

**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 II : TERMS OF REFERENCE 3 to 8

AND

REPLY TO SUBMISSIONS

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TERM OF REFERENCE 3 :

IF YOU DETERMINE THAT THERE HAS BEEN AN UNACCEPTABLE LEVEL OF UNDER-REPORTING, TO SATISFY YOURSELVES WHETHER OR NOT THIS WAS AN ISOLATED CASE RATHER THAN EVIDENCE OF A SYSTEMIC ISSUE FOR THE NATIONAL CERVICAL SCREENING PROGRAMME

Introduction

1. This term of reference is pivotal because it broadens the Inquiry beyond Gisborne unless the Inquiry is satisfied the unacceptable level of under-reporting was an isolated case. This does not mean the Inquiry had to embark upon an investigation into other laboratories servicing other geographical areas of New Zealand. Rather TOR 3 simply invites a systemic analysis of the GLL situation given that that laboratory was just one of many laboratories reading smears for women involved in the NCSP.
2. It is submitted that there is no lack of evidence inhibiting the Inquiry from reporting fully on TOR 3. The detailed evidence and submissions directed to answering TOR 2 as to the factors that are likely to have led to unacceptable under-reporting can be carried over to answer TOR 3. Many of the factors that led to unacceptable under-reporting by GLL (or which enabled that under-reporting to continue undetected for so long) mean that the Inquiry:
 - 2.1 Cannot be satisfied that GLL was an isolated case of unacceptable under-reporting; and
 - 2.2 The Inquiry is justified in going on to relate the GLL situation to laboratory reporting for the NCSP generally.
3. Carrying out the systemic analysis, ie relating the GLL circumstances to the NCSP generally, is complicated by having to apply the factors identified under TOR 2 to the circumstances existing over the last decade or so during which the NCSP has operated.
4. In part the systemic analysis involves applying a risk assessment to an historical situation, ie given that unacceptable under-reporting by GLL

continued until Dr Bottrill's retirement in 1996 and remained undetected until March 1999 (Tracy Mellor's first brief of evidence) is the health of women in other parts of New Zealand also at risk?

5. In part the systemic analysis also involves learning from the Gisborne situation so that any necessary changes to the NCSP still required today in order to avoid a reoccurrence are made. In para 11 of our opening address we expressed this aspect as follows:

Essentially the Inquiry is into what went wrong with cervical screening in Gisborne in the early 1990s in order to find out whether anything arising out of that situation still contains lessons for the way in which the NCSP operates today.

6. Our submission on TOR 3 in summary is that:
 - 6.1 You are able to determine that there has been an unacceptable level of under-reporting in Gisborne;
 - 6.2 You cannot be completely satisfied that Gisborne was an isolated case of unacceptable under-reporting; and
 - 6.3 Some of the circumstances relating to GLL are evidence of systemic issues for the NCSP.
7. Rather than attempt to retrace the evidence relevant to TOR 2 and apply it to TOR 3 this part of our submissions mainly addresses the relevance of the HFA's National Laboratory Review (NLR) to TOR 3. In summary the NLR, although not conducted specifically for the Inquiry, is relevant to the Inquiry in four particular respects, namely:
 - 7.1 It is relevant to whether GLL was an isolated case of unacceptable under-reporting or not;
 - 7.2 It is relevant to identifying systemic issues for the NCSP;
 - 7.3 It provides a risk assessment about whether historical systemic issues raise concerns for women's health today;

- 7.4 It provides a snapshot about current practice in the private laboratories which are now being subjected to new operational policy and quality standards for the NCSP (Peters exhibit 40) and performance monitoring against those standards (Peters exhibit 42).
8. We deal with each of these four points under separate sub-headings, although there is some overlap between them.

GLL – an isolated case or not?

9. It is submitted that even taking account of the NLR evidence (James DuRose and Dr Gabrielle Medley) the Inquiry cannot be completely satisfied that during the last decade or so there was not an unacceptable level of under-reporting by other New Zealand laboratories.
10. The evidence of Professor Skegg about the NLR (summarised in counsel assisting submissions) indicates that the work would have had to be done on a far more scientific basis if such specific assurances were to be given. Clearly, as Dr Medley confirmed, the HFA did not have the luxury of time to carry out such an exercise (B2711).
11. Once the preliminary information available from the Sydney re-read became available to the HFA, urgent action was required to assess the potential risk to women in case another Gisborne situation existed in other parts of the country:

As a result of the early results from the re-reading of the cervical slides from the HFA's investigation into cervical pathology in Gisborne/Tairāwhiti, the HFA began to consider whether a similar situation could have occurred elsewhere.

The overall objective of the practice review has been to gather enough evidence to establish whether community laboratories in New Zealand were practising within acceptable standards in their reporting of cervical cytology during the period 1990 – 1999. (JD/HFA/001 at p4)

12. In answer to questions from Ms Janes, Dr Medley also explained her understanding of the purpose of the NLR:

Q: Was it your understanding that this review was being undertaken in order to try and provide information for the Inquiry panel or was it something the Health Funding Authority felt that its time had come?

A: I think it was done to try and identify if there were other major areas in NZ where a situation similar to the one in Gisborne could be occurring due to the massive failure of a laboratory. Clearly those of us that are involved with cervical screening know that every laboratory will have false negative smears. Regrettably that's part of the industry and clearly there are ways that are being continually tried to minimise those errors, to improve those errors not only by auditing within laboratories but also by technical improvements as well. But granted that at this stage this is not the case, that this is an imperfect programme, it's an imperfect test –

Q: But was it your understanding that it was carried out with the speed with which it was carried out in order to try and be able to present evidence to the Committee of Inquiry?

A: I don't think the primary objective was the Inquiry. The primary objective was to identify risk to women. Now clearly it was known that the data would presumably be used for an Inquiry, but that was not – the primary purpose was to try and make sure that women who were in danger, that we could identify if there were areas of danger. And I think that was the primary purpose of the review. (B2714-5)

13. But this was no easy task. Professor Duggan for instance asked Dr Cox about the overall objective of the practice review as detailed on page 4 of Exhibit 1:

Could a study be designed to answer that objective? (B/2604)

14. Dr Cox answered:

I actually think that's extremely difficult to do retrospectively at this point. But that's just my first sort of approach. And I would rely on the expertise of pathologists to guide me and debate how you would set standards with data that you have, in terms of retrospectively. You can certainly specify what should be collected in the future and specify things in the future. But I would defer to the pathologists. (B/2604)

15. This is exactly what the HFA did. It engaged with the RCPA's Cytology Focus Group and the result was the development of a standard laboratory questionnaire (Exhibit JD/HFA/003). Considerable planning was completed resulting in the laboratories being advised of the objectives,

process and timeframes for the review when the questionnaire was distributed on 7 December 1999. (Exhibit JD/HFA/003).

16. Then the specific details of the assessment and evaluation process resulted from Mr DuRose's meeting all the laboratories in December 1999 to discuss the questionnaire and laboratory review processes (Exhibit JD/HFA/004).
17. The five Cytology Focus Group members plus three international cytopathologists independently assessed all of the laboratory questionnaires (Exhibit JD/HFA/005). Two members of the Cytology Focus Group, Dr Sage and Dr Peter Fitzgerald, together with Dr Medley, formed an evaluation panel with Mr DuRose and Tracy Mellor of the HFA.
18. The two New Zealand pathologists then carried forward the evaluation panel's work as members of a multi-disciplinary Advisory Group. This Advisory Group considered the information about six laboratories identified by the evaluation panel as warranting further attention. The names of all the pathologists involved and other members of the multi-disciplinary Advisory Group can be found at Exhibit JD/HFA/001 at page 021. Drs Sage and Fitzgerald, it will be seen, were members of the questionnaire assessment panel, the evaluation panel and the multidisciplinary Advisory Group.
19. The HFA acknowledged that the NLR did not represent a thorough assessment of the quality of cervical cytology in New Zealand (JD/HFA/006 at p67). However once the purpose of the review is appreciated and that it was essentially a review by respected cytopathologists of historical and current laboratory practices in New Zealand, it is submitted reliance can be placed upon the NLR to conclude that over the relevant period there were no other laboratories practising like GLL.
20. It is submitted that Dr McGoogan's evidence directed to TOR 1 also supports the HFA's approach to, and conclusions arrived at, in relation to

the NLR. In summary, Dr McGoogan's evidence emphasised the inherent difficulty in reviewing the practice of cytopathology due to the known problem of false negatives and the lack of internationally accepted benchmarks, but that one can draw certain conclusions based upon the way in which a laboratory practises (Dr McGoogan's evidence in this regard is summarised at paragraphs 26-68 in Part I of our submissions).

21. While Professor Skegg as an epidemiologist was critical of the NLR methodology in several respects (as summarised in counsel assisting's submissions) Dr Medley as the HFA's principal cytopathologist adviser for the review was supportive of the methodology to establish that Dr Bottrill's method of practice was an isolated case:

Q: Were you comfortable with the design of the study?

A: I believe that for the exercise we were doing which was a risk assessment exercise which was required to be done quite speedily that I was satisfied that we were doing what we could in that particular setting. Clearly we were not doing a comprehensive review of laboratory performance to set standards. That was not what it was yes I was comfortable with the methodology. Sorry about all the provisos. (B2711)

22. It should be noted that Dr Medley is an eminent cytopathologist as appears from her curriculum vitae produced as exhibit JD/HFA/011. At the time Dr Medley gave evidence she had in fact just recently retired from the position of Director of the Victorian Cytology Service, a position which she had held since 1987. Her retirement coincided however with her appointment as Director Emeritus of the Victorian Cytology Service. It is submitted that in relation to a review of laboratory practice Dr Medley's evidence is to be preferred to that of Professor Skegg's.
23. Dr Medley was called at short notice and did not have a brief of evidence but was questioned on behalf of the Inquiry panel by counsel assisting Ms Janes on 27 July starting at B2678. Dr Medley confirmed that the NLR did not purport to be an article of research or study. Rather it was essentially a response to a serious situation equivalent to emergency surgery rather than elective surgery (B2679).

24. There was some attempt to be critical of the NLR based upon individual data indicators used in the study. Mr DuRose however confirmed (para 62) that the correct approach was to look at the four data indicators overall, namely:

?? Assessment of the questionnaire profiles of each laboratory;

?? Analysis of reporting rates from NCSR data 1991 to June 1999 against selected benchmarks;

?? Cytology/histology correlation data for 1996 to 1998; and

?? Estimates of incidents of cervical cancer for NCSP by region 1990 to 1995.

25. Dr Medley confirmed this approach:

Yes I think a response to this sort of situation is to gather pieces of a jigsaw and that's exactly what this review was trying to do. It was trying to examine a number of markers that one could put together and although it wouldn't give you a complete picture it does give you at least a partial picture of what you wanted to know. (B2680)

26. Although Dr Medley was not involved in the design of the questionnaire to laboratories she said:

I believe the major broad groups of laboratory performance were covered in the questionnaire. I might have perhaps used different wording but I think the essential thing was that the areas of laboratory performance were covered. (B2681)

27. Dr Medley confirmed that a two day meeting of the HFA evaluation panel on 15 and 16 February this year reached a consensus view of concerns about the 17 laboratories within the review (B2683). These concerns were handed over to the HFA Advisory Group. Dr Medley was not a member of the Advisory Group but she confirmed that the New Zealand cytopathologists, Dr Sage and Dr Fitzgerald had been members of both the evaluation panel and the multi-disciplinary Advisory Group – see JD/HFA/001 p21).

28. When questioned by Professor Duggan about the difficulty of assessing laboratory practice in New Zealand over a 10 year period Dr Medley responded:

I think basically the nature of this review has been a risk assessment and it was in the nature of a risk assessment that I was looking at this documentation and as such I guess it had a different focus to it if I was trying to develop a code of practice. I regarded this as a risk assessment exercise essentially so that it looked at each of the characteristics that were being described for each laboratory in terms of what risk is there to women in this behaviour or in this method of functioning. (B2687)

29. In taking this approach Dr Medley said:

I think one of the most important things in cervical cytology which is a very subjective discipline is the opportunity to have more than one pair of eyes on a slide and more than one brain to discuss a slide so I guess one of the most important areas of this questionnaire to me was where the sole practitioners and were there sole practitioners who were actually screening slides because it's my belief that under usual circumstances pathologists are not trained screeners so to me I suppose I ranked the different areas of the questionnaire in terms of what I considered to be the greatest risk and to me that was the single greatest risk and that was not the case for any other practice...(B2687)

30. One of the criticisms of the NLR was that the benchmark of .5% reporting rate for high grade abnormalities was possibly inappropriately low. Dr Medley however confirmed that this sort of focus upon one indicator alone was inappropriate:

Well remembering that this was not a research study this was a risk review, we had to establish what we considered to be risky or potentially risky practice and I think there's been a lot of discussion about the setting of a level of .5 for the level of high grade reporting but this level was set not because it was the level that was the standard in Australia or any other country but I think it was set because what we were trying to establish was did we have any other laboratory that would be classed in the same category as Dr Bottrill's laboratory would be and therefore that particular level was set in the knowledge that it was just one of the pieces of the jigsaw we were trying to put together. I think that it's important that it wasn't the single thing on which everything was hinged. (B2695) (See also B2711, 1)

31. Dr Medley however frankly acknowledged to Professor Duggan that for the first half of the review period there were considerable difficulties with a lack of information stating:

I would not believe that this review could reassure you about the years of 1991 to 1996 in a wholehearted manner.

32. On the other hand while unacceptable under-reporting could not be ruled out, a laboratory practising like GLL would have been clearly identified as an outlier. GLL was not one of the 17 laboratories included within the NLR but information about GLL was included in the NLR Final Report (exhibit JD/HFA/001) for comparative purposes. A summary of the comparison is made at page 34 of that exhibit:

In summary, the Gisborne laboratory was below the practice review's high grade benchmark in 1994/95 and below the total abnormality benchmark throughout 1991-95. 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.

Also, an understanding of all the other community laboratories' practice in cervical cytology has been obtained via the questionnaire. It is understood that a feature of the Gisborne laboratory during the period 1991-1995 was that a sole pathology practitioner was "primary screening" the smears and that there was minimal internal quality control.

33. GLL was clearly identified as an outlier from the preliminary analysis right through to the above statement in the NLR final report:

HFA Report dated 27 October 1999:

Gisborne 1994/95 (GL) represents Dr Bottrill's reporting which is the smallest rank for both *high-grade %* and *low-grade %*. This gives some assurance that any other potential problems are unlikely to be as extensive as the HFA's Gisborne Investigation. (Exhibit JD/HFA/002, p007).

