have about a fellow pathologist to the Medical Council or any other
16 appropriate body. My concerns is that this issue is being taken up with Dr
17 Teague at most, and I emphasis at most, hypothetically all that Mr Grieve
18 could establish was whether or not Dr Teague was acting in conformance
19 with a view that he hopes to establish in evidence from Dr Farnsworth. The
20 Royal College has already given evidence, we had members of the Royal
21 College come from Australia, namely Dr Davies, he was not asked to look at
22 the slides, he was not asked what steps he would take if having looked at the
23 slides and knowing the circumstances of Dr Bottrill's practice what he
24 would do, nor was that asked of Dr Tie. Therefore if this line of questioning
25 were pursued it would be impossible for the inquiry to come to any
26 conclusion as to the state of mind of the Royal College of Pathologists as a
27 body, the most you could do would be to compare Dr Teague's state of mind

1 with that of Dr Farnsworth. The other concern the inquiry has is that Dr
2 Farnsworth is not an independent expert witness, she has been engaged by
3 the Health Funding Authority, she has done a re-reading of slides, she has
4 seen many slides now from Gisborne laboratory, she has provided evidence.
5 It is difficult really to say even with the best of intentions, whether Dr
6 Farnsworth could give a clear and unbiased opinion as to what would be the
7 appropriate steps to take in the circumstances. Had there been an indication
8 given at the beginning of the inquiry when the Royal College was first
9 giving its evidence and had all members of the Royal College who appeared
10 before the committee of inquiry been asked to undertake this exercise and
11 had Mr Grieve indicated that he had independent expert evidence from a
12 pathologist to the effect as to what that pathologist would do had he or she
13 read the slides, and knowing of Dr Bottrill's practice, then the committee
14 would have allowed the line of questioning but given that none of those
15 steps were taken, it does not seem to the committee to be appropriate to
16 allow the line of questioning to continue. It would not be reasonable in all
17 the circumstances to recall witnesses from the Royal College particularly
18 those who have come from Australia, even if they were willing to give
19 evidence and even if Mr Grieve did have an independent expert, the other
20 difficulty is that this inquiry must complete the evidence it needs to report to
21 the Minister by the end of next week. The inquiry considers that the
22 evidence it has scheduled between now and next week together with the
23 evidence it has heard to date is sufficient to enable it report to the Minister on
24 the terms of reference any additional information that Mr Grieve might wish
25 to produce even if relevant would be an added bonus but without it the
26 committee still is confident that it can properly inform the Minister as to the
27 matters of concern to her as set out in the terms of reference and so for those

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1 reasons, Dr Teague is not to be asked to identify the slides and Dr
2 Farnsworth is not to be asked to comment on them for the purposes of this
3 inquiry. We will now adjourn until 12:00.

4

5

INQUIRY RETIRES FOR MORNING

6

ADJOURNMENT UNTIL 12:00 AM

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INQUIRY RESUMES AT 12:05

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CHAIR CLARIFIES RULING

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CHAIR: Before we start with this witness I would just like to say,

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adding to my ruling before the break, that I would not want it to be thought

8

that I consider Dr Farnsworth to be a bias witness. I do not. My concern

9

about her being used in the manner in which Mr Grieve wanted to explore

10

evidence with her was that it was not possible to exclude the perception of a

11

potential for bias and it seemed to me that the questions could only be

12

pursued with someone who was completely new to the issue and therefore

13

had all appearance of independence. Mr Grieve when you are ready.

14

15

MR GRIEVE CONTINUES XXN OF WITNESS

16

MR GRIEVE: Dr Teague when you were asked for your view about

17

the advisability of conducting a re-read, did your opinion coincide with Dr

18

Tie's that one of the reasons why a re-read was, shall we say, inadvisable

19

was because the available screening programme statistics at the time

20

indicated that Dr Bottrill's performance was within national perimeters?

21

A: That was a factor yes.

22

Q: One of the factors.

23

A: A factor.

24

Q: And of course I think you advanced that statistical approach when

25

you gave evidence earlier at the medical practitioner's disciplinary

26

committee hearing didn't you?

27

A: Yes I believe so.

1 Q: And then later at the High Court trial?

2 A: That's right.

3 Q: Now are you aware that at this inquiry those statistics have come
4 under some scrutiny?

5 A: Yes.

6 Q: And do you accept, we may be able to short circuit this, that it's now
7 apparent that there are a variety of reasons why at best they could be
8 described as misleading?

9 A: No I don't accept that they could be described as misleading, they are
10 of limited value but they are the only statistics we have.

11 Q: Well let me just take you through some of the reasons for suggesting
12 that there were major shortcomings in relation to them. First of all, they
13 related didn't they I perhaps better make sure we're talking about the
14 same thing. We're talking about the statistics that became available in 1996,
15 those statistics are the ones that were produced by Mr Boyd as exhibit 48.

16 A: Yes sir.

17 Q: Now these are a composite copy, when they were originally available
18 they did not have the names of the laboratories on each of the pages, and
19 that's something that's developed in front of the inquiry, but you know,
20 don't you, that at the relevant time Dr Bottrill had a set of these statistics
21 relating to his own laboratory?

22 A: That's correct, yes.

23 Q: And those were the ones which you were relying?

24 A: Yes, that was one of the factors which I took into account.

25 Q: Now they were statistics for a period, as the letter says, from I think was
26 it 1991 – I suppose from the inception of the programme through to 30 June
27 1994?

1 A: Correct

2 Q: And am I right that that, therefore, at the inception was some time in
3 1991?

4 A: The programme was phased in around the country – and I'm not sure
5 exactly when Tairawhiti started, but around that period.

6 Q: And one of the matters that's been produced by way of criticism of the
7 statistics, given the period that they cover, was that for a significant part of
8 the period we had the opt-on phase of the programme?

9 A: Absolutely.

10 Q: So that the statistics did not cover all those women whose slides would
11 have been read by Dr Bottrill?

12 A: Absolutely.

13 Q: Right. And you accept that that's a reason for at least looking at the
14 numbers with some care?

15 A: It is a limitation of those statistics, yes.

16 Q: Then another limitations that's been mentioned and thrashed to death,
17 and I don't want to re-thrash it except to mention it, and that is there was no
18 histology/cytology correlation so that there's no positive predictive value
19 element incorporated in these statistics?

20 A: That's right. So you couldn't assess false positives out of it.

21 Q: Or false negatives?

22 A: No, no. Positive predictive value is a measure of false positivity.

23 Q: Well, I thought it was a measure – I may be wrong – of the reliability of
24 the smear-reading, irrespective of whether it was negative or positive.

25 A: It's the ability to predict a positive result correctly.

1 Q: I see, all right. Now, another reason advanced as a limitation of these
2 statistics is that they, being National statistics, took no account of the local
3 demographics – for example, of Tairawhiti – would you agree with that?

4 A: Yes.

5 Q: And of course one of the important factors in that regard was at the
6 time, and still is, certainly was the incidence of invasive cancer in the
7 Tairawhiti region?

8 A: Yes, we didn't know that at the time.

9 Q: when you say you didn't know it at the time, are you saying that, what,
10 in 1996 when these statistics became available, that you – and I'm talking
11 you personally, and we can enlarge it to pathologists generally – did not
12 have any knowledge about the fact that Tairawhiti had a very high incidence
13 of invasive cancer?

14 A: No, not specifically. I think I would have predicted that it may have
15 had a slight higher rate of cancer, given its demographics. I don't believe
16 that there were figures available to me covering the period in consideration.
17 I believe there was a document that I've seen in evidence -

18 Q: I'll just find it.

19 CHAIR: Glackin, volume 11, p37, tab 62.

20 WITNESS: Yep.

21 MR GRIEVE: Now this is, of course, deaths, mortality – have you got the
22 document marked “Figure 39”?

23 A: Yes, I have.

24 Q: and the rate there, obviously Tairawhiti is at the top of the Area Health
25 Board as they were then, with about 12 deaths/100,000.

26 A: Right.

27 Q: Do you say that you weren't aware that that sort of thing was occurring?

1 A: I'm not sure that I was aware of that particular statistics, but even had I
2 been, again I would have to interpret that with extreme caution in relation to
3 these other statistics, which as you've already pointed out, related only to a
4 small sub-set of the population.

5 Q: Let's go over the page, because the next page deals with incidence.
6 This is an ethnic issue. You will see that the incidence figure for NZ non-
7 Maori women was obviously, it would appear, comparing internationally,
8 broadly comparable.

9 A: Yes.

10 Q: But if you look down at the bottom of the graph you'll see that for NZ
11 Maori women they were second highest only to Brazil.

12 A: That's right. That was back in 1986.

13 Q: Yes. So, I take it you'd make the same comment, that you weren't –

14 A: We also have the paper that has also been produced in evidence of the
15 NZ contraceptive study which shows slightly different information.

16 Q: but broadly speaking we now know, don't we, that even now Tairāwhiti
17 has a high incidence rate?

18 A: Absolutely .

19 Q: And from those figures it's apparent that that's not just a sudden
20 phenomenon, that was the case back then as well?

21 A: Yes.

22 Q: And I take it you accept that, given that high incidence and high
23 mortality rate, you would have expected a higher incidence of high grade
24 abnormality in this community, wouldn't you?

25 A: I think that is a simplistic and erroneous conclusion, sir. You cannot
26 relate the incidence of the disease to the rate or reporting of high grades.

27 Q: Do you say there's just no correlation at all?

1 A: No, there are other factors involved in it, and the first factor which one
2 has to take into account is whether you're dealing with a whole population or
3 not, in other words is the population that you've got the statistic on
4 representative of the whole population because the cancer refers to the
5 whole population and so this is perfectly illustrated I believe if we go to
6 the New Zealand Health & Contraceptive Study which is already in evidence
7 from Skegg I believe. Page 124 whilst it represents relatively small numbers
8 you will see that the relative rate or rate ratio for reporting of dysplasia and
9 worse in the maori in that study was less than the European rate. It's table 2
10 and sixth figure down on the right hand side. I believe Professor Skegg has
11 already referred to this in evidence and it shows you the effect of eschewed
12 population. As well as that, the rate of high grades will depend on the
13 screening interval and we can't necessarily assume that the screening
14 interval is the same in various areas in fact many of these cases that we've
15 seen had quite small screening intervals. The rate of high grade abnormality
16 seen depends also on the level at which referral occurs, the level of high
17 grades also very markedly is effected by whether the population or at least
18 the screening statistics apply to only screening population or whether they
19 apply to women being treated or in post-treatment phase. They also depend
20 vitally on the number of new entrants coming into a programme in other
21 words if you are looking at previously unscreened population you will get
22 higher rates of high grade albeit from the same general population so all of
23 these factors need to be considered, it's not just a simple, the incidence is X
24 therefore this should reflect Y.

25 Q: But it's a guideline isn't it, broadly speaking, you would I suggest,
26 where you have a population such as Tairāwhiti with a high incidence, and

1 it's not just high, a very high incidence of invasive cancer you would expect
2 to see a correspondingly high rate of high grade smears.

3 A: Only sir if the population being screened was representative of the
4 population as a whole and there was evidence and Professor Skegg has
5 already gone over this and he's already alerted to the fact that these statistics
6 probably come from a population, a subset of the population in which we
7 would reasonably predict the incidence of abnormality may well be lower.
8 We knew from studies when we were setting up this programme that in fact
9 the higher risk groups tended to be under represented in screening and they
10 were under-represented on the Register.

11

12 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

13 PROFESSOR DUGGAN: Dr Teague what you're saying, if I
14 understand you correctly, is that if all of the women in the Tairāwhiti region
15 who had invasive cancer had never been screened, there wouldn't be any
16 high grade disease reported in the region.

17 A: Absolutely, at least on that statistic there wouldn't be because that
18 represents the screened women yes.

19 Q: Well we do know that some of the women in Tairāwhiti are screened
20 and in fact they have some of the highest enrollment rates in New Zealand.

21 A: At that stage however these statistics applied, this was the real
22 problem with the opt on system, these statistics only apply to a subset of
23 about 20-25% of women and as Professor Skeggs already said, probably
24 represented the women who were least likely to have dysplasias. At least
25 they were the lower risk groups.

26 Q: So these particular statistics go to June 1994?

27 A: Yes.

1 Q: When did the ..

2 A: The legislation was enacted in 1993, I'm not sure exactly what
3 month.

4 Q: So there's at least 12 months of ...

5 A: I'm not sure, the figures were about 20-25%. In 1994 onwards they
6 started to rise and we now have very high enrollment rates at around 90%.

7 Q: I think we do actually have that figure for the enrollment rate of
8 Tairawhiti in 1994 it actually was quite high, it's in Glackin's brief.

9 A: Well I mean the other way of looking at it is that there were I think a
10 total of 7,000 smears looked at and we know there are about 5,000 per year
11 done.

12 Q: You do accept that invasive squamous cancer is preceded by high
13 grade.

14 A: Absolutely, that's the whole point of cytology but the actual rates that
15 you will see it at depend on all those other variables.

16 Q: It was 58% in 1994.

17 A: Prior to that?

18 Q: It was 27% in 1993. 24% in 1992 and 14% in 1991.

19 A: Yes, so overall that statistic would have represented I believe
20 somewhere between 20-25% overall.

21

22 CHAIR CONTINUES XXN OF WITNESS

23 CHAIR: Would that then not make the statistic falsely reassuring in the
24 sense that it would really be focussing the lower level of reporting would
25 really be focussing on the sort of women who had decided to opt on to the
26 Register and they are in the lower groups.

1 A: Yes the information I've always agreed is of relatively limited value
2 but what I was looking for was some indication here that there was a
3 problem, that there was under-reporting. Those statistics certainly don't
4 exclude it as we come to see but never did I claim that they excluded it. Had
5 those statistics pointed to the Gisborne laboratory being at the lower end of
6 that, then that would have pushed me further I think.

7 Q: But as they stood could the statistics not, when it came to deciding
8 whether or not a re-read exercise would be a good idea, the statistics which
9 showed that Dr Bottrill's reading was within the average, might they not
10 have given you a false sense of comfort that this wasn't a systematic
11 problem.

12 A: In retrospect ma'am they obviously did but I did the best I could with
13 those statistics at the time.

14 Q: I accept you say that you did you did the best you could at the time,
15 but does this not highlight one of the difficulties with statistics if they are not
16 based on good sound information they can lead you astray even with the best
17 will in the world.

