1

2 **WEDNESDAY 26 JULY 2000**

3 **THE HEARING RESUMED AT 9.30 AM**

4

5 MRS MARSHALL OPENS FOR THE CANCER SOCIETY

6 MRS MARSHALL: I'm Betsy Marshall of the Cancer Society of NZ and I
7 will be opening for the Society and introducing the Society's three
8 witnesses. I have prepared an opening statement and I trust that you have a
9 copy before you. It is with a grave sense of sadness and concern that the
10 Cancer Society of New Zealand, which participated as a party in the
11 Cartwright Inquiry thirteen years ago, again should be taking part in an
12 Inquiry relating to cervical cancer in New Zealand. Although the issues may
13 be different, the fact remains that the full potential of screening to reduce the
14 number of women who develop or die from cervical cancer has not yet been
15 achieved in New Zealand. For a number of years prior to the Cartwright
16 Inquiry, the Cancer Society advocated for effective cervical screening in
17 New Zealand. As an independent, non-profit agency that receives no direct
18 financial support from government, the Cancer Society could not have
19 undertaken such advocacy without the generosity of the public that supports
20 its work through donations. Since the early establishment of the National
21 Cervical Screening Programme in 1989, the Cancer Society has played a key
22 role in advocacy for an organised approach to cervical screening through its
23 involvement in a number of national advisory groups. As a staff member of
24 the National Office of the Cancer Society, I have been privileged to
25 represent the Cancer Society on of seven of these committees, and my
26 evidence is given in that capacity. One of the key roles of the six regional
27 divisions of the Cancer Society is to provide support and advocacy for those
28 who develop cancer. Within the context of this Inquiry, this role has been

1 clearly demonstrated by the efforts of Janice Hobbs in bringing the problems
2 in the Gisborne region to the attention of health authorities. Her brief of
3 evidence describes these efforts in detail. Advocacy for effective screening
4 would not be possible without the expertise and advice provided to the
5 Society on a voluntary basis by those who serve on its advisory committees.
6 In the area of screening, we acknowledge the substantial contribution of Dr
7 Brian Cox, who is appearing at this Inquiry as an expert witness for the
8 Cancer Society. Dr Cox not only has provided expert advice on screening,
9 but he has also led recent multi-agency initiatives to establish a national
10 cancer control strategy for New Zealand. His evidence also describes this
11 important issue and a number of other issues relevant to this Inquiry. He
12 will also assist the Inquiry by referring to the Heath Funding Authority data
13 placed before it. This Inquiry is charged with making findings of fact on a
14 number of issues. One fact that is no longer in doubt is that cervical
15 screening can save lives. To do this consistently and effectively, however,
16 screening must be carried out in the framework of a properly organised
17 programme. The World Health Organization has formulated the criteria for
18 properly organised cervical screening programmes, and those criteria are in
19 evidence before the Inquiry. Appropriate programme management, as
20 outlined in the World Health Organization managerial guidelines for
21 cervical cancer screening programmes, also plays a key role in programme
22 effectiveness. In the view of the Cancer Society of New Zealand, the
23 National Cervical Screening Programme, notwithstanding all its flaws and
24 inadequacies, has resulted in a reduction in incidence and mortality from
25 cervical cancer compared to what was expected. That it has done so is a
26 tribute to the work of those who have fought for its continued survival
27 against formidable odds. The first Term of Reference, requiring a
28 determination whether there has been an "unacceptable level of under-

1 reporting" is one that was difficult to address prior to this Inquiry. Put
2 simply, there has never been in place in the National Cervical Screening
3 Programme adequate measures of acceptable or unacceptable levels of
4 reporting. There have been a range of systemic issues which have
5 undermined and compromised the effectiveness of the National Cervical
6 Screening Programme, to the degree that the establishment of an Inquiry
7 such as this to address the issue of mis-reporting, was seen by many of those
8 committed to the screening programme as inevitable. A number of these
9 systemic issues are addressed in our evidence. An effective screening
10 programme must incorporate mechanisms for monitoring and quality
11 assessment, both of the discrete components of the screening pathway, such
12 as laboratory services, and of the overall operation of the programme. The
13 National Cervical Screening Programme was initiated without adequate
14 monitoring and evaluation procedures which, as recommended by the World
15 Health Organization, should have been established at the outset. Cancer
16 Society witnesses testify to their frustration as proposals for evaluation of
17 programme performance in the years from 1989 to 1996 were met with
18 resistance or inertia. Assessment and evaluation of the effectiveness of a
19 screening programme is dependent on the reliable and comprehensive
20 collection and routine analysis of statistical data. Again, this has never been
21 the case for the National Cervical Screening Programme. Data analysis in
22 the years to 1996, and indeed more recently, has been incomplete and
23 sporadic, and the evidence will show repeated advice from experts
24 committed to the programme to address this issue. An effective screening
25 programme depends also on stability and continuity of suitably qualified and
26 experienced staff. Yet the operation of the national co-ordination unit of the
27 National Cervical Screening Programme has been characterised by a lack of
28 staff with the range of expertise required to address the multi-faceted aspects

1 of the programme, as well as a high turnover of personnel. As Professor
2 McGoogan has stated, a properly organised programme must include
3 systems for responding to incidents. Not only has there been no adequate
4 system for identifying failures in the operation of the National Cervical
5 Screening Programme but when local and national Cancer Society officers
6 reported concerns over the misreporting of cytology of one woman in
7 Gisborne, over two years elapsed before there was action to address their
8 concerns. An opportunity to address the issues earlier was therefore lost.
9 The National Cervical Screening Programme has been designed and
10 modified over the past ten years to fit whatever health system prevailed at
11 the time. Screening programmes cannot operate to their full potential for
12 protecting public health when they are vulnerable to politically driven
13 instability in health system structures. The National Cervical Screening
14 Programme has struggled to survive successive re-structuring and, in
15 particular, to remain a national programme within a system of devolved
16 responsibility for health services and the formal split of accountabilities
17 between personal and public health services. The Cancer Society's view is
18 that in a devolved health system, the Department (Ministry) of Health, which
19 has had ultimate responsibility for the National Cervical Screening
20 Programme, has had a predominant focus on policy and regulation. This
21 focus has resulted in the neglect of the operational requirements of the
22 programme that must be monitored routinely. This Inquiry provides an
23 opportunity to identify the major weaknesses of the National Cervical
24 Screening Programme which, if addressed, could result in a programme of a
25 high international standard. As such it would ensure that the best possible
26 efforts are undertaken to maximise the benefits while minimizing the risk of
27 harm to the women of New Zealand. According to the World Health
28 Organization, the implementation and maintenance of uniform standards of

1 performance, quality assurance and control require a central agency with
2 responsibility for these functions. If such an agency, and the programme for
3 which it is responsible, is to function effectively, it must be free of political
4 instability. There must be no ambivalence or compromise of its integrity. In
5 the case of the National Cervical Screening Programme, the expert view is
6 that there must be an independent National Cancer Control Agency,
7 adequately resourced in both funding and staffing. As a minimum, the
8 central offices for the National Cervical Screening Programme and the
9 national breast screening programme, the data bases for these programmes
10 and the Cancer Registry should be placed in this agency. Within this agency
11 there must be an individual answerable for the performance of the National
12 Cervical Screening Programme. The full potential of cervical screening can
13 only be realised with a quality service assured through appropriate
14 monitoring and evaluation. All obstacles to the appropriate monitoring and
15 evaluation of the National Cervical Screening Programme therefore must be
16 overcome. In some cases this will require amendments to legislation or the
17 promulgation of regulations for existing legislation. The central office of
18 the National Cervical Screening Programme must have the capacity to
19 receive the information generated through routine programme monitoring
20 and evaluation and to respond to problems identified. Nothing less than
21 what is outlined in these steps will achieve the full potential of screening
22 while ameliorating the potential risks, risks that we in New Zealand have
23 carried at the potential cost of human lives.
24
25 CHAIR ADDRESSES MRS MARSHALL
26 CHAIR: Thank you Mrs Marshall.
27 MRS MARSHALL: Madam Chair, I would like to now call the Society's
28 first witness, Dr Brian Cox.

1 CHAIR: Yes, thank you very much.

1 MRS MARSHALL calls –
2 DR BRIAN COX (sworn)
3
4 MRS MARSHALL XXN WITNESS
5 MRS MARSHALL: Dr Cox is your full name Brian Cox?
6 A: Yes.
7 Q: Are you currently the director of the Hugh Adam Cancer
8 Epidemiological Unit in the Dept of Preventive and Social Medicine at the
9 University of Otago?
10 A: I am.
11 Q: Have you prepared a brief of evidence?
12 A: Yes.
13 Q: And can you confirm that to the best of your knowledge this is a true
14 and accurate record?
15 A: Yes I can.
16
17 MRS MARSHALL ADDRESSES CHAIR
18 MRS MARSHALL: Madam Chair before Dr Cox answers any
19 question, there's a matter of an exhibit that I'd like to produce through this
20 witness.
21 CHAIR: Yes.
22 MRS MARSHALL: Perhaps if Madam Registrar could distribute this.
23 Madam Chair this is an exhibit that we would like to produce through Dr
24 Cox as it's come to hand since the exhibits were submitted by the Society.
25
26 MRS MARSHALL CONTINUES XXN OF WITNESS
27 MRS MARSHALL: Dr Cox this document, have you had a chance to
28 look at the document?

1 A: Yes I have.
2 Q: And does this remind you in general terms of a conversation which I
3 had with you several years ago?
4 A: Yes.
5
6 MRS MARSHALL ADDRESSES CHAIR
7 MRS MARSHALL: May we produce this as an exhibit for Dr Cox.
8 CHAIR: Yes you may Mrs Marshall and certainly if anyone's got any
9 objection I see that it's your letter anyway it should be fine.
10 [Exhibits BC/CS/001 to 43 produced].
11 MRS MARSHALL: Madam Chair there are a few matters that I
12 would like to raise with Dr Cox before he is cross examined.
13 CHAIR: Certainly.
14
15 MRS MARSHALL CONTINUES XXN OF WITNESS
16 MRS MARSHALL: Dr Cox you state in your brief that you're an
17 epidemiologist and a public health medicine specialist and that you did your
18 Ph.D. in epidemiologist in the control of cervical cancer. Could you please
19 define the respective disciplines of epidemeology and public health
20 medicine, or put perhaps more simply, what is an epidemiologist and what is
21 a public health medicine specialist?
22 A: Epidemiology is a scientific study of the causes, determinants and
23 natural history of disease, including the impact of health services upon them.
24 Disease and illness I should say. Public health medicine is a little more
25 difficult to define, it's a specialist branch of medicine which involves the
26 application of knowledge of epidemiology, clinical care, health services and
27 health service administration in the activity of improving the public's health
28 and wellbeing.

1 Q: A number of witnesses have been asked to comment on the mix of
2 expertise that's needed among those involved in cervical screening and in
3 particular in the national co-ordination of the unit of the National Cervical
4 Screening Programme. I'm wondering if perhaps Madam Registrar Dr Cox
5 could be shown Glackin 35, volume 7, p2. I think several witnesses have
6 been asked to comment about issues that are outlined on this page. You
7 will of course recognise this as a report of an advisory committee of which
8 you and I were both members?
9 A: Yes.
10 Q: and I'm wondering if you could just look particularly at the specific
11 recommendations, No. 1 and 2, and if you could just read those out.
12 A: Specific recommendations are as follows: 1) programme needs good
13 operational leadership with public health perspective on a full-time basis;
14 2) to address the multi-faceted aspects of the programme, paid staff with
15 expertise from several disciplines are required, skills include medicine,
16 epidemiology, statistics, computing and cytology.
17 Q: Dr Cox we've heard from Dr Peters, or evidence also from Dr Peters,
18 that she is the first public health medicine specialist to be responsible for the
19 National Cervical Screening Programme. As an epidemiologist and public
20 health medicine specialist how important do you think it is for the screening
21 programme to be lead by a public health medicine specialist?
22 A: I think it's vital and I think its also been expressed in the World Health
23 Organisation guidelines for managerial guidelines of Cervical Screening
24 Programmes. Certainly many of the areas of knowledge that are required
25 are part of training in public health medicine.
26 Q: You've read out the second recommendation here as well on this page
27 which relates to the mix of expertise needed in the national co-ordination
28 unit. I wonder if you'd like to perhaps comment further or expand on what

1 you, as an epidemiologist and public health medicine specialist feel is
2 important to have within that mix?
3 A: Well the skills are listed. I feel, in terms of the epidemiology, it is
4 useful to have someone who is also medically trained – in other words, a
5 medical epidemiologist, because there is quit each lot of clinical matters that
6 come into screening issues and a lot of those I think are a bit hard to learn
7 "on the run" so to speak. Particularly the manner in which people interpret
8 information in the medical community etc., so I think that's important. The
9 statistics is important. Somebody's got to be able to produce these reporting
10 requirements. Somebody's got to look after a Screening Register etc., so
11 you need computing knowledge and cytology you obviously need – certainly
12 in terms of laboratory performance and its clinical meaning. And public
13 health is important to oversee all that, and I would say that since Dr Peters
14 has come into the programme at the beginning of this year to take over or to
15 also include aspects of the personal health, but since she's been involved
16 over the last 2 years it's been a quantum leap in terms of the ability of people
17 to liaise with the agency that's currently running the screening programme.
18
19 PROFESSOR DUGGAN: Good morning Dr Cox.
20 A: Good morning.
21 Q: While you are on the definitions I wonder if you could explain to the
22 panel the difference between a statistician and a biostatistician?
23 A: A biostatistician is essentially a statistician who particularly works with
24 health service data and clinical research and other aspects of health research.
25 There are some tools or methods of study that are used in those areas which
26 are not all that common in terms of the way statistics is applied in other
27 fields, and so a biostatistician will have particular special knowledge in
28 those particular areas. I should say actually a biostatistician – biology in

1 general in fact – there are many different methods used in terms of the study
2 of biological issues, so it gets into ecology and various other things. But in
3 terms of what we're used to, a biostatistician that I usually relate to is
4 working in the health sector, health area, health data.
5 Q: In terms of analysing data from the Registry is a biostatistician more
6 appropriate than a statistician?
7 A: In terms of – you mean the Screening Registry?
8 Q: Correct.
9 A: Yes. I think there are some advantages in having a biostatistician over
10 an above a statistician in that role. After a period of time, after about 2
11 years, I would expect them to learn sufficiently to be able to cope.
12
13 CHAIR: You'd expect a statistician to be able to learn sufficiently to cope?
14 A: After a coupe of years I would expect them to be basically equivalent.
15 Q: Could you say why you think a biostatistician is preferable to a
16 statistician in this area?
17 A: It's partly because of the – they're more used to looking at data that's
18 associated with, if you like, the natural history of disease or with disease
19 processes, and there are some of that learning if your like, or understanding
20 is required to make full use of the data in front of you. I mean, a statistician
21 that's adequately supervised by an epidemiologist would work as a good
22 combination as well. You can make up for a deficiency in one area by –
23 PROFESSOR DUGGAN: Would a biostatistician require supervision by an
24 epidemiologist?
25 A: I believe so. My experience says that's the case.
26
27 MRS MARSHALL: Dr Cox perhaps if we could then turn to another issue,
28 and this relates to the incidence of cervical cancer in NZ and in Tairawhiti. I

1 think you were present weren't you yesterday when Professor Skegg was
2 cross-examined.
3 A: Yes
4 Q: And I think he was directed to Mr duRose's exhibits, and perhaps if I
5 could ask madam registrar to refer to you exhibit 1 of Mr duRose, volume 1,
6 tab 1, p12.
7 A: Yes.
8 Q: And you will recall the discussion about this table yesterday and in
9 particular the rate of 30/100,000 that is attributed to Tairawhiti. Yesterday
10 Professor Skegg mentioned that you'd be in a position to comment further
11 on this rate and I wonder if you would do so, please.
12 A: The Tairawhiti rate in here is about 50% higher than the national
13 average. This rate has been compared with other countries, and I think
14 Professor Skegg made the point that there are differences in terms of the
15 way the rate's calculated because of the age groups that are included and I
16 have looked at the NSW Cancer Registry data that is published for 1998-
17 1992 and you can calculate an equivalent 20-69 world standardised age
18 adjusted rate for 100,000 which is what the final column is and for NSW it
19 comes to 16 per 100,000 so if we wish to compare New Zealand at about 20
20 if you like, there's a difference of 4 per 100,000 between us and NSW and
21 Tairawhiti is just under twice the NSW figure. I think Professor Skegg had
22 calculated that I calculate it the other way, I take this data and make it into a
23 0.85+ but I can't because the additional age numbers for other ages are not
24 provided.
25 Q: Dr Cox two more questions. You mentioned in your brief that you
26 are a member of the Health Funding Authority Advisory Group for the
27 Gisborne investigation. Have you read the brief of Mr Ron Jones which

1 covers the colposcopy examinations of women identified with abnormalities
2 through the Sydney re-read .
3 A: Yes I have.
4 Q: And Madam Registrar if you could perhaps refer Dr Cox to Mr Jones'
5 brief of evidence to table 5, there are no page numbers but it's about the fifth
6 page in.
7 A: Yes table 5.
8 Q: This table shows the comparison of the cytology and histology results
9 taken at the time of colposcopy. As an epidemiologist and public health
10 medicine specialist how would you interpret this table?
11 A: Well I find it interesting that there are 3 women with cancer out of
12 477 and if you include the CIN II and CIN III, I'll leave out the
13 AIS/glandular just for the sake of argument, you end up with 65 out of 477
14 women who have had high grade or cancer at biopsy from colposcopy that is
15 a consequence of the re-read exercise and some people may feel that that's
16 quite low considering these people had high grade re-read result or
17 whatever the precipitated colposcopal examination since May 1999 and this
18 particular population is, of all the women who've had if you like high grade
19 at the re-read, this particular population represents those that are most likely
20 not to have an abnormality because they won't have had a colposcopy
21 earlier, in other words they haven't had persistent disease that has come to
22 notice that in that group the proportion if you like of false positives is likely
23 to be highest, false positives at the original re-read, so that within this group
24 of women, and also there's been quite a great chance of regression with, I
25 think there are estimates of about 70% of even carcinoma in situ of the
26 cervix regressing back to normal over a period of 10 or 15 years and it's
27 slightly higher in younger women than it is in older women so the people
28 who've been brought back to colposcopy as a consequence of the re-read

1 are precisely the women who are most likely to end up with if you like, they
2 are quite likely to have a minimal abnormality and I just thought that if some
3 people interpret that as a rather low pick up rate as a consequence of the re-
4 read, they need to take that into consideration.
5
6 CHAIR INTERJECTS AND XXN WITNESS
7 CHAIR: Could you just elaborate on that what do you mean by a
8 minimum abnormality?
9 A: Well what I mean by a minimum abnormality in terms of there we
10 have a CIN I/HPB or normal because sometimes, I'm not entirely sure of
11 this and you'll have to ask the pathologist but the progression through the
12 low grade to high grade during regression, I'm not sure whether it
13 disappears altogether or regresses back through the low grade and back to
14 normal. I don't know whether that's been clarified by the pathologists or
15 not.
16 CHAIR: I see what you mean.
17
18 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
19 PROFESSOR DUGGAN: I don't think anybody has the answer to
20 that.
21 A: That's why I included it.
22
23 MRS MARSHALL CONTINUES XXN OF WITNESS
24 MRS MARSHALL: Finally Dr Cox I'd like to refer you to your brief
25 of evidence to paragraph 229 which is on page 61.
26 A: Yes.
27 Q: And the second sentence in particular I think relates to an issue that
28 was raised yesterday with Professor Skegg, it relates to a study that you both

1 published predicting the incidence of cervical cancer without organised
2 screening. You may recall that Professor Duggan asked Professor Skegg
3 about this yesterday and Professor Skegg said that you'd be in a position to
4 elaborate based on your calculations for this article.
5 A: Well in the article we projected likely rates of cancer into the future
6 taking into account that women under the age of I think about 35 or 40 at
7 that time had higher rates of cervical cancer and therefore a higher risk and
8 so we projected that the incidence rate and the mortality rate would increase
9 without improved screening from or since the late 1980's if there wasn't
10 improvement from say 1990 onwards then we'd have this increase and using
11 the more conservative projection, because we did make several projections
12 based on a few assumptions that were required because you tend to need to,
13 the figures in the projections in terms of absolute number of cases that
14 would develop and the absolute number of women who would die and
15 compared that with the current number of deaths and number of cases, to
16 calculate an estimate of how much there has been a reduction over what
17 would have been expected rather than just a reduction from if you like,
18 previous rates and so there is at least a 35% reduction in incidence of
19 mortality from cervical cancer compared to what was expected and I believe
20 a large amount of that is due to the National Cervical Screening Programme
21 and that a further reduction should be anticipated because often it takes 15
22 years for the full impact if you like of screening programme to flow through
23 in terms of reduced incidence and reduced mortality purely because the
24 screening programme is interested in picking up if you like high grade
25 disease which on average takes 12-15 years to develop into invasive cancer
26 anyway so this is the lay factor in terms of the prevention of the disease.
27 Q: Thank you Dr Cox. Dr Cox would now be pleased to answer any
28 questions.

1
2 CHAIR INVITES XXN
3 CHAIR: Thank you Mrs Marshall. Any questions? Mr Corkill, anyone
4 else, Mrs Sholtens. Very well are you agreed with order?
5
6 MRS SHOLTENS XXN WITNESS
7 MRS SHOLTENS: Good morning Dr Cox.
8 A: Good morning.
9 Q: You are currently the chair of the monitoring group that provides
10 monitoring services to the National Breast Screening Programme?
11 A: Yes, that's true.
12 Q: And you are also currently in discussions with Dr Peters relating to the
13 provision of monitoring services for the Cervical Screening Programme?
14 A: That's correct.
15 Q: And you are also, together with your colleague Dr Richardson,
16 undertaking the formal evaluation of aspects of the screening programme for
17 the Ministry of Health?
18 A: Yes, I'm responsible for that, we have several staff involved.
19 Q: I just want to ask you a few questions about that evaluation process.
20 A: Yes.
21 Q: The process was initiated in 1996 within the Ministry, wasn't it?
22 A: I believe so. At some stage they began an interaction – I think they put
23 out an EOI at the end of 1996, an expression of interest.
24 Q: So basically a request for a proposal went out for the community of
25 interest?
26 A: I think it might have been advertised in the newspaper.
27 Q: And you and your group submitted an indication that you were
28 interested in providing some assistance here?

