

**UNDER THE HEALTH AND DISABILITY SERVICES
ACT 1993**

**IN THE MATTER OF THE MINISTERIAL INQUIRY
INTO THE UNDER-REPORTING OF CERVICAL
SMEAR ABNORMALITIES**

**SUBMISSIONS ON BEHALF OF THE MINISTRY OF HEALTH
AND THE HEALTH FUNDING AUTHORITY**

PART I: TERMS OF REFERENCE 1 and 2

Counsel:
K I Murray
Barrister
Level 3, Landcorp House
101 Lambton Quay
P O Box 5516
WELLINGTON
Telephone: (04) 499 9389
Facsimile: (04) 499 4620

Counsel:
M T Scholtens
Barrister
Level 6, Castrol House
36 Customhouse Quay
P O Box 10048
WELLINGTON
Telephone: (04) 471 0646
Facsimile: (04) 471 0672

INDEX

	Page
INTRODUCTION	4
TERM OF REFERENCE ONE	
Introduction	9
Professor Skegg’s evidence - What is “unacceptable?”	10
Dr McGoogan’s evidence - Principles and Problems	13
Tracy Mellor’s evidence - The HFA Gisborne Investigation Reports	23
Dr Farnsworth’s evidence – Unacceptable Under-reporting Established	27
Dr Wain’s Evidence – Confirmation of Unacceptable Under-reporting	33
James DuRose – The National Parameters	36
Dr Bottrill – Unacceptable Under-reporting Accepted	36
TERM OF REFERENCE TWO	
Introduction	38
Ministry of Health approach to evidence before the Inquiry	39
Summary of factors arguably leading to under-reporting	41
Dr Bottrill’s Competence And Cytology Practice	42
Possible Warning Signs	43
To the Department of Health (1989)	43
To the Midland RHA (1994)	46
To Dr Teague (1995)	46
Other opportunities for warning?	48
Quality Around Subsidised Services (1990-1996)	48
Health Benefit provided under the Social Security Act regulations to 30 June 1993	49
Purchase under the Health and Disability Services Act 1993	52

Implementation Of The NCSP	61
Introduction	61
Early steps towards a National Programme	62
The Ministerial Review Committee: September-November 1989	69
The Straton Report: July 1990	75
Expert Group: December 1989 – January 1991	80
Ministerial Policy Statement: 18 October 1990	85
Policy Confirmation by New Minister: February 1991	86
Key Development Issue One: Opt-on versus Opt-off Programme	87
Key Development Issue Two: Laboratory Services to the NCSP – Policy Development and Implementation	89
Straton/Expert Group Recommendations	89
The 1991 Laboratory Policy	93
<i>Para.4.1.2: TELARC Accreditation</i>	94
<i>Para.4.1.3: Role of Department in confirming criteria for accreditation is met</i>	94
<i>Para.4.1.4: TELARC criteria/standards</i>	96
<i>Para.4.1.5: Cytology Workforce and training</i>	99
The 1993 update	100
<i>CALC submission on the 91/93 policy review</i>	103
Public Health Commission Advice	105
The 1996 Policy	105
TELARC Accreditation and Cytology Standards: What happened?	106
Further review of TELARC criteria by CALC/CSLAC: 1993-95	107
Would an earlier requirement for accreditation have been realistic?	108
(i) <i>Existing services stretched</i>	109
(ii) <i>Limited tolerance for change</i>	109
(iii) <i>TELARC accreditation backlog</i>	110
(iv) <i>Pressure to increase payments</i>	111
(v) <i>Cytology services primarily provided outside the Programme</i>	111
(vi) <i>Mandatory accreditation a novel concept</i>	112
Conclusion	114
APPENDICES	
A. “Summary of Useful Statistics”: Appendix N to Azimuth Report, November 1988, plus references	
B. Response by Ministry of Health Relating to NCSP Standards and Monitoring 1990-1997	
C. List of Evaluations and Reviews of NCSP	

INTRODUCTION

1. One of the great values of inquiries such as this one is that they take a relatively narrow area of human activity and subject it to a high degree of scrutiny. As the evidence unfolds, gradually a picture begins to emerge. An assessment can then be made about how successful we have been in achieving shared goals – in this case safeguarding women’s health and wellbeing from the known risks and incidence of cervical cancer.
2. When something goes wrong our sense of disappointment and failure is palpable. Inevitably we focus upon the negative. We all feel sadness for those who have suffered. Yet paradoxically if we are to make improvements an inquiry such as this is required to be unemotional, analytical, objective, constructive and balanced.
3. In New Zealand over recent years we have seen the examples of two major inquiries which failed to achieve their full potential because of various defects in the inquiry processes and resulting reports. We are referring to the Royal Commission of Inquiry into the Mt Erebus Disaster and the Winebox Inquiry.
4. In the Erebus Inquiry, as is well known, harsh and unfounded collateral findings about one of the parties and some of the witnesses who gave evidence at the Inquiry tended to obscure the valuable aviation safety lessons to be learned from the accident. Fortunately the resulting litigation produced some useful guidance from the Privy Council about the standard of proof required for findings to be made by inquiries: see *Re Erebus Royal Commission* [1981] 1 NZLR 618 (CA); [1983] NZLR 662 (PC).
5. More recently with the Winebox Inquiry, again it is well known, a harsh and legally incorrect onus of proof was imposed on one of the parties to the Inquiry and legal errors were made. Once the courts had stripped away the central core of the Inquiry’s report therefore we were left no wiser about whether New Zealand’s tax base had been unlawfully plundered or not: *Peters v. Davison* [1992] 2 NZLR 164 (CA); *Peters v. Davison* (unreported judgment of Anderson and Robertson JJ 20.8.99 Ak Registry CP432/97).

6. On the other hand the Cartwright Report is a model of its type. Despite the sad and distressing evidence that Judge Cartwright heard her measured and objective assessment of that evidence and the findings she made have had enduring authority.
7. In the course of this Inquiry it has been suggested more than once that the lessons of the Cartwright Report have not been learned. However, a sense of balance and perspective is required. That report provided the incentive for the establishment of the NCSP. It may well have been established anyway but nowhere near as quickly. On the other hand some of the evidence we have heard shows that political pressure to implement such a programme led to a premature and difficult birth for the NCSP.
8. The extensive criticism leveled at the early stages of the Programme and the failure to detect the Gisborne situation earlier than it was detected, needs to be balanced against the considerable successes of the Programme and the many lives that have been saved as a result. The position is neatly captured in Professor Skegg's evidence:

My first point is that, despite many false starts and interruptions, the NCSP has achieved a great deal. There is now a much greater awareness among women and health providers of the need for cervical screening; a high proportion of the population at risk have been screened and included on the register; access has been improved by involving a wider variety of health workers in screening; and guidelines have been developed for taking smears and for dealing with women who have abnormal results. The whole system is under-pinned by numerous dedicated staff at the local level.

Secondly, improvements in cervical screening before and since the establishment of the NCSP already appear to be saving many women from serious illness and premature death. I have already mentioned the unfavourable birth-cohort trend that was noted in the 1980s. In 1992 Dr Brian Cox and I published projections of cervical cancer mortality and incidence in New Zealand over the next two decades. It was clear that both mortality and incidence rates would increase if screening services were not improved. [Cox B, Skegg DCG. Projections of cervical cancer mortality and incidents in New Zealand: the possible impact of screening. Journal of Epidemiology and Community Health 1992; 46: 373-377]

In absolute terms, the projections indicated that the then current 100 deaths per year could increase to about 148 deaths per year, while there could be a much larger increase in incidence from 235 new cases per year to about 440 per year. Such estimates are inevitably imprecise, but it was concluded that plausible improvements in cervical screening were likely to be accompanied by only small changes in the burden of cervical cancer; if screening services were not improved, on the other hand, there would be striking increases in both mortality and incidence.

In the event, the numbers of deaths and new cases of cervical cancer have both declined during the 1990s. In 1997 there were only 73 deaths from cervical cancer, the lowest number (and mortality rate) for at least half a century. In 1995, the latest year for which incidence data are available, there were 231 women registered with cervical cancer. In terms of mortality, we have already achieved a public health target set for 2005. The decline in mortality and incidence rates is believed to reflect improvements in cervical screening since the mid-1980s.

The largest reduction in the incidence of cervical cancer during the 1990s has been among Maori women. Nevertheless, much more work needs to be done to close the gap between Maori and non-Maori.

Given the recent achievements of cervical screening in New Zealand, we must hope that the present Inquiry does not damage confidence in the NCSP to an extent that women or health providers reduce their commitment. Of course this does not mean that we should fail to address any deficiencies or ways in which the scheme could be improved. (First Skegg brief, paras 43-48)

In addition it was the Inquiry's other expert witness, Dr McGoogan, who provided the timely reminder that "*A poor screening programme does not cause women to develop cervical cancer*".

9. We suggest that the results of the NCSP speak for themselves – we are not dealing with a poor National Cervical Screening Programme. We are dealing with a very successful one that seems to compare well with those in other developed countries about which evidence was heard. But it has been let down by a serious lapse in the professional standards of a single pathologist combined with inadequate systems for the early recognition of an unacceptable level of under-reporting.
10. Overall it seems the success of the Programme is due to emphasis upon the enrolment and screening of large numbers of women with timely referral to colposcopy services for those women suspected of having cervical abnormalities. These were of course the two key performance indicators which the Ministry emphasised and closely monitored formally through the funding agreement mechanism and operationally through the National Coordination role.
11. Unfortunately this monitoring of performance indicators did not include the quality of smear reading despite its critical importance to the integrity of the screening pathway. As the evidence has demonstrated, it is no easy matter to design and implement procedures for the accurate measurement of laboratory and programme sensitivity and specificity. Those performance indicators which were adopted tended to provide the assurance about the success of the Programme but

ironically this may have camouflaged potential areas of failure in crucial parts of the screening pathway.

12. It is easy to be critical of this situation with hindsight, but we need to keep in mind that no medical professionals, including pathologists and even those practising in the specialised field of cytopathology, rang alarm bells about the dangers inherent in Dr Bottrill's mode of practice.
13. It now seems apparent that the full complexity of what was involved in running a national cervical screening programme was not fully appreciated in its early days. The Programme was built upon an existing health system which across the board relied upon the professional competence and skills of medical professionals. The fact that Dr Bottrill was qualified as a registered medical practitioner, a registered specialist and Fellow of the RCPA was seen as sufficient in itself.
14. The Inquiry of course has heard from several experts that the application of normal standards of medical care are not appropriate for the special nature of screening programmes. Professor Skegg for example said :

“Screening programmes differ in fundamental ways from the usual processes of diagnosis and treatment. First, they involve approaching people who are apparently healthy and urging them to undergo a test. This means that those offering screening have a particular ethical obligation to ensure that the benefits outweigh the risks.” (Skegg first brief, para 16)

15. However, it cannot be assumed that the combined expertise and wisdom of the highly qualified cytopathologists, epidemiologists, gynaecologists and public health specialists that the Inquiry heard evidence from in the year 2000 was reposed in those involved in the Programme over the last decade or so. The fact that it has taken that accumulated knowledge and expertise to answer the terms of reference is testament to the difficulties involved in establishing Dr Bottrill's inadequate performance even now.
16. Fortunately the NCSP has developed considerably since Dr Bottrill retired in 1996. All laboratories providing services for the Programme are required to be IANZ accredited, they employ cytoscreeners and they participate in internal and external QA assurance practices. In addition the HFA is now in the process of implementing detailed operational policy and quality standards for the practice of cytology in New Zealand. Coupled to these standards there are performance

indicators based upon internationally developed quality assurance criteria for all steps in the screening pathway all of which will be subject to a system of routine monitoring.

TERM OF REFERENCE ONE: TO DETERMINE WHETHER THERE HAS BEEN AN UNACCEPTABLE LEVEL OF UNDER-REPORTING IN CONSEQUENCE OF MIS-READING AND/OR MIS-REPORTING OF ABNORMALITIES IN CERVICAL SMEARS IN THE GISBORNE REGION.

Introduction

17. The approach adopted to the submission on this term of reference is to present a more or less comprehensive outline of the main portions of evidence relevant to the first term of reference. This is presented generally in the order in which the evidence was given. The witnesses who dealt with the first term of reference were: the women affected, Professor Skegg, Dr McGoogan, Tracy Mellor, Dr Farnsworth, Dr Wain, James DuRose and Dr Bottrill.
18. While in the early stages of the Inquiry it seems there were insuperable difficulties involved in answering this term of reference the evidence built to the point where Dr Farnsworth's evidence conclusively answering the first term of reference in the affirmative. The summary of the evidence which follows speaks for itself with little required in the way of additional submission.
 1. The Inquiry began with harrowing evidence from 8 women which included smear history summaries. On the face of it those histories indicated under-reporting of smears read by Dr Bottrill and to a greater or lesser extent this appeared "unacceptable" in that histology results and clinical conditions suggested that the women probably had high grade abnormalities and/or cancer despite Dr Bottrill reading one or more slides as negative. In addition the Sydney re-read results for these women all indicated high grade abnormalities present on the smears that Dr Bottrill has read as negative.
 2. Unfortunately it quickly emerged that answering Term of Reference 1 may not be straightforward. Some of the women had a deno carcinoma which a smear is not designed to detect; there was also the progression and regression factor so that smears read as negative by Dr Bottrill may in fact have been negative at the time he read them; the Sydney re-read results indicated numerous high grades were read as normal but as between Dr Bottrill and Sydney it could not be assumed that

the former was wrong and the latter was right. The Inquiry therefore called independent expert evidence. The first such expert was Professor Skegg.

Professor Skegg's Evidence – What is “unacceptable?”

3. The essential difficulty with answering Term of Reference 1 is the problem of false negatives:

While everyone strives to keep them to a minimum, false negatives and false positives will inevitably occur – with any medical investigation, and especially with a screening test. It needs to be emphasised that error by a pathologist (or cytological screener) is only one of the possible reasons for a false negative cervical screening test. Other reasons may be that the smear was not taken adequately or that, even though the smear was taken correctly, no abnormal cells were included. There are inherent limitations of the test, quite apart from the frailties of the professionals involved. (para.25)

4. Professor Skegg, at Para.60 indicated that comparisons of high grade abnormalities reported by different laboratories is an extremely crude approach because it takes no account of underlying prevalence of disease in the particular population or whether the laboratory reports were accurate. At para.61:

An incompetent pathologist might produce results with both a high false negative rate and a high false positive rate. In contrast, an expert might be able to keep both of these rates relatively low.

5. And as to the Sydney results he said at para.62:

While the results that have been announced certainly give cause for concern, they do not allow any firm conclusions to be drawn. ... there is no a priori reason why we should assume that the results from Sydney are more reliable than those from Gisborne.

6. Professor Skegg goes on to argue at para. 64:

Hence I would argue that an “unacceptable level” of under-reporting is one that leads to a substantial number of cases of invasive cancer that could have been prevented.

7. And this leads Professor Skegg to recommend the best way to assess the scale of the problem would be to conduct a retrospective study of the then identified 40 cases of women with invasive cancer in the Gisborne region.

8. He said this is the best way but not the only way, he recognised his study may not be feasible and also that it would not necessarily provide a definitive answer if the population size was too small or the follow-up period too short for a sufficient number of cases. A886, 17-16.

9. His next choice would be to carry out a slide review comparing Dr Bottrill's slides with samples of slides from other New Zealand laboratories read blind by a panel of other community pathologists in New Zealand. This would indicate whether Dr Bottrill's practice was substantially different from those of his peers but then a judgment would need to be made as to whether that difference was unacceptable (A887, 117-27).

10. Professor Skegg in answering a question from Mr Hodson indicated that what was "unacceptable" would need to be judged objectively:

I don't think New Zealanders living in certain towns would expect an inferior service to New Zealanders living in other towns. A94, 10

11. Professor Skegg was then questioned by Mr Murray about the Sydney re-reading starting at A950 pointing out that the HFA could do a study with a database comprised of:

- ?? Dr Bottrill's original reports;
- ?? The Sydney re-read results;
- ?? Entries on the NCSR;
- ?? Colposcopy and treatment information;
- ?? Cancer Registry information.

12. Professor Skegg's immediate reaction was:

The two approaches would be complementary, this is very common in epidemiology, that associations between factors and diseases are investigated in a prospective way and a retrospective way. A951, 25-29

13. Professor Skegg preferred his study over the HFA study, however because:

The most important criterion of an unacceptable degree of under-reporting is the occurrence of invasive cancer in women who have had negative smears. I don't believe women who have had false negative smears but have not developed invasive cancer have been harmed by what happened. A952, 13-19.

14. However, Professor Skegg's thesis is debatable because the screening test is designed to identify women with pre-cancerous abnormalities so that they have the opportunity of treatment at that stage because it is not known which abnormalities will progress to cancer and which will regress naturally. This was put to Professor Skegg at A952 by Mr Murray and at A953 by the Chair, i.e. under-

reporting is “unacceptable” if it does not enable a sufficient number of women to be treated at the pre-cancerous stages.

15. Nevertheless Professor Skegg remained sceptical of the Sydney re-read. The fact of the subsequent histological correlation of all Sydney high grade results was not regarded by him as helpful because of the problem of regression and progression.
16. The issue with s74A of the Health Act was then identified as a potential problem with Professor Skegg’s study. A958 –A961.
17. On the other hand the problem with the Sydney re-read was that the histology correlation was done some 5 and up to 10 years later prompting the question from the Chair:

How can you take the colposcopy results into account at all? A963, 6

And further down the answer at line 17:

I don’t think you can. I’m just reluctant to discount the value of [the HFA study] without studying the protocol in detail.

18. Mr Corkill’s cross-examination starting at A973 also deals specifically with TOR1 suggesting that Professor Skegg’s test of what is unacceptable is an **“outcomes-based approach compared to a standards-based approach which really looks at the question of whether on the day the screener or reader got it right or wrong.”** Professor Skegg is assuming (wrongly it is submitted) that the Inquiry would only be established to investigate unacceptability from an outcomes point of view (lines 21-28).
19. Mr Corkill therefore (correctly it is submitted) puts to Professor Skegg:

I simply want to suggest to you that it is equally arguable that the Committee of Inquiry has to concern itself with standards of under-reporting in considering terms of reference 1. A974, 10

But Professor Skegg persists with his theory by saying:

.... But if it had not harmed anyone then I think it would be difficult to make a positive determination in relation to the first term of reference as I read them but clearly I’m not the person who should decide that. A976

20. And then Professor Duggan at A992 says:

So the ideal study would be to do the entire country and then look at the data by region

Yes, absolutely so. That would indicate to what extent, if any, the Tairawhiti region was exceptional.

21. A further approach to TOR1 is then raised by Tthe Chair at A995, namely by reference to the standard of care expected of a practising pathologist. In that regard Professor Skegg produces the American Society of Cytopathology “Guidelines for Review of GYN Cytology Samples (PAPS tests) in the context of litigation or potential litigation” DSC/CA/0009.
22. Despite Professor Skegg’s hesitation about reliance upon the HFA Gisborne investigation data initially he did actually change his mind when that data had been produced to the Inquiry and its significance explained by the evidence of Dr Farnsworth in answer to Professor Duggan’s questions.
23. Professor Skegg when he was recalled was specifically asked by Mr Hindle in relation to TOR1 whether he still regarded his proposed audit as necessary. In reply he said:

No, because the situation really is worse than I had anticipated. I no longer believe that the study I proposed is essential in order to answer the first term of reference. (B2300)

24. Professor Skegg did go on however to say that his proposed study would still be highly desirable for the Inquiry.
25. Professor Skegg was still slightly hesitant to say the high level of under-reporting by Dr Bottrill was unacceptable because he felt it was more for a pathologist to say (B2298, 1) but eventually when questioned by Mr Hodson about his proposed study he said:

I certainly still think it would be the best way and did have some concerns as to whether the term of reference could be clearly established without such a study but just as you saw the results that have emerged from the Health Funding Authority Review appear to me to be so striking and clear cut and as I said yesterday the situation is really much worse than I had envisaged and so I think yes there is now clear evidence that there was an unacceptable level of under-reporting. (B2441, 20-26)

Dr McGoogan’s Evidence – Principles and Problems

26. Dr McGoogan impressed as an independent expert cytopathologist but her expertise only served to confirm the difficulties involved in answering Term of Reference 1.

27. The phenomena of regression and progression are covered at paras.35–37 of her brief and in particular:

While the likelihood for regression decreases with increasing severity of CIN there is no way of predicting the clinical outcome of any individual lesion.

And:

CIN is not cancer. It represents a pre-cancerous stage that if left untreated might progress to cancer.

28. At para.48 of her brief and following Dr McGoogan confirmed the definitions of “sensitivity” and “specificity” as given by Professor Skegg. The evidence explained the trade-off between sensitivity and specificity and that all screening programmes have false negatives and false positives:

Thus most false positive and false negative results are phenomena of the screening test rather than incompetence or negligence.

29. Paragraph 51 and more particularly at para.52:

All screening programmes have false negatives and false positives. It is impossible to run a screening programme without false negatives and false positives. Therefore the false negative and false positive rates can never be zero (ie, sensitivity and specificity cannot be 100%). Thus most false positive and false negative results are phenomena of the screening test rather than incompetence or negligence. In most cases the word “error” should be avoided. The challenge for those managing screening programmes and their quality assurance is to strike a good balance between the false positive rate and the false negative rate.

It is worth noting that a poor quality cytopathology service may have both a high false negative rate and a high false positive rate. In this situation, most true high grade lesions would be missed and reported as negative. At the same time the laboratory would report many cases as high grade lesions which are actually within normal limits or only low grade. Thus the reporting profile and laboratory statistics may appear to be within the normal range but the laboratory has both a low sensitivity and a low specificity.

30. And further at para.53:

Moreover, the “truth” or at least something approximating to the truth must be known in order to calculate sensitivity and specificity in a meaningful way. This is not possible and thus a surrogate “reference diagnosis” must be defined for positive and negative results. However, in cervical screening no consistently used reference diagnosis exists. Ideally one would compare against biopsy diagnosis but biopsy reporting also has a sensitivity and specificity less than one hundred percent.

31. And further at para.54:

Finally, and most importantly, the sensitivity of the whole screening programme rather than of individual screening tests within it must be

considered. The sensitivity of any one test does not fully represent the sensitivity of the programme as a whole.

32. And further at para.56:

False positive and false negative rates are only partial expressions of a broader concept of diagnostic accuracy. Positive Predicted Value (PPV) is the probability of disease being present in those individuals with a “positive” test result and is another expression of diagnostic accuracy. Likewise Negative Predicted Value (NPV) measures the probability that those individuals with a negative test result are disease free.

33. And to keep matters in perspective, Dr McGoogan at para.76 says:

Even in the poorest quality laboratory some women with CIN3 will have been identified, referred for colposcopy and treated so they have not developed invasive cancer.

34. Paragraphs 105 and 106 of Dr McGoogan’s brief are particularly apposite, namely:

There is no easily measurable and reproducible “gold standard” or “truth” against which to measure false positive and false negative smear results. Colposcopic assessment and the histological assessment of cervical biopsies both have a sensitivity and specificity less than 100%. The biopsy taken may not be representative of the most abnormal area in the cervix and the histopathology report is subject to observer variation by the histopathologist. Agreement between pathologists is high for CIN3 but poor for CIN1 (12). The true outcome of a negative smear may not be apparent for several years. There is biological progression and regression of all grades of CIN with time. Even a delay of one month between a smear being taken and colposcopic assessment of the woman’s cervix could result in a CIN1 lesion completely regressing or appearing de novo during that time.

A commonly used surrogate for a gold standard to test the accuracy of cervical smear reporting is review of the slide or slides by another experienced cytologist or by a panel of cytologists. *Here there is enormous potential for bias.* The interpretation of cervical smears is a subjective assessment based on minor variations of cell colour, shape, size and density in which some diversity of opinion is inevitable. The information available at the time of primary screening is important as is the frequency of abnormal smears in the laboratory workload, the expectation that the next smear will be negative, the workload a screener is expected to deliver each day and the condition of the original slide. The knowledge that a patient later developed cancer will naturally influence the degree of confidence of the reviewer in assessing any minor degree of abnormality or equivocal changes present in a previous cervical smear. It is acknowledged that while the inter-observer and intra-observer variation for high grade lesions show fairly good correlation, those for ASCUS and low grade lesions show extremely poor correlation.

35. After this at paras.108-120 the limiting factors in sensitivity and specificity of the cervical smear are dealt with, with Dr McGoogan concluding at para.121:

The limiting factors of cervical smears can be summarised as the quality of the sample, the presentation for microscopic assessment and the accuracy of the observer.

36. One of the factors that could be relevant to answering TOR1 is the circumstances relating to Dr Bottrill's practice. The scenario of one pathologist with no primary screeners reading approximately 5,000 smears per annum with minimal internal and no external quality assurance procedures carrying the obvious risk of under-reporting. Dr McGoogan thought it would *"require exceptional measures to be put in place by the individual to ensure competence and quality service"*. A1016, 23. When asked by Madam Chair what the quality control measures might be Dr McGoogan said *"I can think of ways but what you are really asking me is if I want to set up a bad service how would I do it with the least risk to women"*.