18 A: Absolutely and I believe that's why we had gone towards getting into
19 the opt off because that would then give us a much strong statistical basis to
20 work from. It was a weak statistical base.

21 Q: And the best shield against such falsely reassuring views in the future
22 would be good quality statistical information would it not?

23 A: It would never happen again because we are now up to around about
24 90% enrollment rates around the country and they can be relied on to more
25 truly reflect the population as a whole.

26

27 MR GRIEVE INTERJECTS AND XXN WITNESS

1 MR GRIEVE: When did you first realise it was a weak statistical
2 base?

3 A: When I say weak I would say that I couldn't rely on it in its entirety
4 to exclude under-reporting but it didn't to me give me an indication that
5 there was under-reporting. That's all I read into those statistics.

6 Q: Did you realise that there were shortcomings with those statistics
7 when you advised Ms Mellor about the re-read?

8 A: At the time I talked to Ms Mellor we said that based on the evidence
9 that we had previously had, we didn't believe there was evidence of
10 systematic under-reporting. However at the meeting we also conceded
11 because at that stage there was in the public arena the assertion of more
12 cases and more and more cases coming out and in that case an exercise had
13 to be done. Not because of the publicity but because of the alleged more
14 cases and substantive numbers of them.

15

16 CHAIR INTERJECTS AND XXN WITNESS

17 CHAIR: If it hadn't been for the publicity surrounding the Court case
18 though, other persons with similar claims might not have come to light do
19 you think?

20 A: I would hope ... I think that the publicity sped up the process. It
21 would be my sincere belief that as more cases became exposed, it would
22 have happened anyway, but it certainly sped that process up and thankfully it
23 did.

24 Q: Yes but that would depend though on women who were subsequently
25 told that they had a high grade or an invasive carcinoma actually going back
26 over their smear history and querying why it was they had a history of
27 normal smears would it not?

1 A: Ideally it really shouldn't have depended on the women to do that, it
2 should have depended on the analysis we've talked about, it should have
3 been then done and were still struggling to get done.

4 Q: I agree but given that that analysis isn't done and can't be done at the
5 moment in the face of Section 74A of the Health Act, the only way the issue
6 could come to light was if a woman did become concerned about the fact
7 that she had had a history of normal smears and then had been reported as
8 having a high grade abnormality.

9 A: And then I spoke with Tracey Mellor who said in every area of New
10 Zealand there will be one or two cases like this. We know that from
11 screening. But how many is too many requires the wisdom of Solomon
12 without a good statistical base.

13 Q: And also there would be those women who even if they found that
14 out, would not take it any further.

15 A: That would happen yes.

16 Q: So really the whole process of it coming to light in the absence of an
17 evaluation of the type that you have mentioned of every woman who gets
18 cervical cancer or of good statistical information is very much a hit and
19 miss process is it not.

20 A: Absolutely, it needs the information base that we're trying to get.

21

22 MR GRIEVE CONTINUES XXN OF WITNESS

23 MR GRIEVE: And you see following on from that, I mean patient one
24 had come forward and her situation was explained as being within the
25 expected false negative range and it wasn't until publicity she pushed it and
26 there was publicity, that something was done.

1 A: It was very good of patient one to push this, but it wasn't the fact that
2 she pushed her own case that brought it about sir, it was the fact that in that
3 publicity there was a concern that there were lots more cases. That's to me,
4 was the greatest and strongest indication that we had to do an investigation.

5 Q: Yes but as I understand it Madam Chair's point was that patient one
6 had reported her situation, had there not been publicity, had she not for
7 whatever reason decided to go to the High Court, what would have alerted
8 the authorities to the problem?

9 A: More cases.

10 Q: Well you see I don't want to come back to it now but you got some
11 information about another case didn't you?

12 A: I got an indication of a possible other case which I tried my best to
13 get confirmed. Sir God alone knows I wish that we could have done
14 something earlier about this situation. However, on the other hand, we
15 know that there are going to be cases like this everywhere around New
16 Zealand and they do not indicate necessitate under systematic under-
17 reporting which is the ??? for a programme. However there are going to be
18 scattered cases, we know that despite a well screened population on a three
19 yearly screening cycle we are going to have about 8% of women who will
20 develop cancer in spite of screening, regularly and through a good laboratory
21 system. We know that, it would be easy to control this process if any case of
22 cervical cancer that occurred in a screened woman was an indication of a
23 problem. I don't think one can undertake these sort of exercises lightly.
24 There is a cost, and I'm not talking just of a financial cost which is
25 substantive, but there is also a cost to the women in the area concerned too
26 and so I believe you have to have reasonable grounds to undertake such an
27 exercise.

1 Q: By such an exercise you mean a re review.

2 A: Yes the sort of exercise that's gone on here.

3 Q: Absolutely but in the absence of this sort of exercise and in the
4 absence of publicity, how do we know that if this occurs in the future there's
5 going to be a mechanism to do something significantly more quickly than
6 was done in this case.

7 A: As soon as we get the review of cancers I believe this would not
8 have occurred if we had review process for every cancer that occurred.

9 Q: I want to try and understand this Madam Chair if I may, my initial
10 reaction to that is well that's retrospective and too late but I think I can say
11 that I may be wrong about that. Are you suggesting, or is your proposition
12 that if you conduct a review of all known cases of cancer of the cervix, by
13 checking on those cases albeit historically, it will alert you to potential issues
14 that may have contributed to those cases and thus prevent cases occurring in
15 the future.

16 A: Yes I'm saying that and I believe that that should be done not as an
17 isolated retrospective analysis, but as a continuing ongoing assessment.

18

19 CHAIR INTERJECTS AND XXN WITNESS

20 CHAIR: But Dr Teague that doesn't happen and at the moment it can't
21 happen legally without the consent of the woman concerned.

22 A: It needs to happen.

23 Q: Well it would require legislative change for it to happen would it not.

24 A: I would certainly support that change.

25 Q: And given that we have to deal with what is before us at the moment
26 rather than what we would like to have in place and the gold standard you
27 have mentioned can't be done at the moment unless the consent of the

1 woman concerned is contained, what else do we have to ensure that
2 something like this doesn't happen again?

3 A: Well I think we have now much tighter stricter guidelines no the
4 accreditation of laboratories, there are no laboratories now practicing
5 cytology in this country who are not accredited, there are no laboratories in
6 this country who do not have quality external and internal quality assurance.
7 We now have the histology/cytology correlation running.

8 Q: And although that doesn't highlight false negatives, it is an indication
9 generally of the accuracy or reporting is it not?

10 A: Yes, it's one of the things that we would look at.

11

12 PROFESSOR DUGGAN: Dr Teague, are there not standards required as
13 well?

14 A: In terms of?

15 Q: The laboratory practice.

16 A: In terms of what sort of practice. I'm sorry, I'm not trying to be obtuse,
17 you mean performance standards or outcome standards?

18 Q: Performance standards.

19 A: There are a number of performance measures that are being put in place
20 currently. The standards in the past have been mostly process standards
21 rather than performance standards.

22 Q: And what is your comment with regard to the performance standards –
23 are they needed or not?

24 A: Absolutely. In fact, there are Minutes there where I'm advocating that
25 sort of thing.

26 Q: So in terms of laboratory practice, in your opinion, there is a need for
27 accreditation as well as performance standards?

1 A: Absolutely, and I think the accreditation must look at your performance
2 against those standards. There must be an internal ethos of looking at
3 yourself against those standards as well.

4

5 CHAIR: In this case, the issue in respect of Patient One, my understanding
6 is this first came to light when as a result of a medical misadventure claim
7 there was a report of the Medical Council. That's correct?

8 A: Yes.

9 Q: My understanding is that the law by which the ACC –

10 MR GRIEVE: Madam Chair, you mean a report – Medical Council or
11 MPDC?

12 CHAIR: Was it the MPDC?

13 MR GRIEVE: First, and then on appeal.

14 CHAIR: Sorry, and then the Medical Council, yes. My understanding is
15 that the law which required the ACC to communicate to the MPDC about
16 medical misadventure claims that had been upheld was changed when the
17 ACC was privatised, so that that requirement was no longer in place. Are
18 you aware of that?

19 A: No, I'm not.

20 Q: Do you consider it important that there be a requirement that whenever
21 there is a claim upheld for medical misadventure that it is referred to the
22 MPDC?

23 A: I would wholeheartedly support that, yes.

24 Q: In this particular case of witness One, my understanding is that the issue
25 came to light round about 1995, and yet ultimately a re-read was not
26 triggered until 1999.

1 A: Hmm. That's correct, and obviously in retrospect that's very sad. But
2 based on the information that was available to me, I didn't believe that it
3 necessarily indicated systematic under-reporting.

4 Q: Which, in turn, underscores the importance for having good quality
5 statistical information of a type which would allow decisions such as
6 whether or not to have a re-read to be made promptly and effectively, would
7 it not?

8 A: A great part of my life in the last 12 years has been trying to get that sort
9 of information made available, gathered and made available.

10 Q: And you agree with what I said or not?

11 A: Absolutely.

12

13 PROFESSOR DUGGAN: Dr Teague I would just like to clarify one thing
14 with you. We've already gone through the scenario of if no woman who
15 develops invasive cancer is screened there should be no high grade reported?

16 A: Oh no, no, I didn't say no high grade, but the difference in rates may be
17 quite different between the two populations. I mean, it's basic statistical
18 theory that if you are going to have a high – we all accept that there will be
19 high incidence of high grade abnormality if there is a high incidence of
20 cancer, but that assumes that you are dealing with a homogenous population,
21 and we know that that's not so. We know that there are women who are,
22 and there are groups of women at higher risk than other women. So it is not
23 a homogenous population. And in fact I believe there are papers out where
24 laboratories have looked at trying to do quality control through subdividing
25 their own laboratory statistics into high risk clinical practices as opposed to
26 low risk clinical practices. So the population is not homogenous.

1 Q: Do you accept that the rate of abnormalities in a group of women
2 presenting for PAP smear interpretation is higher amongst those who are
3 being referred to colposcopy clinics for a cervical abnormality as opposed to
4 those who are in the general population?

5 A: Absolutely.

6 Q: And why is that?

7 A: that's because we're getting – they are already at that stage selected by
8 abnormality.

9 Q: So there is an increased likelihood that the cervix is abnormal and
10 therefore the smear will be abnormal?

11 A: Yes. That's why, in this country, there is a differential between hospital
12 reporting rates and community reporting rates. That's why the Australian, in
13 looking at the statistics there, they have tried to differentiate between these
14 two categories by doing statistical analysis on women who are seeing GPs
15 and nurse smear-takers as opposed to women seeing gynaecological
16 specialists who will represent a selected population.

17 Q: therefore, in the early years of the programme - let's deal with the
18 period covered by the statistical reports, the incidence of invasive cervical
19 cancer in some of the regions is higher than in others?

20 A: Yes, we have some retrospective analysis now available to us which
21 would certainly indicate that.

22 Q: So you would expect that?

23 A: Yes.

24 Q: Therefore, would you expect that the frequency reporting of high grade
25 in those two regions should be the same or different?

26 A: If the other criteria is satisfied.

1 Q: Hypothetically, if one assumes that the characteristics of the population
2 being enrolled in the first 4 years of the programme are the same at each
3 region and the only variable is the incidence of cancer.

4 A: If that's the only variable, then yes, that obviously is so.

5 Thank you.

6

7 CHAIR: Dr Teague there's just one point I would like to clear up
8 completely just for the purpose of getting everything into the evidence. That
9 is, you'd said earlier that the histology/cytology correlation was an
10 indication of accuracy of reporting.

11 A: Hmm.

12 Q: That is because it tends to show whether or not someone is reporting
13 false positives or true positives?

14 A: Yes. Obviously women in general don't have histology done unless
15 there has been a report of some abnormality.

16 Q: And therefore, in terms of being an indication of accuracy of reporting
17 generally, one would extrapolate from someone who keeps reporting too
18 many false positives in terms of querying whether or not they were likely to
19 be reporting false negatives as well?

20 A: That's not necessarily so, to be honest. You may in fact have a
21 laboratory which has set its own internal, what, limits slightly high. So it
22 doesn't necessarily follow that they would equally be under-reporting.

23 Q: Well then, in terms of the benefits of the histology/cytology correlation,
24 it's of benefit in recognising over-reporting, is it of any assistance in
25 recognising under-reporting?

26 A: In an indirect way, yes, because when you then go back, as a laboratory
27 should, and retrospectively analyse - if you get a positive cytology then you

1 should retrospectively analyse your previous smears on that person. The
2 histology is confirmation that that was a true positive rather than a false
3 positive. So it has an indirect help in that regard.

4 Q: So indirectly the histology/cytology correlation does help in identifying
5 whether or not there are false negatives?

6 A: It's an aid to that because it confirms the true positive diagnosis.

7

8 PROFESSOR DUGGAN: And you say that because in your opinion if you
9 are over reporting you are also under-reporting.

10 A: No I didn't say that at all but it means that it's a measure that you
11 aren't over reporting and therefore Because one of the measures of false
12 positively that is used, it's used in Australia and I would hope that we may
13 look at it here, is the percentage of normal smears reported in the five years
14 prior to a histologically confirmed high grade or worse smear. The other
15 statistic that's currently in use in Australia which is the slightly weaker one
16 is where it just goes on the smear results alone and it does make a difference
17 of several percent and that in fact is illustrated in one of my exhibits, I think
18 it's my exhibit 2, page 6. These figures, the second and third transverse bars
19 refer to previous, at least reporting rates, for previous sorry they refer to
20 the reporting rates for high grade epithelial abnormality and the first column
21 shows that the aggregate is .77 but if it's done on the basis of histologically
22 confirms abnormality it becomes .61% so there's a difference there of about
23 .16% which is quite a significant difference in percentage. You see the two
24 columns I'm talking about it's the bottom row not less than .5% high grade
25 epithelial abnormality and then the same expression is repeated in the next
26 column down. The difference between those two statistics is that one is
27 histologically confirmed, the other one isn't so it does have an impact.

1

2 PROFESSOR DUGGAN CONTINUES XXN OF WITNESS

3 PROFESSOR DUGGAN: What are some of the reasons for failure
4 of histology to confirm cytology diagnosis of high grade?

5 A: Well the colposcopist may have missed the lesion entirely and
6 particularly if it's high in the endocervical canal that can well happen. There
7 an intrinsic error rating reporting anyway, again it's a subjective process and
8 although we all accept it as a gold standard it is still a subjective process and
9 relies on the ability of the person to interpret the changes in front of them
10 and the ability of the colposcopist to find the lesion and to biopsy it
11 accurately.