1 A: Yes.
2 Q: the evaluation was intended to be in two stages, do you recall that?
3 A: Yes, we were to develop an evaluation plan and then after consideration
4 I think the Ministry were going to then choose or decide what they wanted
5 evaluated.
6 Q: And the initial request for a proposal was for that stage one
7 A: Yes.
8 Q: So to prepare a plan of the evaluation?
9 A: that's right, an evaluation plan.
10 Q: And your group won the tender, effectively, to prepare that?
11 A: Yes.
12 Q: Plan for the evaluation?
13 A: Yes.
14 Q: and you signed a contract for that early in 1997, 28 January?
15 A: Yes.
16 Q: You provided a draft evaluation plan in June 1997?
17 A: I think it's my recollection.
18 Q: I think we have that document in evidence, that's Ms Glackin's exhibit
19 47 in volume 9.
20 A: I'm quite happy to take your word on it.
21 Q: Can I actually ask you to have a look at that because it raises a number
22 of questions I want to clarify with you. Volume 9, Exhibit 47. That
23 document is referred to as a draft evaluation plan.
24 A: Yes.
25 Q: And in fact it took some time to finalise, didn't it?
26 A: It did take a little bit of time, yes. I believe it's partly because – well
27 the draft I think was then sent out – if I recall was sent out to other groups
28 and some feedback on the plan was received and then we had the task of

1 incorporating the feedback into a final document for the Ministry. I mean,
2 the plan involved reasonably wide consultation around NZ with various
3 groups of people, including a hui at the Rangitahi marae in the Bay of Plenty
4 etc.
5 Q: So the evaluation plan when it was finalised, decisions then had to be
6 made about what matters were the subject of evaluation, moving to 2?
7 A: That's right.
8 Q: And there was an issue about how much the programme could afford to
9 evaluate wasn't there?
10 A: There probably was an issue - that wasn't my issue.
11 Q: what the Ministry did was they consulted about what various
12 stakeholders thought were the priorities for evaluation?
13 A: I believe that is the process they went through. It also occurred at a
14 time, during a time when the programme was moving or to be moved from
15 the Ministry to the Health Funding Authority and I believe there may have
16 been a difference of opinion between the Ministry and the Health Funding
17 Authority in terms of either the value or the nature of the evaluation plan
18 that had been prepared.
19 Q: And in the end the Ministry retained responsibility for seeing this
20 process through?
21 A: Yes.
22 Q: Are you aware that as a result of consultation by the Ministry there was
23 little consensus about what matters were a priority for evaluation?
24 A: To me it went into a black hole. I mean, I –
25 Q: You don't know what happened between then?
26 A: We just waited. We got on with some other things.
27 Q: Right. Then decisions were made that 3 particular aspects of your
28 evaluation plan should be evaluated?

1 A: Yes, that's right.
2
3 CHAIR: I wonder if I could just interrupt Mrs Sholtens, because we are
4 right at a point where I'd like to get some clarification myself. If the
5 witness could be shown Glackin's brief of evidence, p113, para 369, which
6 deals with this issue from her perspective.
7 MRS SHOLTENS: This is in exhibit 47 ma'am.
8 CHAIR: No, her brief of evidence. If you would read that para, that is Ms
9 Glackin's evidence setting out the Ministry of Health's perspective on the
10 draft evaluation plan that you completed in June 97, which I believe is the
11 document at Glackin 47.
12 A: Is this para 369?
13 Q: Yes. At para 369 Ms Glackin is saying that the estimated costs of a
14 complete evaluation well exceeded the funding available and so it was
15 decided to request stakeholders views on the priorities for evaluation. First
16 question I would like you to answer Dr Cox is, given the draft evaluation
17 plan that you had prepared, which is a fairly substantial document which by
18 my reckoning goes to 147 pages all up, firstly from the perspective of doing
19 a full evaluation of the Cervical Screening Programme do you think that it
20 was appropriate to decide not to go ahead with the complete evaluation but
21 to instead focus on certain priorities for evaluation; in other words, how
22 essential is everything in your draft evaluation plan?
23 A: Well, they end up having to put relative weights on different things
24 which is the process they did because they were unable to fund all of it, in
25 fact I would say that I'm pleased that they didn't come back and say yes to it
26 all and we'll give you that amount of money because actually looking back
27 on it now I think there was a lot more work than we anticipated in doing the
28 complete plan so in terms of the things that they chose –

1 Q: Well what I'm first interested in is hearing from your perspective, my
2 understanding is that this would have been the first thorough examination of
3 the screening programme is that correct?
4 A: Yes.
5 Q: Now from your perspective as one of the designers of the study how
6 essential was it in terms of the integrity of the programme for the full
7 evaluation plan to proceed as you had first envisaged in June 1997, that's
8 from your perspective how important was it?
9 A: I think it was very important and I think almost all aspects of the
10 programme needed evaluation at that time. There were some issues that
11 were part of the evaluation about if you like health service structure which
12 was changing and you can't change the health service just to get the Cervical
13 Screening Programme right, it's not that big an issue although it is a major
14 issue and so it may not have been appropriate at that time if you like to go
15 through in great detail the structural part of that evaluation because the
16 structures were being imposed anyway, it would have been a waste. But
17 apart from that I think all aspects of that plan were.
18 Q: Except taking into account the new proposed health structures, given
19 that they would have an impact on the delivery of the programme, would it
20 not have been worthwhile to make an assessment of those structures to test
21 whether or not ultimately the programme would function effectively within
22 the new structures or whether it ought to be set out as a stand alone body in
23 the way that you have now suggested in your brief of evidence?
24 A: I agree with your point, I think it would have been useful.
25 Q: So that would have been worthwhile too.
26 A: It would have been.
27 Q: So that I can get a fully standing then of your draft evaluation plan,
28 could it be said that this was a Rolls Royce plan that was aiming to achieve

1 too high an ideal in terms of evaluation or was it just a very sensible plan
2 that needed to be fully implemented in order to be sure that the programme
3 was working effectively?
4 A: I don't consider it a Rolls Royce plan. One of the issues has been that
5 there was an under-estimation of the requirements of an organised screening
6 programme in New Zealand after Cartwright. The quantum leap was needed
7 and some people never made it and I don't believe this is a Rolls Royce
8 evaluation, it's an extensive evaluation and at the time some of it I must say
9 was even suggested as part of the EOI, as part of the expression of interest
10 that things should be included by the Ministry itself in the first place and I
11 think it was then the cost that they went oh how can we manage this now
12 and so that they then if you like picked off things that they considered
13 essential or more essential than others given the budget they had.
14 Q: In your view though was everything in the draft plan essential?
15 A: Yes virtually everything, I mean yes everything.
16 Q: So in your view was this a circumstance where the budget should
17 have been increased to allow the draft evaluation plan to proceed as
18 originally planned.
19 A: Sorry I missed the first part.
20 Q: In your view should the budget have been increased, you'll not at
21 paragraph 369 Ms Glackin is saying that the complete evaluation exceeded
22 the funding available so should the budget for the plan or the funding for
23 the plan have been increased to allow the draft evaluation to proceed?
24 A: I believe so and I believe the legacy of the one off cost was because
25 things had not been done in a staged manner in the earlier years and so that it
26 then hit someone's annual budget as a large item.
27 Q: In paragraph 370 Ms Glackin sets out there how after there was the
28 consultation on priorities which was inconclusive, there was a decision taken

1 on advice of CSLAC to concentrate on three aspects that would highlight
2 safety and quality assurance. Do you think that it was sufficient to
3 concentrate on the three aspects set out in paragraphs 370.1 to .3 rather than
4 all the other aspects in your draft evaluation plan?
5 A: I would say if you had to start making choices about the 14 different
6 components of the draft plan or the evaluation plan, these are very
7 reasonable priority areas. I would quality they're little in terms of the
8 aspects of structure that you mentioned before which would involve issues
9 of staffing.
10 Q: Yes.
11 A: Are not included here and I can understand from the Ministry's
12 perspective why they may not wish them to be there.
13 Q: But would those issues of staffing and structure have an impact on
14 the programmes effectiveness in your view?
15 A: Yes.
16 Q: So just to sum up your evidence is that the choices that were made,
17 although reasonable priority areas in your view the entire plan should have
18 proceeded.
19 A: Yes.
20 Q: Thank you.
21
22 MS SHOLTENS CONTINUES XXN OF WITNESS
23 MS SHOLTENS: Those 3 aspects that were decided as being the
24 priorities, in your evaluation plan I think the 1st one the assessment of
25 registered data, you estimated would probably take about 2 months.
26 A: That's true.
27 Q: And the 2nd one the assessment of the appropriateness of follow up
28 and treatment you thought would probably take 6 months.

1 A: That's true.
2 Q: And the third one audit of screening histories and treatment of
3 women with cancer, that was one where you observed that it would
4 possibility take 18 months but that may be depended on ethical approvals.
5 A: Yes I mean both the others are also dependent on ethical approval as
6 well but there are specific aspects about that listed under 370.3 that I thought
7 were likely to require a little bit more discussion with the Ethics Committee
8 than the others.
9 Q: Right. And the draft evaluation plan discusses those issues doesn't
10 it?
11 A: It's a while since I read it but I believe it does.
12 Q: One the Ministry had decided to proceed with those three items, it
13 then was required by the usual rules that apply to spending public money to
14 go through another tender process wasn't it?
15 A: Yes.
16 Q: And so it issued another request for proposals and you submitted an
17 expression of interest.
18 A: Yes.
19 Q: And that was in about Sept/Oct of 1998.
20 A: Yes.
21 Q: Then the tender documents were issued at the end of 1998.
22 A: Yes I believe so.
23 Q: Tenders, including one from your group, were received at the end of
24 February in 99?
25 A: Yes.
26 Q: Then there was some negotiation before the final contract was signed in
27 May 1999?

1 A: Yes.
2 Q: Now since then you and your group have been working on these 3
3 aspects?
4 A: Yes.
5 Q: You report 3 mthly to the person who's identified as the person who
6 you report to?
7 A: Absolutely.
8 Q: And issues relating to the potential for a need for regulations were
9 identified late last year surrounding access to register data?
10 A: Yes.
11 Q: that's the first time those issues were raised, wasn't it?
12 A: I believe so.
13 Q: While there was always an understanding that ethical approval raised
14 issues that would need to be dealt with, it hadn't occurred to yourself or the
15 people that you had been negotiating with that their might be a need for
16 regulations as well?
17 A: No, that's true – didn't anticipate that.
18
19 CHAIR: Did the Ministry of Health officials have any idea of the impact of
20 s74A of the Health Act on your project?
21 A: I don't believe they did, I think it was a surprise to them as well, but
22 you'd have to ask Ministry officials.
23 Q: That was the impression they gave you from your dealings with them?
24 A: That's the impression that I had.
25
26 MRS SHOLTENS: Thank you Dr Cox, I have no further questions, ma'am.
27

1 XXN MR CORKILL:
2 Q: Dr Cox, can you please go first to volume 6 of Glackin, tab 26, which is
3 the first statistical report which I think you and two others were involved in
4 the preparation of.
5 A: Yes.
6 Q: Now this covered data up to May 1992?
7 A: It did, excluding the Wellington Area Health Board region.
8 Q: Because?
9 A: the Wellington Area Health Board Ethics Committee declined the
10 release of aggregated data – i.e. non-identifiable tabulated data – to the
11 Department of Health at the time for inclusion into this report.
12
13 CHAIR: Could I just be clear about this because I picked that up from your
14 evidence. Did that mean that for the purposes of preparing the statistical
15 report for the national programme you had to go to every Ethics Committee
16 relating to ever Area Health Board to get approval?
17 A: I'm not entirely clear of the process. I don't think we did. The
18 Department of Health was pursuing collecting the data; in fact it was John
19 Brackenbury who was contracted to work within the Department of Health
20 at the time who was looking after the establishment of the Cervical
21 Screening Registers around the country who sought to extract the data from
22 the regional registers, put it on one computer in Wellington so that we could
23 do this particular report. And I don't know the process that they went
24 through to extract the data in terms of approvals.
25 Q: Just to get a better understanding of what you had to go through to
26 prepare this first report because of the 14 separate registers you had to in fact
27 take information from those registers and then put them on a separate unified
28 database?

1 A: Yes, John Brackenbury did that. The Register was set up so that the
2 common software platform also provided a facility for extracting the data
3 from the individual registers in a unified manner.
4 Q: So it wasn't essential to have the separate database then, you could have
5 just gone into the 14 national registers?
6 A: My discussions with John Brackenbury suggested that it was
7 cumbersome, somewhat awkward but could be done, and we did it for the
8 purposes of this particular report in 92.
9 Q: which was cumbersome, the setting up of a separate register or going
10 into the 14?
11 A: I think it was cumbersome logistically, I'm not sure it was that
12 cumbersome from a computing point of view but it may have had some
13 difficulties there as well, because we were aware that at the time that the
14 separate registers were being set up with a common software platform
15 occasionally someone locally would do something to the software because
16 they felt that it didn't quite fit their requirements and they really wanted to do
17 something with it a little different.
18 Q: So the cumbersome approach would have been if you hadn't set up your
19 own database but instead just gone into the 14 separate registers?
20 A: Yes I think the setting up of the database centrally, if you like you've
21 got more control over it, so you can actually sort out the problems quicker
22 and as soon as there's an issue you can sort it out quicker. It takes a bit of
23 time.
24 Q: if the Register had been set up as a single register at that time would it
25 have made your job easier?
26 A: Definitely.
27

1 MR CORKILL: At that stage the programme was opt-on?
2 A: True.
3 Q: Was that a limitation in terms of the statistical analysis, particularly of
4 laboratories, that was carried out in this report?
5 A: It meant that you couldn't firmly genrealise the information to all the
6 other women who were having cervical smears, who were not in the
7 screening programme. And because you had a relatively low proportion
8 who were actually enrolled in the programme, you couldn't be sure that there
9 was something special or different about those women compared with all
10 women who were having smears, so it became more difficult to generalize
11 the results to the population on the screening at large.
12 Q: Please turn to p20 of the report, table 8, it's the average proportion of
13 cytology reports for certain cytological categories. We have there under no
14 abnormality a range for hospital laboratories 64 to 88 and community
15 laboratories 67 to 97%.
16 A: Yes.
17 Q: And I think at p23 of the report in the comments section you drew
18 attention, third last sentence of the para, to this wide variation in reporting
19 between laboratories, is that correct?
20 A: Yes. Can I comment about the figures in the table, table 8.
21 Q: Yes, please.
22 A: I must admit that at the time I was interested in the amount of short
23 interval re-screening that may have been occurring regarding screening
24 frequency, but was somewhat surprised that at least one community
25 laboratory had reported 97% of their smears as having no abnormality. We
26 did try to restrict I think I did restrict the laboratories that were included in
27 this table in the sense that - I forget what figure I had, if they had less than
28 so many hundred smears processed I think I dropped them out of the range

1 because I didn't think it was fair to include them because they may have been
2 outliers by chance, if you like, because the pattern wouldn't have established
3 itself. And I was also interested that there were some laboratories where
4 36% if you like, or 33% depending which figure the hospital community row
5 you look at, had at least some abnormality – whether it be infection,
6 inflammation or any of the other neoplastic conditions reported.
7 Q: Now just putting that to one side for a moment and going on to the
8 second statistical report, which is volume 7, tab 37 –
9
10 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
11 PROFESSOR DUGGAN: Dr Cox just from an epidemiological
12 viewpoint this range in the reporting rates what did that mean to you?
13 A: The commonest mistake that's made that people's reporting rates are
14 looking at things by percentage of smears rather that percentage of women
15 and I acknowledge that this particular table is by percentage of smears and it
16 was intended to actually have two tables, both this table and a table similarly
17 presenting percentages of women. John Brackenbury was completing a
18 contract in the Ministry of Health, he was contracted in to specifically look
19 after the establishment of the Screening Register within the Area Health
20 Boards and he was leaving I think within about 6-8 weeks and felt that he
21 didn't really have time to do the computing, it's a slightly more technical and
22 complicated actually in terms of screening data set to present data per 1,000
23 women or as a proportion and so we didn't actually complete it and it was
24 important I thought to at least have one table that looked at laboratory ranges
25 of some sort to if you like flag the issue and I thought that would be
26 sufficient to at least start discussion about variations in laboratory practice
27 and the committee of public accounts, the second report in the UK, it
28 identifies that reporting rates tend not to follow patterns of disease in terms

1 of cervical cytology reporting and variations in reporting rates are more a
2 matter of variations in practice in pathology practice than they are in terms
3 of the underlying nature or prevalence of the disease in the population so I'm
4 not sure, I've almost lost your question sorry.
5 Q: That's OK I think you've answered it.
6
7 MR CORKILL CONTINUES XXN OF WITNESS
8 MR CORKILL: Volume 7 tab 37 is the second report which you did not
9 participate in the preparation of is that correct?
10 A: Where are we.
11 Q: Glackin exhibit 7, tab 37 but if we go to the same table at page 22 of
12 the report, again we have a wide variation for no abnormalities for both
13 hospital and community laboratories.
14 A: That's correct. In the 1st report we developed a hierarchy of the
15 reports of smears that were included in the comparative table a similar table
16 that was in the 1st report so that, because within the Screening Register data
17 set more than one Bethesda code for a particular smear is recorded, some up
18 to 6 different codes, that's extremely rare, but there are quite a proportion
19 with 2 or 3 Bethesda codes associated with a single smear and so you could
20 have for example a smear that had, and I'm not entirely sure whether this is a
21 combination that's compatible with a clinical situation but for example could
22 have atypia and high grade so you end up with two codes and we developed
23 a hierarchy where if you like the high grade would be taken as the result of
24 the smear rather than the atypia and it's been reported to me that this
25 particular table in the 2nd report doesn't have that hierarchy but I'm not sure,
26 I don't think it's stated anywhere that the same hierarchy as used in the 1st
27 report was actually used in the 2nd report so the averages if you like,
28 percentages for atypia low grade and all the other abnormalities of various

1 descriptions are not strictly comparable with the 1st report in my view but the
2 one thing that is comparable if you like is the no abnormality column and I
3 was unhappy that the gap had not closed in terms of the width of the
4 variation in reporting the proportion with no abnormal between the 1st and
5 2nd report when this came out.
6 Q: Again in the comments section on page 24 of the report, the same
7 observation is made as had been made at the end of the 1st report, namely
8 this report has established that there is wide variability between
9 laboratories. Do you see that at the start of the 2nd paragraph.
10 A: Yes.
11 Q: Are you surprised that no attempt to deal further with this variation
12 beyond making that simple comment is evident in this report given that it is
13 precisely the same comment in the 1st report.
14 A: Yes I'm very disappointed by that and there was considerable delay
15 between the 1st and 2nd reports anyway, a matter of 2 years at least and I
16 would have expected some comment about what had been done in the
17 previous 2 years to try and look at this variation further and what was
18 anticipated in the future in terms of addressing this particular issue.
19 Q: So in other words this issue had come up twice in two statistical
20 reports, it called out for attention.
21 A: Yes it had basically been present since 1991 through to at least 1994
22 without obvious redress in this particular document.
23
24 CHAIR INTERJECTS AND XXN WITNESS
25 CHAIR: Who was the person, because I am aware that you were a
26 member of CSLAC and part of CSLAC's role was to advise the Ministry on
27 monitoring and evaluation of the programme, to the best of your knowledge
28 who was the person who would have had the responsibility for reading the

1 statistical reports and recognising something like this fact that Mr Corkill
2 has raised in questions with you?
3 A: The process that was chosen in terms of, if I recall in terms of
4 discussion at the cervical smear advisory committee meetings subsequent to
5 the first report when we discussed it was that the matter needed to be
6 referred to CALC and most pathology issues when they arose, I can't say all
7 because I can't remember them all but the great majority, most pathology
8 issues were referred by the Ministry to CALC for discussion/comment or
9 recommendations I believe.
10 Q: And then who had responsibility within the Ministry to the best of
11 your knowledge to follow up with CALC to see what recommendation it had
12 and then who would be responsible within the Ministry for deciding whether
13 or not to accept the recommendation and to do something or not to do
14 something?
15 A: The National Cervical Screening Programme co-ordinator would be
16 the first person who would receive that information and receive a
17 recommendation and I would expect that person to have discussed it with
18 their immediate superior if you like within that hierarchical structure at the
19 least, specifically issues of this nature which are relatively serious and of a
20 clinical nature, they would have needed some sort of medical input into
21 interpreting the information and what might be done about it I would have
22 thought.
23 Q: So without that medical expertise was there a possibility that
24 someone might not realise the importance of this issue?
25 A: Yes absolutely. The thing is the difficulty has been over a long
26 period of time because of the relative lack of expertise and experience of
27 screening within the Ministry or before that the Department of Health and I
28 must say to some extent within the Health Funding Authority now to fully

1 appreciate the importance of some pieces of information over and above
2 other pieces of information and if you like see the wood from the trees.
3 Q: Yes. And then my understanding is given that the delivery of the
4 programme was being handled by Area Health Boards and then later by
5 RHAs and CHEs. The national co-ordinator within the Ministry of Health,
6 even if she had recognised the importance of the problem, would then have
7 had to have persuaded those bodies who were the bodies who were actively
8 involved with the laboratories to do something; is that right?
9 A: Well I think first of all they would have to persuade their immediate
10 superiors to some extent, then there would have been an issue about the way
11 the Ministry or Department interacted with the Area Health Boards, which is
12 not an area I'm very familiar with at all. And the regional co-ordinators
13 were employed by the Area Health Boards, initially through tagged funding,
14 and it was quite difficult even when the money, if you like, was tagged by
15 the Ministry I believe, for the full amount of money that was put to the Area
16 Health Boards to sometimes always been spent in the area of cervical
17 screening. Then there was no longer tagged funding – I think it was after
18 the first 3 years, and the health reforms process came in and then the ability I
19 think of the Dept or the Ministry to influence matters became even loser.
20 Q: and in terms of this issue you've raised of the ability of someone
21 receiving the information to fully understand the implications of the
22 information received, given that screening is something that is done to a
23 healthy population really with a view to trying to ensure that disease does
24 not develop rather than treating someone who was already ill, does that
25 require a different understanding of health issues?
26 A: I believe it requires a different level of quality assurance of the service
27 provided by a quantum. I'm not sure what magnitude I would put on it.
28 The usual situation where someone presents to a Dr with symptoms is that I

1 think it's been put by Cochrane and Holland in 1971 – I probably won't say
2 it exactly right, but essentially the Dr does the best he/she can with the
3 knowledge available and is in a position, if you like, to try things that might
4 work where other remedies have failed, providing that they're reasonably
5 sure that it's not going to severely harm the patient because they're trying to
6 make the person better. But if you invite people to come into a screening
7 programme you have a different ethical responsibility to ensure that what's
8 provided is on average beneficial and that the benefits outweigh the harms
9 on average. And because of that, and also because of the fact that patients
10 who have symptoms and signs – even if you like the test is wrong or
11 something goes awry, there's a signal for that patient, because their
12 symptoms haven't got better, they don't feel better so they come back.
13 CHAIR: Yes.
14 A: And so they may come back after a delay, and the delay is unfortunate
15 and sometimes very critical, but they will come back. And that gives, if you
16 like, the health service another go at getting it right. In screening situations
17 the great majority – well, people are asymptomatic, they don't have
18 symptoms or signs, they come along often actually to be reassured that
19 they're ok rather than to come along to have something found. You get one
20 crack at it, which is the test. And if you miss it at the test, then by the time
21 they come through – you may get another go because you're screening
22 frequency, you may have them routinely coming back in an interval so that
23 you actually get another go at actually detecting the condition in a major way
24 in the way cervical screening actually works. But there's no cue from the
25 patient to come back if something's wrong because they don't have
26 symptoms. So you get one go at the test and therefore there's a greater need
27 for a higher level of quality assurance and sometimes clinical audit, in terms
28 of the care of those people.