Evaluation Panel Report dated 2 March 2000:

The first step was to analyse the cervical cytology abnormality reporting rates for all laboratories, from the records held on the National Cervical Screening Register. Although this identified Dr Bottrill's Gisborne laboratory as an "outlier", it did not provide enough evidence to gain assurance about the practice of

reporting of abnormalities in other New Zealand laboratories.
(Exhibit JD/HFA/006, p069)

First Advisory Group meeting on 27 March 2000 – “Comparison with Gisborne”:

It was also noted that Gisborne can be identified as an outlier in some key areas, and that the information available to the meeting does not suggest that any other laboratory is likely to demonstrate a similar pattern of under-reporting. These key areas are:

?? Dr Bottrill was acting as a primary screener, whereas in all other laboratories primary screening is and has been done by a screener and not a pathologist.

?? Prior to 1996 (the period that Dr Bottrill was practising) the total abnormality reporting rate for Gisborne was the lowest, and the high grade abnormality reporting rates were among the lowest.

?? Gisborne is the only laboratory reporting such low rates of abnormalities for an area of such high incidence / high risk demographics (high proportion of Maori women) (Exhibit JD/HFA/007, p182).

34. The matter of the review having the capability to identify Dr Bottrill's Gisborne Laboratory as an outlier was raised with Mr DuRose (B/2228-2231).

Ms Janes: Mr DuRose can I take you to page 34 of Exhibit 1 please which are the results for Gisborne Laboratory and it indicates that the abnormality rates for 91-93 high grade was 0.67 so that was above the benchmark wasn't it?

A: It was again for data that we didn't put a lot of weight on.

Q: But assuming that you had received the same data on the same self reporting basis as the other laboratories, this would have been the accepted high grade rate?

A: No we would have looked further because 94/95 was 0.49%.

Q: And the total abnormality rate was 3.0 both in 91 to 93 and 94/95?

A: Yes.

Q: Based on the correlation of the statistics in Dr Boyd's 29 and P14 of yours, what reliability can the committee place on the statistics because on a superficial look Dr Bottrill's laboratory would not

have been a significant outlier either in the current review, given there's been on follow-up obviously and that's got to be subject to that, but just taking it at face value, the statistics in the current review, how reassuring can they be for the panel in that there are significant variables that may or may not have been taken into account.

A: The Gisborne Laboratory would have been followed up based solely on the fact, if nothing else, if no other information was there and you apply this review that we did to those figures, they would have been followed up based solely on the fact that they were below the benchmark with .49, the total abnormalities were the lowest throughout, and they were in an area of incidence that was 30/100,000, the second highest in the country.

Professor Duggan: Now if we take Dr Bottrill's laboratory as an example, his indicators are acceptable?

A: No they're not, he's below the benchmark for 94/95 and he would have been followed up based on this review without knowing anything else.

Q: He's within the range however?

A: No, he's not with the range, he's below the benchmark of 0.5% for high grades and would have been followed up. We did not exclude anybody based on any other indicator if they fell below that high grade benchmark for any time period 1994 onwards.

Q: He had a rate of 0.49.

A: He would have been followed up. Anybody who fell below that, to find out and understand it, we would factored in even more so the fact that this happened, it was happening in an area where the incidence is so high.

Q: So, the figure of 0.5 is an absolute?

A: That figure was an absolute for this review.

35. There was considerable interest by the Inquiry Panel in how the benchmark for abnormality reporting rates was set. The review's Evaluation panel agreed to these benchmarks when they met on 15 February 2000 and acknowledged that they could have been set higher:

The Panel discussed the fact that the 0.5% benchmark for high-grade abnormality could have been set at a higher rate especially during the early 1990s when the NCSP commenced. However it was considered important to identify laboratories that were reporting outside these benchmarks. This approach also

recognises the absence of any specific standards or targets in New Zealand. Due to the possibility of variable reporting to the Register and possible inaccuracies of translation of results into correct Bethesda codes, 5% was regarded as an appropriate minimum reporting rate for Total Abnormalities. This encompassed all categories of abnormality, so as to minimise the influence of incorrect categorisation of individual grades of abnormality for the Register. (Exhibit JD/HFA/006, p071)

36. Dr Medley further explained the rationale behind setting the high grade reporting benchmark at 0.5% (B2656):

Q: An additional area is that 0.5% benchmark for high grade and I believe you were present when Dr Cox and Professor Skegg addressed that. Would you care to comment on their concerns about setting the rate at that level?

A: Well as I've already said I think setting it at the level was done because that was the approximately level at which Dr Bottrill was operating and in this one piece of this gathering of evidence we were trying to identify whether there was another laboratory which was operating at that level.

Q: You set the bar deliberately low for this?

A: No it was not the purpose of this review to set a standard for the future and I'm not commenting on the standards that have been set in the draft standards document. In Australia the standard is .5 but I totally accept what Dr Cox and Professor Skegg have said about the different demography of New Zealand but for the purposes of this exercise it was set not deliberately low but set to try and ascertain if there were areas of comparable practice in this one indicator. This is not to say that this was necessarily the desirable standard or the correct standard ...

Q: Do you have some concern that it might have been set too low?

A: I think for the purposes of this exercise probably not. I was just glancing at the graphs to identify whether it would have been very different if we'd set it .1 or .2 higher and I suspect we would probably not, I haven't looked in detail, it wouldn't have made very much difference to what we did. I think it's an exercise that can be gone through for interest but I think it would make very little difference.

37. The HFA also took actions to minimise potential confounding factors with respect to the reporting rates and other data (exhibit JD/HFA/002, page 006). In completing its preliminary analysis the HFA obtained women

specific smear results from the Register for the period 1996-98 by accessing the highest smear only and then the last smear only per woman. These data sets are displayed on page 22 and 23 of Exhibit JD/HFA/002. These reporting rates at woman level did not result in significant change to how laboratories compared with one another in their reporting rates of smears and this supported the use of reporting rates as one indicator of laboratory performance for the purpose of the review.

38. As stated by Dr Medley:

I gather the actual ranking if you would call it that or the relationships of the laboratories one to another are not changed at all by that process so that in fact converting smears to women which was done subsequently showed no significant change in the patterns that evolved. (B/2712)

39. The fact that some laboratories read hospital smears was factored into the review by gathering this information through the questionnaire (Exhibit JD/HFA/003, p043) and this was in turn factored into the decision making of the evaluation panel.
40. The preliminary analysis was also adjusted for age or ethnicity.

However, the preliminary analysis of reporting rates data was subjected to indirect standardisation for both age and deprivation and these factors “only explained a small amount of variation between laboratories, <10%” (Exhibit JD/HFA/002, p006).

41. Dr Medley also clarified why a benchmark couldn't be set for the cytology/histology correlation data for 1996-98 and that it was “dangerous” to do so with this data.

Firstly, we didn't really have a comparable correlation for the different periods, we only had one period to look at. It was, if you like, a sort of “snap-shot” of correlation. We were aware that the correlation depends very heavily, in fact totally, on two lots of referral to the Registry and two lots of accessing data. Firstly, accessing the data from the laboratories in terms of cytology reporting; and then secondly, accessing the data to the laboratory for histology reporting. We were aware that the accessing of that data was not totally able to be relied on, but there were quite considerable time lapses and I think for that reason it was more used as a guide, as perhaps a helpful

indicator but no specific benchmark was set for it. I think that to actually pin a very specific number on to something that you know has perhaps some doubt in the way that the figures have been obtained or that the figures can be obtained, I think is quite dangerous. (B/2696/7).

42. Therefore a reasonable conclusion on the “isolated case” issue we submit is that although unacceptable under-reporting during the last decade in other parts of New Zealand cannot be ruled out Dr Bottrill’s substandard method of practice was an isolated case.
43. We submit that by drawing out this distinction between “unacceptable under-reporting” and Dr Bottrill’s method of practice the Inquiry can derive considerable assistance from the NLR that is not apparent if the excessively critical stance of counsel assisting is adopted.

Identification of Systemic Issues for the NCSP

44. In addition to the NLR’s value in demonstrating that no other laboratories practised in the same manner as Dr Bottrill’s the Review also assists with confirmation of systemic issues relevant to the NCSP. Although the NLR did not include hospital laboratories this is not a significant omission as the 17 private laboratories encompassed by the review reported 94% of cervical cytology (DuRose brief para 11).
45. The NLR identified five laboratories that had been providing information for the NCSR based upon Bethesda coding errors. One of these was for histology and the others for cytology (JD/HFA/001 pp34-62). These five could have been indicative of a wider problem of data integrity for the NCSR. The coding errors discovered by the NLR would not have been detected by the Cox/Richardson evaluation. Professor Duggan asked Dr Cox about this:

Q: In the event that you may have missed this Mr DuRose in his brief of evidence informs us that a number of the laboratories had coding errors in their data, that is the cytological report or diagnosis if you will is assigned a code and then that information

is transferred to the registry and we do not yet know who is responsible for checking the accuracy of that data in terms of its coding. My question to you is would your study have identified that problem?

A: No we were particularly looking at what was on the register and what was on in terms of the fields and information on the register could be used to provide more information than was currently being produced through the annual statistical reports, etc, so that was more the focus of that. (B/2629)

46. There was also considerable variability in laboratory practices discovered over the nine year period reviewed – such as the introduction of rapid slide review procedures for internal quality assurance. A one page summary of the results of the review is at exhibit JD/HFA/001, p14.
47. Further, it is of concern that the practices of six laboratories required further clarification:

As a result of the preliminary conclusions reached by the evaluation panel, the multidisciplinary advisory group considered the available information from six laboratories in total, three with respect to current practice (1999) and three with respect to past practice. The main issue with all of these laboratories was that the rate of reporting abnormalities during some period had been outside either of the benchmarks set by the evaluation panel. Some of these laboratories were also asked to give further clarification to their previous response to the questionnaire in addition to being invited explain the situation when a benchmark has not been met. (JD/HFA/001, p006)

48. All of these laboratories did subsequently provide further data for reporting rates and procedures. They have either undertaken specific projects or made changes to some practices as recommended by the Advisory Group. It can be seen from this further data five out of the six laboratories, (c, L) (e, K) (g, G) (i, M) and (m, P) ultimately met or exceeded the high grade benchmark of 0.50% from 1994 (JD/HFA/001, p034-062). That leaves just one laboratory (a, E). It was just below the benchmark in the past and services an area of lower incidence of cervical cancer.
49. However, having six out of seventeen laboratories identified with concerns that required explanation and clarification could be considered as an

indicator of a systemic issue. Also, a further six laboratories, (b, A) (h, I) (j, C) (l, F) (o, N) and (p, O) received specific suggestions to consider from a quality improvement perspective (JD/HFA/001, p034-062). One of these (p, O) subsequently clarified that they had in fact employed a cytotechnologist (B/2277).

50. The NLR does therefore tend to confirm the principal systemic issues that arise out of answering TOR2. That is, the major systemic issues that have to be remedied for the NCSP in future:
 - 50.1. Implementation of comprehensive NCSP quality standards across the full screening pathway but specifically including smear reading and reporting;
 - 50.2. A system for mandatory accreditation and auditing against the comprehensive quality standards;
 - 50.3. Comprehensive performance indicators of an internationally acceptable standard and specifically including benchmarks for measuring laboratory sensitivity;
 - 50.4. Routine monitoring of laboratory performance indicators to detect if a laboratory's performance is falling below established benchmarks and quality standards;
 - 50.5. Routine evaluation of all cases of cervical cancer to determine whether the screening programme is failing at any point along the pathway.
51. The fact that not all of these elements have been applied to the Screening Programme since its inception in 1991 and that many are still not in effect today necessitates a risk assessment of whether there could be concerns for the health of women in other parts of New Zealand.

Risk assessment about whether historical systemic issues raise concerns for women's health today

52. Obviously this issue has been the focus of all the HFA's work firstly in relation to Gisborne and then nationally. Some reassurance in this regard can be obtained from the results of the information provided by the laboratories themselves in response to the NLR questionnaire as summarised in Exhibit JD/HFA/001 (page 13):

Key points from questionnaire responses about the standard of cervical cytology in New Zealand community laboratories during 1990 – 1999 include:

- ?? **All of these laboratories had screener(s) in place and there is no indication of any pathologist performing primary screening.**
 - ?? **All have been using some form of rescreening since 1992 and all attempt to feedback to screeners errors on individual cases.**
 - ?? **As of 1999 all but one laboratory was undertaking 100% rapid review rescreening for internal quality control.**
 - ?? **The pathologists in all laboratories are reviewing the majority of abnormal smears.**
 - ?? **All laboratories have been registered as accredited by Telarc (IANZ) since 1995 and all have participated in the RCPA cytology QC Programme since 1995.** (Note that Mr DuRose clarified that all these community laboratories were accredited in cervical cytology by February 1996 (B/2162-B/2163))
53. This basic factual information produced by the NLR is unaffected by Professor Skegg's criticisms about methodology. While unacceptable under-reporting in the early 1990s cannot be excluded, provided women responded to the NCSP's three yearly recall for repeat smears the NLR provides reasonable assurance that any abnormalities that should have been detected would have been detected after 1995 (subject to the usual problem of false negatives that occurs in all laboratories).
54. It is also important to note that during 1994/95, a time period that Dr Bottrill was practising, another New Zealand laboratory (code o, N) had a high grade reporting rate of 2.28% (exhibit JD/HFA/001, p060). This is similar to the 2.5% high grade rate from the Sydney re-read of Dr Bottrill's

Gisborne Laboratory's work. This was in a region that had an incidence of cervical cancer higher than the national average in 1990-95. Therefore the Sydney re-read rate is not that exceptional as there is one laboratory with a similar high grade reporting rate to the Sydney re-read during the time Dr Bottrill was in practice.

55. The plain fact of the matter is that the NLR established that Dr Bottrill's extremely poor level of practice was an isolated case and that after February 1996 all smears read in private laboratories would have been subject to Telarc (IANZ) accreditation procedures and the RCPA Cytology QA Programme.
56. Even prior to 1996, many laboratories reading cytology were voluntarily Telarc accredited and so complied with the quality assurance measures intended to apply to the Programme at that time – see Walker, exhibit 1. These included the 1990 recommendations of CALC, adopted by Telarc in 1991 (GRB/MOH/022) and important aspects of the 1995 standards by CSLAC (GRB/MOH/025 and affidavit of Walker, para 8). Those laboratories that were not Telarc accredited would nevertheless have been familiar with the standards as part of the consultation that took place during their development. Earlier standards adapted for New Zealand by a sub-committee of the New Zealand Society of Cytology and New Zealand Society of Pathologists (the Fitzgerald Committee Standards) were also the subject of extensive discussion among the members of these groups in the late 1980s (GRB/MOH/019 and Dr Teague at B/1401 and ff).
57. Counsel assisting's final submissions at pp105-107 summarise the evidence of Messrs Robertson, Walker, Linehan and Beer to indicate that although Telarc (IANZ) accreditation was not an absolute guarantee of confidence it built in numerous safeguards and it was a requirement of accreditation that the laboratory also participate in inter-laboratory proficiency testing such as that offered by the RCPA QA Programme.
58. Mr Hindle asked professor Davies about the Royal College's QA Programme starting at B/1193. In particular Professor Davies explained:

The external quality assurance programme consists of circulated slides that are distributed about four times a year I think, about five slides, and these are plugged in to the normal days work and treated in a similar than not identical way. Firstly they are stain smears so they don't check the staining by the laboratory, that's checked in a separate process and all of the cytotechnologists will screen all of the slides and they will all score their results and they are likely to be also looked at by the cytopathologist. Then the individual scores that they have on these are sent by facsimile to the offices of the QAP Pty Ltd who will fax back the target values, that is the right answers, to the laboratory while they still have the slides and then they will check off their performance, so this performance will be held synchronously by the performing laboratory and also centrally and of course their performance over a year is aggregated and published as the final annual report for the laboratory and also of course put together in the total report for the system so that it's in outline. I'm not quite sure how that resembles, it's probably fairly similar, to most of those systems used internationally. (B1196-1197).