37. Very significantly Professor Duggan asked Dr McGoogan at A1020:

Could I ask you for your own personal opinion on whether pathologists who have not been trained in the skills of primary screening should function as a primary screener

I have a very high regard for the skills of primary screeners, it is an exceptionally difficult skill to develop and maintain day in and day out. It is not a skill which I have as an individual. I would have to undertake a similar training and concentrate my training in that area to achieve the same skills.

You, as an acknowledged expert in cytopathology, do not consider you should function as a primary screener

Yes, I agree.

38. At A1043 Mr Hindle then asks Dr McGoogan about the American Society of Cytopathology Guidelines (Exhibit DCS/CA/0009). Dr McGoogan points out the guidance is on the review of slides for individual cases of litigation and not directly relevant to the Inquiry.

39. There are also questions from the Chair about whether the guidelines would assist with answering TOR1 at A1043 with Dr McGoogan frankly acknowledging at A1044, 20:

But the word unacceptable to me gives me great difficulties because I'm not sure of the context or how to measure that – it's a very subjective word.

40. But when pressed with the difficulty she said at A1045 1:

On the one hand the level may be so awful that it's an easy decision to make but where you draw the line I find it very difficult.

41. Dr McGoogan at line 17 also thought the guidelines in litigation were very different from a major re-screening situation:

I think the situations are very different. What I think we are trying to evaluate here is whether there was a consistent problem existing over a period of time, whereas in cases of litigation it is whether a judgement made at a specific point in time meets satisfactory levels of competence.

42. Dr McGoogan confirms that Dr Bottrill's 1994 lab results, Exhibit GRB/MOH/029 do not enable conclusions to be drawn – A1045.
43. Starting at A1048 Mr Hindle puts the Sydney re-reading exercise, Exhibit TM/HFA/085 to McGoogan. She had concerns about the delay in time between the original reporting of the smears and the expertise in year 1999, 2000 as general quality had improved over that time both in smear taking and smear reporting. A1055, 23. She had concerns that the terminology in use in Sydney would be different. A1056, 1. Concerns about transcription error (at line 7) and also notes that the Sydney laboratory re-coverslipped 50% of the slides (line 14).
44. She also has concerns about the use of ASCUS, A1060 and data integrity at A1062. Dr McGoogan emphasises the need to keep the ASCUS category separate. (Possibly unaware that Sydney did just that as shown in the FHA's Interim Report, TM/HFA/085). Also at A1064 there is concern about different Bethesda coding (Dr McGoogan possible unaware that the Sydney screeners used their own coding with an electronic translation to the New Zealand code).
45. At A1092 Mr Hindle asked Dr McGoogan to deal with TOR1 and "*the problem behind the question*". Dr McGoogan refers to first the absence of a standard for sensitivity and secondly TOR1 deals with abnormalities generally, ie all grades. In her lab the standard range for sensitivity of primary screening set by the programme is 85-95% (line 19) – the sensitivity is calculated by rapid review applied to every individual as well as the laboratory overall, ie a false negative rate of 5-15%. This is based upon the UK ABC document, Exhibit EM/CA/005, Appendix 5, page 42, ie calculation of the sensitivity of primary screening for high grade lesions or worse, ie CIN2, CIN3 or invasive carcinoma including all carcinomas. See A1094. And at A1095 Dr McGoogan confirms there is no standard for abnormalities less than high grade.
46. Coming back to Gisborne in 1990-1996 Mr Hindle asks:

Accepting that there is no objective standard, does there come a point at which the performance is so bad that you could nonetheless as a matter of commonsense and judgment nevertheless describe it as unacceptable –

Yes I think there is. A1095, 11

47. And then she was asked at line 20:

How would you go about trying to make that judgement I think that one must start with the understanding that whatever figure we end up attaching to a false negative rate is going to be a rough estimate and not an exact figure. And from the rough estimate of the false negative rate it may be obvious because this estimate has a false negative rate so large that it would be difficult to see how this would meet anyone's definition of a quality service or a minimum standard of service. so I think I don't see how given the data available you can calculate an exact false negative rate and that's why yesterday I was suggesting that perhaps approaching some measurement of sensitivity for this particular laboratory from a variety of different angles by putting all the information together, may give one more stable ground on which to make a judgement as to what its sensitivity rate was and to whether it was unacceptable. A1095, 20-29 and A1096, 1-3.

48. This led to a discussion of the difficulties that are involved concluding with a question to Dr McGoogan about whether these sort of problems arose in the Inverclyde situation and at A1099 is the explanation of how they were dealt with:

One we looked at the professional standards and professional practices within the laboratory under investigation. and we calculated a false negative rate by a methodology that was published and the false negative rate for high grade lesions was 50% and the professional practices in the laboratory under investigation raised many questions about meeting professional standards as opposed to quality standards and the two together allowed us to say the quality was unacceptably low.

Am I right to summarise what you have told us by saying you have a difficulty making a quantitative judgement if you haven't got objective quantitative information but you can look at all the available information and in making a true judgement, a common sense judgement you can also take into account your analyses of laboratory practice and come up with a judgement yes, may I read the first sentence from the summary of conclusions of the Inverclyde report – third exhibit, p9. (reads)

1.1.1 Our review shows that sensitivity to detect abnormalities in respect of cervical smears reported at Inverclyde Royal Hospital between May 1987 and February 1992 was lower than to be expected from a laboratory with good practice.

I think that sort of approach might help you in your attempt to fulfil your first remit, looking at whether the sensitivity was lower than that to be expected from a laboratory of good practice. A1099, 1-18.

49. Then Dr McGoogan went on to provide a list of possible methodologies for tackling the problem:

49.1 She supported Professor Skegg's proposed cancer audit.

49.2 She suggested calculating the PPV for Dr Bottrill's lab, ie look at the histology confirmation of Dr Bottrill's detected high grades and this will tell you his false positives (PPV in the UK is 65-85%). See A1100.

49.3 Sample re-reading of slides A1103.

49.4 Do a study of the existing data on the Screening Registry.

49.5 Get from the labs their performance over the period A1107 and then, after acknowledging the difficulties:

... It's a commonsense judgment that the panel are going to apply at the end of the day rather than a statistical answer. A1111.

50. Mr Grieve's cross-examination of Dr McGoogan starting at A1118 then deals specifically with TOR1 with regard to the professional practices of the laboratory in question (which had to be put on a hypothetical basis at that stage). Dr McGoogan had already been asked what sort of safeguards someone practising like Dr Bottrill would have had to put in place to ensure an adequate service for women and she listed six criteria:

50.1 External quality assurance.

50.2 Frequent interaction with other pathologists.

50.3 Frequent attendance at cytology meetings.

50.4 Laboratory accreditation.

50.5 Internal quality assurance.

50.6 Biopsy correlation of cytology.

51. It was not clear whether Dr Bottrill had his results correlated by biopsy leading to Dr McGoogan agreeing at A1133, 18 that 5 and possibly 6 out of 6 of her criteria for proper professional practice had not been satisfied. Further at A1135 Mr Grieve asked Dr McGoogan about the context in which Dr Bottrill worked and

Would you agree that his failure to meet those criteria amounted to breach of his duty of care that you mentioned yesterday ...

The practices as described to me so far would fail to meet the standards I would expect from a laboratory with good practice.

52. And further, at A1136, 9:

I would have concerns that someone practising in the way described would not be meeting my standards of duty of care in a professional context. Confirmed at A1137, 3

53. Then Mr Grieve moved on to questions about the Sydney re-read and at A1138, 7:

In other words, if one was disposed to view the Sydney results as saying something about Dr Bottrill's smear reading competence, and assuming that the results said something indicating incompetence, you would be aided in coming to that conclusion by your views about his mode of practice, do you agree with that ...

I believe that the circumstance in which he was practising must be taking in consideration when looking at the attempts to derive evidence as to what his false negative and false positive and Positive Predicted Value were. Was that what you were asking?

Yes, it was.

54. It was then suggested on the basis of the Mitchell and Medley article and the nature of the high grade abnormalities commented on by Dr Farnsworth in her report that Dr Bottrill had failed to diagnose what were obviously high grade abnormalities.

55. There was extensive discussion of this issue, culminating at A1144 with Dr McGoogan being reluctant to give a conclusive answer.

56. At that point the evidence digressed into the significance of Dr Bottrill using small cover slips with Dr McGoogan commenting:

It does however mean that the practice would result in some slides being called negative because no abnormal cells were under the cover slip when abnormal cells were present in fact on the glass slide. That is why I say it is not good practice. A1150, 21.

My instructions are that there are no New Zealand required standards for cover slip sizes, so that in those circumstances my suggestion to you is that the responsibility falls on the – in this case Dr Bottrill, to see that relevant material was in fact covered by an appropriate cover slip, would you agree with that ...

Yes I would.

57. Mr Grieve's cross-examination then moves to whether a high incidence of cervical cancer in Tairawhiti – i.e. Professor Skegg's 40 per 100,000 figure would correlate with a high rate of abnormalities:

Assuming the reported high grade abnormality smears comes from a cross section of the population then you expect a correlation, don't you – high grade

abnormalities with high incidence cancer of the cervix, correct? again, if you identify and treat the high grade abnormalities you might not get a high incidence of cervical cancer . These are not simple, straight forward questions to answer. Its likely that in a population who are going on to develop high levels of high incidence of cervical cancer, one would also expect smears from women showing high grade abnormalities at a higher level than in a population with very low incidence of cervical cancer. A1152, 20-28.

58. Mr Grieve then refers to TM/HFA/085, Table 1 on p.8 and puts Dr Bottrill's .54% of high grade abnormalities reported out of a total of 23,000 slides suggesting this is much lower than you would expect from a high incidence area. Mr Grieve also puts the UK benchmark of 1.6% plus or minus .4% and suggests that in a population that has a high incidence of cancer of the cervix, .54% is suspiciously very low, to which Dr McGoogan replies:

... It's a percentage that I would want to investigate further because it is surprisingly low (A1153, 27)

59. But she goes on to refer to a further 71 cases which Dr Bottrill reported as outside normal limits which complicates the matter. Mr Grieve persists:

If it transpires that the incidence of cancer of the cervix in Tairawhiti is very high, then give or take all the pluses and minuses that you want to, you would expect a correlation between high incidence cancer of the cervix and high grade smears wouldn't you, as a broad generality? ...

Yes.

And when seeing that figure of .54% just let's call it very low, let's not put precision on it ...

Yes.

That would cause you to ask questions wouldn't it

Yes.

Because you know, don't you, that an incidence of 30-40 cancer of the cervix per 100,000 is third world unscreened population-type statistics isn't it...

It's certainly very high.

Third world, that's the sort of statistics you get? ...

Those are the statistics you get in 3rd world countries. (A1155, 1-13)

60. Then Professor Duggan lends assistance by referring to more precise figures for both Maori and non-Maori women for 91-93 and 94-97. A1155. And then at A1156, 15:

In this region for the period you would expect a high percentage of high grade abnormalities and that's what Sydney has shown ...

Yes.

And putting Sydney to one side, if you put all these features together and you know as well that Tairāwhiti population of women is well screened, I think the percentage is something like 90%, then something is wrong somewhere isn't it ...

It's certainly worth investigation, yes.

And one of the things that might occur to you as being a possibility at least is that whoever was doing the screening was getting it wrong ...

One of the things you would have to consider is under-reporting of smear results, yes. A1156, 15-23.

61. Then Mr Murray's cross-examination gets Dr McGoogan to confirm a point (which she may have been unaware of in her earlier answers) namely that Sydney has separately identified the number of slides it reported as ASCUS H so that there could be a direct comparison between Dr Bottrill's high grade reporting rate and Sydney's high grade reporting rate – see A1190.
62. It was then put to Dr McGoogan that Sydney's reporting of 2.53% is extraordinarily high if you take an assumed New Zealand benchmark of 1% A1191 and A1192. But Dr McGoogan agrees that that could be explained by a number of factors in relation to Gisborne such as socio-economic factors, demographic factors?, a high Maori population, and the possibility that Gisborne may be an unscreened population - so that the Sydney results indicate prevalence rather than incidence figures. On that basis Dr McGoogan was prepared to confirm the answers given to Mr Grieve that the high rate of high grade abnormalities reported by Sydney, namely 2.53% would be expected to correlate with the high incidence of invasive cancer in Gisborne.
63. At that stage the questioning of Dr McGoogan was on the basis of an assumed New Zealand rate of 1% high grade abnormalities being reported as an average of all laboratories in New Zealand. A1193, 1-9. This 1% average was indicated in the third NCSP statistical report and later confirmed by Tracy Mellor's supplementary brief, para.26 and TM/HFA/88.
64. Mr Kirton then started putting to Dr McGoogan the individual patient records, with Dr McGoogan's comment being:

My first comment would be that it is extremely dangerous to extrapolate from individual cases, and you've mentioned 3, 4, 42 women who have developed cervical cancer during this time. For example, if the other 39 examples showed

no evidence of laboratory error one would be inclined to interpret this in a very different light than if every one of the other 39 histories showed varying degrees of laboratory error. One must be careful not to make judgments on very limited evidence, the second comment I have is that I would like to know whether these three smears and in particular the smears in December 1990 and in May 1992 fell within that smear description we've already discussed of the difficulty to diagnose smear with very small numbers of abnormal cells and cellular appearances which are difficult to interpret. A1208, 6-17

65. And then a question from the Chair:

Dr McGoogan of the 42 women Professor Skegg prepared this study of, if it were found, for example, that 20 of them had false negative smears and that this had occurred on 2 or more occasions, what would that indicate to you if anything ...

Not a great deal, to be frank. A1209, 16-18

66. After a digression into what Professor Skegg's study would show Mr Kirton asked:

At the end of the day, have we come to the point where it's a matter of assessing a significant range of different factors that may have applied in Dr Bottrill's laboratory in making a commonsense judgment ...

Yes. A1223, 4-6

67. And in relation to Inverclyde Dr McGoogan said what she did was:

By putting all the information together we came to an approximation of the false negative rate which at 50% for high grade lesions was a number that most professionals would find unacceptably low (Dr McGoogan meant high and corrected herself at A1225, 20).

68. Dr McGoogan then said they took account of professional practices in the laboratory and:

The wording used in the Inverclyde Inquiry Report was that the false negative rate was less than that – sorry, it was higher than that expected of a laboratory with good practice.

So a comparative outcome ...

Yes. A1224, 11-26.

Tracy Mellor's evidence – The HFA Gisborne Investigation Reports

69. Tracy Mellor produced two highly significant exhibits being the HFA's Cervical Screening Pathology Investigation Gisborne/Tairwahiti Interim Report dated 6 March 2000 (exhibit TM/HFA/085) and later in the Inquiry Tracy Mellor also produced the Action Update Report of June 2000 (TM/HFA/087). These exhibits

are highly significant because of the preambular words to the terms of reference which state:

To conduct an inquiry into the reading of abnormalities in cervical smears in the Gisborne region prior to March 1996, taking into account the results of the reviews of cervical cytology and histology samples carried out by the Health Funding Authority ...

70. Clearly the weight to be given to these exhibits needs to take account of the expert opinion evidence given by Professor Skegg and Dr McGoogan as to relevant principles and also the direct evidence of Dr Annabelle Farnsworth.
71. Despite the cautionary evidence by Dr McGoogan in particular as to re-read bias, the problem of false negatives, potential for data error and so on **it is submitted that a high degree of reliance can be placed by the Inquiry upon the two crucial HFA exhibits to find that there was a high level of under-reporting in the Gisborne region that was clearly, by any standards of professional practice, “unacceptable”.**
72. This submission rests upon Dr McGoogan’s approach to the problem, namely: paying due regard to all the variables in cervical cytology one can look at the professional standards (or lack of them) that applied in the subject laboratory when evaluating the results produced on a re-reading. This was the approach taken by Dr McGoogan at the Inverclyde Inquiry.
73. **It is further submitted that Dr McGoogan’s expert evidence as to the significance of professional practice can be applied not only to Dr Bottrill’s laboratory but also to the Sydney laboratory.** In other words the Sydney results showing a very high level of false negatives in Dr Bottrill’s laboratory are not surprising given the very poor professional practices of that laboratory. Conversely the Inquiry can expect that the very high standard of professional practice that applied in the Sydney laboratory (and its satellite laboratories) would be indicative of a very low level of false negatives among the Sydney re-read results.
74. A suggested underlying tension with reliance upon the HFA’s Gisborne investigation was that the primary purpose of the investigation was to identify all the Gisborne women who might have been placed at risk by Dr Bottrill’s practises to ensure that adequate follow-up and treatment was provided, rather than to

identify the level of under-reporting per se for the purposes of an inquiry. However it was always envisaged that the Sydney re-reading results would provide some basis for assessment of Dr Bottrill's performance:

The primary objective of the re-reading was the safety, health and well being of the women concerned. It was considered that re-reading of these cervical cytology slides would also assist in being able to determine the extent of the problem with respect to the pathologists reading of cervical smear tests. (TM/HFA/085, section 3.0 preparation and logistics)

75. Some attempts were made to suggest that the rightful predominance of the principal objective for the re-reading compromised any attempt to achieve the second objective. However the fundamental point about this is, that if it is accepted that the Sydney results are accurate to a higher degree, **the abnormalities reported by the Sydney laboratory were there to be seen by Dr Bottrill.**
76. Appendix 3 to exhibit TM/HFA/085 is Dr Farnsworth's report to the HFA which includes the statement on the second page of that report that:

The criteria used to make the cyto-predictions were the conventional appearances described initially by Papanicolaou Koss and others in the 1940s and 1950s. The terminology has changed somewhat since then but the appearances are essentially the same.

77. And at para.26 of her brief Dr Farnsworth says:

The abnormalities that were detected were not difficult to find. They were not found as a result of extensive searching but rather were very apparent. There are no new cytological criteria that were used that would not have been available in New Zealand in 1991 – 1996.

78. If one just focuses on high grade abnormalities reported by Dr Bottrill originally and by Sydney on the re-read we can see from exhibit TM/HFA/087 Appendix 1, Table 1.1 that of the 22,976 slides involved Dr Bottrill reported 123 of them as showing cancer or high grade abnormalities (.54%) whereas Sydney identified 573 slides showing cancer or high grade abnormalities (2.49%).
79. Probably the most significant part of the HFA's Action Update Report TM/HFA/087 is the histology correlations for both Dr Bottrill's laboratory and the Sydney laboratory. that is dealt with in Dr Farnsworth's evidence below.
80. Tracy Mellor also produced a number of other exhibits of particular significance and relevance to TOR1, namely:

TM/HFA/088 showing starkly that the high grade reporting rate in Gisborne during the period April 1991 to March 1996 was 0.53% compared to the national average of 1.0%. Whereas in the period March 1996 – June 1999 after Dr Bottrill had retired Gisborne’s high grade reporting rate went up to 1.71% compared to the national average of 0.96%. A similar phenomenon is also indicated for the low grade reporting rate during both of those periods.

Exhibit TM/HFA/092 Cancer of the Cervix Uteri Regional Analysis New Zealand 1990 – 1997 showing, again graphically, a high incidence of age standardised cervical cancer rates for the Tairāwhiti area 1990 – 1993 and 1994 – 1997.

TM/HFA/094A as requested by Professor Duggan this table develops exhibit TM/HFA/088 to show the year-by-year high grade and low grade reporting rates of Dr Bottrill’s laboratory compared to the national average reporting rate of community laboratories, ie excluding treatment laboratories. Again a significant increase in Gisborne area reporting rates shows up after Dr Bottrill’s retirement consistent with the high incidence of cervical cancer in Tairāwhiti shown in TM/HFA/092.

TM/HFA/100 – cervix cancer registrations by region, age standardised for each of the years 1990 – 1997 inclusive showing Tairāwhiti annual registrations relatively high in almost all of those years (to the extent that low numbers can indicate a picture).

81. Additional information sought by Professor Duggan was also provided in oral evidence at B/2012, namely the number of women who had their first smear in each of the years 1991 – 1996. Tracy Mellor explained that she had gone back through the database of the 12,000 women whose slides had been read between those five years and identified the first smear that each of those women had had since the beginning of 1991 (she couldn’t say that it was the first smear the woman had ever had):

1991 - 4,271
 1992 - 3,147
 1993 - 2,093

1994 - 1,490
 1995 - 1,114
 1996 - 165 (part year until Dr Bottrill retired)

Total 12,280

82. At B/2014 Tracy Mellor was then asked to compare those figures with the high grade results being reported by Dr Bottrill with reference to the table 3 and 4 on p.9 of Exhibit TM/HFA/085 with Tracy Mellor explaining:

... Just to point out that the reporting rates, both for high grade and all abnormalities, are approximately the same throughout each of the five years reported there, even though it's quite clear from the figures that I've just given that in the second half of the period, certainly in 1994 and 1995, that well over half of the women are coming for at least a second smear and we'd not seen any corresponding decrease in the reporting rates (B2014, 27).

83. And despite an objection from Mr Hodson and on being pressed by the Chair:

Q. Well can you see what it would signal to you then?

A. Yes, it clearly signals that there has been – that abnormalities have not been detected at the rate that one would have expected. And it's simply a signal of that in itself.

Q. So you would see it as a signal of under-reporting?

A. Yes. (B/2016, 13-20)

84. Finally, although Tracy Mellor was pressed several times about the accuracy of the Sydney re-read data being recorded B/124; B/2027; B/2032 Tracy Mellor expresses confidence in the HFA data but confirms that it is being audited and the audit results are yet to be provided to the Inquiry.

Dr Farnsworth's Evidence – Unacceptable Under-reporting Established

85. Dr Farnsworth obviously impressed as a highly qualified cytopathologist who was passionate about her vocation and the practice of cytopathology at high professional standards. Apart from her professional qualifications she has 15 years experience as a practising cytopathologist and since 1995 has headed up the Cytology Department at Douglass Hanly Moir Pathology. In that position she has had responsibility for processing some 150,000 cytology smears per annum. Douglass Hanly Moir and its satellite laboratories that carried out the re-reading work clearly operated at high professional standards and in accordance with all

Australian accreditation and external quality assurance requirements (Exhibit TM/HFA/0028).

86. Dealing first with her evidence in chief and specifically her brief of evidence statements relevant to TOR1 are:

I am entirely confident that each slide has been correctly logged in and the result has been issued for the correct women. (para 10)

It is important to note that both the reading and reporting was done without any prior knowledge of the results that had been previously issued. (para.13)

Our own internal checks of reporting correlate with that reported by the HFA in their interim report TM/HFA/0085. (para.14)

We have obviously been able to look at our overall reporting rates by our normal computer programs, which correlate with the reports for the HFA. (para.16)

The obviousness of the abnormal material on the abnormal slides and the actual appearances of the cells astounded us. These appearances continued throughout the whole re-reading exercise. We had not anticipated any of this. (para.22)

In our laboratory we have approximately 75% confirmation of our normal high grade lesions as being high grade with a further 15-20% being confirmed as a CIN lesion. (para.23)

The abnormalities that were detected were not difficult to find. They were not found as a result of extensive searching but rather were very apparent. There are no new cytological criteria that were used that would not have been available in New Zealand in 1991 – 1996..

87. Turning then to further evidence in chief in the transcript Dr Farnsworth was quite confident that the HFA had reproduced in its exhibits the results that had been reported by her (B1646, 11) and then went on to confirm her confidence in the integrity of the process being mainly electronic transfer of data and her own laboratory's internal checks that correlate with the final report from the HFA. (B1646, 19).
88. Dr Farnsworth further confirmed that the methodology for the re-reading required by the HFA did not constrain her in any way. B1647.
89. Dr Farnsworth said she was conscious of the potential for bias but:

All we received was the original request form and they were in fact entered into our system, processed exactly as we do our normal routine work. I think it's important to remember that we are an extraordinarily busy laboratory. We weren't a research institution. We function at a fairly high level, so this was not a precious exercise. B1649

90. She was asked at B1649 whether it is scientifically correct to suggest that all things being equal her laboratory's 75% correlation on histology for high grade abnormalities could be taken as applicable to the re-reading exercise (recognising that such a correlation with histology taken within 6 months of the cytology sample was not possible). Dr Farnsworth was brought back to this question specifically at B1651, 17:

Q: I realise that we can't do that correlation but if we could do it.

A: Yes absolutely if that's what you're asking me ...

91. Then Dr Farnsworth produces what has probably become the single most critical exhibit in the whole inquiry, namely exhibit AF/HFA/004 consisting of the handwritten summary of cytology/histology correlation for both Dr Bottrill's laboratory and the Sydney laboratory. It is recognised that these results are for only 269 women out of 429. Significantly Professor Duggan gets Dr Farnsworth to confirm that any confounding factors that apply to this correlation exercise would be the same for both laboratories. B1677 (The number of women with high grade abnormalities became 418 in the HFA Action Update Report TM/HFA087 but this does not affect the correlation B1713).
92. Then Dr Farnsworth goes on to speak to her overhead presentation of smear examples (B1681) and says:

.... There's a concept of prevalence and incidence. I mean when we talk about cervical cancer we talk about new cancers/year, prevalence is all the cancers. From what I saw, from what my numbers would indicate, we were looking at a population of prevalence, we were looking at women, these hadn't just developed these tumours, these had been there for a long time. So this was a whole area where you had essentially a group of women who had developed the disease much more in its original form, if you like, rather than a screened population. But that's again my opinion.

Q: Does that mean that with a screened population you're more likely to pick the disease up at an earlier stage so it doesn't develop to that degree?

