

**UNDER THE HEALTH AND DISABILITY
SERVICES ACT**

**IN THE MATTER OF THE MINISTERIAL
INQUIRY INTO THE UNDERREPORTING
OF CERVICAL SMEAR ABNORMALITIES**

**CLOSING SUBMISSION OF BA CORKILL,
COUNSEL FOR WOMEN AFFECTED**

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SECTION I: THE WOMEN AFFECTED

EVIDENCE OF WOMEN AFFECTED

An analysis of the evidence of the women affected is relevant for two purposes.

Firstly, to ascertain the extent to which their individual case histories are of assistance with regard to Term of Reference 1, in regard to underreporting.

Secondly, to identify other features of their cases, which give rise to cause for concern, and which it will be submitted needs to be the subject of comment by the Committee of Inquiry in due course, for the purposes of other Terms of Reference.

It will be recalled that attached to each brief was a summary of the smear history, and related relevant treatment. That material is not repeated in detail here.

What is set out below are other particular themes, which emerged from their individual cases.

Patient 1:

1.1 Brief and Exhibits:

- ?? Smear history, page 13: Four slides misread by Dr Bottrill between 1990 and 1994 (page 13).
- ?? Paras 2, 5: Patient 1 a nurse, and vigilant with all aspects of her health; regular smears.
- ?? Para 13 ff: Hysterectomy and radiotherapy at age 27.
- ?? Para 5: Clinical symptoms noted by GP

- ?? Para 1/WA/001: ACC case notes, ACC claim lodged 24 April 1995.
- ?? Exhibit KJT/MCNZ/001: 20 November 1995, complaint to Medical Practitioners Disciplinary Committee lodged.
- ?? KJT/MCNZ/0013: Notice of Appeal by Patient 1 to Medical Council.
- ?? KJT/MCNZ/005: Dr C A Teague co-ordinated a gynaecological cytology review panel; see also analysis of expert re-readings of Patient 1's slides, exhibit 1/WA/001, page 1.

1.2 Oral evidence:

- ?? Notes page A27, clinical symptoms.
- ?? Notes page A17, schedule of income lost, \$481,691.72, exhibit 1/WA/002.

1.3 Wain Brief: page 3-5 – failure to recognise smears led to delay in diagnosis, progression to advanced disease and need for radical treatment

1.4 Hobbs Brief: para 9-27 – chronology as regards disclosure of disciplinary case.

Patient 2:

2.1 Brief:

- ?? Smear history, page 8: Four slides misread by Dr Bottrill between 1992 and 1993; Sydney reread indicated all slides should have been called high grade. Dr Bottrill read slides 1 and 3 as normal, and slides 2 and 4 as low grade.
- ?? Para 1: Patient 2's sister had been diagnosed with cervical cancer, so she was extra cautious about having regular smears.

?? Para 3: Two GP's aware she had "progressed" to a CIN III in 12 months after 3 normal smears, but took no steps to establish cause.

2.2 Oral evidence:

?? Notes, page A34: did Sydney rereads disclose ASCUS H;

?? Notes, page A35: understanding distinction between high grade disease and cancer

?? Notes, page A36: management was in accordance with guidelines

2.3 Wain: page 5-7: had diagnosis of CIN been made earlier treatment would have been same, with same risk of complication such as secondary haemorrhage. There was a lack of information and understanding of difference between CIN and invasive cancer.

Patient 3:

3.1 Brief:

?? Smear history, page 5: Two slides misread by Dr Bottrill, 1991 and 1992. Sydney reread indicated first slide as ASCUS H and second as low grade. A further expert report read both smears which Dr Bottrill had read as normal as high grade (3/WA/001A).

?? Para 1: Patient 3 was a nurse and vigilant with all aspects of her health including smears.

?? Para 12: No longer trusts medical profession.

3.2 Oral evidence:

?? Notes A42: ACC applied for, cover granted, but no compensation paid (due to no time off work).

- 3.3 Boyd: Notes A159-160: management should have been 3 month return rather than 12 months – issue of registry having a mechanism to ensure management recommendations are consistent with diagnosis.
- 3.4 Wain: CIN eventually picked up, no significant clinical consequences from delay; patients supposition that second LEITZ was required because of delay is not necessarily the case.

Patient 4:

4.1 Brief:

?? Smear history, page 13, 4 smears read by Dr Bottrill as normal (1988, 1989, 1992 and 1995); Sydney reread the 1992 smear as high grade, colposcopy recommended, and 1995 as inconclusive, endocervical abnormality cannot be excluded, recommend colposcopy.

?? Para 3(f): despite clinical symptoms from 10 April 1996, not referred by GP.

?? Para 5 : clinical symptoms 4 October 1996, still not referred.
: appointment with specialist, delay in biopsy being arranged.

?? Para 13: issue of adequacy of information given by specialist

?? Para 17: adequacy of response from regional co-ordinator

4.2 Oral evidence:

?? Notes A44: adequacy of information from GP

?? Notes A46: hysterectomy sample discloses no high grade squamous lesion.

- 4.3 Wain brief; page 9-12: recognition of abnormalities prior to development of symptoms would have allowed earlier diagnosis, with need for less radical treatment.

- 4.4 Wain - cross examination: notes B1931-1933, by 1995, glandular lesion became more prominent; overgrowth of glandular component; role of a pap smear in diagnosing an adenocarcinoma.
- 4.5 McGoogan - cross examination notes A1233-A1236; plausible reasons for high grade in 1992, and adenocarcinoma in 1997.
- 4.6 Ms S Reid - cross examination notes B774-775, 781-782: discussion between patient and Ms Reid in March 1997, as to why screening programme had not protected her – was her reaction as Programme Manager appropriate. The Programme Manager had a discussion with patient 4 in March 1997, discussion with Janice Hobbs in June 1997 (regarding another patient), and there was overall an increasing number of high grades in that year: something should have been done within THL.

Patient 5:

5.1 Brief:

?? Smear history, page 10: Two smears read by Dr Bottrill, 1991 and 1995 as normal; reread by Sydney as high grade; problem not recognised until 1998.

?? Para 4: clinical symptoms

?? Para 23: wrong slide had been reread by Hamilton Medlab.

?? Para 30: loss of trust in medical profession;

5.2 Oral evidence:

?? Notes, A62/24: concerns as to who should now take her smears – GP or smear taker

?? Notes, A63-A70: concern because wrong slide number given to Medlab Hamilton.

?? Notes, A64: believed smear process was foolproof, had to self educate; was not given adequate information as to programme

?? Notes, A66: information given as to opt on/opt off

: Management rules of programme require repeat smear within 12 months after 1st smear – not done

?? Notes, A64-67: Use of brush smear/thin prep.

?? Notes, A68: reference to VAIN in registry printout

?? Notes, A72: communication of results to patient by nurse.

5.3 Wain brief:

?? Page 12 – 13: two separate disease processes: dysfunctional uterine bleeding resulting in menorrhagia, and CIN 3; no apparent consequences from delay

5.4 Dr B Boyd, notes, A128-A133:

?? Was she enrolled properly, given first registered smear in 1995, and not required to have a further smear for three years.

5.5 Oral evidence of Ms S Matchem: B3527-3531, explanation of VAIN entry.

Patient 6:

6.1 Brief:

?? Smear history, page 7: 1991 smear read by Dr Bottrill as normal, by Sydney as high grade; smears read by Gisborne Hospital 1992 and 1993, patient not informed of results.

?? Para 12: treatment by colposcopist

6.2 Oral evidence:

- ?? Notes, A74-5: information given at public health clinic.
- ?? Notes, A75: reaction of colposcopist
- ?? Notes, A76: thought if had smears would be protected
- ?? Notes, A76: not told result of 1992 smear, should have been contacted by doctor or hospital
- ?? Notes, A78: school education did not refer to pap smears
- ?? Notes, A78: further smear in post natal period
- ?? Notes, A79/13: no explanation given as to why information not given by hospital.

6.3 Wain's brief:

- ?? Pages 13-14: possible delay in diagnosis due to missed smear, but investigation of inconclusive smear in 1991 may not have revealed CIN. No apparent consequences from such delay.

6.4 Dr R Jones evidence: notes B1617-1619: patient 6 extremely angry when she attended for colposcopy and was not thinking rationally.

Patient 7:

(Died 14 June 2000, Poroporoaki, B1)

7.1 Brief

- ?? Smear history, page 9: smear read by Dr Bottrill, 1995 as normal, some blood present, repeat interval; reread by Sydney CIN III, refer for colposcopy; smear read by Dr Padwell, 1996, repeat in 3 years.
- ?? Para 4: clinical symptoms 1996
- ?? Para 8: clinical symptoms 1999

?? Para 22ff: reread smears

7.2 Oral evidence:

?? Notes, A55: ASCUS H?

?? Notes, A55, A57: clinical symptoms displayed, not responded to appropriately.

?? Notes, A57: were management requirements of register met, in respect of 1996 smear read by Dr A Padwell at Gisborne Hospital.

?? Notes, A58: delay in health care, March 1999 to August 1999.

7.3 The Sydney reread result dated 3 November 1999 was as follows:

“Diagnostic category: inconclusive

Specific findings: A high grade lesion cannot be excluded

Endometrial cells are present

Sub optimal for assessment

Reliable assessment is precluded by blood and inflammation

Specimen adequacy: endocervical component is absent

Recommendation: colposcopy is recommended”.

Thus, the report was ASCUS H, and the specimen not adequate; patient should have been referred for colposcopy.

7.4 Wain brief, page 14-16: abnormality likely to have been present at time of first smear (1995); likely she suffered considerably from failure to diagnose at an earlier stage. Some questions regarding clinical management at the time of the smears, and whether there was a failure to recognise or investigate an abnormality on the cervix.

7.5 Wain, oral evidence, B1933-1934: could have been successfully treated in 1995; life would have been saved.

7.6 Cox, oral evidence, B2498-2503: this case demonstrates need for clinical audit.

Patient 8:

8.1 Brief:

?? Smear history, page 12: smear read by Dr Bottrill as normal, 1994, high grade by Sydney; colposcopy undertaken in 1996, invasive squamous carcinoma.

?? Para 3: smear taken 1994, no test result given.

?? Para 5: diagnosis of cancer, August 1996.

?? Para 30: significant consequences

8.2 Oral evidence:

?? Notes A51: ASCUS H?

?? Notes, A52/11: suspicions of midwife

?? Boyd A134-135 (transcript incorrectly records her as witness 5 at lines A132/14 and A132/28 – correct at A133/14) – issue as to receipt of treatment from a gynaecologist, and no smear taken; not enrolled properly.

The question was raised as to whether this was an ASCUS H case. The Sydney result dated 28 October 1999 was as follows:

*“Diagnostic category: High grade epithelial abnormality
Specific findings: cellular changes are consistent with cervical intraepithelial neoplasia (Grade 3, CIN III).
Specimen adequacy: satisfactory for assessment
Endocervical component is present
Recommendation: Colposcopy is recommended”*

Here, the specimen was adequate, and it was not ASCUS H, but CIN III.

8.3 Wain brief: page 16-18: patient poorly screened, despite multiple interactions with gynaecologists and other doctors for a complex history;

earlier diagnosis by either correct reading of August 1994 smear or more frequent opportunistic screening or more astute clinical judgment would have detected the cancer at an earlier and more treatable point.

- 8.4 Wain - cross examination: notes B1934: different report of 1994 smear would have resulted in successful treatment.
- 8.5 R Jones – cross examination notes B1558: Ca Cx diagnosed, would expect review of cytology – no evidence this occurred.
- 8.6 Hobb's brief: paras 52-56: involvement in reread of smears, in 1999.

Patient 9:

9.1 Brief:

?? Para 6: Patient diagnosed with cervical cancer in 1997, and died on 25 February 1999 (para 1).

?? Para 16: Three smears read by Dr Bottrill in 1988, 1991 and 1993, all reported as normal. The 1988 smear was discarded and could not be reread; Sydney reported the 1991 smear as ASCUS H, and the 1993 smear as high grade.

?? Para 17: A further smear, taken in 1996, was misread at Gisborne Hospital (9/WA/001, Tab A).

?? Exhibit 9/CA/001, Tab F, clinical symptoms present from 1996.

- 9.2 R Jones – cross examination notes B1558: Ca Cx diagnosed, would expect review of cytology – no evidence this occurred.
- 9.3 C Teague – notes B1314-1325: case brought to the attention of Dr Teague by GP in October 1998; Dr Teague advised that a slide read originally by Dr Teague was “malignant as hell” (B1316/25); Dr Teague also telephoned Dr Bottrill's counsel as well (B1320/11).

Patient 10:

9.1 Medical notes (fully summarised in this case, as Patient 10 did not submit a brief, and her notes were not seen by Dr Wain):

28 January 1987: Smear – dysplasia to mild degree, grade 2 (Auckland Diagnostic Laboratory). No indication smear repeated in 6 months as recommended.

22 May 1990: Smear – read by Dr Bottrill's laboratory as, "no endocervical cells present". No recommendation but practice should have meant that smear repeated. Confirmed by Dr Hitchcock as unsatisfactory with recommendation to be repeated in 3 months. No repeat smear taken by gynaecologist at Gisborne Hospital. First opportunity for early diagnosis missed.

June 1991: EUA, Laparoscopy and chromtubation at Gisborne Hospital. Diagnosis – cyst on right ovary.

24 November 1992: Smear – read as normal by Dr Bottrill, unsatisfactory by Dr Hitchcock, and CIN II by Sydney. Second opportunity for early diagnosis and treatment missed.

23 July 1993: Smear – read by Dr Bottrill as low grade and Sydney as CIN I. Dr Bottrill's recommendation was to repeat at post natal check up and Sydney was for a colposcopy.

- October 1993: Smear – read by Dr Padwell, Gisborne Hospital as CIN III. Treatment delayed because of pregnancy.
- 30 June 1994: Cone Biopsy and D&C at Gisborne Hospital. Histology report – HPV with CIN III completely excised. (Medical Diagnostics, Palmerston North). This was the first occasion on which treatment was provided, despite options for diagnosis and treatment since 1990.
- 17 February 1995: Smear and currettings at Gisborne Hospital. Reported by gynaecologist to patient as normal. Report on currettings was insufficient for diagnosis. Dr Dady's report was that adenocarcinoma likely to have been present, currettings should have picked it up. Third opportunity for diagnosis and treatment missed.
- 11 January 1996: Smear – read by Dr Padwell, Gisborne Hospital as normal. Examination by gynaecologist at Gisborne Hospital, Dr Wijerante who reported cervix as healthy. Because of continuing debilitating pain and heavy bleeding, patient requested hysterectomy. Referred for hysterectomy after second opinion from Dr Naidoo recommended it and only with reluctance on the part of Dr Wijerante.
- 29 April 1996: Hysterectomy – Gisborne Hospital for endometriosis. Histology showed well differentiated adenocarcinoma with minimum invasion.
- 9 July–16 August 1996: Radiotherapy – Palmerston North Hospital.

- October 1996: Patient sought medical attention on several occasions for ongoing abdominal pain.
- 22 July 1998: Referred by Dr Van de Mark to gastroenterologist.
- 15 January 1999: Diagnosed by Dr Edge, gastroenterologist as suffering from radiation damage to small and large bowel.
- 11 May 1999: Admitted to Gisborne Hospital for surgery to the small bowel. Operations on 12 May 1999, 21 May 1999 and 9 June 1999 followed by many months in Gisborne and Auckland Hospitals. Now has colostomy bag, and is unable to work or care for children without assistance. She requires ongoing pain relief and treatment.
- 23 August 1999: Dr Van de Mark, in her letter to ACC, stated earlier diagnosis would have resulted in less invasive surgery.
- 10.2 Hobbs brief, paras 43-51 – professional support of Patient 10 by Ms Hobbs.
- 10.3 There was a failure of clinicians to follow up on inadequate tests; earlier diagnosis and treatment was possible on at least three occasions: 1990 (GP error); 1992 (Dr Bottrill error); 1995 (O&G error), given heavy bleeding, persistent abdominal pain, and pain during intercourse, over a long period of time.
- 10.4 Having regard to evidence of Dr Wain (B1932), an endocervical component was absent in the 1990 smear which would be necessary for the diagnosis of a glandular abnormality; if, however, that smear had been repeated the problem may have been diagnosed; Pap smears can assist in the diagnosis of adenocarcinoma. Similarly, colposcopy in 1992 may have diagnosed the problem.

Patient 11:

11.1 Brief:

- ?? Smear history, page 10: smears read in 1991 and 1992 by “Y-FC”, in Dr Bottrill’s laboratory, repeat after oestrogen treatment.
- ?? Para 5 ff: clinical symptoms
- ?? Para 29, 30, explanation of cultural issues for Maori women.