59. Professor Davies went on to explain how this is linked to the system of accreditation:

The information is held in confidence by QAP Pty Ltd and by the laboratory but when the laboratory is inspected for the purposes of accreditation it has to be disclosed to the inspectors its performance in not just cytology but everything so one of the major activities of the inspectors for accreditation is to review both the internal and external quality control programmes of the various laboratories and see that they are performing satisfactorily. (B/1197)

60. An example 1998 Annual Report of the RCPA Quality Assurance Programme was produced as Dr Teague exhibit 2. Page 2 of that report includes a table showing that by 1998 27 New Zealand laboratories were participating in the RCPA QA Programme.
61. The intent of the HFA's Final Report of the NLR was to summarise the entire review, not just the work of the Advisory Group. It was unfortunate that the Advisory Group did not get the opportunity to discuss fully the final Report, especially the executive summary, which had been circulated as a draft on 23 June (Exhibit JD/HFA/010, p271). However, the HFA's evidence was due soon thereafter and this caused significant time pressure.

62. The Advisory Group did provide the consensus decisions and recommendations for the 6 laboratories as detailed from page 035 in JD/HFA/001. The information provided for these laboratories in this part of the Final Report (JD/HFA/001) came directly from the minutes of the four meetings held with the Advisory Group (JD/HFA/007, 008, 009 and supplement to 010).
63. All these decisions and recommendations had been reached by the Advisory Group by their last meeting held 28 June 2000. The HFA was implementing these actions with laboratories and some were still in progress at the time Mr DuRose gave evidence.
64. For example, the corrected figure for laboratory (a, E)'s histology/cytology correlation had not been calculated because the Register had not had the opportunity to input the correct data supplied from the laboratory. The HFA can now inform the Inquiry that this has been done and that (a, E)'s histology/cytology correlation analysis for 1996-98 as used in the practice review is updated as follows:
- Histology/cytology correlation:** **70%** laboratory's high-grade squamous cytology confirmed as high grade squamous lesion on histology. (previously 27%)
- 85%** laboratory' high-grade, low-grade, squamous cell carcinoma cytology (squamous) confirmed as a squamous lesion on histology. (previously 55%)
- (Confirmation by affidavit can be provided)
65. Dr Medley was satisfied that the Review had probably gone as far as it could; it would be a huge waste of public money to embark on a further slide rereading and it was time to draw a line in the sand (B/2715).
66. Overall therefore both the HFA and the Inquiry can have a reasonable level of confidence that at least since 1996 laboratory practice in New Zealand has been conducted at an adequate standard and that by now most women on the Programme will have already had at least two smears read by Telarc (IANZ) accredited private laboratories.

Transition to the new operational policy and quality standards for the NCSP

67. It follows from the last submission that current laboratory practice should align reasonably well with the new Operational Policy and Quality Standards and this was the conclusion of the NLR. The Final Report included a comparison of current practice identified in the review against the draft NCSP standards (JD/HFA/001, pp15-20). This information was provided to all the laboratories included within the Review together with an individual feedback report for each laboratory that included:

?? The data for that particular laboratory identified during the Review;

?? Generic and in some cases specific practice suggestions;

?? Detailed comment on their response to the questionnaire prepared by Dr Medley recognising the collated comments from all the assessors (DuRose brief, para 24).

68. In providing feedback to the laboratories and linking their current practice in 1999 with the then draft NCSP standards a recommendation was made to the laboratories as follows:

1. For each laboratory to review their current practices in cervical cytology and consider possible implications to their own practice in relation to:

?? Appropriate current practice identified from this review;

?? Their specific questionnaire feedback compiled from the assessors;

?? The proposed draft standards of the NCSP;

Explanation: This represents an opportunity to incorporate the results of this practice review and to consider current practices in relation to the proposed Policy and Quality Standards for the NCSP (JD/HFA/001, p15).

69. Dr Medley highlighted that one of the more important results of the practice review was that the interactive process helped establish a relationship between the HFA and the laboratories:

... I think it has to be realised that this review really was a very interactive review. I think in many ways that's a good part of its value that it has established a relationship between the system and the laboratories which became an ongoing relationship so that when there were doubts these were expressed back to the laboratories, the laboratories had the opportunity to provide data and I think that this interaction between the system and the laboratories will probably in the long run turn out to be one of the most valuable results of this process because given that we are about to see standards introduced there's always a great deal of paranoia among laboratories when anybody is going to impose standards, but I believe that this process that's gone out will make them really quite grateful for the opportunity to have specific standards to work to and having developed this relationship with the system and having had the opportunity to feedback problems with the system that they believed prevented them achieving their best performance I think is going to be one of the most important outcomes of the process. (B2698)

70. Significantly an almost final word by Dr Medley was:

... I think a review such as the one that we've had, though it may not be able to completely alleviate the anxieties, will have played a significant role in initiating better practice in laboratories for the future. (B2733).

71. This leads in naturally to our submissions on TORs 4, 5 and 6 and the work of Dr Peters and her team which, when implemented, will overcome the systemic issues arising out of the Gisborne situation and greatly enhance the quality and integrity of the Programme overall, ie beyond the scope of the Inquiry's immediate focus.

TERMS OF REFERENCE 4, 5 AND 6:**TO IDENTIFY CHANGES ALREADY MADE ... OTHER CHANGES AGREED TO BE IMPLEMENTED ... AND RELEVANT PROPOSALS THAT COULD AMELIORATE RISKS OF UNDER-REPORTING****Introduction**

72. Our submissions on Terms of Reference 2 and 3 have addressed the considerable changes that would have ameliorated the risks of under-reporting since the early days of the NCSP when Dr Bottrill was practising. In summary:

72.1. In 1993 the opt-off legislation resulted in a substantial increase in data volumes on the Register and the addition of histology (increasingly from 1994) in order to facilitate correlation with cytology;

72.2. In 1997 the 14 regional registers were reconfigured into a national one to greatly improve the accuracy and utility of the Register information;

72.3. In 1996 a high quality updated national policy for the NCSP was approved by the Minister;

72.4. All private laboratories in fact attained Telarc (IANZ) accreditation in cytology by 1996;

72.5. In 1995 and 1996 provider contracts replaced the basic s51 Notices to make laboratories accountable for quality assurance as a condition of payment;

72.6. Telarc accreditation became compulsory through the RHA provider contracts in the Central Region in 1995 and in the Midland Region by the end of 1996;

- 72.7. Accreditation carried with it the requirement for participation in external quality assurance programmes such as the RCPA QA Programme;
- 72.8. The accreditation process involving Telarc (IANZ) included the application of the draft General Medical Standards for Diagnostic Laboratories (the Sax standards), the 1991 CALC cytology standards and other cytology standards, some of which are noted in the affidavit of Mr Walker at para 8..
73. In addition a new Medical Practitioners Act was enacted in 1995 coming into force on 1 July 1996 providing among other things for ongoing proficiency assessment. Complaint procedures were greatly enhanced by the Health and Disability Commissioner Act 1994 and the Code of Health and Disability Services Consumers' Rights (SR1996/97). These and other proposed legislative changes are dealt with in more detail below.
74. Dr Peters' evidence then picks up the chronology of developments since 1998. In that year the Ministry's responsibilities for the NCSP were transferred to the HFA. This paved the way for Dr Peters' appointment as a public health specialist to manage the Programme, increase its financial and human resources and commence a top-down review.
75. The work of Dr Peters and her team has been in the process of completion and implementation while the Inquiry has been in progress. This has required Dr Peters to produce serial evidence as follows:
- 75.1. Initial brief of evidence covering the period April 1998 to 13 March 2000 including three volumes of exhibits nos. JMP/HFA/001-038;
- 75.2. A supplementary brief of evidence covering developments during the period 13 March 2000 to 16 June 2000 and a fourth volume of exhibits nos. JMP/HFA/039-048;
- 75.3. Oral evidence on 4,5 and 6 July;

- 75.4. Answers to specific questions by the Inquiry provided by way of affidavit, sworn on 27 July 2000;
- 75.5. Further oral evidence on 1 and 2 August 2000.
76. As all this evidence covers changes already made, in the process of being implemented as well as changes agreed to be implemented the main points of this evidence are summarised under Terms of Reference 4,5 and 6. Further developments since Dr Peters last gave evidence will need to be traversed in a further affidavit from Dr Peters as close to the Inquiry's reporting date as practicable.

Transfer to the HFA

77. Dr Peters produced the formal legal documents transferring responsibility for the NCSP from the Ministry to the HFA including an instrument by the Director-General of Health appointing the HFA to maintain the NCSR pursuant to s74(A)(1) of the Health Act 1956 (Exhibits JMP/HFA/003, 004, 005).
78. Notwithstanding the transfer the Ministry maintained its role of providing policy advice to the Minister and responsibility for monitoring the HFA with respect to the NCSP and responsibility for servicing the national Kaitiaki Group (Peters' first brief, para 52).
79. Dr Peters also produced two letters clarifying that the planned Cox/Richardson national evaluation of the NCSP would remain a Ministry responsibility while the HFA's work would be forward-looking (JMP/HFA/007).
80. The then National Coordinator, Di Best, as well as the two Register staff, Sandy Macham and Philip Saysell, both transferred to the HFA. Rather than relying on a single Coordinator for the NCSP a manager, two co-ordinators, one Maori and one non-Maori, two FTE project officer analysts and a half time support Coordinator were appointed between July and

December 1998 with responsibilities for managing both the cervical and breast screening programmes. In other words there was a change from a national Coordinator approach to a team concept (Peters' first brief, paras 70-73).

81. Although the transfer of the Ministry's responsibilities for the NCSP to the HFA was intended to alleviate fragmentation of the Programme that had occurred in the past there was still a considerable division of functions for the Programme between the public health and personal health operating groups within the HFA (Peters' first brief, paras 75-85). Nevertheless the transfer to the HFA and the appointment of Dr Peters in November 1998 in particular was consistent with the first WHO guideline for effective cervical screening programmes, namely:

a central office or individual responsible for planning, co-ordinating and monitoring and evaluating the programme. (Peters' first brief, para 90)

82. While there has been much criticism of the Programme during the time it was managed by the Ministry, Dr Peters points out that one of the most important features of a successful Programme is achieving high levels of enrolment and coverage among the eligible population. Dr Peters produced the latest monthly statistics from the NCSR to show enrolment rates of 91% and 5 year coverage of 85% (JMP/HFA/013) stating:

These rates are an indication of the commitment of those who have worked in the Programme over the past decade. (Peters' first brief, first para 92).

HFA Review of NCSP

83. The HFA's review of the Programme began with a study by Dr Robyn Whittaker (JMP/HFA/015) followed by the development of a framework for population-based screening programmes (JMP/HFA/016). The purpose of the framework was to ensure consistency in managing both the breast and cervical screening programmes. It also provided a broad strategic direction for both programmes based on, among other things, the

WHO Guidelines. This internal analysis then led to co-ordination meetings with providers and a hui with Kaimahi in February 1999. (Peters' first brief, paras 105-109).

84. This initial work raised concerns about some key aspects of the Programme, in particular:

84.1. Lack of detailed mandatory operational policies and quality standards;

84.2. Absence of sufficient ongoing monitoring and evaluation linked to quality improvement processes;

84.3. Divided roles and responsibilities within the HFA.

85. The decision had just been taken to give priority to these areas when at about the same time (29 March 1999) the Gisborne situation came to the attention of Dr Peters' team via a letter from Stuart Grieve QC. (Peters' first brief, paras 110-114).

86. As the Gisborne situation unfolded and Tracy Mellor in the Personal Health Operating Group at the HFA managed the HFA's response, Dr Peters, in the Public Health Operating Group, launched several substantial review projects which commenced with the injection of \$1.4m to strengthen the Programme. (JMP/HFA/019).

87. Three broad projects were defined:

87.1. The NCSP project

87.2. The Strategic Project

87.3. Other operational tasks

(Peters' first brief, para 119).

88. The NCSP project was subdivided into four sub-projects:

88.1. Operational Policy and Quality Standards;

88.2. Evaluation and Monitoring;

88.3. Public Health;

88.4. Information Management.

Operational Policy and Quality Standards

89. The policy and quality standards sub-project aimed to develop detailed operational and quality standards for all aspects of the screening pathway. Dr Peters produced a first draft of this manual as JMP/HFA/020. When the litigation with the Midland private laboratories was settled in March this year with agreement to increase the cervical cytology fee to a national figure of \$21 the opportunity was taken to incorporate those draft standards into the contractual arrangements with the private laboratories nationally together with the draft General Medical Standards for Diagnostic Laboratories (the Sax standards) (see Tracy Mellor's supplementary brief of evidence at paras 28 to 38 and also Dr Peters at B/236-7).
90. Between the time that her initial brief of evidence was prepared and the time she came to give evidence Dr Peters and her team had completed consultation on the first draft of the manual and with her supplementary brief of evidence was able to produce an updated draft of the Policy and Quality Standards Manual as JMP/HFA/040. This document contains chapter 5 specifically relating to quality requirements for laboratory services setting out 21 proposed standards consistent with the European Guidelines (B/3438-B/3450).
91. The intention is that these new Operational Policy and Quality Standards for the NCSP will be applicable for an initial twelve month period so that they can be tested, strengthened or modified based upon actual experience (Peters' supplementary brief, para 6). The process of implementation of a further development of the manual since Peters' exhibit 40 is under way at present (October 2000). Minimum volumes of smears per laboratory have been set at 15,000 per annum with additional minima for primary screeners (3000 slides per annum) and for pathologists (500 abnormal slides per annum).