12

13 MR GRIEVE CONTINUES XXN OF WITNESS

14 MR GRIEVE: You referred a moment ago to the fact that a laboratory
15 should retrospectively analyse previous smears. Was that in the case of low
16 grades, I just don't remember the context in which you said that?

17 A: I think the strongest indication for a retrospective review is with high
18 grade lesions and particularly of any smears that are previously normal.

19 Q: Now assuming a laboratory has a woman's previous smears in those
20 circumstances, recognising that at times there's problems with that, but
21 assuming that a laboratory does, then similarly as with high grades would
22 you accept that if invasive cancer is found in a smear or subsequently
23 becomes known to the laboratory they should also retrospectively review the
24 smears?

25 A: That certainly would be usual practice.

26 Q: Right. So that presumably you would have expected then MedLab
27 Gisborne post 1996 to have reviewed smears in that context?

1 A: If it comes across a high grade smear and there is a history of normal
2 smears I think it should do that.

3 Q: Right. So would you expect the laboratory to pull out the smears and
4 certainly I suppose start with the reports, pull out the smears and have a
5 look at them again?

6 A: Yes I think so and as I've said particularly if they're previous report
7 was normal because there is a normal transmission through the steps to high
8 grade, if the last smear was low grade then that could be normal
9 progression.

10 Q: If they found undertaking that exercise that there had been a misread
11 or error, call it what you will, what would you expect the laboratory to do
12 about it.

13 A: Well I think the guidelines that I have read about overseas would
14 state that if a laboratory reviews that case and it's their own case, they should
15 document that review and it should be available for accreditation inspection.
16 They should report it if it made any difference to the management of the
17 patient.

18 Q: Would you expect that the information should via the referring
19 medical practitioner get back to the patient concerned?

20 A: If it made any difference to the management of the patient and I think
21 that's in conformity with what Professor McGoogan said as well.

22 Q: Now we're coming up to lunchtime Dr Teague and I'm hoping to be
23 able to sit down but there is one issue that I've got to cover with you and I
24 hopefully may be able to do it quickly. You recall that when I began we got
25 into this issue of the level of under-reporting in Tairawhiti and whether you
26 accepted that the level was given all the subsequent information now
27 available, whether you accepted that that level was unacceptable in terms of

1 term of reference 1 and in that context you were asked to look at Dr Tie's
2 transcript and the material referred to there and in the expectation that you
3 would be asked about it. Now I take it that you have done those things,
4 looked at the Dr Tie transcript, I think it's pages 1104 for about 10 or 12
5 pages and you've looked at all those materials. Is that so?

6 A: Yes, I just want to be very precise, can I have a copy of that transcript
7 please.

8 Q: You'll see that cross examination of Dr Tie on 13 July starts off
9 towards the end of page 1104 is that right.

10 A: Yes I've got 1104, 1005.

11 Q: And it goes right through for another 10, there's a total of 10 pages
12 approximately.

13 A: Yes.

14 Q: Now you've had a chance to look at all that?

15 A: Yes I have.

16 Q: And the materials to which Dr Tie was referred?

17 A: Yes.

18 Q: Do you having considered all that material, first of all do you agree
19 with the answers given by Dr Tie?

20 A: Not entirely I believe that there is, and I put it in my brief already sir,
21 I believe that there is evidence of substantial under-reporting in Gisborne. I
22 don't think one can regard the starter as showing anything other than that. I
23 believe the assessment of whether it's unacceptable is a subjective one and it
24 depends on your perspective. And I don't wish to be drawn into that
25 subjective assessment. I am very cognisant of having looked through, now,
26 the supplementary volumes of Tracy Mellor and the supplementary volume
27 of Professor Skegg. I have read also the recent brief of evidence of Mr

1 Jones. The thing that stands out to me in all of those documents is that the
2 final evaluation on this is incomplete. Each one of these documents refers to
3 substantive areas of incompleteness. I have not played any part in the role of
4 this evaluation, for obvious reasons, and I am prepared to state that there is
5 evidence of substantial under-reporting in Gisborne. Whether it's
6 unacceptable needs a lot more – what, it's a subjective conclusion. I don't
7 think we have all of the evidence yet needed to make that. To be
8 unacceptable has to relate it to practices of a similar type, at a similar period
9 in NZ. I believe it would probably be – we would probably have sufficient
10 to say that this would be unacceptable in this year, in a reasonable sized
11 laboratory. As for a small provincial laboratory in NZ, in the early 1990s, I
12 think that there's a lot more work to be done.

13 Q: Dr Teague, when you say that you have to look at similar practices, are
14 you saying that Dr Bottrill's practice, as a sole practitioner –

15 A: No, that apparently is unique as far as I know.

16 Q: And it shouldn't be measured against that or a similar practice, should
17 it?

18 A: No. You've got heaps of experts here have all said the same thing, and I
19 could refer you to the exhibits if you like.

20 Q: Do please.

21 A: If we go to the Tracy Mellor supplementary – paras 16, 17 and 29 I
22 think.

23 Q: Yes.

24 A: Can I refer to the Jones?

25 Q: Yes.

26 A: If we go to Jones, para 9, the Skegg supplementary, which I think in its
27 entirety points, and the evidence of McGoogan. That's a substantive lineup

1 who were saying that to make this final determination we need to do some
2 more. I am prepared to accept that there is clearly substantive under-
3 reporting, but that's as far as I would go with it. I mean, I didn't do the
4 review, and all of these other experts who have taken part in this review are
5 reluctant to come to that final conclusion as I read these documents.

6 Q: Well, as I read their evidence it's not something they're being asked to
7 do, is it?

8 A: Well,

9 Q: That's the task for the inquiry.

10 A: Yes, absolutely.

11 Q: So if they are not specifically asked to determine whether or not there
12 has been unacceptable under-reporting it's not surprising that they haven't
13 dealt with it?

14 A: But I think each of them has said that the evaluation of this is still
15 deficient at present.

16 Q: I hadn't actually seen the evaluation that is being undertaken, for
17 example, by the Health Funding Authority as being down for the purposes of
18 establishing whether or not there was unacceptable under-reporting but
19 rather as a matter of re-reading slides to ensure that women's health was not
20 put at risk.

21 A: I think that's part of whether something is unacceptable. To me that's
22 intrinsic, that definition.

23 Q: that's your view?

24 A: Yes.

25

26 MR GRIEVE: So you will say substantial but not unacceptable?

1 A: I didn't say it was not unacceptable, I said we haven't yet got the final
2 chapters on that unacceptability.

3 Q: so, "might be" unacceptable?

4 A: Absolutely, may well be.

5 Q: Right.

6 A: And I think that the people who have been at the centre of these
7 processes are the ones to make that recommendation and the panel to make
8 the final determination.

9 Q: I just want to ask you to just follow this through briefly. Entering your
10 reservation about unacceptability as you do, are you looking at it from the
11 perspective of a cytopathologist looking for statistical verification of
12 unacceptability?

13 A: No, it's a term that is not a statistical term, sir.

14 Q: I know that.

15 A: Unacceptability is another term.

16 Q: I understand that doctor, but you see,

17 A: I think as a scientist. As a scientist I believe that there is evidence of
18 substantial under-reporting here.

19 Q: Right. And so we are, to put it another way, dealing with something
20 that's semantic and subjective, you say?

21 A: Absolutely.

22 Q: Because, of course, it will be a matter of law for the Committee of
23 Inquiry to decide whether scientific proof of this subjective notion is
24 required at all, won't it?

25 A: Absolutely.

26 Q: Madam chair, I'm going to have some lunch.

27 CHAIR: Does this mean you've finished?

17/07/2000

B/1403

1 MR GRIEVE: Yes, it does.

2 CHAIR: We will adjourn until 2.15.

3

4

5

LUNCHEON ADJOURNMENT 1.08 P.M. TO 2.15 P.M.

6

1

2

THE HEARING RESUMED AT 2.20P.M.

3

4

DR TEAGUE (On former oath)

5

6

MS SHOLTENS: Dr Teague, as you know, I appear for the Ministry of Health and the Health Funding Authority. I am instructed, and indeed it is appropriate, to first acknowledge your contribution to the cervical screening programme over the last 10 years, or longer. Certainly, it's plain from your own evidence, and my instructions are that you have always bent over backwards to assist those who've been trying to get this programme operating in an appropriate way. You have made your expertise readily accessible to the programme, in particular to the National co-ordinators over the years, and that of course is something that is just so important to these sorts of programmes to be able to function in NZ. I want to ask you first, just a number of questions about the various quality standards put in place over the last 10 years for laboratories surrounding the programme. We know from Dr Boyd's evidence that before the National programme was set up in 1990, the pathologists and the cytologists had discussed standards, of course going back years, but we've basically started with the 1986 standards. I think we've referred to them as the Fitzgerald standards, they're in the evidence at Dr Boyd's volume 5, exhibit 19. And they were, for the time I understand, fairly extensive, would you agree.

24

A: Yes, they were.

25

26

CHAIR: Were they compulsory?

1 A: No, they weren't. these standards were formulated when I was not in
2 NZ, but I came to them after I returned to NZ. I remember that they were
3 the subject of debate at several meetings, NZ Society of Cytology, NZ
4 Society of Pathologists. These was, I believe, in the end, an acceptance of
5 these as optimal standards to which laboratories could aspire to, but it was
6 recognised that most laboratories in NZ could not conform to them at that
7 time.

8 Q: Dr Teague when you use the word "standard", can it include something
9 that is recommended as opposed to something that is mandatory?

10 A: I think that there are different types of standards, and I believe that there
11 are standards which may be optimum, and there are standards which may
12 represent a minimal standard by which, and they should be mandated. There
13 are problems with them types of standards, as I see it. the problem with the
14 optimal standard is that anybody can always say "Well, I never quite got
15 there but I'm trying", and might never get there if there wasn't a will to do
16 so. The minimum standards have to be set at a, for want of a better words "a
17 lowest common denominator". And the danger with those is that people,
18 because they conform to them, think that's all they have to do. That in fact
19 there is then no incentive to get better.

20 Q: And you would see a minimum standard as a mandatory standard?

21 A: Absolutely, but I think that there should be in place perhaps both.

22 Q: Just so that I can be clear, for NZ between 1990 and 1996, were there
23 ever any minimum standards, or shall we say mandatory standards for
24 laboratories in terms of laboratory practice?

25 A: Not that I recall. We, in 1989/89 the cytology committee that I was part
26 of made some recommendations to TELARC concerning certain standards.
27 They were a relatively small set of recommendations but they met what we

1 believed were urgent problems. And they are in evidence. We subsequently
2 set more comprehensive standards in 1995 and I believe that there are –
3 well, there are now, a much more comprehensive set of standards about to be
4 put in place now.

5 Q: And those 1995 standards were adopted by TELARC?

6 A: Yes, I can't in the end answer for TELARC, but we sent them to
7 TELARC as standards that we recommended from the programme.

8 Q: But at the time, in any event, membership or accreditation by TELARC
9 was not compulsory, was it?

10 A: No. that was also part of the first set of recommendations we made.

11 Q: and at this moment in time, are there to the best of your knowledge any
12 laboratory standards that are mandatory?

13 A: In relation to cervical cytology, if you mean mandatory by law no, I
14 don't think so.

15 Q: but there is a standard imposed via funding contracts which is that
16 laboratories be TELARC accredited?

17 A: Absolutely, yes.

18 Q: And with that accreditation you bring in all the standards that TELARC
19 requires?

20 A: That's right, and those are quite substantive now.

21 Thank you. I just wanted to be clear, Mrs Sholtens on what was voluntary
22 and when and what was compulsory and how.

23

24 PROFESSOR DUGGAN: Could I just ask a question here? The TELARC
25 standards, these are process standards?

26 A: Yes, they are not performance or output standards.

27 Q: They are not performance standards?

1 A: No. However, we have endeavoured to use the programme and the
2 quality assurance programme to give data, sufficient collective data to
3 TELARC so that it knows what sort of data is going out from both of these
4 organisations to laboratories. So their inspectors, they can inspect those
5 records and confirm compliance.

6 Q: So the only performance standard that the TELARC assessors look at
7 the Royal College of Pathologists external quality assurance programme
8 standards?

9 A: That's right. There is a set of performance standards now going out at
10 this time.

11 Q: And what ones are those?

12 A: Look, I couldn't go through it. I'd have to go through – I think it's in
13 evidence, the document on draft standards for laboratories.

14 Q: Is this in Peters?

15 A: Yes.

16 Thank you.

17

18 CHAIR: Would you see a voluntary standard as being akin to a guideline?

19 A: Yes, I see optimum standards as being voluntary and minimum standards
20 as being compulsory.

21 Q: So on your analysis, then, between 1990 and 1996 NZ had no minimum
22 standards in place for laboratories?

23 A: It had the recommendations to TELARC but obviously it took a while
24 for TELARC registration to become compulsory so you're correct yes.

25 Q: Just to go back a little the 1986 Fitzgerald optimum standards for the
26 time, they were the subject of discussion weren't they when CALC was
27 asked to basically come up with some quality standards for the programme.

1 A: Yes.

2 Q: And I presume from what we can see of the minutes and this for the
3 record is volume 4 of Dr Boyd's evidence at pages 11 and 12 but I presume
4 basically it was acknowledged then that those were not appropriate for the
5 programme as matters stood in 1989/1990.

6 A: No given that it had been mandated that current providers provide the
7 service, we couldn't have applied it at that point.

8

9 CHAIR INTERJECTS AND XXN WITNESS

10 CHAIR: Why is that?

11 A: If we had put in place those standards, we would have lost every
12 training centre in New Zealand because I think it included a
13 recommendation which I think was from the international academy of
14 cytology that you needed a minimum of 23,000 smears per year to do
15 training. None of our training institutions were putting through anywhere
16 near that number of smears. I think there are other examples like that.

17

18 MRS SHOLTENS CONTINUES XXN OF WITNESS

19 MRS SHOLTENS: Do you want to have a look at those?

20 A: Perhaps I should.

21 Q: They're in volume 5 of Dr Boyd's exhibits at tab 19.

22

23 CHAIR INTERJECTS AND XXN WITNESS

24 CHAIR: I see here Dr Teague on page 1 it talks about standards
25 required for optimal practice and on page 2 it says it is important that
26 clinical laboratories in New Zealand offering service and diagnostic

1 cytopathology should have guidelines indicating that standards required for
2 optimal practice and also accreditation.