A: Exactly

93. Mr Grieve's cross-examination of Dr Farnsworth then starts at B1739 with questions in particular about how obvious the abnormal smears were:

.... If you're going to ask me for the number of keratinizing squamous cell cancer slides I saw, I can't give you that number. But what I can say is that in our high grades that we called, the overwhelming majority were extremely obvious cytology to me and to the other pathologists and to our laboratory staff.

They were not cases that we anguished about in terms of is this something or is this not something. (B1744, 22-28)

94. Mr Grieve then embarks upon a long process of endeavouring to have Dr Farnsworth confirm that she would expect a correlation between her high rate of reported abnormalities and the high incidence of cervical cancer in Tairawhiti. Eventually Dr Farnsworth says:

I still believe that the incidence of cervical cancer in this region is to me surprisingly high given the number of pap smears that were actually being done in this area. (B1786, 14)

95. And this leads to the Chair confirming with Dr Farnsworth that if the slides were being repeatedly misread this would defeat an underlying assumption of the screening programme that, although false negatives will occur, the likelihood of a mis-reading of a woman's smear each time the smear is sent into the laboratory is very slight. Dr Farnsworth says if this occurred:

It would have a serious impact on the programme. (B1789, 6)

96. And further:

But there has been an assumption that laboratories performing gynaecological cytology, whichever way they choose to set them up, will follow normal process that people would be aware of and there is literature going back from the mid 80s about quality assurance processes, the actual method of screening a slide was described, I haven't got it with me, but there's a very large textbook written by a man called Leopold Cos published in the 1960s that describes the method of screening a slide. That knowledge base is present in the worldwide literature so when one does all this extra layer of checking and quality assurance and performance standards there is an underlying assumption that those very, what I would also term basic processes, are being carried out. (B1789, 13-23)

97. And Dr Farnsworth goes on to talk about the professional responsibility of the pathologist concerned indicating that a practice such as Dr Bottrill's

Would certainly be of major concern to me. (B1790, 11)

98. At the same page reference Dr Farnsworth goes on (as did Dr McGoogan) to explain the extraordinarily difficult task of primary screening and the skill required and the steps she would take professionally if she found a pathologist working in an isolated way without external quality assurance procedures (B1790 – B1793).

99. Further on in her evidence when being questioned by Professor Duggan Dr Farnsworth says as a possible explanation for the type of smears she was seeing:

Well, it was a lack of quality control but also a lack of methodical process because reading pap smears is an incredibly laborious and intense job that I think we've actually heard evidence already that it's very hard. (B1825, 6-12)

100. Dr Farnsworth reiterated many times that the cytology smears she reported as high grade were obvious. They were “*readily predictable*”.

Q: They were as clean as your face?

A: Absolutely.... (B1826, 10-20)

101. The memorable highlight of Dr Farnsworth's evidence however was her answers to Professor Duggan's astute questions about the histological correlation of the abnormalities reported by both laboratories. This questioning is found in the transcript starting at B1843 and concluding B1878. It will be recalled that the questioning consisted of drawing out the histology results from initial colposcopy presented for 3 separate time periods by Tracy Mellor in her exhibit TM/HFA/087 at pp49, 50 and 51. This information was all brought forward and summarised in exhibit AF/HFA/004 in 3 separate sections:

Section 1 - High grade correlation over all time periods

Original results 51%

Re-read results 50.7%

Dr Farnsworth then confirmed that this shows the correlation of both laboratories are the same but that Sydney found 3.5 times more high grades than Dr Bottrill, the conclusion being the extra high grades found by Sydney were true high grades which were very good cytology predictions allowing for CIN 2 and 3 regressions and this conclusion being sound because it was a comparison of both laboratories on the basis of the same criteria (B1850).

Section 2 – False Positives

Original results:

For all years 3.9%

Post May 1999 2.3%

Re-read results:

For all years 28.9%

Post May 1999 42.8%

Dr Farnsworth's conclusion:

It means that Dr Bottrill has a very low false positive rate, especially compared to the Sydney re-read.

...it would be of great concern if your false positive rate was extremely low because it would mean that you are therefore missing a large number of the high grade lesions that you're in fact looking for. (B1858, 24)

And then a question from the Chair:

Could that mean if you had a very low false positive rate that there was a greater likelihood that you may be under-reporting?

A: Absolutely, and in fact that's exactly what we're talking about here. We're talking about, it's like the eternal balance of sensitivity v specificity ...

Q: Therefore, if you were looking for indicators of under-reporting could one possible indicator of under-reporting be a very low false positive rate?

A: Yes. By the way, it's important that any one indicator is not taken alone. (B1859, 1-15)

Section 3 – High Grade Correlation

Original laboratory:

High grade cytology – 17%
Other abnormal cytology – 51%

Re-read results:

High grade cytology – 61%
Other abnormal cytology – 40%

And Dr Farnsworth confirmed that these correlation figures certainly could indicate under-reporting consistent with the .5% rate of abnormalities detected by Dr Bottrill compared with the 2.5% detected by Sydney. (B1866, 19).

Dr Farnsworth went on to conclude in relation to the Dr Bottrill 17% correlation that it's extremely low and unacceptably low (B 1869, 12) and then pressed further, Dr Farnsworth said that on a scale of 1-10 with 10 being the worst level of under-reporting she would score Dr Bottrill with an 8 (B1869, 18).

102. Then Mr Grieve resumes cross-examination with Dr Farnsworth agreeing that an explanation for Dr Bottrill's results could be his inadequate training (B1881, 23). She further agrees that practising in the way he did without accreditation and external quality assurance involved running an enormous risk. (B1884, 25).

103. Significantly when Mr Hodson rose to cross-examine Dr Farnsworth the Inquiry had clearly reached a point where an unacceptable level of under-reporting had been established – Mr Hodson making it clear that he had no instructions from Dr Bottrill to criticise or correct the evidence that Dr Farnsworth had just given. (B1886).
104. Most of Mr Hodson’s cross-examination was directed at showing the distinctions between Dr Bottrill’s methodology and the Sydney laboratories such as re-coverslipping, use of cyto-screeners, use of targeted re-screening with up to 3 people looking at each slide, the Mitchell and Medley article about typical false negative smears not being published until 1995, possible defensive medicine being practised in Australia because of exposure to litigation and general improvements in knowledge and technique since Dr Bottrill’s retirement. To all this Dr Farnsworth was prepared to accept that she would expect a higher rate of detection of abnormality in the Sydney laboratory (B1901).
105. However, when questioned about this by Professor Duggan Dr Farnsworth confirms that the techniques used by the Sydney laboratory were all available to be used in the period 1991 – 1996. (B1901).
106. And then in answer to questions from the Chair Dr Farnsworth agreed that Dr Bottrill’s method of practice was not good practice and there comes a time when a pathologist should recognise that they are practising inappropriately. (B1902).

Dr Wain’s Evidence – Confirmation of Unacceptable Under-reporting

107. Dr Wain’s evidence was based upon his study of the clinical records for patients 1 – 9. He had also been sent the briefs of evidence but not clinical records for patients 11 – 20. There was some concern that his evidence may have been influenced by the briefs of patients 11 –20 when he had not had the opportunity to confirm their evidence by studying the clinical records for those women. He did however confirm his opinions notwithstanding that risk. (See B1973 and following).
108. Significant passages from Dr Wain’s brief are the following:

Review of these cases has given me an impression of the situation in relation to cervical screening in the Gisborne area during this time, with a particular

opportunity to see some of the end stage consequences of failed cervical screening. Although I recognise that it is only a small sample of the total population of the women of Gisborne, it did seem to contain a larger number of mis-reads, and particularly a larger number of repeated mis-reads, than one would expect to find in such a group. The overall impression gained is a sense that this is an effectively unscreened population of women who are presenting with the range of cancers typical of an unscreened population. (para 23)

In relation to the Gisborne experience, there seems to be a pattern of women who have repeatedly had their smears mis-read. The fact that smears have been taken along the way, and now in retrospect have been found to be abnormal, serves as a documentation of the natural history of the disease in each of these women. Amongst this group of women, I saw a display of the range of clinical behaviour of cervical neoplasia from spontaneous regression in some cases, through to persistent indolent disease and to fatal progressive invasive cancer. The total number of mis-read smears in this group of women, and repeatedly in particular women, suggests that the events were not random misfortune but more suggestive of a pattern of very poor laboratory performance, in which abnormalities were repeatedly not detected. (para 26)

Although in some cases, the delay in diagnosis seems to have had no major medical consequences, this has tragically not been the case for many others. It is clear that several women have lost the chance to have their cervical pathology diagnosed at a treatable point and gone on to develop advanced and fatal cervical cancer. (para 28)

109. Mr Corkill then cross-examined:

Q: If there has been routine under-reporting, then would you agree that these outcomes, even in respect of pre-invasive conditions, are wholly unacceptable?

A: Yes I would agree with that. B1935, 4-7

110. And further at B1936 Dr Wain said:

Within the limits that this is a small sample of the population, it's the end of the spectrum, it's what happens to women at the end of the cervical screening pathway and so I think you can draw in inference that somewhere along the way things were going wrong very badly. B1936, 5-8

111. Dr Wain also thought the fact that 12,000 women had been screened was a high level of screening but the outcome was not consistent with his clinical observations which was a striking feature. B1937

112. Dr Wain was also referred to Tracy Mellor's supplementary evidence at p7 which referred to 25% of the women having their first colposcopy before Dr Bottrill retired and 56% since the Gisborne investigation began in May 1999. B1936. Over the following two pages of the transcript he confirmed that this was another indicator of under-reporting because the identification of abnormalities is normally coincident with colposcopic follow-up.

113. Dr Wain was also referred to TM/HFA/087 p45 showing the number of slides re-read per woman with a higher degree of abnormality than the original result. Dr Wain confirmed Dr Farnsworth's evidence that the way in which a screening programme works is to overcome the known false negative rate by having women repeat their smears over a certain time interval so that it would be a rare event for the same woman to have a smear misread twice. Dr Wain referred to the extreme example where one woman who had 6 pap smears all read incorrectly:

Though I think it's rare to have 1, but it happens, so I think for one woman to have it happen to her twice is very unlucky and uncommon. For it to happen 3 times, and by the time you get to 6 it becomes almost unbelievable. B1940, 21-24

114. Then starting at B1946 Professor Duggan takes Dr Wain to the 2 tables consisting of the last page of TM/HFA/087 which show the time periods for the first diagnosis of cancer. After taking Dr Wain through the two tables Professor Duggan asks:

Q: Would you agree with this summary, that all of the women who developed cancer were re-read by Sydney as cancer high grade or ASCUS H?

A: Yes.

Q: Whereas only 12, which is 30% of the women who developed cancer had their smears read by Dr Bottrill as cancer or high grade?

A: I would agree with that.

Q: What do those rates mean to you?

A: I think that no. 1 it confirms to me that the Sydney re-read is likely to be correct in those women since they've all been subsequently to have cancer, and no. 2 that Dr Bottrill wasn't very good at picking up women with definite abnormalities on their cervix.

Q: Could this be under-reporting by Dr Bottrill?

A: I think it is almost certainly under-reporting.

Q: Could it be anything else?

A: When you compare the two I can't think of anything else that it could be. B1950

115. And then the Chair follows that line of questioning to ask where on a 10 point scale with 1 being the lowest and 10 being the highest would you put the level of under-reporting on the basis of that table which is table 5.6 in the exhibit 87 of Mellor Supplementary. Dr Wain gives it at 10 confirming that it is completely

unacceptable. He confirms that looking at the 2 tables he can say of the women who developed invasive cancer in the Tairāwhiti region:

They're a screened population but they've got no benefit from screening.
B1951, 22

116. Professor Skegg was also prepared to accept that the same two tables in TM/HFA/087 page 52 established clear evidence of unacceptable under-reporting. (B2294) Dr Cox was also asked to assume the women had abnormalities throughout the period 1991 to 1999 and concluded that if the Sydney laboratory had read the smears instead of Dr Bottrill twice as many cancers would have been detected – B2561, 4. Dr Cox also calculated the Sydney laboratory's false negative rate at .949 compared to Dr Bottrill at .436 (Ex BSC/SC/050)

James DuRose – The National Parameters

117. The DuRose evidence was not particularly relevant to under-reporting in the Gisborne region. The HFA's National Laboratory Review did not include Dr Bottrill's laboratory. However figures for his laboratory were included to provide some comparison with the national parameters.
118. The New Zealand laboratories' reporting patterns of high grade and total abnormalities are set out in the tables to Mr DuRose's first exhibit starting at page 24. The position of Gisborne laboratories is shown in relation to the national average on pages 24, 25, 26 and 27. Gisborne laboratories had among the lowest reporting rates for high grade abnormalities, pages 24 and 26 and had the lowest reporting rate for total abnormalities, pages 25 and 27.
119. At page 34 of Mr DuRose's exhibit 1 the percentages are set out and:

In summary, the Gisborne laboratory was below the practice reviews high grade benchmark in 1994/95 and below the total abnormality benchmark throughout 1991-1995. This is an area of incidence of cancer that was above the national average during this period and is an area of the highest proportion of Maori women. It is understood that a feature of the Gisborne laboratory during the period 1991 to 1995 was that a sole pathology practitioner was "primary screening" the smears and that there was minimal internal quality control.

Dr Bottrill – Unacceptable Under-reporting Accepted

120. Dr Bottrill said at the last paragraph of his brief:

The statistics provided by the Sydney re-read came as a complete bomb-shell to me. I have read the evidence of Dr Farnsworth and it is now clear to me that I under-reported many slides. There were many more in this category than there should have been. I can only say that I had no knowledge of this in my practising career. I was and I remain greatly distressed to find that my misreading of slides has caused so much pain and suffering to so many people.

121. Then starting at B3077 Mr Grieve specifically put the Sydney re-read results to Dr Bottrill and specifically Dr Farnsworth evidence at B1869, 13, i.e. Dr Bottrill's 17% detection rate was "extremely low" and "unacceptably low". Then the question was put to Dr Bottrill:

Do you now accept, from what you've seen, read of the evidence that's been given, that during the period 1991 to March 1996, there has been an unacceptable level of under-reporting of cervical smears in the Gisborne region as a consequence of your misreading and/or misreporting of those smears?

A: Regretfully yes. (B3079, 24)

TERM OF REFERENCE TWO: IF YOU DETERMINE THAT THERE HAS BEEN AN UNACCEPTABLE LEVEL OF UNDER-REPORTING, TO IDENTIFY THE FACTORS THAT ARE LIKELY TO HAVE LED TO THAT UNDER-REPORTING

Introduction

122. It seems beyond doubt that, for the period under consideration at least, Dr Bottrill was not a competent screener of cervical cytology. Furthermore, he was the sole screener, working without the support of a primary screener and had extremely poor, if any, quality control/quality assurance processes around his reporting of cytology.
123. The lack of quality control/quality assurance processes within Dr Bottrill's laboratory is an issue that stands separate from the issue of quality assurance around laboratory services to the National Cervical Screening Programme. Over the relevant period many of the smears read in the Gisborne region were not for women enrolled on the Programme. Those women have suffered just the same. The Inquiry must consider the issue of quality assurance in its historical context and comparisons can legitimately be made with other parts of the health sector. Dr Bottrill was solely responsible for the provision of quality service by his laboratory. He failed in that responsibility.
124. He also failed the NCSP. Rightly or wrongly, women looked to the fledgling Programme to ensure quality of outcome; to detect pre-cancerous lesions and reduce the prospects of cancer. The Programme, it might be said, should not have offered the service if it could not assure its quality. Nevertheless, in the context of other centrally organised cervical screening programmes, it is submitted that the progress made in New Zealand on laboratory quality assurance processes stands up well to international comparison. That does not excuse inferior practises or lack of quality assurance. The important point is that the health sector in general, and the Programme in particular, was certainly not ambivalent to the critical issues of quality improvement and assurance. At the general level, over the relevant period New Zealand was embarking on reforms designed to improve quality throughout the health sector by tailored contracting for quality services with

providers. The 1993 Health and Disability Services Act broke new ground in introducing the concept of appropriate standards for all services across the sector. Within the Programme, laboratory quality focussed on TELARC accreditation, and the development of an opt-off, centralised Register which included histology, and which was anticipated would provide a world-leading monitoring tool.

Ministry of Health approach to evidence before the Inquiry

125. In the initial evidence of Dr Boyd and Ms Glackin, the Ministry provided an overview of the development of the NCSP, with a focus on laboratory quality issues. It was intended to provide a context for the Inquiry and produce the relevant documents located from a very extensive file search. The Inquiry panel was invited to identify the areas and issues it wanted to hear more about and the appropriate witnesses would be provided. The extent of cross-examination of Dr Boyd and Ms Glackin was not anticipated and traversed many areas with which the witnesses were not personally familiar. Their willingness to assist with matters outside their personal knowledge should be seen for what it was – an effort to be of assistance.
126. At the end of the hearings, four witnesses were provided given the Inquiry panel wished to put certain matters to Ministry witnesses and it was not clear what issues would arise. There was perhaps some implied criticism in this approach from counsel for the Royal College and Dr Teague that Ms Grew and Ms Dahl should have been called earlier. As was indicated to Counsel Assisting on a number of occasions, the Ministry and HFA would make available all or any of the National Co-ordinators, if there were issues of concern to the Panel with which they could assist. The Ministry and the HFA took the approach that its role was to assist and facilitate, to the extent possible, the Inquiry in its task. Much work was done throughout the Inquiry hearings to brief further evidence to deal with issues as they arose.
127. There may also be suggestions that the Ministry should have more actively cross-examined witnesses if it did not accept the evidence presented. The Ministry's approach to cross-examination of "historical" witnesses was as follows:

- 127.1 Dr Teague was an important witness as he was the key advisor to the NCSP, through CALC/CSLAC and more informally on laboratory issues which are central to the Inquiry. To the extent the evidence was not already available on the documents, he was cross-examined.
- 127.2 Members of the Advisory Group CSAC (Dr Cox, Ms Marshall and Ms Coney) were seen to be giving evidence on matters relating to the wider Programme and therefore of less direct relevance to the Inquiry. The Ministry took the approach that they were entitled to express their view of issues from their perspective. The fact that another view might be drawn from documents made at the time and already in evidence could be left to submission.
128. To raise each point of potential challenge in such broad-reaching evidence could have taken days in the case of each witness. This was not seen as appropriate.
- 128.1 The Inquiry is not an adversarial process. The task is to co-operate to ensure the panel is informed. It is unlikely that litigating points of disagreement, particularly on peripheral matters, would be helpful. The Ministry's approach is primarily to point to documents created at the time to support its submission.
- 128.2 The Ministry had an obligation to ensure that the Minister's timeframes for the Inquiry were respected and to ensure that the important information, particularly that relating to potential current risks to the public and to the future conduct of the Programme, was received and properly considered by the Inquiry.
- 128.3 Resource constraints required a focused approach.
- 128.4 Extensive cross-examination on historical points of difference would not have been constructive. Health officials must continue to work with, and even rely on, these witnesses now and in the future. The quality of the on-going relationships is seen as much more important than meeting every historic criticism of the Programme.

129. Accordingly, the Ministry is content to rely on the documents and other evidence to answer the unfounded criticisms in submission. It is entitled to do so, and the weight to be given conflicting evidence is a matter for the Inquiry Panel. To the extent the whole picture has not had time to unfold, the Ministry accepts it may face some criticism which it would not necessarily accept as warranted.

Summary of factors arguably leading to under-reporting

130. The factors likely to have led to the under-reporting were:

130.1 Dr Bottrill's lack of competence to screen cervical cytology.

130.2 Dr Bottrill's practice as sole screener, without adequate quality assurance practises.

131. The Department's key contribution to those factors was, in 1969, to register Dr Bottrill as a supervising pathologist to whom payments could be made for laboratory services, including cytology services. This was probably done on the advice of the relevant expert committee, as was the usual practice. From then on his competence to ensure the provision of a quality service was presumed, in the absence of an established complaint or sanction by the relevant professional organisation. There was none. Accordingly, it might be argued that a contributing factor was that Dr Bottrill's services were paid for by the State, arguably without proper regard for quality.

132. However, it was the advent of the NCSP, together with health reforms which focussed on purchasing services that met certain standards, which led to Dr Bottrill's retirement and an end to the under-reporting. They did not **lead** to it. Maybe things could have been done differently and Dr Bottrill prevented from reading slides earlier and that is a matter of real regret. But the position is far from the simple scenario of a failure to heed advice and implement steps in a timely way. Even if it was, it could not have "lead to" under-reporting: that was happening anyway.

133. For the purposes of submission, this term of reference is considered under the following headings as "possible relevant factors":

133.1 Dr Bottrill's competence and cytology practice.

- 133.2 Possible warning signs about the competence of Dr Bottrill to his colleagues and health authorities.
- 133.3 Quality around subsidised services (1990-1996).
- 133.4 A more effective NCSP, implemented in line with the advice of expert advisory groups, might have resulted in closer attention to quality issues relating to Dr Bottrill's laboratory.
134. All these factors have to be judged with a correction for hindsight bias. *"Nothing is so easy as to be wise after the event"* (*Cornman v. The Eastern Counties Railway Co*, 157 Eng Rep 1050, 1052 (Exch 1859). Baruch Fischhoff described the bias as follows:

In hindsight, people consistently exaggerate what could have been anticipated in foresight. They not only tend to view what has happened as having been inevitable but also view it as having appeared 'relatively inevitable' before it happened. People believe that others should have been able to anticipate events much better than was actually the case. ("For Those Condemned to Study the Past: Heuristics and Biases in Hindsight", in Kahneman, Slovic and Tversky, Judgement Under Uncertainty: Heuristics and Biases, Cambridge 1982)

135. The legal process is considered to have done a good job of adapting to the limitations of human judgement in hindsight, e.g. by avoiding generic solutions that psychological research predicts would have been unsuccessful, and by developing rules that take advantage of specific opportunities to avoid the bias (Jeffrey J Rachlinski, *A Positive Psychological Theory of Judging in Hindsight*, University of Chicago Law Review 65, 1998). This Inquiry is faced with a substantial challenge in sifting through the mass of evidence to uncover the real causes of something we only now know to have gone badly wrong.

Dr Bottrill's Competence And Cytology Practice

136. It is apparent that Dr Bottrill was not a competent primary screener. This was the direct cause of the under-reporting. This factor is compounded by the fact that it was neither desirable nor usual practice over the relevant period for a sole pathologist to carry out primary screening. Dr Boyd's understanding was that, in 1989 laboratories usually had a primary screener plus a qualified person such as a pathologist or scientist to re-read those slides classified as abnormal, and also to read some of the normals as a verification check: A552/23-553/2. Mr Walker of

TELARC confirmed that the practice was unique in his experience: B519/19-520/15.

137. It is also plain on the evidence, no doubt traversed by others in submission, that Dr Bottrill had very poor, if any, quality control/quality assurance systems in place surrounding cervical cytology in his laboratory.

Possible Warning Signs

To the Department of Health (1989)

138. This submission focuses on the suggestion made in the course of the Inquiry that three early documents produced by Dr Boyd and Ms Glackin should have set off alarm bells or raised concerns for the National Cervical Screening Unit. The documents are:

138.1 Report on cervical screening services within Tairawhiti by Dr Jane Smith (November 1988): JMG/MOH/062: Glackin Vol.11 p.5.

138.2 The report of the Visiting Medical Practitioner for May 1989: GRB/MOH/031 Boyd Vol.5 p.80 at 81.

138.3 Rough notes on Implementation Unit visit to Tairawhiti Area Health Board in July 1989 (impressions of various people noted, including Dr Bottrill): JMG/MOH/062 Vol.11 p.16.

139. The first document, taking them chronologically, is the report, of November 1988 by Dr Jane Smith, Community Medicine Registrar with the Tairawhiti Area Health Board: JMG/MOH/062. Dr Smith became the first Regional Co-Ordinator in Tairawhiti. The report noted:

[The private] pathologist reports an average of 20 smears per day and he believes that an increase of up to 30 per day will result in an unmanageable workload. The availability of part-time screeners would solve that difficulty, but there is no-one currently available in Gisborne. (Glackin, Vol.11, pp.5-6).

140. The Visiting Medical Practitioner's report from May 1989 was referred to in Dr Boyd's evidence in chief at paras.163-165. He explains the role of the Visiting Practitioner:

Their role was to visit general practitioners and specialists throughout the country, to maintain liaison between the Department and those in practice, to explain changes in health benefits, to promote rational prescribing and appropriate use of laboratory services and to feed back to the Department head office intelligence about major issues affecting practitioners, the effects of current health policy and any other information they felt was relevant. In 1989 cervical screening was an issue and the Visiting Practitioners would have had it on their list of topics for discussion with general practitioners and appropriate specialists, whenever they visited.

Visiting Practitioners did not have a disciplinary function and were not auditors of quality or safety.

141. Dr Boyd reported what he had done in relation to the information that one GP had expressed concern that he had never received an “abnormal” report from Dr Bottrill’s laboratory:

I reviewed the information and concluded that the Visiting Practitioner had done the correct thing by seeking evidence to corroborate the concerns expressed by one doctor and had not found any support among general practitioners and appropriate specialists. (para.163 Boyd evidence in chief)

The Visiting Practitioner had taken the proper steps to check whether the GP’s concerns were shared by others. It cannot reasonably be said that this report of one practitioner’s concern, not supported by other professionals using the laboratory, should have sounded a warning to the Department.