92. When Dr Peters was recalled to give evidence on 1 and 2 August there was protracted discussion about the extent to which draft policy and quality standards and the “Sax standards” could be made legally binding. (B/3289-B3309). Dr Peters confirms that she was not involved in the contractual side and that she would not seek to enforce the minimum smear volumes until the operational and quality standards had been finalised. The Inquiry was pressing for certainty about how the performance indicators could be made binding. It is submitted that the questioning of Dr Peters on this topic became complicated because the distinction between the standards and the performance indicators was not always clear.
93. Ensuring compliance with the standards (JMP/HFA/040) would require an auditing process, ie site visits to laboratories. On the other hand performance indicators were simply targets and non-compliance with them would not of itself indicate a breach of contract. Rather the failure to meet targets would be detected by the independent monitoring group and this would be a basis for inquiry as to whether or not there was a failure in some part of the Programme. Dr Peters confirmed that the only contractual requirement in relation to the performance indicators was that the laboratories had to be contractually bound to participate in monitoring. (B/3306).
94. When Dr Peters continued giving evidence on 2 August the issues about implementation of the two sets of standards documents arose again. There was concern from the Inquiry about identification of the two documents. It is submitted the position is as follows:
- 94.1. The draft Cytology Standards 2000 document referred to in the laboratory contract variation document of 7 March 2000 (TM/HFA/089) is a reference to chapter 7 of the first draft of the Operational Policy and Quality Standards Manual exhibit JMP/HFA/020 and this would incorporate the updated draft of that manual produced as exhibit JMP/HFA/040 – see chapter 5;
- 94.2. The reference to National Quality Standards for Medical Testing Laboratories 1997 in the 7 March 2000 laboratory contract variation

document (TM/HFA/089) is a reference to the “Sax standards” document draft version dated 10 June 1997.

95. The Inquiry was also concerned about the procedures for auditing compliance with these two sets of standards. With regard to the Operational Policy and Quality Standards Dr Peters’ work had not progressed to the point of clarifying who would carry out site visits to establish compliance with those standards as she and her team were giving priority to contracting with an independent monitoring group to monitor the performance indicators (B/206). With regard to the “Sax standards” the affidavit of Mr Walker from IANZ has now clarified (para 14) that the draft National Standards version dated 10 June 1997 with a few minor amendments have been formally adopted to apply for IANZ accreditation purposes as from 1 January 2001.
96. In view of the Inquiry’s need for certainty about these matters for the purpose of writing its report the position summarised here will be confirmed in the update affidavit foreshadowed during the hearings (B/3384).

Evaluation and Monitoring

97. The second major NCSP sub-project is on evaluation and monitoring:

This is necessary to ensure that the overall benefits of the screening programme are greater than the attendant risks and that the programme remains a cost effective use of health resource (Peters’ first brief, para 135).

98. With her first brief Dr Peters produced a draft evaluation and monitoring plan (JMP/HFA/023) with a proposal for developing an independent monitoring group and a proposal that the national performance indicators cover such things as enrolment and coverage rates, incidence and mortality rates and programme sensitivity as well as specific laboratory colposcopy and smear taking indicators. The proposed laboratory indicators were

based upon a review of the international evidence (Peters' first brief, paras 136-140).

99. Again, by the time Dr Peters came to give evidence this work had progressed through an extensive consultation stage summarised in JMP/HFA/042).
100. In her supplementary brief Dr Peters explained the objectives of the monitoring process intended to be implemented (para 18):

The proposed monitoring process will provide regular, overall programme information, for example, enrolment and coverage rates, and detection rates of various cytological abnormalities per 1000 women screened by region, age and ethnicity. However, it will also be possible, using information currently collected by the NCSR, to monitor certain aspects of provider quality. For example it will be possible to correlate individual laboratory reporting patterns against the demographic and coverage of the populations they serve. Using the date of receipt of histology information on the NCSR and correlating this with the date of receipt of the index abnormal smear report will enable some information to be generated regarding timeliness of colposcopy and completeness of follow-up. The monitoring reports which will be generated as a result of this process will provide vital information by which to assess the quality of the Programme and early indications of possible lapses in quality which require further exploration.

101. One of the exhibits that was put to Dr Peters on several occasions was JMP/HFA/018 being the Public Health Operating Group's "Non-discretionary Project" to obtain funding and develop the NCSP. In particular that exhibit stated:

Since the Programme was established as a result of the Cervical Cancer Inquiry at National Women's Hospital (1988), there have been no national quality standards developed, little monitoring or evaluation carried out and no strategic review of programme configuration or direction.

102. Dr Peters agreed this was the position but possibly a little overstated (B/230) and that the four statistical reports also needed to be taken account of (B/367-B/378). Further, although initially Dr Peters stated that there were no quality standards in place when she became Manager of the

Programme (B/390) later when she gave evidence on 2 August Dr Peters acknowledged she had been a little harsh because she had not been aware of the 1991 and 1995 cytology standards and some of the evaluation reports done on specific aspects of the NCSP (B/3367). Also, Dr Peters had not taken account of the “Sax standards” (B/357).

103. But Dr Peters did not resile from her general concerns about the situation pointing out that there were no comprehensive Programme standards for the whole screening pathway and that there had never been a comprehensive evaluation of the Programme including a clinical audit, ie she had not seen the sort of reports required for detecting potential failures within the Programme (B/378 and B/3407).
104. While Dr Peters acknowledged that there may be some delay in auditing laboratories against the new Operational Policy and Quality Standards (B/3370) there was not expected to be any delay in implementing monitoring against the performance indicators. Further, this type of monitoring is not affected by any legal problems to do with s74A of the Health Act because it does not involve the monitoring group inspecting women’s identifiable information (B/204 and B261).
105. In fact this work has further progressed since Dr Peters gave evidence to the stage where the performance indicators have now been finalised and the contract let to Dr Brian Cox of the University of Otago to lead an independent monitoring group. It is expected that the group’s first monitoring report will be available shortly after the end of the first quarter next year. Also this is only preliminary implementation:

The second stage of this work will involve establishing a framework and processes by which all the other aspects of comprehensive monitoring, audit and evaluation can be developed in a robust and systematic way. This will include all providers involved in the Programme. Monitoring compliance with many of the proposed quality standards will only be possible through an audit process. Planning for this developmental work has commenced. (Peters’ supplementary brief, para 19).

106. As work on the monitoring and evaluation sub-project has proceed apace since Dr Peters gave evidence on 2 August these developments will be covered in the update affidavit to be filed with the Inquiry in November.

Public Health and IM Sub-projects

107. Dr Peters' first brief and her supplementary brief also covered the intensive activity carried out on these two other major NCSP sub-projects. This work probably goes into much broader NCSP issues than the Inquiry can realistically encompass within its terms of reference – see for example exhibits JMP/HFA/043 and 044. However, the draft review report of the IM environment was produced to the Inquiry at the request of Professor Duggan (JMP/HFA/057) and this does tend to confirm some of the systemic issues relating to the importance of consistent data being entered into and available from the NCSR.
108. Professor Duggan did persuade Dr Peters to upgrade the priority of the NCSR Register Strategic Review in the list of priorities that Dr Peters gave in evidence, namely:
- 108.1. Finalise and implement the National Policy and Quality Standards;
 - 108.2. Finalise the performance indicators and establish the independent monitoring group;
 - 108.3. Unbundle service volumes for laboratory and colposcopy from personal health contracts and transfer these to the control of the Public Health Operating Group;
 - 108.4. Maintain the integrity of Dr Peters' team;
 - 108.5. Complete a strategic review of the NCSR;
 - 108.6. Produce a detailed brochure about the Screening Programme for Women (this is set out at B/3406 and at B/3421 Dr Peters agreed to insert the Register Review as priority item no. 5).

109. In general terms the evidence relating to the Public Health and IM Sub-projects demonstrates the extraordinary lengths to which the HFA has gone in order to elevate the quality of the NCSP to the highest possible standards. The HFA itself however realises that this work will not deliver results unless it is actually implemented and this led to the development of a separate strategic project to manage the implementation process through yet another round of health restructuring.

Strategic Planning for the NCSP

110. Dr Peters covered this topic initially in paras 164-176 of her first brief. Essentially the strategic project for the NCSP was necessary and had to be brought forward because of:
- 110.1. Proposals for further health sector restructuring; and
 - 110.2. A developing consensus among HFA staff that the existing division of roles and responsibilities made it difficult to manage and plan for the NCSP in total.
111. In particular the division of roles and responsibilities between the Personal Health and Public Health operating groups had become a matter for public discussion and criticism by Professor Skegg and Sandra Coney and Dr Cox also specifically raised the issue in a letter to Dr Peters dated 3 May 1999 after the Gisborne situation became known (JMP/HFA/027).
112. Although an MOU had been developed between the two relevant operating groups within the HFA (JMP/HFA/029), this was not seen as sufficient. A proposal was developed to transfer the Personal Health Operating Group functions to the National Prevention Team in the Public Health Operating Group including the unbundling of personal health contracts and funding. The importance of this occurring was set out in a briefing paper to the HFA Chief Executive (JMP/HFA/030). In particular it was noted in that briefing paper (page 2):

This division of roles and responsibilities has impeded development of the Programme since its inception (including when the responsibilities now with the National Prevention team were those of the Ministry of Health).

113. Work to consider the various strategic options was commenced in November 1999. An internal HFA Strategic Options Paper was developed (JMP/HFA/031) and this considered six possible options ranging from one central agency being the HFA carrying out all functions, through to devolution to District Health Boards.
114. However, the subsequent election of a Labour/Alliance Coalition Government with the stated policy of disbanding the HFA and incorporating its functions into the Ministry of Health and 22 (now 21) DHBs resulted in further analysis of funding and structural options (JMP/HFA/032). Although one of the three specific options considered in that paper was to have the management and national co-ordination and funding all removed to a separate national agency with advantages and disadvantages there set out (pages 12 and 13), this was not the option pursued.
115. Instead the decision has been taken to centralise all functions within the National Prevention Team of the HFA, retaining integrity and expertise of that team in Auckland and have that team then exist as a stand alone unit within the new Public Health Directorate of the Ministry. This directorate is one of eight directorates formed within the new Ministry of Health structure as announced on 29 May 2000 (Peters' supplementary brief, para 29).
116. This National Screening Team as it will be known within the Public Health Directorate will be managed by Dr Peters who will be a third level manager reporting to Dr Don Mathieson, the Deputy Director-General of Public Health who will in turn report to Dr Karen Poutasi as Director-General. Dr Peters confirmed when she first gave evidence on 4 July that she would prefer to have control of the contracting process and all funding for the NCSP and had put briefing papers forward to the Ministry to that effect – see B/224-B/226. Dr Peters confirmed that all personal health

contracting for the Programme will transfer to her team (B/227). Dr Peters also confirmed that the proposal for the new National Screening Team within the Ministry has been confirmed in the new Ministry structure as set out in JMP/HFA/049 and 050 (B/2549-B/243).

117. In view of concerns expressed by some witnesses about responsibility for the Programme returning to the Ministry a number of witnesses, eg Professor Skegg and Ms Marshall gave evidence about a proposal to develop a separate Cancer Control Agency with the suggestion that the NCSP could fall within that organisation. Dr Peters was asked about this proposal several times but on each occasion expressed reservations. In particular Dr Peters pointed out in answer to Mr Corkill that a separate agency is not necessarily immune from restructuring and gave the example of the Public Health Commission which was abolished despite having some responsibilities for health promotion in relation to the NCSP (B/244). Dr Peters also expressed the personal view that “one would have to concede it’s a possible option for the future of the Programme” but it has advantages and disadvantages and “there are so many unknowns it is difficult to proffer an opinion”. (B/252) One of the risks identified was that of isolation from the mainstream health sector. Professor Duggan also pointed out that there may be no merit in having a separate cancer agency if screening programmes are grouped within the Ministry (B/255).
118. The Inquiry Chair also specifically confirmed that the Inquiry Panel can rely upon exhibit JMP/HFA/033 as setting out Dr Peters’ own preference for an appropriate structure (B/290). Also Dr Peters notes that screening programmes are a difficult fit wherever they are but that she envisages the NCSP operating as a stand alone unit within the Ministry (B/445).
119. The Chair also specifically put the cancer control idea of Professor Skegg and Mrs Marshall to Dr Peters:

If you had the choice would you rather see the Programme within the Ministry of Health or a stand alone unit with a sort of cancer control unit that Dr Cox and Mrs Marshall had talked about where all the screening programme and the registers, including the cancer register are located?

A:... I think we've developed quite a lot of expertise so I think that unless there is a view that there is a need for a major upheaval at the moment, by far my preference would be to consolidate what we have started rather than start another restructuring and move into another agency. (B/3459-B/3460).

120. It is submitted that notwithstanding the Cancer Control Agency suggestion there is a complete absence of policy work around that proposal and the Inquiry can therefore do no more than note that such an option has been suggested. It would be most unfortunate if before the detailed policy work was even commenced such an idea gained momentum with the very considerable risk that all the work done by Dr Peters and her team could become fragmented and diverted at this critical time of implementation.
121. As to the concerns about the momentum being maintained within the Ministry the Inquiry Chair specifically asked?

Q: Do you think that you will get the support that you need from the Ministry of Health in order to implement all the hard work that you have done in the draft documents you have put before the Committee in exhibits 40, 42 and 47? (B/3458-9)

A: Well all the indications are that I will. (B/3459).

122. Dr Poutasi's evidence then provides confirmation. Dr Poutasi was called to give evidence late on the evening of Saturday 5 August starting at B/4089. Dr Poutasi confirmed:
- 122.1. The NCSP will be a discrete unit within the Ministry's new Public Health Directorate (B/4091);
- 122.2. Dr Peters has put forward a proposal to have a direct contracting role with providers which was being considered (B/4091);
- 122.3. Decisions being made about the NCSP would not pre-empt any recommendations the Inquiry may make (B/4092);
- 122.4. There is a need for the Programme to have strong central leadership including a wide skill mix (B/4093);
- 122.5. There is Government acceptance of the need for a national cancer control strategy and consultation on a draft strategy has been

completed (B/4094). (Whether the NCSP should be a separate agency was not covered by Dr Poutasi's evidence);

- 122.6. Agreement with the Cancer Society's 6 March 2000 letter (exhibit EAM/CS/041) setting out four key elements for the NCSP to be safeguarded during the restructuring (B/4095);
- 122.7. The intention is to transfer Dr Peters' team "lock stock and barrel into the Ministry of Health with no disruption whatsoever" (B/4095);
- 122.8. Planning is being done to avoid fragmentation of the Programme notwithstanding formation of the DHBs and taking account of the evidence that has been given to the Inquiry (B/4096);
- 122.9. The intention is to retain the expertise of Dr Peters and her team and its institutional memory and to recruit additional expertise (B/4097);
- 122.10. Necessary funding for the Programme will be secured (B/4098);
- 122.11. A pathway through the ethical issues has to be found to ensure the Programme can be effectively evaluated (B/4099);
- 122.12. The NCSR is to be located with the NCSP in the Public Health Directorate but both the NCSR and the Cancer Registry use NHI numbers so that linkage should be possible (B/4100-B/4101).
- 122.13. The NCSP will not be isolated in Auckland because other public health functions of the Public Health Directorate are also located in Auckland (B/4102-B/4103);
- 122.14. There will be linkages between the Public Health Directorate and the Maori Health Directorate in relation to the Programme (B/4103).

123. In addition since the time Dr Bottrill practised there have already been significant changes to legislation and further legislative changes are proposed that will address the risks of under-reporting.