1 Q: so in that sense screening programmes are unique and require a
2 different approach than general treatment of patients?
3 A: I believe so and I think that's why in many areas you can't rely on what
4 has been, if you like, historically and traditionally the usual level of clinical
5 audit or quality assurance, that you actually have to put in special processes
6 over and above that to improve the quality assurance process to a greater
7 degree.
8 Q: And also a false negative smear test in those circumstances could in
9 fact by falsely reassuring. We have for example the evidence of Mrs Ward,
10 I think it is, and we can go to her evidence where she presented to her GP
11 with signs which could indicate cervical cancer but initially she was told that
12 her smear test was normal and so other factors were looked at instead. We
13 shall go to those notes just to check. Could we have the patient's notes
14 please Madam Registrar.
15 MR CORKILL: Patient 7.
16 CHAIR: Yes, patient 7.
17 MR CORKILL: Para 6, ma'am.
18 CHAIR: Yes, para 6 of Mrs Ward's evidence shows the symptoms she
19 presented with then.
20
21 PROFESSOR DUGGAN: Dr Cox on p6 there is a table that summarises
22 her pap test.
23 MR CORKILL: Page 9 of the brief, Madam Registrar.
24 A: Yes, we're getting there, thank you very much.
25 Q: Are you looking at a table?
26 A: Well I can.
27 Q: I prefer a table myself. The first row is a 1975 smear which pre-dated
28 the screening programme, so her next smear is 1995, and if you go over to

1 the third column there is a smear read by Dr Bottrill's laboratory as normal,
2 some blood present, repeat normal interval was the recommendation. So she
3 came back almost a year later, a year plus a month it would appear. In 1996
4 had a smear read by a pathologist called Padwell, and this was reported as
5 blood stained smear no other abnormalities seen, with a management
6 recommendation of repeat in 3 years. Would you agree that this would
7 appear to be an adherence to the programme's guidelines, i.e. you take 2
8 smears 12 months apart and then if there's no abnormality you go on a 3 year
9 screening interval?
10 A: Yes, I would agree with that, except that did the woman have symptoms
11 at this time?
12 Q: She had, in 1996.
13 A: She did suffer from discharges at the time of the 1996 smear and was
14 taking antibiotics and using cream it says.
15
16 CHAIR INTERJECTS AND XXN WITNESS
17 CHAIR: Dr Cox at the time the smear was taken in 1996 there was a
18 blood stained smear, is not bleeding from the cervix one of the signs of
19 cancer.
20 A: Well although I'm a registered medical practitioner I haven't been in
21 the clinical area for some time but it is one of the signs but there are many
22 other common causes of bleeding.
23 Q: Actually if you look at her medical notes which are not numbered but
24 if you find the second smear test which is by Gisborne hospital.
25
26 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
27 PROFESSOR DUGGAN: Dr Cox this particular smear was taken by
28 a nurse smear-taker and this is the smear on August 96 which was the smear

1 read by Padrol and read as negative with a management recommendation for
2 repeat in 3 yrs and if we read the notes from the smear-taker it said bled
3 prior to any sampling, no obvious lesion, I think multipus means
4 multipurous cervix with an ectropian visible. The last smear bled after
5 spatula but normal smear in 95 which was her first smear in 15 years. She
6 was 49 years old at this point. Her complaint was of discharge and irritation
7 in the last week which was worse at night and the smear-taker noted thick
8 white discharge and redness at the entroitus and the smear was taken with a
9 spatula and a brush and the specimen was noted to be heavily bloodstained.
10 A: Yes well my understanding, as I say I haven't worked in the clinical
11 area for a long time, but bleeding at the time of sampling is a clinical sign
12 and –
13
14 CHAIR INTERJECTS AND XXN WITNESS
15 CHAIR: Of what, of cancer or?
16 A: Well it's unusual and my understanding is that that is one of the
17 possibilities and that's why it's a clinical sign so at that point if you like the
18 woman had a clinical sign of cancer in my understanding.
19
20 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
21 PROFESSOR DUGGAN: So if there were clinical signs or
22 suspicions of cancer it should have triggered some other action?
23 A: My understanding is that is the case. It should have triggered referral
24 or I would have thought not discussion with the doctor but I would have
25 thought the doctor himself or herself may have wished to repeat the
26 examination in the first instance. I would have thought that would be an
27 indication for referral.

1 Q: We of course can't take this any further because we have limited
2 clinical information here.
3
4 CHAIR INTERJECTS AND XXN WITNESS
5 CHAIR: If you go back to the table on page 9 you will see there that in
6 the previous year in 1995, again with some blood present, and on rereading
7 of that smear it was found to be CIN III refer to colposcopy. The smear in
8 96 that we've just been discussing with you has not been re-read as that was
9 done by a different laboratory and is not part of the re-read exercise but I've
10 just put this case to you to see whether in your opinion it provides an
11 example of a circumstance where a reliance on the result of a smear test and
12 being part of a screening programme can in fact give a patient false
13 reassurance in the sense that it appears that the clinical signs that cancer
14 might have been present don't appear to have been followed up.
15 A: Yes and this is a particular case where a clinical sign becomes
16 apparent at the time the smear is taken and I would have thought it was
17 unlikely to have been relayed to the patient and the false reassurance comes
18 from two sources or at least two sources. One when a smear is negative,
19 when there's disease present and secondly there is false reassurance also to
20 the doctor if there is signs or symptoms I think there are unfortunately a few
21 examples and in New Zealand there are a few examples where the doctor
22 has obtained false reassurance from a normal smear as much as the patient
23 and some of those cases have come before the medical disciplinary
24 committee from time to time.
25 Q: And so in that sense does that underscore the need for very good
26 quality assurance of a screening programme so that you would attempt to at
27 the very least reduce the chances of these falsely reassuring events
28 happening.

1 A: Yes I think come clinical audit of those that are if you like
2 histologically shown to either be high grade or invasive disease does allow
3 you to start examining that component if you like which appears to be due to
4 the cells not even getting on the smear, that component is to do with the
5 laboratory reporting and that component that may be due to other matters
6 associated with the clinical management of the patient both at general
7 practice level and the gynecological level or any other health professional
8 that's' involved.
9 Q: From what you've seen of this patient's notes just now, I can also say
10 that the patient developed cervical cancer and in fact in a period of time
11 between the first period and the second hearing of this inquiry, she died.
12 Do you consider that this would be the sort of case for which there ought to
13 be a complete clinical audit of this patient's treatment and history?
14 A: Yes and it would be good to be conducted along with others. I don't
15 know what the practice of the clinicians is but some clinicians will go
16 through and look at the audit of the way the patient came to their attention
17 and what might have been done to improve matters, either of sample of their
18 patients or all of their patients, particularly those developing invasive cancer
19 and that has historically been a part of the work of the medical practitioner
20 though I do understand that they do need to have set aside time to be able to
21 do that.
22 Q: Yes but would it also be, my understanding of your evidence from
23 reading your evidence and exhibits attached is that as early as 1989 when
24 you were on the Ministerial Group or the expert group you were saying that
25 there was a need in every case of a death from cervical cancer to go back
26 and look at the smear history of the woman in order to ensure that the
27 programme had been operating effectively.

1 A: Yes and it's more than the programme in the sense that the
2 programme concentrated a lot on up to the point of diagnosis of invasive
3 cancer but actually never got into assessing the management, apart from
4 producing guidelines for the management of abnormal smears and certainly
5 never got into the area of the treatment of women with invasive cervical
6 cancer because if you are talking about mortality then there is a possibility
7 that treatment may not necessarily be optimal even after diagnosis so that
8 the whole pathway if you like then should be reviewed and as you say all
9 cases, we don't have that many cases a year in New Zealand but that is
10 logistically difficult.
11 Q: And from the perspective of trying to determine whether or not there
12 is a systemic problem within a Cervical Screening Programme on this issue
13 of the smear tests being falsely reassuring to the patient and to the patient's
14 clinician, and audit such as this could be helpful because it at the least would
15 ensure that you could follow through with education to clinicians to ensure
16 that they were aware of the importance of not simply relying on a smear test
17 result.
18 A: I think it's an essential activity of the programme in an ongoing
19 manner.
20 Q: Thank you. We've gone beyond the morning break. We'll now
21 adjourn until 11:25.
22
23 INQUIRY RETIRES FOR MONRING ADJOURNMENT
24 AT 11:11 UNTIL 11:25

1
2 INQUIRY RESUMES AT 11:30 A.M.
3
4 MR CORKILL: Dr Cox, we were dealing with the statistical reports, and
5 we're looking at the second of those. Is it your understanding that the data
6 upon which the second statistical report was based was cumulative – i.e., it
7 included the data on which the first statistical report was based?
8 A: That's my understanding.
9 Q: is that a limitation in terms of the material presented in the second
10 statistical report?
11 A: Yes, there was an opportunity to look at what had changed over time by
12 breaking it into the different years, and in particular there was an issue about
13 whether things had changed a lot when the opt-off legislation had been
14 passed and that the practice of enrollment was associated to opt-off rather
15 than opt-on. Now I'm not sure whether it's this report or the next report that
16 covers that period, but certainly by looking at it by individual years you get
17 an idea of what things were increasing significantly and things were
18 decreasing significantly and what was staying the same, in rough terms.
19 Changes are often the thing you want to pick up first. The cumulative
20 report, if there's a major change, say in the last year, you just wouldn't see it
21 because you're just looking at the cumulative data over the 4 year period.
22 You are unlikely to see it I should say.
23 Q: the first report was the period through to May 92 and the second report
24 was carried on through to June 94.
25 A: Yes. I've just noticed there are some tables within the body of the
26 statistical report which are specific to a calendar year, but there's no – there
27 doesn't appear to be any assessment of things that might have changed over
28 time. Certainly not in any extensive manner.

1 Q: now at para 93 of your brief you say that from the time that the first
2 statistical report was published in 1992 it became possible to conduct inter-
3 laboratory comparisons of cytology reporting of the results for women in the
4 programme but this required extraction of data from the separate Screening
5 Registers and collation upon one computer.
6 A: Yes.
7 Q: Was that ever considered?
8 A: After the first statistical report I cannot recall any contact between the
9 Ministry or the Department of Health and myself about statistical reports
10 after the conclusion or the acceptance of the first and the production of the
11 second. So the second, when it was produced it was actually news to me, it
12 just sort of came out of the blue. I'm not sure I can answer the question.
13 Q: Thank you. Coming on to the third report and your involvement in
14 that, you have put in evidence as exhibit 38 to your exhibits, which is your
15 volume 2, you've put in a paper that you prepared in relation to comments
16 for the third statistical report. If you go to a tab that says 35 to 42, then you
17 go to an interleaver which has got 38 on it, within that interleaver.
18 A: Thank you.
19 CHAIR: What exhibit is this Mr Corkill?
20 MR CORKILL: I'm in volume 2 of Cox exhibits, it's interleaver 38.
21 CHAIR: Is this the third statistical report?
22 MR CORKILL: No, this is the Cox exhibits, not Glackin any longer, and
23 I've asked the witness, Madam Chair, about his involvement in relation to
24 the third report and the evidence is this, some comments that he prepared in
25 this document. Now Dr Cox, what were your main concerns at that stage in
26 terms of the anticipated format of the third report?
27 A: Well I think the second and the third reports just continued on a
28 template, if you like, that was initially established under the first report

1 without further developing the possibilities in terms of the information
2 within the screening programme. At this particular time there'd been quite
3 some discussion about histology and I believe that there was difficulty in
4 getting the histology captured onto the Register and a lot of it may have been
5 in paper form. However, the programme had not done the sort of analysis,
6 extensive analysis that was really the data was begging for I might say in
7 terms of providing information to the programme that would be useful in
8 terms of monitoring and evaluation. And I made several points, in
9 particular I referred them to the ?(inaudible) against cancer programme
10 guidelines, which I think were discussed a little bit today.
11 Q: Can we just take that up. If we go to p8 on that document, half-way
12 down under "further comments" you say there "an additional section should
13 also include some comparison by what parameters are available for the NZ
14 programme with the EACP guidelines and the Iceland and other
15 programmes, Victoria Australia experience. The EACP guidelines are the
16 European guidelines that you've referred to in your brief several times?
17 A: Yes.
18 Q: I think you said that you initially forwarded the European guidelines to
19 the programme in July 1994.
20 A: Yes, I believe that to be the case, and I would have thought that this
21 was a great opportunity to see how much of the European guidelines, or
22 other people's guidelines, the screening programme could produce
23 comparable data so that we could compare NZ with, if you like, these
24 various international benchmarks to see how we were going in identifying
25 areas where we needed improvement or areas where we needed to collect
26 data that we weren't currently collecting.
27

1 CHAIR: Dr Cox I would just like to ask you something now about the
2 guidelines, i.e. I have seen the guidelines which you are producing as an
3 exhibit. It hasn't actually been given an exhibit number.
4 MR CORKILL: We could do that now ma'am.
5 WITNESS: I would like to know which ones they are because I have
6 suggested several things over the years.
7
8
9 [Exhibit BC/CS/0044] – the European guidelines]
10 [Exhibit BC/CS/045 – Quality assurance and cervical cancer screening, the
11 Icelandic experience]
12 [Exhibit BC/CS/046 – Control of cancer of the cervix uteri. Bulletin of the
13 World Health Organisation]
14 [Exhibit BC/CS/047 – Cervical cancer screening programme's managerial
15 guideline. World Health Organisation document.]
16 [Exhibit BC/CS/048 – Cervical cancer in NZ national and regional trends.]
17 [Exhibit BC/CS/049 – Projections of cervical cancer mortality and incidence
18 in NZ, the possible impact of screening]
19
20 CHAIR: Dr Cox, if you would look at your exhibit 44, which is the
21 European guidelines for quality assurance cervical cancer screening, this I
22 take it is the full document?
23 A: I haven't read it very recently but I'm familiar with it's contents.
24 Q: Now if you could look please at Glackin volume 7 page 28, top right
25 hand corner 28 which is exhibit 35, this is a report of the cervical screening
26 advisory committee and monitoring and evaluation dated Oct 94 and it was
27 sent to the Ministry by CSLC and it had a number of recommendations and

1 it included material with the report and one of the things that was included
2 appears at page 59 the European Guidelines for quality assurance.
3 A: Yes.
4 Q: Now what appears at page 59 is just appendix A which shows the
5 tables. Do you recall now whether you sent the Ministry of Health the full
6 document or just that part of the document that now appears in Glackin
7 volume 7.
8 A: The full document was sent and when we came to produce the
9 monitoring and evaluation, this first 3 establishment years document to put
10 to the Minister, there was I vaguely remember a discussion saying well we
11 should put in something that indicates the sorts of things that should need
12 to be considered in terms of evaluation and we then copied this section of
13 the European Guidelines but the Ministry certainly were presented with the
14 full copy of the European Guidelines.
15 Q: Thank you that's what I wanted to clear up.
16
17 MR CORKILL CONTINUES XXN OF WITNESS
18 MR CORKILL: Just while we're on that document Dr Cox, I'm talking
19 about exhibit 44 which is the full document, is it correct that it contained in
20 it a number of targets which it proposed for monitoring for perimeters for
21 monitoring the effectiveness of screening programmes and I'm looking at
22 S12, 13 & 14. Perhaps if we go to S13.
23 A: Yes.
24 Q: And we see on that page from time to time sentences in italics which
25 appear to describe particular targets and the first of those for example is just
26 above paragraph 5.2.2 the target for coverage in organised screening
27 programmes in the EEC should be at least 85% within a specified interval
28 of 3-5 years.

1 A: Yes.
2 Q: 5.2.3 if the proportion of unsatisfactory smears for a given smear-
3 taker exceeds 5% explanation should be provided and so on.
4 A: Yes.
5 Q: Where these the targets or guidelines which you thought might be
6 used as a starting point for fixing performance measures, a matter which I
7 think was touched on in the 1994 evaluation report to the Ministry?
8 A: I thought this was a useful place to start, usually when a committee
9 like this comes together across Europe if you like to produce something like
10 this they have some awareness of the variation in screening programmes
11 within different countries and they produce what I would consider a minimal
12 set rather than an all inclusive set and they also take into account what they
13 think is doable in the minimum sense so it seemed to be an appropriate place
14 to start if you like if you were going to have a bare bones approach this is
15 probably where you'd start and at least you'd have a chance of comparing
16 some parameters with if you like the international benchmarks that the
17 European cancer programmes were trying to provide. Now not all of them
18 are actually measurable targets. I think the next one for treatment
19 compliance is a compliance with these guidelines should be monitored
20 including explanation and non compliance. It's not specifically a figure of
21 what level of non-compliance.
22
23 CHAIR INTERJECTS AND XXN WITNESS
24 CHAIR: So these European guidelines for quality assurance in cervical
25 cancer screening are not a Rolls Royce model for quality assurance
26 guidelines in your view?
27 A: They're different levels, they're a very high level summary sort of
28 parameters and there may well be for example in New Zealand, I would have

1 thought we'd be interested in coverage by ethnicity which is not specified
2 for here for example so there's a little bit of adaptation may be required on
3 some of them.
4 Q: Would you expect though for all the matters set out here, I was
5 actually going to take you through each table, that you would expect our
6 programme to address these matters.
7 A: Some of the tables I must admit would be a little bit difficult to
8 collect the data and would require a little bit of special effort and given some
9 of the stances of Ethics Committees, some of it may have been difficult or
10 maybe more difficult now than it was then.
11
12 CHAIR ADDRESSES MR CORKILL
13 CHAIR: Mr Corkill will I interrupt your flow if I do this now?
14 MR CORKILL: Not at all.
15
16 CHAIR CONTINUES XXN OF WITNESS
17 CHAIR: Just for completeness if we could go to the first table please,
18 that's coverage within a 3 year screening round. Firstly if you could tell me
19 from your knowledge of New Zealand statistical repots whether we collect
20 information which would allow us to provide the information contemplated
21 by table 1 and if so do you think that's a good thing to do?
22 A: Yes we can estimate that reasonably accurately.
23 Q: Interval to reporting time. Firstly is that a helpful thing to do and
24 secondly do we do it?
25 A: Yes I think its a very helpful thing to do and I'm not entirely sure
26 whether we routinely tabulate that information or not. I believe that the
27 Register has sufficient data on it to provide that information.

1 Q: But is it being done at the moment.
2 A: I haven’t seen it.
3 Q: Do you think it's something that should be done.
4 A: Yes.
5 Q: Table 3, proportion of unsatisfactory smears. Is this helpful and do
6 we do it at the moment, in other words do we actually gather together the
7 data that we have in a table form such as this or in some other way by which
8 you could see the data set out in this manner.
9 A: Well some of that is what's in the first statistical report for example or
10 a similar sort of frame work except it is not broken down by age of women
11 and it's not presented by women which I think that table is intended to do but
12 I’d need to go back to the text.
13 Q: Would that be a good thing to do to show age of women and to
14 present the information in respect of women rather than smears?
15 A: Definitely because I think the situations that arise in reading smears
16 do vary by age and other things in terms of changes in the anatomy to the
17 cervix with age which are normal I believe.
18
19 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
20 PROFESSOR DUGGAN: So if there is variation between smear-
21 takers in the number of unsatisfactory smears it may actually relate to the
22 age of the population they are taking smears from.
23 A: I believe so.
24 Q: Is that the importance of this.
25 A: At this point I’d really want to discuss the issue with a gynecologist
26 or clinician.
27

1 CHAIR INTERJECTS AND XXN WITNESS
2 CHAIR: But at the moment do we break down the information in this
3 way and if not do you think we should?
4 A: I think we should and we could.
5 Q: OK thank you. Table 4, follow up compliance for abnormal smears.
6 Do we collate this type of information at the moment and is it helpful?
7 A: No I don't believe we do and I think I believe in the first report I had
8 a section on follow up which basically said there was nothing there and I
9 particularly put in the chapter so it could be filled in later because I was
10 conscious someone might use it as a template. It got dropped at the second
11 report.
12 Q: I see, and do you think this information should be available?
13 A: Yes.
14 Q: Table 5, follow-up compliance for women with at least one abnormal
15 smear setting out follow-up intervals in months and the age of women. Do
16 we do this and, if not, would it be helpful; is it something we should do?
17 A: We don't do it and there may be ways of getting this from the Register;
18 there's an issue in terms of – I'd need to have a look at exactly what the
19 Screening Register collects and whether there'd be any need for any
20 additional information. One way I had proposed is a proxy measure of this
21 rather than the actual measure, you may have to actually collect more data or
22 from a different source to fill this table out correctly.
23 Q: Do you think it's necessary to have the information as contemplated by
24 table 5?
25 A: Yes, absolutely, you need that as a sort of measure of what's happening
26 and you identify people who are not followed, but unless you are forced to
27 tabulate people you've not followed up it's very easy to ignore them.

1 Q: Table 6, treatment compliance, number of women by most severe
2 diagnosis within a given screening round, and it gives the age of women and
3 the most severe diagnosis listed. Do we do this and if not should we be
4 doing it?
5 A: No I don’t believe we tabulate this in terms of screening rounds. I
6 don’t think there's been any tabulation of the programme by screening round,
7 which would require a little bit of computing skill and a bit of knowledge of
8 screening databases, or quite a bit, to do it properly, and I don’t think we've
9 captured this – I’m not sure we capture the extent of the column.
10 Q: Should we be doing it or is that aiming too high?
11 A: Yes. We should be trying to do it.
12 Q: Why is that?
13 A: the detection rate of various conditions by age within a screening
14 round, which is useful information to compare in terms of issues as
15 incidence rates and mortality rates, and I think It gives you an idea of the –
16 allows you to make some estimation, if you like, of how effective the
17 programme is being rather than waiting for cancer to develop – sorry,
18 looking for a reduction in invasive cancer some 15 years later. This gives
19 us some sort of process measures in terms of how effective we are likely to
20 be.
21 Q: So in that sense it would be very important information if it helps you
22 to evaluate the effectiveness of a programme?
23 A: Yes.
24 Q: Table 7 treatment, compliance number of women by most radical
25 treatment given – sorry, treatment for given diagnosis with age of women
26 and most radical treatment. Do we do this?
27 A: No, we don’t.

1 Q: If not should we?
2 A: We should but we don’t.
3 Q: And why should we?
4 A: For a given diagnosis there are certainly issues associated with both the
5 management of women with invasive cancer but also there's some issues in
6 terms of the extent of treatment that women with, if you like, high grade
7 disease have undergone to have normal smears subsequent to their treatment.
8 I can think of situations where it helps you measure the extent of the harm
9 that might be caused in terms of treating women with high grade disease or
10 other disease, so it gives you some feel for that as well, which I think is
11 useful.
12 Q: Table 8, smear sensitivity for detection of invasive cervical cancer and
13 it gives you the age and the most severe smear in the last year.
14 A: Well, in this table, given at the latest count there are 219 cases a year
15 and if you started breaking them down too much into too many categories
16 you won't have sufficient numbers to get a good sensitivity estimate. We
17 might have to think of collapsing them, but ideally that’s the case, and
18 certainly over a longer period of time you would be able to get the pattern
19 down to this sort of 10 levels of abnormality.
20 Q: Perhaps the idea would be to collect the information to this degree but
21 to have a collapsed table for the short term to be able to read it, but if you
22 collated the evidence to this degree in the long term you would be able to
23 make use of it?
24 A: Sure, and smear sensitivity of any measure at this point in time for the
25 national programme would be cherished.
26 Q: Do we have any way of measuring smear sensitivity at the moment to
27 your knowledge?