142. The third document was described as “rough notes” of the Implementation Unit’s visit to the Tairawhiti Area Health Board in July 1989. They included the comment relating to Dr Bottrill, under the heading “Impressions”:

**does not employ any cytology assistants and has never tried to even tho he doesn’t particularly want to continue screening all the slides himself.
laid back to the point of almost falling over.
experienced recent ill-health ...
didn’t want to read any more slides than his current 20 per day ...**

143. The first point to note is that these are very informal notes which make a number of subjective judgements. Those judgements were, of course, not disclosed to those individuals at the time. There are, of course, many laid back people in many professions. There are also many people who have recently been ill. That does not mean there is a problem. Being “laid back” does not disclose incompetence – it refers to demeanour; quite a different thing. A procedure existed under the Medical Practitioner’s Act 1968 where the ill health of medical practitioners

potentially impacting on their ability to perform their job was of concern (refer under).

144. A perusal of the whole document reinforces its informality and the caution that must be taken if it were to be relied upon. For example, the notes record that the Director of Community Health Services at Tairawhiti “*didn’t wish to ask questions or discuss the Register. Did not appear to have been well briefed or else hadn’t understood what she had been told*” (Glackin Vol.11, p 13). The Director of Clinical Services at Tairawhiti “*arrived late, concerned at acquiring additional funds for traditional services*” (p 13).

At Vol. 11, p 14 it is noted:

At no time did any of those present appreciate that this was a national health programme even tho it is going to be locally managed and provided. Their inability to understand the concept of having compatible in all boards coloured their vision and they were unable to [see] how this could affect the success of the programme.

Kept going on about what if the government changes. What about ongoing funding as in for ever and ever.

145. Other observations (at p 15) included the fact that the colposcopist asked whether Fiona Saunders-Francis was a nurse or a secretary, and that she thought smears were not effective and cervical screening was not cost effective. A local GP stated the Minister should have told Cartwright that it was the patients’ fault, and “*the others generally agreed.*” (p 16).
146. In summary, it is submitted that the main conclusion one might take from the totality of the rough notes of the visit to Taurawhiti Area Health Board is that there were significant obstacles to overcome if the Programme was to be successfully implemented in that region. Nevertheless, as Dr Boyd accepted in cross examination, the notes raised some concerns particularly in relation to Dr Bottrill’s ill-health, his desire not to read any more slides, and the apparent lack of planning for the future: A552/10-20.
147. Dr Boyd was asked whether, had these three documents been considered together, that should have rung alarm bells. His response was to emphasise the benefit of hindsight and to repeatedly give the qualified “ideally, yes”: A548/4-8; A548/15-16; A551/7-10; A551/16-18; A552/3-5.

148. It is submitted:

- 148.1 One cannot assume the documents were all considered together and there is no evidence of that.
- 148.2 Considered individually, they do not raise significant issues in relation to Dr Bottrill's competence to read slides.
- 148.3 The benefit of hindsight was not available when the information was provided in 1988-89.
- 148.4 If the information had been considered together, alarm bells might have been rung, but that is speculation and, as Dr Boyd indicated, would have been the 'ideal' outcome. The practical reality, given the considerable amount of information received in the sector, the informality of the information and the context within which it was raised is that it is unlikely the alarm bells would have sounded.
- 148.5 Accordingly the Department should not be criticised for a failure to identify Dr Bottrill as a risk. Those who worked much more closely with him did not, and neither did his treating clinicians. It would be unfair to point to three disparate, ad hoc pieces of information and say "Aha!" – someone should have done something. Quite reasonably, it is submitted, no one was alarmed by what they encountered.

To the Midland RHA (1994)

149. The Dr Berkinshaw incident at Good Health Wanganui in June 1994 did raise alarm bells about elderly and ill pathologists becoming isolated from their peer group. These issues were immediately identified by the Midland RHA including concern about Dr Bottrill. This is dealt with in the next section of these submissions relating to the 1993 Health reforms.

To Dr Teague (1995)

150. Perhaps the clearest message that Dr Bottrill's cytology practice was not meeting the standards expected of a laboratory providing services to the Programme was in the information that Dr Teague obtained in July 1995. This is not a reference to

the confidential outcome of the slide re-read in relation to patient 1, but to the information that, despite what Dr Teague thought was a mandatory requirement of the Programme, the laboratory was not TELARC accredited. (See paras.26.19 and 26.2 of Dr Teague's evidence in chief to identify the date as July 1995.) Dr Teague said in cross-examination that he was "*astounded to find there was a laboratory that wasn't registered*": B/1425/9-10. His response was to advise Dr Bottrill to become TELARC accredited or refer cytology work to a TELARC accredited laboratory.

151. Dr Teague obtained this information against the background of his knowledge of patient 1's complaint to the Medical Council of under-reporting by Dr Bottrill. He was a very senior and authoritative specialist, past president of the NZ Society of Cytology, and a member of the RCPA Quality Assurance Cytopathology Programme Committee: Dr Teague's evidence-in-chief paras 2.17 and 2.18.

152. More importantly, he was at that time a member of the primary expert advisory committee to the Programme (CSAC) and the Chairman of the expert advisory committee on laboratory matters (CSLAC). CSLAC had, just five months earlier, drafted a response for the Minister of Health to send to Ms Sandra Coney referring to compulsory TELARC accreditation as being a key achievement of the Programme: Refer CSLAC minutes of 15 February 1995; Boyd Vol.4 p.116. He was the NCSP's key adviser on matters relating to quality assurance and laboratories. CSLAC's terms of reference set in July 1994 specifically acknowledged the Committee's role as being to "*advise on the provision of quality laboratory services associated with the NCSP*" and its four functions included "*Advise the National Co-ordinator of laboratory issues requiring attention and advice*": Boyd Vol.4 pp.79-80. Dr Teague could readily have raised the issue of whether mandatory accreditation was being enforced had he thought it important. He did not raise any concern with the National Co-ordinator, either in relation to the Gisborne laboratory or in relation to laboratory accreditation generally. The fact that he did not is, it is submitted, simply because Dr Teague, New Zealand's foremost authority on quality issues surrounding cytology, did not see it as a cause for concern to be taken beyond the procedures operating through the Medical Council. If he did not, who reasonably would have?

153. Neither did he raise it as an issue with the Programme when, in December 1995, he signed the contract between his laboratory and the Central RHA, despite being “surprised” that this was the first time registration had been made compulsory for his own laboratory: B/1429/1-14.

Other opportunities for warning?

154. The submission could also be made that those medical professionals working with Dr Bottrill, and/or with women who utilised Dr Bottrill’s services and/or the professional organisations to which he belonged, might have picked up warning signs about his competence and/or the practices in his laboratory. We also know that Mr Walker of TELARC was unimpressed when he visited in October 1994 for the pre-audit consultation: para. 23 of his evidence in chief. Perhaps the manager of Dr Bottrill’s laboratory might have had a view on the propriety of providing cytology services with the supervising pathologist as the primary screener. There were many potential opportunities for alarm; but all afflicted with the wisdom of hindsight.
155. As to the possible adverse effects of Dr Bottrill’s health, note that s.34 of the former Medical Practitioner’s Act 1968 provides an obligation on an attending medical practitioner or any registered medical practitioner to give written notice to the Secretary of the Medical Council of all the circumstances if the attending medical practitioner:

... considers that the person is unable, because of some mental disability or the nature and extent of some physical disability that he has, to perform his professional duties satisfactorily and that, because he may attempt to perform those duties, it is necessary in the public interest to prevent him from so doing.

156. Dr Bottrill told us he suffered deterioration of his short-term memory after his bypass operation in 1990 and as a result he gave up his forensic pathology practice: Bottrill para.59 evidence in chief. It is possible that a disability affecting his cytology practice should also have been observed. In evidence he said that possibly he had a form of attention deficit, but that it was not recognised at the time: B/3082/9-12. He had a full medical examination after his bypass to confirm his fitness for work: B/3082/13-16.

Quality Around Subsidised Services (1990-1996)

Health Benefit provided under Social Security Act regulations to 30 June 1993

157. As Dr Boyd said in evidence, the public health sector has for very many years subsidised services for New Zealanders in which quality and safety depended on the professional integrity of the provider, usually a doctor: Boyd, para. 52 evidence-in-chief. In most cases, the Government contribution toward services was provided for under Part II of the Social Security Act 1964 until the Act and its associated regulations were repealed and replaced by the Health and Disability Services Act 1993: Boyd, para. 55. Publicly owned services, ie those provided by Hospital Boards, Area Health Boards and Crown Health Enterprises, were bulk-funded. In the most part, private laboratories were paid a subsidy on a “per service” basis.
158. Dr Boyd noted that a series of Ministerial advisory committees provided advice on the general administration of health benefits under Part II of the Act. One of those committees was the Laboratory Services Advisory Committee (LSAC) which advised on the administration of the laboratory diagnostic services benefit and on adding new tests to the schedule of subsidised tests. Cervical smear reporting had been an approved laboratory test at least since 1971: GRB/MOH/005.
159. The level of subsidy under the Social Security Act was set nationally by Cabinet through amendment to the regulatory regime. It usually followed negotiations with representatives of the relevant professional group: Boyd, para.56. These subsidies were generally referred to as “health benefits”. Pathologists in private laboratories had to accept the Government subsidy or “benefit”, in full satisfaction for any services included in the schedule of laboratory tests published by the Department of Health and based on regulations under the Social Security Act: Boyd, para. 57.
160. Private laboratories such as that operated by Dr Bottrill applied to the Department to be paid for carrying out certain tests. The Department took the advice of LSAC as to whether a particular laboratory should be approved. Approvals related to the specific supervising pathologists.
161. This was the method of “ensuring” quality of services to those subsidised by the Government, i.e. to pay the subsidy to a named registered medical practitioner (in

the case of the laboratory, a supervising pathologist) even when the service was provided by other staff. He or she was then responsible for ensuring an adequate service was provided by the laboratory.

The expectation was of appropriate supervision by the responsible named practitioner. So, for example, the head pathologist at a laboratory received payment for services at that laboratory. He or she was looked to to ensure adequate service. (Boyd, para. 58)

162. Therefore, the competence of the personnel was important. A supervising pathologist such as Dr Bottrill was also a registered medical practitioner. Any complaints that came to the notice of the Department about the quality of service at a laboratory could be taken to LSAC for advice. They could also be referred to the Medical Council as a complaint against the supervising pathologist: Boyd, para. 60. The Department effectively relied on the professional organisations to ensure competency. The professional organisations controlled entry into, discipline within, and exit from, the system. In other words, until 1 July 1996, following the changes to the Medical Practitioners Act in 1995, the competency of the medical profession was effectively self-regulating (as is the legal profession today).
163. On the broad issue of quality assurance, Dr Boyd summarises laboratory internal quality control procedures relating to cervical smear reading and reporting in paragraphs 108 to 132 of his evidence-in-chief. External quality assurance processes are discussed in paragraphs 133 to 158. He noted that laboratories, like most organisations, have introduced processes of checking their own work to varying degrees and that the ways in which quality assurance activity is carried out is at the discretion of the laboratory itself, except where standards are mandated by the purchaser of the service or by the professional bodies to which the laboratory staff belong.
164. Standards only became “legally relevant” across the Health sector with the onset of contracting under the 1993 Health and Disability Services Act. As we have heard, the first contracts with the community laboratories were the subject of protracted and difficult negotiations over three years and which concluded only in 1996/97.

165. Dr Bottrill was registered as a supervising pathologist to whom payments could be made for certain approved tests from 1969: GRB/MOH/017 and Boyd, para.85 evidence in chief. This lasted until 1993. From 1993 to 1996 the services of his laboratory were contracted by the Midland RHA through the mechanism of a s.51 notice pending completion of contractual negotiations.
166. Thus, from 1969 when Dr Bottrill was first registered as a supervising pathologist (GRB/MOH/017 and Boyd para.85 evidence in chief), until 1996 when Dr Bottrill ceased to practice, there were no compulsory minimum quality assurance procedures mandated by either the Department/Ministry of Health, Regional Health Authorities or the relevant professional organisations. There were guidelines and voluntary standards. As Dr Boyd said in evidence, the Programme was superimposed on an existing system of service delivery in which the Government subsidised services provided to patients and in which quality and safety largely depended on the professional integrity and competence of the provider: Boyd, para. 52. It had to deal with the services then in place, as it found them.
167. It is thus submitted that, prior to the implementation of contracting under the 1993 Act, the Department/Ministry of Health relied first on the professional competence of a registered pathologist, and second on the recommendation of the expert advisory committee (LSAC) that a supervising pathologist, and therefore the laboratory, could appropriately be paid for carrying out particular tests. It relied on the disciplinary procedures of the professional organisation to ensure continuing competency. This approach was paralleled almost everywhere in the health sector. This is significant to the Terms of Reference because many slides read by Dr Bottrill (and paid for by the State) were not from women enrolled in the Programme.
168. The relevance of the Programme is, it is submitted, as follows:
- 168.1 The Programme actively encouraged women to undergo smears; and
- 168.2 The Programme is intended to provide, through the Register, an enhanced ability to monitor the quality of smear reading and reporting services provided by laboratories.

169. The optimal position could be said to be that laboratories will be subject to quality assurance processes whether or not they provide smear reading services to the Programme, and further that the Programme itself may provide an over-lay or enhanced quality assurance process. That has been the objective, if not the outcome by 1996, of much of the efforts of officials over the relevant period.

Purchase under the Health and Disability Services Act 1993

170. Whether or not Dr Bottrill was under-reporting cervical smears prior to 1990 we do not know. The evidence did not go that far back. It is possible that he was because of inadequate or a complete absence of training about how to primary screen a smear. On the other hand serious under-reporting could have started from 1990 after Dr Bottrill underwent major heart surgery producing some insidious side effect such as attention deficit syndrome as suggested by Dr Bottrill himself.
171. In any event the evidence focused on the period from January 1990 until March 1996 when Dr Bottrill retired. In the middle of that period the health sector in New Zealand underwent major restructuring. It is therefore necessary to consider whether that restructuring was a factor “... *likely to have led to that under-reporting*”.
172. It is submitted that the 1993 health reforms did not “*lead to*”, in the sense of causing, any under-reporting. All the causes of Dr Bottrill’s under-reporting were already operative before the Health & Disability Services Act 1993 (HDSA) came into force on 11 May 1993 and the four regional health authorities established on 1 July 1993. As a matter of logic that law reform could not have caused something which already existed. Rather the question is what effect if any did the new health structures have on Dr Bottrill’s practice and the NCSP in general.
173. It is submitted that on the one hand the effect of the reforms were positive in that the new statutory focus on the purchase of quality health services eventually caught up with Dr Bottrill and hastened his retirement. On the other hand the statutory purchaser/provider split and more significantly the policy/purchaser split between the MOH and the RHAs had the effect of delegating responsibility for the purchase of services for the NCSP to the RHAs, which had very broad purchasing

functions, thereby potentially diluting the central co-ordination, monitoring and evaluation of the Programme.

174. It is the first of these two effects that is most relevant to TOR 2. In particular given that unacceptable under-reporting was already occurring could it be said that the new system of purchasing Dr Bottrill's services enabled that under-reporting to continue longer than it should have?
175. In this regard the focus comes upon the Midland RHA's performance having regard to its statutory responsibilities during the period 1 July 1993 (when the Midland RHA was formed) until 4 March 1996 (when Dr Bottrill retired) – a period of 2 years and 8 months.
176. It can be seen from the long title to the HDSA that one of the purposes of the Act was to “*Achieve appropriate standards of health services and disability services*” (emphasis added). The statute provided the mechanism for a second tier of quality control to come over the top of reliance upon the professional qualifications, skill and integrity of health professionals upon which the health system had relied previously.
177. **Section 8** enabled the Crown to state its objectives in relation to the standard of health services and under **section 10** an objective of every RHA in carrying out its functions was to meet the Crown's objectives notified to it under s.8 “*in accordance with, and to the extent enabled by its funding agreement*”.
178. **Section 19** stated that “Every purchaser shall purchase services only from persons who maintain standards (including ethical standards) that the purchaser considers appropriate for those services”.
179. Under **section 21** it was the Minister of Health who, on behalf of the Crown, with advice and assistance from the Ministry of Health or such other persons as the Minister may require, negotiated and entered into funding agreements and **monitored the performance of each funding agreement**.
180. The RHAs in turn, as purchasers, were required to negotiate and enter into purchase agreements with providers and **monitor the performance of each**

purchase agreement. (Section 33 repeated the obligation on RHAs to monitor the performance of purchase agreements).

181. However the transition from a substantially statutory and regulatory funding mechanism to a system of negotiated contracts could not occur over night. Section 51 therefore enabled standard terms and conditions of purchasing to be promulgated so that acceptance of payment by any provider in terms of the notice would make them bound by it.
182. Mr Mules produced the 1993/1994 Crown/Midland RHA Funding Agreement which essentially required Midland to maintain the laboratory services which were available in 1992/1993 (CM/HFA/0003 – extract; CM/HFA/51 – full agreement). This was done by way of s.51 notices between the Midland RHA and the laboratories in its region including Gisborne Laboratories Limited. This is explained by Mr Mules in his evidence in chief at paras.33–49. In particular *“This enabled the status quo to prevail during the transition to purchase agreements allowed by s22 of the Act”* (para.37).
183. Mr Mules specifically refuted the suggestions from Mr Corkill that there was a breach of s19 of the HDSA:

I would not agree with that. I think it’s very important to acknowledge the context of what was going on at this time and the place of s51 agreements. They were intended to roll over business as usual until such time as contracts could be negotiated to replace them. Midland would have had probably 800 to 900 s51 agreements but this was providers practising in a historical environment. We needed to move through a process of negotiation and agreement to move those providers onto contracts with the appropriate levels of accountability in them – it was a process of evolution in what was possible. (A1305, 1-11)

184. Mr Mules explained that the s.51 notices were essentially introduced to enable the current situation to continue. Dr Bottrill was entitled to receive payment under the notice as he was qualified under the Medical Practitioners Act 1968 as a specialist pathologist. Additional assurance was gained from Dr Bottrill being qualified as a Fellow of the RCPA and a member of the Association of Community Laboratories, bound by its ethical guidelines.
185. Mr Mules explained that in order to contain uncontrolled expenditure growth on laboratories Midland endeavoured to move quickly towards negotiating individual laboratory contracts. Midland started this process on 23 July 1993 with a letter to

stakeholders in the Midland region (para.58). At para.59 Mr Mules explained that Midland did not have any specific concerns about the quality of provider services but a general concern that s.51 notices did not provide an appropriate framework for emphasis on quality improvement and monitoring.

186. Unfortunately the process of transitioning from s.51 notices to contracts with individual laboratories was affected at the outset by difficulties with ACL which “...interposed itself between the providers and Midland, which made it difficult to develop a clear picture or understanding of the circumstances of individual laboratories” (para.65) and a protracted period of consultation and negotiation followed (para.67).
187. As a matter of law Midland was required to satisfy the consultation obligation in s.34 of the HDSA as a prerequisite to negotiating contracts with the laboratories. Non-compliance with this requirement would have led to court-restraining orders preventing the implementation of contracts: *Wellington International Airport Limited v. Air New Zealand* [1993] 1 NZLR 671 (CA); *New Zealand Private Hospitals Association & Others v. Northern Regional Health Authority* (unreported judgment of Blanchard J 7/12/94 Auckland Registry CP440/94); *NZ Association of Residential Care Homes v. Northern RHA* (unreported Temm J 18/12/96 Auckland Registry CP522/96); *Napier City Council v. Healthcare Hawkes Bay and Central RHA* (unreported judgment of Ellis J 15/12/94 Napier Registry CP29/94); *Bishop & Others v. Central RHA* (unreported judgment of McGechan J 11/7/97 Palmerston North Registry M47/97), *Medlab Hamilton Limited & Ors v. HFA* (unreported oral judgment of Robertson J 23/7/99, Hamilton Registry, CP 32/99). Non-compliance with the statutory consultation obligation would not however have necessarily led to invalidity of provider contracts as against third parties after they had been executed – see s.49.
188. While the highly contentious rounds of consultation and negotiation between the Midland RHA and ACL were continuing the problems at Good Health Wanganui involving Dr Burkinshaw became public in June 1994. Dr Malpass within the Midland RHA immediately recognised the significance of the Good Health Wanganui situation to quality issues in its own region as explained in paras.86–102 of Mr Mules’ evidence in chief. This included the recognition that Dr Bottrill’s response of 23 August 1994 (CM/HFA/0021) to Midland’s inquiries

about quality practices was unsatisfactory (CM/HFA/0022). Midland may have placed undue reliance upon Dr Bottrill's assurance that his laboratory had applied to TELARC for assessment and registration in histopathology and cytopathology given the evidence of Mr Walker that in fact, apart from initial steps, little progress was made towards accreditation.

With hindsight, and it has been brought to my attention that Dr Bottrill was also looking at TELARC accreditation in 1993 [note Mr Hodson objection]. With hindsight I put too much weight on his statement that he was applying for TELARC registration. (A1320, 14)

189. Despite the recognised concern about Dr Bottrill's practice Mr Mules indicated that there was no basis for action given the almost complete absence of quality assurance requirements in the s.51 notice. Midland's response however was to escalate its attempts to achieve quality assurance requirements for laboratories generally. In both CHE and community laboratories throughout the Midland Region the RHA specifically intended to include:

189.1 An internal peer review mechanism which randomly checks results, particularly where interpretation is involved;

189.2 An external peer review mechanism (e.g. Royal Australasian College of Pathologists).

This was set out in Mr Mules' letter to laboratories and hospitals of 25 October 1994 (CM/HFA/0024).

190. Significantly Dr Bottrill did not respond to this letter as he explained because he did not want to impose draconian quality control requirements on others when he planned to retire (B/3069, B/3070). Nevertheless the steps by Midland to negotiate individual laboratory contracts requiring TELARC accreditation and specific quality assurance requirements seem to have influenced Dr Bottrill's decision to retire (B/3103; B/3121) This is so even though the difficulties with ACL were not resolved until November 1996 when the terms of individual laboratory contracts were agreed, including the requirement for TELARC accreditation (see Mules paras.74 – 85).

191. These contracts were not executed by laboratories in the Midland region until February and March 1997. By then of course Dr Bottrill had retired and his

practice purchased by Medlab Gisborne Limited which entered into the new contract (CM/HFA/0018).

192. Although it is irrelevant to TOR 2 and under-reporting by Dr Bottrill, the new contracts annexed the 6 November 1996 version of draft National Quality and Service Standards for Medical Testing Laboratories which had been produced by a joint RHA project co-ordinated by Sylvia Sax. The standards did not become contractually binding until March this year (see Tracy Mellor's evidence in chief, paras.28-38). The draft National Quality and Service Standards for Medical Testing Laboratories however did become operative in 1996 because TELARC has informally assessed for accreditation against them since that time: Affidavit of Walker (7 August 2000) para.13.
193. Much of Mr Mules' evidence was not of course focused upon cervical cytology or the NCSP. Midland's principal focus was to contract private laboratories to provide all diagnostic laboratory testing services required under the funding agreements. Of all the tests scheduled in the s.51 notice the cervical cytology test was only one of them. The **general** diagnostic laboratory service requirements under the funding agreements were shown in the relevant funding Agreement extracts produced by Mr Mules as CM/HFA/0003 – CM/HFA/0006. (The entire agreements are CM/HFA/0051 to 0055 (93/94 to 97/98) and a (almost) complete schedule of relevant provisions is DGL/MOH/008.) This focus on the purchasing of the individual components which contributed to the Programme, rather than an integrated service for women, was a concern at the heart of the Ministry review of accountabilities in 1996, led by Ms Glackin: paras.118-121 evidence in chief, and the report itself: JMG/MOH/039, Glackin Vol.8 pp.10, 20-21.
194. Mr Mules also produced a separate set of extracts from the Funding Agreements for the years 1993 – 1997 inclusive relating specifically to the purchasing requirements for cervical screening services. (CM/HFA/0033 – CM/HFA/0036). Significantly the RHAs were only subject to a "reasonable endeavours" obligation to ensure laboratories providing services to the NCSP were TELARC accredited. It fulfilled its obligation under the Funding Agreement in that regard by attempting to secure TELARC accreditation as a contractual term with laboratories. Given negotiations were with ACL rather than individual laboratories, it was difficult for Midland to differentiate between laboratories for one very minor aspect of the

services it was seeking to purchase. This was acknowledged by Dr Lambie in answer to questions from Mr Corkill: B/3897/6-24.