11.2 Oral evidence:

- ?? Notes, B3047: Y-FC is Dr YF Chan, locum.
- ?? Notes, B3049: unaware of abnormal smear results in 1976.
- ?? Notes, B3050: question of medical attention between 1976 and 1980.
- ?? Notes, B3051: opted onto programme
- ?? Notes, B3052: attitude to retrospective audit

11.3 Memorandum of counsel for patient 11, as to notes in the period 1976-1980:

- ?? 1976: smear taken, Gisborne Hospital
- ?? Para 6: patient was not given advice by hospital of smear result.
- ?? Para 7: smear result not reported by House Surgeon to GP
- ?? Para 8: one further smear 12 May 1987, has been located (normal – no neoplastic cells seen).

Patient 12:

12.1 Brief:

- ?? Smear history, page 17: smears read by Dr Bottrill/YFC as normal 1991 (2 smears) and 1992; Sydney reread the first two as normal,

and the third as ASCUS H. Further smear taken in 1993, outside normal limits, repeat in 3 months; three further smears read as normal (first two Gisborne Hospital, third, Palmerston North, 1994, AW/WA/002, page 41 – no cytopathologist identified on report; 1996, AW/WA/002, page 40, Dr A Padwell); 1999 smear read as CIN III, squamous carcinoma stage IB diagnosed shortly thereafter.

?? Para 14: cancer diagnosed, aged 27

?? Para 26: adequacy as to pamphlet dealing with intended hysterectomy

?? Para 32: adequacy of post-operative care

12.2 Oral evidence:

?? Notes, B3026: brought up to believe should have regular smears

?? Notes, B3027-3028: issue as to who read the 1994 and 1996 smears

?? Notes, B3028: 1994 and 1997 slides have been misplaced

?? Notes, B3030: never received any follow up letters from register, from 1993 onwards

?? Notes, B3031: no name change

12.3 This patient, at age 27 years, has lost the opportunity to have children naturally. She is now seeking ACC to fund IVF surrogacy.

12.4 A query was raised in evidence regarding this Patient's name change. Her surname was Falkiner until date of marriage, 18 October 1997. Originally, on the register, her surname was spelt as Falkner (12/WA/002 page 28). On page 29 of the same exhibit, her surname is spelt Falkiner. We are instructed that this patient has had major difficulties with the Public Health Unit losing her file because her name was spelt variously Falkiner and Falkner. Such confusion may have

been the reason why some of her smear results were not recorded on the register, prior to her marriage.

Patient 13:

13.1 Brief:

?? Smear summary, page 10: smears taken 1990 and 1993, read by Dr Bottrill as normal, and by Sydney and others as high grade; third smear taken in 1996 read by Dr Bottrill as CIN II or III, and by Dr Hitchcock, HGSIL.

?? Biopsy and histology results differ from what is shown on register – VAIN problem, see evidence of Ms S Matchem, supra, (notes B3527-3531).

13.2 Oral evidence:

?? Notes, B3035: misleading nature of registry summary.

Patient 14:

14.1 Brief:

?? Smear history, page 8: smears read by Dr Bottrill as normal, 1992 low grade 1994, (two smears) and 1995, normal. All reread by Australia as high grade.

?? Para 2: regular smears, because of sexual abuse as a young person.

14.2 Oral evidence:

?? Notes, B3038: difficulty for Maori women to come forward

?? Notes, B3039-40: reasons patient came back for further smears in 1993 and 1994

?? Notes, B3040: not informed of 1994 management recommendation that assessment recommended.

?? Notes, B3041: had two fixed addresses, did not receive a letter advising of assessment.

14.3 As requested by the Committee of Inquiry, evidence was obtained as to the follow up for the 17 November 1994 smear. Refer to exhibit EV/WA/003, wherein the GP states he did not refer Patient 14 for gynaecological assessment on receiving that smear report, because she was pregnant at the time. He stated that gynaecological policy at that time was to delay the colposcopy until after delivery. He organised a six month recall. The pregnancy ended in a spontaneous miscarriage on 5 December 1994; he saw her six months later, 12 May 1995, and repeated the smear. See also his references to the signature on the smear results, and the handwritten numbers on the smear records.

Patient 15:

15.1 Brief:

?? Smear history, page 8: smear of 23.12.91 read in Dr Bottrill's laboratory (Y-FC), and reread in Sydney as high grade CIN 3.

?? Para 6: clinical symptoms, further smear and colposcopy taken

?? Para 14: stage 3B carcinoma diagnosed, 4 November 1999.

?? Para 9: advice from ACC is that had smear been correctly read in 1991, treatment would have been commenced then; carcinoma would have been in situ, and could have been completely removed by biopsy. Consequently, she has suffered reduced life expectancy (see report of Dr KR Anderson, 6.3.00, pages 16 and 17 of NC/WA/001).

Patient 16:

16.1 Brief:

?? Smear history, page 14: Three smears read by Dr Bottrill in 1990 (outside normal limits, repeat), 1993 (normal), and 1994 (normal) the second of these was reread in Sydney as ASCUS L, and the third as CIN III (also reread by Dr Hitchcock).

?? Para 5: clinical signs, November 1997

?? Para 7: impersonal treatment by specialist, but note apology in para 9, and patients comments, para 20.

?? Para 11: cone biopsy disclosed CIN 3

?? Para 18: hysterectomy, January 1998, samples confirmed at other hospitals as being extensive CIN 3.

?? Para 27: slides reread by Medlab Hamilton.

?? Para 31: slides reread by Dr G Hitchcock.

?? Para 33: advice that had slides been read correctly in 1990 or 1993, the disease would have been taken care of very much sooner, and would not have had to undergo a hysterectomy.

Patient 17:

17.1 Brief:

?? Smear history, page 11: Four smears read by Dr Bottrill, 1991 normal, 1993 inflammation present, 1994 normal, 1995 atypical repeat 6 months; the first was reread by Sydney as ASCUS H, and the remainder as high grade. Subsequent smears taken in 1997 (unsatisfactory, repeat as soon as possible) and 1999 (normal).

?? Para 5: multiple smears taken, 1991-1997, not advised of result of 1995 smear.

?? Para 6: not advised of result of 1997 smear.

?? Para 7: referred to gynaecology clinic, due to clinical symptoms.

?? Para 13: difficult birth, due to lump in cervix

?? Para 15: cancer stage II diagnosed.

?? Para 30: no longer trusts the medical profession.

?? Para 26: Effects on family (8 children) of late diagnosis and consequent treatment.

17.2 Supplementary brief:

?? Para 3: not told to repeat smear within 6 months

?? Para 7: 1991 smear examined by "Y-FC"

?? Exhibit EM/WA/001: page 26 – ACC letter of 27 April 2000 – Dr Bottrill's misreading of smears between 1991 and 1995 showed a failure to observe a standard of care in school reasonably to be expected in the circumstances. Disease was allowed to continue and progress undetected over a period of four years.

Patient 18:

18.1 Brief:

?? Smear history, page 9: Three smears read by Dr Bottrill, all as normal, 1989, 1990 and 1993; 1993 smear reread twice (first reread by Sydney: atypical cells of uncertain significance; Second reread: repeat 6 months, ASCUS L)

?? Para 12: further smear, 1996, CIN III.

?? Para 15: LEITZ procedure, May 1997

?? Para 18: GP apparently thought misreading of smears “quite rare”.

?? Para 24: does not have much faith in medical profession any more.

?? Paras 2-9: worked for Dr Bottrill 1987–1990.

Patient 19:

19.1 Brief:

?? Smear history, page 8: Three smears read by Dr Bottrill 1991, 1992 and 1996, all as normal; the first 2 were reread in Australia as normal and CIN III (not ASCUS H).

?? Para 6: reactions of Pakeha and Maori women to smear taking.

?? Para 19: client contacted. Never had explained to her the reason for normal smear result, following colposcopy. After Sydney reread, colposcopy results sent in mail. Advised by Dr R Jones to have annual smears as a precaution.

19.2 Exhibit GG/CA/1:

?? p9: Normal, colposcopy – was this regression; if not, was it explained to patient?

Patient 20:

20.1 Brief:

?? Smear history, page 8: Dr Bottrill read smears in 1993, 1994 and 1995 – reread in Australia as low grade ASCUS L, normal and CIN II, HPV.

?? Para 4: unaware of screening programme.

?? Para 12: Patient’s understanding of low grade and high grade.

?? Para 20: Client contacted. Gynaecologist did not explain why results were different.

20.2 Exhibit MF/WA/001:

?? P10: June 1995, CIN II, three normal smears subsequently, normal colposcopy – regression, was this explained to her?

CONCLUSIONS FROM SMEAR HISTORIES OF PATIENTS 1-20:

Other rereads:

21. In a number of examples, rereads of smears read originally by Dr Bottrill were performed not only by Sydney, but also other labs, (e.g. patients 5, 8, 10, 13, 16, and 18). In each case, the rereads from labs other than Sydney confirmed the Sydney result, rather than the result of Dr Bottrill.
22. A further factor tending to confirm the accuracy of the Sydney result in each case, rather than that of Dr Bottrill, is the histology result obtained in each case. That position is summarised in the annexed table. The possibility of progression between the date of the smear and the date of the histology is acknowledged, and not all examples relate to a Sydney reread in any event (patients 1 and 7 were not reread by Sydney). Although the table produced is somewhat crude, it can at least be said that it is yet another conclusion (as is the conclusion just mentioned in para 21.1), pointing towards underreporting. These conclusions are consistent with and reinforce the conclusions as to underreporting reached by such experts as Dr Farnsworth, Dr Wain, Dr Cox and Professor Skegg.
23. 7 of these 20 cases involved cancer of the cervix, and are presumably therefore registered on the cancer registry, and will therefore be analysed more thoroughly in the context of Professor Skegg's audit.

Other Cytopathologists:

24. In the cases of patients 11 and 12, smears were read by Dr YF Chan, presumably when acting as a locum at Dr Bottrill's laboratory. The same applies to patients 10 and 16, smears read by Dr Singh (MS). At para 18 of his brief, Dr Bottrill stated he would go over reports and slides of a locum pathologist for the first week, and thereafter perform the usual 10% random rescreen. It is not known whether the smears in

respect of patients 11 and 12 were carried out in the “first week” of a locum, but prima facie Dr Bottrill carries ultimate responsibility for these smears.

25. In five cases, in addition to smears read by Dr Bottrill, there were also smears read (prior to diagnosis of pre invasive or invasive disease) by other pathologists. They are patient 6, (Gisborne Hospital), patient 7 (Dr A Padwell, Gisborne Hospital), patient 9 (Dr M Chan, Gisborne Hospital), patient 10 (Dr Singh and Dr Padwell, Gisborne Hospital) and patient 12 (Dr A Padwell, Gisborne Hospital).

Causation of adverse consequences:

26. Any issues of causation must acknowledge the role of other cytopathologists in those cases. Even in those cases, however, proved misreading by Dr Bottrill must at least be regarded as a material or contributory cause (for a recent review of causation where there are multiple wrongdoers, and the fact that all a Plaintiff in a tortious action need prove is “material contribution” of each Defendant, see **Holtby v Brigham and Cowan (Hull) Limited** [2000] Lloyds Rep Med 254, 259, per Stuart-Smith LJ).
27. Dr GV Wain reviewed the briefs and comprehensive medical records in the cases of patients 1 to 9, and the briefs and core medical records in the case of patients 11. His conclusions are particularly noted at paras 23 and 26 of his brief; also notes B1935-1936, B1944-1945.
28. In the individual cases he reviewed, he was able to say that failure to recognise abnormal smears had led to delay and the need for more radical treatment e.g. patients 1, 4, 7 (life lost), 8, and 9. Other pathologists have also reached a similar conclusion, for ACC purposes; (see for example, patients 10, 15 and 16). Several women, he said, had lost the chance to have their cervical pathology diagnosed at a treatable point and had gone on to develop advanced and fatal cervical

cancer (para 28). In other cases, delay had not resulted in “adverse consequences”.

29. At para 23 of his brief, he stated, *“this is an effectively unscreened population of women who are presenting with a range of cancers typical of an unscreened population”*; this was consistent with Dr Van de Mark’s observations (Brief, para 27, notes B685, and those of Dr Farnsworth, B1771, B1782, B1786).
30. At para 26, he said he saw a range of clinical behaviours with some indolent disease and fatal progressive invasive cancer.
31. In oral evidence he agreed his conclusions from a clinical perspective were consistent with other conclusions as to underreporting which had been inferred from the biopsy cytology correlations [B1936/9-11].
32. This clinical data, then, is consistent with, and reinforces “unacceptable underreporting”.
33. The final matter which needs to be mentioned in this context is the possibility that other laboratories have also undertaken unacceptable underreporting; it has already been observed that patients 6, 7, 9 and 12 involved Gisborne Hospital. These particular cases suggest unacceptable underreporting in those instances. This conclusion is relevant for the purposes of Term of Reference 3.
34. Dr Padwell indulged in a totally unacceptable practice (Morris, B2901-2), home screening.

OTHER ISSUES ARISING FROM THE CASES OF PATIENTS 1-20

35. From the foregoing summary of individual cases (paras 1-20 above), it can be seen that a number of issues emerge.
36. Clinical issues: in a number of instances, there were clear clinical signs, yet it appears the health professionals involved were content to rely on the smear result. Examples are Patients 4, 5, 6, 8, 10, 11, 12, 14, 16 and 17; this was despite repeated consultation with GPs and gynaecologists for gynaecological problems or obstetrics over lengthy periods. There were symptoms which would have justified a referral; yet this did not occur. The most benevolent submission which can be made is that there was undue reliance by the health professionals on the accuracy of the smear reporting, and a poor understanding of the issues relating to smear reporting by those professionals. Indeed, in the case of patient 18 (para 18), there was an explicit acknowledgement of this ignorance. A less benevolent submission would be that the health care professionals involved were simply inept.
37. Dr Ron Jones, colposcopist, agreed that in a number of the cases (e.g. patients 8 and 9), review of cytology should have occurred (B1558). It did not; Dr Cox agreed that the case of Patient 7 demonstrated the need for clinical audit.
38. There were issues as to proper enrolment on the register; in several cases, (e.g. patient 5), the initial enrolment on the register was not followed up by a recall for a repeat smear within 12 months, (see discussion with Dr Boyd, transcript A122-133 in respect of Patients 6, 4, 5, and 8).
39. Another recurring theme is the lack of information given to the women affected (e.g. patient 4); allied to this is the understanding of issues relating to the screening programme. Women believed that smear results were 100% accurate. There was a consistent lack of knowledge of the false negative rates. Education, background or

culture did not appear to have any influence (patient 5 brief para 2; patient 6, notes A64/5; patient 11 brief, para 3; patient 12 brief, para 2; patient 13 brief, para 2; patient 15 brief, para 4; patient 17 brief, para 4; patient 19 brief, para 11 and patient 20 brief, para 4). Most women did not know about the screening programme, its purpose or the options, particularly in respect of opting on and opting off. Of the 17 women who commented on this issue in their briefs (see following list) or when giving evidence, only 5 had knowledge of enrolling on the programme. This was after advice from the GP or nurse. (Patient 1, notes A24/13; patient 3, notes A39/18; patient 4, notes A45/20; patient 5, notes A63/24, A64/12 and A66/6; patient 6, notes A75/25; patient 7, notes A56/19; patient 7, notes A51/17; patient 11 brief, para 3; patient 12 brief, para 3; patient 14 brief, para 2; patient 15 brief, para 5; patient 16 brief, para 2; patient 17 brief, para 2; patient 18 brief, para 11; patient 19 brief, para 5; patient 20 brief, para 4).

40. Several patients were not informed of either the management recommendation (e.g. patient 14, Notes B3040), or the result of the smear (patient 6, Notes A76/20). They accordingly assumed the smear result was normal.
41. Several patients insisted on further treatment; it was only their insistence which resulted in the problem being diagnosed (Patients 4, 5, 10 and 14).
42. The layout of the registry computer printout needs some attention, due to the confusion that it can create.(e.g. VAIN example, Notes B3527-3531, patients 5 and 13).

Conclusion:

43. The Committee of Inquiry received evidence/records from only 20 women, all of whom had slides reread as high grade, which had not been read as high grade in the first instance; the HFA, on the basis of the Sydney rereads, has given evidence there are 628 women in this

category (i.e. high grade results as reread). There are many more women in other categories.