1 A: Not to my knowledge. There's measurements of laboratory sensitivity
2 but not if you like – I don't believe there's a measure of smear sensitivity at
3 the moment or programme sensitivity. They are different words, but –
4 Q: When you say we measure laboratory sensitivity but not smear
5 sensitivity, what do you mean so I can have a full appreciation?
6 A: In Dr McGoogan's evidence she proposes, or puts forward a method by
7 which the laboratory internally is able to measure something they call
8 sensitivity. Now I tend to call that laboratory sensitivity or just part of it
9 because it's only the sensitivity of the laboratory to be able to detect the
10 abnormality if it's on the slide rather than the sensitivity of the test to detect
11 the abnormality that may be in the woman. So it doesn't include the
12 sampling component, so I tend to separate those two things out.
13 Thank you.
14
15 PROFESSOR DUGGAN: Dr Cox just before you leave that, the contents
16 of these tables for sure would be subject to much debate amongst people
17 interested in this, but just one comment. On table 8 because NZ has a 3 year
18 screening frequency would you need to adjust the time in terms of the
19 sensitivity of the smear?
20 A: I believe the European guidelines put forward two methods of
21 calculating the screening sensitivity for a programme. One by using the
22 cases of cancer that occur within one year of a normal or non-positive smear,
23 and another one including all cases that arise within 3 years of a non-
24 positive, so they give 2 measures and they suggest that both are calculated.
25 And from the Iceland experience I think we are able to set some sort of
26 benchmark for that. So I'm not sure whether that answers your question. It
27 would be relatively rare in any one year I would hope to have cases of cancer
28 in NZ within a year of a cervical smear, and so that's a particular parameter

1 that you might have to collate over a couple of years to get a good measure
2 of it.
3 Thank you.
4
5 CHAIR: I note that the measures for assessing sensitivity in the guidelines
6 appear at S13, which we'll go back to, but you might just like to check them
7 now to see whether that refreshes your memory. 5.2.6.
8 A: Yes. I think that's what I've outlined and I think they've given it my
9 specific age range as well by the looks of it. Thank you.
10 Q: Going then to table 9, distribution of incidence cases invasive cervical
11 cancer cases by stage with the age of women and various degrees. Do we
12 collect this information, could it be made available and if not should it be?
13 A: This is I think clinical stage at time of diagnosis, which is the
14 appropriate staging. We don't collect that stage information nationally,
15 either at the Cancer Registry or through the programme. And at the moment
16 it would probably require a special reporting form from the gynaecologists
17 or oncologists who are treating patients.
18 Q: Do you think it's something that should be done and if so that it should
19 be part of the screening programme rather than the Cancer Registry?
20 A: I don't mind who collects it but it should be collected and it's very
21 important to see whether you are reducing the incidence of stage 2, stage 3
22 and stage 4 disease in particular.
23
24 CHAIR INTERJECTS AND XXN WITNESS
25 CHAIR: So from that perspective is it information that should be
26 readily available to the Cervical Screening Programme manager?
27 A: Yes it should be collated at least probably annually but at least bi-
28 annually.

1
2 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
3 PROFESSOR DUGGAN: Dr Cox do you agree that there should be
4 a consistent staging system used that is also used internationally?
5 A: I think here people use the fego stating system though you would
6 have to get agreement amongst the clinicians to collect it in a certain way
7 and you may need to issue some guidance note for them, just a reminder
8 rather than them having to runaway to the text book. Most gynecologists I
9 would expect that to have in their head but it's useful to have a reference.
10
11 CHAIR INTERJECTS AND XXN WITNESS
12 CHAIR: Table 10 distribution of incidence cases, invasive cervical
13 cancer cases by detection with the age of women, various types of cases, do
14 we have this information readily available?
15 A: No we don't.
16 Q: Should it be?
17 A: Yes it should be, this would mean collating data of women who are
18 not in the programme as well as those who are.
19 Q: Table 11, interval cancers, incidence of invasive cervical cancer by
20 time since last normal smears, with the age of women and then at the bottom
21 years since last normal smear, incident cancer cases, persons years at risk,
22 observed incidence. Do we collect this information?
23 A: No we don't and it's vital.
24 Q: For what purpose.
25 A: For the calculation of sensitivity of the programme you need to know
26 the interval cancers and the number of them.

1 Q: If we had had this information at an early stage would it have allowed
2 the programme manager or someone else having responsibility within the
3 programme to detect under-reporting?
4 A: I think yes, if it was considered that the sensitivity of the programme
5 was too low, it would have resulted in a thorough review of why. I'm not
6 sure because of the relatively low number of cases in New Zealand I'm not
7 sure you'd be able to identify issues down at a small regional level.
8 Q: Right.
9 A: You may for example, certainly for New Zealand as a whole, you
10 may be able to get down to the sort of level of the old 4 regional health
11 authority regions but I doubt if you would be able to identify just from the
12 tabulation down to an issue for example Tairawhiti, though if you did the
13 clinical audit side of things, that's more likely to pick things up.
14 Q: So in order to pick under-reporting up in a particular region such as
15 Tairawhiti the statistical information that we have been going through at the
16 moment would not be so helpful but a clinical audit once someone
17 developed cervical cancer would be helpful if that what you're saying.
18 A: Yes I think you get much more detailed information about the
19 particular cases and the ability to review material etc that would allow some
20 judgment to be made about issues in a region.
21 Q: The difficulty with using detection by a clinical audit though is that in
22 a sense someone is the fall person because it doesn't kick in until someone
23 has developed cancer so that may help other persons that are on the
24 programme whose smears might have been under-reported but it doesn't do
25 much for the person whose already suffering from cancer.
26 A: I agree and that's why I think it's important to include either probably
27 a sample of the women who have a diagnosis of high grade abnormality by
28 histology. I mean there's too many for the whole country but you can

1 sample them and do some sort of audit of that and I think you pick it up
2 earlier.
3 Q: So although table 11 might not be so helpful in identifying a regional
4 issue, do you still think it's vital information to have?
5 A: It's vital for the programme as a whole.
6 Q: And we don't have it at the moment?
7 A: No we don't.
8 Q: Table 12, interval cancers re-evaluation of previous smears.
9 A: Now we're starting to get into some of the, if you like, audit side of
10 things and that's vital.
11 Q: Do we have it?
12 A: No we don't. I must say that interval cancers are actually – there are
13 – because you are identifying issues associated with the practice in some
14 cases there are a whole lot of medico-legal perimeters that people feel can be
15 an obstacle to such audit.
16 Q: Is it necessary?
17 A: It's necessary.
18 Q: And what does it allow you to do if you have this information?
19 A: It allows you to make some assessment of the component of a drop in
20 sensitivity if you like that might be associated with the diagnostic process
21 rather than the fact that there were no smears on the cells or cells on the slide
22 that were abnormal so it allows you to start distinguishing between those
23 sorts of issues I think.
24 Q: Table 13, consumption of smears. What does that mean and do we do
25 it and should we do it?
26 A: This is the number of smears taken, down the second column if you
27 like, and you can then calculate the number of smears for women, there's a
28 special guidance I think within the guidelines as to how you should produce

1 this table and it's helpful as a measure, helps you assess the amount of short
2 interval re-screening that's occurring because you can screen too frequently
3 too in the sense that you create a lot of referral for colposcopy without
4 necessary reduction in incidence and mortality to any significance.
5 Q: So do ewe do this?
6 A: No not routinely and not in the way described.
7 Q: In table 14 distribution of smears, % of women with more than 1
8 smear, do we do that and should we do it?
9 A: I don't believe we do, there have been special reports from time to
10 time but it's not done on a regular basis either quarterly or annually.
11 Q: Table 15 distribution of smears, % of women with an abnormal
12 smear, do we do that?
13 A: No not by age, I don't believe we do.
14 Q: Should we do it?
15 A: Yes. I'm going to probably say yes to just about all these tables. No
16 I don't believe we do that in a routine manner.
17 Q: And why should we do it?
18 A: Now I'm having a bit of stumbling block here. I just think it's
19 important to know the proportion of women who have abnormal smears, it
20 gives you an idea of how much further either follow up in terms of repeat
21 smear of colposcopy is required.
22 Q: Table 16 use of smears in a screening round, do we do that and
23 should we do it if we don't?
24 A: We don't actually do anything by screening rounds for individual
25 women at the moment. We look to some issues by calendar year but that's it.
26 Q: Is there a benefit of doing it by screening round?
27 A: Definitely.

1 Q: Why is that?
2 A: It's partly because the inference you can make from the data that's
3 produced in that manner is stronger and therefore it has more relevance if
4 you like to the screening programme and process and clinical issues
5 associated with it.
6 Q: Incidence of invasive cervical cancer before and after start of
7 organised screening programme do we do that and if not should we?
8 A: We should do it, the screening programme itself doesn't actually
9 produce this data, it should be relatively easy to produce.
10 Q: So it could be done?
11 A: Absolutely.
12 Q: Table 18 mortality from cervical cancer before and after start of
13 organised screening programme do we do this, could we do it?
14 A: It's not routinely done but again it's easy to do. I think it has been
15 done from time to time.
16 Q: Tables 17 and 18 would that be worth while having information as
17 contemplated by those tables for the programme manager?
18 A: Yes, it's the sort of thing you might actually not necessarily do every
19 year. Yes, I think it would be really useful for people, it would help them
20 understand the natural history and the incidence of the disease which they
21 should understand.
22 Q: Having gone through all of these 18 tables then, it seems that a large
23 majority of the tables we do not collect this information in this form or any
24 similar form at the present time; is that your view?
25 A: There are parts of that we have done from time to time but it's not a
26 routine ongoing thing, and most of them we do not collect.

1 Q: For the information that we do collect, as you have said we don't do it
2 routinely. Do you think we should do it routinely or is it acceptable to do it
3 on an ad hoc basis?
4 A: I think it should be done routinely, someone should have responsibility
5 for doing it and it should be fed back to the participants and clinicians and
6 other health professionals of the programme and it helps them – I think it
7 reinforces the reason they do their work. And that's vital because a lot of
8 screening processes are actually relatively – boring's not the right word, but
9 not intellectually challenging. Some of it is, a lot of it is not and it requires
10 a lot of team work between a lot of different players and you need to give
11 them that feedback that what they're doing is actually useful and helpful.
12 Q: Well apart from being a moral booster for those working on Cervical
13 Screening Programmes, what other use can be made of this information?
14 A: Oh well it tells you how you're going and whether you're actually
15 making an impact and identifies areas where you could do better.
16 Q: This information contemplated in tables one to 18 talks about women
17 generally. Given in NZ we have been collecting data on Maori women
18 because of the higher incidence of cervical cancer, should ethnicity be taken
19 into account and should there be separate collection of information for
20 Maori women as well as including them in the general statistics or not?
21 A: I think there should be separate tabulations available for a variety of
22 reasons. I'm aware there's a whole lot of issues about the definition of
23 ethnicity and different data sets which need quite a lot of qualification, and
24 I'm also aware that there's some sensitivity about how that data's presented.
25 I also notice in Dr Peters evidence that it would appear that if you like the
26 gap between Maori and non-Maori in terms of cervical cancer incidence and
27 mortality seems to be closing and I think some of that is attributable, is likely
28 to be attributable to the cervical screening programme in extending the

1 coverage of screening in the population at large to Maori groups over and
2 above the level of screening that was there previous.
3 Q: So therefore should the current programme manager be looking at
4 ensuring that the ways and means are put in place to enable the programme
5 to collate the information contemplated in tables 1 to 18?
6 A: Yes and I believe the Health Funding Authority are trying to do that
7 sort of work at the moment.
8 Q: From the perspective, I know that you and Dr Richardson have already
9 run into with your study, are you able now just to list the obstacles that you
10 could see to the gathering of the information contemplated within tables 1 to
11 18?
12 A: Major and important tables, particularly associated with cancers, the
13 audit of cancers and interval cases of cancer would be dependent on Ethics
14 Committee decision regarding the release of data from the Cancer Registry,
15 which is an obstacle we've come across.
16 Q: What Ethics Committee would you go to because I understand they're
17 regional ?
18 A: I would prefer a national one.
19 Q: For a national programme would a national Ethics Committee not be
20 better to deal with these issues?
21 A: Well I think it's preferable, but I think also that Professor Skegg did
22 warn that it could end up being a national committee of the chairs of the
23 individual committees which would essentially be the same or may be very
24 similar to actually going through roughly 156 members of the Ethics
25 Committees around the country.
26 Q: But at the moment I know that Professor Skegg had to get permission
27 from Tairawhiti Ethics Committee for his proposed study, but you have had
28 to go to the Otago committee for the evaluation you and Dr Richardson are

1 doing. I know that for the preparation of the first I think the second
2 statistical reports there was a need to go to the Wellington Ethics Committee
3 because the Wellington Area Health Board would not otherwise release
4 information. So how do you know which Ethics Committees and which
5 regions you should go to when you're contemplating an exercise on a
6 national basis?
7 A: Essentially an national study, we send it through all the Ethics
8 Committees and the results are collated back. In fact last time I took a photo
9 of all the piles of applications on the desk, but others have done a similar
10 thing. I don't – I'm not against Ethics Committees so don't get me wrong. I
11 think they are very important. The process for some of the work,
12 particularly that that's considered to be most sensitive in terms of issues of
13 the sensitivity of the records if you like, I think that going through an Ethics
14 Committee would be useful process and I think it would be preferable if it
15 just went through one. There's two ways of handling it. One is just to go
16 through your local Ethics Committee for national approval
17 Q: And is that possible?
18 A: Not at the moment that's not the process. Secondly is to have a
19 national committee. So I'm not sure I've helped you there or not.
20 Q: What happens at the moment. Just help me on the practical impact it
21 has on you and what you do when you have a study such as the one you and
22 Dr Richardson are going to carry out and you approach all the Ethics
23 Committees and some are happy to have information made available, others
24 are not – others are but in a particular fashion. I mean, how do you deal with
25 the disparate responses that you could get from 14 separate committees?
26 A: Well I think initially the intention was if your local Ethics Committee
27 collated the responses and then came to you, oft times we – up until very
28 recently anyway we used to get the individual Ethics Committees responses

1 were just forwarded. We then address each of the issues that are raised,
2 usually even if they're collated it's just one to 14, the different groups. We
3 then respond to issues that are raised, take on board ones where we agree
4 that that strengthens the research proposal, we look at what's logistically
5 possible, what we believe is allowable through the Health Information
6 Privacy Code, and reply specifically point by point to the issues that are
7 raised by the Ethics Committee. Unless of course they give approval
8 straight off. And in the usual circumstances we would then get a final
9 decision I believe, unless there's particularly issues that might need further
10 refinement. It's just to create the appropriate understanding between the
11 Ethics Committee and the researcher as to what is actually going on.
12 Sometimes we have to get down to some fine detail about something.
13 Q: Yes, and does that take quite a long time?
14 A: It takes quite a long time and if there are delays you end up in the
15 somewhat embarrassing position of having staff employed all ready to go
16 and we're all tolerant to a degree but it can get a bit testing at times if staff
17 have had to wait for quite some time before we can actually get going so the
18 delay is very off putting.
19 Q: In that sense then is it one of the barriers to research?
20 A: Yes I believe the delay itself is a barrier. It means you're not sure
21 whether you need to employ people in two months time or no months time.
22 Q: It seems to me there can be two types of evaluations, one that is done
23 by the body responsible for the programme and in this instance I would see
24 the evaluation study where the Ministry of Health has engaged you and Dr
25 Richardson as being an evaluation for the Ministry of Health who is
26 responsible for the programme with the Health Funding Authority.
27 Secondly the type of evaluation which is done by an outside medical
28 researcher who has simply a research interest in a particular facet of health

1 delivery here with the programme. How important is that second type of
2 research in terms of being of benefit overall to the effectiveness of the
3 programme?
4 A: If you just bring someone in for a particular part of an evaluation it's a
5 project for them, they sign it off it's gone and the knowledge that they learn
6 about the issue is lost and often the knowledge that's obtained through the
7 process of the monitoring and evaluation project is also needed and actually
8 in terms of implementing what's required in terms of the changes. So people
9 end up with a report that they've paid for but the persons gone and it's really
10 up to the individual receiving the report and their knowledge, expertise or
11 input in terms of how the report has finally been produced to then take that
12 forward and implement it and sometimes there are issues that crop up, I'm
13 not going to call them subtleties necessarily but I think you know what I
14 mean, issues that arise that are actually useful in terms of getting a practical
15 approach to resolving any issues that are identified.
16 Q: So it's not really answering the question I was asking but still, on the
17 basis of what you've said, would that be then a reason for having in house
18 staff carry out the evaluation because they would then hold within the
19 organisation the knowledge they had gained through the evaluation process?
20 A: It's one way of training people but it is on the job training and
21 sometimes it's important to have people with appropriate expertise and you
22 may have to get that from outside initially until the staff within the
23 organisation have undertaken if you like appropriate courses of training or
24 are employed to then conduct it themselves is how I would answer that.
25 Within the organisation it's also possible to down play results that are not
26 particularly appealing to the organisation as a whole and let things slide so I
27 actually believe there is quite a lot of advantage in the independent
28 component of at least some level of the monitoring of the programme. It

1 depends a bit on the interplay between that body and if you like the
2 programme people themselves.
3 Q: The other aspect that I was asking you about though wasn't one
4 where you might have the Ministry of Health engage independent
5 researchers to do an evaluation, but really one where a medical person is
6 interested in doing research on the programme and so wants to do some for
7 of evaluative study on how the programme or an aspect of it is working
8 purely for the purposes of their own independent research. I just wanted to
9 know how important is this, in other words can that help keep the
10 programme honest by being open to being researched by outsiders.
11 A: It's vital, it's also one way you bring in new ideas and some really
12 good ideas are generated from that sort of approach, by having someone who
13 has been thinning about an issue and you get something new out of it, I think
14 it's absolutely vital to have that available as well.
15 Q: And given the present of Ethics Committees and also Section 74A of
16 the Health Act, in your view can independent researchers gain access to
17 sufficient information to be able to do research of an evaluative nature on
18 aspects of the Cervical Screening Programme say for example quality of
19 smear reports?
20 A: Currently no but it's not entirely clear whether it's the act of the lack
21 of regulations that determine that.
22
23 CHAIR ADDRESSES MR CORKILL
24 CHAIR: I'm sorry Mr Corkill I just wanted to go through those tables
25 and I've strayed much further, one ran on from the other.
26
27 MR CORKILL CONTINUES XXN OF WITNESS

1 MR CORKILL: One issue that was touched on a moment ago Dr Cox
2 was the issue of Ethics Committees and the like. What is the current status
3 of the Cox/Richardson evaluation as contracted by the Ministry?
4 A: The current status is that there were three aspects to it, the review of
5 the usefulness of the Cervical Screening Register data, what can be done
6 with that data is ongoing. The assessment of women who have had
7 abnormal smears in terms of their management and follow up has received
8 ethical approval I think about 3 weeks ago. I've been here for a while now, I
9 don't know whether to add a week or subtract a week. So that's been given
10 approval as as I say the first part has also been given approval. The third
11 part which was the audit of screening histories of women with invasive
12 cervical cancer has not been able to proceed. The Ethics Committee feel
13 unable to approve the release of name data from the cancer Register to us to
14 conduct that despite that being the practice of the last 30 odd years and it's
15 covered under the Health Information Privacy Code and we've used it for
16 several national epidemiologist studies over the last 20 years and that has
17 arisen actually not out of, I believe it's not out of our particular application to
18 the Ethics Committee, there happened to be another study that was proposed
19 to the Ethics Committees around the country slightly prior to our application
20 and one of the regional Ethics Committees I understand took a legal opinion,
21 and it was the Otago Ethics Committee and the legal opinion was of the
22 nature that no the law did prohibit the release of that data from the Cancer
23 Registry to the researchers. They also had access to an alternative legal
24 opinion which was the exact opposite and so as a consequence of that the
25 Otago Ethics Committee felt that they couldn't ethically approve it if it
26 meant they might be breaking the law.
27 Q: So in terms of process how is this to be resolved in your
28 understanding.

1 A: Well initially the Ethics Committee requested that we get written
2 consent from women with invasive cancer to have their names released
3 from the Cancer Register. Now we can't do that so we don't know who they
4 are so it would then have to be the Cancer Register that would do that on our
5 behalf. Some of these women would have died, some have them may have
6 been upset by the process and the Cancer Registry do not have the staff or
7 skills or desire to do that, for all sorts of reasons. Their reasoning would be
8 best addressed to them.
9 Q: So that means they don't have the staff to do it and you can't do it
10 because you can't identify the women to contact until you have had access to
11 the Registry?
12 A: Well it's not an easy matter. I think people have in their mind that
13 they've got a list, sure they just write to them, but in fact it's a lot more
14 complicated than that if you want to approach everybody. And you need to
15 approach everybody otherwise you get a biased sample and your results
16 aren't particularly applicable unless you've got almost everybody included.
17 So there's a whole process of writing to people, phoning people. It's an
18 extremely complicated process
19
20 MR CORKILL: Is it still intended to proceed with that particular
21 possibility?
22 A: Not unless the Ethics Committee gives approval it will not proceed.
23
24 CHAIR: I'd just like to tidy this up with you Dr Cox, it seems to me – from
25 the questioning earlier today from Mrs Sholtens – it was the end of 1996 the
26 Ministry of Health decided it would have a full evaluation of the
27 programme. You and Dr Richardson prepared a draft plan dated June 97

1 and you were successful in the tender but the plan ultimately went beyond
2 funding available for the Ministry of Health, is that correct?
3 A: Yes, roughly that's right.
4 Q: And in May 1999 you and Dr Richardson signed off a contract with the
5 Ministry of Health to allow you to carry out the 3 priority areas that they had
6 chosen from your original evaluation plan, correct?
7 A: Yes.
8 Q: And at the moment the first area review of usefulness of register data,
9 what can be done with the data is ongoing, the second priority – assessment
10 of management of abnormal smears, although the contract as signed in May
11 1999 you only got Ethics Committee approval to carry out this aspect of the
12 study 3 weeks ago?
13 A: Yes and we had to adapt it a little to conduct that as well.
14 Q: And the other study hasn't had Ethics Committee approval at all so you
15 can't get access to the Cancer Register and am I right in saying you probably
16 also can't get access to the Screening Register for the purposes of identifying
17 women on that register because of 74A of the Health Act?
18 A: Yes, as part of the Part 2 of the ones you've read out, currently we've
19 developed an arrangement with the Health Funding Authority where they are
20 actually selecting a sample and writing out to people to get consent to
21 release the names to us for the purposes of approaching them for interview
22 and possible access to their medical record if they approve.
23 Q: so the second area of research, assessment of management of abnormal
24 smears that too has run into difficulties with 74A of the Health Act and you
25 have some arrangement using the Health Funding Authority services to get
26 around that obstacle?
27 A: Yes.