3 A: Right.

4 Q: In terms Dr Teague of this concern about training establishments and
5 not being able to meet the minimum requirement of smear-reading I
6 understand at the moment that all the community laboratories do read
7 sufficient smears to meet the new standards that are being developed but
8 again training establishments don't, the hospital laboratories. However if to
9 be competent a pathologist needs to read a certain number of smears I
10 understand the Royal College is 20 abnormal per month, is it not a cause for
11 concern in any event about the quality of training given by these
12 establishments if there isn't a large number of smears being read?

13 A: Absolutely, although in some of the gynecological oncology centres
14 the pathologist will be seeing quite large numbers of abnormal slides
15 although their total workload may not be that great. There has been in the
16 past, and I hope we might return to it, a more cooperative rather than
17 competitive model of providing these type of services and I believe the
18 solution may well come in cooperative models where pathologist work in
19 both sectors to gain the necessary and requisite ongoing competence and
20 experience.

21 Q: Well that would ensure that the Registrars working in the smaller
22 hospital laboratories got a greater exposure to more abnormal smears.

23 A: I think it is important that that is so. We have actually endeavored to
24 help training because of the large volume of smears we deal with.

25 Q: And also given that it seems to be recognised as important that a
26 pathologist read a minimum number of smears per annum to retain
27 competency, do you agree with that view?

1 A: Yes I do.

2 Q: Then it doesn't seem appropriate to be balancing the risk concerned
3 for women's health in allowing smears to be read in hospitals where there is
4 only a small amount of smear reading just for the sake of training registrars.

5 A: The overriding thing is the safety. That must be the overriding
6 feature at the end.

7 Q: So then would you support the imposition of a minimum number of
8 smears even if that had the effect of precluding smaller hospital laboratories
9 from continuing to participate in cytopathology?

10 A: Yes I would, but I would have a concern about major oncology
11 treatment centres where I think it's in women's interest for cytology services
12 to continue to be supplied and in these circumstances I believe that we have,
13 if we look at it inunvatently we can look at cooperative models where we
14 can have onsite access to reviews, regular clinicopathological views.

15 Q: So the problem then that these hospital labs present is not
16 insurmountable, there are ways around it?

17 A: I don't think so I'm sure there are.

18

19 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

20 PROFESSOR DUGGAN: Dr Teague this question relates to my
21 ignorance of the New Zealand training situation. Are the community
22 laboratories precluded from participating in the pot-graduate training of
23 pathologists, or Registrars that is?

24 A: No in fact we have also trained, there are a number of the major of
25 laboratories in New Zealand to my knowledge are registered for training
26 purposes, that's registered for training of pathologists. Often not for
27 complete training but for periods of training.

1 Q: So there are sufficient laboratories then to train registrars in the
2 practice of cytopathology?

3 A: Yes it hasn't been a widespread practice but there are laboratories
4 who are certified to do it and some have done.

5

6 CHAIR INTERJECTS AND XXN WITNESS

7 CHAIR: You've dealt with this at paragraph 16.22 of your brief of
8 evidence and you refer to your own laboratory as providing training.

9 A: We have intermittently yes.

10 Q: In recent times has this ability to have registrars practice both in
11 public and private hospitals on a cooperative basis been stalled by
12 developments in health delivery where a more competitive model has been
13 applied?

14 A: I believe that a competitive model has not been helpful to this
15 process.

16 Q: And there has been competition between community laboratories and
17 public laboratories in recent times?

18 A: Yes there has an as you can see the committees that looked at this
19 have grappled with this problem over the years.

20

21 MS SHOLTENS CONTINUES XXN OF WITNESS

22 MS SHOLTENS: So just coming back to the 1990 situation, the
23 programme effectively asked CALC the committee to come up with some
24 quality control standards or quality control processes to work around the
25 programme at that time?

26 A: I think the programme asked us to make some recommendations to
27 TELARC which we did. We had a limited time frame on which to do that

1 and I think that we dealt, as we saw it, with the most pressing issues of the
2 moment.

3 Q: On that point, just looking through Dr Boyd' exhibit 4 which contains
4 the minutes of CALC at least the ones that were on the Ministry file, page 9.
5 Volume 4 at tab 18, page 9. Is that headed "Cytology Advisory Liaison
6 Committee"?

7 A: That is correct.

8 Q: And then refers to the next meeting.

9 A: Right.

10 Q: So it looks like this is a meeting being brought forward in 1989.

11 A: Right.

12 Q: And we can see in the second para the Department's requested an earlier
13 meeting, so they're under some time pressure presumably, to have the
14 committee's recommendations for quality control as they impinge on the
15 operating of the Register?

16 A: Yes.

17 Q: And so there was effectively an earlier meeting?

18 A: Right.

19 Q: And a number of recommendations appear to come out of that.

20 A: Yes.

21 Q: Page 12, the para that is numbered 3 in the latter half of that page, refers
22 to the Fitzgerald Committee's paper, do you see that, and talks about
23 modifying it?

24 A: Oh, the paper on recommendations, yes. Yes.

25 Q: Now that process seemed to take a little time Dr Teague, the letter that
26 went to TELARC is on p21, and that's dated 15 August 1990.

1 A: Yes, I think the – I mean, this was a committee of volunteers who were
2 trying to do their best to facilitate the introduction of this programme. We
3 had our hands full of some pretty other big priorities. Probably our number
4 one priority at the start was to get a uniform reporting system in NZ which
5 was not in place at the time. And so we did the best we could with the time
6 that we had. That is the first set of recommendations on p21.

7

8 CHAIR: And you had to get the reporting system agreed on by persuasion,
9 didn't you, you had no authority?

10 A: No, we had no authority and we had to persuade a large number of
11 organisations, with diverse interests, to accept this. We had one area in NZ
12 which was half-way formulating its own type of classification and who were
13 naturally somewhat reluctant to accept another one. So yes, it took us a lot
14 of work but we got there.

15 Q: From your knowledge of screening programmes is it usual to set them
16 up in a such a way that key components of the programme, such as the
17 smear-reading codes, for example, have to be introduced through a voluntary
18 committee that has persuasive abilities only and no authority to set key
19 components of the programme in place?

20 A: I don't think it's an ideal situation.

21 Q: Has it happened anywhere else in the world?

22 A: I don't know. I couldn't answer the question. No, I can't answer the
23 question really. But it certainly was not ideal.

24

25 PROFESSOR DUGGAN: Is there a uniform reporting system in Australia?

26 A: there is now. There's a reporting system which was adopted, I think,
27 about 1996. I could stand to be corrected, but it was roundabout that time,

1 and it's an Australian modification of the Bethesda system. Essentially it's
2 similar to Bethesda except it has only two categories of unsatisfactory
3 smears and it has the ASCUS high grade category but in other respects is
4 fairly similar to Bethesda .

5 Q: And was its use, or its creation done the same way as in NZ?

6 A: No I don't think so. I think there were federal committees that met. But
7 I'm really not all that familiar with the Australian situation.

8

9 CHAIR: Do you know why it was that there was this reliance on voluntary
10 committees and their ability to persuade persons to adopt certain measures
11 rather than an approach which was based upon consultation by departmental
12 officials and then decisions made within the Health Dept as to how the
13 programme should be structured and what the key components should be?

14 A: I really can't answer for the department's thinking I don't think. But I
15 think that the Dept had its areas of expertise but I don't think they extended
16 into areas of cytopathology. That may have been part of the reason.

17 Q: But in terms of not only seeking advice from the committee but then
18 leaving it up to the committee to do what it could to have this advice
19 implemented by its persuasive abilities, do you know why that occurred?

20 A: No I can't answer for them.

21

22 MRS SHOLTENS: So the Bethesda Coding system and bringing that into
23 operation in a consistent way was obviously very important.

24 A: It's fundamental.

25 Q: You needed to have consistent reporting of data to be able to monitor
26 and evaluate basically anything didn't you?

27 A: Absolutely.

1 Q: Who suggested that you use the Bethesda Code – where did it come
2 from?

3 A: I think it came via Dr Norman Fitzgerald, and he had been sent a copy I
4 think from Dr George Weed in the US and advanced notification of it. the
5 committee looked at that. It seemed to us like a heaven sent opportunity
6 because there were no vested interests in it within NZ so it was much easier
7 to sell. And it seemed very appropriate for the purpose.

8 Q: Did you need to New Zealandise, to use a fishing industry word, the
9 code in any way?

10 A: Yes, we did. We expanded a lot of the code areas, but in a way that
11 was always compatible with Bethesda itself so that we gave laboratories
12 options on sub-categorisation of various categories but always so that it
13 could be brought back to true Bethesda.

14 Q: And in the end, did the committee make the decision about what codes
15 would be applied to what?

16 A: Yes. Decision - we made the recommendation and it was accepted.

17 Q: We've talked about it being a voluntary, persuasive type role. Was there
18 any recommendation that it be done any other way by your committee?

19 A: By our committee? I can't remember a specific recommendation that
20 we should become other than what we were, although there were other
21 committees as part of the programme.

22 Q: Did you suggest regulating the Bethesda Code?

23 A: No, we didn't. We had got acceptance of it so we believed we didn't
24 need regulation.

25

26 CHAIR: Why didn't you suggest regulating the Bethesda Code at an earlier
27 point in time if you thought it was the best code?

1 A: Well I think because we managed to actually persuade all the
2 organisations in NZ to accept it.

3 Q: If we could just go back to the Fitzgerald standards, I would like you to
4 go through them, starting at p2, "physical facilities". Can you tell me at that
5 time in 1990 when the programme was getting off the ground, what was
6 there to suggest that laboratories, or at least as sufficient laboratories to be
7 available for cytoscreening could not meet the requirements dealing with
8 physical facilities dealing with a first laboratory space?

9 A: I wouldn't have had that knowledge, ma'am, I really wouldn't know. I
10 would have thought this particular paragraph is just basic laboratory
11 practice.

12 Q: You'd expect both laboratories to be able to meet it?

13 A: That particular one for sure.

14 Q: What about safety precautions. I mean lets just go through them and
15 see where the difficulty lay.

16 A: The safety precautions I mean that is basic. c) equipment is basic and
17 that's just part of general TELARC assessment anyway of any particular
18 laboratory function.

19

20 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

21 PROFESSOR DUGGAN: But in the period 1990 to 1996?

22 A: We didn't have compulsory TELARC accreditation. But to me they
23 are just fundamental professional standards.

24 Q: Yes well what I want to know is was it going to be impossible for a
25 sufficient number of laboratories which could have become involved in
26 cytoscreening to meet the programmes needs to meet the standards?

1 A: I can't give you first hand knowledge because I'd only just recently
2 returned to New Zealand I didn't know what was happening but it was
3 mentioned I believe at a New Zealand Cytopathologists meeting and I'm not
4 sure about the New Zealand Society of Cytology that and if I remember
5 rightly it was just said generically that laboratories could not meet all of
6 these standards.

7 Q: Well I'd just like to work through and see because at the moment for
8 example a) b) and c) to you agree that laboratories if they're going to
9 function effectively would be able to meet those standards?

10 A: They should do yes for sure.

11 Q: In fact if they couldn't meet a) b) or c) do you think they ought to be
12 operating at all?

13 A: They shouldn't be operating at all.

14 Q: And then working on to laboratory operation written procedures, is
15 there anything too difficult for a laboratory to meet there?

16 A: That should be straightforward.

17 Q: And management practices, what's difficult about that?

18 A: That's absolutely contrary to the screening programme because we
19 accept specimens from registered smear-takers who are non-medical
20 practitioners.

21 Q: Would you not consider those persons to be allied health care
22 professionals?

23 A: Yes I suppose it would come under that definition as long as that's
24 wide enough to accept that yes.

25 Q: So this is between 1990-1996.

26 A: Yes.

1 Q: And turning over the page, item 2, sound personnel practices are
2 followed. Is there any difficulty for a laboratory between 1990-1996 to meet
3 that requirement?

4 A: I would have thought that's fundamental sort of stuff.

5 Q: And c) retention of records.

6 A: I can't answer for all laboratories but I would know that most
7 laboratories would meet that quite easily.

8 Q: Laboratory personnel, laboratory director?

9 A: That seems straightforward.

10 Q: You've looked over at the following page because the requirements
11 for the laboratory director go from 1-6.

12 A: Absolutely I don't see any problems there.

13 Q: And item b) supervisor.

14 A: I don't think that's of any problem.

15 Q: Over the page you'll see where it says if the supervisor is not the
16 laboratory director his qualifications should be and the qualifications are set
17 out.

18 A: That's a technical qualification the first one and b) are also technical
19 qualifications.

20 Q: So there's no problem in meeting that?

21 A: I can't fully answer that question because I'm not sure of the
22 screening staff in all laboratories in New Zealand. Certainly when I came
23 back to New Zealand I wasn't fully conversant with that.

24 Q: Well what about 2-3 years later, say 1993, by that stage?

25 A: I would have thought that most laboratories would from my
26 knowledge been able to attain that.

1 Q: Well do you think for example that it would be important for a
2 laboratory to have a supervisor who was sufficiently qualified.

3 A: Yes somebody has to take over all charge and they should be properly
4 qualified to do the job.

5 Q: And then c) cytotechnologist. See there is a maximum number of
6 smears.

7 A: I think that is probably one of the things that was alluded to that a
8 number of laboratories in New Zealand could not meet at that time.

9 Q: Shall not exceed a maximum.

10 A: Sorry it's a maximum.

11 Q: What is difficult about c)?

12 A: Nothing.

13 Q: And then d) support personnel?

14 A: Looks fine.

15 Q: Then over the page records and reporting, examinations and reports.
16 Look at a) is there anything which a laboratory between the years 1990-
17 1996 would have found too difficult to achieve in terms of examinations and
18 reports standards?

19 A: No except technically I'm not sure whether all the requesters are
20 registered but other than that minor caveat.

21 Q: Yes were it says health care professionals.

22 A: I think it's probably alright.

23 Q: And then b) recording the specimens. Is there anything difficult
24 about that for the years 1990-1996?

25 A: That's routine practice.

26 Q: And item c) laboratory reports?

1 A: I don't see why laboratories couldn't meet the As long as we
2 accept electronic signature that's fine.

3 Q: And d) reporting procedures, anything difficult there?

4 A: With the exception that we have now recommended a different
5 classification.

6

7 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

8 PROFESSOR DUGGAN: Excuse me Dr Teague would that would
9 have been appropriate for the time?

10 A: At the time it was written I'm sure it was appropriate.

11

12 CHAIR CONTINUES XXN OF WITNESS

13 CHAIR: And then over the page items 2, 3 and 4 is there anything
14 difficult about those items in terms of meeting them in 1990-1996?