44. The Committee has therefore heard from a fraction of the total cohort of women who have been affected by this tragedy. The Committee hardly needs to be reminded of the effect of this tragedy on each of the women and their families. Examples are deaths, (patients 7 and 9), inability to work (patient 10), inability to provide care to children (patients 8-10, 17), and the necessity for ongoing treatment and management, (all patients), and above all, in every case, significant trauma.
45. This evidence is the tip of the iceberg. One has to acknowledge that the full extent of this tragedy has been enormous, and is of course totally unacceptable.

TABLE; PATIENTS 1-20; CYTOLOGY/HISTOLOGY

Patient	Highest Bottrill report (prior to diagnosis)	Sydney	Histology
1	LG (1990)	HG (1990) (Not Sydney)	Ca Cx (1995)
2	LG (1993)	HG (1993)	CIN III (1993)
3	Normal (1991, 1992)	ASCUS H (1991) LG (1992)	CIN III (1992)
4	Normal (1995)	HG (endocervical) (1995)	Aden. (1993)
5	Normal (1995)	HG (1995)	CIN III (1998)
6	Normal (1991)	HG (1991)	CIN II/HPV1 (1999)
7	Normal (1995)	CIN III (Not Sydney)	Ca Cx (1999)
8	Normal (1994)	HG (1994)	Ca Cx (1997)
9	Normal (1993)	HG (1993)	Ca Cx (1997)
10			
11	LG/Atypical Y-FC (1992)	HG (1992)	CIN III (1992)
12	Normal (1992)	ASCUS H (1992)	CIN III (1999)
13	Normal (1993)	HG (1993)	CIN III (1996)
14	LG (1994)	HG (1994)	CIN II/III (1999)
15	Normal (1991)	HG (1991)	Ca Cx (2000?)
16	Normal (1994)	HG (1994)	CIN III (1997)
17	LG/Atypical (1995)	HG (1995)	Ca Cx (2000)

18	Normal (1993)	ASCUS L (1993)	CIN III (1996)
19	Normal (1992)	HG (1993)	Normal colposcopy (1999)
20	Normal (1995)	HG (1995)	Normal colposcopy (2000)

CAUSES OF CERVICAL CANCER

46. A difficult issue is the perception that somehow the incidence of cervical cancer is directly related to sexual behaviour, or that it is a function of sexual behaviour.
47. This is not so, and a strong message needs to be sent by the Committee of Inquiry that it is not so.
48. In the well known text, **Shingleton and Orr**, "Cancer of the Cervix: Diagnosis and Treatment" there is the following passage (p13):

"The fact that unscreened women are at increased risk of developing cervical cancer suggests that all women should participate in cervical cancer screening programmes. Numerous publications exist that relate the risk factors. The following are associated with high risk:

- ?? *Early intercourse (less than 17 years old).*
- ?? *Multiple sexual partners*
- ?? *Early pregnancy*
- ?? *Urban population*
- ?? *Low socio economic status*
- ?? *Immunocompromised smoker*
- ?? *Previous abnormal smear*
- ?? *Failure to participate in screening*
- ?? *Nutritional defects*
- ?? *Infertility (tubal damage)*
- ?? *Use of contraceptives*
- ?? *High risk male partners"*

49. Evidence of the causes and risks have been produced:

- ?? McGoogan Brief, paras 25-32 – see particularly her discussion of role of HPV, not mentioned as a risk factor in above summary.
- ?? Cervical Cancer: Understanding Cancer: Causes (EAM/CS/001, p3)
- ?? Public Health Commission’s statement on cervical cancer (Glackin, Vol 6, Tab 31, page 10-11)
- ?? Note Dr Jones’ observation: *“The perception that there are women of high risk, is I think a very dangerous suggestion because we know it is the male that is the vector. It’s my view that all women should have smears, and I think categorising women according to risk is a perceived risk and not necessarily a real risk”*. (B1565)

50. From the foregoing, it is submitted:

- 50.1 Any woman who has had sexual intercourse can suffer infection by HPV.
- 50.2 Co-factors, such as those identified above, can increase risk.
- 50.3 A Cervical Screening Programme is the only known effective preventative strategy.

51. These are the factors which should be strongly endorsed by the Committee.

SECTION II: TERM OF REFERENCE II

FACTORS LIKELY TO HAVE LED TO UNDER REPORTING:

Scope of TOR 2:

52. It is submitted there are multiple factors which need to be considered.
53. There are various forms of analysis which could be undertaken in identifying those factors, for the purposes of Term of Reference 2. It is our submission that the Commission is required to identify all factors which are likely to have led to the underreporting, whether direct or indirect.
54. Further, for the purposes of Term of Reference 3, the Committee is required to evaluate whether underreporting in the Gisborne region is an “isolated case” or rather, “evidence of a systemic issue for the National Cervical Screening Programme”. A systemic analysis is required here also.
55. Later Terms of Reference require overall evaluations to be undertaken, to mitigate the risks of underreporting of abnormalities in cervical smears.
56. Having regard to those factors, therefore, the Committee is required to conduct a broad inquiry.

Nature of Error:

57. In modern society, it is frequently necessary to analyse accident causation in complex systems. A well known text on this topic is “Human Error” by James Reason (Cambridge University Press, 1990).
58. At Chapter 7, the author addresses errors in the context of systems disasters. The following extract is of assistance:

“In considering the human contribution to systems disasters, it is important to distinguish two kinds of error: active errors whose effects are felt almost immediately, and latent errors whose adverse consequences may lie dormant within the system for a long time, only becoming evident when they combine with other factors to breach the systems defences. (See Rasmussen and Pedersen 1984). In general active errors are associated with the performance of the “frontline” operators of a complex system: pilots, air traffic controllers, ships officers, control room crews and the like. Latent errors, on the other hand, are most likely to be spawned by those whose activities are removed in both time and space from the direct control interface: designers, high level decision makers, construction makers, managers and maintenance personnel.

Detailed analyses of recent accidents, most particularly those at Flixborough, Three Mile Island, Heysel Stadium, Bhopal, Chernobyl and Zeebrugge, as well as the Challenger disaster, have made it increasingly apparent that latent errors pose the greatest threat to the safety of a complex system”. (page 173, case studies of each of those catastrophes are given at page 251-257; there is now a considerable body of literature on such systems analysis with regard to medical error).

59. While the focus of that particular analysis is on technological catastrophes, it provides a valuable insight for analysing system defects.
60. In the present situation there were both latent factors and active factors.
61. This in no way discounts Dr Bottrill’s responsibility and accountability for the underreporting. It is our contention that he was seriously at fault, and incompetent.

62. It is also our submission, however, that there were multiple other factors, suggesting that a range of other individuals/entities also played their part in the disaster.

Blame:

63. In opening, counsel for the HFA/Ministry, submitted that the Committee was not asked “to determine questions of blame. It must avoid the temptation to blame”. The Inverclyde Report was given as a good example of systemic analysis.
64. Any distinction between determining causation and attributing blame, is more apparent than real. The Committee is required to analyse cause and effect; in identifying factors which led to under reporting, it is necessary to identify what went wrong; if that involves a finding that a particular individual, (or organisation), did not do something he or she should have done, then the Committee will have to make that finding, and it should not recoil from doing so.
65. This topic was recently considered by Heron J in **Davies v Transport Accident Investigation Commission** (23.6.00, CP 304/99, Wellington Registry). It was considering the Transport Accident Investigation Commission, which had the powers of a Commission of Inquiry. It was contended that the Commission had acted outside its statutory authority finding that a history of low flying, on the part of the Plaintiff, was outside the Commission’s statutory authority, and represented an apportionment of blame rather than a determination of the cause of accident, and that the apportionment of blame was not merely incidental to the cause of the accident. His Honour found:

“It is not always possible to determine the cause of an accident without an incidental apportioning of blame. Whether it is deemed to be pilot error or a defect in a mechanical component, some blame will fall with either the pilot or the manufacturers of the component by virtue of determining the cause. As Goddard

J said in [Whale Watch Kaikoura Limited v Transport Accident Investigation Commission [1997] 3 NZLR 55]:

“I accept that the Commission takes seriously the need to avoid implying blame where possible, but it is also responsibly aware that the inference of blame can sometimes not be avoided if it is to report independently and that independence and objectivity ensures renditions is makes effective in safe guarding the public welfare and it is vital that these attributes should not be undermined, nor unnecessarily frustrated and hampered by litigation”.

I think in situations such as the present case, where the cause of the accident is implied to be that of pilot error, blame is implicit. Where such a situation occurs, it is essential that the Commission demonstrates in its report that it has considered all other reasonable potential causes, and that its findings are based on sufficient probative evidence. Here the Commission have (sic) gone to considerable lengths in the report to support its findings. It considered all other reasonable potential causes. The motives of the Commission in this case were not to ascribe blame, but to lay a sufficient foundation for their (sic) conclusions as to the cause of the accident.”

66. The public interest and the terminology of the Terms of Reference require clear and unambiguous findings as to what has gone wrong in this case. If the underreporting is “unacceptable” then, so are any contributory causes, and the Committee should say so.
67. Using the categories of “latent” and “active” contributory factors, it is proposed to analyse the history which led to the underreporting, in the following way:

67.1 Latent factors:

67.1.1 Setting up of NCSP

- 67.1.2 Restructuring issues
 - 67.1.3 Financial issues
 - 67.1.4 TELARC accreditation
 - 67.1.5 Monitoring and evaluation, including establishing of standards.
- 67.2 Active factors:
- 67.2.1 1989: Visit to Tairāwhiti Area Health Board by Implementation Unit.
 - 67.2.2 1991: First Rotorua complaint
 - 67.2.3 1993: Second Rotorua complaint
 - 67.2.4 1993: Hitchcock letter
 - 67.2.5 1994: Good Health Wanganui circumstances
 - 67.2.6 1994/5: Wake up calls Midland RHA
 - 67.2.7 Concerns of Programme Managers
 - 67.2.8 Resignation of Dr Cox
 - 67.2.9 Extent of High Grade statistics – Tairāwhiti
 - 67.2.10 Patient 1 case, 1997
 - 67.2.11 Other concerns in Tairāwhiti, 1998
 - 67.2.12 Dr Bottrill's practice.

SECTION III: LATENT FACTORS

SETTING UP OF NCSP

Introduction:

68. Any consideration of the establishment of the National Cervical Screening Programme must begin with the recommendations of the “Report of the Committee of Inquiry into allegations concerning the treatment of cervical cancer at National Women’s Hospital”, 1988 (“the Cartwright Inquiry”). Chapter 10 of the Report addressed a number of key issues in relation to cervical screening, and, inter alia, recommended the implementing of the population based cervical screening programme for New Zealand women (page 209).
69. A high priority was to be accorded to quality control. The Committee recommended careful planning and wise expenditure in that regard.
70. The chronology thereafter is very clear from the evidence, and is summarised, for example, in Dr Boyd’s/Ms Glackin’s briefs, and the “chronology of exhibits”. A particularly helpful summary is that contained in the Cox and Richardson, “Draft Evaluation Plan for the NCSP” (Glackin, Volume 9/47, June 1997). See particularly:
 - 70.1 Pages 39-72: General history of programme
 - 70.2 Page 72-74: History of the involvement of Maori women in the NCSP
 - 70.3 Pages 74-76: History of the involvement and efficacy of the Pacific Island Community in the development of the programme.
71. A feature of the various chronologies placed before the Committee is the clear and strong advice given to both the Department of Health and the Minister, in establishing the programme. That advice is evident in the reports and recommendations of:

- 71.1 Ministerial review report (Glackin Vol 1, Tab 1)
 - 71.2 The Straton report (Glackin Vol 1, Tab 4)
 - 71.3 The Expert Group report (Glackin Vol 2, Tab 5)
72. In the interests of avoiding needless repetition, the chronology is not traversed yet again.
73. In the submissions which follow, it will be submitted that key elements of the expert advice given to the Department of Health and Minister of Health were not adequately followed.
74. In these submissions, an attempt has been made to collate relevant references in the evidence; that collation, however, does not purport to reproduce each and every reference in the evidence to the particular themes. There are of course others which the Committee may well find of assistance.
75. It is submitted that the evidence relied on below, is to a very substantial extent not contradicted by the Ministry of Health. Much of the material relied on is self evident from contemporaneous documents. Further, observations of independent witnesses (particularly Professor Skegg, Mrs Marshall, Dr Cox, and Ms Coney) were not contradicted by cross examination, or (in most instances) even any contrary evidence from the Ministry itself. The inferences drawn from the uncontroverted evidence, as relied on below, cannot be denied.

Opt Off/Opt On:

76. Dr Straton recommended an opt off register rather than opt on; this was the subject of a key recommendation by the Expert Group (Straton report p206, Expert Report, p1). A number of witnesses were highly critical of the fact that this advice was not implemented:

?? Coney:

Brief: para 19.1, paras 164-185

Notes B2760

?? Cox:

Brief: para 85

Notes B2491

?? Skegg:

Brief: para 39

Notes A900.

77. Professor Skegg regarded the failure to have an opt on scheme as resulting in the expenditure of millions of dollars, and the establishing of a complex but incomplete computer system. There were also significant implications for the extent of data obtained by the Register.

78. It appears the decision to institute an opt on scheme at the outset, was due to lack of understanding. The main advantages were and are:

78.1 Mortality and morbidity reduced because women on the register are recalled regularly and can be followed up when they have an abnormal smear.

78.2 The choice to enrol is with the women not the smear taker.

78.3 Screening coverage extended so that the programme can reach its goals and be cost effective.

78.4 The quality of the screening service can be monitored at all points (Coney, para 174).

Histology on Register/Cancer Registry:

79. A second serious flaw in the establishing of the programme related to:

79.1 Failure to record histology on the NCSR register.

- 79.2 Failure to link the NCSR with the Cancer Registry.
80. Advice was given on these topics from an early point:
- 80.1 Ministerial Review Committee – urgent attention to be given to extending histology as a means of quality control and uniformity; links with NCSP and Cancer Registry to be given immediate attention (Glackin Vol 1, Tab 1, page 58 of Report).
- 80.2 Expert Group (accepting the advice of Dr J Straton) - urgent attention should be paid to ability to link cytology and histology results; possible use of National Cancer Registry for initial registration of histology results to be considered, as a matter of urgency (para 11.2.9).
81. CSAC also gave strong advice on both matters:
- 81.1 Histology, Cox brief, paras 37-52 and 105.
- 81.2 Linkages with Register, Cox brief para 43 and 47.
82. Other relevant observations:
- 82.1 Glackin, Notes A251.
- 82.2 Skegg, Notes A893, A900, B2816.
- 82.3 Medley, Notes B2703.
83. Professor Skegg saw the connection of cytology data and histology data as being *“of fundamental importance and it is inexcusable that several years elapsed before this was done”*. He was also critical of the fact that the *“fundamental need to link from the Cancer Registry to the National Cervical Screening Register ... is not even contemplated at the moment... I find it extraordinary that we have spent millions of dollars establishing and maintaining these registers but we are not using them in the way they could be used”* (A893).

Strong Leadership:

84. This was of course emphasised in the World Health Organisation criteria for successful screening programmes, and re-emphasised by Judge Cartwright.
85. Witnesses attested, however, to this requirement not being fulfilled due to:
 - 85.1 Advice as to executive body not accepted by Minister
 - 85.2 Low status of National Co-ordinator
 - 85.3 Inadequate experience/skills of those managing the programme
 - 85.4 Lack of institutional knowledge
 - 85.5 High turnover of staff; difficulty in recruiting and training staff with appropriate expertise.
 - 85.6 Lack of multi-disciplinary content and leadership
 - 85.7 Failure to understand the complexity of a screening programme.
86. References:
 - 86.1 CSAC Report, 1994 (Glackin Vol 7, Tab 35, page 13)
 - 86.2 Boyd Vol 3, Tab 14, Boyd evidence 151-3
 - 86.3 Glackin
Oral evidence A192; A263-4
 - 86.4 Marshall:
Brief: 36, 68, ff, 97-106
Oral evidence B3211, 3234-5.
 - 86.5 Cox

Brief: 91, 96, 120, 129, 133, 142, 164, 177, 179, and 187

86.6 Coney

Brief: para 19.3

86.7 Handiside

Oral evidence: B3718

86.8 Grew

Oral evidence: B4138-9.

87. As Dr McGoogan concluded, the absence of strong leadership was “regrettable” (Notes A1125/16).

Superimposing NCSP on existing structure:

88. Two particular manifestations of this problem were:

88.1 The use of 14 registers:

?? Glackin A445/18 – A449/8

?? McGoogan A1028/1-9

?? Skegg A890

?? Cox B2490

?? Coney B2742

?? Marshall B3244

The central problems emerging from this decision were:

?? 14 systems attempting to recall and recall women in for screening, and to ensure adequate management offered to women with abnormal results.