1 Q: And we sit here now, towards the end of July 2000, given that you had
2 a draft plan in June 97 and a contract signed ultimately in May 99 and given
3 your earlier evidence today that you consider that the draft plan in June 97
4 was essential to carry out, what comment do you have to make on the current
5 state of affairs?
6 A: Currently it's a mess, and I think Professor Skegg eloquently went over
7 many of the issues that he believed were relevant to the consideration that
8 Ethics Committees make of proposals put before them, so I'm not going to
9 go down – I won't repeat that, partly because I can't do it as eloquently as he
10 can. My understanding of the process so far, we applied to the Ethics
11 Committee mid-November of last year; there was quite a long response in
12 terms of different issues, we responded to that. We've had further
13 discussion and meetings of our team to discuss how we maybe able to cope
14 with the various things that were being requested. We developed this
15 process of approaching women through the Health Funding Authority, the
16 national programme initially for consent for the study of abnormals, we are
17 just starting that process – I'm not sure if the first letter's been sent out yet
18 but it's close, to women, for that part of the study. The issue of the release
19 of names from the Cancer Registry has gone to and fro between the Ethics
20 Committee, we've made representation to the Ethics Committee earlier this
21 year and discussed the issues, I think it was in April or March, and they then
22 I believe wrote to the Minister of Health seeking a High Court ruling. The
23 Ministry responded outlining the issues for them and not going to a High
24 Court ruling on the issue. So it was back in the Ethics Committee's court if
25 you like, and the Ethics Committee then wrote again to the Minister or the
26 Minster's office seeking a ruling. There's some interval of time between
27 these events. And I believe that late last wk a letter from the Ministry was
28 sent to the Ethics Committee in reply. Now the correspondence between the

1 Ministry and the Ethics Committee is not available to me so we are awaiting
2 the decision of the Otago Ethics Committee at this point regarding that
3 matter. There's been such a delay that it's unlikely we'll be able to fulfil the
4 full contractual arrangement in terms of the number of women with invasive
5 cervical cancer that we were going to review prior to the contract finishing
6 in the middle of next year at this point.
7 Q: What impact will that have on the study
8 A: It will just end up with smaller numbers and it will be a little – the
9 measures of various things that we get will not quite as accurate as we'd like
10 or quite as precise I think is a better word.
11 Q: If there are smaller numbers will that in some way affect the value of
12 the study?
13 A: To some extent, but I think if we can still complete at least half of it we
14 will have very valuable information to work from.
15 Q: is it possible to carry out meaningful research on cervical cancer or any
16 cancer in circumstances where you don't have to have access to identifiable
17 women's information?
18 A: Could you repeat that?
19 Q: is it possible to carry out meaningful research such as an evaluation
20 study into cervical cancer in circumstances where you do the research
21 without having access into the information of identifiable women? In other
22 words, you can do it on the basis of anonymised data?
23 A: There are some things you can do that way, but you certainly can't
24 approach the women for her experience of the process or to her
25 corroboration, if you like, of the medical record, or bring in all sorts of
26 issues in terms of their access and experience of services etc. so it's very
27 much more limited in terms of being able to feed back knowledge of those

1 aspects of the screening programme and screening process or treatment
2 process into the programme because it just won't happen.
3 Q: I've noticed from your exhibits for example there's the article on the
4 Finland programme, there's your only earlier writing on programmes, I mean
5 given these obstacles that you've outlined to me this morning, it sort of
6 makes me wonder well to what degree is any meaningful research now being
7 carried out on cervical cancer and screening programmes in New Zealand.
8 A: Well we're trying.
9 Q: Has anyone else tried?
10 A: Well I can't speak for – I would expect to be aware –
11 Q: You'd expect to be aware if others were doing this work.
12 A: Yes and I don't believe there's extensive work. There may be some
13 areas in a clinical area which I wouldn't necessarily be involved with. I
14 believe for example National Women's Hospital there's a long history of
15 conducting research that's valuable in terms of screening so I can't speak for
16 them.
17 Q: But overall if there are obstacles to carrying out research of an
18 evaluative nature on the operation of the screening programme what does
19 that mean for the programme?
20 A: Well it makes it different to justify it's existence in the sense of that
21 ethical commitment that I gave earlier which is a basic if you like, it's one of
22 the ethical differences between public health medicine and other branches of
23 medicine so if we are unable to be fairly sure that we are actually getting
24 those benefits, we certainly have the capacity to cause harm by offering
25 screening to people.
26 Q: And independent research into the operation of a Cervical Screening
27 Programme could itself be another measure of quality assurance could it?

1 A: Yes it certainly could ask whether it's being done and what's being
2 done. I would have thought you need to tick the boxes on that.
3 Q: Thank you.
4
5 MR CORKILL CONTINUES XXN OF WITNESS
6 MR CORKILL: So in summary Dr Cox the first two parts of the
7 contract are going ahead.
8 A: Yes.
9 Q: And you would expect them completed within the contract period
10 namely mid 2001.
11 A: Yes.
12 Q: The third part which is the audit using the Cancer Register is in
13 doubt.
14 A: Well it currently cannot proceed so that's fairly well – reasonable
15 doubt.
16 Q: Now about an hour ago I was talking to you about the European
17 guidelines and I just wanted to round that off if I might. What I wanted to
18 just round off there Dr Cox was you sent that material in July 1994 to the
19 programme. I think your evidence states that CSLAC also emphasised the
20 importance of the European Guidelines and again you returned to the topic
21 of the European Guidelines when you were asked to provide some
22 comments for the third statistical report.
23 A: Yes.
24 Q: Clearly in your mind they were a very important document because
25 they were a useful starting point to refining quality assurance measures
26 where they not?
27 A: Yes they provide us with an international benchmark of some
28 description.

1 Q: When do you think it would have been reasonable, given the
2 availability of that material and the strong advice which CSLAC and
3 yourself were giving to the programme as to their relevance, when would it
4 have been reasonable for measures of that kind to have been introduced in
5 New Zealand?
6 A: I would have thought some process of agreeing to those could have
7 been established over a 6 month period and we could have gone on and
8 started measuring at least some of them and have them available, at least
9 some measures available within 12 months.
10 Q: Within 12 months of when?
11 A: When they were received.
12 Q: So you would expect by mid 1995 one should have been making
13 progress on those measures.
14 A: Yes.
15 Q: Just whilst I'm on timing issues, another topic that's been the subject
16 of a lot of evidence is TELARC accreditation and the point in time at which
17 is should have become compulsory. Again given the advice which the
18 Ministerial Review Committee, the Expert Group and the CSLAC gave over
19 1990 and 1991, when do you think it would have been reasonable for
20 TELARC accreditation of laboratories carrying out cervical smears to have
21 been compulsory.
22 A: I think its around 93 if I recall that I would have expected it to have
23 become – serious consideration would have been given to it. I think there
24 was serious consideration to doing that I just don't think anybody was able
25 or felt they could make the decision and one of the problems that we had so
26 much indecision through that whole period and I don't think people
27 recognised the necessity of at least that and my understanding of TELARC
28 accreditation or IANZ is that about accrediting a laboratory whether it says it

1 does certain things, it doesn’t go into monitoring the monthly performance
2 of a laboratory which is the monitoring component so I would have expected
3 that. I believe, I mean it's a wee while since I’ve gone over that, but I think
4 93 I would have expected that.
5 Q: Well we know that in the 91 Government policy it was indicated that
6 TELARC accreditation should be obtained within a reasonable period.
7 A: There was an issue about for some laboratories taking it as being a 2
8 year requirement in terms of getting there so that's why I’ve said absolutely
9 by 1993. That's the reasoning.
10 Q: Thank you. Can we just on another historic topic refer again to the
11 CSLAC report on monitoring and evaluation of 94 which is Glackin volume
12 9 tab 35, page 28 onwards, top right hand corner. Now I think you were a
13 member of the CSLAC which produced this report.
14 A: Yes.
15 Q: The highly unusual I suggest step was taken when this report was
16 prepared of including as an appendix at appendix 3 page 19 of the report, a
17 chronology of all the committees documents and recommendations
18 regarding programme monitoring and evaluation and again at page 23 of the
19 report, a tabulation of all the committees submissions regarding the
20 screening programme, page 24 selected outgoing correspondence from
21 CSLAC and there were other schedules there also setting out relevant
22 chronologies. Why was that step taken?
23 A: We were driven spare.
24 Q: Because.
25 A: By frustration within the Ministry in terms of our recommendations
26 being taken up.

1 Q: And so were you bending over backwards to demonstrate that you
2 had time and again tried to emphasise these matters of monitoring and
3 evaluation through the life of CSLAC.
4 A: I would also add that –
5 Q: Does that mean yes if you're going to add to it.
6 A: Yes. I would add that members of the committee I think were
7 becoming increasingly uncomfortable with the lack of progress on the
8 monitoring and evaluation of the programme and to the point where some of
9 us were feeling professionally unsafe and we were aware of incidence that
10 had occurred overseas and that something somewhere was gonna happen
11 possibility to the extent that an inquiry such as this would eventuate and we
12 took the opportunity at the end of this particular time of this particular
13 committee to write an extensive report and lay out all the things that we had
14 tried to do and tried to get established through the Department of Health and
15 Ministry of Health over the period of our existence, and that's why
16 everything was listed, correspondence was listed. If you write letters to the
17 Director General of Health or other high officials within the Ministry or the
18 office of the Minister of Health I don't know where else you can take them.
19 Q: Now at p2 of the report, under summary of recommendations, you set
20 out your specific recommendations and one of those related to number 4
21 "although some evaluation could be undertaken as projects the committee
22 would like to see a shift towards routine monitoring and evaluation", and
23 you there proposed or recommended an annual statistical report, regular
24 feedback to smeartakers and laboratories re quality, routine monitoring of
25 waiting time for colposcopy and annual expenditure report. Can I ask you
26 again, a timing question, when do you think it would have been reasonable
27 for those measures to have been implemented by within regard to the NZ
28 Screening Programme?

1 A: I think at the latest 1993 again, but there were opportunities before that
2 time for many of those matters.
3 Thank you.
4 CHAIR: Are you going to move onto something else?
5 MR CORKILL: Yes, I am.
6 CHAIR: I want to go through this report with you too, Dr Cox, but I will do
7 it later, but just for now I note the next exhibit 36, which starts on p81, is a
8 letter to the chairperson on CSAC from the Minister thanking her for the
9 letter of 7 November 1994 and the final report of CSAC. And I note it said
10 there that your report succinctly describes the progress and monitoring and
11 evaluation of the programme during the first 3 years of its establishment and
12 that it pulls together a wide range of information. To the best of your
13 knowledge at any time did the Minster or any official of the Ministry of
14 Health communicate with CSAC in any way which appeared to you to
15 contradict the descriptions you had given in the 1994 report in terms of how
16 you described the programme working and your recommendations for what
17 was needed; in other words, did anyone tell you you'd got it wrong, you
18 were over-reacting, that in fact the programme was in better shape than what
19 is described in your report of 1994?
20 A: the manner of reply tends to be in the nature of excuses rather than
21 contradiction, particularly from the national co-ordinators who I actually
22 think at a personal level wanted this thing to be successful and proceed. I
23 think they were – and the staff of the screening unit, were frustrated by
24 decisions further up the chain. We didn't have, well we didn't request it, but
25 also I don't believe – I'm not sure – I don't believe we would have been
26 given the correspondence and memos that they sent between themselves
27 within the organisation, or memos to the Minister or whatever else. So that
28 is all an unknown. So as an advisory committee we had excuses and often,

1 "oh well we can't do this because of that", and, "when this is done we will
2 be able to do this", and issues of resources and I think the task was way
3 beyond – and it's not the individual's fault, it's just the requirements of
4 running the programme and the lack of expertise that we mentioned earlier.
5 The difference between what was required and what they were able to
6 provide was so wide that excuses tended to be used. So there was
7 programme, it was made at a snails pace when it was made, and a lot of
8 things – I think there was an issue, "well, we'll do this for this period of
9 time, we can't do all these other things, then we'll do a bit more". I think
10 the organisation as a body felt very obstructive,
11 Q: So there was never any communication back to CSAC from the
12 Ministry of Health in which the Ministry of Health stated that CSAC had
13 over-stated the case in its report of 1994?
14 A: there may have been but I can't actually recall it, and I think that would
15 have been like putting a red rag to a bull just quietly.
16 Q: So you would be more likely to recall it if it did happen?
17 A: That's one way of putting it, but I can't vouch for that.
18 Thank you.
19
20 MR CORKILL: In terms of that letter that Madam Chair took you to,
21 which is tab 36, the letter from the Minister, did you see that letter when it
22 came back?
23 A: I believe so, I'm sure it would have been attached to the Minutes etc,
24 yes.
25 Q: And we can go through it, but did you regard that as an adequate
26 response, because essentially she was saying everything was ok.
27 A: No, it's not an adequate response, in fact I think the words "lack of" are
28 missing in the first sentence. I'm being facetious.

1 Q: All right, apart from the grammatical problems –
2 A: I think it's one of these polite, nice letters back to an advisory
3 committee that expresses this sort of thing I'm saying before, that we are
4 doing this and we're doing a bit of that and it is getting better and please
5 hang in there" sort of thing.
6 Q: To take number one as an example, the need for good operational
7 leadership, she mentioned that a new national co-ordinator had just been
8 appointed, but of course CSACs point about strong, central leadership had
9 been that you needed multi-disciplinary expertise on the staff, medicine,
10 epidemiology, statistics, computing and cytology. So plainly, that was an
11 inadequate response when none of that expertise was on the staff?
12 A: Vastly inadequate.
13 Q: And so did this letter essentially serve to endorse your frustration that
14 matters were not moving forward as they should?
15 A: Yes.
16 Q: I want to turn to a different topic now Dr Cox, and that is to do with the
17 topic of volumes which I think was another ongoing throughout this period
18 and later, wasn't it?
19 A: Yes.
20 Q: It started as being an aspect of the 1991 policy did it not, that minimum
21 criteria needed to be established?
22 A: It was outlined in 1989 in the ministerial review committee's report too.
23 Q: And is it correct that the first time the matter really came to some sort
24 of a decision was in the meeting of experts in 1998 and I will take you to it, I
25 think it is volume 5 of Boyd. I have now found it in an alternative place,
26 which is your own exhibits volume 2, tab 41. Now that was a meeting of
27 experts which you attended.

1 A: Yes.
2 Q: And tab 41, p2 of the minutes "in general laboratories should be
3 reporting on a minimum of 10,000 specimens/annum unless they make a
4 special case. Now how significant did you think that decision was at the
5 time?
6 A: I thought it was at last a decision that was long overdue and I felt
7 early on in the programme, in the absence of being able to provide good
8 performance measures of what was actually happening or some measure of
9 what was actually happening or going through the laboratory, then there
10 needed to be some recourse to blunter instruments if you like which in the
11 first instance might be laboratory volumes so however that was extremely
12 difficult for laboratories to agree to and probably is too much to expect them
13 to agree to since they are competing with each other and also it wouldn't
14 have meant that the hospital laboratories would not have been able to
15 process gynecological cytology because all of them in fact were processing
16 fewer than 10,000 smears a year at that time.
17 Q: Now there were 4 pathologists at that meeting. I think 3 from
18 community laboratories and one from a hospital laboratory you see that on
19 the first page.
20 A: Yes.
21 Q: What sort of mandate do you believe they had to reach that
22 agreement?
23 A: They had the mandate of their experience and knowledge of
24 pathology and whether they thought that was a good idea or not. I'm not
25 sure whether anybody was representing Colleges or ACL or any other body.
26 Q: That's the issue I was raising.
27 A: Though I would have to have seen their letters of invitation to
28 participate to get a sense of that.

1
2 MR CORKILL ADDRESSES CHAIR
3 MR CORKILL: Madam Chair I'm going to be a while with this topic. I'd
4 like Dr Cox to look at the Peters volumes paper over the lunch and I'll
5 discuss it with him after the break.
6 CHAIR: Yes that's fine we'll adjourn until 2:15.
7
8 INQUIRY ADJOURNS AT 1:02 UNTIL 2:15

1
2 INQUIRY RESUMES AT 2:22 P.M.
3
4 MR CORKILL CONTINUES XXN OF WITNESS
5 MR CORKILL: Dr Cox I asked you to look at the volumes paper over
6 the lunch adjournment and you are no doubt familiar with the issues in that
7 paper?
8 A: Yes.
9 Q: Do you have any views first of all about the particular figure selected
10 having regard to the international figures referred to earlier in that issues
11 paper?
12 A: If we were started a Cervical Screening Programme de novo we
13 would probably make rational decisions, well I'd hope we would make
14 rational decisions about the number of laboratories required to do
15 gynecological cytology for the country and that would probably be
16 something in the order of 2, 3 or 4 and I notice that the WHO suggest that in
17 general 20,000 smears per annum is required to support a certain level of
18 staff that could be considered to allow each other if you like to cross check
19 their work and continuing education within the institution etc. and I'm also
20 aware that the UK have chosen a figure of 15,000 and from the information
21 provided in this working draft of Dr Peter's exhibits it would appear that 8%
22 of laboratories in the UK would appear to be screening less than 10,000
23 smears a year and presumably that's because that's a guideline rather than a
24 mandatory requirement so I'm getting there in the end. I would prefer to see
25 a minimum of 20,000 smears a year and I could understand a figure of
26 15,000 being chosen from the information that I've been provided with
27 though I have concerns in the sense that within a summary of an academic
28 paper is provided within this working draft, looking at high volume v's low

1 volume laboratories and I suspect there is quite a bit of variation about the
2 middle range the 10,000 to 20,000 smear laboratory ranges so I would be
3 reluctant to therefore suggest a minimum at the bottom end of that difference
4 if you like so I would be reluctant to go with the 12,000 minimum volume.
5 As I say my preference would be 20,000 but I could live with 15,000
6 possibility moving to 20,000 within a period of time to allow the work force
7 to adapt, that's the way I would respond to that.
8 Q: Do you understand that an element of pragmatism has perhaps crept
9 into this discussion having regard particularly to the position of hospital
10 laboratories?
11 A: Yes that element has always crept into this discussion. Essentially it
12 means that almost all, I think all bar one of the hospital laboratories would
13 not be able to process gynecological cytology on site though I don't see any
14 reason why they can't cooperate with, combine if you like in the sense of
15 that work and have it all processed at one centre, one site. Now whether that
16 would still get them up to the 20,000 figure that I mentioned is probably
17 doubtful but it may bring them up to a 15,000 figure. I think it's important
18 that at least one hospital laboratory is doing gynecological cytology, one
19 public hospital laboratory is doing gynecological cytology for various
20 reasons in particular to provide a training environment for people in the
21 field. I'm aware that there are lots of issues associated with moving to this
22 sort of volume specification for the laboratories. One of them, there are
23 whole load of implications that are downstream in terms of the interaction
24 between general practitioners if you like and the laboratory staff and also
25 between the gynecologist and the laboratories they currently use.
26
27 CHAIR INTERJECTS AND XXN WITNESS

1 CHAIR: Are all those factors a reason for not having a minimum
2 number of smears standard in place?
3 A: No I don't think there sufficient to overrule that. I think it would be
4 helpful as a blunt instrument and I am sure that there are competent people
5 who are currently working in the environment less than that standard. One
6 of the problems is other sufficient checks and balances on them and other
7 people within their practice allow that to be maintained continuously over
8 long periods of time.
9 Q: I note the evidence from the Tairawhiti Che or Hospital Service I
10 think it now is about their laboratory was that at one point a pathologist, I
11 think was Dr Lapham, decided that there weren't sufficient smears coming
12 to the laboratory to retain her competence and so she then stopped reading
13 smears. It seems to me that although there is outlined this need to have
14 hospitals doing cytology screening as a training exercise, equally if the
15 hospitals are not reading a lot of smears it could one, raise doubts about the
16 competency or the accuracy of the smears being read in the hospital, and
17 two, in any event would it not cast doubt upon the ability to train, in the
18 sense that what is the value of training in a hospital that is reading a very
19 small number of smears?
20 A: I agree there is a problem with that. I would also note in the World
21 Health Organisation guidelines for example they suggest that 50,000 is the
22 sort of level you need to get to make it efficient. I think they mean cost-
23 efficient.
24 Q: So this notion that hospital laboratories need to keep reading cytology
25 for training purposes you would not see as an adequate reason for not
26 imposing a minimum standard of 10,000, which is considered in the Peters
27 exhibit and on your evidence, above and beyond that number?

1 A: I wouldn't see it as over-riding the need for it, I believe.
2 Q: You had said when the programme commenced that you thought
3 cytology could have been read by say 4 laboratories. I had asked Dr Teague
4 questions to this effect and I recall his evidence at one point was that there
5 was a concern when the programme was being started up that laboratories
6 would not be able to cope with the number of smears that would be required
7 to be read. From your knowledge and involvement in the programme, do
8 you think it would have been possible at the outset if a different system had
9 been adopted whereby the programme put out a tender to a number of
10 laboratories and chose what it saw as the 4 best qualified laboratories to do
11 cytology screening for the programme?
12 A: they could have approached it that way.
13 Q: They could have?
14 A: I haven't been involved in it in an administrative level.
15 Q: You don't think there could have been a problem in terms of there
16 being no 4 laboratories in the country that could have handled the number of
17 smears generated by the programme?
18 A: They would have needed time to get prepared to cope with it, but if that
19 was the clear signal and that was going to be mandatory if you like, then
20 they would not have had any options other than to proceed along those lines.
21 There's no real reason for laboratories I suppose not to co-operate in terms of
22 gynaecological cytology so that they have arrangements amongst themselves
23 so that for that part of the work that comes into their particular laboratory
24 it's forwarded to another place where the reading is actually done and then
25 the report comes back to the laboratory, if you like, or directly back to the
26 clinician.

1 Q: So it could have been done either by having 4 laboratories or
2 laboratories in a sense consolidating their cytology reading by sharing it
3 amongst themselves?
4 A: Not sharing so much but deciding amongst a collective, if you like,
5 which one's going to do gynaecological cytology and making sure that that's
6 where that particular work was done. I noticed in this that it's not just
7 hospital laboratories that were below this minimum, I think there were 6
8 community laboratories that would also be below this proposed minimum if
9 I'm correct.
10 Thank you.
11
12 MR CORKILL: Dr Cox if you turn to tab 40, p5.12, this document is the
13 proposed policy and quality standards manual – Peters supplementary
14 exhibits, which is where the volumes document was, and you'll see there Dr
15 Cox the proposed standard 504 that each laboratory site will process a
16 minimum of 12,000 gynaecological cytology smears/annum. Are you with
17 me?
18 A: Sorry, I don't actually have that at the moment.
19 Q: Tab 40, p5.12.
20 A: Yes.
21 Q: A third of the way down you see the discussion we've just been having
22 translated into a standard?
23 A: Yes. These are still working draft I understand.
24 Q: Indeed, and that is why I want to ask you this question: Given that this
25 proposition is still only in draft, as it were, do you see it as important that
26 there is no more beating about the bush on this issue and that there is indeed
27 a standard with which they must comply?