Changes Already made to Legislation

124. It is submitted that two legislative reforms are of relevance:
- 124.1. the new Medical Practitioners Act 1995; and
 - 124.2. the Health and Disability Commissioner Act 1994.
125. The changes made from 1 July 1996 by the **Medical Practitioners Act 1995** were outlined by Dr Boyd: paras.68-73. They are also explained in the opening submission for the Medical Council on 12 July and discussed by Dr Baird at B998-1000, 1002-1003 and Ms Jones in chief at para.95 ff and B1011-1016.
126. Until 1 July 1996, the Medical Practitioners Act 1968 applied to registered medical practitioners including pathologists. The 1968 Act did not provide for reviews of competence of doctors (now in Part V of the 1995 Act). Other improvements in the new Act include statutory oversight requirements for medical practitioners (s.20), maintenance of a reasonable standard of professional competence in order to gain an annual practising certificate (s.52(1)(a)), mandatory reporting by medical practitioners of any colleague who has conditions affecting fitness to practice (s.76), and open disciplinary hearings (s.106).
127. The principal purpose of the 1995 Medical Practitioners Act (s.3) is to protect the health and safety of members of the public by prescribing or providing mechanisms to ensure that medical practitioners are competent to practise medicine. The Act empowers the Medical Council to review the competence of a medical practitioner whether or not the Council has reason to believe that practitioner's competence is deficient. In addition, where a Complaints Assessment Committee (after referral of a complaint or conviction to it) determines that the Council should review the

competence of a medical practitioner (s.91(1)(a)), the Council must review the competence of that practitioner.

128. The 1995 Act also provides that medical practitioners who hold general registration only, may practise any branch or sub-branch of medicine, but only while the practitioner is subject to general oversight by a person who holds vocational registration in the branch or sub-branch of the medicine concerned: s.20. The transitional provisions do not apply these general oversight provisions for a period of five years from the date of commencement of the Act (i.e. until 1 July 2001) for practitioners who have held annual practising certificates for a period of at least five years prior to the commencement of the Act: s.145.
129. The Medical Practitioners Disciplinary Tribunal has the ability to suspend a doctor during the investigation stage of a complaint if there is evidence that the health and safety of the public may be at risk: s.104.
130. The **Health and Disability Commissioner Act 1994** came into force in part on 20 October 1994. The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 (SR 1996/78) came into force on 1 July 1996 along with other parts of the Act: Part IV (the complaints procedure) and ss.76(1) and (2), 81(1) and 81(3): SR 1996/79.
131. The complaints procedure, in force at the same time as the Medical Practitioners Act 1995, empowers consumers to make a complaint about health services other than through the occupational regulatory body responsible for the particular health profession. The Code and Part IV together provide for specific consumer rights, complaints about breaches of those rights, complaints about services outside the traditional regulated professions, and enable awards of money to affected consumers through the Complaints Review Tribunal (in limited circumstances, even if the effect on the consumer is covered by ACC: ss.52 and 54; *Director of Proceedings v. O'Neil* (unreported, High Court Wellington, AP 149/99, 11 August 2000, Gendall J and Ms Dyal)).

132. Any complaint made about a doctor must be referred to the Commissioner before the peer discipline provisions under health occupational registration statutes can operate, and this includes the Medical Practitioners Act 1995: s.39.
133. It is submitted that the Health and Disability Commissioner Act and its interface with health occupation regulation allows greater scrutiny of health services, and is more likely to expose systemic problems than the earlier complaints system.

Relevant Changes On The Current Legislative Programme

134. There are three potentially relevant legislative measures currently under development:
 - 134.1. Proposed amendments to the Medical Practitioners Act 1995;
 - 134.2. Proposed Health Professionals' Competency Assurance Bill; and
 - 134.3. Health and Disability Services (Safety) Bill.
135. The changes proposed to the **Medical Practitioners Act 1995** were discussed in Boyd at paras.169-171 and in exhibits GRB/MOH/033 (the recommendation to the Minister), 034 (the consultation document) and 035 (the proposed legislative bid).
136. Both Dr Baird and Ms Jones from the Medical Council spoke of the changes being advocated by that body. The current proposals, yet to be approved by Cabinet, include amendments which are intended to:
 - 136.1. Strengthen the competence provisions of the Medical Practitioners Act;
 - 136.2. Increase reporting between agencies involved in investigation and discipline of complaints concerning medical practitioners;

- 136.3. Give the Medical Council improved power to suspend medical practitioners when it is considered that they are a risk to public safety;
- 136.4. Allow access to patient records if audit or follow-up is necessary, when a doctor's incompetence raises implications for the safety of similar patients; and
- 136.5. Allow supervision provisions of general registrants to be more flexible.
137. Consequential amendments to the Health Act 1956 are also proposed to allow the Director-General of Health and her delegates (whether inside or outside of the public service) to access patient information where an issue of public safety is brought to her attention (see GRB/MOH/034, Vol. pp.132-3). This will facilitate the Director-General's ability to undertake, for example, "look-back programmes" of a kind contemplated by Professor Skegg in the course of the Inquiry.
138. A further consequential amendment is proposed to the Accident Insurance Act 1998, to require ACC to report error as a result of negligence or misconduct of registered health professionals, to the appropriate registering authority or any other appropriate body.
139. In para.384 of his submissions for the women affected, Mr Corkill refers to the consultation paper to be released relating to the mooted **Health Professionals Competency Assurance Bill**. The discussion document was publicly released on Monday, 2 October. It is anticipated that a policy paper will be put to Cabinet by the Ministry after submissions have been received and considered, around mid-November.
140. The principal purpose of the proposal is to assure the health and safety of the public by establishing further processes to ensure that health professionals in all areas are competent to practice. It is proposed that registering authorities be empowered to assess the competence of practitioners and register them in an appropriate scope of practice within which they are competent to practice. Alongside this, it is proposed that

registering authorities be empowered to review the ongoing competence of practitioners and require them to participate in a competence programme if necessary. It is also proposed that the legislation provide mechanisms for disciplining registered health professionals who practice outside their competence, and people who practice without being registered.

141. The proposed legislation would use the concepts in the Medical Practitioners Act as a starting point. These concepts are:
 - 141.1. Lay participation in both registration and discipline functions;
 - 141.2. Registering authorities are responsible for ensuring practising practitioners maintain their competence throughout their careers;
 - 141.3. Registering authorities are empowered to establish the detailed requirements for registration as opposed to those being designated in legislation; and
 - 141.4. Separation of the registration and disciplinary functions which provide for the continuation of separate, independent registering authorities for the different professions and have the ability to accommodate profession-specific provisions.
142. Nurses, including those who take smears, would be subject to the new competencies required by their profession.
143. **The Health and Disability Services (Safety) Bill** is currently before Parliament. It revokes current licensing legislation for in-patient care and provides a new statutory framework for ensuring consumer safety in the provision of hospital and residential care services. The Bill, as reported back to the House by the Health Committee, contains an enabling clause which allows a number of specified health and disability services to be brought within the Bill's scope by Order-in-Council. It is presently proposed that the enabling clause be widened to include all health and disability services. This will ensure that the Bill may be extended to cover any service where that is considered a necessary and desirable regulatory mechanism to address safety issues.

144. Under the proposal, coverage could not be extended unless the Minister is satisfied that sector standards are in place and effective providers and purchasers of health and disability services have been consulted, and the Minister considers it to be desirable or necessary. The Bill gives providers a minimum of six months to comply with the standards. At this stage, this additional measure is a proposal by the Minister which has yet to be considered by Government. It would require amendment by Supplementary Order Paper to the current Bill and therefore a high measure of cross-party support. Other Government agencies have agreed in principle with the extension of the scope of the Bill and the Ministry is optimistic that the changes will be accepted.

Further Changes Which May Be Required

145. Legislative access to the personal medical records of women without their consent to facilitate audit and evaluation of the programme is a matter of policy which will require broad consultation before legislative measures can be introduced. Subject to final Cabinet confirmation, the Minister has just secured Cabinet agreement to preparation of a public discussion document and for policy work to be undertaken on regulations to enable access to information on the NCSR. It is anticipated that changes will include:
- 145.1. New regulations under s.74A to enable persons studying cancer to have access to personal information on the NCSR in defined circumstances where informed consent will not be necessary;
 - 145.2. An appropriate link between the Cancer Registry and the NCSR;
 - 145.3. Clarification of access to information on the Cancer Registry and the NCSR for audits of the medical history of women developing cancer, by accessing linked Cancer Registry information and NCSR information;

- 145.4. Clarification of circumstances where informed consent is not necessary;
- 145.5. Expanded regulation making powers.

TERM OF REFERENCE 7:**TO COMMENT ON ANY OTHER ISSUE THE INQUIRY TEAM BELIEVES TO BE OF PARTICULAR RELEVANCE****Maori Women's Data and the Kaitiaki Regulations****Submissions made by other counsel/persons**

146. The following relevant submissions have been made on this subject:

- 146.1. Submissions of Counsel Assisting (Part 2) Term of Reference Seven paras.452-460.

The Ministry largely agrees with these submissions. There is no evidence that the National Kaitiaki Group was responsible for the delay in the publication of the statistical report on Maori women's data in 1999 (LRE/MOH/004). Delays in releasing statistical reports such as this have resulted from issues relating to data quality, staff changes, reviewing of draft reports, other priorities and structural changes.

Any proposals to make changes to the Kaitiaki regulations or to s.74A in relation to Maori women's data would, of course, require appropriate consultation.

- 146.2. Closing submission of the Cancer Society of New Zealand Inc, Part 2, section 7: Term of Reference Six – Appendix B (pp.115-123).

This submission contains a useful summary of relevant evidence. In terms of the recommendations one should take into account the current position. The regulations provide already for mandatory relevant considerations (Regulation 5(3)) which are in turn reflected in the criteria which the Kaitiaki Group applies, set out on p.4 of the 1999 statistical report: LRE/MOH/004. The applications themselves must comply with regulation 4 and

therefore should clearly spell out the benefits associated with the use of the data for Maori women.

Pursuant to regulation 5(4) and (5), the National Kaitiaki Group must notify the Director-General, and the Director-General informs the applicant, of the decision and reasons must be provided. It is submitted that a refusal to release information can plainly be subject to judicial review given the clearly constrained statutory discretion exercised by this Group.

The Terms of Reference prepared by the Ministry of Health for the Group are exhibit 1 to the affidavit of Helen Wyn. They note (p.2) that other persons may be invited by the Ministry of Health to assist the National Kaitiaki Group with its deliberations. There is also the ability for the Minister to appoint whomever he or she sees fit to the Group pursuant to regulation 7(2), subject to consultation with the Ministers of Maori Affairs and Women's Affairs.

The regulations provide that applications are to be dealt with "as soon as reasonably practicable" (regulation 5(1)) and this is reiterated in the Terms of Reference.

The Terms of Reference also provide an expectation that the Group will meet up to four times per year in Wellington either face-to-face or in teleconference, depending on the number of applications received: Wyn affidavit paras.3-4. The National Kaitiaki Group also teleconferences for urgent applications when so required. We are advised that over the last two years, there has been a decline in the number of applications.

- 146.3. Closing submissions of Prue Kapua – Counsel for Maori Women
Affected: paras.9-11.

Ms Kapua is supportive of the continuation of the National Kaitiaki Group. She has made some important points in this respect which are fully supported by the Ministry. The National

Kaitiaki Group was established in response to requests from Maori women expressing their very real concern relating to the protection of their data on the Register. The Ministry has not received any submissions or requests from Maori women to change the regulations.

The Ministry supports the submission that the National Kaitiaki Group has not been restrictive in allowing access to Maori women's data for the purpose of research, particularly in regard to early identification of any trends in abnormal reporting of smears.

Explanation for graphs depicting the incidence of cervical cancer and mortality rates showing different rates in the two statistical reports

147. The rates for incidence in mortality are different between the 1998 NCSP Third Statistical Report (JMG/MOH/051) and the 1999 Maori Women in the NCSP Report (LRE/MOH/004).
148. The discrepancy is explained in the note on p.13 of the 1999 Report regarding mortality information (from the Cancer Registry) and on p.14 below figure 4 relating to incidence rate. Appendix A on p.45 describes the relationship with the earlier report and the difference in data. This is expanded by Ms Matcham in SMM/HFA/019 (Vol.2).

Issues around the collection of ethnicity data for the NCSR and Cancer Registry

General

149. Over the period that the 1999 Maori Women in the NCSP Report covers, the census ethnicity question has changed several times (1986, 1991 and 1996) which has resulted in a different number of people enumerated as Maori each time: see pp.5-10 of LRE/MOH/004. Furthermore, in September 1995 a change was made to the collection of ethnicity information for all births and deaths. The shift was a shift from historically used "biological" concept of a Maori (i.e. half or more Maori blood) to cultural affiliation, where a person has the option to self-identify with one or more ethnic groups. A person is identified as belonging to the

Maori ethnic group if they select “Maori” as either their only ethnic group or as one of their ethnic groups.

150. This change was made to align the ethnicity question asked on the birth and death registration forms with the ethnicity question in the 1996 census. As a consequence, however, the changes in ethnicity classification has disrupted the historical series of ethnic-specific information, and 1996 is the start of a new time series.
151. A similar change was made to the collection of hospital admission data. From 1996, the collection of ethnicity information was changed to enable people admitted to hospital to self-identify with up to three ethnic groups.
152. These changes mean that pre- and post-1996 ethnic-specific mortality and morbidity rates are not comparable.

National Cervical Screening Register

153. The ethnicity data in the 1999 Report are based on the ethnicity of the woman recorded on the Register at the date when the data were extracted (December 1998). The NCSR does not keep an archive of previous ethnicity records for women if their recorded details are subsequently updated. It was not possible to analyse these data based on the recorded ethnicity of women on the NCSR as at 31 December 1995. Information, including ethnicity, is collected by the enrolment form and since 1996 is verified in a follow-up letter. Before 1993, each NCSP area had its enrolment forms and collected ethnicity information in a variety of ways. The ethnicity section was often recorded by a smear-taker rather than the woman herself or in some cases not at all.

Cancer Registry Issues

154. As at July 2000, the evidence was that information on the Cancer Registry is published on the NZHIS website (provisional data up to 1998) and provisional data for 1999 is available from the Registry on request, as is other information. Analysis can be performed on data for a fee: Cohen affidavit paras.7 and 8. Confirmed data was available in hard copy for

1996 and earlier, with a 1997 data publication currently under preparation: Cohen para.14.5. The Registry compares well internationally: Cohen para. 14.6.