?? Data collection problems.

The Ministry witnesses were unable to say who took this decision (B4131).

88.2 The location of the programme within the Department/Ministry of Health:

?? Skegg A900/15

?? Coney B2765-2774

?? Handiside, para 11

89. The concerns of these witnesses were:

89.1 Large organisation, with a wide variety of responsibilities

89.2 Highly politicised environment

89.3 Policy emphasis of Ministry, rather than operational emphasis.

89.4 Large hierarchical structure, NSCP a small part only.

90. A related problem was the disjointed fashion in which the programme was implemented:

90.1 Coney, B2799-2800 (also Dr Medley)

90.2 Marshall, B3218, B3281

90.3 Skegg, A926/13

90.4 McGoogan, A1041/10-15

90.5 Grew, B4121.

General Comments on Establishment:

91. The foregoing are examples of a serious failure to accept advice.

92. Witnesses characterised the problem as largely caused by the Department of Health:
- 92.1 Foot dragging and lack of commitment (Coney, B2744)
 - 92.2 Ambivalence, (Marshall brief, para 78 ff)
 - 92.3 Department of Health did not particularly want the initiative of a national cervical screening programme imposed through a Ministerial inquiry (Cox B2665).
 - 92.4 Lack of senior management commitment to NCSP, (Handiside, para 47, B3693).
93. It seemed the Department had no plan (Coney, para 104), and many decisions about the programme were made at departmental level, in the absence of policy, or contrary to the recommendations of the Cartwright Report, (Marshall, para 45).
94. Many witnesses referred to the tension between the Department and the Expert Group; it is submitted this was a consequence of the fact that the Department did not want the programme:
- 94.1 Glackin, A119/13
 - 94.2 Boyd, A597
 - 94.3 Marshall, B3230
 - 94.4 Coney, para 53 ff
 - 94.5 Marshall, para 54 ff
 - 94.6 Teague, para 11.10, CAT/RCPA/0005
95. A related aspect of this problem was a failure to obtain the views of consumers (Coney brief 19.5, 23, 141-163). Ms Coney said that the failure to accept advice gave rise to an analogy: “[the Department] was a huge liner in Tahiti, and [the CSAC] lifeboat was back at the

Wellington wharf". (B2807-8). At bottom there was a failure to recognise the importance of the WHO guidelines, she thought.

Conclusion:

96. Advice simply was not accepted (Coney B2808, Cox B2661), because the Department was not convinced it should set it up.

97. This raises a serious ethical concern:

97.1 Coney (B2740/25)

97.2 McGoogan (A1201)

97.3 Skegg, Brief II, para 26, B2382-7.

98. A screening programme should not be set up at all, encouraging well women to participate and to rely on the accuracy of smear reporting if the programme had not been set up properly.

RESTRUCTURING ISSUES

99. The NCSP has constantly been the subject of change, since its inception. This impeded development of the programme, caused loss of institutional knowledge and created split and dysfunctional accountabilities.
100. The main elements of restructuring, which damaged the programme were:
 - 100.1 Internal realignments within Department/Ministry from Health of Women and Younger People Policy, to Population Health Services (1991-1992). (JMG/MOH/084)
 - 100.2 Transfer from AHB regime to CHE. Establishment of PHC, and subsequent dis-establishment of same (1993-95) (Glackin Brief, para 70 ff)
 - 100.3 KPMG review as to location, 1993 (Glackin Brief, para 88)
 - 100.4 Review of Advisory Committees 1994 (Glackin Brief, para 33 ff)
 - 100.5 Review of accountabilities, 1996 (Glackin Brief, para 114 ff)
 - 100.6 Transfer of RHA functions to THA, July 1997
 - 100.7 Transfer of programme from Ministry to THA/HFA (May 1998, Peters Brief, para 44)
 - 100.8 Split of programme between public health operating group and personal health operating group, within HFA (Peters Brief, 61-79).
101. The plethora of reviews is chronicled fully in Ms Glackin's brief. Further references:

- 101.1 Cox Brief, paras 73-130 (particularly CSAC discussions and documents relating to the continuation of the NCSP during changes to the health system).
- 101.2 Marshall Brief, paras 107-110 – the constant changes meant there was a constant fight for survival. It was so much of a struggle, that CSAC was obliged to write a comprehensive report to the Minister on monitoring and evaluation, annexing schedules of all advisory letters written to the Minister, and to the Ministry (JMG/MOH/0035);
- 101.3 Skegg, A933/20: accountabilities transferred on a regular basis;
102. Ms Coney summarised the matter thus:

“So we spent the entire 10 years fire fighting on behalf of the programme, trying to – you know there was a KPMG review, there was a review of accountability, there was just an endless stream of where are we going to put it, PHC, Ministry, all of which did not add to the strength of the programme and actually weakened it, so that there was this continual diversion into things that were completely peripheral to the programme but actually damaged its health. We’ve lost sight of the focus, the purpose of a health system which was to deliver good quality health care to New Zealanders and improve their health status”.
(B2766).

103. In addition to the battering suffered by the programme as a result of constant change, there were the complex problems created by the “cascade of contracts” which were introduced with the 1993 reforms. Split responsibilities and accountabilities arose from that point. The Screening Register and the Cancer Registry were (and are) run by different entities. These are examined below.

FINANCIAL ISSUES

Adequacy of Resources in Ministry:

104. Ms Handiside concluded, as a reason for “lack of achievement” during her period as National Co-ordinator, that there was “a lack of resources” including expertise (para 47, see also paras 24, 34, 35 and 43).
105. Particular examples, it is submitted, which flowed from an unwillingness to commit resources to the programme at Department/Ministry level were:
- 105.1 Reluctance to proceed with reconfiguration – approved in 1993, not actually instigated until 1996 (Handiside, para 35)
- 105.2 Low priority given to monitoring and evaluation of screening history of women developing cervical cancer. This had two consequences – the extraordinary time taken to implement such audit, and the decision to implement only 3 of the 15 recommendations advanced by Cox/Richardson. (These topics are dealt with below).
- 105.3 Statistical reports were also the victim of resource constraints (BC/SC/004, page 114-5).
- 105.4 Low status of the National Co-ordinator’s position, and the unwillingness to accept CSAC advice to the effect that multi disciplinary expertise was required in-house. (CSAC Report 1994, Glackin Vol 7, Tab 35)

Funding for providers:

106. Three reports were prepared by Terri Green, Economist, dealing with the first three establishment years of the programme. (JMG/MOH/104).

107. In the second of those reports, the author stated:

“Unlike the first establishment year, when regional allocations were tagged and were passed on in full to local programmes, the actual funding to programmes for 1991-92 was determined by area health board management. In addition to the identified 1991-92 allocations, there were significant unspent tagged funds from the first year (the regions expended only 37% of 1990-91 allocations). The advice from the Department of Health was that programmes should be funded at the level of the identified 1991-92 allocations, but the utilisation of unspent 1990-91 funds was not specified. The outcome was that some programmes received only the 1991-92 identified funding, while others received in addition, some or all of the unspent 1990-91 funds.... Except in the case of the two smallest Boards (Tairāwhiti and the West Coast), where Area Health Boards topped up the funding to achieve 1990-91 expenditure levels, the final funding appeared to be unrelated to actual levels of expenditure in the first year.” (Page 3 of “Second Establishment Year”, emphasis added).

108. Table 1 of that Report shows the regional funding allocations for the first two years. Tairāwhiti was allocated \$100,000 for the first year, but reduced to \$61,800 for the second year. (Compare Auckland, which had its allocation increased by over \$250,000.)

109. Table 2 shows the actual regional funding over the two years, and it will be seen that Tairāwhiti had \$61,864, identified funding in the 1991-92 year, but spent \$111,911. Thus, as the author concluded, the Area Health Board must have topped up the funding.

110. What is of particular concern here is the arbitrary nature of the funding allocations across the two years; Tairāwhiti was known to be a high risk area. Although it was a small region, it nonetheless had fixed costs. A funding allocation scheme which saw its allocation drop by

\$40,000, when it was attempting to establish the programme was quite inappropriate.

111. (For a general summary of the funding in first three years, see the Cox/Richardson evaluation plan, Glackin Vol 9, Tab 47, pages 56, 59 and 63).
112. Other data with regard to the Tairawhiti region:
 - 112.1 In April 1991, the National Co-ordinator noted that tagged funds were not being used for the purpose for which they were tagged, and "Tairawhiti wants to pay off a debt" (Glackin Vol 14, Tab 75, page 74).
 - 112.2 Glackin, Vol 14, Tab 75, page 90, report for December 1991 meeting of programme managers, "development of CSP seriously inhibited by a lack of funds".
 - 112.3 Glackin brief, paras 186-195; during 1992 staff working on programme were reduced, the Programme Manager left and not replaced, Systems Administrator carried out both positions; para 200; Regional Co-ordinator was reduced to carrying out "reception duties".
 - 112.4 JMG/MOH/092: replacement for Cervical Screening Programme Manager not appointed, 12 months on; a resource issue?
 - 112.5 Ms S Reid brief, para 16 – from outset there was a perception that programme was under-funded in terms of employment of staff, development of resources for promotion. See also her report, at the Managers Meeting of 1-3 September 1993 (Glackin, Vol 11, Tab 62, page 5), that "many things are not being done as Sharon Reid does not have the resources".
113. In short, there were severe constraints both at provider level, and within the Ministry.

Payments to Laboratories:

114. Different financial issues arise with regard to payment to laboratories. Should those payments have been tagged to TELARC accreditation? The advice was that it should be so tagged.
115. Dr J Straton, (Glackin Vol 1, Tab 4, page 47 of report) advised that the system of accreditation of laboratories should be tied to reimbursement of laboratories for reading smears; no doubt she had in mind the Australian practice, where, for example, in NSW Medicare benefits could only be paid to accredited cytology labs, GVW/CA/001, page 29.
116. In February 1992, a legal opinion was sought as to TELARC accreditation (GRB/MOH/041). Inter alia, Mr Clark, the solicitor who gave the opinion, concluded that it was not an option to compel a laboratory to become TELARC registered, via the Social Security legislation and benefit payment regime.
117. No consideration was given to the Social Security (Laboratory Diagnostic Services) Regulations 1981, which in Regulation 6, provided for the revoking of recognition of any pathologist, or the altering of conditions attached to any recognition (Regulation 6(2), and 6(3)).
118. The legal opinion did not consider this possibility (Boyd A541); Dr Boyd agreed a "consultation document" could have been drafted on the basis of Regulation 6 (Boyd A542/3).
119. Ms Glackin would have expected the analyst concerned to "have gone back to legal" (B4133). The passing of regulations may well have speeded up the process (B4134).
120. CALC recommended that laboratories be TELARC registered, enforced by lack of payment if not registered (Teague Brief, 16.10 and B1420, and Glackin Vol 3, Tab 11, page 25).

121. When the health reforms commenced, the social security regime was rolled over into the s.51 notice for pathologists (Mules Vol 1, Tab 9 at Schedule 2 of the document, Clause 3; precisely the same regime of conditional recognition).
122. Mr Mules agreed that on the face of it there was no reason why Midland RHA could not have specified quality assurance provisions in its s.51 Notice (A1278/20); they made a conscious decision not to do so (A1280/3) instead opting for subsequent inclusion of the matter in a contract.
123. The advice given, therefore, by Dr Straton in 1990 was not finally implemented in the Midland region until at least early 1997, a delay which it is submitted was wholly unacceptable. Even then, it was not implemented properly; this topic will be dealt with in more detail when dealing with TELARC registration.

Control of funds by NCSP:

124. A final financial issue is that raised by Dr Cox at para 40: the recommendation of the Ministerial Review Committee (s.9.17), that the reading of all smears should fall under the auspices of the programme, and that this could be achieved by transferring the money budgeted for cervical smears under the laboratory benefit scheme, to the NCSP. At B2662-3, Dr Cox agreed that the programme would then have been more readily able to impose minimum standards on laboratories in respect of reporting, and further he did not know why that recommendation had not been accepted. No evidence has been adduced to explain why not.

TELARC ACCREDITATION

125. The chronology in relation to this issue is as follows:
- 125.1 1988, Porirua workshop, recommendation that laboratories would be TELARC accredited (Teague B1425).
 - 125.2 18 July 1989, CALC minutes (Boyd, Vol 4, Tab 18, page 11), TELARC to be used to assess adequacy of practice.
 - 125.3 1990: Expert Group recommended all labs apply for TELARC registration by 1991, to be registered by 1993 (para 12.2.2, Glackin Vol 2, Tab 5, page 203).
 - 125.4 July 1990: Dr J Straton (Glackin Vol 1, Tab 4, page 48), advised a strict timetable for accreditation should be established, after which reimbursement for smears taken should not be made.
 - 125.5 15 August 1990: CALC letter to TELARC, regarding guidelines (Boyd Vol 4, Tab 18, page 21).
 - 125.6 1990, CALC recommended TELARC accreditation become compulsory (Teague B1424).
 - 125.7 1991: Government Policy (Glackin Vol 5, Tab 15); para 4.1.2, reasonable time to labs to obtain registration, up to 2 years.
 - 125.8 December 1991; CALC recommended registration of laboratories be compulsory, and it was now required that labs reporting to Register be registered (Cox brief, para 80).
 - 125.9 October 1992: Dr Teague advised private and public laboratory pathologists that it would be compulsory in New Zealand from 1993 for labs to be TELARC accredited. (Boyd Vol 1, Tab 4, Minutes, 1.10.92, page 18 of Minutes).

- 125.10 1993: CSAC confidently expected TELARC registration to be compulsory by end 1993 (Teague, B1265).
- 125.11 January/February 1993, NCSP newsletter (Women's Health Action Trust, Vol 2, page 471), all labs to be TELARC registered by "end of this year".
- 125.12 May 1993: Proposed cervical screening indicator for key performance indicator as to TELARC registration (JMG/MOH/102) – not implemented; no evidence of follow up by National Co-ordinator as to number of hospital labs accredited, or as to whether any community labs were accredited.
- 125.13 August 1993: Minister advised that, in that year, there had been an introduction of compulsory TELARC registration for cytology labs (JMG/MOH/087, page 5).
- 125.14 October 1993: Government policy (Glackin Vol 6 Tab 27, clause 4.1.2, two year requirement removed).
- 125.15 November 1993: CALC, when informed by National Co-ordinator that provision should be included in RHA Funding Agreement for cytology services to be purchased only from TELARC registered labs, stated "that a reasonable period of grace needs to be given for a "new" laboratory to become registered and that this could mean that some laboratories will go out of business". (Boyd Vol 4, Tab 18, page 63).
- 125.16 Purchase Guidelines from 1994/95 onwards for RHA's required absolute obligation for TELARC accreditation; funding agreements referred only to "reasonable endeavours" (Lambie Vol 3, Tabs 4, 5 and 6 compared with Lambie Vol 4, Tab 8, Funding Agreements).

- 125.17 1994/95: Midland Health Service Requirement definition (Mules Vol 2, Tab 37, page 91, all labs servicing NCSP should be TELARC registered).
- 125.18 Sax standards, required all medical laboratories as at 30 June 1996 to be accredited or assessed by an approved accreditation body (Clause 1.3, SS/HFA/0026); those standards however were “draft”, and when annexed to a contract (e.g. Gisborne Medical Laboratory Limited, CM/HFA/0018), they were to be “attached as appendix 5 to the contract on their completion”, clause E16. Those draft standards were never “completed”, i.e. by the giving of RCAP approval, (Sax brief, para 53).
126. Despite the laudable expectations from the outset, this requirement, even at 1997, was not compulsory, because it was subject to an event which never occurred, namely ratification by RCAP. The “compulsory” accreditation never happened in the period under consideration.
127. Ms Dahl seemed to believe that “they did have accreditation processes in place” (B4147). But as the Norton review (Glackin, Vol 5, Tab 25, page 14) showed, some labs were TELARC accredited and some were not. There is no evidence to show that this particular information was followed up.
128. The issue itself was never followed up by the Ministry (whether by the programme co-ordinator, or the performance monitoring branch), or the RHA, particularly in the period after the “Good Health Wanganui” alert.
129. As Exhibit JMG/MOH/087 shows in May 1993, the Minister was misled on the matter.
130. A factor in the “dilution” of the obligation appears to have been the view expressed by CALC that, even in 1993, a “reasonable period of grace” needed to be given. Professional self interest was put before the need for proper quality assurance.