15 A: I don't see why not although I suspect that a lot of laboratories would
16 not have put out annual reports but it could have been done.

17 Q: And then over the page quality control practices, in terms of
18 specimen preparation. Was there anything difficult about requiring that to
19 be done between the years 1990-1996?

20 A: I understand that some laboratories may have been using other than
21 the papindiculau stain at that time but I would agree with that
22 recommendation.

23 Q: And would it have been easy enough for them to move to the
24 papindiculau stain?

25 A: With a bit of persuasion yes.

26 Q: Or by regulation.

27 A: Or by regulation yes.

1 Q: It could have been tied in with the Social Security regulations.

2 A: Yes that's not a thing I would tie in by regulation because who knows
3 next year there may be a new stain that's accepted as the norm. I mean, I'm
4 quite happy to see a regulation that states that it should be used by an
5 acceptable staining method.

6 Q: And then the microscopy?

7 A: As we've now come to learn, para 3 would not have been attainable by
8 the Gisborne laboratory as it stood at that time, but I don't see why it could
9 not have been mandated.

10 Q: Yes, that was the use of the two persons to screen?

11 A: Yes.

12 Q: Putting aside Gisborne laboratories in principle between 1990 to 1996
13 there would have been some laboratories who would have had no difficulty
14 meeting this requirement?

15 A: Absolutely.

16 Q: And then over the page at item 4, that could have been achieved?

17 A: Yes.

18 Q: And then clinical correlation, would that have been achievable?

19 A: Yes. 4 would. Many laboratories would conform to those. Even at that
20 time many laboratories would have done so.

21 Q: proficiency testing when available?

22 A: That's a forward looking thing, yes.

23 Q: It does say when available the laboratory shall participate in a
24 proficiency testing programme.

25 A: That's reasonable.

26 Q: And then "personnel performance", would that have been achieved
27 between 1990 to 1996?

1 A: In general terms, yes. To be honest, it's only in the last few years that
2 we have relatively sophisticated computer systems which allow us to track
3 the diagnostic process – I shouldn't use diagnostic should I? – to use the
4 process right through the laboratory. So from screener to screener to
5 pathologist able to record each of those opinions, match it to the slide and
6 then match those statistics, those sort of programmes, that sort of software,
7 that sort of computerware has only really become available widely in NZ in
8 the last few years. So a somewhat lesser degree of that could be achieved
9 manually, but at a sophisticated level probably not.

10 Q: But it was possible to go some way towards achieving it – in other
11 words, you are not suggesting that the absence of sophisticated computer
12 programmes meant it was unnecessary to attempt any internal quality
13 control?

14 A: Oh, no, absolutely not. But we have much more sophisticated ways of
15 doing it now.

16 Q: So looked at overall as at 1990, and certainly 2 years later, say, as at
17 1992, would it have been possible to have found laboratories who could
18 have conformed to these standards?

19 A: Yes, certainly. I think a number of laboratories certainly would have.
20 My recollection of this was that there was more material in it at one stage,
21 but yes, I think we could have.

22 Q: so therefore, what stopped the imposition of these optimal guidelines as
23 mandatory standards for laboratories that were going to do screening for the
24 programme?

25 A: In retrospect I don't know. I don't know whether these are a modified
26 set of recommendations because my recollection was that the original set of
27 recommendations were somewhat larger than this, but I may be wrong. I'm

1 trying to recall events a long time ago and events which occurred principally
2 before I actually came back.

3 Q: What might help you on p1, these are the recommendations of a sub-
4 committee, it says "our recommendations are based on those made by the
5 American Society of Cytology and have been adapted to meet NZ
6 conditions" which would suggest perhaps you have in mind the American
7 standards.

8 A: It's possible, I really can't recollect.

9 Q: well if these recommendations were seen as being adapted to meet NZ
10 conditions and they were put forward for consideration at a meeting of
11 cytology members in 1986, would you not expect laboratories – this is all
12 shown on p1 – by 1990 to have brought their practices up to a level by which
13 most of them would have had no difficulty in meeting these standards?

14 A: I believe that most well run practices should have been able to achieve
15 these sort of levels of standard, yes.

16 Q: Did CALC ever give any consideration to recommending that instead of
17 using all the existing laboratories that were doing work under the Social
18 Security Regulations that only certain laboratories who met standards such
19 as these be used for the purposes of the screening programme?

20 A: We recommended that laboratories should be TELARC registered and
21 we had hoped that that could be enforced by a lack of payment if you weren't
22 registered.

23 Q: At the time I believe 50% of the laboratories were TELARC registered?

24 A: Yes, that was voluntarily done.

25 Q: And they would have been, those TELARC accredited laboratories
26 would have been sufficient in number to deal with the number of smears
27 coming in?

1 A: I don't think so at that point. At that point NZ was under extreme stress
2 and in fact we were getting out to reporting times of more than 3 months in
3 some laboratories. As I pointed out in my submission I think, we had a
4 large increase in cervical screening following immediately on the heels of
5 the Cartwright Inquiry and laboratories were almost universally under stress
6 at that time. I don't believe – I mean, this is just a personal opinion and it's
7 not based on a high degree of evidence, but I don't believe that if we had
8 shut down a significant number of laboratories the others would have coped.
9 I think most laboratories were stretched to the limit.

10 Q: And is that a reason for leaving TELARC accreditation as a matter of
11 compulsion until 1996/97?

12 A: Absolutely not. We wanted and recommended – there was no reason
13 that TELARC accreditation shouldn't have been put in place as soon as
14 possible. However, there has to be a lead-in time for TELARC
15 accreditation; it is a substantive process, and for a laboratory that has never
16 undertaken it, it is a process that, in general, would take a year and maybe
17 slightly longer. And because it seemed clear that we were going to try and
18 make TELARC accreditation compulsory – and I think because of
19 professional interests of pathologists too – a lot of them were trying to get
20 registered at that time and TELARC itself had a backlog, I believe – well,
21 you've heard from TELARC people that there was a substantive backlog for
22 TELARC.

23 Q: The first National Screening Programme policy document referred to
24 TELARC accreditation being achieved within a reasonable time and it was
25 suggested to be 2 years. That came out in 1991, it was suggested by 1993.
26 Was that a reasonable goal to have in place?

27 A: We believe so, yes.

1 Q: And by that time – in other words, by 1993, would there have been
2 sufficient TELARC accredited laboratories to undertake the work of the
3 programme?

4 A: That's going back a wee while, probably but I can't give an absolute
5 assurance on that.

6 Q: Was there the possibility that laboratories wouldn't want to be
7 TELARC accredited because it was too much trouble and if it had been a
8 matter of compulsion in terms of getting the work from the screening
9 programme they would have turned their backs on it and said well we would
10 rather not do cytoscreening for the screening programme if we have to be
11 TELARC accredited?

12 A: It's not an attitude that I remember encountering. That's all I can say.

13 Q: So there was no need then for the programme to adopt a degree of
14 leniency about requiring TELARC accreditation because it was running into
15 that type of attitude.

16 A: I don't believe so.

17

18 MS SHOLTENS CONTINUES XXN OF WITNESS

19 MS SHOLTENS: So in 1990 there was the recommendation to TELARC
20 and then TELARC came back to CALC in about, the minutes show late
21 1993, asking for some further advice?

22 A: Right. I mean I haven't check the dates but I take your word for it.

23 Q: Just for the record it's the minutes of Boyd exhibit 18 page 63 but
24 there's no need to go to that. So they effectively asked for some further
25 minimum standards to be developed.

26 A: Yes.

1 Q: And at one stage in that development process and I'm looking her at
2 page 86 of those minutes, 19 August 1994, page 2 heading 5, so at mid 1994
3 you tabled the INPAC document that was in place for Australia at that time.

4 A: That's right.

5 Q: And I think in your evidence you've said you've always encouraged
6 the adoption of the Australian standards is this the sort of thing you are
7 talking about?

8 A: It was part of it. We're really a group of very interested individuals.
9 We didn't have a lot of horsepower so we believed that the most efficient
10 thing to do was to take whatever we could get from wherever we could get it
11 and then adapt it rather trying to reinvent the wheel ourselves.

12 Q: Sensible. So you tabled this document and then the suggestion was
13 that that be used as a basis.

14 A: Yes and we modified that, we debated it, we modified it and that was
15 the basis of the 1995 recommendations I think.

16 Q: Right and we've got those if you just turn up Boyd volume 5 the next
17 volume, that's tab 25.

18

19 CHAIR INTERJECTS AND XXN WITNESS

20 CHAIR: These standards are tab 25 on page 40 National Cervical
21 Screening Programme standards for laboratories, were they voluntary or
22 compulsory?

23 A: They were standards that were sent from the programme to TELARC
24 to accept or reject as standards for when they did TELARC inspection.

25 Q: What happened to them?

26 A: TELARC was a ???, it had it's own

27 Q: Well did TELARC accept them?

1 A: We had a member who was both on our committee and also on the
2 TELARC committee and informally I believed they accepted most of those
3 recommendations.

4 Q: So they were really recommended standards and at the time in 1995
5 no laboratory was compelled to comply with these standards?

6 A: Well contractually as I've said in December 1995 we signed a
7 contract with the Health Funding Authority and part of that was compliance
8 with TELARC.

9

10 MS SHOLTENS CONTINUES XXN OF WITNESS

11 MS SHOLTENS: These standards had been the subject of a fair amount
12 of consultation with laboratories generally as I understand it. They were
13 sent out.

14 A: Yes I believe there was wide consultant, as wide as we could do it.

15 Q: So all laboratories knew about it?

16 A: I can't give you an absolute guarantee that all laboratories knew about
17 it but we consulted as widely as we could.

18 Q: You would expect that if a laboratory was providing services to the
19 screening programme it would have received a copy of these standards in
20 draft during 1994 and then during 1995 when they were finalised?

21 A: I can't give you an absolute assurance of that.

22 Q: By you would expect that that would have happened?

23 A: I would have thought that might have happened.

24

25 CHAR INTERJECTS AND XXN WITNESS

26 CHAIR: Do these standards differ much from the ones we have looked
27 at earlier at page 1 tab 19 of volume 5 Boyd, that's the Fitzgerald standards?

1 A: They vary a little bit in terms of detail. They tend to cover most of
2 the same sorts of areas.

3 Q: So why was it, in your view, that in 1990 CALC knew of the
4 Fitzgerald standards, in 1995 it's developing other standards for TELARC, it
5 seems all the time CALC is looking at standards, sending them out, getting
6 people's views on them and really nothing happens after that.

7 A: At that stage the only sort of standard body that we had for New
8 Zealand was TELARC so what we took was a dual approach, what we tried
9 to do was develop the standards to recommend them to TELARC and then to
10 recommend that TELARC accreditation become compulsory. That was the
11 method of applying.

12 Q: I see.

13 A: And it should be noted that two of the authors of that original
14 document were members of CALC.

15 Q: And that really was the best you could do as a body that only had
16 persuasive powers.

17 A: Absolutely.

18

19 MS SHOLTENS CONTINUES XXN OF WITNESS

20 MS SHOLTENS: So in terms of developing the quality assurance
21 standards around the programme this was the key method.

22 A: This is only a tiny segment of quality assurance.

23 Q: Certainly, around some certain aspects of laboratory performance yes.

24 A: Yes.

25 Q: And of course by 1995 when these standards were developed you
26 expected that TELARC accreditation would be happening as a matter of

1 course so if laboratories weren't accredited they would be well on the way at
2 least to being accredited.

3 A: Yes to be honest by 1995 I was astounded to find that there was a
4 laboratory that wasn't registered actually.

5

6 CHAIR INTERJECTS AND XXN WITNESS

7 CHAIR: You were expecting that from 1990 weren't you, or 1991.

8 A: We had recommended before that in 1989 and in 1988 at the Pairewa
9 workshop I think and we had recommended that contractual obligations
10 should be put on laboratories to make them conform to that.

11 Q: Right so the first recommendation came out in 1988 at the Pairewa
12 workshop that laboratories be TELARC accredited?

13 A: Yes.

14

15 MS SHOLTENS CONTINUES XXN OF WITNESS

16 MS SHOLTENS: The TELARC accreditation chronology effectively then
17 is that the 1991 policy that Madam Chair has referred to which said
18 effectively within two years, so you anticipate in 1993. Now in 1993 that
19 policy was updated or amended and I think you've referred in your
20 paragraph 6.23 to the fact at that stage the two year period was substituted
21 with the words within a reasonable period and you have referred to the fact
22 that in the early 90's TELARC was subject to an amount of overload. Is that
23 right?

24 A: Yes there certainly was a period in the very early 90's when
25 TELARC was overloaded and I'm not quite sure if the 6.23 is referring to.

26

27 CHAIR INTERJECTS AND XXN WITNESS

1 CHAIR: Was TELARC overloaded in 1993?

2 A: I can't remember the exact years but it certainly was overloaded in the
3 very early 90s and it was taking – and I'm just doing this off the top of my
4 memory – I think in part over a year to get to some laboratories.

5 Q: When the screening policy document from 1992 was amended in 1993
6 to remove the finite term for having TELARC accreditation of 2 years to just
7 reasonable efforts –

8 A: Sorry, can I just come back to that, please. I don't have the reference in
9 front of me.

10 MS SHOLTENS: Sorry, it should be 16.23 of your brief.

11 CHAIR: It might be better if you looked at the policy documents
12 themselves.

13 A: I have got to it now. That I think is a generic thing, that if a new
14 laboratory is coming into the market there has to be a period in which it has
15 to be able to achieve registration. I think these sort of clauses are written
16 into most sort of agreements like this.

17 Q: Well if you would like, please, at Glackin volume 6, tab 27, p35, and
18 Glackin 5, tab 15, p16: that document that you have, which is volume 5, tab
19 15 at p16 at para 4.1.2, you will see the sentence beginning “all cytology
20 laboratory servicing the National Cervical Screening Programme”

21 A: Yes.

22 Q: And you will see at the end “a reasonable period of time will be allowed
23 for laboratories to obtain registration. This may take up to 2 years.”

24 A: Yes.

25 Q: And if you look at the next document, which is the 93 policy document,
26 Glackin 6, p35, you'll see there at the top of the page “it is expected that
27 laboratories not so registered will apply and gain such registration. A

1 reasonable period of time will be allowed for laboratories to obtain
2 registration” and you will note no mention of a 2 year period.