1 A: Yes I think there should be no more beating around the bush and that a
2 standard should be set and it should be at least comparable and justifiable in
3 terms of what others have set elsewhere and the limited amount of research
4 on the outcomes by laboratory size that we have.
5
6 CHAIR: Could we just pause there. Mr Murray, I just want to check with
7 you yet again.
8 MR MURRAY: I know.
9 CHAIR: My understanding is that chapter 5 of these draft standards has
10 been incorporated by a variation in the existing contracts into the contracts
11 the Health Funding Authority has with laboratories; is that correct?
12 MR MURRAY: That's my understanding from Tracey Mellor's evidence
13 but if I can just clarify one point with Dr Beattie?
14 CHAIR: Yes.
15 MR MURRAY: Only with private laboratories.
16 CHAIR: So as at the current time, all private laboratories doing cytology
17 screening in NZ must comply with standard 504 – i.e. they must process a
18 minimum of 12,000 gynaecological cytology smears/annum; is that
19 correct?
20 MR MURRAY: Yes. Although I say yes, but –
21 CHAIR: Well it doesn't look like it from the body language behind you. I
22 really need to know what the picture is here.
23 MR MURRAY: I think it's a problem of the law and the fact, so Tracey
24 Mellor's evidence was quite clear on the law really because of the variation
25 to the contracts and that has incorporated these into the private laboratory
26 contracts even though there's still a step to go before the working document
27 is rounded off as a final. But I expect that on the question of compliance
28 with minimum smears there is a real practical issue of whether on day one,

1 that that variation came into effect, did it bite on any laboratories that were
2 below that and, if so, what's the answer.
3 CHAIR: Well I would like to know all of that because this to me is now, to
4 start using legal terms, looking more and more like a conditional contract
5 than an unconditional contract, because to my way of thinking an
6 unconditional contract is an absolute, you have a legal obligation to do it
7 from the time the contract is entered into, you must do it. Your conditional
8 contracts depend whether or not obligations have to be performed depend on
9 certain events. Now if the situation here is that chapter 5 is legally in force
10 but in circumstances where the performance of the obligation is dependent
11 on certain events and that obligation hasn't actually kicked into effect yet, I
12 very much need to know that.
13 MR MURRAY: We still have Dr Peters to come back on some other points
14 and I think that might be a convenient opportunity to just get Dr Peters reply
15 on that point, which I hope will sit comfortably with what Tracey Mellor
16 said as well.
17 CHAIR: And it may too be necessary I think to have the full contract so the
18 committee can read the contract, hear submissions from lawyers as to how
19 they see the terms of the contract.
20 MR MURRAY: We are obtaining that.
21 WITNESS: Can I comment.
22 CHAIR: Yes, Dr Cox.
23 WITNESS: Presumably 12,000 smear/annum would be in the contract, but
24 a year has not passed.
25 MR CORKILL: Madam Chair, my reason for raising this issue is because I
26 understand this document – whether or not it has been incorporated into a
27 contract – still has to have the word "draft" attached to it. To the extent that

1 there is any further discussion around these issues, I wanted this witness to
2 comment on this issue.
3 CHAIR: Yes, well I accept all of that Mr Corkill, although I don't want to
4 get caught up with terminology in the sense that the fact you choose to call
5 something a draft doesn't affect its legal standing if you actually incorporate
6 it into a contract so it becomes the terms of the contract. So the fact that
7 it's called a draft doesn't make it a draft legally, but I need to know in
8 substance what is actually happening with this document.
9
10 MR CORKILL REPLIES & CONTINUES XXN OF WITNESS
11 MR CORKILL: Dr Cox's position is clear, there should be a measure or
12 there should be a standard on this issue, is that correct?
13 A: Yes.
14 Q: Moving along, paragraph 247 of your brief, you make a
15 recommendation relating to the topic of central organisation and you talk
16 about a central suitably staffed office with an individual who is responsible
17 for the programme. Could you please just elaborate on the disciplines that
18 you think should be within such an office.
19 A: I believe those disciplines are outlined probably in two places. One
20 in the Oct 94 report of CSLAC which I haven't got the list with me but it's
21 there. I could read them out.
22 Q: Just so we're clear about what you're saying if you could go to
23 Glackin 35 you're talking about the CSLAC evaluation report?
24 A: Yes.
25 Q: And the list that we saw earlier today on the same page has the
26 recommendations setting out the various disciplines which should be
27 incorporated.

1 A: Yes and I think the WHO managerial guidelines themselves have a
2 list of disciplines which are not too dissimilar.
3 Q: So just for the record, tab 35, page 2 of the report, paragraph 2. You
4 got that?
5 A: Yes. I've added a health economist here. It does vary a little
6 depending on the document you look at I must say. But certainly public
7 health medicine specialists should lead it and I think it should be an
8 epidemiologist or a pathologist or biostatician I would think would be in –
9 and the pathologist may be required and I'm not sure exactly how many
10 tenths they would be required. I doubt if they would be required full time
11 and other expertise – I'm not sure we're referring to that particular
12 paragraph when you read then out to me earlier.
13 Q: The disciplines I read out were from paragraph 2 on page 2 of the
14 report.
15 A: Fair enough.
16 Q: Another recommendation you also make in your brief is at paragraphs
17 253 following where you elaborate on the need for a cancer control agency
18 for New Zealand.
19 A: Yes.
20 Q: Now at paragraph 17 of your brief you refer to the fact that you chair
21 the national cancer control steering committee.
22 A: Yes.
23 Q: Also the task force of that committee.
24 A: Yes.
25 Q: And in the next paragraph you have also acted as a consultant for the
26 WHO on national cancer control programmes. My question is in relation
27 firstly to the cancer councils that you refer to in your brief, in Australia do
28 you see them as some sort of model which should be applied here?

1 A: The cancer council's certainly in Victoria and NSW I believe are set
2 up under statute by their local state Depts of Health and they have a board
3 which reports, now I'm not sure at exactly what level within the Dept of
4 Health that it reports whether it's of the Minister, I think it may be of the
5 Minister of the State Dept and it may vary between Victoria and NSW.
6 That body, some of it's work is very similar to the Cancer Society of New
7 Zealand. Other aspects of it's work are not something the Cancer Society
8 has conducted, for example the Cancer Registry for example in NSW lies
9 within the cancer council and I think that's the same in Victoria where they
10 have what's called an anti cancer council.
11 Q: Pausing there do you see that model that you are describing as
12 relevant for New Zealand.
13 A: Very relevant to New Zealand and I think a statutory body is an
14 appropriate way forward.
15 Q: Could you describe the main roles that you would see such an agency
16 fulfilling?
17 A: Well it certainly would have a monitoring and evaluation role but also
18 a role in the running of the breach screening programme the Cervical
19 Screening Programme the cancer registry and there are other aspects of
20 cancer control associated with some aspects of treatment guidelines
21 assessment of survival after diagnosis, it would also co-ordinate to some
22 extent the activities of different agencies that are all involved in different
23 aspects of cancer control from primary prevention through screening
24 treatment rehabilitation and palliative care and it would identify where
25 improvements might be or resources might be best focused for
26 improvements to be made in terms of reducing the burden of cancer and the
27 suffering of people after diagnosis. So it would have that gambit and be
28 specifically focused on those aspects.

1 Q: Earlier in this inquiry Professor Skegg produced as his exhibit 8 an
2 editorial which he and you and others published in the Medical Journal.
3 You will recall that, you can look at it if you wish but I'm sure you know
4 what I'm talking about.
5 A: Yes.
6 Q: December of last year.
7 A: Yes.
8
9 CHAIR ADDRESSES MR CORKILL
10 CHAIR: Could you just say if it's in the exhibits.
11 MR CORKILL: It's loose exhibit Skegg 008.
12 CHAIR: Thank you just so it's noted in the record.
13
14 MR CORKILL CONTINUES XXN OF WITNESS
15 MR CORKILL: What is the current status of this issue. There was a
16 workshop in Porirua last year, August, there is a committee that has been set
17 up under you. This article has been published. What do you understand the
18 current status of this issue to be?
19 A: Small correction the workshop was in Wellington downtown but the
20 current status of this issue is that the workshop unanimously recommended
21 the establishment of a cancer control secretariat through a consortium of
22 agencies and they specifically looked at various models and did not favour a
23 secretariat developed within the Ministry of Health or one of the funding
24 agencies, they sought a secretariat set up in a different institution from one
25 of the major funders of the initiative and it would be supported by funds of
26 the different agencies and some agencies could participate without
27 necessarily offering funds because they're relatively small and couldn't
28 afford to contribute and this small secretariat would work with various

1 organisations involved in aspects of cancer control in New Zealand to
2 develop a national cancer control strategy for the country and through the
3 process would develop an investment by the different agencies into the final
4 national cancer control strategy so that they could reflect that in their
5 business plans and other aspects of their work and it would make the great
6 amount of work that's done by numerous organisations to reduce the impact
7 of cancer in the community. By increasing that organisation of that would
8 make a bigger impact on our cancer mortality and incidence rates which are
9 relatively high by world standards.
10 Q: What do you understand the government's current view on this issue is?
11 A: currently I believe the government are pursuing an approach of trying
12 to incorporate a national cancer control strategy within their NZ health
13 strategy initiative that they started earlier this year and is primarily driven –
14 well, it is driven by the Ministry of Health, which is, as I say, contrary to the
15 recommendation of the workshop that we had last year. Several agencies
16 have come forward with funding for the consortium approach to a cancer
17 control approach to a cancer control secretariat and we currently have
18 sufficient funds, particularly from the Cancer Society and the Child Cancer
19 Foundation and I've asked the Health Funding Authority, who initially were
20 prepared to put forward $50,000 in their last financial year, whether that still
21 applies in their budget for this financial year so that we can establish a
22 cancer control secretariat and forward the intentions of the cancer control
23 workshop participants of last year.
24 Q: And it's your optimum position that such an agency should be set up
25 and that these screening programmes, breast and cervical cancer, should
26 reside within that agency?
27 A: Yes, the cancer control secretariat is a different initiative than having
28 an agency, but in the end, whatever NZ national cancer control strategy is

1 developed, needs to be owned by somebody or an organisation who has
2 some dedication to seeing that through and the best way I believe to ensure
3 that that happens is to have a national cancer control agency with the
4 components that I suggested at the very least.
5
6 CHAIR: To what degree are these ideas of yours and the ideas of the
7 persons at the national workshop influenced by knowledge that in the new
8 restructuring there will be the Ministry of Health in a policy funder role with
9 22 District Health Boards?
10 A: I think I and a lot of other people are concerned that 22 District Health
11 Boards certainly gives plenty of scope for 22 different variations of lots of
12 things. And that to some extent that will include the practice of the care of
13 patients and to make advances in the area of cancer control there's been an
14 increased awareness that a multi-disciplinary approach is required to the care
15 of many patients with cancer. For some particular cancer sites more than
16 others. A lot of this awareness actually has come out of experience
17 overseas with treatment of patients detected through screening in fact but it's
18 not just in that area, and that's developed over the last 10 years. If we get
19 down to 22 small areas it may be very difficult to establish multi-disciplinary
20 teams in the treatment of cancer. Currently most of the – there are only I
21 think radiotherapy units in public hospitals. I don't think there are any in
22 private for example. So even if you've got 22 small areas you still are
23 going to need quite a lot of referral to more major oncology centres. That
24 will take co-ordination in itself and there should be I think greater co-
25 ordination between the oncology centres as well.
26 Q: And to what extent are these concerns coloured by the past experience
27 when the Cervical Screening Programme was split between the 14 Area
28 Health Boards in terms of the delivery of aspects of the programme?

1 A: I don't think my personal view of this is actually influenced much by
2 that, it's more something that has arisen in the overseas literature and
3 certainly the World Health Organisation now recommend to countries that
4 they establish national cancer control programmes. It would seem
5 appropriate – I take that back a little. From the experience with the
6 Ministry and the Dept of the screening programme within the Dept or
7 Ministry of Health may not be the best siting for such an initiative.
8 Q: Do you hold concerns for the Cervical Screening Programme's future
9 in terms of my understanding is that in the short term it is envisaged that the
10 programme will remain with the Ministry of Health/Health Funding
11 Authority but at the moment there is no long term view on where it will fall
12 within the reformed health structure with the 22 health boards.
13 A: I have major concerns about that. And I think that applies to any
14 national programme, whether it be breast screening, cervical screening or
15 any other service that needs to be required at a national level.
16 Q: Can you imagine any way in which the programme could operate if
17 parts of the programme, or even all of the programme, were in some way
18 devolved to the 22 District Health Boards?
19 A: No. I mean currently the smear taking is the only thing that's devolved
20 right out there, and those people in general do a tremendous job.
21 Thank you.
22
23 MR CORKILL: Just a final topic Dr Cox. I would like you to go please to
24 the supplementary evidence of Tracey Mellor, p49 of tab 87. You have seen
25 this material and had a good chance of carefully it, is that correct?
26 A: Yes.
27 Q: Are there some issues arising out of these tables you would like to
28 discuss with the Inquiry team?

1 A: Yes.
2 Q: Could you please do so.
3 A: This is tables 5.3 through to 5.6?
4 Q: Yes.
5 A: I'd like to start, if I may, on 5.6 because I believe that this table is very
6 crucial to the terms of reference 1 as has been identified yesterday. I would
7 like to use this table to estimate the laboratory sensitivity for the detection of
8 high grade or cancer of both Dr Bottrill's laboratory and the Sydney
9 laboratory. And to do that I would like to invoke an assumption that of
10 those who've developed cancer right through to beyond May 1999 that they
11 had either cancer or high grade throughout the entire period.
12 CHAIR: What period's that?
13 A: From 91 right through. Now I realise that it is possible, although I
14 think a relatively small probability, that high grade or worse has not been
15 present throughout, and for many of these it may have been high grade and
16 then subsequently developed cancer. And if I invoke that, the original
17 laboratory or Dr Bottrill's laboratory, which is 5.6b, we end up with 12 of 39
18 detected and that I think it's probably to be fair appropriate to include the
19 two low grade reports on the original result as it's possible that that could
20 have precipitated, the low grade disease may have been all that was present
21 in the earliest time period as well so I'm trying to be inclusive here and that
22 ends up with an original laboratory sensitivity of 35.9% in my calculations
23 and if you do a similar, which is 14 over 39, and if you a similar thing for the
24 re-read at the Sydney laboratory and I'm not including ASCUS H in at this
25 time because I think that ASCUS was originally a category in itself and it
26 got split so it's possible if the reporting that was more usual in 1991-1996
27 applied then ASCUS H may well have ended up just being ASCUS so I'll
28 exclude that and you end up with 37 out of 39 being positive which would

1 give a sensitivity for that laboratory of 95%. Now I realise that I would also
2 like to invoke a benchmark of say 85% laboratory sensitivity. Now I know
3 normally in terms of Dr McGoogan's evidence that has been calculated in a
4 very different manner to do with rereading of slides within the laboratory but
5 if I invoke that then Dr Bottrill's sensitivity as I measures is statistical
6 significantly lower than that benchmark and moreover the benchmark would
7 have to be 51% for the difference between the benchmark and Dr Bottrill's
8 laboratory to not be statistical significant and I believe that even under the
9 assumptions I need to invoke if you like to calculate these sensitivities, a
10 figure of 51% would not be agreed on by anybody.
11
12 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
13 PROFESSOR DUGGAN: Could I just ask you to clarify one thing.
14 For Dr Bottrill's laboratory you are accepting as a predictor of the cancer his
15 6 diagnosis of cancer in the first row, the 6 of high grade in the second row
16 and the 5 low grade.
17 A: Sorry I have missed that. I take that back.
18 Q: That's the pathologist's greatest joy to correct an epidemiologist.
19 A: I can recalculate things but I still don't think and I'm pretty sure –
20
21 CHAIR INTERJECTS AND XXN WITNESS
22 CHAIR: Could you please recalculate so we've got something.
23 A: 43.5%. And I therefore need to do something a little different. In
24 which case the benchmark cut off that I mentioned before would not be 51%
25 it would be 59% and I still believe that would not be a level which would be
26 acceptable.
27

1 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
2 PROFESSOR DUGGAN: Just for the committee how did you
3 calculate that benchmark of 59%.
4 A: I believe the variants for a binomial proportion which is what the
5 laboratory sensitivity is is what's called PQ/N. P which is this probability
6 here of .435 x 1 minus that figure divided by the number overall which is 39
7 and the square root of that figure is the standard deviation. By taking that
8 standard deviation and multiplying it by 1.96 which is a standard figure in
9 the normal distribution table for 95% confidence interval or limit you get a
10 figure of something like .15. You then have to add that to your original .435
11 because when you just multiply the standard deviation by 1.96 you get the
12 difference between a benchmark and this particular figure then you have to
13 add that difference to the figure so from that I calculate that the benchmark
14 would need to be 59% for there not to be a statistical significant difference
15 between Dr Bottrill's sensitivity invoking the assumptions I did and the
16 benchmark. Obviously the re-read laboratory has a figure and I hope I got
17 this right of 95% sensitivity and is obviously – would be very acceptable.
18 Q: So the Sydney reporting is acceptable?
19 A: On the basis of table 5.6 and the assumptions that I invoked except in
20 terms of it's estimated sensitivity. There are other issues with the Sydney
21 laboratory but not related to the sensitivity.
22 Q: What about Dr Bottrill's result.
23 A: Dr Bottrill's result I believe is unacceptable low.
24
25 CHAIR INTERJECTS AND XXN WITNESS
26 CHAIR: You said you've used as a reliable benchmark a figure of 85%
27 where did you get that from?

1 A: Well I didn't necessarily say it was reliable I just said I would invoke
2 it partly because in Dr McGoogan's evidence in calculating the laboratory
3 sensitivity a very different way which was by relooking at slides, their range
4 of laboratory sensitivities .85 - .09, 85% or 95% for their standard as you
5 like.
6 Q: So your using it as a rule of thumb here.
7 A: I was trying to use that as a rule of thumb as a starting point. I realise
8 the benchmark and the way this is calculated is quite different and so I
9 actually prefer to calculate what the benchmark would need to be.
10 Q: And on that basis then you have a benchmark of 59% and in your
11 view that would be too low by anyone's standards.
12 A: Yes.
13
14 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
15 PROFESSOR DUGGAN: Dr Cox even if you were not to evaluate
16 this data without using the 85% benchmark put forward by Dr McGoogan, a
17 sensitivity of 95% for Sydney v a sensitivity of 43.5% for Dr Bottrill, could
18 you comment on those just approaching it as an inter-laboratory comparison
19 where variables for each laboratory are essentially controlled except for the
20 reporting of the smear?
21 A: Well obviously that difference is even greater than the benchmark I
22 invoked and is highly statistically significant. The issue here is that
23 laboratories set their own tradeoff between sensitivity and specificity, which
24 is a technical term. I think they've been defined to the Inquiry earlier. And
25 each laboratory is probably different in the balance between sensitivity and
26 specificity they choose. Unfortunately some laboratories it occurs by
27 default rather than by intent. I think here we have a situation where we have
28 a, if you like, two opposite extremes where the Sydney laboratory has a high

1 sensitivity in terms of laboratory reporting and Dr Bottrill's laboratory has a
2 relatively low sensitivity. As a consequence I believe he has a high
3 specificity and I've estimated that from the data available as well.
4
5 CHAIR: Could you give us that too?
6 A: I will shortly. And the Sydney laboratory has a high specificity but it's
7 lower than Dr Bottrill's. So we have this contrast and the tradeoff is that if
8 the Sydney laboratory had been, if you like, reading the smears through to
9 the time period of 1991 to 1996 then we would most likely detect something
10 like twice as many cancers and we would have had about 3., or maybe 3
11 times the amount of referral for colposcopy or having a repeat smear. I
12 must say that in these calculations I have to acknowledge that there is a
13 combination of both screening smears and diagnostic smears within the
14 series, but I would expect that the presence of diagnostic smears to actually
15 increase the sensitivity because most times I would expect an indication or
16 signs or symptoms on the request form which would heighten the readers
17 index of suspicion when reading the smears in the first place.
18 Q: the assumption you have made that the women concerned were likely to
19 have cancer or high grade abnormality between 91 and 99, how comfortable
20 are you with making that assumption – in other words, is there a high
21 probability that that was so, a low probability, in the middle – what?
22 A: I believe there's a high probability that great majority of those people
23 who developed the cancer during the period will have had high grade or as
24 I've said earlier, low grade or cancer present on their cervix all the way
25 through.
26 Q: So if you were doing this as an epidemiological study you would feel
27 scientifically comfortable about making that assumption?

1 A: I would feel some nervousness about making the assumption, and in a
2 way I am disappointed in the sense that from the way the tables are created,
3 you expect that the individual record data would allow this to be calculated
4 in a different way that might be much more informative and reduce that
5 possibility. So I have some nervousness about the assumption but I think, in
6 terms of comparative purposes, it applies to both.
7 Yes, thank you.
8
9 MR CORKILL: I think you had some more?
10 A: Oh, the specificity issue?
11 Q: Yes.
12 A: Well, I hope I haven't made any boo-boos in this one either, but I don't
13 believe I have.
14 Q: We'll pick them up.
15 A: Thank you very much. I would like to have the opportunity to
16 thoroughly check these.
17 Q: It's called peer review.
18 A: That's right. A legal peer review, I like it. Now looking at Tracey
19 Mellor's additional tables that were provided to her supplementary brief, I
20 think that is in 1997, have I got that right?
21 Q: I think they are Skegg tables are they?
22 A: No, they are not.
23 CHAIR: The locum's tables.
24 A: They had all smears not including a locum and including a locum. 97,
25 thank you. I've gone to the second table, the summary of grade differences
26 and it should read "including all smears" up at the top left hand corner, but
27 the second table "summary of grade differences (diagnosis)" and I've used
28 the far right hand column where it says "cancer or high grade" and added

1 those two together. That's for the original report, the total in cancer or high
2 grade was 123. Now we have had calculated from tables 5.3 and 5.4 of the
3 supplementary brief of Tracey Mellor the false positive rate I think
4 everybody's described it as, and I think it was 3.9% if I recall for Dr Bottrill
5 and 28.9% for the Sydney laboratory.
6 Q: That's correct.
7 A: So what I've done is if you take these 123 reports of cancer of high
8 grade I've used the 3.9% figure to calculate the number who are probably
9 true high grades. And by subtracting – sorry, I've calculated the number
10 who were falsely positive – in other words, they had a cancer or high grade
11 result but were actually normal is what I meant. And if you subtract that
12 total from 22,000 in 96, which is half-way down there which is the total
13 normal results – actually it should – no, that's right, and then take that
14 difference and put it over the 22,000 in 96 you get an estimate of the original
15 laboratory's specificity. And that I calculate to be 99.5%. I can provide
16 these calculations in a better form.
17
18 CHAIR: If you could remember to walk us through every step because your
19 evidence is being recorded and of course it may be that someone else will
20 want to read your evidence to see whether or not it stands up or not, so we
21 need to have it all in evidence and if you can give us a full breakdown of the
22 calculations in writing that would be helpful.
23 A: Sure, so my calculation is that we have - the mathematical formula
24 would be 22,096 minus 123 times (1 minus 3 over 76) all divided by 22,09
25 and then I came to a figure of 99.5% and in terms of the specificity of the
26 reading of the smears for the Sydney laboratory I then used a similar
27 approach using 29.8% as the number of people with positive diagnosis who
28 were normal.

1 PROFESSOR DUGGAN: 28.9%
2 A: 28.9% I'm sorry that's what I meant to say I obviously meant to say
3 something else I'm very sorry.
4
5 CHAIR INTERJECTS AND XXN WITNESS
6 CHAIR: Please try to be specific. I notice sometimes mathematicians
7 will round things up or say it doesn't matter if something is a little bit wrong
8 but it does worry us.
9
10 WITNESS REPLIES
11 A: Thank you. And so I end up using the very last row and using as the
12 total 22,976 minus the unsatisfactories of 1,206 so I get a figure of 21,770
13 and so the re-read specificity I calculate to be 21,770 minus 573 which is
14 29+544x(1-22/76) / 21,770 and I get a specificity of 98.1%.
15
16 PROFESSOR DUGGAN CONTINUES XXN OF WITNESS
17 PROFESSOR DUGGAN: Dr Cox what does that mean?
18 A: The specificity is the probability that someone does not have high
19 grade or cancer will have a negative test. The sensitivity is the probability
20 the someone with high grade or cancer will have a positive test which is a
21 report of high grade or cancer and I would say that in screening what
22 determines positive and negative is about what action is taken and that's why
23 the high grade is being used as a cut off because it definitely would result in
24 referral.
25
26 CHAIR INTERJECTS AND XXN WITNESS
27 CHAIR: And in terms of the specificity of Dr Bottrill's laboratory
28 99.5% what comment do you make about that level of specificity.