131. The evidence was that all the experts considered this an essential step which needed to be “strictly” adhered to (e.g. Straton, Glackin Vol 1, Tab 4, page 48). Professor Skegg considered the absence of compulsory accreditation was “extraordinary and unacceptable”, A927/3.
132. There was uncontraverted evidence that TELARC registration would have reduced the likelihood of the misreading of smears, substantially. This was because a laboratory would have to have established internal and quality assurance arrangements:
 - 132.1 Teague, B1481/ 8-21;
 - 132.2 Walker, Brief 49-50
133. Notwithstanding the cardinal importance of this obligation, and despite what the Minister was being told, the Ministry did not ensure that TELARC accreditation was indeed compulsory; nor, from 1993, was the Ministry supported by CALC on this issue.

MONITORING AND EVALUATION

Meaning of these terms:

134. Key references are:

134.1 BC/CS/0047, WHO Managerial Guidelines, page 27-28.

134.2 BC/CS/0044, European Guidelines, s.5 (see especially s.5.5 for monitoring in the long term)

134.3 Peters exhibit 23, pages 5 and 6.

134.4 Cox B2608, 2612

134.5 McGoogan: A1185 (discussion of quality assurance concepts)

134.6 Glackin Brief: 275

134.7 CSAC Report on Monitoring and Evaluation, October 1994, Glackin Vol 7, Tab 35 – “Special Statement” on page 30 of this document, highlights “routine information” and “specific investigations”.

135. Monitoring tends to be an ongoing routine process, and evaluation an overall review, which would identify possibilities for improvement. There is inevitably overlap.

What advice was given?

136. Advice was consistently given from the outset, that monitoring and evaluation was critical. From the CSAC perspective, this was well summarised by Dr Cox in his brief (paras 57, 59, 65, 101, 108, 121, 132, 133, 145, 153, 176-7, 191, 209, and 214).

137. Other references:

137.1 Straton: “A major deficiency so far has been the failure to incorporate any formal evaluation into any of the pilot projects, or any other aspects of the programme” (1990), (Glackin, Vol 1, Tab 4, page 62-63).

137.2 Expert Group (Glackin Vol 2 Tab 5, page 208-211, 214, and final page of document), which recommended proposed terms of reference for Expert Group, which included monitoring.

137.3 CAT/RCPA/0012, page 2, Minister emphasised “shift from policy development to implementation and evaluation of the programme”.

137.4 1991 Government Policy (Glackin Vol 5, Tab 15), emphasised evaluation and monitoring at s.7 (repeated in 1993 policy).

137.5 CSAC memoranda, especially Glackin Vol 5, Tab 12 and Glackin Vol 5, Tab 13.

137.6 1994 CSAC report, Glackin Vol 7, Tab 35.

137.7 1997 Cox and Richardson, draft evaluation plan for the NCSP (Glackin Vol 9, Tab 47).

What happened – routine monitoring:

138. For convenience, the various aspects of “monitoring and evaluation” as identified by the Ministry in its evidence (Glackin brief 274 following), are dealt with.

139. First, monitoring of Area Health Boards by the Department, 1990 to 1993. This is said to have occurred by measuring progress against statements contained in the 1991 Government policy and the service statement (Glackin Vol 5, Tab 16).

140. No quarterly reports from the Area Health Boards were produced in evidence, but according to Ms Glackin (Brief 287), the contract performance indicators reported on included:

140.1 Colposcopies per 1,000 women

140.2 Women waiting longer than 6 months for colposcopy.

140.3 Percentage of women on the NCSR who had had a smear in the last three years.

140.4 Percentage of cervical cancer detected at stage one of the disease.

141. There were no indicators of quality.

142. Dr Lambie produced extracts from the Tairawhiti AHB Funding Agreements for 1990/91, 1991/92, 1992/93. (Lambie Vol 4, Tab 8). These documents indicated “actuals” and “targets” for similar categories (e.g. pages D, E and G of this exhibit). When compared against the performance indicators for Area Health Boards, which had been recommended by the Expert Group (Glackin Vol 2, Tab 5, para 14.2), and given also that it was recognised at the time that some measurement of the quality of smear reading needed to be undertaken (CSAC advice 1991, Glackin Vol 5, Tab 13, page 3), the actual indicators implemented were quite inadequate.

143. The next category of performance monitoring is that which occurred from the inception of the health reforms in 1993. Dr Lambie outlined a “monitoring framework” which included (brief para 54):

143.1 Review of contracts

143.2 Monitoring of national information systems

143.3 Funding agreement information requirements

143.4 Quarterly reports against performance indicators

144. As regards the first three mechanisms, the only apparent formal monitoring which the Ministry carried out for the NCSP, was the contracting review. That identified the fact that the screening contracts “generally do not appear to cover the detail of the requirements set out in the funding agreement” (Lambie para 65).
145. For contracts relating to the NCSP, the problem was more significant. For example in respect of TELARC accreditation the position was that since 1991, the government policy had included an expectation that accreditation would be completed by 1993; this was expressed as an absolute obligation in the Purchase Agreements; a conflicting, or at best diluted, obligation was contained in the Funding Agreements, namely the requirement that an RHA use its “reasonable endeavours” to ensure TELARC registration (Mules Vol 2, Tabs 34, 35 and 36).
146. Further, the contractual review simply recommended that the contents of the report be noted, and that “RHA’s address areas where they are not performing well in contracting and contract documentation” (para 66, Lambie). It also concluded that there was a need “to develop better monitoring processes” (Lambie, para 67).
147. However, the Ministry did nothing further until 1999, when it reviewed the HFA’s initiatives in that regard. It reached the alarming conclusion that there was “no systematic monitoring of quality by the HFA” but that “the changes underway were expected to lead to considerable improvements in quality monitoring” (Lambie Brief 69). Nothing had apparently happened between the two reviews.
148. In short, the formal monitoring of RHA contracts by the Ministry’s performance monitoring branch was desultory.
149. No examples were given in evidence of the second and third monitoring mechanisms mentioned by Mr Lambie (para 54).
150. As to the fourth, (quarterly reports against performance indicators, see Glackin Vol 13, Tab 74), these in the main concentrated on colposcopy

waiting times and enrolment levels. They did not touch on quality matters at all.

151. They were quantitative performance indicators, the Ministry making a distinction between quantitative and qualitative indicators (Lambie, para 56).
152. Mr Lambie agreed that a performance indicator in respect of TELARC accreditation could have been implemented (B3908/5). It was discussed, and a decision made not to implement such an indicator (B3909). It was decided such a matter would be included in the Funding Agreement as a “relatively absolute requirement in terms of service obligations rather than as performance indicators” (B3909/10, B3938).
153. Notwithstanding the inclusion of this obligation in the “service obligations”, the only evidence given of obtaining advice as to the number of labs which were TELARC registered, was JMG/MOH/102, when there was a faxed exchange between TELARC and the Department of Health. This was the only query undertaken by the Performance Monitoring Branch on this issue (B3913/6). This key component of the Government policy, was not monitored properly by the Ministry.
154. This problem was catalysed by the “confused accountabilities” which existed between the Ministry and the RHA:
 - 154.1 Glackin Vol 8, Tab 40 at page 1;
 - 154.2 Glackin brief, 291;
 - 154.3 Mules evidence, A1465/10-A1465/17;
 - 154.4 Lambie B3915-3920;
155. Dr Boyd, expressing a personal view, stated the cervical screening was not a viable part of the business model. (Boyd evidence A154-5).

National Co-ordinator:

156. Both Ms Glackin (brief, para 323 following), and Mr Lambie (brief, 78 following) suggested that “operational monitoring” could be carried out through the programme, that is, via the national co-ordinator and local co-ordinators.
157. Ms Handiside gave clear evidence of the limitations of the role of National Co-ordinator:
- 157.1 Lack of resources, (B3691);
 - 157.2 Not having power to implement changes – that resided with Senior Managers (B3693/18).
 - 157.3 Variable knowledge of Senior Managers (B3693/22).
 - 157.4 Managers not always responsive and able to understand issues presented to them (B3693/28).
 - 157.5 Consequently, not able to achieve or influence Senior Managers to allocate resources, e.g. for monitoring and evaluation (Brief, para 46).
 - 157.6 Trusted that people responsible for contracts and review of contract performance were doing so, and would report to National Co-ordinator (B3783).
 - 157.7 No one person had overall responsibility (B3785-6).
158. Given these limitations, the national co-ordinator could not possibly carry out or be accountable for effective monitoring.

Advisory Committees:

159. Ms Glackin stated the Advisory Committees played a role in formal and operational monitoring (Glackin, para 335).
160. Ms Grew and Ms Dahl both agreed however that by their nature they were advisory only (B4148-9).
161. The reality was the Department/Ministry did not allow the Advisory Committees to perform their “monitoring/evaluation” role, because the advice of those Committees – on many topics - was never accepted. As Professor Skegg stated, they were often ignored (A900/24). The best example of this is the topic of monitoring and evaluation itself, and the extraordinary lengths which CSAC went to to try and implement proper monitoring and evaluation.
162. The serious unwillingness of the Ministry to accept advice from its Advisory Committee resulted, for example:
- 162.1 In the Committee producing a comprehensive report on monitoring and evaluation, with its highly unusual chronicle of advice given over a period of years (1994).
- 162.2 In CSAC members being “driven spare” feeling “professionally unsafe” and “frustrated” (B2536-7).
163. The Advisory Committees were in an untenable position. They were presented with possibilities which were unacceptable e.g. 4 regional cervical screening registers, unlinked, (see Cox brief para 110). Their tenure was tenuous; in early 1994, the continued existence of Advisory Committees was reviewed (Glackin brief, 93-97; exhibit Vol 7, Tab 33; exhibit JMG/MOH/087; Glackin, oral evidence, page A260-1, Neal, para 36).

164. At the time of the health reforms, there was concern that Dr Teague had raised issues in the media. Plainly there was discomfort, as far as the Ministry was concerned, with the “watchdog” role, which the Advisory Committees may have carried out. So they were reviewed.
165. Note that the Advisory Committees were not:
- 165.1 consulted as to the review of Advisory Committees in 1994 (Glackin evidence, A261/3)
- 165.2 consulted as to the review of accountabilities in 1996. (Glackin evidence, A277/9).
166. There was astonishment when it was decided to dis-establish CALC (Neal, para 36; see also CAT/RCPA/18 as to declining frequency of meetings).
167. Note also the UK practice that it would be “unthinkable” for the Advisory Committee not to be followed (McGoogan, A1026, A1087-9, A1230-1) – the New Zealand position was more akin to a working party, than an Advisory Committee.
168. The committees in short were never empowered or permitted to fulfil a proper monitoring or evaluation role.

The Register As A Monitoring Tool: Statistical Reports

169. Ms Glackin suggested these reports facilitated monitoring. The details of the four statistical reports are:

	Reference	Data up to	Date published
1 st report	Glackin Vol 6, Tab 26	May 1992	August 1993
2 nd report	Glackin Vol 7, Tab 37	June 1994	October 1995
3 rd report	Glackin Vol 9, Tab 51	December 1995	June 1998
Maori report	Earp, Tab 4	December 1995	1999

History of Statistical Reports:

170. The history of the statistical reports is found in:

?? Glackin

Brief, para 341-346

Cross examination A271-A275

?? Teague

Brief, para 22

Cross examination: B1430; 1437; 1488-1501.

?? Cox

Brief, para 76-84, 87, 92, 136, 193, 194, 206, 210, 211

Cross examination B2489-B2494; 2504-2506, 2587.

?? Grew

Cross examination: B4158-4160

171. From the foregoing, it is evident:

171.1 First report was seen as a “basic template” for future reports (Cox, Brief 87).

171.2 Dr Cox was not directly involved in the subsequent reports.

171.3 Ms Grew referred to data which was apparently available at the time of the first statistical report (B4158-4160), which, according to her evidence was “aggregated” (B4159/8), and was insufficiently robust to be included (B4160/13). That data gave no ability to quantitatively monitor lab quality (B4160/19).

171.4 Note also the CSAC 1994 report (Glackin, Vol 5, Tab 35, at page 7), where there was a recommendation for an annual statistical report to reflect the state of the programme, and in order to chart the progress of the programme over time.

171.5 Particular attention should be given to BC/CS/0038, which records Dr Cox's comments on the draft proposal for the third statistical report; there he noted comparison of histology with cytology should be conducted; international comparison was now possible using the European Guidelines; there should be a separate section summarising cervical cancer incidents and mortality, statistical and epidemiological tests of trends or differences in rates or proportions, so as to assess major results. This advice was not taken (see also Cox B2534-5).

171.6 Note also para 43 of Ms Handiside's brief, drafting of statistical reports given a low priority which resulted in untimely production of outdated data. This was apparently due to "resource constraints" (BC/CS/004, p114-5), and notwithstanding CSAC advice.

Content of Reports:

172. Several witnesses were asked to critique the statistical reports:

172.1 McGoogan: A1033-4, A1075-9, A1185-6

172.2 Teague: B1488-1501

172.3 Peters: B369-380

172.4 Cox: B2592-3

173. The following themes emerged:

173.1 Little information apart from population coverage (McGoogan A1034/4).

173.2 Dealt with managerial issues rather than quality issues (McGoogan A1034/3).

- 173.3 Variability in denominators for different periods of time (McGoogan A1075/19, Teague B1499, Cox B2592).
- 173.4 Documents were difficult to read, and difficult to ascertain whether any meaningful information could be derived (McGoogan A1077/7).
- 173.5 Reports would not assist in deducing whether there were smear reading problems (McGoogan A1078/6, Teague B1494).
- 173.6 Reports not produced in a timely fashion (McGoogan A1079, Teague B1498, Peters B374, Glackin 263).
- 173.7 No incidence of cancer on a regional basis shown, which could skew figures (Teague B1497).
- 173.8 Deals with numbers of smears, not numbers of women (Cox B2593).
- 173.9 Reports were not at a sufficient level of detail to indicate whether problem lay within the programme; false sense of security could be given (Peters B375).
174. The main conclusion drawn by the witnesses was that the statistical reports did not amount to a basis for monitoring or evaluation (e.g. Peters B377, Teague B1491). Indeed, Dr McGoogan identified the third report, in particular, as “very unhelpful” (A1079/23).
175. Ms Glackin at para 346 of her evidence stated that the three yearly screening cycle of the programme “limited the usefulness of more frequent reports”. That statement is completely contrary to the advice of the experts, which was and is that there should be annual statistical reports (CSAC 1994 report, Dr Wain, NSW registry example, Dr McGoogan, 953, Cox B2670).

Standards/Performance Measures:

176. The establishing of standards and/or performance measures would have facilitated monitoring; however, the chronology in respect of the anticipated development of both standards and performance measures is disheartening. They should have been in place from the outset, and not later than 1988 (McGoogan, A1041/16).
177. As to standards:
- 177.1 The 1991 policy anticipated development of these (Glackin Vol 5, Tab 15, clause 4.1.3).
- 177.2 Some “guidelines” were developed by CALC in May 1991, and sent to TELARC; those “recommendations”, which TELARC assessors were required to discuss during assessments, did not include minimum number of slides, nor internal quality control; nor were they mandatory (Boyd Vol 5, Tab 22).
- 177.3 In 1993, CALC (Glackin Vol 13, Tab 71, para 4.1.4) thought that the 6 criteria of the policy document were “somewhat arbitrarily plucked out from the many criteria actually used”.
- 177.4 On 15 February 1995 (Boyd, Vol 4, page 110), CSLAC discussed standards.
- 177.5 19 June 1996 (Boyd, Vol 4, page 150), CSLAC finalised standards, and agreed they should be sent to TELARC and circulated to all laboratories (Handiside, B3720-1).
- 177.6 Supplementary brief of GD Walker (para 3 following) – states that standards were never implemented by TELARC, notwithstanding the fact that a TELARC staff member had liaised with, and was involved in providing advice as to the

contents of the document; the 1995 standards were never put before, or approved by TELARC Committee, MTPAC.

178. There is a similar unsatisfactory chronology in relation to performance measures, as follows:

178.1 The Ministerial Review Committee proposed competency standards, including sensitivity and specificity, in November 1989 (Glackin Vol 1, Tab 1, page 124 of document).

178.2 The 1991 policy (Glackin Vol 5, Tab 15, para 7.1.2), required performance indicators to be developed by Department of Health, and negotiated with Area Health Boards.

178.3 The same obligation was repeated in the updated Government policy of October 1993 (Vol 6, Tab 27, para 7.1.2).

178.4 1994: CSAC gave comprehensive advice as to “monitoring and evaluation measures” for the programme (Glackin Vol 7, Tab 35, page 8 following). This was backed up by reference to the tabulation of parameters contained in Appendix A of the European Guidelines, together with a further schedule of “Annual minimum performance measures”, developed by the “Working Group for the development of cervical cytology registries, data collection, monitoring and evaluation” (1992, Australia; see Appendix 6 of 1994 report by CSAC).