3 A: Yes.

4 Q: What was CALC’s reaction to this change in policy, do you recall?

5 A: No, I don’t recall it, and I suspect that this slipped us by without being
6 noticed, ma'am.

7 Q: Can you recall now whether there was any reason to remove the finite
8 time frame for obtaining accreditation?

9 A: Absolutely not. I can't remember any reason for it. I would think it’s
10 most likely to be an accidental omission out of the last bit of that sentence I
11 would think. I know of no reason why it should have been dropped at all. In
12 fact, until you've pointed it out to me today I didn't even know it had been
13 dropped. It was when we came to put my brief together that I first came
14 across this.

15 Thank you.

16

17 MRS SHOLTENS: Because of course by 1993 that 2 year period would
18 have basically been up so the standard could have been strengthened to say
19 they all will be TELARC registered unless (inaudible)

20 A: Yes, I think that at this stage we were probably looking at really new
21 entrants to the market rather than people already in the market.

22 Q: Your laboratory, you say in your para 16.14 of your brief, was required
23 by contract to be TELARC accredited?

24 A: Yes.

25 Q: In 1995.

26 A: Right.

27 Q: Now you were contracting with the Central RHA?

1 A: That is correct.

2 Q: Was this a new contract or an amendment to the S51 Notice, do you
3 recall?

4 A: I can't recall exactly what it supplanted, but I actually signed that
5 contract so I know I had been involved in negotiations on it, and I can't at
6 this stage recall what exactly it supplanted. It was the first time laboratories
7 had ever had a formal contract like this.

8

9 CHAIR: In the past when s51 notices were issued had you signed any
10 documentation?

11 A: No I believe that I was not involved in laboratory management at that
12 time so I was unaware of that.

13 Q: And was it in December 95 did you say?

14 A: December 1995 is when I signed the contract.

15

16 MRS SHOLTENS: Have you been aware of the process of developing
17 National quality standards for laboratories at the more general level?

18 A: Yes, I have.

19 Q: Was there a reference to those developing standards do you recall in that
20 contract? It may be unfair to ask you this.

21 A: Honestly, without having a look back at that contract, I know that there
22 are references in modern contracts – I'm not sure of the 1995 one.

23 Q: Were you surprised at all that December 1995 was the first time the
24 compulsory accreditation matter was drawn to your laboratory's – made a
25 legal requirement on your laboratory?

26 A: Yes. Because I was so centrally involved in cervical screening I was
27 unaware – I mean, I was aware that this was the first time it had been put in

1 our contract, I had imagined that other laboratories – I mean, it was well
2 known that we were TELARC registered, I didn't know what was happening
3 elsewhere – I really didn't.

4 Q: But it didn't surprise you?

5 A: Well, we'd asked for it for many years beforehand. This was the first
6 time it actually got put in a hard contract. But this was the first laboratory
7 contract that I believe was ever signed by laboratories in a true contractual
8 form. And I was not around when the s51 was issued, and I don't know
9 what its contents were.

10 CHAIR: Pick a time that is convenient for you Mrs Sholtens.

11 MRS SHOLTENS: This would be convenient thanks ma'am.

12 CHAIR: We will adjourn until 3.45.

13

14 MID-AFTERNOON ADJOURNMENT 3.29 TO 3.45 P.M.

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INQUIRY RESUMES AT 3:50

MS SHOLTENS CONTINUES XXN OF WITNESS

MS SHOLTENS: I want to turn Dr Teague to the subject of laboratory statistics and what was available in the early days in particular of the programme. Up until well lets say 1990/1991 to the first statistical report that was published in 1993 and it related to data on the Register to August 1992 and you had a role in putting that information together didn't you?

A: It was done primarily by Brian Cox and John Brackenberry but I came in later to look at some of the laboratory sides.

Q: So you had a specific focus on the laboratory statistics?

A: That's why I was asked to look at it, to look at the laboratory aspects of that.

Q: At that time as we know we had the 14 registers operating and the various health boards, they were all using the same software and the idea was as I understand it that for something like that statistical report, the data was aggregated.

A: That's right.

Q: And there were problems with that weren't there.

A: Absolutely yes. That data aggregation I think in the first instance was done by John Brackenberry and Brian Cox.

CHAIR ADDRESSES MS SHELTONS

CHAIR: Ms Sheltons what exhibit is this.

1 MS SHOLTENS: The first statistical report ma'am?

2 CHAIR: Yes.

3 MS SHOLTENS: Is in Glackin volume 6 exhibit 26.

4 CHAIR: Thank you. Just so we can be sure.

5 MS SHOLTENS: Yes for the record.

6

7 MS SHOLTENS CONTINUES XXN OF WITNESS

8 MS SHOLTENS: So it was effectively a manual process of aggregating
9 the statistics from the 14 area health boards?

10 A: They had to be individually brought in and collated.

11 Q: What the Register could do as I understand it fairly automatically was
12 provide laboratory statistics for the laboratories within the Area Health
13 Board region against the average for that region.

14 A: Yes but there was a problem with that because often laboratories
15 crossed boundaries and statistics were incomplete for a particular laboratory.

16 Q: In some regions such as Tairāwhiti there was really only the Gisborne
17 laboratory reporting most of the cervical smears.

18 A: Yes plus the hospital plus I suppose there would be the odd ones who
19 had smears read elsewhere.

20 Q: So the laboratory statistics reports that were produced in the regions
21 at the time, and I understand there was some, effectively showed laboratory
22 statistics against the average for the Area Health Board.

23 A: I don't think they actually did identify individual laboratories they
24 were area statistics not by laboratory.

25 Q: Can I just ask you to have a look, to see if we're talking about the
26 same thing, we've got an example in Dr Boyd's volume 5, exhibit 32, page 9
27 on my count. You should have a document that's left hand cover is dated

1 March 29 1993. It's dated left hand corner March 29 1993, Cervical
2 Screening Programme Bay of Plenty Area Health Board laboratory smears
3 by the Bethesda code for the period March 1992 to March 1993.

4 A: Yes.

5 Q: In the two right hand columns you've got percentage laboratory and
6 percentage Area Health Board.

7 A: Yes.

8 Q: Is this the sort of report that you recall seeing?

9 A: I saw one of these reports, I'm not sure that these were widely
10 distributed centrally in fact I think this might be the only one that I've seen.

11 Q: This one went to the CALC committee didn't it.

12 A: Yes and the other thing is I'm not sure that these were sent to the
13 laboratories either.

14 Q: You see on the top right hand corner the reference under the page
15 number, QOS LAB, that's the quality of smear laboratory report as I
16 understand it.

17 A: Yes.

18 Q: And then we've got 5 pages I think of QOS LAB, and then we start
19 another report which is a different laboratory and we have two pages of that
20 report and then we go to a QOS AHB, quality of smears by Area Health
21 Board.

22 A: Right.

23 Q: It would be that sort of information that appears in that quality of
24 smear by area of health board that would be aggregated for the statistical
25 report?

26 A: Yes they report together for that report.

27

1 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

2 PROFESSOR DUGGAN: Excuse me Dr Teague do these codes
3 refer to the quality of the smear?

4 A: Which codes, the A codes are quality of smear, the B codes are
5 general recommendations and the C codes are descriptors.

6 Q: So A is the quality?

7 A: Yes, A1 is satisfactory, A2 is satisfactory but limited and A3 is
8 unsatisfactory.

9 Q: And the B codes?

10 A: B codes are general recommendations and B1 is normal and repeat at
11 the normal screening interval, I can't remember all these codes, I think B2-
12 B7 or B2-B6 is repeat in 6 months and so on.

13 Q: And the C codes?

14 A: The C codes are the descriptive codes of the report.

15 Q: Are the C codes the

16 A: Abnormalities. The description of abnormalities.

17 Q: Lets for argument say the diagnosis?

18 A: Yes just for argument sake yes. So the usual smear report is A1 B1
19 which is a normal smear.

20

21 CHAIR INTERJECTS AND XXN WITNESS

22 CHAIR: What is the difficulty with the word diagnosis, I've noticed
23 that in the women's reports from laboratories the word diagnosis is used.

24 A: I think it's a sort of conceptual terminological argument rather than
25 ??.

26

27 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

1 PROFESSOR DUGGAN: Now in these quality of smear reports Dr
2 Teague, is there any difficulty in interpreting these reports?

3 A: I don't think these were every meant for public consumption these
4 ones. That, to be honest, is the only example I ever saw of this sort of
5 document.

6 Q: So these never went out to?

7 A: No, as far as I know, they never went out to the laboratories and they
8 were, as far as I know, internal documents within the areas.

9

10 CHAIR: So for example, with the one I'm looking at at p102, which is the
11 Bay of Plenty Area Health Board, this is a document that the Bay of Plenty
12 Area Health Board regional co-ordinator or someone working under her
13 would have generated, is it?

14 A: That's right.

15 Q: But she would have kept it in-house, it wouldn't have gone to
16 laboratories?

17 A: I would presume so.

18

19 MRS SHOLTENS: So the laboratories themselves, they still did get,
20 though, a laboratory's reporting pattern report didn't they, which was called
21 in those early days a quality of smear report; that's certainly the evidence of
22 the register/co-ordinator.

23 A: I can't recall that, but if that's so then that's so.

24 Q: In your practice, were you the sort of person who would have seen?

25 A: At that time probably it should have come to me. I don't recall seeing
26 those sort of reports. I think that the practice may have been variable
27 between Area Health Boards.

1

2 CHAIR: Is this an example of the consequences of having the programme
3 fragmented with the different Area Health Boards?

4 A: Yes, I'm sure.

5

6 PROFESSOR DUGGAN: Dr Teague, Sharon Reid in her evidence makes
7 reference to the first QS report generated 31 July 1991.

8 A: Hmm.

9 Q: She was the regional co-ordinator for Tairawhiti.

10 A: I don't recall that going anywhere beyond Tairawhiti.

11 Q: So you never received any reports in your laboratory?

12 A: No, we didn't have access to data of any individual laboratory.

13

14 CHAIR: When do you recall first getting any data from the screening
15 programme?

16 A: You mean feedback to our laboratory personally?

17 Q: Yes.

18 Q: I think at the same – on individual laboratory statistics was at the same
19 time as that report that's been discussed earlier today.

20 Q: That's Exhibit 48?

21 A: Yes.

22

23 MRS SHOLTENS: 1996.

24 A: Yes, 1996, that's the first one that I recall receiving.

25 Q: So you're not familiar with the process of sending out laboratory
26 statistics to laboratories?

27 A: Other than that 1996 one.

1 Q: Can I ask you if you assume for the moment that you might have
2 received one of these, looking at it, of what assistance would it have been to
3 you?

4 A: Pretty little in the form that it's in now. I'd have to have done some
5 mathematics to make some sense of it.

6 Q: and that would have taken some time?

7 A: Yes.

8 Q: You would have done that?

9 A: In this form, yes it would have taken quite some time.

10 Q: And would the information you eventually receive be useful to you?

11 A: If I'd done some work on it, amalgamated all the categories and then
12 done my calculations it may have been some use to me, yes.

13

14 CHAIR: Without going through that process can you say one way or the
15 other?

16 A: Without doing it – it is meaningless without doing the calculation.

17

18 MRS SHOLTEN: Can I ask you to look at the CALC minutes again, that's
19 volume 4 of Dr Boyd's evidence, tab 18 – this time p31, which is the
20 minutes of the meeting of 10 April 1992. Is that the page where the last
21 heading is "National cytology register statistics"?

22 A: Yes.

23 Q: And that records a discussion of a document tabled – it looks like the
24 pre-cursor to this first statistical report that we're talking about, where
25 you've tabled a document showing the sort of information that can be
26 extracted from the Register but this particular document has the National
27 averages against the laboratory statistics.

1 A: Yes, this was our sort of recommendation which eventually led to the
2 type of letter that we saw in 1996.

3 Q: So there was a recommendation at this stage that these reports be
4 produced and sent to each laboratory?

5 A: Yes.

6 Q: You don't recall that happening?

7 A: No, I don't.

8 Q: The statistics themselves at this stage would have gone to the
9 laboratories, the ones that you had before you at this meeting?

10 A: No, they didn't.

11 Q: Simply put into the statistical report itself?

12 A: Yes. It was a struggle to get these out from the 14 sites and it was a
13 struggle that I personally wasn't involved in. Brian Cox and John
14 Brackenbridge did that extraction.

15 Q: The register had only been in operation for a very short time when you
16 considered these statistics. Can you recall how useful they might have been?

17 A: Sorry, in terms of the statistics embodied in the first statistical report.

18 Q: I realise I'm asking you to try and recall what you were looking at back
19 in 1992, but we know that the Register had been gathering information for
20 about a year, it was an opt-on system.

21 A: Yes. I believe that there would have been of some interest to me in
22 those statistics as a person who was running a laboratory. I think that those
23 statistics were based on reporting hierarchies and other things that were
24 relevant to the programme in terms of safety rather than relevance in terms
25 of laboratory statistics. By that I mean that only the highest grade of any
26 diagnosis was included on those statistics at that time, whereas a laboratory
27 statistics, laboratories are more interested in the totality of what's reported.

1 So that there were differences in the type of statistics that you would
2 produce for the two purposes. If that makes sense.

3 Q: So to provide a useful report to a laboratory you'd need to aggregate
4 some of those codes for a start?

5 A: Yes. You really need to collapse them down quite considerably so that
6 it's easier to digest, and you need to not be interested in only the highest
7 abnormality but in all abnormalities in terms of laboratory statistics.

8 Q: So the 1996 figures that were referred to, and just the ones for the
9 Gisborne laboratory appear in volume 5 of Dr Boyd's evidence at tab 29,
10 that's the sort of format that you wanted to see?

11 A: Yes, I think that was the first of the laboratory statistics produced, and
12 that was produced after the 14 registers had been collapsed into one
13 database. I think that was a process that took approximately 2 years because
14 although the 14 register sites had a common software, they had diverged
15 their databases so far that it took approximately 2 years to get the data back
16 into shape so it could be collapsed back into one database.

17

18 CHAIR INTERJECTS AND XXN WITNESS

19 CHAIR: Why had the databases diverged so far to use your words?

20 A: I think individual Register sites had wanted to look at various things
21 within the parameters of the software they had developed different ways of
22 handling their data. I can't answer the technical reasons why they had done
23 that but I believe that Sandy Mathcham will be giving evidence and she
24 would be well placed to answer that question.