155. An issue arose in the course of the Inquiry over the information release policy of the NZHIS (Cohen exhibit 2) and in particular the procedure set out on p.3 under heading 4 which requires Ethics Committee approval before the Registry will release information containing personally identifiable information (other than relating to the requestor).
156. It is accepted that this policy procedure was narrowly focused and we are instructed that it will be changed to broaden its scope taking into account all relevant legislation. The correct legal position, it is submitted, is that a request to NZHIS for identifiable information from the Cancer Registry (from a person who is not the subject of the information) is a request for official information. As such it is subject to the principle of availability under s.5 of the Official Information Act 1982.
157. Section 9 of that Act will likely be relevant. A typical scenario is that the NZHIS staff will ask themselves whether the withholding of the information is necessary to protect the privacy of natural persons, including that of deceased natural persons, under s.9(2)(a) and, if so, then whether that might be outweighed by other considerations which render it desirable in the public interest to make that information available: s.9(1).
158. Relevant to this balancing exercise is the fact the NZHIS, as part of the Ministry, is subject to the Privacy Act 1993, being an agency within the definition in that Act. It is also subject to the Health Information Privacy Code 1994: clause 4(2) and Schedule 1 to the Code refer.
159. Rule 10 limits the uses to which health information can be put. Its focus is on purpose: the basic rule is that information obtained for one purpose cannot be used for any other purpose unless an exception applies.
160. Rule 11 relates to permitted disclosure. As the Privacy Commissioner's commentary notes, the decision to disclose, when permitted by the Rule, remains within the agency's discretion. Rule 11(1)(c), which permits

disclosure where it is a purpose for which the information was obtained, may frequently be relevant to requests for Cancer Registry data. Section 4(2) of the Cancer Registry Act refers to the purposes of the Cancer Registry being:

“(a) To provide information on the incidence of, and mortality from, cancer; and

(b) To provide a basis for cancer survival studies and research programmes.”

161. Therefore, where a researcher’s proposal aims to use information on the Cancer Register to study cancer survival, NZHIS could disclose Cancer Registry information under this part of Rule 11. There is no ability for NZHIS to require ethical approval to be obtained as a condition of disclosure.
162. It is possible to argue that no issue of personal privacy arises (requiring a balancing exercise under s.9) because the Code recognises that disclosure of Registry information can be made in the circumstances. However, given that disclosure is discretionary even when the Code requirements are met, it is submitted that the better view is that the balancing exercise is required, although the principle of availability is strengthened by the application of the Code in such a case. It is nevertheless conceivable that individual cases might arise where the balancing favours privacy, particularly if the impact upon the research is unlikely to be significant. In such a case it is unlikely that the purpose of the Cancer Registry Act will be frustrated by concerns of individual privacy. In difficult cases, the views of the relevant ethics committee may be of interest to the NZHIS, but it can not abdicate its statutory duty to decide a request for information to that ethics committee.
163. Another potentially relevant rule is Rule 11(2) which sets out circumstances where, if the consent of the individual or his/her representative is prima facie necessary, it need not be obtained if the agency believes on reasonable grounds that it is either not desirable or not practicable to obtain authorisation from the individual and one of paras.(a) to (k) apply. Paragraph (c)(iii) of Rule 11(2), disclosure for research

purposes for which ethical approval (if required) has been given, may be relevant. Ethics Committee consideration before disclosing data to researchers might be relevant if concerns arise as to the relative balance between the public interest and personal privacy which could in turn be addressed by the Ethics Committee by the imposition of conditions on use of the information. However as noted above, the NZHIS, not the ethics committee, remains responsible for the decision on disclosure.

The Cox / Richardson Evaluation and s74A

164. While it appears, on analysis, that there are no insuperable legal difficulties involved in making information available from the Cancer Registry for research or audit purposes, s74A of the Health Act is clearly strongly protective of women's identifiable information on the NCSR. The Director-General's response to the Inquiry's subpoena is an indication of that situation.
165. On the other hand:
 - 165.1. The Director-General is the custodian of the information on both the Cancer Registry and the NCSR and could therefore identify the women who are diagnosed with cervical cancer even though they have been participants in the NCSP;
 - 165.2. An audit of those women's individual situations could be carried out with their consent; and
 - 165.3. This means it is possible to conduct an evaluation of the NCSP under the existing legislation, at least to the extent that sufficient women can be located and give their consent to obtaining screening history information on the NCSR and clinical records.
166. Although legal issues seemed to become a major consideration during the Inquiry they need to be kept in perspective. Drs Cox and Richardson did not anticipate any legal difficulties when they prepared their draft

evaluation plan of 9 June 1997 (JMG/MOH/047) to carry out an evaluation of the NCSP on behalf of the Ministry:

The audit would consist of the Cancer Registry releasing to a *bona fide* research investigator the name, address, date of birth and name of the clinician for each women (sic) registered with invasive cervical cancer. A letter would then be sent by the investigator to the clinician seeking approval to approach the woman. A similar letter seeking approval to approach the woman for interview would also be sent to her general practitioner. Provided both approved an approach by the research investigator, a letter inviting the woman to participate ...would be sent. For women who indicate their willingness to participate, their gynaecologist and general practitioner would also be asked for information regarding their cervical screening history ... women would also be asked for permission to contact the local pathology laboratory and for those who were part of the National Cervical Screening Programme, permission to obtain information regarding their cervical smears within the Programme would be sought.
(page 98)

167. It is submitted that the Ministry should not be criticised for failing to identify legal problems with evaluation of the NCSP because if the evaluation had proceeded according to the 1997 evaluation plan there were none. It must also be remembered that both the Cancer Registry and the NCSR were administered by the Ministry at that time.
168. Subsequently a contract was entered into for three components of the evaluation plan, which after consultation by the Ministry were regarded as a priority. The details of that process were explained by Dr B/2480 ff). The three components of the evaluation as listed in the contract (JMG/MOH/108) are as follows:
- 1. An audit of the screening histories and management of women with invasive cervical cancer;**
 - 2. An assessment of the appropriateness of follow up and treatment of women with abnormal smears; and**
 - 3. Assessment of whether the NCSP provides appropriate data for evaluating the NCSP.**
169. The Ministry has been advised by Dr Cox that the last of these components has been done although the assessment report is still being written up by

the evaluators. The second component of the evaluation is under way with Dr Peters' team assisting with obtaining women's consent. It is the audit of screening histories of women who develop invasive cervical cancer that has become problematical.

170. Between the 1997 Cox/Richardson evaluation plan and May 1999 when the evaluation contract between the Ministry and the University of Otago was entered into, the evaluators' methodology for their work has changed to a three-step process consisting of:

170.1. Accessing the Cancer Registry details of women diagnosed with cervical cancer;

170.2. Approaching the HFA for details about those women from the NCSR;

170.3. Obtaining access to the general practitioner medical records of women with invasive cervical cancer to establish the women's screening histories.

171. These three steps were set out at pages 5 and 6 of the protocol produced as JMG/MOH/109 which is part of the evaluation contract between the Ministry and the University of Otago.

172. It is evident from that protocol that the evaluators did not anticipate legal problems. In particular they stated:

A match will be requested from the Health Funding Authority using names, date of birth, address and National Health Index number between women diagnosed with cervical cancer and the records of the National Cervical Screening Register under section 5(e) of tems 74A National Cervical Screening Register of the Health Act 1956 to ascertain the screening history of women with invasive cervical cancer. (pages 5 and 6)

173. Section 74A(5)(e) of the Health Act states:

No person may disclose information on the Register that identifies a woman, unless the information is disclosed - ...

(e) For the purpose of giving access to the register in accordance with regulations made under subsection (7)(a) of this section to persons studying cancer.

174. It seems that when the evaluation contract was signed in May 1999 no one realised that no regulations had been made under s74(7)(a) to enable access to the NCSR “to persons studying cancer”.
175. It was only when Dr Cox wrote to the HFA on 15 December 1999 to commence the evaluation that Dr Peters sought legal advice specifically related to the proposal (B/3430). This was in addition to the advice she was already seeking from Longworth Associates on the legal issues associated with establishing routine cancer audit with both the breast and cervical screening programmes. The opinion of Longworth Associates dated 3 February 2000 provided to Dr Peters pointed out that no regulations had been made under s74A and that:

In respect in either access to the NCSR or disclosure by the HFA from that Register to the Otago researchers, the only way women’s records could be disclosed under s74A of the Health Act with any degree of certainty as to the legality of that disclosure, would be under the exception that requires the consent of the woman concerned. (Exhibit DCS/CA/026, para 5.1)

176. Both the Longworth opinion and the Crown Law Office opinion of 23 August 2000 indicated there was an interpretation issue around the words “persons studying cancer”. In that regard it is submitted the law needs to be clear as to:
- 176.1. The right of full access to the NCSR by private researchers, ie persons studying cancer; and
- 176.2. The right of the Ministry itself, or its contracted researchers, to carry out an official evaluation of the NCSP.
177. In that regard the Ministry has started the process for legislative change as noted in para 145 above. The Ministry is also working with Drs Cox and Richardson to ensure that the clinical audit component of the NCSP evaluation can proceed. It is intended that a slide review exercise be added to the evaluation. Progress should be facilitated by recognition that the

Cancer Registry can release information to the evaluators without the requirement for ethical approval. However, given that the evaluators themselves wish to have ethical approval the Ministry understands a revised application for that is now being prepared. While the 1996 National Standard for Ethics Committees (DME/REC/0090) clearly provides exemption from Ethics Committee approval for internal clinical audits, see ss3.1 and 3.3 in the Fifth Schedule, where the evaluators are to approach clinicians for highly sensitive health information it is submitted Ethics Committee approval is appropriate. While it is undisputed that NCSP evaluations must be able to proceed it is highly desirable that the methodology of evaluation is sanctioned by an Ethics Committee. The Ministry can consider whether any amendment to the National Standard for Ethics Committees is required in the light of the consultation it proposes prior to amendment of s74A of the Health Act. The Inquiry's report will obviously be of value in that regard.

TERM OF REFERENCE 8:**TO MAKE RECOMMENDATIONS, CONSISTENT WITH s4(a) OF THE HEALTH AND DISABILITY SERVICES ACT 1993, AS TO ANY FUTURE ACTION THE GOVERNMENT OR ITS AGENCIES SHOULD CONSIDER TAKING**

178. In view of the unique position of the Ministry in having the role of implementing the Inquiry's recommendations in accordance with the Minister's instructions, the Ministry has decided not to make submissions under this term of reference. Nevertheless the Ministry and the HFA obviously hope the Inquiry will give a strong endorsement to the HFA's work on the Programme to assist the implementation process which is now under way.

REPLY TO CLOSING SUBMISSIONS OF OTHER COUNSEL AND OF WHIRT ADDITIONAL TO ORAL SUBMISSIONS OF COUNSEL FOR MOH/HFA

Reply to Closing submission of B A Corkill, Counsel for Women Affected

38. Counsel refers to the lack of a follow-up by recall for a repeat smear within 12 months after initial enrolment. The practice was, where enrolment was accompanied by advice that a previous normal smear had been taken within the past five years, a normal smear at enrolment would result in the allocation of the usual three year recall period. This practice was consistent with the treatment protocol of June 1992: JMG/MOH/022 , vol 5 at p.22 item 4, and Boyd A120/7-20.

At the time Dr Boyd was questioned, the Panel did not have access to the Individual Women's Details Reports from the Register (example at SMM/HFA/011). These reports were subsequently provided to counsel for the women affected for association with their medical files. They confirm what occurred for patients 4, 5, 6 and 8.

Patient 4 was enrolled on 9 January 1992 with a previous normal smear in 1989 noted at enrolment. Her smear result on enrolment was normal and she was allocated a three year recall. The standard category 500 letter (eg SMM/HFA.009 p.3) was recorded in the Report as sent to her confirming her enrolment and advising the result and recall period on 17 January 1992.

Patient 5 was enrolled on 3 March 1995 with a note of a previous normal smear in 1991. Again, the result of the 1995 smear was normal and a three year recall was allocated and advised to her.

Patient 6 was enrolled on 2 December 1993 with a previous normal smear in 1993 noted. The results of her smear were inadequate and the recommendation was B2B3 (please repeat the smear when convenient). The default recall of three months was set. The Register Report notes that, on 24 January 1994, a letter (category 9000) was sent to patient 6 at the

address on the Register advising a repeat in three months. An example of the letter is SMM/HFA/009 p.32. According to patient 6's report, The Register does not record when recall letters were sent. Patient 6's recall letter would have been due for generation in May 1994, when 102 recall letters were generated. Change of addresses are recorded on the Report in January 1996, March 1997, June 1997, July 1998 and September 1998 (when her next smear was recorded) would indicate that the site was continuing to locate her.

Patient 8 was enrolled on 31 August 1994 with a previous normal smear noted in 1993. The result of her initial smear was normal, a three year recall allocated and a letter sent accordingly on 5 September 1994.

This position can be contrasted with, for example, patient 7 who was enrolled on 26 July 1995. The Register notes that it was more than five years since her previous smear. Although the result of the first smear was normal, because the last smear was more than five years ago a letter was sent (category 1000: SMM/HFA/009 p.6) advising a further smear in 12 months. A further smear 13 months later is recorded on the Register.

The evidence referred to in paras 39 and 40 of submissions of counsel should be considered in light of the information as to letters sent recorded on the Individual Women's Details Reports, and the advice forms provided to smear-takers for the woman as part of the enrolment form:

SMM/HFA/004 and 005. Because it was not relevant to the terms of reference, the Panel has heard very little evidence of the education programmes and advertising surrounding the Programme.

78. The decision to proceed with an opt-on programme (or more correctly to delay the promotion of legislation required for an opt-off programme), was made by consecutive Ministers of Health in 1990 and 1991 pending resolution of confidentiality/privacy issues and securing the necessary public and practitioner support.

79-83 The advice to the Minister was consistent that the programme should not be delayed while the Register was extended to include histology. The

Register was to be given less rather than more emphasis and resources in the early 1990s.

- 91 Dispute that the submissions provide “examples of a serious failure to accept advice”.
- 96 The evidence does not support this conclusion. The Department followed Ministerial direction, as it must. Consecutive Ministers were committed to a national programme.
- 97 No experts advised that the programme should not proceed until issues such as opt-off/histology on the Register/reconfiguration to single register (all important issues in 1991) had been completed.
- 106 The heading “Funding for Providers” is incorrect: these reports do not deal with funding for key service providers, i.e. laboratories, smear takers, etc.
- 124 Counsel notes that no evidence was adduced to explain why the money budgeted for cervical smears under Laboratory Benefits was not transferred to the NCSP. This was not an issue that was raised with Ministry witnesses. The Inquiry should not assume, as Dr Cox did, that it would have been a simple matter. This brief explanation is offered. Laboratory payments were payments on behalf of the Crown (POBOCs) under the Public Finance Act. This expenditure is not controlled by a Department or Ministry, but by the Treasury. To transfer such expenditure to a Department budget was a matter for Treasury and the Minister of Finance. Transfer of such funds to (shrinking) Departmental budgets would have had significant implications for funding across government departments.
- 125.8 Cox para.80 contains a reference by Dr Cox to minutes of the Programme Managers’ meeting in December 1991 (his exhibit 15, also JMG/MOH/75, Vol.14 p.105). He was not present at that meeting. He draws conclusions in his brief which are not stated in the minutes. The minutes record Dr Teague reporting that compulsory TELARC registration will be delayed for two years because training for cytoscreeners does not finish until the end of 1992 and accreditation is an expensive, time consuming process.