178.5 1995-1999: Nothing further done to develop performance indicators/performance measures, until the HFA commenced such process, with its “draft national indicators” (Peters brief 136).

Evaluation:

179. Turning from monitoring to evaluation, there were a number of limitations, which, even had there been a willingness to undertake

monitoring and evaluation, would have made such difficult, if not impossible:

179.1 Opt on programme until mid 1993

179.2 14 separate registries, making collection of data difficult

179.3 histology results not gathered; position changed in 1993, but obtaining of histology results was slow, and even now histology results are not complete (Matchem brief, para 100-101).

179.4 Privacy issues – particularly relevant for clinical audit, see below.

179.5 Absence of performance measures, see above.

Clinical Audit:

180. This was a particular aspect of evaluation, which bears consideration. The experts were agreed as to its importance:

180.1 Skegg, brief para 55

180.2 McGoogan, evidence A1068, A1099/26

180.3 CSAC report (1994), page 7 (“Introduction of medical audit”), and Cox-Richardson Evaluation Plan 1997, page 98-9.

180.4 Medley B2705-6

180.5 Cox B2502-3

180.6 Peters B372.

181. CSAC, and in particular Dr Cox, recognised the importance of this tool, and went to some lengths to have it implemented (Cox brief, para 144, 168, 195, 199).

182. Ms Handiside gave graphic evidence of the attempt by Dr Cox to raise this matter, in person, with Dr Durham, by presenting his paper on the audit of screening history of women developing cancer (B3676-3677). Dr Cox himself said that some CSAC members were feeling “professionally unsafe” (B2537).
183. Ms Handiside linked the failure to obtain this “audit tool” as to a reason why Dr Cox resigned, because he did not want to “have blood on his hands” (B3702).
184. Evidence was given that this type of audit has been contracted to the University of Otago; the process has been the subject of considerable delay (B2480-B2488). There is now a complete impasse, as a consequence of privacy issues, and whether (and if so on what basis), the approval of Ethics Committees is required.
185. The overwhelming expert evidence was that there was an absence of monitoring and evaluation, during the period of nearly 10 years operation of the programme, and that this was unacceptable:
- 185.1 McGoogan, A1083/29 - A1084/3;
- 185.2 Skegg, brief, para 52-7;
- 185.3 Peters, when asked to comment on Dr Cox’s letter of May 1999 (Peters, Volume 3, exhibit 27, oral evidence, (B445-451);
- 185.4 Peters affidavit, exhibit JMP/HFA/0056, HFA risk classifications, confirming “little monitoring or evaluation” (page 1); situation should have been detected had appropriate monitoring of the programme occurred, and this highlighted structural deficiencies in the programme (page 3).
- 185.5 Cox brief, para 214-217 – insufficient monitoring and evaluation, because Ministry appeared to want to manage NCSP for political reasons; insufficient expertise within Ministry for good evaluation and monitoring ever to be achieved, and for

measurement against international benchmarks, as per European guidelines.

186. It is apparently the Ministry's case that there was some monitoring and evaluation. On analysis, it has to be acknowledged that monitoring of quality issues was almost entirely absent. Ms Dahl stated there had been "small evaluations", "small monitoring reports" (this appeared to be a reference to the statistical reports, which had significant limitations), and a "lot of ad-hockery" (B4169).
187. The significance of proper monitoring and evaluation was signalled right from the start, and as Dr McGoogan affirmed, the need for it was well known throughout. That even now it is still not fully implemented represents a serious failure on the part of those who were responsible for establishing, and maintaining the programme, from the early stages. All credit is due to the HFA for the work it has achieved in the last year or so in that regard, but it is appalling that the situation was allowed to degenerate to the point it had, by 1999. Dr Straton identified the absence of formal evaluation, as a "major deficiency" in July 1990 (Glackin Vol 1, Tab 4, page 62).
188. In Professor Skegg's view, a lack of resources for monitoring and evaluation was "no excuse whatsoever" (B388). 10 years on, the continued absence of proper evaluation is outrageous and unethical.

OVERSEAS SCREENING PROGRAMMES AND LITERATURE

NSW:

189. How does progress in New Zealand compare with progress overseas?
190. The position in New South Wales was discussed by Dr GV Wain and Dr A Farnsworth. The chronology is:
 - 190.1 Late 80s : NATA accreditation became compulsory (Farnsworth, para 9). See also description of NATA accreditation in "Making the Pap Smear Better, (GVW/CA/001), page 29. On page 30 see table as to registration status of laboratories: 136 out of 145 labs registered, and 9 further (unregistered) labs assessed; Medicare benefits could only be paid to accredited cytology labs.
 - 190.2 1987/NATA/RCPA inspection and registration process introduced: occurs each three years (Farnsworth, para 9, Wain para 41).
 - 190.3 1990: NSW programme established, (Wain B1984).
 - 190.4 1991: National Screening policy agreed (Wain B1989); policy set out at GVW/CA/002, p210.
 - 190.5 1992: Annual Minimum Performance Measures (developed by the Working Group for the Development of Cervical Cytology Registries, Data Collection, Monitoring and Evaluation). (Appendix 6, CSAC Report, Glackin Vol 7, Tab 35).
 - 190.6 1993: Specific guidelines for cervical cytology first introduced (Farnsworth, para 9)
 - 190.7 1993: Making the Pap Smear Better, recommended establishment of an organised approach to the prevention of cervical cancer (Wain, para 30, Notes, B2001; BVW/CA/001).

- 190.8 1997: specific guidelines for cervical cytology revised and became requirements (Farnsworth para 9, Wain para 42).
- 190.9 1999: "Requirements for Gynaecological (cervical) Cytology, 1997, (GVW/CA/005) became compulsory in January 1999 (date is recorded at GVW/CA/006, p311).
191. Dr Wain stated that he would not hold up the NSW programme, as a "model for the world to follow", but as an example of how difficult it is to do (B2002).

Victoria:

192. At B2734-5, counsel for HFA/Ministry stated it was intended documentation relating to the Victoria programme would be put in. At the time of preparation of this submission, counsel has received no such documentation.
193. In "Making the Pap Smear Better" (GVW/CA/001) page 29, reference is made to the position of Victoria where the Pathology Services Accreditation Act 1984 was proclaimed on 2 March 1990. It is said the Act established a Pathology Services Accreditation Board responsible for ensuring that pathology services in Victoria met the required MPAAC standards. NATA and RCPA were the main inspection agencies in Victoria as elsewhere.
194. Farnsworth, B1714: Victorian Cytology Register one of the first in the world.

Other Australian States:

195. At notes B1987, Dr Wain gave an indication of the inception of state registers, from 1987 to 1996, approx. A general history appears at GVW/CA/008, p353-4.

England:

196. The English position is conveniently summarised in Appendix 4, “The Performance of the NHS Cervical Screening Inquiry in England”, report by the Comptroller and Auditor General, 1998 (EM/CA/012):
- 196.1 1988: Faculty of Community medicine established National Co-ordinating Network of cervical screening programme; it was the pre cursor to the NHS cervical screening programme.
 - 196.2 1991: Government published, “the Health of the Nation”, which laid out a strategic approach to improving the health of the people in England, including cervical screening.
 - 196.3 1992: National Co-ordinating Network published “Guidelines on Clinical Practice and Programme Management”. Department of Health, issued guidelines on “fail safe actions” for use by health authorities in drawing up and reviewing fail safe systems. Department of Health issued a white paper, “The Health of the Nation”, which set out cervical screening targets.
 - 196.4 1993: Department of Health issued “The Health of the Nation, Key area handbook on cancers” which set out the principal elements of a successful cervical screening programme.
 - 196.5 The NHS Executive issued “National Cervical Screening Programme”, which updated the 1988 document.
 - 196.6 1994: The NHS Executive issued “Quality in Cervical Screening Programme”, which contributed to guidance on specifying standards.
 - 196.7 National Co-ordinator appointed for the NHS Cervical Screening Programme.

- 196.8 The National Co-ordinating Network published “assessing the quality and measuring the effectiveness of cervical screening”.
- 196.9 1995: NHS Cervical Screening programme published “Achievable standards, benchmarks for reporting and criteria for evaluating cervical cytopathology” (EM/CA/005) includes section on audit of screening histories of women who developed invasive cancer, (page 27).
- 196.10 1996: NHS Cervical Screening programme published “Quality assurance guidelines for the cervical screening programme” (EM/CA/006) and “Standards and Quality in Colposcopy” (includes section on role of audit, page 15).
- 196.11 1997: NHS Executive issued “Cancer screening: Quality assurance and management”; NHS Cervical Screening programme published “Guidelines for Clinical practice and programme management” (EM/CA/014).
197. As to evidence in relation to the UK system, see Professor McGoogan:
- 197.1 Notes, A1028-9: governance of programme.
- 197.2 Notes, A1114/5-18: external quality control of the NHS cervical screening programme pre existed the accreditation system for laboratories, the CPA system. External quality assurance involves the proficiency testing scheme. Cyto-screeners must prove their competence by taking a test once a year. Results are evaluated by an external person and returned to the lab. That scheme has been running since the late 80s.
- 197.3 Notes, 1170-1: every region set up a quality assurance team in late 80’s.
- 197.4 Brief, para 74-84: note importance of BSCC Code of Practice for Cytopathology Laboratories 1986 (para 81).

Scotland:

198. The Scottish position is conveniently summarised at Appendix 2 of the Inverclyde report (Exhibit EM/CA/003); inter alia, the chronology is:

198.1 1986: BSCC published a recommended Code of Practice for laboratories providing a cytopathology service, including guidelines on workload and staff requirements, laboratory recommendation and facilities, training and qualifications of non medical staff, information systems, quality control in cytopathology and cytology reporting.

198.2 1987: the Strong Report recommended that all Health Boards should work towards a systematic screening programme, with one person to be responsible for the overall organisation of the service. Detailed recommendations for quality assurance were specified in appendix 5 to the report, including staff training and supervision, internal quality control and external quality assessment.

198.3 1988: Department of Health published a protocol for a proficiency testing scheme in gynaecological cytopathology under the auspices of the Advisory Committee on assessment of lab standards. The scheme was introduced nationwide under the encouragement and direction of a national co-ordinating committee for EQA and gynaecological cytopathology. As at 1993, Scotland, all regions in England, together with Wales and Northern Ireland had a scheme in operation, and almost every laboratory in the country, where cervical smears were being screened, were participating.

198.4 See also Dr McGoogan's evidence, which outlines the Scottish programme A1036-7, particularly emphasis on strong central leadership.

Relevant International Literature:

199. The following documents either were, or should have been, in the possession of the Department of Health, or relevant external advisors, such as members of the Royal College of Pathologists:
- 199.1 American Society of Cytology guidelines, approximately 1986 – these are referred to in the report and recommendations of the New Zealand Society of Cytology, (Boyd, Vol 5, Tab 19). There it is recorded that the recommendations were based on those made by the American Society of Cytology.
 - 199.2 British Society for Clinical Cytology, recommended Code of Practice for all laboratories providing a cytopathology service (1986); referred to in the Inverclyde report (Exhibit EM/CA/003, page 70), and plainly a key document.
 - 199.3 Council on Scientific Affairs, American Medical Association, “quality assurance in cervical cytology”, (Boyd Vol 1, Tab 3).
 - 199.4 WHO: Cervical cancer screening programmes Management Guidelines, AB Miller, 1992, Exhibit BC/CS/047 (referred to by CSAC in its October 1994 report, (Glackin Volume 7, tab 35, footnote 30, page 16)
 - 199.5 Committee of Public Accounts, second report, cervical and breast screening in England, exhibit BC/CS/0025, page 3 following (forwarded to National Co-ordinator by July 1993 (see page 2, same exhibit); footnote 29 on page 16 of CSAC report, monitoring and evaluation of the NSCP, October 1994 (Glackin Volume 7, tab 35)).
 - 199.6 Coleman et al, European Guidelines for quality assurance in cervical cancer screening (exhibit BC/CS/0044), referred to as footnote 18 in 1994 CSAC report on monitoring and evaluation.

199.7 “Making the Pap Smear Better” (exhibit GVW/CA/001, 1993, referred to at footnote 19 of 1994 CSAC report on monitoring and evaluation (supra)).

199.8 Report, Inquiry into cervical cytopathology at Inverclyde, 1993, exhibit EM/CA/003.

The New Zealand Comparison:

200. It may be argued that the New Zealand National Screening programme “evolved”, perhaps in the same way as elsewhere, and that there are parallels between the difficulties of evolution in New Zealand, and those experienced elsewhere.

201. It is plain from the above analysis that there were some fundamental safeguards in those overseas jurisdictions where evidence has been adduced. So:

201.1 In New South Wales, Medicare benefits could only be paid to an accredited cytology laboratory. That may well have been the reason why so many of the labs became accredited with NATA, by February 1993 (table 1 of “Making the Pap Smear Better”). Such a system was in place from 1987. This was no doubt also behind Dr J Straton’s recommendation, in her review of the New Zealand programme (Glackin Volume 1, tab 4, page 47). This advice was given in July 1990.

201.2 There was a desultory attempt to deal with the issue, both in terms of the attempts to have labs TELARC accredited, and in terms of the legal advice as to whether payment could be tagged to accreditation (considered above).

201.3 The other fundamental difference between the Australian situation and the New Zealand situation, was the complexity

created by state and federal jurisdictions, and the different administration of health care in Australia (see Wain, B1961).

- 201.4 In the UK, there was a proficiency testing scheme in gynaecological cytopathology. The scheme was introduced nationwide under the National Co-ordinating Committee (which co-ordinated the various cervical screening programmes). By the date of the Inverclyde Report in 1993, almost every laboratory in the country where cervical smears were being screened was participating.
202. In short, therefore, there were fundamental safeguards, which never existed in New Zealand at all.
203. When assessing the New Zealand position, it is less relevant to consider the stage which had actually been reached in overseas countries, and more relevant to consider the advice which was being given in the New Zealand context.
204. That advice was twofold. Appropriate practice in managing a screening programme was apparent by reason of the comprehensive international literature which was available, and known to those involved in programme administration in New Zealand; secondly that advice was given to the Minister and the Ministry, particularly by CSAC.
205. It would be simplistic to suggest that merely because an overseas jurisdiction was not making particularly good progress, (if that is proved), that somehow lack of progress in New Zealand can thereby be excused.
206. In the end, it is submitted, the real relevance of the overseas position is as a means of assessing the availability of advice to those involved in establishing the New Zealand programme.
207. Dr Cox stated that a reasonable timeline for New Zealand would have been:

1993: Compulsory TELARC accreditation (B2536)

1993: Routine monitoring and evaluation (B2536)

1995: Establishing of performance measures (B2535)

SECTION IV: ACTIVE FACTORS

208. Submissions are now advanced as to the series of “active errors” which occurred in this chronology. Synonyms are “triggers”, “red flags”, “wake up calls”; all such terminology was used in evidence.

**VISIT TO TAIRAWHITI AREA HEALTH BOARD BY
IMPLEMENTATION UNIT**

209. The references are:

209.1 Boyd, Vol 5, Tab 31 (letter to Dr Boyd from visiting practitioner);

209.2 Glackin, Vol 11, Tab 62, page 11-17, visit by Implementation Unit, July 1989;

209.3 Boyd evidence, A573/14-A581/20.

209.4 Glackin evidence, A300-A305.

210. The evidence establishes:

210.1 Concerns had been expressed with the visiting medical practitioner by Dr Koster; in 3½ years, Dr Bottrill had not produced a single abnormal smear; the visiting medical practitioner asked other GPs and two O&G specialists, but none had had similar results. That was as far as the visiting practitioner took the matter. He did not raise the issue with Dr Bottrill.

210.2 Dr Boyd referred the report from the visiting practitioner to the Implementation Unit (A573/14, A573/27 - A574/1).

210.3 It is likely the Implementation Unit would have read the report (A574/9).

210.4 The report raised matters of concern (A574/20).

210.5 Those concerns were endorsed by what the Members of the Implementation Unit, Fiona Saunders, Frances & Peter Millar, observed when they met with Dr Bottrill, namely:

210.5.1 He had experienced recent ill health;

- 210.5.2 He did not want to read any more slides than his current 20 per day (also endorsed by Dr J Smith's previous report of November 1988, made available to the Department, (see Glackin Vol 11, Tab 62, page 11, especially page 5, "An increase up to 30 per day will result in an unmanageable workload").
- 210.5.3 He was "laid back to the point of almost falling over". (Ms Glackin accepted this was a criticism, page A304/22).
- 210.5.4 He did not employ any cytology assistance and had never tried to even though he did not particularly want to continue screening all the slides himself.
- 210.6 It was agreed that this documentation disclosed "very major concerns" (Boyd A577/23), particularly when one had regard to:
- 210.6.1 Tairawhiti as a high risk area for cervical cancer (Boyd A575/3), and was in a remote and outlying region (A571/21).
- 210.6.2 Dr Bottrill wished to read a low number of slides (Boyd A575/6, A581/18).
- 210.6.3 Dr Bottrill's ill health (Boyd 581/18).