1 A: It's extremely high. It's unfortunate that it appears to have occurred at
2 the consequence of an unacceptable level of sensitivity. I would have
3 thought it would also be very difficult for a laboratory, and I'm quite
4 prepared to be correct on this by pathologists who are used to looking at
5 their laboratory etc, I think it would be quite difficult for a laboratory to have
6 such a high specificity and a high sensitivity although I am quite prepared to
7 be corrected on that issue. The Sydney specificity of 98.1% is very
8 acceptable by international standards and I think anything over sort of 97%
9 is appropriate.
10 Q: Well in terms then of Dr Bottrill's laboratory which had a sensitivity
11 of 59% and specificity of 99.5% what conclusions can you draw from those
12 figures – I'm being corrected I understand the sensitivity was 43%.
13 A: Yes.
14 Q: Sensitivity of 43% and a specificity of 99.5%, what do you conclude
15 from those figures in determining whether or not he may have been under-
16 reporting?
17 A: I believe there was an unacceptable level of under-reporting in Dr
18 Bottrill's laboratory.
19 Q: If you had to put it on a scale between 1-10 with 10 being the
20 highest, 1 being the lowest, could you put it on a scale.
21 A: I won't do that.
22 Q: You won't. That's fine. But your quite clear it was unacceptable
23 under-reporting.
24 A: Absolutely.
25
26 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
27 PROFESSOR DUGGAN: Just looking at the numbers, does
28 anything leap out at you to account for such a result in terms of Dr Bottrill's

1 practice when I believe I heard you say that the Sydney practice is more in
2 line with what is usual practice.
3 A: The Sydney laboratory on the face of the calculations that I've made
4 which seem to be very much in line with usual practice and Dr Bottrill's
5 laboratory is therefore very different from usual practice and indeed I think
6 the Sydney laboratory almost four times more people would have a second
7 smear or referral to colposcopy than under Dr Bottrill's regime.
8 Q: Is there anything from these numbers that will allow you to deduce
9 what was unique to Dr Bottrill's practice that eventuated in such numbers?
10 A: It strongly suggests that the index of suspicion was set far too high
11 within his laboratory and that he therefore didn't allow some women with no
12 abnormality if you like to come through even if they would have had
13 abnormal smears. I'm not saying it very well you may have to ask it again.
14 Q: Could I ask you to explain, and if you can't please say you can't, what
15 you mean by index of suspicion?
16 A: I mean the alertness if you like that someone has to abnormal changes
17 that are apparent when they are reading the tests, looking at the smears and
18 so that's probably not a good explanation. I am also aware, I should have
19 stated earlier, that the Sydney laboratory when they recoverslipped I think it
20 was 50% if I recall correctly the slides, there was also a comment that
21 therefore more material was available to them. I think it was another extra
22 25% of the 50% so they were looking at more cells for some of the slides
23 than was originally the case and that appears to be an issue in terms of the
24 application of coverslips so that would also increase their sensitivity over
25 and above I expect Dr Bottrill's laboratory.
26
27 MR CORKILL CONTINUES XXN OF WITNESS

1 MR CORKILL: Dr Cox back at table 5.3 and 5.4 was there anything
2 else you wished to say in relation to those tables.
3 A: Not really I initially looked at 5.4a and 5.3a to try to a similar thing
4 but I think the time period is quite long and 91-96 and you have all sorts of
5 problems with disease arising de nova or regressing so that's it difficult to
6 use that to calculate a sensitivity for the two laboratories so I did initially and
7 then decided to throw it away but I did use the figures – those tables are used
8 as previously to work out the false positive.
9 Q: Thank you no further questions.
10
11 CHAIR ADDRESSES INQUIRY
12 CHAIR: Does anyone else have any questions. Yes Mr Kirton. We
13 shall break now and then start. We'll start at 3:45.
14
15 INQUIRY RETIRES UNTIL 3:45
16

1
2 THE HEARING RESUMED AT 3.47 PM
3
4 MR KIRTON CONTINUES XXN OF WITNESS
5 MR KIRTON: Dr Cox, I want to traverse some territory you covered
6 earlier with regard to the ethical obligations that you felt as a professional
7 giving advice to the Minister. First, I would like to clear up one point in
8 your brief at para 168 which you refer to a CSAC minute of 15 June 1994
9 and I wonder whether we could go to that, your exhibit 004 at p122. I think
10 the minutes themselves start at p116. In your evidence you say "again it
11 was proposed that there should be a review of the slides of women who
12 developed invasive cervical cancer. The national co-ordinator agreed to
13 investigate this proposal" and that appears in the minute at p122, is that
14 right?
15 A: Yes, there should be a proper review of their slides as well.
16 Q: So the concept of a review is not something that has come out of this
17 Inquiry, it's something that has been considered for a significant period of
18 time, is that correct?
19 A: Yes, I believe it was mentioned in the ministerial review as well of 89.
20 It's been repeatedly suggested over many, many years.
21 Q: Do you know what the action was of the national co-ordinator
22 following that meeting on the 15 June 1994; was there any result from that?
23 A: I'm not aware of any response. Nothing happened, if that's what you
24 mean.
25 Q: Can I now move on to the issues that I wanted to cover in terms of the
26 ethical consideration. At paras 158 to 162 of your brief you've outlined
27 various elements of the government's policy for cervical screening and I
28 wonder if we could turn to that now, the reference is Glackin volume 6, tab

1 27. You'll see there that's the government policy, updated on October
2 1993?
3 A: Yes.
4 Q: If you could go to p8 you will see there "responsibilities of Ministry of
5 Health/RHAs etc, including the CSAC?
6 A: Yes.
7 Q: If you could now turn to p10 at 8.1.5.
8 A: Yes.
9 Q: And you read there "the main responsibilities of the CSAC and there
10 are three dot points, do you see that?
11 A: Yes.
12 Q: And they were to provide ongoing advice to the Minister of Health, is
13 that correct?
14 A: Yes.
15 Q: To advise on the monitoring and evaluation of effectiveness and
16 efficient of the programme?
17 A: Yes.
18 Q: And identify any additional issues which the Minister of Health should
19 address?
20 A: Yes.
21 Q: Do you think you discharged those duties?
22 A: I think we discharged them well and as much as we could.
23 Q: You referred earlier to the notion of some ethical obligations with
24 regard to monitoring and evaluation?
25 A: Yes.
26 Q: And you referred to I think I'm correct in quoting you as saying that
27 you felt professionally unsafe. Is that the term you used?

1 A: Yes I believe it was an equivalent term.
2 Q: Could you describe what you mean by that in terms of that ethical
3 obligation to deliver your responsibilities under 8.1.5.
4 A: well my ethical responsibility as a public health medicine specialist is to
5 give advice - in this situation to give the best advice I can with my expertise
6 and knowledge and make it available to the Minister and the Ministry for the
7 conduct of the National Cervical Screening Programme and that advice, if
8 unheeded, or if failures occur, then that reflects on the individuals who are
9 involved, regardless of whether they gave good advice and it wasn't acted
10 upon. The fact of just giving good advice that wasn't acted on I don't think
11 in the end allows you to feel comfortable that you've discharged your
12 professional responsibilities, although at times it's difficult to see what else
13 you could do. And so at that point, if there was a failure of the National
14 Cervical Screening Programme and I continued to be involved I felt that that
15 would reflect on my competence as a public health medicine specialist.
16 Q: Do you think there was similar obligations on your colleagues on
17 CSAC?
18 A: Certainly other medical professionals on that group had a similar
19 responsibility. I believe that other members of the group who were either in
20 other health professional areas or as individuals without necessarily having a
21 professional qualification also felt a similar responsibility.
22 Q: the outcome of your concerns, or the CSAC concerns found their way
23 into the 1994 report, is that correct, in terms of listing?
24 A: Yes.
25 Q: - to the minister, highlighting to the Minister and the Ministry that these
26 issues were important and had been raised on numerous occasions?
27 A: Yes.

1 Q: And you say in para 177 that this report arose from the frustration of
2 the committee regarding the implementation of the monitoring and
3 evaluation, is that correct?
4 A: Yes I think its completeness and extent was a direct consequence of the
5 frustration and the degree of frustration that the advisory committee had
6 experienced over the entire duration of its existence.
7 Q: Can I turn you now to para 214 to 218 of your brief where you refer to
8 your resignation from CSAC
9 A: Yes.
10 Q: Can you say that you resigned as a direct consequence of the lack of
11 implementation of CSAC's advice to the Minister and the government?
12 A: Yes. Further, my length of involvement had been considerable over a
13 period of time and that these matters had not been addressed and knowing
14 the natural history of cervical cancer I was concerned that any further
15 involvement laid me open to being in a responsible position, if you like.
16 Q: So there was an ethical imperative at stake?
17 A: I felt that, yes, an ethical imperative involved in my resignation.
18 Q: and just looking at that section, your para 215 in terms of some of the
19 rationale for resigning, you say "I felt that the Ministry of Health appeared to
20 want to manage the programme for political reasons rather than making sure
21 it was effective." Can you describe why you've made that statement?
22 A: the programme has always been highly political and in many ways if it
23 hadn't been it probably would have died. And it also would have been not
24 left as untouched as it was by the health reforms, that a lot of emphasis was
25 put on screening coverage of women, the acceptability of programme issues
26 to women if you like in terms of their initial participation. Whenever CSAC
27 tried to go beyond that into some of the clinical issues there didn't seem to be
28 any follow-up or flow-through with Ministry staff, that whenever there were

1 questions about the screening programme it was “our coverage is improving,
2 we’re doing better”, etc, etc, and that was if you like what I consider the
3 political front end of the screening programme rather than the quality
4 assurance process of other aspects of the screening programme. And I
5 believe that there were occasions when the government officials used the
6 improving coverage that had occurred with the move to opt-off to feel
7 comfortable that the programme was succeeding and was working etc, etc,
8 and I must say I believe it has worked in large part throughout NZ. We do
9 have an issue in Gisborne which is most unfortunate.
10 Q: But nevertheless is it true that the monitoring, the critical component of
11 monitoring and evaluation was simply not progressed?
12 A: No, it was not progressed in the way or speed or whatever that it
13 should have been.
14 Q: Can I now take you back in terms of the policy document and that’s
15 again the Glackin exhibit, and we were at p10.
16 A: Yes
17 Q: if we could return to p8.
18 A: Yes.
19 Q: If you go to the top of that page at 7.1.4 you will see there that “the
20 national co-ordinator will be responsible for ensuring that the National
21 Cervical Screening Programme is monitored and evaluated nationally.
22 A: I see that.
23 Q: At the very bottom of the page at the last dot point it says the main
24 responsibilities of the Ministry of Health are to coordinator monitoring and
25 evaluation of the programme you see that?
26 A: Yes.

1 Q: In terms of that ethical obligation we talked about for CSLAC you
2 see an ethical imperative applying on the Ministry in terms of ensuring that
3 that monitoring and evaluation took place.
4 A: Yes.
5 Q: So they had a similar –
6 A: I believe they did and I also believe that health professionals within
7 the organisation had some ethical responsibility as well.
8 Q: Can you say that the ultimate internal responsibility rested with the
9 Director-General of Health?
10 A: The ultimate responsibility I believe rests with cabinets and the
11 Minister but in terms of within the Ministry itself, the ultimate responsibility
12 does rest with the Director-General of Health.
13 Q: I point you to 8.1.2 the main responsibilities of the Ministry of Health
14 do you see that.
15 A: Yes.
16 Q: So in terms of that particular prescription do you see the Ministry
17 having the same responsibility as CSLAC did at 8.1.5?
18 A: Yes in terms of providing, coordinating monitoring and evaluation of
19 the programme.
20 Q: And do you see that responsibly resting with the Director-General of
21 Health.
22 A: I think it is always harsh on the head of the organisation to be totally
23 responsible to everything that is occurring beneath it but ultimately that's
24 were it resides.
25 Q: Was there ever an issue of the Director-General of Health resigning
26 in the way that you did and not fulfilling that obligation under 8.1.2.
27 A: Not that I'm aware of you'd have to ask the persons or person
28 involved.

1 Q: Your not aware of that.
2 A: No.
3 Q: Just while we've still got that document in front of us, if I could take
4 you back a page or two pages to page 6, at 4.1.3 do you see that?
5 A: Yes.
6 Q: The Ministry of Health will be responsible for confirming that those
7 laboratories carrying out cytology screening and histology for the national
8 programme will meet the requirements in 4.1.4 does that refer to TELARC
9 accreditation?
10 A: It certainly does. It appears to yes.
11 Q: Would you agree with the evidence of Ms Glackin in her brief at
12 paragraph 291 that at paragraph 4.1.3 could be read as intending that the
13 Ministry would in some way be responsible for confirming that laboratories
14 were meeting all the requirement criteria required for TELARC registration.
15 Is 4.1.3 equivocal?
16 A: Well if it is I don't believe that's it's intent –
17
18 CHAIR ADDRESSES MR KIRTON
19 CHAIR: Pause. Can this witness give an interpretation of 4.1.3. It's
20 really ultimately would come down to a legal matter.
21 MR KIRTON: Can I rephrase the question Madam Chair.
22
23 MR KIRTON CONTINUES XXN OF WITNESS
24 MR KIRTON: In your opinion does 4.1.3 leave any room for inferring
25 that responsibility for TELARC accreditation falls anywhere except with the
26 Ministry of Health?
27 A: No I don't believe it does.

1 Q: Thank you.
2
3 CHAIR ADDRESSES MR KIRTON
4 CHAIR: Are you going to move on to a new topic.
5 MR KIRTON: No I've just got a –
6 CHAIR: No it's just that I do want to ask Dr Cox some questions about
7 that very policy so –
8 MR KIRTON: Can I just follow through this little bit.
9 CHAIR: You finish and then I'll come in.
10
11 MR KIRTON CONTINUES XXN OF WITNESS
12 MR KIRTON: Just in general terms do you regard this policy
13 document as a guideline or open for interpretation in terms of what is to be
14 implemented and what is not?
15 A: It certainly is a guideline.
16 Q: Do you think it's a guideline.
17 A: Certainly the way it's perceived if it did not, it should have a rider on
18 it somewhere.
19 Q: It's Government policy though is it not.
20 A: Yes.
21 Q: In what circumstances would you describe or would you consider that
22 divergence from the Government policy of the day should be made. Is there
23 any internal reason for not complying with it?
24 A: I don't believe so unless there are mixed messages coming from the
25 Minister in the sense that there is a policy that is presumably signed off by
26 the Minister but other correspondence or conversations which imply
27 otherwise.

1 Q: And so do you expect the Minister and the Government would expect
2 follow through on that policy unless there was some other reason for which
3 they would want to change it.
4 A: Yes.
5 Q: Do you think it's a negotiable document in terms of if the Ministry of
6 Health are to contract the policy into implementation do you think it is their
7 position to negotiate anything other than what is in here?
8 A: I would not think so but surely that's up to the degree of flexibility
9 that the Minister and the Ministry allows.
10 Q: One of those issues could be resources could it.
11 A: Yes it could well be.
12 Q: Professor Skegg made commentary yesterday bout the cost of
13 monitoring and evaluation of the Cervical Screening Programme and from
14 my recollection said in fact that it was a very small monetary part of the
15 entire programme do you agree with that? I think he said resources were not
16 an issue.
17 A: Initially in the first 3 years I don't believe the Government fully spent
18 the $36 million that was initially assigned though I haven't seen the budget
19 of expenditure over that period of time but from various comments and bits
20 of information that I have had I believe that because of the difficulties in
21 getting up and running and because of the delays that savings were made if
22 you like. In terms of the monitoring and evaluation I will assume that you
23 don't mean the actual establishment of the Screening Register and some of
24 those establishment costs you actually mean the process of using data that
25 became available or initiating other forms of investigation to evaluate the
26 programme. There was quite a bit of evaluation I'm aware of that occurred
27 in different Area Health Board regions regarding enrollment and recruitment

1 issues and there were lots of quite disparate evaluations and I think that's
2 were most of the evaluation money was spent.
3
4 MR KIRTON ADDRESS CHAIR
5 MR KIRTON: Madam Chair that's the end of that segment.
6 CHAIR: Thank you.
7
8 CHAIR CONTINUES XXN OF WITNESS
9 CHAIR: Dr Cox while we've got this document open, Glackin volume
10 5 tab 15 which is the Government policy for National Cervical Screening
11 1991. If you would go to paragraph on page 16 that's headed laboratories
12 paragraph 4 you'll see at 4.1.2 it says that all cytology laboratories servicing
13 the screening programme should be registered with TELARC and that a
14 reasonable period of time will be allowed for laboratories to obtain
15 registration this may take up to 2 years. Then see at 4.1.3 which is the
16 passage that Mr Kirton took you to – the Department of Health will be
17 responsible for confirming that those laboratories carrying out cytology
18 screening for the programme meet the requirements set out in 4.1.4.
19 A: Uh huh.
20 Q: And then you see the requirements set out in 4.1.4, "the criteria for
21 registration by TELARC will be established by CALC and the Department
22 of Health to be consulted, and the criteria will include"- and there are a
23 number of matters including reading of minimum smears, employment of
24 adequate numbers of suitably qualified staff.
25 A: Yes.
26 Q: Etcetera, going over the page. What I would like to know from you, in
27 terms of your role on CSAC, because I've picked up from the CSAC minutes
28 that it had a responsibility for advising the dept on monitoring and

1 evaluation of the programme, is that to the best of your knowledge was
2 CALC responsible for any delays in developing criteria for the purposes of
3 4.1.4?
4 A: I'm not aware either way. There were particular issues about the way
5 CALC was formed and who it was accountable to and I believe at this time
6 it didn't have terms of reference – certainly not ones that were specified by
7 the Department of Health because it wasn't a Department of Health
8 committee; it had no formal requirement, if you like, to report to the CSAC.
9 We, except I think in rare instances, never saw the minutes of this
10 committee. There I think were times when we asked for them, though I
11 believe we did on a couple of occasions, but I don't really know. First, I
12 can't actually be sure that we did ask for the minutes but I believe that there
13 were a couple of times when we did. Anyway, we never saw the committee
14 minutes. In fact at one point CSAC was getting a little frustrated because
15 we were then told, when we started getting into issues that weren't
16 monitoring and evaluation we were reminded of the fact when it suited the
17 Ministry officials to remind us of the fact. At point I believe we even
18 discussed at one committee the establishment of a pathology sub-committee
19 of our CSAC committee which of course with CALC's already existence
20 was a little bit ludicrous. So at a later date, and I think it was 95 or 96, the
21 issue – when it changed its name to CSLAC – of terms of reference came up
22 and I don't believe that a laboratory committee actually sat for very long
23 with terms of reference – I think it then went into not receivership but the
24 equivalent.
25 Q: Well, from what you knew of CALC, was it a body that was in a
26 position to develop criteria which would include the criteria set out at 4.1.4?
27 A: I believe CALC was established as this co-operative of ACL, the Royal
28 College and the Society of Cytology, and it's a big ask for that group with

1 their own particular interests to come together to agree on all this. And
2 really without some – there's two ways of doing it, one is basically to impose
3 it or the other is to have a very formal process by which certain – a process
4 by which you could reach these conclusions and have it ticked off over a
5 period of time and it would have to not rely on people withdrawing from the
6 process when it suited them. So it may, I would suggest to the team that
7 strong consideration should be made about thinking about mandatory issues,
8 I think it might save the process.
9 Q: Yes. In your experience does the approach which is dependent on
10 consensus, persuasion of persons and facilitation work effectively?
11 A: Well it depends what you're trying to come to and I think in most
12 circumstances it is preferable that at some point someone has to realise that
13 that is not going to produce a result that is necessary and other avenues are
14 required. Unfortunately the Ministry or the Department of Health did not
15 pursue other avenues such as regulation or any other leverage.
16 Q: when it comes to the question of doing something such as imposing
17 standards such as the need to read a minimum number of smears, in your
18 experience is that something that can be done in a consensus way or
19 ultimately should that be something done by way of regulation if consensus
20 is not working?
21 A: I believe if consensus is not working then you may need to resort to
22 regulation, and it depends on the circumstances of the laboratory structures,
23 and in NZ we have historical development of many laboratories serving
24 relatively small populations, with some large ones.
25 Q: Just to continue with this document, from your experience of screening
26 programmes I would like your opinion on a policy document, which this is,
27 which in one clause says that cytology laboratories should be TELARC
28 accredited; in the next clause it says that the Department of Health will be

1 responsible for confirming that the cytology screening is going to be carried
2 out to meet the requirements in the following clause, and that following
3 clause says that criteria for registration by TELARC will include – and it
4 sets out a number of things. What is your opinion of a policy document that
5 sets this up in circumstances where the development of the criteria, or the
6 establishment of the criteria – to use the word in the document – is to be
7 done by an advisory committee which has no terms of reference?
8 A: It's bizarre.
9 Q: And the impact would be that if the advisory committee failed to
10 establish the criteria set out in 4.1.4 then there wouldn't be any TELARC
11 accreditation because until that criteria is established there is nothing for the
12 Ministry of Health to be responsible for confirming that the requirements in
13 4.1.4 are met; do you see what I mean?
14 A: Yes, I think I see what you mean, and also it asks the CALC to specify
15 to TELARC what they should and shouldn't do. And it has no formal
16 relationship with TELARC either; I'd call it a floating committee.
17 Q: Yes. So in terms then of the Cervical Screening Programme and the
18 structure this policy was attempting to set up for the role of laboratories in
19 the implementation of the screening programme, how effective do you think
20 this policy is?
21 A: Not very effective. It doesn't appear that the process has been thought
22 through.
23 Q: Does it appear to you, given your role on CSAC, your obligation was
24 there to monitor and evaluate the programme, when it came to looking at
25 this aspect of the programme what could you have made of this policy
26 document and whether or not it was being followed?

1 A: It was of limited use to CSAC, but also in the climate of the day it did
2 indicate to us that there was some government commitment to a National
3 Cervical Screening Programme.
4 Q: Just for completeness if you would look please at volume 6 of
5 Glackin, the 93 policy starts at page 26 and the particular part I've been
6 referring to to do with laboratories starts at page 34 in the top right hand
7 corner and goes on to 35.
8 A: Starts when enrolling.
9 Q: Yes top of page 24 see that headed laboratories.
10 A: Number 4 laboratories.
11 Q: And you will see 4.1.2 starts on the bottom of the page.
12 A: Yes got it.
13 Q: Firstly you will note at 4.1.2 that the clause has changed in the sense
14 that whereas in the 91 policy it said a reasonable period of time will be
15 allowed for laboratories to obtain registration this may take up to 2 years
16 you'll note that the phrase this may take up to 2 years has been deleted. Was
17 CSLAC aware of that?
18 A: I'm not entirely sure if we discussed that or not. I'd be surprised if
19 we didn't but I cannot categorically say that we did.
20 Q: Was CSLAC concerned about whether or not laboratories were
21 TELARC accredited.
22 A: Yes there were numerous discussions which sometimes created a
23 little friction regarding TELARC accreditation and also the understanding
24 that CSLAC had that accreditation was one thing and it didn't imply that
25 quality assurance was being monitored in an ongoing manner so TELARC
26 accreditation was considered a rather minimal requirement on laboratories
27 and that it needed to be supplemented by some other quality assurance
28 process that was ongoing to be of sufficient reassurance to CSLAC.