Dr Teague is also noted as reporting that 80% of laboratories were registered and 50% accredited.

- 125.12 Not correct to say no evidence of follow-up by National Coordinator as to laboratories accredited. See Valerie Norton's report (early 1993) JMG/MOH/025, CALC meeting late 1993 Boyd Vol.4 p.63, Sue Dahl's evidence p.B/4149/26 to 4150/6.
- 126 Not correct. Compulsory TELARC accreditation was achieved in the Midland region by way of contracts signed in early 1997 (agreed late 1996 per Mules evidence) and TELARC accredited against the draft Sax standards from then on: refer Walker.
- 140 See evidence produced: actual figures for 1990/91 and targets for 1991/92: JMG/MOH/62, Vol.11 p.26.
- 141 Confuses performance indicators recommended by the Expert Group (where the Department was to be the primary contractor) and performance indicators implemented in the funding agreements between the Minister and the RHAs, where the RHAs were to be the primary contractors and the Ministry was engaged only in "exception monitoring". RHAs monitored performance under individual contracts (of which there were none for laboratories until 1996). Programme monitored regionally and nationally directly through Regional Programme Managers and National Coordinator.
- 142 Note Dr Lambie had available the Monitoring Framework document when providing his evidence: B/3889/6-19. Not required to be produced.
- 147 Incorrect to say nothing happened between the two reviews. Eight examples of review activity are given by Dr Lambie in para.62 of his brief.
- 148 Not correct: see paras.70 and 71 of Dr Lambie's brief.
- 157,158 Ms Handiside's evidence is to be contrasted with that of Ms Grew and Ms Dahl. The failure of the Coordinator to effectively progress monitoring and evaluation was part of the concerns of the senior managers in early 1996 that lead to the Review of Accountabilities: Handiside B/3763. The National Coordinator was responsible for effective

monitoring of the programme. The quarterly Programme Managers' meetings were the forum for operational monitoring, or finding out what the problems were out in the regions and co-ordinating the Programme centrally: B/3690. When issues arose the advice of the expert committees was relied upon: B/3692-5. See examples provided in GRB/MOH/032 and Boyd paras.166-168.

- 162 The 1994 report was produced for the Minister at the end of CSAC's existing term (CSAC was then re-appointed with revised terms of reference for a further period). CSAC was obliged to report to the Minister under its terms of reference and could be expected to be frank in its views. The Minister described the 1994 report as a description of progress with the NCSP including monitoring and evaluating, not lack of progress: Glackin Vol.7 p.81. As an advisory committee to the Minister, CSAC was free at any stage to raise issues with the Minister which he or she in turn could raise with the Ministry. There is no evidence in the documents of the time that members of CSAC were feeling "professionally unsafe". The contemporaneous documents point the other way. Dr Cox's letter of resignation in 1996, which came at a time when the national evaluation was about to be tendered, was very positive and praised the Programme as "impressive": Cox Vol.2 Ex.39. The minutes of CSAC of 12 June 1996 acknowledge that "the NCSP is highly successful by international standards": Glackin Vol.4 p.183.
- 163 There was no discomfort with the "watchdog" role of the Advisory Committees. They were reviewed as part of the review of all committees and their continuing existence was supported within the Ministry. Refer Glackin Vol.7 tabs 33 and 34.
- 165.1 Wrong: the Advisory Committees were consulted. For CALC/CSLAC, see Boyd Vol.4 pp.71 and 77 (and previous discussion of desirability of formal terms of reference at Vol.4 pp. 61-62). For CSAC, see Glackin Vol. 7 tab 36 (p.85) letter from Chair to Minister.
- 166 This submission is irrelevant. Mr Neal resigned from CALC before the issue was first raised in November 1993 and was not present when the

review was carried out in 1994 in consultation with CALC. As the Department had not established CALC, it could not disestablish it; the proposal was that it become a formal advisory committee to the Ministry and this was agreed: Boyd Vol.4 pp.61-2 and 71.

- 175 The statement attributed to Ms Glackin is not complete and is misleading.
- 176 See submissions for the Ministry/HFA paras.294-351
- 181 Note the contemporaneous documents behind Dr Cox' evidence: **Cox para.144** refers to CSAC meeting of 11 March 1994: minutes are at Glackin Vol.4 p.10.

Cox para.168 refers to CSAC minutes of June 1994: Glackin Vol.4 p.63 where, after a discussion about false negative rates, Dr Teague recommended the NCSP monitor registrations for cervical cancer at the Cancer Registry and that there should be a proper review of their slides; a process that would need ethical approval. The National Coordinator agreed to investigate this monitoring proposal “and noted that the implementation of option 4 [a reconfigured register] would assist in monitoring”.

Cox para.195 is a reference to CSAC minutes of August 1995: Glackin Vol.4 p.131. The minutes note the need for Ethics Committee approval and an arrangement with the Cancer Register and that Brian would write up a minimum set of questions needed in terms of Wellington Ethics Committee's document, and a working group would support the Programme on the issue. The working group was Brian Cox (facilitator), Clint Teague, Ivor Singsam and Marie Lennard.

Cox para.199: Here Dr Cox refers to the paper he produced for CSAC about the audit of the screening history of women (BC/CS/0036), considered at CSAC on 27/28 February 1996: BC/CS/0004 p.135(b). This was discussed at length at this meeting *with action agreed to be taken by Dr Cox*. The minutes note that the issue arose as to who was to pay for the review and it was noted that the Health Research Council could be approached for funding. “*The study could be done by a masters student or*

a doctorate (Brian will investigate possible candidates for study within the Department of Social and Preventative Medicine at Otago). Action: Brian.” Regional peer review groups were also suggested to perform a monitoring function. Peter Moody was to initiate consultation with the RNZCGP and Clint Teague “or some other CSLAC member” could raise this with the pathologists.

At the same meeting it was noted that funding was available for evaluation and monitoring strategies. This was Dr Cox’ last meeting.

- 182 Dr Cox’ evidence that some CSAC members were feeling “professionally unsafe” is inconsistent with the minutes: see for example 12 June 1996, Glackin Vol.4 p.183:

“CSAC do not wish the document to state that the CSAC perceives the programme as failing”

and:

“CSAC acknowledged that the NCSP is highly successful by international standards”

Note also that Dr Cox’ paper was something he had agreed to do at previous CSAC meetings.

- 183 Dr Cox’s own statement and Ms Handiside’s subsequent description of Dr Cox’s resignation (because he did not want to “have blood on his hands”) is contradicted by his letter written at the time (Cox Vol.2 Exhibit 39), which refers to the Programme as “impressive” and his reason for resignation as his “numerous current commitments”.
- 184 It is incorrect to say there is, or was, a “complete impasse” with relation to the national evaluation. It is more correct to say there have been many obstacles which have had to be worked through but the three elements of the evaluation are proceeding.
- 187 The reference to Dr Straton’s identifying the absence of formal evaluation as a “major deficiency” in July 1990 is a reference by her to formal evaluation of pilot projects and other aspects of the Programme. At that

stage evaluation studies were formative in nature, looking to improve aspects of the Programme and evaluate different components of the Programme. There were many evaluations of various aspects of the Programme over the subsequent years (refer appendix C to MOH/HFA submissions Part One).

- 201.1 Note NPAAC Guidelines for Gynaecological (Cervical) Cytology (1993): GM/HFA/001 were the basis for the 1995 CALC recommendations to TELARC: GRB/MOH/025. No minimum standards or benchmarks for assessing under-reporting were included in the Australian guidelines or CALC standards.
- 201.4 Proficiency testing has been part of the RCPA External Quality Assurance Programme: Professor Davies B/1196/19ff, to be (at least) encouraged as part of TELARC accreditation since 1991: GRB/MOH/021 (CALC recommendations).
- 221 The process proposed by CALC for dealing with possible indications of inadequate laboratory performance was related to issues arising as a result of analysis of histology/cytology correlation following the implementation of histology onto the Register: refer Boyd paras.125-129, Teague p.1460/20-1461/13
- 239.3 One of the four situations referred to related to wrongly reported smears, the other three referring to smear taking failures.
- 244/245 It is submitted the circumstances surrounding the resignation of Dr Cox have been reconstructed after the event. See earlier submissions.

Reply to Closing Submission of Counsel Assisting

- 54 The Porirua Workshop recommendations referred to in this paragraph were not consensus recommendations of the Workshop. These are listed at Boyd Vol.3 p.86.
- 55 The 1988 Azimuth Report was prepared on the basis that the decision to proceed with a cytology-only register had already been made. Its recommendations, including 14 nationally coordinated but separate registers, was subject to broad consultation including the Porirua Workshop. In the end, the computer system purchased and implemented did not follow the Azimuth recommendations: Boyd A112/2-18.
- 60 The “opt-on” register decision had not been made at this stage. Rather, a refusal to promote the necessary legislation for an “opt off” Register was by the Minister after the Ministerial Review Committee and the Expert Group had reported in 1990. The decisions to exclude histology from the initial register and to set up a system of 14 separate registers were given at an early stage. It is not known whether these decisions were made at the departmental or ministerial level, but we do know the very tight timeframes imposed by respective Ministers to have the Programme “live”.
- 61 The submission refers to Ms Coney’s evidence that the Committee felt it was made clear to them by the DOH that significantly delaying the start of the NCSP was not acceptable. This was the view of the Minister: while not committed to launching the Programme on 30 November 1989, she wanted to be able to show continued progress: SC/WHAT Vol.1 pp.24 and 28-9. It is not right to say that the Government implemented the NCSP without delay, against the advice of the Expert Group. Both the Ministerial Review Committee (Glackin Vol.1 p.14 para.2.24 and p.59 para.8.15) and the Expert Group (e.g. Glackin Vol.2 p.24 para.3.3.5) recommended that the Programme not be delayed while register issues/evaluation of pilot programmes be further investigated/resolved.

- 65 While the Department reported to the Minister that it was not in full agreement with certain aspects of the Expert Group's report, those decisions were ultimately matters for the Minister.
- 66 Re tensions between the Department and Expert Group – see Straton Report, Part VII (Glackin Vol.1 p.264-269).
- 70 In relation to the asserted consensus:
- 70.1 This was the agreed approach in subsequent policy;
 - 70.2 The Minister declined this recommendation as early as December 1988;
 - 70.3 The Minister declined this recommendation as early as December 1988;
 - 70.4 The emphasis was on a **centrally-linked** NCSP Register; the capability of linking cytology and histology results was to be deferred; it was not seen as something that should hold the Programme up;
 - 70.5 The Minister declined to promote the necessary legislation in 1990 and the Associate Minister in 1991 required that the support of women and practitioners first be demonstrated. This concern was echoed by Cabinet in 1992;
 - 70.6 This would be the consequence of the Register once those histories had built up;
 - 70.7 The policy recommended that criteria for smear reading be established;
 - 70.8 Compulsory accreditation was not seen to be necessary for some years;
 - 70.9 Agreed; this became national policy;

- 70.10 Not accepted by the Minister beyond the budget for national coordination.
- 71.3 The only relevant contract which the Ministry monitors is its contract with the HFA. The HFA monitors contracts with the laboratories and other providers.
- 71.9 Standards and performance indicators have been implemented by TELARC which assesses laboratories against those standards.
72. Note the Expert Group did not want to delay the Programme to enable appropriate evaluation of the pilots: Glackin Vol.2 pp.23-24 (3.3).
73. Query the relevance of this to the Terms of Reference, and the reliance on the views of one witness. Matters not put to Ministry witnesses.
- 78 Note the contrast between the establishment of the cervical screening programme and the establishment of the breast screening programme, both of which were piloted at the same time but with the cervical screening programme being imposed largely on existing screening services and under intense public and political pressure. The national breast screening programme, by contrast, was not launched until December 1998, after standards and procedures had been worked out: JMP/HFA/31/2; Teague B472/23 ff.
- 81 The submissions cite the personal views of one witness, Dr Boyd, as comprising what is now considered the ideal, and implicitly criticises the fact that this operational structure has never been applied to the Programme. As the witness made plain, his views were personal ones and this submission does not reflect Ministry policy. The evidence of Dr Poutasi cited in support does not refer to this. Also note again the reference to monitoring contracts. This was the responsibility of the HFA both before and after the transfer of the NCSP to the HFA in 1998.
- 92 Between 1990 and 1993 the Department was responsible for coordinating, managing and evaluating the Programme and the Area Health Boards were responsible for implementing it within their regions in accordance with the

recommendations of the Cartwright Report. As it was a national programme, implementation at the regional level was subject to central oversight and coordination.

- 93 The submission that a central register was necessary before it became possible to correlate Gisborne Laboratory's cytology and histology results is not correct. Once those results were entered onto the Register (from about 1996 on a routine basis) these could have been analysed from the local register where histology results were read locally. Of course, correlation of results could have occurred at the laboratory level as part of internal quality assurance, without the assistance of the Register.
95. It is not quite correct to say that a "philosophy of self-regulation" existed during this period. The evidence is that health services have always relied upon the competence of professionals and regulation by professional organisations. There was no reluctance to impose quality control and standards upon laboratories: it was intended that these be imposed for the first time through the contractual requirement of accreditation and any other quality control/standards contractually imposed. One should not over-simplify the public policy issues surrounding the benefits and detriments of regulating through legislation (both primary, secondary and tertiary) and regulating through contract, particularly where matters of quality are concerned. These are issues about which there is much academic debate.
- 97 It is true that the National Coordinator had "only the power of the particular organisation in which the NCSP was located" at her disposal. However, when that was the Department or Ministry of Health, then that included the ability to access the full range of powers open to the Ministry, including regulatory advice to the Minister and contracting mechanisms. Of course the National Coordinator had to operate within the usual framework for middle and senior managers, as has Dr Peters as a third tier manager in the Health Funding Authority. Therefore, the ability to identify issues, make a case for action and influence colleagues in order to remedy concerns is absolutely fundamental. An effective National Coordinator, if faced with difficulties implementing policy decisions

which she perceived to be critical, had many avenues open to her for action. Ms Handiside's evidence needs to be considered in the context of a relationship of conflict with her managers and concern within the Ministry that she was not achieving important aspects of the Programme such as the development of a monitoring framework, and national evaluation of the Programme, despite resources being made available: B3749-3754. Note also:

~~///~~ Ms Handiside was not overly concerned about the issues around provision of histology to the Register as she considered the period (from 1993 to 1996) to be an acceptable transition time: B3698 ff;

~~///~~ Standards for laboratories took time to develop but this was not a concern: B3724 ff;

~~///~~ The Policy review was delayed: B3727;

~~///~~ The second statistical report was delayed: B3728;

~~///~~ She was aware TELARC accreditation was not yet mandatory: B3728;

~~///~~ There was no work plan to implement the 1993 policy: B3746.

There are no documents which indicate she raised any concerns with the Ministry's commitment and financial support of the Programme at the time, nor raising any concerns surrounding TELARC accreditation with the Performance Management Branch.