It should have rung an alarm bell (A577/8, A580/8), particularly because of the relative isolation of the practitioner and the community. Dr Boyd said that ideally he would *'like to have seen more from the local co-ordinator once the programme was established'*.

211. It is submitted that not only was the Unit on clear notice of potential concerns involving Dr Bottrill, but so also were those involved with the programme regionally; for example, Dr Smith was aware of the

concerns. She was initially the Community Medicine Registrar for the Tairāwhiti Area Health Board, and by the time of the July 1989 visit, she was the Cervical Screening Co-ordinator (Glackin Vol 11, Tab 62, Page 12). Later she became Medical Officer of Health (Reid B875). Those operating the programme nationally and regionally were seriously remiss, in not following up this concern.

1991, FIRST ROTORUA COMPLAINT

212. At paras 166 and 167, Dr Boyd referred to a complaint in relation to Rotorua, for March 1993. It transpired that there were in fact two complaints, the first of which was in 1991. See:
- 212.1 GRB/MOH/043, where Dr Teague carried out a cytology review
 - 212.2 Glackin Vol 3, Tab 11, page 113 ff
 - 212.3 Teague brief, 25.6-25.8
 - 212.4 Glackin Vol 3, Tab 11, Page 25 (CSAC meeting of 12 December 1991) – NZ Society of Pathologists had recommended that the Rotorua laboratory become TELARC registered; if the lab did not become so registered, cervical smears taken as part of the screening programme would not go to the Rotorua laboratory after 1993.
213. This complaint therefore, was a prompt for compulsory TELARC accreditation.
214. CSLAC was told 15% of high grade lesions are missed. (Glackin Vol 3, Tab 11, page 25). This is an example of a theme of regular reliance on the false negative rate, when concerns were expressed.

1993: SECOND ROTORUA COMPLAINT

215. A further complaint surfaced in 1993, regarding a Rotorua laboratory.
See:
- 215.1 Boyd Vol 5, Tab 32, particularly pages 87, 93 and 94.
- 215.2 Boyd, Evidence, page A584.
216. Dr Risley, the Medical Officer of Health for the Bay of Plenty Area Health Board, considered the complaint raised “*serious matters and needs urgent investigation*”.
217. At a CALC meeting of 28 April 1993 the view was taken that because the numbers cited in the report were small, (presumably it was thought the false negative rate was again a factor) there was nothing to substantiate a problem at Rotorua Medlab (Tab 32, page 108).
218. The co-ordinator replied accordingly (Tab 32, page 93).
219. Dr Boyd agreed that if this was a second complaint (which it was), then this “serious matter” warranted some form of follow up and ongoing monitoring (Boyd, A584/21-28).
220. There is no evidence that such follow up was given (see also Teague brief, para 25.10).
221. A short time later, on 17 November 1993, CALC proposed a system for dealing with inadequate laboratory performance, as follows:
- 221.1 NCSR identifies a problem with a laboratory’s quality assurance data.
- 221.2 Issue to be presented to CALC and the lab concerned.
- 221.3 CALC will monitor the situation and review the issue after 6 months, at which stage CALC may visit lab in question, present

the problem, and check to see if there is a simple explanation or suggest remedial action.

- 221.4 If no improvement, then CALC would present the issue to TELARC and/or NZ Society of Cytology, and/or NZ Society of Pathologists (Glackin Vol 4, Tab 18, Page 65).
222. There is no evidence that this system was implemented in respect of the Rotorua complaints, (or, subsequently, in respect of Dr Bottrill's laboratory).
223. In short, two significant complaints emerged from Rotorua: a complaint system was conceived, but it was never implemented.

DR HITCHCOCK'S LETTER, 1993

224. Dr Hitchcock, acknowledged by Dr Boyd (A585/5) to be a senior pathologist and a member of CALC, wrote to the National Co-ordinator, referring to a potentially dangerous situation.
225. There is no evidence as to what follow up, if any, occurred.
226. Dr Boyd agreed that the complaints system was "ad hoc" (A585/16-21).

GOOD HEALTH WANGANUI – 1994

227. This was a very significant prompt. References are:
- 227.1 GRB/MOH/045
 - 227.2 Boyd B586-9.
228. As to the Ministry's reaction to the Good Health Wanganui issues:
- 228.1 Dr Feek thought there would be some mechanisms in the proposed Medical Practitioners Bill, dealing with competence (Boyd A586).
 - 228.2 To Dr Boyd's knowledge, other than those advising entities who were purchasing and had the contracts with the providers, the Ministry did not audit any health professionals (Boyd A587/10-12).
 - 228.3 On any view, Dr Birkenshaw's circumstances raised serious concerns as to performance, and quality assurance, particularly for pathologists.
229. Given all the concerns which had been expressed as to the need for TELARC registration, so as to ensure internal and external quality assurance, the stark reminder presented by Dr Birkenshaw's errors were potentially significant to those involved with the cervical screening programme. They needed to ensure that TELARC accreditation was indeed compulsory.
230. As has already been submitted, however, at this stage the obligation to become TELARC accredited was being diluted.
231. Whereas the profession had initially taken a strong line in support of compulsory accreditation, by 1993 it was backing off and stating that a "new" laboratory (i.e. one new to TELARC accreditation) needed a "reasonable period of grace", and that compulsory accreditation could

mean that some laboratories would go out of business. (Glackin Vol 4, Tab 18, page 63). At that point, professional self interest was placed before patient safety; it was a view that was reflected in the contractual arrangements, which required RHA's only to utilise "reasonable endeavours" in obtaining TELARC registration.

232. In 1994, it was focusing on the drafting of disclaimers and continuing to take refuge in the false negative phenomena (see, for example, letter drafted for Minister to send to Ms Coney, after consultation with CALC, dated March 1995, SC/WHAT/007, page 405-414; CALC consideration Boyd Vol 4, Tab 18, page 115-6) – further examples of the priority given to professional self interest.

MIDLAND RHA, 1994-95:

233. The pathology problems at Good Health Wanganui precipitated some limited action by the Midland RHA. See:
- 233.1 Mules, Vol 2, Tab 19-Tab 29;
 - 233.2 Mules, Evidence, A1288-A1307;
 - 233.3 CM/HFA/0039;
 - 233.4 CM/HFA/0042;
234. The chronology was:
- 234.1 17 August 1994: letter sent by Dr P Malpass on behalf of Midland to a number of local hospitals and private labs (Tab 20);
 - 234.2 23 August 1994: Dr Bottrill responded stating he did not participate in any external quality control; he said there was little likelihood of a major misdiagnosis of the type referred to (Tab 21);
 - 234.3 28 September 1994: Mr Woodham forwarded a Memorandum to Mr Mules, indicating, inter alia, that the response from Gisborne Laboratories was unsatisfactory. Mr Mules was asked to determine what action, if any, he wished to take (Tab 22).
 - 234.4 6 October 1994: A meeting was held between Midland and ACL; Dr Bottrill attended, but there was no attempt to discuss the quality assurance issues with him was taken (CM/HFA/0042, Mules A1291-1293).
 - 234.5 14 October 1994: A complaint was dealt with by Midland Health in relation to a pathologist at Lakeland Health; Dr Malpass stated in a letter that the matter was important, and a request

was required within 7 days as to quality assurance systems (CM/HFA/0039). Lakeland Health responded in suitable terms.

- 234.6 18 October 1994: Dr Malpass sent a further memorandum to Mr Mules emphasising his concern; he proposed that Midland insist forthwith that providers have internal and external quality programmes in place. This was of the utmost importance to ensure that appropriate quality pathology services were implemented.
- 234.7 Contrary to the position which had been taken in relation to the Rotorua laboratory, no similar request was sent to Dr Bottrill, requiring confirmation as to quality assurance concerns (Mules 1197-8). Mr Mules attempted to distinguish the two situations. Dr Bottrill's response clearly raised serious concerns for Dr Malpass; it should have provoked Mr Mules into direct action. The same approach should have been undertaken, as was undertaken in respect of Rotorua Hospital.
- 234.8 25 October 1994: A further generic letter was sent out to all laboratories, proposing the institution of quality programmes, via s.51 Notices, and asking for responses by 3 November (Tab 24). It was said the proposal would be implemented with some urgency. No reply was ever received from Dr Bottrill, and nor was there any follow up with him.
- 234.9 28 October 1994: ACL responded to Midland, stating, inter alia, "all laboratories have intimated that they have in place appropriate programmes" (Tab 28). This clearly conflicted with the advice given by Dr Bottrill (Tab 21); Mr Mules agreed that his index of suspicion was raised by the discrepancy, (A1300/6), but it still did not stimulate any direct contact with Dr Bottrill.
- 234.10 Nor was there, at that time, any review of an earlier document, filed by Dr Bottrill in May 1993, stating that he had made

application for TELARC accreditation (CM/HFA/0043, Mules A1300-1).

235. From the foregoing, it is plain that there were a number of concerns which arose out of this exchange of correspondence, including, a frank concession by Dr Bottrill that he did not participate in external quality control, and discrepancies on the documentation as to whether he was or was not TELARC registered. This was in the context of serious competency problems of a Wanganui pathologist. The RHA acted inconsistently:

235.1 It did not raise its particular concerns with Dr Bottrill, as Dr Malpass plainly thought should occur.

235.2 Mr Mules did not take the opportunity of speaking with Dr Bottrill at the meeting of 6 October;

235.3 There was no direct follow up with Dr Bottrill, when he failed to answer the second letter sent to him of 25 October 1994;

235.4 It did not cause any enquiry to be made with local GPs or other practitioners.

235.5 All this is to be contrasted with the way it reacted to Rotorua concerns.

236. To the Board, it was acknowledged that the practices in respect of internal peer review, and/or internal control were “probably inadequate” (Tab 29).

237. The RHA had obligations under s.19 of the Health and Disability Services Act 1993, as follows:

“Maintenance of appropriate standards – every purchaser shall purchase services only from persons who maintain standards, (including ethical standards) that the purchaser considers appropriate for those services”.

238. On behalf of the women affected, it is submitted that failure of Midland RHA to respond to the inadequacies of which it was on clear notice, was unconscionable.

WAKE UP CALLS

239. There were at least three overseas developments through this period, which the evidence establishes constituted “wake up calls”. They were:

239.1 The paper, “The Pap Smear Histories of 237 Patients with Cervical Cancer” (Med J Aust 1992, 157: 14-16, Wain GV, Farnsworth A and Hacker; see Wain’s brief, page 30, Cox’s brief, para 114, and B2668). Dr Cox agreed that this was a wake up call for the programme, and that it was indicated to the programme as such;

239.2 There was considerable discussion as a result of Australian litigation, *O’Shea v Sullivan* (1994) Aust Torts Reports 81-273. Judgment was delivered on 6 May 1994. It involved a claim against a GP (for inadequate clinical examination), and a pathologist (for failure to exercise reasonable care in examining and reporting a pap smear). The Plaintiff succeeded and damages were awarded. At para 167, Dr Cox confirmed that this case prompted considerable discussion on false positive and false negative rates. This can be seen in the minutes of CSLAC meetings, e.g. 29 June 1994 (Boyd, Vol 4, Tab 18, Page 82), 19 August 1994 (Boyd, Vol 4, Tab 18, Page 96), and 15 February 1995 (Boyd, Vol 4, Tab 18, Page 107). It is to be noted that the focus of the discussion, however, was on the drafting of a laboratory disclaimer. Whilst it is not surprising that pathologists should be concerned as to possible legal liability, since litigation had ensued in Australia, what is very surprising is that no attention whatever was given to the real question which underlay the problem. That was the avoidance of underreporting, by the adoption of proper quality assurance techniques. It was in this respect that Dr Cox was highlighting this situation as a “wake up call”, which was not heeded.

239.3 Smear tests that went wrong in Britain; (Cox, para 150, B2668). In the NCSP newsletter of March/April 1994 (BC/SC/0029), reference was made to a number of UK situations (Birmingham, Gatehead, East Sussex and Grennock), where errors had occurred. Dr Cox's evidence was that CSAC advised the National Co-ordinator that this type of event could occur in New Zealand, and that appropriate quality assurance was needed to minimise the risk of such an event occurring. This was yet a further wake up call.

CONCERNS OF PROGRAMME MANAGERS

240. It is plain that the Regional Programme Managers had a number of concerns, for which references are:
- 240.1 Glackin, Vol 14, Tab 75, page 120, Minutes of Meeting 23-24 July 1992 – laboratories – “reliability dubious”.
 - 240.2 GRB/MOH/042 – letter from Bay of Plenty Area Health Board, as to standards of laboratory reporting, 20 August 1992.
 - 240.3 Glackin, Vol 14, Tab 75, Page 184, Meeting 3-5 March 1993, issue as to quality of smears, caution should be taken until “quality of laboratories is addressed”.
 - 240.4 Glackin, Vol 9, Tab 49, Page 83 of Report – concern as to variation in lab reporting, “what appears to be persistently and widely disparate reporting”. Local Programme Managers wanted to know how local lab reporting compared with national average and where the differences might be explicable. Also, which individual had responsibility for this aspect of the quality assurance of the programme.
 - 240.5 Boyd evidence A562-7;
 - 240.6 Handiside evidence B3680-1;
241. Dr Boyd agreed that there was a consistent theme of concerns from the Programme Managers about disparate reporting, from 1992 to 1997; that Programme Managers did not know which individual had responsibility for QA; and that something was “*seriously wrong*” if that was the case. (Boyd A568/17).
242. Ms Handiside was referred to the letter written on 9 October 1995, on behalf of the Managers, by Di Best (Sax, exhibits, Tab 12), and their reservations that there was a wide range of reporting over the country, especially with regard to less than optimal smears. Ms Handiside

agreed this was a concern of the Programme Managers, which CSLAC would have been aware of as well.

243. Again, it is submitted these concerns should have prompted a significantly more serious commitment to monitoring and evaluation.

RESIGNATION OF DR COX

244. The resignation of Dr Cox, following as it did in an attempt on his part to institute clinical audit, should have prompted serious reflection as to why he was going.

245. Relevant references are:

245.1 Cox:

Brief: para 214-8;

Oral evidence: B2537 – members of Committee felt “professionally unsafe”

219.2 Handiside:

Oral evidence: B3676-7; Ministry officials were aware of the frustration.

B3702: Dr Cox resigned because he did not want to have blood on his hands, because there would be a calamity like this.

EXTENT OF HIGH GRADE STATISTICS – TAIRAWHITI

246. At a Managers' meeting in September 1995, Ms Reid was "still trying to extract the incidence of and number of deaths from Ca Cx for last three years". She sought help (SRR/THL/002, Tab 3, page 3). In evidence (B747-749), she said that her query "wasn't answered" (B748/17). She thought this was a national responsibility, and expected a response either from the National Co-ordinator or one of the other co-ordinators from around the country. There is no evidence it was received.
247. By the time of the Managers meeting of 18-19 June 1997, Ms Reid, reported:
- "Seemed to be getting more HGIL's but haven't been able to evaluate yet. Especially from own clinics". (Glackin Vol 11, Tab 62, page 69).*
248. According to the evidence of Ms Glackin (A305-6), this issue was discussed with the National Co-ordinator, Ms Best, who "found it very concerning". Apart from keeping the issue under review there was nothing they could do directly about it. The information as to the extent of High Grades was on the Register and available to the Ministry, but there is no evidence it was extracted. Ms Glackin acknowledged it was an alarm bell. There is no evidence any steps were taken as a consequence.

PATIENT 1 CASE, 1997

249. The decision of the Medical Practitioners Disciplinary Committee on the complaint of Patient 1 was given on 5 June 1997 (KJT/MCNZ/0010, page 254). There was an appeal to the Medical Council, and its decision was delivered on 10 December 1997 (KJT/MCNZ/0018, page 307).
250. Ms Marshall, of the Cancer Society, was informed of the case (Marshall brief, 114-118). She spoke to the national co-ordinator. It would appear from a contemporaneous note sent by Ms Marshall to Ms Hobbs on 1 August 1997 (BC/CA/043), that the conversation with Ms Cook had taken place shortly before that date. Ms Glackin had no knowledge of the conversation (A310/10). Ms Hobbs confirmed (para 23) that as at 10 June 1997, the National Co-ordinator had knowledge of the case.
251. There is no evidence of any follow up. Even if the National Co-ordinator did not know whose case it was, or who the pathologist was, it is submitted that there was plainly a line of communication via the Cancer Society, back to the patient. Had further information been required, it could have been obtained.
252. This was precisely the sort of situation that had arisen in **O'Shea's** case, and which had led – quite precisely - to a great deal of discussion and concern. In this instance, the NCSP did nothing.
253. Later that year, the appeal hearing took place before the Medical Council. The Director-General's appointee, Dr Eastwood, participated (Boyd, A590). There was no evidence that, following the hearing of the appeal, anything was "brought back to be taken further within the Ministry" (Boyd A591/7).