1 Q: And I see that with the 93 document again you have the situation
2 where in 4.1.4 the criteria for registration be TELARC is set out to include
3 again such tings as the reading of minimum numbers of smears, employment
4 of adequate numbers of staff etc. I won't go through them all and once again
5 under 4.1.3 the Ministry of Health is responsible for confirming that
6 laboratories are meeting the requirements in 4.1.4 but of course the Ministry
7 can't actually carry out that responsibility under CALC has actually
8 established the criteria in 4.1.4.
9 A: I believe 4.1.5 seems to have changed a little we know have the
10 Ministry of Health , CALC, TELARC and other relevant organisations
11 unlisted which would develop and monitor standards for the training –
12 Q: That's cytology laboratory assistance, that's a different one.
13 A: I'm confused. So we're still stuck with CALC in terms of what's
14 being asked of them.
15 Q: Yes and from your knowledge, we haven't heard from CALC yet on
16 this point, but from your knowledge as a member of CSLAC and someone
17 very interested in Cervical Screening Programme was CALC capable of
18 discharging the role that it was given in 4.1.4?
19 A: It would have been most surprising if they were able to discharge
20 those responsibilities.
21 Q: Thank you.
22
23 MR KIRTON CONTINUES XXN OF WITNESS
24 MR KIRTON: Dr Cox if I could finally take you to page 31 paragraph
25 99 of your brief the questions I want to consider now relate to the issue of
26 why the Ministry of Health or possible reasons why the Ministry of Health
27 did not respond and did not meet it's responsibilities.

1 A: Could you repeat the paragraph.
2 Q: 99, 100 and 101. You say there are paragraph 99 you express
3 concern that since the restricting of the Department of Health in Oct 92 the
4 interests of the Department of Health appear to have become more dominant
5 than the provision of a good Cervical Screening Programme to women and
6 that the last time this occurred so strongly was in 1989 and resulted in a
7 ministerial review of the programme. Can you tell me what you mean by the
8 interests of the dept appear to be more dominant?
9 A: Well the health reforms were announced I think in Aug 91 if I recall.
10 That created of course a great deal of anxiety within various organisations
11 the potential of new organisations to be set up such as the public health
12 commission, the Regional Health Authorities and that there was a lot of –
13 the focus if you like of the Department of Health then became about what it
14 got to keep and what it got to loose I suppose in terms of staff and
15 responsibilities etc and was reorganising itself head over turkey to adjust and
16 in that climate there was a great desire to fit parts of the screening
17 programme if you like into the various new structures that were established
18 in one way shape or form, either all within the Ministry or some out there
19 and some inside the Ministry, some in the public health commission.
20 Q: Do you mean the purchase of provider split.
21 A: Yes that's what I mean.
22 Q: So there was a new economic model that was in operation is that
23 correct?
24 A: Well I think that's what created all the restructuring so yes and in that
25 circumstance the issues associated with the screening programme I believe
26 got a much lesser priority than the need to appear to reform the programme
27 into a new model.

1 Q: Can I just explore that a little. By that do you mean that the
2 programme itself didn't fit within that model or do you mean it simply got
3 lost in the rush to the new model?
4 A: A mixture of both but I think a lot of the former rather than the latter.
5 National programmes in general including I believe blood bank services and
6 other national services, national radiation laboratory services and various
7 other national health services didn't fit well with the new model of the
8 funder provider split and devolution to regions and the screening programme
9 was another example of that and also had a high, as I said before, political
10 profile so major restructuring of the screening programme I think may have
11 been perceived to, and they probably did have evidence that it would have
12 resulted, in an outcry in certain various quarters.
13 Q: So there was constraint on moving it out based on the political
14 imperatives.
15 A: Yes.
16 Q: But on the other side a strong desire to push it out because it needed
17 to fit the model.
18 A: Yes I believe that's the conflict.
19 Q: You said earlier in your evidence in terms of your qualifications in
20 being a public health specialist that part of your role or the role of a public
21 health specialist was to consider models of health service delivery and am I
22 correct in saying health economics were a pat of that?
23 A: A little part of it.
24 Q: Are you familiar with the concepts, now that we're talking about
25 economic models, of budget holding independent practitioner organisation
26 or HMO's are they familiar terms to you?
27 A: Yes they're familiar terms and I believe I have some summary
28 understanding of the concepts of them, I haven't actually worked in an

1 agency to see if you like what it feels like in the raw to work in such an
2 agency.
3 Q: Would it be fair to say then that these models, these budget holding
4 models are mechanisms used to control costs by having the budget held as
5 close to the delivery of the service – for example with the GP as possible.
6 A: I understand that's the basic theory.
7 Q: Do you also understand that the holding of those budgets is reliant upon
8 an enrolled population with that for example of group practice or a general
9 practice group?
10 A: I'm aware that it's very difficult for them to operate without such an
11 enrolled or captive population.
12 Q: So in your words this captive population, the information about the
13 enrolled people is of critical concern?
14 A: Certainly in various things I've been involved in that appears to be the
15 case. That would be my perception from the involvement that I've had for
16 example in the initial establishment of the breast screening programme at an
17 earlier point in time.
18 Q: Is it possible Dr Cox, in your experience and commentary in your paras
19 99 to 101, that the vital information contained in the Cervical Screening
20 Register and the management of the programme itself would have been
21 considerations in terms of an economic model when driving or pushing out
22 the programmes or devolving those programmes; would that explain some
23 of the behaviour?
24 A: It fits. I can't say it's cause an effect.
25 Q: It's a possibility?
26 A: It's a possibility.
27 Q: Finally, just in terms of where we are in the year 2000, do you consider
28 the threat of devolution still to hang over the National Cervical Screening

1 Programme in terms of that drive for expenditure control and budget holding
2 arrangements?
3 A: I do, but then I don't have experience or knowledge of whether a good
4 and well organised Cervical Screening Programme exists in other countries
5 under that sort of arrangement, and it may well be possible to have such a
6 national screening programme under that arrangement and I would need to
7 take advice from those involved in other programmes overseas in terms of
8 what obstacles or difficulties would arise in such a structure.
9 Thank you that's all I have Madam chair.
10 CHAIR: Thank you. Mr Hindle.
11
12 XXN MR HINDLE:
13 Q: Dr Cox, just two very short subjects. My friend Mr Corkill asked you
14 some questions about the first statistical report and the second statistical
15 report. Can I complete the tour by asking you about the third statistical
16 report.
17 A: I will allow you to do so.
18 Q: That's at Glackin, tab 51. I've asked Madam Registrar to put the report
19 in front of you but I'm going to try and deal with the subject as economically
20 as possible.
21 A: Right.
22 Q: First of all, I see from the report that your name appears nowhere on it.
23 A: Fine.
24 Q: Were you involved in the preparation of that report?
25 A: No, I was given a draft I think at a fairly final stage to comment on,
26 which I did, and that's one of my exhibits. I was not involved in the report
27 that I can recall. I certainly wasn't involved – I don't believe I was

1 involved in either the second or third report except in making comments on a
2 fairly final draft of the third report.
3 Q: Perhaps I can ask this: In your brief of evidence at para 214 to 218 you
4 are discussing your resignation from CSAC?
5 A: Yes.
6 Q: And I was curious to note that after para 215 where you made the
7 comment about the Ministry of Health wanting to manage the programme
8 for political reasons and before para 217 where you talk about your
9 assessment of insufficient expertise, you've mentioned that you were
10 involved in the draft proposal for the third statistical report. Just the
11 juxtaposition of those ideas, was it something about what you were asked to
12 do for the third statistical report that contributed to your resignation from
13 CSAC?
14 A: Yes. I don't believe it's arrogance to believe that I did expect some
15 consultation over the second and third statistical reports in terms of their
16 format and what tables etc were desirable to produce and if necessary how
17 they might be produced. And I felt that these two reports had come out – I
18 think there was some delay in terms of the third statistical report. As I say, I
19 was aware that it was in a fairly final stage and I'd made a relatively – I'd
20 made my comments about it, and I felt that what was being proposed was far
21 less than what was possible or required at the time and felt very disillusioned
22 about the commitment of the Ministry of Health to even providing a good
23 and thorough annual statistical report of the programme. At that point I felt
24 that if they don't have that commitment at their end, so to speak, that it
25 would be better that I wasn't involved. There was also an issue that
26 occurred to me that my lack of involvement in the second and third reports
27 could have been because a perception of a conflict of interest did exist
28 between me being on the CSAC committee as well. If I was also involved in

1 the actual production of the reports, maybe my membership of the
2 committee was an obstacle in some manner, and to free that up it was also
3 appropriate to resign as well and see what happened. I didn't actually think
4 there was a conflict in terms of the way it could be managed but in the new
5 environment there was a lot of new interpretations if you like of a conflict of
6 interest and that was also considered.
7
8 PROFESSOR DUGGAN: Dr Cox, were you consulted on the latest
9 statistical report 1996 to 1998, it's in a working draft in Peters, exhibit 47?
10 A: I was sent this working draft for comment, but that's all.
11 Q: It's got lots of tables.
12 A: It's got humungus number of tables.
13 Q: 17 tables.
14 A: And actually I looked at the first 22 pages and stopped because I didn't
15 really have the time to go through 144 pages and I made some comments
16 and left it at that.
17 Q: If I could ask you: In terms of the tables from the European guideline
18 document and this current draft report, does the current draft report contain
19 any of those tables that you listed as being advantageous to the programme?
20 I do accept that you haven't read it all in detail.
21 A: there may be one or two, but the vast majority, no. The vast majority
22 of the tables in the European guidelines are not in there and I don't believe
23 that they are necessarily flagged for inclusion at a later stage when
24 appropriate data is able to be collected. There's two ways of handing it:
25 one way is to if you like put in a blank table and say that "we desire to
26 collect the information and to complete this able as soon as possible or at a
27 later date" and give a fixed time by which you expect it to be available. The

1 other way is just to ignore putting in such tables altogether and then, if you
2 like, it’s not obvious that they're not there.
3
4 CHAIR: If the tables are there in blank form, one it’s obvious to persons
5 reading the document that that information isn't currently available in the
6 document; and secondly, it serves as a reminder to those creating the
7 statistical report that they will have to address that in the future.
8 A: Yes and if it's blank in too many reports it becomes an
9 embarrassment.
10
11 PROFESSOR DUGGAN INTERJECTS AND XXN WITNESS
12 PROFESSOR DUGGAN: Dr Cox of the 79 tables and 18 figures
13 present in this document, how many of them relate to monitoring and how
14 many relate to evaluation?
15 A: This is the 4th.
16 Q: The 96-98 draft document.
17 A: I don’t have it on front of me but most of them – this is the first time I
18 think quite some detail in terms of changes and things over time has been
19 included but most of it's related to monitoring of if you like the easy to
20 monitor aspects of the screening programme.
21 Q: And what would be an example of that.
22 A: Coverage by age, ethnicity, many of those sorts of parameters which
23 are relatively easy to estimate from the Screening Register and consensus
24 data. We still don’t have an individual list of women invitation list in New
25 Zealand’s programme so in a way it's not what you’d technically call a
26 population based screening programme for that reason but with high
27 coverage estimated you can assume – you may be able to assume it's
28 equivalent but it does mean that you don’t know what your denominator is in

1 terms of your coverage you have to get a census figure and use that as an
2 estimate.
3 Q: It would be classified as a utilisation Registry.
4 A: Yes I think that's right.
5 Q: As opposed to a population based.
6 A: Yes.
7
8 CHAIR INTERJECTS AND XXN WITNESS
9 CHAIR: Just so we can be confident Dr Cox could you please take the
10 time to go to page 3 of exhibit 47 Peters where the tables are listed and first
11 tell me by reading the titles to the tables does that give you an indication of
12 what they are or a sufficient indication?
13 A: Yes I believe it does.
14 Q: Well if you wouldn't mind just reading through so you can be
15 satisfied, just to read through to be reassured as to whether or not there are
16 any tables of the type contemplated by the European guidelines that would
17 assist in monitoring and evaluation of the programme.
18 A: Well I believe there are some.
19 Q: If you could identify them and just place a tic. Just say what number
20 table.
21 A: Well many of them are repeats of a similar measure if you like.
22 Certainly coverage I believe they've used the term enrolled in place could be
23 calculated from the figures provided in the tables along with the census
24 figures. Time since previous smear I can't exactly recall whether that's in
25 the European guidelines but this is an extremely useful measure. The thing
26 over the page we actually have A standardised and A specific reporting rates
27 for different psychological appearances which I think is covered per 1,000

1 smears rather than per 1,000 women, most of those tables are per 1,000
2 smears which is unfortunate.
3 Q: My understanding of your evidence is that you consider it's better to
4 say per women rather than per smear.
5 A: Absolutely there are a lot of reasons why.
6 Q: Could you say why.
7 A: Well it's similar to this issue of proportion of high grade smears
8 where there are many reasons why someone might have more than one
9 smear and you end up including, someone has 6 high grade smears in a
10 period of time then they contribute 6 times more than someone who just has
11 1 and therefore clinically it's not particularly useful. Issues associated with –
12 there's not in here on staging of tumors, issues about treatment, I forget some
13 of the other categories. Basically there's a minimal amount that's in here
14 that's also in the European guidelines and certainly in many of the key areas
15 like interval cancers that allow you to calculate sensitivity that's not included
16 in this particular paper.
17 Q: Is there much statistical information here that would help you to
18 calculate sensitivity or help you in any other way to determine if there was
19 under-reporting or something that would ring alarm bells in some way about
20 smear reading?
21 A: There's nothing here I'm not sure if there's anything here by region or
22 by laboratory there might be some by laboratory. Sorry there's rather a lot of
23 stuff here. Not in any major way it would be fairly hit and miss.
24
25 MR HINDLE XXN WITNESS
26 MR HINDLE: Just back to the third statistical report quickly. Glackin
27 tab 51. In the inquiry we've heard a number of observations about that
28 report I just want to run through them with you and get your comment. One

1 is that the data presented in that report was current as at 31 Dec. 95, report
2 published June 98 and that was too late the information was outdated. Do
3 you have a view?
4 A: Yes it's an unusual delay. I must admit even the first report appeared
5 to have a 1 year delay before it was officially released. The value of the
6 information is much reduced by the delay in publication and I don't know
7 whether that was intentional.
8 Q: Another criticism that we've heard and if you refer to page 9 under
9 the heading method of data analysis in particular, that's page 212 at the top
10 right hand corner, some comment that if you read in particular the 2nd, 3rd, 4th
11 paragraphs different population denominators have been used for difficult
12 aspects of the report reducing the value of the analysis in the report do you
13 have a view on that.
14 A: Can I just read them through?
15 Q: Please do. I draw your attention in particular to the 3rd and 4th
16 paragraphs the mean age distribution of the estimated 95 New Zealand
17 usually resident population used in the calculation of age specific rates.
18 A: Right.
19 Q: And then the next one down regional population coverage calculated
20 using 1991 men de facto populations by the Area Health Boards.
21 A: Yes do you want me to comment.
22 Q: Yes that's been the subject of some attention in the inquiry and the
23 suggestion that it devalues the worth of the information in the report, do you
24 have a view on that.
25 A: One's 91 and one's 95 and I get you. It does make quite a difference
26 in terms of the uses – you want the mean de factor populations by Area
27 Health Board to add up to whatever you use for the national total and to get
28 the regional estimated value someone has to do a bit of work in terms of

1 making estimations, using whatever estimation formula they have of census
2 data and so someone's defaulted to what's easily available which was the
3 regional stuff and probably out of the 91 census whereas annual mean age
4 distributions for the whole country are done on a per year basis from the
5 census so it is not particularly satisfactory, but I can see how it has arisen.
6 Q: Another comment which was made about this report is that it reports
7 essentially by numbers of smears rather than by numbers of women.
8 A: Yes.
9 Q: Do you have a view on that?
10 A: That is a fundamental flaw that has been recognised for at least two
11 decades in terms of assessing the effectiveness of screening programmes,
12 and there are certain circumstances where it is valuable to report by
13 proportion of smears if you like, and I believe some of those are around
14 certain laboratory and smear taking issues. But in general, the vast majority
15 of data should be reported using women as the denominator. It gives far
16 more valuable information about the effectiveness or likely future
17 effectiveness of the programme.
18 Q: Just if I can take you to the foreword at p195, top right hand corner, do
19 you see in the third para there the foreword states "the University of Otago
20 has been contracted by the Ministry of Health to scope an evaluation", and
21 then the next para "the programme is developing a process to review the
22 history of women who develop squamous cell carcinoma while enrolled in
23 the programme and this information will be summarised in the next report".
24 Is that the work that you were doing, the evaluation work that you were
25 doing or is this perhaps something else?
26 A: I believe it's most likely to be what we were proposing, although it is
27 possible that someone else had made an approach to the Ministry to do a
28 similar sort of thing. If they had I wasn't actually aware of it, but since that

1 doesn't actually reference us by name, if you like, or the university, I suspect
2 that to be the case.
3 Q: A different subject altogether. I think that you were here throughout
4 the period of time that Professor Skegg gave his evidence, is that so?
5 A: Yes.
6 Q: And you will have heard and no doubt listened to the debate around
7 what I'll call the duRose study?
8 A: Yes.
9 Q: I don't want to go through it blow by blow but can I ask you, having
10 heard that evidence and in particular Professor Skegg's commentary as to
11 whether the duRose study provides a comfort level as to the present
12 effectiveness of the screening programme, did you agree with Professor
13 Skegg's comments?
14 A: yes, I did.
15
16 CHAIR: Could I just ask you, have you yourself read the duRose study?
17 A: I have read through it.
18 Q: How much time have you spent on it?
19 A: I think I've read through it twice. There are some parts I know
20 reasonably well but others not so well.
21 Q: The concern I have is to find out whether or not your agreement with
22 Professor Skegg's view is based purely on what you might have heard
23 yesterday or whether it's based on a thorough evaluation of the duRose study
24 done by yourself?
25 A: It related to several mattes. One, my knowledge of fragments of it
26 while it was occurring.
27

1 PROFESSOR DUGGAN: Dr Cox, were you consulted on this study?
2 A: No, and that isn't necessarily appropriate anyway, but I understand there
3 was a lot of debate in terms of what advice was given and whether it was
4 fully incorporated.
5
6 CHAIR: It might pay to go to the duRose study Mr Hindle. I know you're
7 trying to save time, but at the end of the day I want to be sure just what this
8 witness has based his opinion on.
9 MR HINDLE: I will do that but perhaps before I do that can I just take you
10 back to the train of thought you had. You were asked by Madam Chair
11 effectively what your level of knowledge of the study was and you said it
12 was based on several things.
13 A: I only said one.
14 Q: You started by saying fragments that you were involved with while it
15 was taking place. Did I hear that correctly?
16 A: Yes.
17 Q: What did you mean by that?
18 A: There were occasionally small snippets of information passed to me,
19 verbally, from colleagues. There was also some, I suppose I provided some
20 peer review for part of Dr Snead's document which is included, and I was
21 aware of the nature of some of the measures that were being used to try and,
22 if you like, grade the laboratories, and I knew that they were trying to go
23 through a ranking exercise.
24 Q: So the subject matter of the material is something that you were
25 familiar with before you saw Mr duRose's evidence?
26 A: Not the actual tables and content. There was a little bit in one of the
27 exhibits that I was aware of.

1 Q: I think you said that you read the material twice?
2 A: Yes, I've read the material twice.
3 Q: And did you read it for the purpose of forming a view as to whether it
4 provided the sort of assurance that it was offered as?
5 A: I read it with the view of – I didn't consider it in that late, I was looking
6 at it in terms of what was done, whether I thought it was, if you like, not so
7 much the right way to go about it but whether the tables were useful in
8 giving a robust guide if you like to the ranking of laboratories which they
9 were trying to undertake. Is that helpful?
10 Q: Yes. But you read it with a specific purpose and you then presumably
11 heard the evidence and followed what was discussed here yesterday?
12 A: Yes
13 Q: Do you think that your view that you agreed with Professor Skegg's
14 comment would be changed by further study of the report? Would you
15 want to have more time?
16 A: I don't believe so.
17 Q: So you feel familiar enough with the material to say that you agree with
18 the comments of Professor Skegg?
19 A: The general thrust of his comments I agree with entirely, and I believe
20 that it is likely that – for example the document was not signed off by the
21 advisory committee so it's not entirely clear, and I would be surprised if the
22 advisory committee fully endorsed the document necessarily.
23 Q: Ma'am, I really don't want to go through it all over again, but I think –
24 CHAIR: No, it's all right. Professor Duggan intends to, so perhaps if we
25 leave it there.
26 MR HINDLE: I'll butt out for awhile.
27 CHAIR: Do you have no more questions?

1 MR HINDLE: I beg your pardon, I have no more questions.
2 CHAIR: Well, as it's 5.00 we will adjourn now and have questions from
3 the panel in the morning. Overnight Dr Cox it would be of assistance to the
4 panel if you could please look at Peters exhibit 47 (which is the draft
5 statistical report) with a view to comparing it with the European guidelines
6 in your exhibit (which is exhibit 44), and it would be particularly helpful if
7 you could identify those tables and any other information in the report that
8 assist with monitoring the programme and then, as a separate exercise, those
9 tables or other information that would be helpful in evaluating the
10 programme. And I believe that if you look at exhibit 40, Peters volume 2
11 there is a draft evaluation and monitoring plan which gives the definitions of
12 monitoring and evaluation. Would you be familiar with those definitions or
13 perhaps you should just acquaint yourself with them.
14 A: I will acquaint myself with them.
15 Q: Madam Registrar could you please show Dr Cox exhibit 23 of Peters
16 2, pages 244 and 245 and also it might help you too as Professor Duggan
17 wants to go through the DuRose study with you to have another look at that
18 overnight. I'm sorry you've been kept over another day and Mr Murray
19 apologies to Dr Medley for detaining her. We don't expect to be too long
20 tomorrow with Dr Cox and we will move straight into hearing Dr Medley's
21 evidence.
22
23 MR MURRAY REPLIES
24 MR MURRAY: Yes Dr Medley's rescheduled her flight so she's with
25 us all day tomorrow but leaving on the first plane on Friday morning.
26 CHAIR: I'm most grateful to her for taking that step.
27

1 MR CORKILL ADDRESSES CHAIR
2 MR CORKILL: Madam Chair when I was cross examining this witness
3 the complicated arithmetical calculation came up. I wonder if on Ms
4 Marshall's behalf can I suggest that the witness can liaise with her to get that
5 produced in some sort of written form overnight.
6 CHAIR: Yes and that way anyone who wants to query it can do so.
7 Very well we will adjourn until 9:30 tomorrow morning.
8
9 INQUIRY ADJOURNS AT 5:02 P.M.
10