104 The Ministry did not seek to become a policy branch. The Ministry was restructured in accordance with Government policy and legislation in 1993. Section 74A(7) did not permit regulations requiring compulsory accreditation of laboratories. This could have been secured through the s.51 notice or through the contracting process and ultimately was.

115 Note there were no contracts for the NCSP directly with laboratories. The laboratory contracts were generic. The same situation existed with contracts with general practitioners as smear takers. Services for the NCSP were one small part of services purchased from providers.

- 126 It is not fair to say an opportunity that would have led to Dr Bottrill's under-reporting in 1995 was lost, given that the comparison he sought was made available early in 1996 (GRB/MOH/047) and these figures did not demonstrate Dr Bottrill as an outlier.
- 128 The standards were faxed to TELARC by Dr Teague in September 1995: affidavit of Lucy Wright.
- 129 There is no evidence that CALC "probably assumed that the National Coordinator would actually confirm this information through TELARC". Mrs Dahl said that from time to time she did. Dr Teague was aware that Dr Bottrill's laboratory was not TELARC-accredited in 1995. He did not consider it a matter that should be raised with the National Coordinator or CSLAC. Ms Handiside said she knew (either from CALC/CSLAC or TELARC) that not all laboratories were accredited: B3728/20-24.
- 130 While there was certainly concern about the appropriate accountabilities between organisations, which ultimately led to Ms Glackin's review of accountabilities in 1996, the documents also demonstrate debate as to where the Programme should be sited: for example the PHC continued to lobby for responsibility for the Programme.
134. Dr Cox agreed that a person reading the 1991 policy would form the clear view that the Ministry of Health was responsible for ensuring that laboratories were TELARC-accredited. However, a person reading the Funding Agreement would also see that it specifically obliged the RHA to use reasonable endeavours to ensure that laboratory services for the Programme were delivered by TELARC-accredited laboratories. The 1991 policy was referred to in the Funding Agreement, but not its precise words. The ambiguity spoken of by witnesses is limited to that extent. It is submitted there was no ambiguity with respect to the **setting** of criteria for TELARC (as opposed to contracting with TELARC-accredited laboratories); that remained the responsibility of the Ministry and CALC under the policy and in practice.

- 136 The evidence was that the Ministry was not in a position to **confirm** that the criteria for accreditation along the lines set out in the policy **were being applied** in laboratories: Glackin para.291. This advice was repeated by CALC in 1994: Glackin para.292 and Exhibit 71. The policy intent was that TELARC would be delegated the role of assessing laboratories against that criteria. In fact it assessed against the criteria that was recommended to it by CALC in 1990.
- 137 One might say the issue of mandatory accreditation of laboratories servicing the NCSP “slipped through the cracks” generated by these split accountabilities. It is submitted that a better view is that the NCSP suffered as a result of other priorities during a period of extensive change. The intended mandatory TELARC accreditation was delayed as other issues were negotiated. When one focuses on the Programme, one can only say this was very unfortunate, particularly given the impact it is likely to have had on the latter years of Dr Bottrill’s practice. When one focuses on wider health outcomes and best use of limited resources, the picture may be different.
- 138 The Minister’s policy guidelines were the beginning negotiating document. It was the “wish list”. The Funding Agreement was the negotiated outcome of what was realistically feasible within the allocated resources.
- 172 One could equally say that, had the laboratory performed a look back on the high grades it was reporting, the same information about under-reporting would have been available.
- 186 To the extent issues relating to training are relevant, they were not put directly to Ms Handiside or Mr Mules, the primary witnesses of fact.
- 187 Dr Boyd’s evidence was that he was not aware of significant concerns about shortages of laboratory assistants after 1994 (Boyd para.107). Further training of cytoscreeners would not necessarily have increased the prospects of Dr Bottrill being able to employ a part-time cytoscreener from 1990 to 1996 in Gisborne.

- 189 This may be a reference to the document “*Quality Control and Cytotechnicians in the NCSP*” (a discussion paper at Boyd Vol.4 p.91, discussed at several meetings including CSAC 26 July 1995: GRB/MOH/52 at p.5 and finally on 19 June 1996: Boyd Vol.4 p.150).
- 192 It is important to consider the Cancer Society’s opening statements in light of the fact of false negatives. It is not enough to say that one anonymous report of possible misreporting should have given rise to earlier action. Dr Cox, who received the same information from Ms Marshall as the National Coordinator, did not disagree with the Programme’s suggested response to the information: BC/CS/43.
- 199 The September 1996 comment is made in the circumstances where CSLAC has been disbanded. Prior to that, CALC/CSLAC was the forum where these matters were raised.
- 211 Again, to the extent it is relevant, these were circulated to laboratories: GRB/MOH/18; Vol.4 p.150 (foot) after much debate with CALC/ CSLAC.
- 213 Note a review of laboratories was carried out in 1993 by V Norton: JMG/MOH/25.
- 226 Note that TELARC has its own cytology-specific criteria which it assesses against but which have not been provided: affidavit of Graham Walker (7 August 2000) para.8. Note that the 1995 standards are a modified version of the 1993 NPAAC Australian guidelines: refer GM/HFA/001.
- 237 Note that, had the NCSP been delayed while the appropriate standards and monitoring were put in place, then the timetable might have resembled that for the breast screening programme, also first piloted at the same time in the late 1980s, but launched in December 1998. It is speculation to suggest that the requisite standards and processes could have been put in place and been operating for a sufficient length of time to have enabled the under-reporting in Tairawhiti to have been discovered sooner. A significant amount of data is required for meaningful analysis.

- 224 Not correct that data showing incidence by region was documented and available for comparative purposes only as a result of this inquiry. Information on incidence and mortality is available from the Cancer Registry and will be analysed by region for a fee. Dr Duncan received a 10 year analysis of cancer incidence in Tairāwhiti in February 2000 at a cost of \$770 (including GST): Cohen affidavit paras.6, 7 and 9. In its August 1997 publication the Midland HFA considered the incidence of cervical cancer in the Midland region, noting it to be of concern that there was a higher rate of incidence in Midland than all New Zealand: CM/HFA/0041, pp.8, 79-81.
- 250 The results of the Sydney re-reading exercise related to all smears taken, not simply those on the Register. Given the number of smears on the Register available for analysis when Dr Bottrill retired (refer GRB/MOH/048), it cannot be said that the existence of performance indicators would have called Dr Bottrill's performance into question very much earlier.
- 260 Note Valerie Norton checked on TELARC accreditation of laboratories in early 1993 and TELARC itself reported to CALC (and the National Coordinator) in November 1993.
- 268 No legal provision for the Department to contract directly with laboratories. Payments made pursuant to the Social Security Act as health benefits.
- 292 Dr Lambie is referring to the RHA's obligation to ensure TELARC accreditation and Ms Glackin (para.291) is talking about confirming that laboratory met the criteria set out in 4.1.4. These are two different things.
- 298 Although revised in 1993 to take account of the health reforms, the policy continued to be referred to as the 1991 policy in many areas of the Ministry. The 1996 policy was completed after the 1996/97 funding agreement was signed.
- 316 This is another example of statistics from all smears re-read in Sydney and not what was achievable from results held on the Register over the period.

- 325 Again, the false-negative rate referred to uses considerably more information than would have been available at the time, including diagnoses available now that were not available then.
- 329 The need or desirability for an electronic link between the NCSR and Cancer Registry is debatable; both registers are under the control of the Director-General and information can readily be cross-referenced using the National Health Index.
- 336 With reference to the way the Europeans monitor their national programmes, one should not place too much emphasis on the European guidelines. Dr Cox was not aware of their adoption anywhere other than in Iceland: Cox B2563/5-8 and Dr Medley confirmed that. She noted that, even in Iceland, the reporting is not complete in terms of the Guidelines: Medley B2733/24 ff.
- 356 Note that the annual publications “Progress on Health Outcome Targets” include references to the national evaluation under the heading “strategies”: DGL/MOH/014 pp.16, 26 and 36.
- 359 Again, note the laboratory review by V Norton in 1993.
- 362 Of the 17 areas for evaluation, items 1, 3 and 10 have been contracted for. Items 2, 3, 7, 8 and 8 have been the subject of routine or annual monitoring since the early days of the Programme. Item 13 has been the subject of a number of evaluations as have items 15 and 16: refer Appendix C to MOH/HFA Submission Part 1.
- 385 Note that the first statistical report, authored by Dr Cox, Dr Teague and Mr Brackenbury, was intended to, and did, provide a “template” for later statistical reports. The second and third statistical reports were referred to the expert Advisory Committees in draft for comment both on the usefulness of the layout and the content.
- 392 Note that earlier laboratory comparison tables were prepared in 1988 and 1990 in an attempt to establish some sort of benchmarking:

GRB/MOH/27 and during the preparation of the first statistical report in 1992: Boyd Vol.4 pp.31-2, Teague B1436/15 ff.

407 Correct, unless the woman or next-of-kin consented.

Reply to Closing Submissions of Counsel for the Royal College of Pathologists of Australasia and Dr C A Teague

- 4.2 TELARC accreditation did become compulsory in the mid-1990s. No advice was received from Dr Teague, CALC or CSLAC from the beginning of 1994 to the time when TELARC accreditation became compulsory that non-TELARC accredited laboratories were a concern that needed to be addressed.
- 5.2 CALC was seen by the Expert Group as the appropriate body to develop laboratory standards for TELARC. Funding for the Group was covered for part of its first year (1989) by the New Zealand Society of Pathologists and the Royal College of Pathologists. Subsequently the Health Department/Ministry took over the provision of travel costs and costs associated with the meeting venue, and provided secretarial support because of the assistance provided to the Programme: Boyd Vol.4 p.1.
- 5.3 Not so; see for example Boyd Exhibit 4 p.9 para.2.
- 5.4 Evidence is that CALC's advice was followed and implemented.
- 5.5 Not correct to say that Dr Peters' standards are in line with the Australian standards "*brought to the Ministry's attention by CSLAC in 1995*". CSLAC's 1995 standards followed the 1993 National Pathology Accreditation Advisory Council Guidelines for Gynaecological (Cervical) Cytology which did not provide for the type of benchmarking and minimum standards envisaged by Dr Peters: refer GM/HFA/001 for the Guidelines and Dr Teague's cross-examination at B1422/9-25, and CALC minutes at Boyd Vol.4 p.86. The subsequent Australian guidelines revised in 1997 and providing more explicit standards were referred to the Programme at the Expert Group meeting in 1998: JMG/MOH/076 (Vol.16 p.1). (The NPAAC Australian guidelines were revised in 1997 and became compulsory in January 1999: GVW/CA/005; date at GVW/CA/006 p.311.)

- 8.1 This submission is rejected.
- 8.1.1 The Ministry paid fees and allowances to all advisory committee members according to amounts specified by regulation and which were common to all committees. CALC was an exception as it was not formally established as an advisory committee either to the Minister or Ministry. Nevertheless travel and other expenses were paid for by the Ministry, and secretarial facilities provided. Members of its successor committee, CSLAC, were paid the standard fees and allowances.
- 8.1.2 The Ministerial Review Committee, the Expert Group and CSAC were all constituted as advisory groups to the Minister under the relevant legislation. CSLAC was constituted as an advisory group to the Department in 1995.
- 8.1.3 Subject to recommendations being accepted or rejected by the Minister, and prioritising with limited resources, recommendations were actioned.
- 8.1.4 The advisory groups all reported directly to the Minister save CALC (self-established) and CSLAC which was a technical advisory group to the Department.
- 8.1.6/8 The Committees had advisory powers, as all advisory committees had under the relevant legislation.
- 8.11 Note unfortunate editing of the quotation which starts just after Dr Tie had to acknowledge the involvement of the RCPA in many HFA initiatives: the Sax project, Gisborne Investigation, National Laboratory Review and Dr Peters' work. RCPA not as distant from Government as it tries to suggest.
- 10.1 In assessing the value of the statistical reports the Inquiry is asked to note that the first report was prepared by Drs Cox and Teague with Mr Brackenbury, and the second and third reports were the subject of consideration in draft, advice and approval by the two relevant advisory committees.

Reply to Final Submission of the New Zealand Women's Health Information and Resource Trust

Note counsel refers to the paragraph numbers of the submission as originally provided and upon which objections were made and ruled on 22 September. No subsequent version was provided to counsel for the Ministry/HFA.

31. The position taken by the [Ministry] of Health on the Programme Register and release of patient information for monitoring, auditing and research purposes follows recent legal advice interpreting legislation passed some time ago.
- 34-35 The allegations are rejected and it is submitted the evidence does not support these conclusions. The Department and Ministry were responsive to massive changes in government policy over the period of the implementation of the Programme.
- 3.2 Much of the analysis in Term of Reference Three, to the extent it focuses on “public health administration as the central cause of systemic failure leading to under-reporting in Gisborne”, is rejected. Pejorative statements unsupported by evidence and political commentary from one doctrinal perspective are put to one side, as are points which have been previously covered in reply to other submissions.
- 3.17 The evidence is that funding responsibility transferred to the Ministry of Education: Boyd paras.102-105.
- 3.20 The NCSP National Coordinator role was advertised three times prior to the position being filled by Ms Grew, a senior administrator as sought by the Minister, with a clinical nursing background.
- 3.21 Wrong. There was no such circumvention and it was not until 1998 that the Programme was transferred to the Health Funding Authority: Glackin paras.141-143. In 1997 the Associate Minister of Health was Hon Neil Kirton. While he wanted to see consultation after the Steering Group

Report, the lead Minister, Hon Bill English, accepted the Ministry's recommendation: A351/6-432/16, JMG/MOH/046, Vol.8 p.82. The issue was overtaken by events as the Steering Group decided to transfer operational coordination to the HFA. The communication strategy was approved by the Associate Minister of Health, then Hon Tuariki John Delamere on 15 February 1998: JMG/MOH/048; Vol.9 p.151.

3.24 and

3.45 These very strong statements were not the subject of evidence from Ministry officials and certainly not put to Dr Poutasi. Counsel note with some concern that they are made in the name of a Minister in the current administration and presented by a former Associate Minister of Health, both of whom were and are well placed to raise concerns such as these in other fora.

3.30 There is no evidence to support the last statement.

3.31 There is no evidence to support the last statement.

3.35 It is submitted that the lack of systematic monitoring and auditing of Register data and the lack of cytology/histology correlation for some years had nothing to do with the contracting process. These were matters which came within the responsibility of the National Coordinator and were not directly affected by the contracting process.

3.37 This submission was emphasised orally by Mr Kirton. He said he did not know what part of compulsory was misunderstood by the Ministry, given the policy guidelines appeared to make TELARC accreditation compulsory. As the evidence explained, the policy guidelines were the starting point for negotiation. They were desired outcomes, not requirements. The Funding Agreements recognised what was feasible and realistically able to be achieved within the time and resources available, and sought to make these binding contractual obligations.

3.39 This submission speculates on matters which were the subject of privileged contractual negotiations. It ignores the possibility that prioritising a broad range of matters according to their perceived

significance might have included evaluating the quality control issues and/or safety risks associated with those matters.