195. A significant issue that emerged was whether there was an ambiguity between the responsibilities of the Ministry and the RHAs respectively in relation to the NCSP. At the time the RHAs were formed the 1991 Ministry NCSP policy was in force, and that was revised in October 1993. Although the 1993 policy document set out the respective responsibilities of both the Ministry of Health and the Regional Health Authorities it emerged from the evidence of Mr Mules that Midland thought the Ministry was responsible for specific cytology standards in laboratories (Mules para.124) whereas Ms Glackin pointed out that the Ministry did not have a direct contractual relationship with the laboratories to fulfil this responsibility (Glackin para.291).
196. Mr Mules in his brief at paras.109–137 gave his perspective of the NCSP from the Midland RHA point of view and outlined Midland’s responsibilities in relation to the NCSP 1991 and 1993 policy documents and the Funding Agreements.
197. Apart from purchasing laboratory services through s.51 notices the Midland RHA purchased the Tairawhiti Regional NCSP services through its contract with the Tairawhiti CHE. Mr Mules produced a series of quality and contractual documents relevant to that relationship: CM/HFA/040. Starting at A1253 Mr Mules explained the documents in that exhibit. They usefully indicated how Midland’s obligations under the funding agreement were implemented through the contract with Tairawhiti Healthcare Limited, the quality assurance requirements in that contract and that there were two performance indicators which Midland had to monitor and report on to the Ministry, namely enrolment of women and colposcopy waiting times. (A1257 – A1258).
198. Mr Mules also noted the NCSP was somewhat unique:

The point is we certainly regarded the National Cervical Screening Programme in a different category than the other services we were purchasing. That’s for two reasons. One, it was very well documented and secondly, the Ministry had a direct operational relationship with the programme managers in the field that was not the case with any other service that we purchased. (A1370, 17-22)

This distinction between the issue of laboratory contracts and the wider screening programme issues is illustrated again by an answer to the Chair about why mandatory laboratory accreditation took so long to be achieved:

I think it depends a lot on through which door one looks at the issue, whether one looks at it through the door of the cervical screening programme or whether one looks at it through the door of laboratory contracts. Your question was about the first of those. In our contracting approach as I've described we were looking at it primarily through the second door, which is our overall relationship with laboratories. So we were trying to move the laboratories per se to TELARC accreditation rather than singling out cervical cytology and just trying to get those departments of each laboratory TELARC registered.

Would it be correct to infer then that the screening programme and quality controls for cytology relating to the screening programme became subsumed in the wider issue of TELARC accreditation for laboratories generally ...

Yes.

And would it also be correct to infer that because the regional health authorities ultimately saw the contract base model as one that would deliver quality of service as a long term goal it was prepared to allow time to go by while it worked to achieving that goal so in the grand scheme of things a 3 year delay before accreditation became mandatory was acceptable delay ...

Yes. (A1386)

199. Then at the end of Mr Mules' evidence under sustained questioning from the Chair it is clearly established that Mr Mules' belief was that paras.4.1.3 and 4.1.4 of the Ministry's 1993 NCSP policy were the responsibility of the Ministry. This culminates with the question:

But you accept under the policy the policy document states it will be the Ministry of Health who carries these matters out ...

Yes.

You thought the Ministry of Health was doing it, therefore the RHA wasn't doing it

Yes. (A1460, 7)

200. On the face of it, certainly during the early stages of the Inquiry this looked as though specific cytology standards and monitoring of the requirement for laboratories to be TELARC accredited had slipped through the cracks. When Dr Lambie gave evidence this whole topic was picked up by the Chair (starting at B3915): Mr Mules' evidence was summarised for Dr Lambie who was asked specifically whether he was aware of these difficulties and whether it illustrated blurred accountabilities but Dr Lambie's response was:

It's hard for me to see looking back and with my experience that there was the ambiguity now explains (sic) in terms of that laboratory issues. There certainly may have been ambiguity other areas. (B3917 – B8918)

201. Dr Lambie, correctly it is submitted, brings the whole discussion back to para.10.4 in the Funding Agreement and says:

The RHAs are to use reasonable endeavours to ensure a number of things happen including TELARC accreditation (B3921)

202. Thus, in the end despite its apparent significance in the evidence, it is submitted this issue did not lead to, cause, or allow the continuation of unacceptable under-reporting by Dr Bottrill. In the case of those laboratories who were voluntarily accredited by TELARC they had been accredited against the 1991 cytology standards developed by CALC and reproduced as a TELARC document since 1991 (GRB/MOH/0022). This was confirmed by Mr Walker: B/544/2-16. Specific cytology standards covering the criteria listed in 4.1.4 of the NCSP 1993 policy document (CM/HFA/0032) could have been more directly implemented through a specific funding agreement obligation upon Midland RHA (rather than the general obligation to purchase services in accordance with the 1991 policy) although such specificity in the Funding Agreement would have been most unusual. Even if this had been done the s.51 notices prevailed during the full 2 years 8 month period between the Midland RHA's formation and Dr Bottrill's retirement. Specific cytology standards introduced through the contractual purchasing procedure would not therefore have had any effect on Dr Bottrill.
203. The Ministry recognised the difficulties for the Programme of an interpolated purchaser and sought to address them in the Accountabilities review (JMG/MOH/039). Unfortunately, the attempt to "close the gaps" was delayed by the Minister. Nevertheless, the Ministry was ultimately successful in moving the programme in to the one HFA in early 1998, which set it on its current path.
204. In summary therefore it is submitted the purchasing mechanism introduced by the HDSA and the greater emphasis placed upon quality assurance did have an impact on curtailing the period during which Dr Bottrill was under-reporting. That period could have been shorter but for the difficulties encountered by the Midland RHA in transitioning from s.51 notices to standard laboratory contracts requiring TELARC accreditation. As Mr Mules said:

One can only speculate about what process the Department of Health would have taken to get mandatory TELARC accreditation in place in laboratories if it carried on under the Social Security Act. Presumably some sort of regulation would be introduced to give effect to that. (A1442, 10)

Implementation of the NCSP

Introduction

205. A key theme that appeared to dominate during the hearings was the implication that, had the Programme been implemented in a different manner, perhaps more closely according to expert advice, that may have led to systems being in place which would have alerted relevant authorities to the under-reporting by Dr Bottrill at an earlier time. A close analysis of the advice of the various expert groups does not support this conclusion and it is not accepted. The realities of the time must be considered: political, social, financial and even technological. What was reasonably possible must be considered, not what might have been ideal. It is submitted that the Inquiry should be careful not to fall into the trap which caught experts, politicians, officials and observers alike in the early days; that of under-estimating the complexity of the implementation of the Programme. By comparison, the breast screening programme, for which planning and pilot programmes commenced at the same time as the NCSP, was not implemented until 1998. To quote Dr Muir Gray when comparing, in the UK context, the gradual evolution of cervical screening to the “clean slate” creation of breast screening:

Breast cancer screening was like knitting a new cardigan ... but with cervical screening it was a bit like winding up all the balls of wool again, writing a pattern and knitting it while carrying on wearing it at the same time.

Gray M, *Milestones over 10 years* In: CSPR 1998 Sheffield: NHSCSP Publications; 1998, and quoted in Husain & Butler, Cytopathology in the UK: 1854 to the Present, Diagnostic Cytopathology, Vol.22 No.3, 204 at 205

The analogy is apposite. Criticism has sometimes been strongest from those furthest from the needles.

206. It will be submitted that, even if the implementation of the Programme was deferred for the shortest possible time, and resourced sufficiently, to ensure that the following key planks of the programme were in place it is still unlikely that Dr Bottrill’s under-reporting would have been observed until the Register had been

operational for a number of years. Those matters which appear to be of primary importance, with the date they occurred in brackets, are:

- 206.1 The passage of necessary legislation enabling cytology and histology to be forwarded to the Register (1 July 1993);
 - 206.2 The development and implementation of laboratory systems to ensure the consistent reporting of both cytology and histology results to the Register (cytology 1990, histology 1993);
 - 206.3 The passage of necessary legislation authorising “opt-off” enrolment (1 July 1993);
 - 206.4 The establishment of a single database nationwide register (February 1997);
 - 206.5 The requirement for, and compliance of sufficient laboratories with, TELARC accreditation as a condition of payment for laboratory services to the NCSP (1996);
 - 206.6 The establishment of appropriate standards for accreditation in cytology (1990, 1995, 2000);
 - 206.7 The recruitment and training of appropriate programme staff to enforce the legislation, monitor the performance of laboratories and monitor and evaluate the data from the Register (ongoing).
207. And it must be remembered that the concerns focus on only one step in the screening pathway; officials had to implement, monitor and evaluate the success of them all.

Early steps towards a national programme

208. This section comments on the context of the beginning of the National Screening Programme in New Zealand. The key points are:
- 208.1 A national cervical screening programme was planned prior to the Cartwright Inquiry.

- 208.2 The Cartwright Inquiry brought the issue of cervical cancer and the benefits of screening into the public spotlight.
- 208.3 The result was both a significant increase in opportunistic screening and significant political pressure for a national programme to be implemented within unrealistic timeframes.
209. Dr Boyd describes the early development of cervical screening in paras.29 to 51 of his evidence in chief. He was responsible for cervical screening during the 1980s as the Deputy Director, and then Director, of the Clinical Services Division of the Department of Health until 1987 and from 1987 to April 1989 as manager of the Primary Health Care Programme. There is no suggestion that he was not personally committed to the planned national programme. From April 1989 responsibility passed to the special separate National Cervical Screening Programme Unit established within the Department in 1989.
210. Payment for the cytological examination of cervical smears by the government was being made in 1971: GRB/MOH/0005. In 1977 the Department published the first set of guidelines for the frequency of taking smears: GRB/MOH/0006. These were updated in 1985 (“The Skegg Guidelines”) and published in the Medical Journal: GRB/MOH/0007. They focused mainly on improving the coverage of screening and describing the screening intervals.
211. A meeting was called by the Department of Health and the Cancer Society in April 1986 to take a wider view of screening issues. The record of its proceedings is GRB/MOH/008. It is of interest in considering how the Programme might have been developed but for the impetus or pressure of the Cartwright Inquiry. Participants, noted in Boyd Vol.2 p.22, included Ms Betsy Marshall, Mr Jim Fraser and Professor David Skegg. The meeting looked at how to:
- 211.1 set up an effective national programme;
 - 211.2 improve facilities for screening;
 - 211.3 improve the quality control of smears;
 - 211.4 improve facilities for diagnosis and treatment; and

- 211.5 evaluate and monitor such a programme.
212. The meeting expressed the aim of designing a national screening programme “within three to four years”. It recommended evaluation of existing pilot studies, exploration of cultural differences and attitudes to screening, expansion of colposcopy services and better promotion of screening. In a specific reference to quality control in laboratories, it recommended attracting more people to become competent smear readers with better remuneration, career structures and training. It also recommended that each laboratory should develop its own quality control by examining each abnormal smear at least twice by two different people of differing seniority and by establishing close links with treatment groups so that biopsies obtained at colposcopy may be reviewed by the same laboratory group that examined the original smear. Pilot studies continued in the Waikato and Otago by the Cancer Society and in Nelson, Kawerau, Wanganui and Oamaru by the Department of Health.
213. Subsequently, the Cartwright Inquiry began in June 1987 and the resulting report was published in August 1988. It recommended, among many other things, the urgent establishment of a nationally planned, population based, cervical screening programme. The Inquiry report acknowledged concern among women’s health groups that, with the implementation of the Area Health Board scheme (restructuring with the focus on regionalised delivery of services), the Health Department might leave the responsibility for screening to the regions. Judge Cartwright (as she was) favoured a centralised programme based on regional organisation, which allowed for the development of programmes appropriate to the region, while at the same time being co-ordinated at national level (Cartwright Report pp.207-208). The benefits of regional organisation were also acknowledged by Dr Judith Straton in her 1990 report (Glackin Vol.1 p.269-270). In accordance with those recommendations, the Programme as implemented was a nationally co-ordinated programme implemented regionally.
214. The fact that there were 14 separate registers appears to be related to the requirements of regional organisation as well as an inability to practically and cost effectively create one single data base. On the latter point, see Matcham para.40 evidence in chief:

I believe that, in 1990, the technology platform for the Register could rightly have been seen as state of the art. A similar Ingres database on PCs was being installed in Probation Offices within the Justice Department where I was working at the time. However, by today's standards the IT environment in 1990 was primitive. It would have been technically possible to have networked the regional computer databases to a central site in 1990, but at significant cost. A much larger central computer would have been necessary. Telecommunication lines 10 years ago were many times more expensive than they are today. I expect that the increased risk of exposure of the Register to computer failure as a result of a centralised computer may have been another consideration.

215. There was no evidence to conclude whether the decision to have 14 separate registers was a Departmental or Ministerial one. But it was a given by 1988: B4130/5-4131/6. The use of the National Master Patient Index register was plainly in the mind of the architects: Ministerial Review – Glackin Vol.1 p.11; Straton Report – Glackin Vol.1 p.213; Expert Group – Glackin Vol.2 p.4.
216. Immediately after Judge Cartwright made her recommendations, the Minister of Health, the Hon David Caygill, stated the government's commitment to having a nationally co-ordinated, population based screen programme operational by mid 1989. A meeting in September 1988 between the Minister and Director-General of Health and the Chairs of Hospital Boards and Area Health Boards, discussed the implications of the Cartwright Report (GRB/MOH/0011). They agreed that a national programme would not be beyond their resources if good use could be made of community facilities, training provided, and colposcopy services made more efficient. Even at this early stage, the emphasis on screening coverage, (which was given very significant emphasis by all the various advisors to the Programme), is observable. The Department prepared a paper for the meeting entitled "Towards a more effective cervical screening service for women in New Zealand" (GRB/MOH/0010), covering key issues. That report noted (Boyd Vol.2 p.139) that:

A recent report from the World Health Organisation states: "The extent to which screening programme have succeeded or failed to decrease mortality from invasive cervical cancer is largely reflected in the extent of coverage of the population at risk by screening".

217. Under the heading "Maintenance of High Quality" and sub-heading "(c) Laboratory Services", the issues relating to laboratories were accurately identified. These included the fact that external quality assurance procedures were very limited in New Zealand. It was noted that there was no requirement for TELARC

registration. The New Zealand Society for Cytology and the New Zealand Society for Colposcopy and Cervical Pathology had received recommendations concerned with the standards required of cyto-pathology services, but it was not known how widely those recommendations had been adopted (this is a reference to the “Fitzgerald Committee” recommendations: GRB/MOH/0019). The report noted that as a result of recent publicity (a reference to the Cartwright Inquiry), laboratory cytological services had been stretched in some areas. Practical training was considered an urgent issue and it was noted the Minister of Health had approved the allocation of \$238,000 over three years from the Work Force Development Fund to enable the establishment of a 12 week block course in cervical cytology for laboratory assistants (up to 20 participants per year). The report also noted that a review of laboratory services was required. It would need to include the development of quality control measures to ensure that cytological services in laboratories maintained a consistently high standard [Boyd Vol.2 pp.143 – 144].

218. It is submitted that this paper illustrates that the Department was well aware of the issues surrounding quality relating to a national programme, including the key issues surrounding quality in laboratories. This was a year before the Ministerial Review Report, and two years before the Straton Report or the Expert Group report which, it is submitted, might be considered to be less well-focused on the key issues for laboratories. None of these latter reports referred to the Fitzgerald Committee standards, for example, despite them being well-known to expert members such as Dr Teague.
219. The Department also commissioned Azimuth Consultants, an information technology company, who were engaged on the pilot screening programmes, to define the requirements of a nationally co-ordinated cervical screening programme in New Zealand. The report which contained considerable material provided by the Department, was provided in November 1988 (Proposal for a Nationally Co-ordinated New Zealand Cervical Screening Programme, Vol.1: GRB/MOH/0012). It is a comprehensive report which recommended that it be given wide circulation and discussion, including to all those who were to participate in the planned workshop at Porirua in December 1988. The appendices to the report, which are not in evidence, contained a “summary of useful statistics” relating to quality in

laboratories. These included sensitivity percentages, positive predictive values for CIN3 and invasive cancer, repeatability of a negative cytology result, a recommended minimum number of cervical smears that a laboratory should process in a year (15,000); staffing rates and levels of screening by a laboratory officer. Given the interest of the Inquiry in such benchmarks, the relevant appendix to this 1988 report is attached as **Appendix A** to this submission. Again, it is submitted the Department can be seen to be heading in the right direction at this early stage on laboratory quality and monitoring issues.

220. The Azimuth Report and other documents were referred to participants in a large workshop (approximately 100 people) held in Porirua from 6 to 8 December 1988. The Minister, the Hon David Caygill opened the workshop, indicating that the role of participants was to:

- **recommend how we should structure a national programme;**
- **identify resource needs;**
- **determine what the training needs are, and are likely to be.**

What we need to know, in essence is: what do we need to do to get a national screening programme up and running as soon as possible? (GRB/MOH/0013; at Boyd Vol.3 p.60)

221. The workshop was not particularly successful; there was little consensus: Boyd A684/16-19. There were six recommendations made to the Minister of Health. They are recorded in the Workshop draft report (Boyd Vol.3 p.86) and repeated in the notes of a subsequent meeting on 15 September 1988 (GRB/MOH/0014) when officials referred them to the Minister. The Workshop in essence recommended that the control and funding of, and accountability for, the Programme be through an executive group. It also recommended appointment of two National Coordinators, one being Maori.

222. All relevant decisions at the Workshop recommendations were taken by the Minister at a meeting with officials on 15 December 1988. Brief notes recording the decisions appear at Boyd Vol.3 pp.113-114. Funding options were discussed and viable options identified included:

222.1 a net addition to Vote: Health as part of next year's new policy (a delay of three to four months and particularly difficult);

222.2 “off the top” grants to Area Health Boards; or

222.3 Area Health Board priority funding as reflected in the Board’s contracts with the Minister of Health.

Further work was to be done on these options.

223. As to other recommendations, the Minister did not support the concept of a “free” service at point of contact. Reasons were noted. He asked that any further announcement concerning the outcomes of the Workshop and the proposed implementation of the screening programme await the decision regarding the method of funding (not, as it turned out, made until April 1989). Officials were consequently inhibited from further discussion on implementation with interested parties. This may have contributed to the acknowledged perception of “nothing happening”, and/or to the concern about lack of communication (see Ministerial Review Committee Report).

224. Decisions on the other recommendations were:

224.1 A national co-ordinator position should proceed (as had already been advertised) with appointment on merit. While the notes of the meeting are not explicit, it is nevertheless clear that the Minister did not support a separate Maori co-ordinator.

224.2 A steering group would be set up with advisory, not executive, functions. It would have a time limited role with advisory and monitoring functions. Membership would be the responsibility of the Minister of Health with advice from the Minister of Women’s Affairs.

224.3 Reference was made to exploring the use of the Electoral Roll as a base line source of information for the register, and to the concerns about existing service provision, particularly waiting lists for colposcopy.

225. Funding decisions were not made by April 1989 when the National Cervical Screening Implementation Unit was set up outside the primary health care programme, for which Dr Boyd was responsible. The then Hon Helen Clark became the Minister of Health on 30 January 1989 (date of warrant). In his Budget speech in July 1989 the Hon David Caygill, then Minister of Finance,

announced the government was making available \$14m in 1989 and \$12m in subsequent years to implement the National Programme. His original expressed intention of having a programme operational by mid 1989 did not, however, come to pass and the money allocated was not all spent in the 1989 financial year.

The Ministerial Review Committee: September-November 1989

226. The Hon Helen Clark appointed a Ministerial Review Committee in September 1989 in response to widespread concerns that progress was unsatisfactory. The Minister's concerns are spelt out in her memorandum to the Director-General of 25 August 1989: JMG/MOH/099:

In my view the current state of misinformation and concern among those groups who have an interest in the success of this programme clearly shows that the Department has not been successful in developing a programme which has the support of the community and can feasibly be put into operation by the end of the year.

There is widespread concern that there has been too much emphasis placed on the development of the national register and the computing system necessary to operate a register and recall system, at the expense of action on developing smear taking programmes. I share this concern.

My objective is to use the money made available by Government to raise the awareness of the necessity for smears among those women not currently being screened, and to encourage all women to have regular smears. The importance of the register and ensuring all women are enrolled should probably be secondary to that.

In requiring that a review team be established, therefore, I am expecting them to look at the progress to date, and make recommendations concerning the appropriate course of action and the appropriate allocation of the available funds. It should not be assumed that the funding split between computing, administration costs and smear benefits is in any sense fixed. I believe it is likely that we should be spending more of the money on paying for smears and ensuring that those groups not currently being smeared are provided with easy access to smear takers. (emphasis added)

227. The Ministerial Review Committee met three times. Membership is noted in para.15 of Ms Glackin's evidence in chief. It included Ms Sandra Coney, Dr Brian Cox, Ms Betsy Marshall and Dr Clint Teague. It reported to the Minister in November 1989. Its report is JMG/MOH/0001.
228. The key points to make in relation to this report are as follows:
- 228.1 The main "problem" found to exist with the development of the Programme to date was not a lack of action by the Department but poor communication.

- 228.2 The Review Committee's expressed function and intention was to give general direction to the Programme rather than detailed recommendations, yet it made 107 specific recommendations, many at a very detailed level. This underlines the complexity of the task.
- 228.3 A significant emphasis of this Report, as with others, was on gaining acceptability for the Programme among women and therefore increase coverage.
- 228.4 The Review Committee understood the limits of the proposed cytology register then under development, and recommended a comprehensive population-based Register and urgent attention to extending the cytology register to include histology. Nevertheless, it did not want to delay the Programme establishment to deal with these issues. It also expressed concern at the (relatively high) level of resource going to Register matters and recommended it be capped at 15% of the budget.
- 228.5 The Report debated the merits of opt-on and opt-off and on balance recommended an opt-off basis for the Programme, but did not appear to consider the need for legislation to achieve this.
229. It noted that many of the "perceived problems" had arisen from poor communication. As Ms Glackin notes (para.19) all of the Committee's key recommendations were implemented, although some not as rapidly as many would have liked. The Committee reported that it was unable, in the time available, to provide detailed recommendations and its function was to provide general recommendations on the direction of the Programme. Nevertheless, it expressed 13 "major conclusions" (Glackin Vol.1 pp.6-8), made 53 recommendations on a very wide range of issues and a further 54 specific Register-related recommendations in Appendix III.
230. The overview (Glackin Vol.1 pp.5-8) demonstrates the divergence of opinions on various matters. For example, a major area of concern related to the relative weight being given to the register, versus the development of smear taking programmes, and the possible resource cost of such a split. The Report noted that, for the Programme to succeed, women in general must understand "*the need for*

the programme and be comfortable with the objectives and means of achieving them. Considerably more emphasis therefore should be put on community involvement.” These comments underline the context of a programme which began with considerable emphasis on “front end” issues such as education, community involvement and enrolment. The evidence of Tairawhiti’s second Regional Co-ordinator, Sharon Reid, demonstrates this was her focus, and is testimony to the success of her approach to this end.

231. The Review Committee acknowledged that the potential of the screening programme was hindered by the lack of a comprehensive population health register. The issues surrounding such a register were controversial and difficult. The Review Committee, nevertheless, saw the development in the short term of a cytology register for the Programme as *“an expedient in order to allow the programme to proceed within a reasonable timeframe”* (Glackin Vol.1 p.7).
232. It decided that the cervical screening programme should not be put on hold while a population register was constructed, providing work on a strategy for the link to a population based register proceeded (para.2.4, Glackin Vol.1 p.8). This was part of Azimuth’s continuing work. See also para.2.15: the first priority should be to establish a cytology register. An overview of the Cervical Screening register proposal to date was Appendix 2 to the Ministerial Review Report (Vol.1 p.77). Information from laboratories is discussed on p.82. It is noted that all private diagnostic laboratories (18) are either currently computerised or should be within the next 18 months so that data will be supplied in electronic form. At II.20 it is noted:

At this stage it is only intended to collect cervical smear results from three public hospital laboratories as the other laboratories are considered to be processing too few smears to be able to maintain a satisfactory smear reading standard.

233. Significantly, at II.21 it is noted:

The only [register-generated] report currently proposed for monitoring laboratory performance is one which summarises work throughput in a laboratory and provides an estimate of the average time taken to process a smear.

234. At p.85 in II.31 it is noted that:

At this stage ... no provision has been made for the Department to collect data from the 14 Area Health Boards and analyse it, which in effect means that by installing comparable hardware and software in each Area Health Board the potential exists to develop a national cervical screening register, but the steps required to link the 14 systems still need to be mapped out.