25 Q: So was that one of the consequences of not having a national
26 coordinator with sufficient authority to require a standardised approach to
27 data entry?

1 A: Yes in part I suppose, I think it was more a problem of having 14
2 different almost independent databases operating. I think that was the main
3 problem.

4

5 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

6 PROFESSOR DUGGAN: By that do you mean did you have a
7 situation whereby there was no consistency in how the data was being
8 analysed amongst these 14 registers?

9 A: You'd have to ask Sandy Mathcham but I don't believe there was
10 even a consistency of the type of data or the way it was handled on each of
11 these 14 registries. There was sufficient divergence for it to be an enormous
12 problem to get it back into one database.

13

14 CHAIR INTERJECTS AND XXN WITNESS

15 CHAIR: So what use would it have been whilst it was with the 14
16 different registries.

17 A: In terms of laboratory quality assurance I believe relatively little
18 because the numbers of laboratories are relatively small and you really
19 needed the national data to make sense out of all of this.

20 Q: Just following on, you've been asked about the document that you
21 tabled prepared by Brian Cox relating to information able to be extracted
22 from the national cytology Register. I note that in Boyd volume 1 page 124,
23 it actually starts at 107 which is a private and public laboratories meeting
24 held on 1 October 1992. [Document produced to witness]. Page 107 you
25 will see it's the minutes of the public and private meeting of laboratories and
26 at page 124 you will see a heading there laboratory statistics and you are
27 mentioned and it says an initial set of statistics has been generated by the

1 Register. These have been generated by the central register and not Area
2 Health Board registers. Can you explain that please. This is in 92.

3 A: I think that's probably in relation to the data used for this first
4 statistical report I think.

5 Q: And that first statistical report was when?

6 A: I'm just trying to remember what it actually did refer to but ...

7

8 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS

9 PROFESSOR DUGGAN: Could it possibility be exhibit 13 in your
10 own evidence?

11 A: No that was from our own laboratory as an exercise. It's quite a big
12 document the first statistical report.

13

14 MS SHOLTENS ADDRESSES CHAIR

15 MS SHOLTENS: The first statistical report ma'am is Glackin volume 6
16 tab 26 and it analysed data to 18 August 1992 so it would fit with the dates
17 we are looking at.

18 CHAIR: If the witness could be shown that just so we can be clear
19 about what document is being talked about, there are so many references to
20 statistical reports etc.

21 A: I can't exactly recall but I believe it would be referring to that
22 document.

23

24 PROFESSOR DUGGAN CONTINUES XXN OF WITNESS

25 PROFESSOR DUGGAN: Earlier Dr Teague you accepted that
26 hospitals would have a higher rate of abnormality in their reporting
27 frequencies because of the level of disease in the population.

1 A: Yes in the population they are dealing with yes.

2 Q: At that same meeting, two thirds of the way down, page 124, Dr
3 Marian Gurley stated reporting rates would depend on the types of
4 laboratory for example National Women's deals with a lot of abnormalities.

5 A: That's just a reflection of what I'm saying.

6 Q: Was there any consideration at that time that the level of reporting by
7 a laboratory might also be influenced by the level of incident cancer in the
8 population that that laboratory was screening?

9 A: I think that was not contemplated at that time, I think we were trying
10 to get the basic laboratory statistics in place first, then we would get the
11 epidemiology put on top of it, I mean that in my own way was my concept.

12 Q: You do accept that that's an important consideration in the context of
13 evaluating these statistical reports being sent to the laboratories?

14 A: Yes

15

16 MS SHOLTENS CONTINUES XXN OF WITNESS

17 MS SHOLTENS: Can I just take you back Dr Teague to that Gisborne
18 laboratory table at Boyd volume 5 tab 29. I think you thought, you
19 mentioned you thought the Register might have been reconfigured by the
20 time these were produced. Can I just let you know the evidence on this
21 point was not yet, this was prepared for the second statistical report in 1996
22 and Ms Mathcam I think is probably the clearest place to find the evidence
23 that reconfiguration was completed about March 1997. So this was another
24 exercise of getting the statistics from the regions and manually collating
25 them.

26 A: Right.

1 Q: You also referred in answer to questions from the Chair to
2 inconsistencies between the regions. Are you talking about inconsistency
3 using the Bethesda coding system?

4 A: No and I think the question would more appropriately put to Sandy
5 Matcham who had to deal with these inconsistencies and she would know
6 the exact nature of them.

7 Q: You're familiar with the fact that there were problems getting
8 laboratories to report in a consistent way using Bethesda weren't there?

9 A: Yes there was at times a variability in the reporting I suppose. There
10 were also a degree of misconception about the obligations of the
11 laboratories. The Bethesda system as was initially published, the
12 descriptors were very short abbreviated, not even sentences and it was
13 always intended that a laboratory would format it's own written comment
14 and obviously from laboratory to laboratory that might differ, the exact
15 wording of it, but the intention was that it should have the same meaning
16 and indeed it was that conference that we have looked at in private and
17 public laboratories, the object of that particular meeting, amongst it's objects
18 was to try and get some more uniformity in that reporting.

19 Q: Uniformity in the reporting on Bethesda was so fundamental to
20 getting useful statistics wasn't it?

21 A: Yes, although what goes to the programme is not the written report,
22 or the worded report which does vary – even to this day it varies between
23 some laboratories, but the codes which underlie the meaning of those words
24 – the codes go to the programme.

25 Q: So consistent use of particular codes is very important?

1 A: Yes. By and large, I think, that was generally achieved. There was
2 more divergence in terms of the words that were used on the reports, I
3 believe, than the actual codes that underlay them.

4 Q: What was inputted onto the Register was just the codes?

5 A: Just the code, yes, and then the code had its set of phraseology that went
6 with each one.

7 Q: One of the key problems in pulling the data together, we've heard, is the
8 number of duplicate enrolments. Are you familiar with that problem?

9 A: I mean, I've heard that there were duplicate enrolments. That's about as
10 familiar as I am with it.

11 Q: You know that –

12 A: there were, I believe, a number of women who had somehow got –
13 different women who had the same NHI number of identifier, and indeed
14 there were some women who had several NHI numbers attached to them.
15 So that was a problem. But again, Sandie Matcham is the one who knows
16 that sort of detail.

17 Q: This report that we have the example of for Gisborne laboratories at
18 Boyd tab 29, that went to what was then Cervical Screening Laboratory
19 Advisory Committee for comment before it was sent to all the various
20 laboratories?

21 A: No, those individual reports were never seen by CSLAC.

22 Q: Can I just ask you to look at the relevant minutes and then you can tell
23 me what they did look at.

24 A: Sure.

25 Q: Again, volume 4 of Boyd, tab 18, p156.

26 A: What we were shown was the format of that document not the actual
27 individual laboratory statistics.

1 Q: So are you saying you really just saw a proforma report and not the
2 actual statistics?

3 A: Absolutely, hmm.

4 Q: Did you think at any stage that you should see the actual statistics?

5 A: No, I don't believe that the committee did request to look at other
6 laboratory's individual statistics. What it did do was, however, as it
7 recommends there, is that the profile should be sent to TELARC and so
8 TELARC should be able to inspect those individual laboratory statistics.

9

10 CHAIR: I see that at p156 of Boyd Volume 4 the document's described as
11 a benchmark document which laboratories would find useful as an internal
12 quality measure.

13 A: Hmm.

14 Q: I understood that earlier today you had accepted that there were
15 limitations to these statistics?

16 A: Absolutely, there are limitations for a lot of reasons, but at least it was a
17 start, it was better than what we'd ever had before.

18 Q: And I think also you accepted that if the limitations weren't clearly
19 recognised by the person reading the statistics they could be falsely
20 reassuring?

21 A: Possibly that's right.

22

23 MRS SHOLTENS: And I think in your para 19.6 of your brief you
24 basically tell us that really only fairly recently, when registrations reached a
25 significant number, have these sorts of statistics become of real value?

1 A: Yes, I think that is corroborated by Professor Skegg's evidence as well,
2 and also I'm sure Brian Cox, that whilst we were operating on the opt-on
3 system we only had a small sub-sample size of laboratories.

4 Q: So you must, in terms of trying to figure out priorities, getting women
5 registered in the programme obviously was a key priority in the very early
6 days and numbers is important in terms of being able to use statistics in a
7 sensible way to evaluate or monitor what's going on?

8 A: Obviously there has to be a time lag before you can generate useful
9 statistics.

10 Q: And consistency of reporting by laboratories is also important?

11 A: These I think would have been valuable documents in terms of trying to
12 achieve some of those objectives. The ones which don't need a lot of extra
13 statistical knowledge or other knowledge would be things like unsatisfactory
14 smears, the proportion of various types of reasons for unsatisfactory smears
15 or less than optimal smears – those sort of things could be usefully read out
16 of that quite easily I think.

17

18 PROFESSOR DUGGAN: Dr Teague, in the early years before the
19 implementing committee began its work and the programme was still in its
20 design phase and policy setting phase, was there a meeting to discuss what
21 needed to be done and was there any priority setting mechanism?

22 A: Not that I particularly recall, although the expert group made a number
23 of recommendations of things that should or must be done to run a
24 successful programme.

25 Q: So if there was no priority setting meeting would it be correct to say,
26 then, that everything was a priority or everything was not a priority? I'll say
27 it this way: everything needed to be done?

1 A: Absolutely.

2 Q: And one thing was not more important than something else?

3 A: Yes.

4 Q: Okay.

5

6 MRS SHOLTENS: Since March 1997, when the Register was
7 reconfigured, laboratories have been able to receive reports showing their
8 reporting statistics against the National averages?

9 A: Yes.

10 Q: I think in most regions those are generated 6 mthly – are you familiar
11 with that?

12 A: No, I'm not sure – I really can't answer because at this stage I am now
13 no longer administering our cytology dept, but I believe that we received 3
14 or 4 such reports since then.

15 Q: When did you stop that role?

16 A: About the mid-90s, I'm not sure of the exact date. But the first report
17 was that, and then I believe that there were subsequent similar reports sent
18 out.

19 Q: Do you know what your laboratory did with those reports?

20 A: Yes, it examined those reports and if we saw that we had any areas of
21 concern then we would meet and discuss what we might want to do about it.
22 And that would be the director, the clinician in charge of the laboratory plus
23 the charge cytotechnologist would look at those statistics and see if they
24 thought there was anything that we should do.

25 Q: And histology reports for the laboratory have also been available on a
26 similar sort of format for the last 2 years?

27 A: Yes, I'm not sure exactly when they first – I know that the databases

1 goes back two years, I'm not sure when they actually became available.

2 Q: Turning to the subject of histology and the Register, again we will be
3 hearing from Ms Mathcham on this, the legislation which require histology
4 came into effect on 1 July 1993, the same time as the opt off change.

5 A: Yes.

6 Q: Now you'd be familiar with the process from there, the very slow
7 process of histology coming on to the Register. Perhaps if I could ask the
8 witness to be shown one of Ms Matcham's exhibits ma'am. Exhibit 20 in her
9 volume 2.

10

11 CHAIR INTERJECTS AND XXN WITNESS

12 CHAIR: While we're waiting for that could I just ask you something
13 please Dr Teague. I'll just read it out to you. Dr Boyd in his evidence at
14 paragraph 128 says "As Judy Glackin says in her evidence the programme
15 was unable to start providing laboratories with feedback from the
16 histological examination of specimens taken at subsequent colposcopy
17 examinations until histology results were routinely entered into the Register
18 in 1996" and I see that you have said at your paragraph 20.18 "correlated
19 histology results have become available in the last six months".

20 A: I think that Dr Boyd's statement is that they were potentially able to
21 do so from 1996 onwards. I believe that the reports became available, the
22 database has been available covering the last two years and I'm not sure, it
23 was my recollection that it was actually available in the last six months but it
24 may have been slightly before that.

25 Q: Thank you I just wanted to tidy that up.

26

27 [Exhibit produced to witness]

1 MS SHOLTENS CONTINUES XXN OF WITNESS

2 MS SHOLTENS: Just the first page I'm looking at, front and back. These
3 are recommendations by CALC relating to putting histology onto the
4 Register.

5 A: Yes those are the snowmed codes that we suggested should be used.

6 Q: So we had the same issues in some ways as using Bethesda for
7 cytology didn't we. You had to come up with a code that laboratories would
8 use consistently in order to ensure that the data being put on the Register and
9 used made sense?

10 A: Yes.

11 Q: And the other issue that this recommendation covered was the fact
12 that it might not be possible for laboratories to comply with the new
13 legislation at this stage?

14 A: I think the legislation stated that you had to submit histology reports
15 to the Registry where a woman had not opted out of that position and I think
16 it was worded in whatever suitable medium or some words like that so that it
17 didn't prescribe that it had to be electronically, and indeed when it first
18 started off, I don't think either the programme or the laboratories were set up
19 for the electronic transmission of this data. That was phased in.

20 Q: Ms Mathcham's evidence just to summarise it, is that the laboratories
21 could not send the information electronically at this stage and the Register
22 could not accept it electronically until about mid 1994.

23 A: Right.

24 Q: And at that stage they still could not fully process that histology that
25 took another year and a bit before they could actually associate the histology
26 on the Register with the cytology.

1 A: Yes I think up until that point laboratories had complied with the law
2 by sending their copies of the written reports.

3 Q: Hard copies yes.
4

5 CHAIR INTERJECTS AND XXN WITNESS

6 CHAIR: Was the snowmed code imposed as part of the legislation or
7 was it voluntarily accepted.

8 A: Well if you're going to send it by electronic means the most
9 expedient way of doing so is again to have a set of codes and snowmed was
10 the code that's almost universally used in laboratories for this sort of coding.

11 Q: So it was accepted in a voluntary way in the way that the Bethesda
12 code was?

13 A: Yes it was.
14

15 MS SHOLTENS CONTINUES XXN OF WITNESS

16 MS SHOLTENS: Ms Matcham talks about a backlog entering hard copy
17 histology onto the Register until about the end of 1996.

18 A: Yes.

19 Q: Since then the Register still receives some histology in hard copy and
20 still has to enter the data themselves are you aware of that?

21 A: Yes I was aware that there were some sites still submitting paper
22 documents.

23 Q: And as Madam Chair mentioned in your brief of evidence you talk
24 about only really receiving the histology cytology correlation reports in the
25 last six months for your laboratory.

26 A: Yes.

1 Q: You would understand that if laboratories in your local regions
2 hospitals were not providing data in electronic form, it would take some time
3 before that histology information would come about.