235. Interfaces with other registers are discussed in II.37 on Vol.1 p.88. Register reservations and recommendations of the Review Committee are contained in Appendix III commencing on Vol.1 p.90. It noted the significant and widespread concern about the cost of implementing and running a computerised cervical screening register. Concerns were expressed to ensure that the linkages between registers were sufficiently thought through to be achievable in the future (Para.III.43) and recommendations were made that immediate attention be given to those matters. In summary, there was no suggestion that the Programme not proceed until a comprehensive population health register was implemented. The difficulties in monitoring the Programme at a national level without such a register were acknowledged but did not deter the committee from wanting to proceed with the Programme without delay.
236. At para.2.21 of the Report (Vol.1 p.13) two further reservations were expressed, including whether it would be possible to link cytology results with cervical histology results. At para.2.24:

As was the case with the development of a population register, committee members were concerned that requiring histology results to be incorporated onto the cytology register from the outset would delay the implementation of the overall cervical screening programme. (Vol.1 p.14)

237. At Vol.1 p.59 (para.8.10) the Committee notes that pathology laboratories have already gone a considerable way down the track of establishing quality control checks on the reading of cervical smears. Quality control processes are noted, including a 10% review and that some laboratories also have a sample of their smears re-read by another laboratory:

Laboratories should be commended on their current efforts to establish and maintain consistency in the reporting of cervical smear results. If consistency in reporting at a national level is to be achieved, however, these systems should be developed further and arrangements such as the analysis of a subset of smears by another laboratory on a regular basis considered. (para.8.12)

238. Appendix IV sets out suggested performance indicators across the range of screening services. These suggested indicators appear in Glackin Vol.1 pp.126 to 127. As a first step, a set of minimum standards of competency for laboratories and cytologists should be developed and “when this has been done”, a set of performance indicators that relate closely to those guidelines would need to be compiled. In advance of these, the Review Committee suggested “the following sorts of indicators” for monitoring the performance of laboratories.
- 238.1 numbers of smears analysed;
 - 238.2 average turn around times;
 - 238.3 notification of smear results;
 - 238.4 percentage of false negative CIN3 found histologically;
 - 238.5 percentage of true positives found at biopsy;
 - 238.6 specificity of the screening procedure; and
 - 238.7 sensitivity of the screening procedure.
239. The last four indicators all require correlation between histology and cytology and the ability to analyse a significant number of results. They were not achievable by the Register in the short term. That is not acknowledged in the Report.
240. At para.8.14 (Vol.1 p.59) there is a further reference again to investigating the mechanisms which facilitate the linking of cytology and histology results. It was noted there was currently no single classification or coding system for recording histological results in New Zealand (or in any other country). The significance of this obstacle should not be understated.
241. Para.8.15 again recorded that the Review Committee did not recommend that the introduction of the Cervical Screening Programme be held up while issues surrounding the collection of histological information are resolved. It recommended work begin in the near future. It did.
242. The recommendation to consider “extending the cytology register to include histology information” needs to be seen in context. As at late 1989 there was no

“cytology register”. The Programme was still about 14 months from having 14 registers operating in the 14 Area Health Board regions. As Ms Glackin says:

There was much to be done and the early priorities were to encourage and facilitate women to have smears, to ensure smear takers took smears correctly and at appropriate intervals, to encourage smear takers to promote the NCSP, and to report the necessary information to the laboratories. It was then necessary for laboratories to have sufficient staff to competently process the smear slides. Laboratories had to then report information in a consistent form to the Register. (para.19, evidence in chief)

243. The histology project alone was complex. Providing feedback to the laboratories on the quality of their smears was a first step for the Register. The addition of histology to the Register raised not only technical issues. It required legislation, consistent coding and reporting systems by laboratories and computer software for the transference of results from laboratories to the register. All of these further measures involve changes to existing laboratory practice and added cost for laboratories. It was not feasible to expect that they would occur within a brief timeframe.
244. It is perhaps ironic that, given the emphasis now placed on the Committee’s recommendations regarding the addition of histology and the importance to the Programme, and monitoring in particular of a comprehensive population health register and future “linkages” between registers, the Review Committee also recommended capping Register expenditure to 15% of the budget and not delaying implementation while these issues were resolved. It must be emphasised that this budget did not include the payments to smear takers or pathologists who continued to be remunerated by way of health benefits under the Social Security Act 1964.
245. The Expert Group recommended by the Ministerial Review Committee was established almost immediately and met for the first time on 8 December 1989. Meanwhile, the Department had advertised again for a National Co-ordinator, attempting to attract interest from senior health service managers by appointment at a high grading as required by the Minister: JMG/MOH/0002: Vol.1 p.132. The Department was unable to recruit anyone to the position prior to 5 June 1990 when the first national co-ordinator, Gillian Grew, took up her position.

The Straton Report: July 1990

246. At the request of the Expert Group, the Department commissioned a review of the Programme to date by Dr Judith Straton who reported in July 1990. The report is discussed by Ms Glackin in paras.30 to 33 of her evidence.
247. The key points relating to Dr Straton's report are:
- 247.1 It noted the lack of a usable and acceptable population register, histology data to correlate with cytology, and epidemiological information for monitoring. It recommended urgent attention to the issues through working groups. At the same time it noted the Register was still at an early stage of development, and it supported a focus on the front end of the Programme, with less emphasis on the Register.
 - 247.2 The approach by the Department to allowing (albeit limited) flexibility by different Boards in implementing the Programme was in accordance with her advice.
 - 247.3 The approach of the Department and Area Health Boards to a focus on evaluation of components of the Programme was in accordance with her advice.
 - 247.4 The Report places the tensions between the Department and Expert Group in context.
 - 247.5 The Report provides the genesis of the 1991 policy on laboratories including the "4.1.4 criteria for TELARC accreditation" (discussed separately).
248. It is submitted that the conclusions and recommendations by Dr Straton were extremely relevant and helpful. Her report provides a useful perspective of the high expectations and pressures on the Department at the time, the considerable progress that had been made and the under-estimation by all involved of the complexity of the task. Her key recommendation was to move the focus away from progress with the Register and to take a more broader view, by measuring progress in a number of areas such as cooperation with provider organisations, public and professional education, training of nurse smear-takers and ad hoc

surveys of the number of women screened in particular groups (p.276). Her recommendations are summarised at the end of her report. There are 41.

249. The register is discussed at Vol.1 p.213 by Dr Straton. She notes the pilot site had been linked to the NMPI as a population register, but that there is not a usable and acceptable population register. In its absence, a cervical screening (cytology) register has an important role to play. On p.229 she notes that the lack of histology data means the correlation of cytology and histology results (using the Register) will not be possible. Problems with achieving a common coding system for histology were discussed. Unsurprisingly, there is no suggestion that regulation would achieve consistent reporting. This was not a matter where compulsion was likely to achieve performance by laboratories. She recommends (p.230) that a working party be established, including representatives of CALC, to develop mechanisms for incorporating histology data into the Register, including an examination of the legislative requirements. She then notes that epidemiological information for monitoring “does not seem to be routinely available”. She notes that there is no provision in the specifications of the Register for generation of tables such as the number of smears by age group, the types of results by age group, *“and these questions are apparently not being considered at present. This situation seems to have arisen partly because the need for these reports has not been considered, and partly because of failure to obtain agreement about what information was needed”*. She suggests the monitoring function of the Register needs urgent attention and recommends the establishment of a small working party to define the data required for monitoring and then work with Azimuth systems to ensure that it is readily available. Difficulties in keeping the Register up-to-date, particularly where people die or move, were acknowledged: p.231.
250. At p.233 she notes the concerns being expressed about the desirability of having identical hardware and software for the Register in each Area Health Board. It is noted that a national system was found to be very cumbersome in England and Wales and was abandoned in favour of local systems based on Area Health Authorities. She notes on the other hand that all Boards will need to have a common approach to interfacing with the NMPI, and the fact that some laboratories service a number of different Boards, lends in favour of a single

system. She did note that there are arguments for giving Boards some flexibility in the arrangements, however, for example in the management of recalls and the sending of results. While a basic text for the various letters might be suggested, Boards should be given the flexibility to adjust them according to local needs. This is, in fact, what occurred and, as Ms Matcham points out, created some significant difficulties in the course of the reconfiguration of the Register into a central database: Matcham evidence in chief paras.82-85.

251. At p.235 Dr Straton expresses the view that *“over-emphasis on the Register has meant that the inevitable delays in establishment of something as complex as the Register have led to criticism that ‘nothing is happening’. The political impetus to demonstrate that something is indeed happening has led to the setting of unrealistic deadlines. There seems to have been under-estimation of the complexity of the task of establishing an operational and effective Register in one Area Health Board, let alone the whole country ...”*. *“It must be recognised that, while progress has been made, the Register is still at an early stage of development”*. She predicted that it would take two to three years for full operation in all regions (i.e. 1992-1993).
252. Laboratory services are the subject of Section V of Dr Straton’s report. Her recommendations are discussed later in this submission under the heading *“Laboratory Services to the NCSP – Policy Development”*.
253. In the course of the Inquiry there has been some reference to difficulties between the Expert Group (in place December 1989 to August 1990) and the Department (which Gill Grew and Betsy Marshall both indicated were pretty much ironed out once Gillian Grew’s appointment as National Co-ordinator was made). There is a reference to ill feeling in relation to the creation of health education and publicity materials in Dr Straton’s report (pp.238-239). The Expert Group had appeared to *“veto”* particular health education materials prepared by the Department. Dr Straton noted it was appropriate for the Expert Group to monitor health education materials *“but it is not their role to design them”*.
254. Dr Straton’s analysis of the problems with the organisational structure and decision-making processes in relation to the overall management of the screening programme (her Chapter VII) is interesting. She notes at Vol.1 p.264 the widely

held perception that the cervical screening programme is being developed in an atmosphere of secrecy, and that is something that the Health Department is doing “on its own”. There is a perception that the Programme is a centrally-driven initiative. She identified the original decision not to establish the Expert Group as recommended by Judge Cartwright as contributing to this perception. It will be recalled that the Minister had decided in December 1988 that an Expert Group with advisory functions would be established and that the Minister would be responsible for the appointments. The Expert Group was not in fact appointed until 1 December 1989.

255. Dr Straton goes on to comment that the atmosphere of secrecy has been “*perpetuated to some extent by the present Expert Group ... The style of operation of the Expert Group so far seems to have precluded this interactive approach [recommended by the Ministerial Review Committee] and exacerbated the suspicion of the Programme*”. Part of the problem was that everything stopped for the Ministerial review (p.265) and that, with the establishment of the Expert Group, “*there seemed to have been no mechanism for carrying on the work of a cervical screening unit ... There seems to be a perception that the implementation of the recommendations of the Ministerial Review Committee is entirely the responsibility of the Expert Group and has little to do with the Health Department. Since the Expert Group has taken some time to come to grips with its role, very little appears to have happened since September 1989, a period of nine months*”.
256. At p.267 Dr Straton noted that the problems which seem to have arisen with respect to the function of the Expert Group included a “*lack of clear definition of the role of the Expert Group vis a vis the Health Department, communication difficulties with the Department, and difficulty in coming to grips with policy formulation and decision-making*”. Dr Straton noted that the terms of reference for the Group were clearly spelled out and that there needed to be a maximum of support and back-up from the screening unit in the Department. This does not appear to have been the case with the strong feeling both in the Expert Group and in the Department that the Expert Group must work on its own independently of the Department. She noted that it was not certain that the Expert Group was clear about its role as an advisory group or whether some members, at least, believed that the Group had executive powers. Dr Straton was of the view that the role

should be advisory and that the advisory nature of the role should be clearly spelled out to all concerned. An example of the difficulties indicated by Dr Straton at p.269 was the fact that draft policy and guidelines for Area Health Boards were prepared by the Department and first presented to the Ministerial Review Committee in October 1989 *“and yet this document does not appear to have been used as a basis for the Expert Group to work on”*.

257. Attention is drawn to these points because of what appeared to be an emphasis in the Inquiry that delays and miscommunications were largely, if not wholly, the fault of the Department of Health. It is submitted that would be an unfair oversimplification of a complex set of circumstances. The Report also supports the submission that the Department’s planned Programme was, to a degree, disrupted by, rather than assisted by, the Expert Group. The problem of low morale and a “loss of institutional memory” within the Health Department is noted even in June 1990 by Dr Straton at p.265. It is not a phenomenon confined to the mid-1990s. The Department’s concerns with the Expert Group are expressed in a memorandum to the new Minister on 28 January 1991: JMG/MOH/105 (which replaces JMG/MOH/008).
258. Interestingly too, Dr Straton reflected the thinking of the time in her recommendation that the Programme be regionally, rather than centrally, controlled and implemented:

in line with the devolution of responsibilities for the health of regions from the Health Department to the Area Health Boards, the responsibility for implementing organised cervical screening should lie with the Area Health Boards. It does not make sense to have cervical screening as the one aspect of health care which is centrally controlled and administered. (pp.269-270)

259. Evaluation, monitoring and research were dealt with in section 8 of the Report commencing on p.271. Dr Straton noted that a major deficiency so far had been a failure to incorporate any formal evaluation into any of the pilot projects, now being planned but at a rather late stage. She noted that there was a need for evaluation studies which are formative in nature and aimed at improving the various aspects of a national programme. The range of issues to be considered in evaluation of the different components can be found in the report of the Working Party on the development of national cervical cancer screening strategy prepared

for the Australian Health Minister's Advisory Council in November 1987. The areas of evaluation referred to in this section of her report describe the types of evaluation of aspects of the delivery of services and recruitment of women which was the focus of the early evaluations of the National Cervical Screening Programme at the national and regional levels. The key point here is that, as Dr Peters said this sort of evaluation was appropriate for the Programme in its early stages.

Expert Group: December 1989 to January 1991

260. As noted earlier, the Expert Group appointed by the Minister met for the first time in December 1989. Membership included Ms Coney, Ms Marshall and Dr Teague (see Glackin brief of evidence Appendix, for membership).
261. The key points relating to the Expert Group's work are:
- 261.1 Its summary recommendations (May 1990) were largely implemented;
 - 261.2 It drew heavily on Dr Straton's work;
 - 261.3 Its "policy statement" became the basis of successive Programme policies until the major revision completed in 1996;
 - 261.4 It focused on strategies aimed at the "front-end" of the Programme;
 - 261.5 It did not want to delay the Programme's commencement to enable further trialing.
262. On 30 May 1990 the Expert Group gave a summary report to the Minister, found in the first few pages of JMG/MOH/0005: Glackin Vol.2 pp.1-6. It is fair to say that most of the 10 recommendations were followed. The appointment of seven Maori and four Pacific Island Regional Coordinators was not accepted by the Minister (see her memorandum to the Director-General of 18 October 1990: JMG/MOH/006 at Glackin Vol.2 p.81). The recommendation that a national population-based programme be developed from three linked registers (cytology, population register and histology register) with an initial focus on the centrally organised cytology register was not implemented in that way. As the Inquiry has heard, the national population register (the NHI, previously the NMPI) has taken a

long time to develop into the comprehensive tool it is today. Instead of proceeding with the link to the National Cancer Registry with its broader cancer focus and limited registrations, histology has been incorporated into the cervical screening register.

263. Again, it is difficult to see why there has been such a pervasive air of criticism at the Inquiry relating to the departmental response to the Expert Group's recommendations. The fact that legislation to support the Register, require histology reporting and allow an opt-off system was in place three years later is, it is submitted, a significant achievement. A very significant measure of education and support was required at both the community and professional level to both ensure sufficient political support for the legislation and for those measures to be acceptable to women and health care providers. Significant privacy issues arose.
264. The "policy statement" by (or advice of) the Expert Group dated August 1990 is at Glackin Vol.2 pp.7-80. It became the basis for the Programme's policy, as first stated by the Minister in October 1990 (JMG/MOH/006: Vol.2 pp.83-94), then by the Associate Minister of the new Government in February 1991 (JMG/MOH/008 Vol.2 pp.132-133) and in more detail in August 1991 (JMG/MOH/015: Vol.5 p.10).
265. The Expert Group's policy statement picks up many of the recommendations of the Straton report. Note that in her foreword, the chairperson notes that the Expert Group's task has been made difficult by the non-existence of a written policy on the NCSP. It does not acknowledge the draft policy and guidelines for Area Health Boards prepared by the Department and provided to the Ministerial Review Committee in October 1989. This was referred to by Dr Straton (Glackin Vol.1 p.269) as work which could be built on by the Expert Group, rather than "re-inventing the wheel".
266. In section 3 commencing at Glackin Vol.2 p.22, the Expert Group discusses the special social characteristics, and the characteristics of New Zealand's health care system, that differ from countries overseas with successful programmes. The Expert Group identified nine characteristics which made a screening programme particularly difficult in New Zealand. It is submitted this was a reasonable analysis. In summary the characteristics were:

- 266.1 wide cultural diversity;
 - 266.2 small and highly mobile population spread over a wide area, with significant demographic differences between regions;
 - 266.3 considerable freedom in obtaining health care (no requirement to be registered with a single general practitioner);
 - 266.4 the primary medical care system is a partially-subsidised private one, implying considerable autonomy in the delivery of services by individual practitioners and little direct control by the Department of Health (this includes the delivery of laboratory services);
 - 266.5 the cost to the consumer in gaining access;
 - 266.6 doubt among sections of the medical profession about the efficacy of screening and, as a result, distrust of health care services on the part of some consumers;
 - 266.7 absence of any national health registration system to facilitate “call” of women to be screened;
 - 266.8 the existence of a centralised health administration actively moving towards a decentralised management structure; and
 - 266.9 the poor health status of Maori.
267. The Expert Group noted that because of these characteristics, some elements of the NCSP have been designed specifically to meet New Zealand requirements. These are listed on p.23. A review of these assists an understanding of the emphasis by those charged with implementing the system on front-end communication and strategies for women and smear-takers.
268. The goals and objectives recommended by the Expert Group (pp.27 and 28) were adopted by the Programme in its initial 1991 policy: JMG/MOH/0015 Vol.5 p.12 (screening coverage, incidence and mortality). These were revised as the NCSP developed. The targets in reduction of incidence and mortality rates have been, and continue to be, achieved.

269. Section 6 of the Expert Group's policy statement referred to strategies for an effective screening service. Again the emphasis was very much on the front end with implementation strategies focusing on greater use of existing primary health care services. Note, for example, on p.35 under para.6.2.2 (fifth bullet point) liaison with professional associations to ensure that providers have access to continuing education was recommended, but no reference to pathologists, the NZ Society for Cytology or the Royal College of Pathologists of Australasia etc is made.
270. The Register itself is the subject of section 11 of the policy statement. The Expert Group states in the opening paragraph (perhaps over-states), that "*the National Cervical Screening Register consists of registers in each Area Health Board linked to a central register (presently the NMPI) using common software, with strong national coordination and support*". At this stage, of course, the Register was not operating in each Area Health Board, there was no linkage between sites except through the use of common software and the National Coordinator herself had not long been in the position. It appears from para.11.1.5 (p.51) that the Expert Group misunderstood the role of the NMPI. It did (and does) not provide a "link" but simply a unique patient number which can be linked to patient records in appropriate circumstances.
271. The only concern expressed by the Expert Group about the Register was in para.11.1.9: that the cytology registers as then configured were confined to recording cytology results. The Expert Group noted that expansion to include relevant histology was an urgent priority, "*not only to ensure that women with abnormal smears are being properly followed up, but also to evaluate the quality of smear recording in laboratories*" (p.52).
272. At para.11.2.8 (p.54) the Expert Group noted the management information reports that would be generated by the Programme and, at para.11.2.9 noted that representatives of the Department and the Expert Group should "*research and report to the Expert Group on the methods by which relevant histology data can be obtained and used by the Programme. This review should include an assessment of direct submission of histology results to the cytology registers, the possible use of the National Cancer Registry for the initial registration of the histology results, and the possible legislative requirements involved*". The review

was seen as a matter of urgency by the Expert Group and was carried out by Azimuth Consultants.

273. Under the heading “Monitoring” on p.55, the Expert Group noted that epidemiological information from the registers should be analysed “at regular intervals” to monitor the success of the NCSP in reducing mortality and morbidity from invasive cervical cancer. This was done as part of the annual health status monitoring using data from the Cancer Registry which, because it is compulsory to register all cases, is more complete than the NCSR (which does not include women not enrolled in the NCSP).
274. Section 12 is on laboratories. This is covered later in this submission under the heading “Laboratory Services to the NCSP – Policy Development”.
275. Section 14 relates to evaluation and monitoring. Twenty nine (non-exclusive) aspects of the Programme requiring evaluation by the Area Health Boards were identified (pp.62-64). Most of those items were in fact the subject of evaluation. At the national level, the National Screening Co-ordinator was responsible for ensuring that the Programme was monitored and evaluated. The Expert Group noted it was also the Co-ordinator’s role to make sure that progress towards achieving the goal and objectives of the NCSP was evaluated (as was done annually). It noted that epidemiological information would be available from the Register but that, to date, no software had been developed to carry out this task. In other words, it acknowledged the information was not yet accessible for that task.
276. The Expert Group noted that, as part of a process of reviewing this aspect of the Register, consideration would need to be given to the consequences for epidemiological studies of women being able to opt out of the NCSP. There would be no information available on those women for evaluating the success of the Programme. This indicates a focus on information from the Register rather than clinical information from women both inside and outside of the Programme for evaluation purposes. No specific method for monitoring or evaluation at a national level is referred to.
277. The emphasis of the Expert Group was also on the front-end of the Programme. It also wanted action, notwithstanding it might be more prudent to do further

piloting. For example, at p.24 there is some discussion of Dr Straton's proposal to pilot the Programme in a large urban area before implementing it in all large Area Health Boards, but weighed this against the impact of further delays. The Expert Group noted:

3.3.5 It is critical to the success of the NCSP that some aspects of policy be actioned immediately. It is essential that women and provider groups support the programme, and that the strategies for public and professional education and consultation be implemented forthwith.

Accordingly the implementation of the Programme continued with this emphasis on the gaining of support for the Programme, without completing and testing appropriate systems for all aspects of the Programme. That is to be contrasted with the approach to the breast screening programme, implemented nationally only in 1998.

Ministerial policy statement: 18 October 1990

278. The first significant statement of policy is the Minister's statement of 18 October 1990 following consideration of the Expert Group's August statement. The Minister's policy is exhibited together with a covering memorandum from the Minister to the Director-General as JMG/MOH/006. This statement was issued approximately one month before the 1990 General Election which saw a change from a Labour to a National government.
279. The policy statement accompanied the announcement of interim funding for all Area Health Boards. The Minister noted that the Expert Group's advice was to provide "*the basis for on-going policy development*". The statement set out the aims of the screening programme and the specific objectives (coverage, incidence and mortality) and the priority groups. The Minister noted "*it is important to build on the service which is currently available rather than attempt to replace it*". General practitioners' comprehensive registers should continue to be the prime method of recall for women using existing services and the national register would provide a back-up. Again, the emphasis was on front-end recruiting of women into the screening programme, simplifying enrolment procedures and educating providers. Concern about over-screening was expressed (p.87). It was acknowledged (p.88) that it would take some months for full installation and

implementation of the Register to be completed for all Boards (it was February 1992 before all Boards had fully operational Registers). The Minister also did not see outstanding Register issues as reason for Boards to hold back on establishing screening services:

While a national register is important for optimal long-term results, in the short term the priority must be to get appropriate screening services in place in all regions.

280. The Minister's statement indicated that "opt-off" legislation would not be promoted at that stage, as recommended by the Expert Group (p.90):

The Expert Group has recommended that legislation be introduced to require that all smear results be automatically entered on the Register. While I am sympathetic to the recommendation I believe the issue should be addressed as part of the proposed wider cancer legislation. That will provide for the general issue of cancer registers and will also cover the relevant confidentiality issues. Until that time it will continue to be necessary to obtain specific consent from each woman for information to be entered on the Register.

This is addressed further under the heading Opt-on versus Opt-off Programme.

Policy confirmation by new Minister: February 1991

281. The Government changed in November 1990 and, on 1 February 1991, the incoming Associate Minister of Health, Katherine O'Regan, released a statement of the government's policy on cervical screening. The Department's advice was that it was essential for government to endorse a national policy at the earliest possible date so that there could be standards against which to develop responsibilities, relationships and strategies for achieving the objectives of the Programme (Vol.2 p.130, foot).
282. The policy statement is a very brief statement of just over one page (Glackin Vol.2 p.132-3). It set out the objectives and priority groups on a similar basis as in the previous Minister's policy statement, save for a change in the age of the target group. This was as a result of the modifications to the 1985 Skegg recommendations following the five yearly review by the Working Group led by Charlotte Paul (JMG/MOH/010: Glackin Vol.2 p.137). The Minister expressly

confirmed that the policy statement of the Expert Group was the basis for the government's policy, save for a few exceptions.

283. Then, in June of 1991, a fuller policy document was issued which was based on the Expert Group's advice but taking into account the Paul review: JMG/MOH/015; Glackin Vol.5 p.10. The policy was intended to and did prescribe standards for the Programme including the mortality and incidence aims, standards for routine screening, transfer of information to the Register, recall, consent, education and health promotion. These are matters which had been progressed to a reasonably developed stage by the Department and Expert Group.
284. While not as explicit, the policy also mandated the establishment of standards and accreditation procedures for laboratories, and envisaged evaluation and monitoring (in general terms) at various levels within the health system, in accordance with the advice of the Expert Group. Again this reflected that these issues were not seen as immediate priorities by the various groups involved in the Programme at a national level.
285. When questioned by Mr Hindle about the importance of the para.4.1.4 criteria for TELARC accreditation, Professor Skegg observed:

When the programme was being started I think attention should have been focused on them even more strongly, but I do think it was appropriate that the first priority of the programme was to obtain a better coverage of the population being screened, because I think the evidence is that that would achieve the most substantial and most rapid control of the incidence in mortality. So I would not have been in favour of delaying the programme for several years while these matters were attended to but I would expect them to be attended to as soon as possible and some could have been dealt with almost immediately. (p.A881/14-22)

Our submission is that that is what happened.

Key Development Issue: Opt-on versus Opt-off Programme

286. The Programme commenced as a voluntary one, requiring consent for a woman's results to be entered on the Register. From 1 July 1993, following amendments to the Health Act (s.74A), the Programme became "opt-off". The factual position is summarised in Ms Glackin's evidence in chief, paras.237-246.
287. A voluntary registration system was perhaps the natural outcome of the Cartwright Inquiry recommendations, which emphasised informed consent and patient choice. Legislation (as required for an "opt-off programme) was not referred to in the

Cartwright Report or the Report of the Porirua Workshop. The Workshop identified as key principles that “*the Programme should recognise that women need to be empowered to be responsible for their own health*”, that it should “*ensure that women’s dignity, respect and needs are primary*” and “*recognise that women are owners of their own information*” (Boyd Vol.3 pp.65-66). Under the heading “Access” it noted that “*the Programme must be developed in a way which maximises choice*” (Boyd Vol.3 p.66). The emphasis appeared to be on voluntary registration.

288. The Ministerial Review Committee appeared to be the first voice to question the appropriateness of voluntary registration: Glackin Vol.1 pp.14-16 and p.17 (recommendation 4). If there was an awareness among members of the Review Committee that legislation was required to implement recommendation 4, it is not revealed in the report.
289. The issue was picked up by Dr Straton in her report of July 1990 (Glackin Vol.1 p.219). She acknowledged the need for specific legislation to allow clinicians and pathologists to give data to the registry, concern about privacy and the need for considerable community support. She recommended (Vol.1 p.220) consultation and extensive community education campaigns take place with a view to introduction of legislation to allow for an opt-out system (with appropriate safeguards to protect confidentiality). She acknowledged the time delay before enactment of legislation could pose problems in maintaining the momentum of the establishment of the Register.
290. Her recommendations were endorsed by the Expert Group in both its summary of key recommendations to the Minister on 30 May 1990 (Glackin Vol.2 pp.1, 4-5) and in its “policy statement” of August 1990 (Glackin Vol.2 p.198, para.11.2.2). The Expert Group noted in that paragraph that:

The full legal and ethical implications of this policy need to be fully ascertained by the Expert Group and the Department of Health and, if necessary, legislation should be proceeded with.

291. The Minister’s response to this recommendation was set out in her policy statement of 18 October 1990: Glackin Vol.2 p.90:

The Expert Group has recommended that legislation be introduced to require that all smear results be automatically entered on the Register. While I am sympathetic to the recommendation I believe the issue should be addressed as part of the proposed wider cancer legislation. That will provide for the general issue of cancer registers and will also cover the relevant confidentiality issues. Until that time it will continue to be necessary to obtain specific consent from each woman for information to be entered on the Register.

292. As Ms Glackin said in evidence, the issue was controversial. At a meeting with Programme Managers in April 1991, the new Minister (Hon Katherine O'Regan) advised that the Government was reluctant to enact any legislation which would make the Register compulsory. Good privacy legislation would also be necessary: JMG/MOH/75; Vol.14 p.60. After extensive consultation with women, in November 1991 the Associate Minister of Health endorsed the requirement for legislation to bring about an opt-off register. A paper went to Cabinet in April 1992 (shortly after the local registers became operational in all Area Health Boards. On 4 May, instead of simply endorsing the legislative proposal, Cabinet invited the Minister to further test public support and report to the Cabinet Social and Family Policy Committee: JMG/MOH/065 and 066, Vol.12 pp.142-148. This was done and the legislation passed in 1993. In the context of standard timeframes for policy development through to statutory enactment, there cannot be said to have been any unusual delay.

293. The consequences for the Programme of the change to opt-off in July 1993 were dramatic:

Overnight 80-99 percent of all smear results from various laboratories were being forwarded to the Register ... (as opposed to 20-40 percent prior to the introduction of the legislation). (Glackin para.246)

This meant that significant numbers only then began to come through the Programme so as to eventually permit meaningful monitoring of the performance of laboratories and evaluation of the Programme at a national level.

Key Development Issue Two: Laboratory Services to the NCSP – Policy Development

Straton/Expert Group Recommendations

294. Laboratory services were the specific subject of Section V of Dr Straton's Report: JMG/MOH/004 Vol.1 pp.256-261. Dr Straton noted that the need for high quality laboratory services was an aspect of the Programme that seemed to have received

much less attention in New Zealand than the recruitment of women to be screened. She noted matters needing attention as including “accreditation and quality control, training of cytoscreeners, the coding of results, and the interface between the laboratories and the NCSR” (p.256). She expressed the opinion that there should be a system of accreditation of laboratories carrying out cervical cytology screening, which is tied to the reimbursement of laboratories for reading smears. Public hospital laboratories should also be included. She observed that criteria for accreditation should include the screening of a minimum number of smears per year, the employment of a certain proportion of qualified staff at each level, the maximum workload for each screener, the satisfactory participation in both internal and external quality assurance procedures, and co-operation in providing cytology and histology reports to the National Cervical Screening Register.

295. These observations formed the basis for the Expert Group’s policy statement (Glackin Vol.2 pp.57-58) and the Government’s NCSP policy in respect of laboratories (Glackin Vol.5 pp.16-17), discussed further below.
296. At p.257 Dr Straton also noted that those laboratories reading as few as 50 smears per year (yes, 50) should not continue to read smears and that it would be desirable, for efficient functioning of the Register, for the Register to interact with fewer laboratories. The matter was obviously one of debate. Dr Straton noted that it had been argued that some of the public hospital laboratories which were reading lower number of smears could still provide an effective service, as they screened a high proportion of abnormal smears through their role in the investigation and follow-up of women with abnormalities. It would be feasible to have a different cut-off point for laboratories which read diagnostic smears as well. These issues were not referred to by the Expert Group, who were content to leave the setting of a guideline for a minimum number of smears per year for CALC and the Department to “negotiate with TELARC” as criteria (guidelines) for TELARC registration.
297. At Vol.1 p.258 Dr Straton noted that there was still a great deal of work to be done in negotiating the provision of data by all laboratories to the Register. Again, there was no suggestion of regulating for the provision of data. Feedback to laboratories for quality control purposes was discussed at pp.259 and 260. One method of assisting laboratories with quality control was the provision of feedback

on the distribution of grades of abnormality for that laboratory. She notes that it should also be possible to provide information about false negatives and false positives and finally the provision of histology to the Register would be essential for the correlation of cytology and histology reports.

298. Laboratories were dealt with in s.12 of the Expert Group's statement (Glackin Vol.2 pp.57-58). Recommendations were made in paras.12.2.2 to 12.2.6. These recommendations were picked up, with a number of changes, in the 1991 Government Policy. The Expert Group's recommendations were as follows (Glackin Vol.2 pp.57-58):

12.2.2 The Expert Group recommends that by 1991 all cytology laboratories servicing the NCSP should have applied for registration with the Testing Laboratory Registration Council of New Zealand (TELARC) and should be TELARC registered by December 1993. The only exceptions will be if TELARC itself is unable to meet these deadlines or if a laboratory is newly set up, necessitating a reasonable period of time in which to obtain TELARC registration.

12.2.3 The Department of Health should be responsible for confirming that those laboratories carrying out cytology screening for the NCSP meet the recommendations set out in 12.2.2. Such confirmation should become a requirement for receiving the laboratory benefit for reading NCSP smears.

12.2.4 The criteria for registration by TELARC should be negotiated with TELARC by CALC and the Department of Health. The criteria will include guidelines on:

- ?? **the reading of a minimum number of smears a year**
- ?? **the employment of adequate numbers of suitably qualified staff**
- ?? **the maximum workload for each cytoscreener**
- ?? **adequate in-service education**
- ?? **the satisfactory participation in both internal and external quality assurance procedures**
- ?? **co-operation in providing cytology reports to the cytology register.**

12.2.5 The Department of Health, CALC, TELARC, and other relevant organisations will set standards for the training of cytology laboratory assistants. The Department of Health is responsible for ensuring that there are sufficient training facilities to meet the cytology screening workforce requirements of the NCSP.

12.2.6 Developing a mechanism for linking the histology results of cervical tissues submitted to laboratories for diagnosis to the cytology register is an urgent priority for the Department of Health. The register will also be developed so that laboratory staff have direct access to a woman's previous smear history when reading smears. (emphasis added)

299. The concepts in para.12.2.3 of :

299.1 **guidelines for TELARC;**

299.2 **negotiation** of criteria with TELARC; and

299.3 the **joint role** of CALC and the Department in that process;

first appear in handwritten annotations on Dr Teague's draft of the Expert Group policy statement (CAT/RCPA/0004, Vol.2 p.197).

300. As has been pointed out in the course of the Inquiry, there were difficulties with the Expert Group's proposed policy:

300.1 The "guidelines" would have to be negotiated with TELARC because TELARC was an independent organisation and could elect to accept/modify or decline to take into account guidelines offered by CALC and the Department.

300.2 Even if the guidelines were applied by TELARC, laboratories were not required to be TELARC accredited under the proposed policy until December 1993 (over 3 years away) and even then there would be exceptions if TELARC could not meet the demand.

300.3 CALC was a group of industry participants with a vested interest in ensuring any guidelines or criteria were acceptable to its constituent members.

301. These issues are rightly raised. Nevertheless, this was the advice of the Expert Group at the time. It was modified only slightly in the 1991 policy (referred to under).

302. It is submitted that, at the time, the setting of laboratory quality standards was not in fact a high priority for the Programme. The Expert Group's proposed policy in other areas was considerably more detailed. By 1991, standards had been set for smear taker competency (Boyd, para.67.1 evidence in chief) and the Skeggs' screening guidelines were reviewed by the Paul Committee. Dr Teague accepted in answer to a question from Dr Duggan that there was no real priority setting by the Expert Group – everything needed to be done: B1445/6-18. He also appeared to believe the Expert Group said the Programme should be delayed until proper measures were in place: B1473/23. That was not the case: Expert Group report para.3.3.5 (Glackin Vol.2 p.24). Nevertheless, as will be seen, the quality

assurance standards for the Programme was an urgent issue referred to CALC in July 1989. It appears that, by August 1990 it was assumed that these issues had been resolved by CALC's recommendations to TELARC (referred to under).

303. We know that, at the time, existing standards had been developed around cytology and adapted for New Zealand by the Fitzgerald Committee in 1986: GRB/MOH/019. Any criticism of the Department for a failure to adopt and apply standards at the inception of the Programme must be tempered in light of the expert advice given at the time. The Expert Group, of which Dr Teague is a member, elected not to adopt existing standards. It recommended the development of standards and their application through an independent accreditation body. Even then, accreditation was to be voluntary for at least another three years. Dr Teague accepted in answers to questions from the Chair that the Fitzgerald cytology standards could probably have been adopted by the Programme in 1990/1991: B1412-1419.

The 1991 Laboratory Policy

304. The recommendations of the Expert Group were translated into Government policy with some changes. The relevant paragraphs from the 1991 policy (JMG/MOH/015) are as follows (Glackin Vol.5 pp.16-17):

- 4.1.2 All cytology laboratories servicing the National Cervical Screening Programme should be registered with the Testing Laboratory Registration Council of New Zealand (TELARC) or other recognised authority. It is expected that laboratories not so registered will apply and gain such registration. A reasonable period of time will be allowed for laboratories to obtain registration. This may take up to two years.**
- 4.1.3 The Department of Health will be responsible for confirming that those laboratories carrying out cytology screening for the National Cervical Screening Programme meet the requirements set out in 4.1.4.**
- 4.1.4 The criteria for registration by TELARC or other recognised authority will be established by the Cytology Advisory Liaison Committee. The Department of Health will be consulted. The criteria will include:**
- **reading of a minimum number of smears a year;**
 - **employment of adequate numbers of suitably qualified staff;**
 - **maximum workload for each cytoscreener;**
 - **adequate in-service education;**
 - **satisfactory participation in both internal and external quality assurance procedures;**
 - **provision of cytology reports to the cytology register.**

- 4.1.5 The Department of Health, the Cytology Advisory Liaison Committee, TELARC, and other relevant organisations will monitor standards for the training of cytology laboratory assistants.**
[emphasis added]

Paragraph 4.1.2: TELARC accreditation

305. The first point to note is that para.4.1.2 is somewhat changed from the Expert Group's equivalent para.12.2.2. It could be said to be stronger given that it states that laboratories servicing the Programme "should be registered" with TELARC or similar authority. However, in using the word "should" rather than "must", and in noting that a reasonable period of time will be allowed to obtain registration, which "may take up to two years", the policy does not express a clear requirement for registration. This is to be contrasted with the 1996 policy (GRB/MOH/001 at Boyd Vol.1 p.28 (p.20 of the Policy)) which requires laboratory accreditation in cytology and histology to be eligible for reimbursement for reading smears.
306. This "looseness" in the policy has been the subject of criticism during the Inquiry and it must be accepted that, with the benefit of hindsight, an earlier requirement for accreditation may have forced Dr Bottrill to retire from cytology screening (at least for smears read as part of the Programme). However, the realities of the situation must also be considered and these are discussed further under the heading 'Would an earlier requirement for accreditation have been realistic?'

Paragraph 4.1.3: Role of Department in confirming criteria for accreditation is met

307. Paragraph 4.1.3 of the 1991 Government policy varies from the Expert Group proposed policy in two respects.

307.1 First, instead of referring to the Department's responsibility to confirm that laboratories are TELARC accredited within a reasonable period (i.e. referring to the **previous** paragraph of the policy), it refers to the **subsequent** paragraph, 4.1.4, which requires CALC to establish criteria for TELARC registration.

In the context of the Inquiry, it appears that 4.1.3 has been read as meaning the Department will check that laboratories meet the **criteria** which CALC establishes. It is submitted that that was not the intention. The intention was to make the Department responsible for confirming that laboratories

were becoming TELARC accredited within a reasonable period. The task of ensuring they met the established criteria was the very task TELARC (or equivalent) had been delegated. The Department did not have the expertise or resources to undertake a monitoring function of that nature at that time: Glackin paras 291-2; also noted by CALC in its 1994 submission on the policy at JMG/MOH/071, Vol.13, p.31. The reference to 4.1.4 is probably a typing error, which is carried over into the 1993 revision.

307.2 Secondly, the words “such confirmation should become a requirement for receiving the laboratory benefit for reading NCSP smears” proposed by the Expert Group are omitted from the policy. The words “such confirmation”, it is submitted, referred to confirmation of appropriate steps being taken towards TELARC accreditation.

308. During the period 1991-1993 the consistent advice of CALC and Dr Teague to the National Co-ordinators, reflected in various minutes, was that good progress was being made toward accreditation: B4136, 4142, 4126/22-26; B4127/18-24. Information as to laboratories with accreditation was obtained from TELARC at different times, e.g. by Valeri Norton in mid 1993: JMG/MOH/025, Vol.5 p.178. At that time TELARC is reported to have advised that nine community and five hospital laboratories are registered with them for cytology testing. Several other laboratories have applied for accreditation. Her report went to CALC in draft on 28 April 1993 (Boyd Vol.4 p.36).

309. By November 1993, when it was intended that accreditation become mandatory, the advisory committee’s advice was that non-“registered” laboratories were not reading a large volume of cytology. The minutes of the CSAC meeting of 5 November 1993 record that Terri Green asked how many laboratories were not TELARC registered:

Clint Teague replied the number is very small. (Glackin Vol.4 p.35)

The minutes of CALC two weeks later on 17 November 1993 record the following:

The meeting discussed TELARC accreditation of laboratories. The National Co-ordinator explained that she is interested in including in the RHA Funding Agreement with the Crown a stipulation that cervical screening laboratory services be purchased only from TELARC registered laboratory services. The meeting supported this but noted that a reasonable period of

grace needs to be given for a “new” laboratory to become registered and that this could mean that some laboratories will go out of business. The meeting observed that the laboratories that are not registered are not reading a large volume of cervical cytology. (Boyd Vol.4 p.63)

Dr Bottrill’s laboratory would probably have fitted the category of one that would have gone out of business.

310. The issue of enforcing accreditation was raised with CSAC much earlier, as recorded in the minutes of 12 December 1991: Glackin Vol.3 p.25-foot. The minutes note:

Discussion followed about how accreditation could be enforced. Clint Teague did not think that this would be a big problem. Most laboratories were moving towards accreditation, although there may be a problem with hospital laboratories. Requirement of compulsory TELARC registration for reading cervical smears is a first for laboratories. Compulsory registration has been accepted by laboratories as sufficient time has been given for laboratories to gain registration. NATA in Australia similarly require registration before laboratories can claim subsidies.

Subsequent legal advice (in 1992: GRB/MOH/041) was that payment could not be tagged to accreditation under existing regulations. It is accepted it could have been the subject of new regulation by the Executive, but in the context of the risk of potentially disruptive and expensive (in financial and human resource terms) litigation as was occurring in other areas of the health sector (eg pharmaceutical pricing), together with the impending reforms which would provide a means to achieve the desired outcome and which were likely to be in place before any litigation was resolved, the approach taken was not unreasonable. Sue Dahl’s expectation was that compulsion would be achieved through contracting: B4134/6-14.

Paragraph 4.1.4: TELARC criteria/standards

311. Paragraph 4.1.4 of the 1991 Government Policy differed from the Expert Group’s proposed policy by dropping the reference to “negotiation” with TELARC and simply saying that the criteria for registration would be “established” by CALC. The Department would simply be consulted under the 1991 Policy. The reference to “guidelines” was dropped in favour of the more absolute “criteria”. The criteria themselves were unchanged save for the insertion of the concept of “co-operation” in the last criteria relating to the provision of cytology reports to the Register.

312. The insertion of this provision into a policy approved in June 1991 is odd given the recent work done by CALC for TELARC; culminating in TELARC issuing an advisory note to members of its Medical Laboratory Accreditation Programme in May 1991: GRB/MOH/0022. CALC had provided standards to TELARC for accreditation in cytology in August 1990, and these had just been published.
313. In summary, CALC minutes of 18 July 1989 note that TELARC would like to have “*specific recommendations from laboratories as to assessment requirements*” for accreditation purposes (Boyd Vol.4 p.11). The minutes record that the Fitzgerald Committee paper was to be “considered and modified so that recommendations on standards and quality control could be made to the relevant parent bodies and TELARC” (Boyd Vol.4 p.12). As can be seen from the minutes, Dr Norman Fitzgerald and Dr George Hitchcock, two of the four-person subcommittee which produced the “New Zealandized” recommended standards (GRB/MOH/020) were also members of CALC at this time.
314. At the meeting of 4 May 1990 a letter from TELARC concerning accreditation standards was discussed and the main points noted (Boyd Vol.4 pp.17-18). Dr Teague responded on behalf of CALC on 15 August 1990 (Boyd Vol.4 pp.21-23) reporting the Committee’s recommendations. These do not appear to be based at all on the Fitzgerald Committee, yet Dr Teague was unable to say why not.
315. These recommendations became the substance of the May 1991 advisory note referred to earlier. Mr Walker confirmed they were applied by TELARC in its accreditation process for cytology: B544/2-16. The matters covered included most of the “criteria” referred to in para.4.1.4 of the 1991 Government Policy.
316. In July 1989 the NCSP Implementation Unit was also seeking urgently from CALC, recommendations concerning quality control that might impinge on the operation of the Register: Boyd Vol.4 p.9. Quality control was discussed at the CALC meeting of 18 July 1989: Boyd Vol.4 pp.11-12. The limits of the information on the Register were noted:

Financial restraints and the proposed timeframe for starting the NCSP will allow only the cervical smear results and the patient and smear-taker’s registration numbers to be put on the register. Therefore, QC from the NCSP will only be available on the adequacy of smears and not of colposcopy histology/cytology results etc through the Registry. Comparison of statistical parameters between the laboratories will be possible from the registry [sic]

317. There is a reference to TELARC wanting specific recommendations. As for the Programme, CALC noted it had been provided with a standard classification system (Bethesda) and that the delay in reporting time should be minimised. It appears that was the extent of quality assurance advice offered to the Programme by CALC, at least for the time being.
318. The CALC recommendations noted at Boyd Vol.4 p.12 relating to monitoring information to be provided to smear takers and laboratories were all implemented by the Programme: Sharon Reid evidence in chief, paras 12-14; B760/5-28 and Sandra Matcham. The further recommendations at pp.18 and 19 were also implemented.
319. There are no minutes available for the 1991 meetings of CALC when the 1991 NCSP policy may have been discussed. Dr Teague believes there were none. Perhaps CALC's role had been completed for the moment. CSAC, however, considered the policy at its meeting on 16 July 1991 (Glackin Vol.3 p.10). The only relevant comment recorded in the minutes was that the issue of accreditation of the laboratories *"is now being dealt with by the policy. The Department will negotiate with CALC about the necessary steps to achieve this"* (Glackin Vol.3 p.14). Dr Teague was noted as present at this meeting of CSAC (Glackin Vol.3 p.10).
320. According to the minutes, CSAC discussed the issue of a minimum number of smears at its next meeting of 13 September 1991: Glackin Vol.3 p.18:
- A discussion then took place on the number of laboratories which are processing too few smears each year to retain their level of competency. Brian Cox distributed the 1986 WHO paper entitled "control of Cancer of the Cervix Uteri" which commented on the number of smears which a laboratory should do to retain competency. The discussion concluded with the comment that to set a figure for the number of smears a laboratory should process each year is too difficult and is really an issue for pathologists rather than the Advisory Committee. (emphasis added)**
321. Dr Teague tabled the 1991 TELARC recommendations at the CSAC meeting of 12 December 1991 (Glackin Vol.3 p.25). There was no comment about these recorded in the minutes, nor was there reference to the fact that they affected the requirements of the 1991 policy in 4.1.4, without fulfilling those requirements precisely.

322. Thus the failure to deal with criteria for TELARC accreditation strictly in accordance with the policy, and even to observe that some criteria had already been set and others rejected, was overlooked not only by the National Co-ordinator and her staff, but also by the two expert advisory groups. They included a number of people from the original Expert Group that had decided on the criteria to be set in the first place (picking up Dr Straton's recommendations), and Dr Teague who was centrally involved in settling on and advising the criteria to TELARC.
323. One can only hypothesize as to why this occurred, and why the error was repeated in the 1993 "updated" policy. It is submitted that it was well understood that the criteria set out in 4.1.4 had in fact been established by CALC in 1990 (except where CALC had rejected the validity of the criteria, as it did for the setting of minimum numbers of smears to be read and with CSAC's apparent blessing), and that they had been applied by TELARC since 1991. Certainly in the year 2000 it might be easy to criticise the adequacy of the advice given by CALC and CSAC, and the criteria that were selected for TELARC. With hindsight, the establishment of a minimum number of smears for providing cytology services to the Programme (and preferably generally as well) might have contributed to an earlier exit by Dr Bottrill. The failure to set a minimum did not cause the under-reporting; possibly it enabled it to continue longer than it otherwise should have. It is entirely arguable as to when a minimum number should have been set. One was not recommended by any expert group until 1998. The Co-ordinator (and the Department) relied on the advice of the Expert Advisory Group on this as with most technical issues, (much as Dr McGoogan suggested occurs in the UK!).

Paragraph 4.1.5: Cytology workforce and training

324. The 1991 Government Policy stated that the Department, CALC, TELARC "and other relevant organisations" will "monitor" standards for the training of cytology laboratory assistants. The Expert Group had also referred to the setting of standards and to the Department ensuring sufficient training facilities. This was not included in the 1991 policy. The CIT course had been established at Heretaunga in 1990 with seeding funding from the Department for three years. Beyond that time funding would come from CIT's bulk grants from the Ministry of Education. As it turned out, the course could not attract sufficient enrolment numbers (10) to ensure funding. This issue is briefly covered in Boyd paras.102-

105, evidence in chief. In 1992 the Bachelor of Medical Laboratory Science degree course commenced, and is today offered through Massey and Otago Universities and the Auckland University of Technology (Boyd para.90, evidence in chief).

The 1993 Update

325. In October 1993 the Associate Minister approved an updated version of the 1991 policy to reflect the structural changes to the sector, the changes to the Programme (opt-off) and Register (inclusion of histology) that had been made from 1 July 1993 through the Health Amendment Act, and the establishment of the Interim Kaitiaki Group to protect Maori data: JMG/MOH/027. Ms Handiside, a member of the NCSP head office team from January 1993, and National Co-Ordinator from September 1994 to August 1996, confirmed this: B/3703/19-27 as did the Co-ordinator of the time, Sue Dahl: B/4126/4-8. There was no intention to make other substantive changes. As she explained to CALC in November 1993, "*Government policy cannot be changed without wide consultation*": Boyd Vol.4 p.61. Note that the 1993 revision was still referred to as the 1991 policy, as is seen in documents such as the Health Funding Agreements.

326. The introduction to the policy stated:

The purpose of this revision is to update the policy for regional health authorities, the Public Health Commission and for cervical screening programme manages and service providers. (Glackin, Vol.6, p 27)

The goals, objectives, targets and standards remained the same: Glackin, Vol.6, pp.30-31.