4 A: There was a big logistic problem yes.

5 Q: So I think Ms Matcham's evidence shows that that's an issue in
6 Wellington not necessarily everywhere else where these reports have been
7 available for some time.

8 A: Yes I accept that.

9 Q: I want to turn now to the subject you refer to in your paragraph 20.10
10 to 20.12 that's what they call the Fuer Report.

11 A: Yes.

12

13 CHAIR ADDRESSES MS SHELTONS

14 CHAIR: Ms Sheltons is the Fuer Report in evidence?

15 MS SHOLTENS: Yes it is ma'am I'll find that. It's page 55 of your
16 evidence.

17

18 MS SHOLTENS CONTINUES XXN OF WITNESS

19 MS SHOLTENS: Now Dr Boyd refers to this process the same exercise in
20 his paragraphs 122 to 130. He refers to the fact that Azimuth, the computer
21 consultants, were asked for their advice as to how to configure the Register,
22 or to add to the Register to accept histology.

23 A: Right.

24 Q: And one of the exercises they had to go through was to figure out how
25 the programme wanted to use the histology information for monitoring
26 purposes.

27 A: Yes.

1 Q: and again CALC was asked for its advice on this subject, wasn't it?

2 A: Yes.

3 Q: And CALC effectively set up a sub-committee to work out a process for
4 using histology information for monitoring purposes, is that right?

5 A: Yes, it certainly set up the sub-committee which came up with those
6 SNOWMED codings, which was to get the histology information on it, and
7 there was certainly an input into Azimuth as to what should be done with
8 that information. I'm not sure of the mechanism for that. I certainly
9 myself, I know I spent quite a bit of time with Janet Phuah to look at those
10 sort of issues.

11 Q: If I just have a quick look at Ms Glackin's Exhibit 23 and make sure
12 that's the one I want. I'm looking now at volume 4, tab 18 of Dr Boyd, the
13 CALC minutes, where the Azimuth initial report was discussed, and it was
14 at the meeting in April 1993, p34, and at the foot of the page there's
15 reference to the histology report where the Azimuth Consultants, that
16 included Janet Phuah, have joined the meeting and they presented their
17 report (which is in Ms Glackin's evidence) and on p35 CALC discussed the
18 report and made the following recommendations, and you will see, Dr
19 Teague, (d), a recommendation that a small technical group meet to discuss
20 and make recommendations on a number of things, and you were a member
21 of that group?

22 A: That's right. I think that group essentially what it did achieve and did
23 was the SNOWMED codings.

24 Q: Then Dr Boyd's exhibit 20, volume 5, tab 20, this is a draft
25 implementation of histology in the Register draft quality assurance process.
26 And you'll see on the last page there's a letter to yourself, and I'm assuming
27 that this is a covering letter which went to you with this report, that says

1 “please find enclosed the outcomes as recorded by Janet Phuah of the CALC
2 technical group’s meeting held 20 August.”

3 A: Those are tables of the SNOWMED codes and their equivalents in
4 cytology coding.

5 Q: And the front page, the first page of exhibit 20, that is a draft quality
6 assurance process for using histology from the Register?

7 A: I think these were the sort of fundamental building blocks for it to be
8 used for that purpose, that’s right.

9 Q: And this draft quality assurance process was developed by the technical
10 group that you were a member of?

11 A: I can't remember the exact number or who had input into that document,
12 I certainly remember that I had some input myself. It may well have also
13 included John McKafferty and Roger Davies.

14 Q: Yes, I think that’s what I would take from the record. Now this was
15 also accompanied around the same time with the next document, Boyd
16 exhibit 21, a discussion paper that the record will show also went to CALC
17 at the same time, and we’ll come to those minutes. Do you recall this
18 discussion document? It appears to record the ideas and issues discussed
19 between Ms Sue Dahl and Ms Janet Phuah – Sue Dahl being the National
20 co-ordinator of the programme at the time.

21 A: Yes. I mean, you can see how many documents I've had to look at
22 through this process.

23 Q: Certainly. It’s not immediately familiar to you?

24 A: No.

25

26 CHAIR INTERJECTS

1 CHAIR: Would you like the witness to look at these documents overnight
2 Mrs Sholtens – there's only 10 minutes to go?

3 MRS SHOLTENS: That might be of assistance, ma'am, yes.
4
5

6 MS SHOLTENS CONTINUES XXN OF WITNESS

7 MS SHOLTENS: The exhibit 20 which I think Dr Teague you have
8 referred to exhibit 20 in your own brief.

9 A: Yes I did yes.

10 Q: And 21 and then perhaps the relevant CALC minutes, if I just give
11 the reference and then I can move on to a different topic for the last few
12 minutes.
13

14 CHAIR ADDRESS MS SHOLTENS

15 CHAIR: Yes if you just give Dr Teague the references to all the
16 documents you want him to look at overnight.

17 MS SHOLTENS: The relevant CALC minutes are the 17 November 1993
18 ones, that's page 59 of volume 4 tab 18 and in particular pages 7 and 8 of
19 those minutes which is 65.

20 CHAIR: Are you writing it down for Dr Teague?

21 MS SHOLTENS: I'll give him a note.
22

23 MR HODSON ADDRESSES PANEL

24 MR HODSON: Is there no prospect of sitting until 6 to try to finish this
25 witness.

26 CHAIR: No the committee has a number of questions too, sorry but
27 we've spent a long of time on this witness and there are issues which the

1 committee needs to cover which haven't yet been covered. You have
2 questions too don't you Mr Hodson?

3 MR HODSON: 15 minutes.

4

5 MS SHOLTENS ADDRESS CHAIR

6 MS SHOLTENS: Ma'am I wonder if I could leave the remaining ... I've
7 only really got the extension of this topic to cover with this witness. I know
8 my friend has a matter to raise with you.

9 CHAIR: Mr Murray does, very well. Well we'll deal with that then?

10

11 MR MURRAY ADDRESSES CHAIR

12 MR MURRAY: Just time tabling matters ma'am because I am conscious
13 people want to know what to read and when to read it. We have a series of
14 witnesses mainly from the Health Funding Authority but also from one
15 witness from the Ministry. The witness after this I propose to call is Tracey
16 Mellor to give her supplementary brief of evidence and Ms Mellor has some
17 new exhibits to add which are the answers to the questions that the panel
18 asked so the easiest way to get some of this information in is just to get Ms
19 Mellor to produce some additional exhibits.

20 CHAIR: Could you circulate those at the end of this session because I
21 want people to have had sufficient opportunity to read the exhibits.

22 MR MURRAY: Yes I can do that. The second witness I had proposed
23 to call was Mr Ron Jones, the colposcopist, whose actually here but Mr
24 Jones brought to my attention a large addendum to his brief of evidence and
25 I have just had a quick skim through it and it has made me realise that it's not
26 appropriate that I call Mr Jones for two reasons. 1) the procedural one is
27 that we haven't circulated the addendum which is almost as long as the brief

1 and 2) the substantive contents of the evidence means that I should probably
2 not call the evidence and so what I propose is to pass the brief that has been
3 circulated and the addendum if it's available over to my friends counsel
4 assisting, they can decide whether the evidence needs to be called, how and
5 when, so I'll leave that to one side but I think it is important because Mr
6 Jones is here that he speaks with counsel assisting about whether he will
7 give evidence and if so when, just so he is inconvenienced to the minimum
8 possible. After Tracey Mellor I would propose to call Dr Farnsworth who
9 will be here from Australia tomorrow. I hope she will not mind if I call
10 Tracey Mellor first because of the obvious need to get in the supplementary
11 evidence and the update report before Dr Farnsworth gives evidence that
12 builds upon that situation. The witness that would then, according to the
13 timetable come, would be Dr David Lambie but Dr Lambie is heavily
14 committed in Wellington on a restructuring managers meeting going over
15 Wed and Thur so I would propose to call Dr Lambie on Friday but I do not
16 anticipate any glitch with the timetable at all because if we go from Mellor
17 to Farnsworth we might then have DuRose and that is a logical unfolding of
18 that evidence which goes basically from the update on the Gisborne review
19 it goes to Dr Farnsworth's evidence about her re-reading and then into the
20 wider issues of national laboratory reporting and performance. So if it's
21 consistent with the convenience of the inquiry and I'm conscious that the
22 inquiry members will also have their own views on this, but I would like to
23 start Tracey Mellor as early as possible tomorrow, then go on to Dr
24 Farnsworth and then Jim DuRose and I realise that Dr Wayne has to be
25 interposed somewhere because he's in from Sydney so that whatever we're
26 doing on Thursday we may have to make a break but if that pleases you
27 Madam Chair and the members of the inquiry that's how I would like to

1 present the witnesses that I have and I hope that by announcing that it will
2 give everyone fair warning about the witnesses that are coming up and the
3 reading that might be required.

4 CHAIR: If we have Dr Farnsworth tomorrow, Mr Hodson you've about
5 15 minutes don't you for Teague.

6

7 MR HODSON REPLIES

8 MR HODSON: Ma'am we've been told for a very long time that Dr
9 Farnsworth is the 18th of July and only the 18th of July. I'm very much
10 concerned that we will hardly have time to assimilate the information that
11 Tracey Mellor gives before we've got Dr Farnsworth and I'm even more
12 concerned that Mr Jones isn't going to be called before Dr Farnsworth
13 because Mr Jones is the only witness who actually knows the results of Dr
14 Farnsworth's work and it would only be fair I would have thought for us all
15 to question that.

16 CHAIR: Well firstly in terms of Ms Mellor her supplementary brief of
17 evidence has been available since the committee reconvened so she's not
18 really going to say anything more than what's in her supplementary brief
19 other than answers she might give to questions on cross examination.

20 MR HODSON: Yes ma'am.

21 CHAIR: In terms of Mr Jones, is it possible to fit Mr Jones on
22 tomorrow as well then, because I've read both the brief and the addendum
23 and it didn't seem to me that it would take a great deal of time, given that it
24 will be taken as read.

25

26 MR HINDLE REPLIES

1 MR HINDLE: I was just going to say ma'am that in view of the fact
2 that a brief has been circulated I think he must be available in case there are
3 any questions so it is just a question of timing and the addendum does need
4 to be circulated. I certainly haven't seen it myself yet.

5

6 MR MURRAY REPLIES

7 MR MURRAY: And I hadn't been aware that it had been passed to the
8 panel either so there are some issues there I suspect. But in any event I'm
9 not planning to call Mr Jones. Dr Farnsworth will be here tomorrow and I
10 know she wants to get away as quickly as possible but I think the main thing
11 is we at least try and get supplementary brief of Ms Mellor in and I'll speak
12 to Dr Farnsworth this evening when she arrives or first thing tomorrow
13 morning and ensure that if she is to come after Tracey Mellor that she is
14 happy with that.

15

16 CHAIR ADDRESSES MS SHOLTENS

17 CHAIR: Ms Sholtens how much longer do you anticipate being with Dr
18 Teague?

19 MS SHOLTENS: Half an hour ma'am.

20 CHAIR: Right now I don't want you to feel rushed on that.

21 MS SHOLTENS: No that's just my best estimate on what I've got to
22 cover.

23 CHAIR: Who else wishes to question Dr Teague.

24

25 MR RENNIE REPLIES

26 MR RENNIE: I don't wish to question Dr Teague ma'am but I indicate
27 that we had made arrangements, if I may say, with all the usual difficulty for

1 Dr Teague to stay over tomorrow but to the extent that we are all by Air
2 New Zealand, we are required to leave at 1.35.

3 CHAIR: That should be all right, because I was anticipating that his
4 evidence would be completed by about 11.00. That might be being over-
5 generous anyway.

6 MR RENNIE: It may well be, I just really wanted to signal that because
7 there are consequential overseas issues which flow on from there and I
8 would otherwise be asking for consideration for an earlier start. And while I
9 am on my feet, if I could just observe that I had assumed, on the briefs I had
10 read, that Mr Jones would precede Dr Farnsworth, and indeed I had
11 originally made some arrangements to be here to deal with that, although I
12 think they have fallen over as a result of the time pushing out. But I just
13 observe that otherwise the sequence does seem very surprising.

14 CHAIR: So you would rather have Dr Jones here before Dr Farnsworth?

15 MR RENNIE: Well, yes, although I may not in fact now be able to stay for
16 that length, ma'am, but it's really just a question that one would think that Dr
17 Farnsworth might be asked – as my friend Mr Hodson has said – about the
18 correlation between the cytology and the histology, which seems to be one of
19 the most critical remaining issues in the inquiry, if I may say so.

20 CHAIR: Do we need to have Ms Mellor's evidence before Mr Jones?

21 MR RENNIE: I wouldn't myself have thought so ma'am, but perhaps I will
22 defer to my friends.

23 CHAIR: Because one possibility strikes me is if we were to start at 9.00am,
24 we could hear Dr Teague and then move to Mr Jones, and then Tracy Mellor
25 and then Dr Annabelle Farnsworth, and we would finish. I think if we start
26 at 9.00am we shouldn't contemplate going beyond 5.30. I would really like
27 to finish at 5.00 with the prospect of coming back on Wednesday. So I think

1 that's probably the best way to do it. Mr Hindle, how long do you anticipate
2 you have questions for Dr Teague?

3 MR HINDLE: There's still 15 minutes on one very narrow subject.

4 CHAIR: There are a lot of issues that I've been through with CALC
5 minutes and various issues considering his long involvement in the inquiry
6 that he can clarify.

7 MR HINDLE: I'm quite happy to say I only really wanted to cover the
8 statistical reports and ask a few questions about them and one or two matters
9 of clarification in the brief. So it wouldn't be very long at all.

10 CHAIR: All right, well on that basis we will have an early start at 9.00am
11 and after Dr Teague we will move to Mr Jones. Now if we do that it does
12 mean that everyone's going to have to read his addendum tonight. Does that
13 give everyone sufficient time? It's about as long as his brief.

14 MR MURRAY: Has it been circulated yet ma'am?

15 CHAIR: No, it hasn't yet I don't think. It can be made available as soon as
16 we adjourn. So on that basis we will have Dr Teague, then Mr Jones, then
17 Tracy Mellor, then Dr Farnsworth. Hopefully we will get through 3 if not 4
18 tomorrow. So we will adjourn until 9.00am.

19

20 THE HEARING ADJOURNED AT 5.03 P.M. TO RESUME ON

21 TUESDAY 18 JULY 2000 AT 9.00 AM