327. As also stated in the introduction, a comprehensive review of the policy was to be completed, in co-operation with the PHC, by 30 June 1994. The considerable number of matters then under review were noted:

These include reviews of the most appropriate placement of the national co-ordination of the Programme and Register within the health sector; development of management processes for the protection of Maori and Pacific Island data on the Register; review of the number and configuration of site registers comprising the NCSR; reviews of NCSR documentation, reports, forms and letters; implementation of Bethesda coding; implementation of histology data on the NCSR; and ongoing evaluation and monitoring. (Glackin, Vol. 6, p 28)

328. The policy for laboratories saw several apparently minor changes from 1991:
- 328.1 The inclusion of references to the provision of histology and use of SNOMED coding in para. 4.1.1;
 - 328.2 The reference *‘This may take up to two years’* which appeared in para. 4.1.2 on the 1991 policy (with reference to the reasonable period of time allowed to obtain TELARC registration) was omitted;
 - 328.3 The references to the Department of Health in paras. 4.1.3, 4.1.4 and 4.1.5 were replaced with references to the Ministry of Health. Once again, the fact that criteria had already been set by CALC and applied by TELARC was not acknowledged;
 - 328.4 The reference to monitoring the standards for the training of cytology laboratory assistants in para. 4.1.5 was expanded to “develop and monitor” such standards. This was more in line with what the Expert Group had initially recommended, and may have related to the CIT course being “in abeyance” in 1993 (refer CALC minutes of 16 June 1993: Boyd Vol.4 p.47). It took a considerable time for the NCSP to get agreement from CALC on quality control and cytotechnicians, including draft competencies for cytotechnicians, developed by the Ministry for in-house training: Boyd para.106 evidence in chief. Refer CALC minutes of 19 August 1994 (Boyd Vol.4 p.87), and minutes of CSLAC on 15 February 1995 (Boyd Vol.4 p.112).
329. The National Co-Ordinator at the time of the policy update was Sue Dahl. She explained the basis for the omission from para.4.1.2. She emphasised there was no intention to dilute the policy:

The reason for updating that was to reflect the health reforms, to reflect the changes in the health structure. We did not review the policy, we updated the policy. The removal of the two year clause, I can’t exactly remember how it occurred but it was not to make it more lukewarm or to reduce its impact; it was based on advice that laboratories were working towards TELARC accreditation. Many of them were already there and we didn’t need to put something in there that said 2 years. There were other ways to make that occur. Meanwhile we had also started to review with the CALC committee the TELARC criteria for accreditation and there was no expectation at the time that it was going to take as long as it took. There was an expectation that that would have been finished within several months (B/4126/6-17)

330. Nevertheless, as Dr Lambie accepted in answer to questions from the Chair, it is much harder to assess the adequacy of the move towards accreditation when a subjective “reasonable period of time” is stated rather than an objective and finite timeframe: B/3896/5-14.
331. The policy intent, if not the actual meaning of the words when poured over by lawyers, was plainly for TELARC accreditation to be compulsory by 1993. This was the import of all the evidence, including the Minister’s policy statements to the RHAs at the commencement of negotiations. It was intended that the mechanism would be as a term of the contract between RHAs and laboratories under the Health and Disability Services Act which, in the circumstances of the time, was a sensible approach. That is indeed what occurred when contracts were finally negotiated in 1995 and 1997. No one had predicted it would take so long. However, the “roll-over” period under s.51 provided a distraction, and the “reasonable endeavours” obligation in funding agreements with RHAs from 1 June 1994 to 30 May 1997 obviously did not **require** the RHAs to secure services from accredited laboratories only. It must be borne in mind that this “reasonable endeavours” clause reflected a quite properly negotiated position that the (non-binding) policy either could not in fact be achieved within that timeframe, or that it did not have sufficient priority among all the obligations on the RHAs (designed to achieve appropriate standards of health and disability services across the sectors) to be elevated to an absolute obligation.
332. The fact that there was a “rollover” period was apparently understood at the time: according to the minutes it was raised at CALC in June 1993: Boyd Vol.4 p.48. Many members of CALC operated laboratories and would have been aware of the contracting position. CALC would also have been aware of the “reasonable endeavours” clause in the 94/95 Funding Agreements if copies were provided as requested in June 1994: Boyd Vol.4 p.70.
333. The Funding Agreements themselves were signed by the Minister. They are contracts at the highest political level and reflect decisions based on a prioritising of matters across the health sector, in the public interest. It is submitted that the Inquiry must recognise this policy context and resist any temptation to supplant its own judgement for where the TELARC obligation should have sat in priority to the very many other obligations on the Regional Health Authorities.

CALC submissions on 91/93 Laboratory Policy Review

334. Dr Teague had no recollection of consideration by CALC of the 1993 revision: B/1427/10-20. The record shows that CALC was asked to, and did, consider the update at its meeting of 17 November 1993: Boyd Vol.4 pp.58 and 61. The only comment noted is a question as to when para.4.1.2 would change.
335. Then, as part of the consultative process involved in the substantive review of the policy, CALC was invited to, and did prepare a submission on the 1991/93 policy (see the invitation at JMG/MOH/032, Vol.7, pp.1 and 4, and the submission itself at JMG/MOH/071 Vol.13, p.31). The submission was over Dr Teague's name as chair of the CALC and was discussed at the meeting of CALC on 29 June 1994: Boyd Vol.4 p.76. The Co-ordinator's report noted that Dr Teague was representing CALC on the policy review steering group: Boyd Vol.4 p.78.
336. The CALC submissions referred to the difficulties with the "current" policy. They did not include any reference to the absence of a finite period for TELARC accreditation. As to the Ministry's obligations under para.4.1.3, CALC noted:

The Committee believes that this paragraph should remain the same except that the requirements as set out in 4.1.2 should be substituted. The reason for this is that the Ministry of Health does not have the expertise and nor would it seem an appropriate function for the Ministry of Health to confirm that laboratories were meeting detailed requirements related to TELARC accreditation. The intent of this paragraph would be met by substituting 4.1.2 which then means that the Ministry of Health would be responsible for confirming that laboratories carrying out cytology screening and histology for the National Cervical Screening Programme are accredited by TELARC or other registered authority. (Glackin Vol.13 p.31)

337. As to para.4.1.4 the Committee submitted as follows:

4.1.4 Reads "The criteria for registration by TELARC or other recognised authority will be established by the Cytology Advisory Liaison Committee in consultation with the Ministry of Health. The criteria will include:" and there is a list of six criteria. The Committee believes that this paragraph should read "The criteria for accreditation will be established by TELARC or other recognised authority in consultation with the Cytology Advisory Liaison Committee and the Ministry of Health" The reason for this suggested change is that TELARC is an autonomous Government Sponsored Agency which the Committee believes would have no legal responsibility to be directed by either CALC or the Ministry of Health. On the other hand, TELARC has consulted both the Ministry and the CALC over the years and has accepted recommendations as they have been made.

1.1.4. CALC had a considerable discussion concerning the six criteria set out in the Policy Document. There is concern in two matters of principle. One is that these six criteria are only part of many many criteria which are

currently used in the assessment of a cytology laboratory. In their own right these criteria would not guarantee a satisfactory cytology service and appear to be somewhat arbitrarily plucked out from the many criteria actually used. The second matter of principal [sic] relates to the fact that these and the other criteria are under review by the Cytology Advisory Liaison Committee and the Ministry of Health and it would be perhaps unwise to set in place criteria which may indeed be subsequently rejected by the Review. (Glackin Vol.13 pp.31-32)

338. Thus CALC considered the six criteria to be “somewhat arbitrarily plucked out from the many criteria actually used” and thought it unwise to set in place criteria which might be subsequently rejected by the current review of TELARC standards. That review by CALC was requested by TELARC in 1993 as seen in the minutes of CALC’s meeting of 17 November 1993 (GRB/MOH/018, Vol.4, p.63 under the heading “Development of Minimum Standards for Medical Laboratories – TELARC”). Ms Dahl said it arose out of her earlier discussions with TELARC about the adequacy of the criteria that TELARC was then using to accredit laboratories: B/4126/22-26. The anticipated completion date was 31 August 1994, as noted in the subsequent CALC minutes of 19 August 1994: Boyd, Vol.4, p.86. That accords with Ms Dahl’s observation that she expected revised minimum standards to be put in place during 1994.
339. So in 1994 the expert advice to the Programme was that the criteria referred to in the policy were not appropriate because they were just a selection of what was in place at present, and would shortly be reviewed. As we know that was not entirely correct; although the TELARC standards from 1991 did address most of them, it did not set a minimum number of smears to be read per annum.
340. In its comments on the revision of policy, CALC did go on to refer to the continuing appropriateness of three of the stated criteria, including the first:

Reading of a minimum number of smears a year; this criteria had been the subject of considerable debate and no consensus in the world literature. Indeed the Committee is not aware of any scientific evaluation on which such a figure could be based. The Committee is aware that there have been recommendations in this area made by committees in various parts of the world but without hard documentary evidence to support the figures arrived at. The Committee feels that it may be more profitable to adopt a different approach along two lines. Firstly, that regardless of sizes (and therefore number of smears a year), a laboratory should meet certain performance standards, i.e. outcome measures which the programme will become well placed to measure, and would be in keeping with Australian initiatives in this area. The second approach may be to have criteria which would preclude “professional isolation” which the Committee felt probably was more important than an arbitrarily defined number of smears read a year. (Glackin Vol.13 p.33)

341. The issue of whether the later recommendations to TELARC should include a minimum figure was again debated and rejected by CSLAC – see minutes of 15 February 1995: Boyd Vol.4 p.110, last 3 paras and top of p.111. The approach ultimately taken was to modify the NPAAC guidelines to include the following:

- D. Pathologists whose laboratories are handling only small numbers of cytological samples should seriously consider whether the numbers being seen are sufficient to maintain the appropriate technical and diagnostic skills of staff members. If not, it is in the patients' best interests for samples to be referred to institutions where the necessary skills are available. (GRB/MOH/025, Vol.5 p.44)**

Public Health Commission Advice 1994

342. In March 1994 the Public Health Commission published its “contestable” advice to the Minister on cervical cancer: JMG/MOH/031. It recommended new outcome targets (Glackin Vol.6 p.131). It briefly referred to laboratory services at Glackin Vol.6 p.143, noting that “*all cytology laboratories servicing the NCSP have to be registered with ... TELARC*” and that “*ongoing monitoring of cytology screening staff is performed by the individual laboratories*”. Very general recommendations were made which were fed into the wider policy review process: Glackin para.92 evidence in chief.

The 1996 Policy

343. The revision of the NCSP, intended for 1994, was subject to delays which meant it was not published until June 1996. The policy is GRB/MOH/001. In the Foreword by the Associate Minister, she referred to the Policy Advisory Group which oversaw consultation and included representatives of Maori, Pacific Islands women, laboratories, women’s groups, purchasers, providers and the Ministerial Advisory Committee. She noted that over 75 submissions had been received. She observed:

Current targets were developed with input from statisticians and an epidemiologist, and were based on available data from the ... Register. However, there is room for further development and refinement of targets and indicators. (Boyd Vol.1 p.5)

That message was repeated under s.3.6.2 of the Policy under the subheading “Monitoring Processes to be developed”: Vol.1 p.37; p.29 of the Policy.

344. The laboratory policy specified TELARC accreditation for reimbursement of smear reading services: para.3.4.2, Boyd Vol.1 p.28. This was enforced in private laboratories through contracts as explained by Mr Mules, and with CHEs – see Midland RHA contract with Tairawhiti Health Care CM/HFA/0040 p.27 which specifically incorporated the 1991 NCSP policy, updated as at October 1993.. The policy also required a number of quality control processes and mechanisms to be in place in laboratories, including to minimise the incidence of false negative and false positive results. It noted:

In future, laboratories will be required to meet the National Quality and Service Standards for Medical Testing Laboratories (under development).
(Boyd Vol.1 p.29)

This is a reference to the standards covered in Sylvia Sax’s evidence.

345. Plainly the NCSP policy was not, by itself, legally enforceable. It was a set of principles and standards, which governed the conduct of the Programme and in accordance with which the RHAs and then THA/HFA were required by the Minister of Health to purchase services.

TELARC accreditation and cytology standards: What happened?

346. There are two key relevant points to the NCSP policy relating to laboratories from the period 1990 to 1996. They are:
- 346.1 That TELARC accreditation was intended to be mandatory by 1993, possibly subject to issues relating to TELARC backlogs and new laboratories entering the system.
- 346.2 Criteria for accrediting cytology units would be established by CALC and provided to TELARC and would include a number of noted criteria.
347. TELARC accreditation was achieved for all private laboratories during the early to mid-90s. Several hospital laboratories came later. It became mandatory in the first contracts that were signed with private laboratories over a period from late 1995 to early 1997 (in the latter case back-dated to 1996) following negotiations

which commenced in 1993. All laboratories providing cytology and histology services to the NCSP are now TELARC accredited: Walker B580/5.

348. Criteria for accreditation by TELARC, at the detailed level of minimum cytology standards, were first developed by CALC at the request of TELARC in August 1990. They were accepted by TELARC and published in 1991. The criteria set by CALC essentially included all the points noted in para. 4.1.4 of the policy, save for the setting of a minimum number of smears. CALC could not agree on that criteria at this point, or subsequently when it debated the issues again in 1994 in relation to the 1993 policy, and in 1995 in relation to further minimum standards for TELARC. CSAC agreed in 1991 that *“it was really an issue for pathologists rather than the Advisory Committee”*: Glackin Vol.3 p.18. So while the appropriateness of those criteria was apparently revisited by CALC and considered by CSAC, the policy statement was not.

Further review of TELARC criteria by CALC/CSLAC: 1993-95

349. A further request from TELARC for CALC to review the minimum standards for cytology was made in November 1993 after discussions between TELARC and NCSP staff. The guidelines ultimately produced by CSLAC were based on, and very similar to, the Australian NPAAC guidelines introduced in 1993, (produced by Dr Medley: GM/HFA/001) but with a little more detail. They were subject to wide consultation among laboratories before being forwarded to TELARC in 1995. The CSLAC minutes of 26 July 1995 record that Dr Teague would *“amend the draft TELARC standards and forward to TELARC”*: GRB/MOH/052.
350. Quite extraordinarily, and unknown to anyone until enquiries were made of Mr Walker in the course of the Inquiry, according to TELARC they were not received. This is even more difficult to understand given it appeared from comments made in the CSLAC minutes that Margaret Lovell-Smith, a member of CSLAC, was a ‘TELARC member’: Boyd Vol.4 p.112. In any event, Mr Walker has advised that TELARC have indirectly or directly assessed against some of the criteria contained in that document. TELARC would have required the standards to be expressed as mandatory, although as he says, laboratories may not necessarily fully meet all of the specifications and technical expert assessors’ advice is relied on. Mr Walker referred to a number of CSLAC’s “standards” as not expressed

appropriately, including the standard relating to laboratories handling only small numbers of smears: “standard” at Boyd Vol.5 p.44 and TELARC comment at Walker affidavit para. 9(c).

351. Accordingly, TELARC accreditation was implemented progressively during the early to mid-1990s for cytology laboratories. Accreditation was against (inter alia) standards set by CALC in 1990 plus further standards developed by TELARC/ IANZ itself. TELARC accreditation provided a thorough peer review of laboratory practices every four years and a “paper audit” annually.

Would an earlier requirement for accreditation have been realistic?

352. The answer is probably no, at least not without compromising other measures such as smear turn-around times. The reasons why, and other relevant contextual matters are, in summary:

352.1 All cytology reporting services were stretched in 1990-91;

352.2 TELARC accreditation services were also under pressure from increased demand;

352.3 There was a limit to the amount of change that could be imposed on and undertaken by laboratories;

352.4 There was ongoing pressure on the Government for increased payments to laboratories;

352.5 Most cytology services provided by laboratories and subsidised by Government prior to 1993 were not for women enrolled in the Programme;

352.6 Mandatory accreditation for quality assurance was a novel concept, as was regulating for quality assurance outside of professional self-regulation.

These points are expanded below.

(i) *Existing services were stretched*

353. In response to questions from the Chair, Dr Teague confirmed, referring to the period of 1990/91 when CALC was recommending minimum standards for cytology to TELARC:

At that point NZ was under extreme stress and in fact we were getting out to reporting times of more than 3 months in some laboratories ... We had a large increase in cervical screening following immediately on the heels of the Cartwright Inquiry and laboratories were almost universally under stress at that time ... I think most laboratories were stretched to the limit.
(B/1420/11-19)

354. Dr Boyd's evidence was that, as a result of the Cartwright Inquiry publicity, there had been a 10 to 25% increase in cervical smears for reading across laboratories: Boyd para.96.

355. While Dr Teague considered that was no reason for leaving compulsory TELARC accreditation until 1996/97, he noted there had to be a lead time:

... It is a substantial process, and for a laboratory that has never undertaken it, it is a process that, in general, would take a year and maybe slightly longer.
(B/1420/25-27)

356. That was consistent with the evidence from TELARC itself. It required a "substantial commitment": Robertson para.25 evidence in chief.

(ii) *Limited tolerance for change*

357. Is it reasonable to have expected a Programme that was imposed on existing services (which were already stretched) to have so radically changed the mode of the provision of those services in a very short timeframe? Consider the consequences for laboratories of the commencement of the Programme. Laboratories had to change their cytology reporting methods to adopt the Bethesda code. They had to provide information to the Register, something they had not done before. They received new information about their reporting patterns which was expected to lead to improved quality assurance processes within the laboratory. They may have had to adjust to an increased volume of smears. Obtaining consistency in the reporting of smear results using the Bethesda code proved to be a significant challenge. That was a priority: as Dr Teague agreed, the importance of consistent reporting is plain if the Programme was to be effective and the Register a useful tool: B/1442/13-22. Dr Teague said that his "concept"

was to get the basic laboratory statistics in place first, and later “*get the epidemiology put on top of it*”: B/1441/4-6. An expensive, resource-intensive and time-consuming accreditation process would have been a heavy impost on laboratories who were already required to adjust to the increased demands of the Programme. It would have meant even slower reporting times which, as Dr Teague pointed out, were already more than three months in some laboratories: B1420/11-12. Notable is Sharon Reid’s evidence that Dr Bottrill was providing a “superior service” in this respect with turnaround times of 10 days or less: Reid para.24.

358. Then in mid 1993 there was another major challenge for laboratories with the passing of the “opt-off” legislation, dramatically increasing the cytology test results to be reported by a laboratory to the Programme. Dr Bottrill’s laboratory carried the bulk of the increase of eligible women enrolled in the Programme in Tairawhiti from 27% in 1993 to 58% in 1994: Glackin para. 205. The reporting of histology results was also required. Again, consistency of reporting using the SNOMED code had to be established, and computer systems installed to enable the provision of test results in electronic form. The latter has proved a long and difficult exercise, with two laboratories still unable to report results electronically.

359. Programme staff worked closely with laboratories directly and through CALC to achieve a significant measure of change. The Regional Co-ordinators consulted and negotiated with, cajoled and threatened the laboratories in their regions in order to secure a timely, accurate and quality service for women enrolled in the Programme.

(iii) ***TELARC accreditation backlog***

360. During the early 1990s there was significant demand for TELARC accreditation which resulted in a backlog. This was acknowledged by Dr Teague: B/1420/27-B/1421/4.

361. Even in 1993 it is noted that it took over four months before TELARC visited Gisborne Laboratories following a request for information: paras.10-12 of Mr Walker’s evidence in chief. In answer to questions from Mr Hodson, Mr Walker indicated

- Q. Does the interval of four months indicate that TELARC was busy at that time?
- A. Yes it does.
- Q. There was very considerable pressure from all manner of organisations wanting accreditation in the early 90's?
- A. Yes, that was a very rapid growth period. I indicated earlier that at my assuming responsibility of the Programme [in 1993] around 50% of the laboratories were accredited and that rapidly increased to 85 or 90% as of 97 I would say. It was a very rapid growth period for us. (B500/20-28)

(iv) *Pressure to increase payments*

362. At the same time as they might have been imposing accreditation and other quality standards on laboratories, the Department/Ministry was facing ongoing pressure from private laboratories to increase the level of payment for cytology services. No doubt this arose from the pressure on their own budgets. The potential implications of mandating TELARC accreditation, at a time when in 1993 only 12 of 24 laboratories reading cytology were accredited in cytology, do not take much imagination. Had many or all of the (very well organised) community laboratories, which were not TELARC accredited in the early 1990s, determined to “dig in” and decline to meet the accreditation requirement, the Programme might well have been jeopardised. It is emphasised that this was never threatened or even suggested – as Ms Grew said, laboratories were generally very co-operative. Neither does Dr Teague recall such an attitude: B1421. One can nevertheless see the difficulties faced by the Midland RHA in its attempt to purchase quality laboratory services at a reasonable price through its extremely difficult negotiations with ACL over the period 1993 to 1996.

(v) *Cytology services primarily provided outside of the Programme*

363. Dr Bottrill, like other laboratories, read slides for women who were not enrolled on the Programme, as well as for those who were. This is likely to have been a large part of his work, at least in the “opt-on” period of 1991 to 1993 when only 14%, 24% and 27% (respectively), of eligible women in Tairawhiti were enrolled (Glackin para.205). The equivalent figures in 1994, 1995 and 1996 were 58%, 64% and 72% respectively. (Despite great improvements in enrolment earlier, by 1996 Tairawhiti (together with the Hawkes Bay) had the lowest level of eligible women enrolments: Boyd Vol.4 p.148). The suggestion that non-accredited laboratories be excluded from providing screening services to the Programme

could not have simply been extended to exclude those laboratories from providing screening services generally. Indeed, we are not aware of any such suggestion. The state paid for the reading of a woman's smears whether or not the woman was enrolled in the Programme.

364. The suggestion that payment be linked to accreditation could have created a perverse incentive to laboratories to decline to provide services to the Programme, unless accreditation was mandatory for all cytology services. There was no ability to link reimbursement to accreditation in the bulk funding arrangements that existed in relation to public hospital laboratories.
365. There are, of course, other arguments that can be made. Regulation is always an option open to the Executive and might have been used to mandate accreditation. However as discussed earlier, it is unlikely that, even with the necessary support, that would have been a simple solution.

(vi) ***Mandatory accreditation a novel concept***

366. Mandatory accreditation for quality assurance was still a relatively novel concept in the public sector in New Zealand in 1990. Exhibit GDW/IANZ/001 indicates that, by the end of 1990, 20 out of 68 medical laboratories were accredited, with only 12 accredited for cytology. Dr Robertson of IANZ (TELARC) produced a list of what seemed to be a raft of other regulatory accreditation requirements: JMR/IANZ/006. In the health sector in particular there was a reference to accreditation of laboratories for food and water testing having been required by regulation since the early 1980s. While the Inquiry has not received evidence on this point, we can advise that this is not so. There is no legal obligation, other than may arise under contracts with various providers, for accreditation of such laboratories by IANZ or anyone else. There are only policy statements. There is no payment for services which is dependent on accreditation.
367. As for "Inspection Bodies" (JMR/IANZ/006 p.3), the position is simply that IANZ is contracted by the Ministry to assess auditors to audit food safety programmes and water supply. No information has been able to be found relating to toy testing.
368. The requirement for dairy industry accreditation is, as Dr Robertson explained, related to the very high barriers that have to be overcome to gain entry into

overseas markets. This is primarily a trade, not a health, issue – with significant consequences as the UK customs saga over compliance with the requirement that butter importations contain no more than 82% milk fat demonstrates. While the requirement for accreditation may emanate from MAF, there is no payment by the state involved; all costs are met by the industry.

369. It is submitted that, had TELARC accreditation been made compulsory from 1994 on, and assuming that step would have stopped Dr Bottrill from providing cytology services (at least for the Programme) two years earlier than he did, then the number of other laboratories that would also have been excluded might have compromised, possibly even jeopardised the Programme, particularly given the increased demands as a result of the 1993 “opt-off” reform and the introduction of compulsory reporting of histology to the Register.
370. Dr Teague’s personal opinion was that the Programme could not have functioned using only TELARC accredited laboratories in 1990/91:

I don’t believe that if we had shut down a significant number of laboratories the others would have coped. (B/1420/17-18)

He was unable to say with certainty, in answer to a question from the Chair, what the position would have been in 1993:

Q. ... by 1993, would there have been sufficient TELARC accredited laboratories to undertake the work of the Programme?

A. That’s going back a wee while, probably but I can’t given an absolute assurance on that. (B/1421/10-14)

371. By the end of 1993 the number of TELARC accredited laboratories had only increased by two to 14 from the 12 that were accredited for cytology at the end of 1990: GDW/IANZ/001. The same exhibit shows a further six were accredited in 1994, four in 1995, one in 1996 and three (hospital) laboratories in 1997 and 1998. (Note that Chitra Subramaniam’s figure to CALC of 22 accredited laboratories in November 1993 (Boyd Vol.4 p.63) appears to be based on those laboratories that were generally accredited (first column of Mr Walker’s exhibit GDW/1AN2/001, excluding Blood Services) rather than those accredited for cytology (second column) of which there were 14. Counsel Assisting’s cross-examination of David

Lambie (B3939) repeats this error. Mr Walker's evidence and Ms Norton's figures from 1993 coincide.

Conclusion

372. In the absence of mandatory TELARC accreditation, the only other way Dr Bottrill's level of under-reporting could have been detected earlier might have been through a sophisticated level of monitoring of laboratory data from the Register. We have seen what was available by way of information from the Registry in August 1996 and know it did not disclose any problem: GRB/MOH/048.
373. There are very many "what ifs" that **might** have affected this. For example, what if the Minister in 1990 had decided to persuade her colleagues to rush through Parliament, pre-election, legislation to create an opt-off Programme similar to that in Victoria? What if the reporting of histology had been legislated for before 1993? What if an audit of deaths from cervical cancer in Tairāwhiti had occurred in 1993?
374. Dr Bottrill continued his unacceptable under-reporting of abnormalities at a time when the processes that might have identified him were still under development. The criticism that might be leveled at the speed and competence of that development process is a matter for careful judgement of all the relevant circumstances, recognising the power of hindsight bias. It is clear from the evidence that many committed people worked extremely hard over this period to design and implement a successful screening programme and that has, to a very significant extent, resulted in the reduced level of incidence and mortality from cervical cancer in New Zealand women today.