254. Turning to the position of Tairawhiti Healthcare Limited, the same issues were raised with the Programme Co-ordinator:
- 254.1 Hobbs, para 23;
- 254.2 Reid, para 27-32; B749-756, 773-783;
255. Not only did the Regional Co-ordinator have knowledge of the case of Patient 1, but so also did a member of the Outpatients Department staff, who discussed the case with Ms Reid.
256. In fact there were a number of worrying concerns in 1997:
- 256.1 Ms Page, (Patient 4) had raised her case, which also involved a misread, with the Co-ordinator (Patient 4 brief, para 17), in March 1997.
- 256.2 In June, Ms Hobbs had raised the case of Patient 1 (supra).
- 256.3 In the same month, the increase of high grades was reported to the Programme Manager's meeting (supra).
257. Notwithstanding this significant cluster of prompts in the early stages of 1997, no steps were taken.

OTHER CONCERNS IN TAIRAWHITI

258. Dr Duncan confirmed that at THL it was known:
- 258.1 Dr Bottrill had been ill, was nearing retirement and wished to dispose of his laboratory (B873);
 - 258.2 His lab was not TELARC registered (B874);
 - 258.3 Midland RHA was concerned, following the Good Health Wanganui situation, where unfortunate pathology problems had arisen (B874-5), and there were significant parallels between Dr Birkenshaw's situation and Dr Bottrill's situation;
 - 258.4 Dr Duncan agreed that he would have expected, when the Good Health Wanganui concerns arose in 1994 (B875), that the Medical Officer of Health should have undertaken enquiries (B875-6). No such enquiry was undertaken.
259. In August 1998, Dr Van de Mark was interviewed for a piece in the Gisborne Herald (JMG/MOH/098). She was concerned because she considered rates of cervical and uterine cancer in the Midland region to be twice that of the rest of New Zealand. At the time she spoke to the National Co-ordinator (B620, 630). In fact she had been prompted to keep a private notebook (B615), because of her concerns.
260. There was a discussion between Dr Van de Mark and Dr Duncan, following publication of this article (B618, B886). However, notwithstanding the expression of those concerns, nothing was done.

DR BOTTRILL'S PRACTICE

261. Mr Grieve QC will discuss the particular factors relating to Dr Bottrill's incompetence, and the less than optimal practice, which directly caused unacceptable underreporting.

CONCLUSION

262. The foregoing are not the only errors. Other parties will make submissions as to other faults. They must be considered as well.
263. The foregoing represents a catalogue of ineptitude and missed opportunities. Over a 10 year period, there were numerous prompts which should have stimulated action, whether at the systemic level, or in response to obvious concerns. It is incredible that so much information had emerged, but so little had been done.
264. Each of these multiple factors must be regarded as having contributed, directly or indirectly, to the ultimate underreporting. Had any one of the “latent factors” not arisen, it is likely the significant underreporting would have been avoided; had any one of the “active factors” prompted action, it is likely the significant underreporting would have been avoided.

SECTION V: TERM OF REFERENCE 3

Introduction:

265. This term of reference requires consideration of the question as to whether, if there is a proved unacceptable level of underreporting, that was an isolated case, rather than evidence of a systemic issue for the NCSP.
266. The main evidence relating to other community labs is the HFA work produced by Mr J Du Rose.

The 6 Laboratories:

267. The HFA review covered 17 laboratories, excluding Dr Bottrill's. A decision was made by the Evaluation Panel to obtain further clarification from 6 laboratories. Given the criticisms (referred to below) of the way in which the criteria were assembled, there may well be an outstanding issue as to whether further clarification should have been sought from other labs, over and above the six. That is an issue which is very difficult to resolve on the data placed before the Committee. It may well be an issue which should be considered further by the members of the Advisory Committee in light of the criticisms advanced at the Inquiry hearing.
268. For convenience, the references in relation to the 6 laboratories where further information was requested, are summarised (the page references are to Mr Du Rose's exhibits):
- 268.1 Laboratory (a,E):

?? 36: Evaluation Panel comments. Further review needed. Issue as to high grade and total abnormalities below benchmarks, 1991-1995. Coding and data entry errors

contributed significantly; issue of staff attending more conferences and other educational endeavours from 1996.

?? 233: Advisory Group recommended HFA work with this laboratory to ensure accuracy of results.

?? 253: 600 previous histology results incorrectly coded, but this made no difference to clinical management. Lab making further corrections; no further need for Advisory Group to consider this lab.

268.2 Laboratory (g,G):

?? 47: Evaluation Panel comments; total abnormalities below benchmark prior to 1996, and high grade below benchmark 1994-95. Possible ASCUS/AGUS issue. Limited rereads to be undertaken.

?? 234: Plan between HFA and laboratory proposed.

?? Exhibit 10, page 4 at Advisory Group meeting of 28.6.2000, insufficient time to consider; some follow up of patients still required; clinical review process to be established to enable laboratory to obtain advice on follow up cases; it appeared women would be advised of the clinical review.

268.3 Laboratory (m,P):

?? 56: Evaluation Panel comments: low abnormality rates.

?? 267: Issue as to CIN II cases, should have been reported as high grades to Register; issue of follow up.

?? Exhibit 10, page 3-4: 79 women being followed up potentially; HFA and lab to establish a clinical review process, to ensure appropriate follow up; whatever the outcome, each of the 79 women to be informed of the

clinical review, including advice that they could request a further assessment or repeat smear, if she so wished.

268.4 Laboratory (c,L):

- ?? 38: Evaluation panel comments: need to clarify quality control practices, and explanation for significant change in profile of reported abnormalities in 1999.
- ?? 234A (unnumbered page following page 234): Ongoing issues as to implementation of a “collaborative project” to address the issues identified by the review from a quality improvement perspective.
- ?? Exhibit 10, p2: meeting between Advisory Group and representatives from laboratory c,L: coding error identified. Advisory Group recommended that labs submit a proposal to be agreed with the HFA, showing how they would better monitor the practice relating to definition of ASCUS and AGUS.

268.5 Laboratory (i,M):

- ?? Evaluation Panel comments: high grade abnormalities below or marginally above the benchmark, throughout 1991-1999. Demographic factors could provide an explanation.
- ?? 235: Option of a more formal review of slide samples to remain open; practice assessment, monitoring and improvement plan had been sent by HFA to laboratory (see 272-3).
- ?? Exhibit 10: This laboratory not discussed at meeting of 28.6.2000.

268.6 Laboratory (e,K):

- ?? 42: Evaluation Panel comments: total abnormalities below the benchmark throughout 1991-1999. Considerably higher rates in other geographic locations with similar incidence. Sample reread to be undertaken; these were rapidly rescreened by the screening staff of relevant hospital laboratory. Results noted.
- ?? 269-270: Pathologist decided to exit cervical cytology. Concerns considered “minor” rather than “major”, for 1999. Laboratory to ensure that appropriate systems are established to enable those taking over to maintain appropriate quality assurance processes (e.g. “prior negative reviews”).

269. The above summary is rudimentary, but it demonstrates a variety of significant concerns. It also confirms that the lab review is ongoing.

Criticism of HFA Review:

270. The work was the subject of a good deal of criticism, particularly by Professor Skegg. In the end, however, there was a clear consensus from the experts who considered it. The question posed by Term of Reference 3, as to whether there is a systemic issue for the programme, cannot be answered (Skegg B2362, B2367, B2377, Cox B2637, B2631, B2633; Medley B2710). The main reasons given as to why this is so were:

270.1 The review is based only on cervical smears, not women (Skegg B2309, B2350-1; but see also Medley B2712).

270.2 There was no adjustment in the data for factors such as age or socio-economic status or ethnicity, and use of places having

either higher or lower than average Maori population is an extremely crude approach (Skegg B2309).

270.3 On the approach adopted in the study, Dr Bottrill would not be an outlier (Skegg B2356-7).

270.4 The coding errors may have caused the high grade reporting average to be set too low (Medley B2698, B2709, and B2718).

271. Dr Medley advised the Committee that the work carried out was primarily a “risk assessment exercise” to ascertain whether women were at risk (B2687); what they were looking for was to see whether there were any other situations, such as that of Dr Bottrill (B2691). They had particular regard to sole practitioners, who were regarded as being in an area of greatest risk, and those with a higher work load of screening. All factors in the questionnaire, she said, were considered.

272. It was her view that the labs reviewed appeared to be practising within acceptable practices at the time of assessment in early 2000, but that she was unable to exclude the possibility that there may have been previous systemic error causing systemic underreporting. She considered that although the review had not been able to completely alleviate anxieties, it has played a significant role in initiating better practice in laboratories for the future (B2733).

273. For his part, Professor Skegg considered that this work emphasised:

273.1 The urgent necessity for the proposed national audit to be carried out (B2434-5).

273.2 That a group should be convened to debate and design any further evaluation (B2434)

273.3 That the HFA should now put its efforts into ensuring the programme is as effective and safe as possible (B2436).

Discussion:

274. It is submitted the HFA study has to be seen for what it was, a risk assessment exercise only; the Committee is plainly not in a position to conclude whether Dr Bottrill's case was isolated; nor can the Committee exclude the possibility of wider consequences of systemic error.
275. As the summary at para 268 above shows, and indeed the entire HFA study shows, there are a range of problems such as lack of adequate training and education, quality assurance provisions, and any form of statistical analysis in several instances. It is a reasonable inference that all of these are related to systemic issues identified earlier, particularly an absence of proper monitoring and evaluation.
276. It has already been submitted, also, that the multiple latent and active factors discussed in regard to TOR 2 contributed to Dr Bottrill's underreporting.
277. If those factors led to unacceptable underreporting in the case of Dr Bottrill, they could equally have led to unacceptable underreporting elsewhere. This study does not rule that possibility out.
278. Analysing the evidence of the women affected, reference was made to examples of underreporting by other pathologists, particularly those employed at Gisborne Hospital, (para 33 above).
279. The review work carried out by the HFA did not cover hospital cytology at all.
280. As Dr Medley observed, the possibility of rereading 10 x 2 million smears would be logistically impossible and a huge waste of money; she said the money would be far better spent drawing a line in the sand and making sure that all women were screened regularly in the near future (B2715). That is one approach, but the other "urgent necessity"

is the national clinical audit, which would provide a reasonable prospect of dealing with underreporting by both community laboratories, and hospital laboratories.

281. It is submitted that of all the matters to which urgent attention needs to be given, as a consequence of this Inquiry, the national audit is at the top of the list; privacy and ethical problems must be resolved as a matter of the utmost urgency.
282. Despite the criticisms, the HFA work should not be abandoned; Professor Skegg's proposal that a group be convened to debate and design any further evaluation is worth building on. At the very least, the Advisory Group should maintain its oversight of the unfinished HFA work, in relation to the 6 laboratories which were identified; that group should also consider the expert evidence given to this Committee of Inquiry, and whether any further evaluation is accordingly required, not only of the 6 laboratories, but of the entire group of 17.

Recommendations: Term of Reference 3:

283. It is submitted the Committee should accordingly recommend, with regard to this Term of Reference:
 - 283.1 The National Clinical Audit should be undertaken as a matter of urgent necessity (expanded on below).
 - 283.2 The Advisory Group should be convened to oversee the ongoing HFA work, and to debate whether any further evaluation of the 17 laboratories is required.

SECTION VI: TERMS OF REFERENCE 4- 6, 8

284. The remaining Terms of Reference deal with changes which have already been made (presumably since the Gisborne concerns arose), or changes which still have to be implemented, and other proposals and recommendations which could ameliorate risks of underreporting, or which are consistent with s.4(a) of the Health and Disability Services Act 1993. For convenience, these Terms of Reference are dealt with globally, according to the particular topics which counsel has identified as being relevant.

National Clinical Review: audit or research?:

285. The importance of clinical audit has already been stressed in these submissions (paras 180-188, supra), and that Professor Skegg considered there was an urgent necessity for it to be carried out. A good description of the process appears in the Cox-Richardson Evaluation Plan 1997 (Glackin Vol 9, Tab 47, page 98-9).

286. Drs Cox and Richardson, in the case of the proposed National Audit (and Professor Skegg and his colleagues in respect of the Gisborne Audit), have applied to Ethics Committees for approval. Having regard to the criteria contained in the National Standard for Ethics Committees (July 1996), Appendix 5, and in the CIOMS Guidelines, there is doubt as to whether an activity of this kind is one for which Ethics approval is needed. As the Crown Law Office opinion of 23 August 2000 suggests, such studies can properly be regarded as “audit”, not “research”; similarly, it may also be regarded as “access to personal health and disability information for the purpose of monitoring the quality of care”. In both instances, ethical approval is not required. It is unclear why approval was on this occasion requested. It is not for an Ethics Committee to regard a particular proposal as “research”, merely

because such a generic term has been used by applicants, perhaps incorrectly.

287. A second general point relates to the privacy issues. The privacy issues are different for the Cancer Register and the Screening Register.

Cancer Register:

288. The main difference between Otago Ethics Committee and the University of Otago is as to the form of an initial approach to women affected. The Otago Ethics Committee proposes that the Cancer Registry should initially approach participants, enclosing an information sheet consent form and questionnaire (DME/REC/010); the University of Otago proposes that women's medical advisors be asked first whether they would judge it appropriate for them to approach the women directly, allowing the doctor to discuss the issue with women if necessary, and avoiding the causing of undue distress. (DME/REC/011, and Cox-Richardson Evaluation Plan 1997, page 98-9).
289. It should be noted that according to the latter exhibit, the University of Otago in fact used their proposed method in a current study of men with prostate cancer, and it was said to be well accepted.
290. The Minister of Health has informed the Otago Ethics Committee that situation is covered by the Health Information Privacy Code and the Cancer Registry Act, and that privacy issues are a matter for the Cancer Registry. (DME/REC/015). The advice in that letter is confirmed by the Crown Law opinion (para 110), which confirms that disclosure under Rule 11(1)(c) of the Health Information Privacy Code does not require patient consent for a purpose in connection with which the information was originally obtained. This was also the view of the Privacy Commissioner (Slane submission, para 23 ff).

291. In the recent Court of Appeal decision of **Harder v The Proceedings Commissioner** (CA240/99, 17.7.2000), the majority, Elias CJ, Thomas and Tipping JJ, at para 23, made the point that it is necessary, in considering any privacy principle, to view that principle, “alongside the balancing provisions of s.14(a)”. The Court stated:

“They [the balancing provisions] require the Commissioner and an implicitly others involved in the interpretation and administration of the Act, to have due regard for the protection of important human rights and social interests that compete with privacy, including the general desirability of a free flow of information and the recognition of the right of Government and business to achieve their objectives in an efficient way”. (Emphasis added).

It is submitted that point is of particular significance when considering Rule 11(2)(a) of the Health Information Privacy Code, and endorses the view expressed by Crown Law and the Privacy Commissioner.

292. Section 66 of the Privacy Act defines “an interference with the privacy of an individual”. Such an interference arises if, and only if any action which allegedly breaches a privacy principle, also causes harm (as defined in the section) to an individual. Given that individuals’ personal information would be kept confidential to an auditor, and not published, it is difficult to see what harm would be likely to occur and, therefore, whether as a matter of law an individual’s privacy would be breached.

293. There are difficult issues of principle to be balanced, but it is very surprising that those involved have been unable to reach a pragmatic solution, that would enable the present proposal to proceed. They should be encouraged to do so, as an immediate priority.

294. In the absence of any such solution, a legislative solution must be developed, as a matter of the utmost urgency.

295. The Cancer Registry Act provides for the promulgation of regulations on such matters as are contemplated by or necessary for giving full effect to the Cancer Registry Act and its due administration. The Long Title of the Act provides that it is to make better provision for the compilation of the statistical record of the incidence of cancer in its various forms, and to provide a basis for the better direction of programmes for research and for cancer prevention. It is arguable that a regulation dealing with the release of data for monitoring and evaluation of the National Cervical Screening Programme (and for any other scheme relating to cancer) could therefore be the subject of a regulation. If the parliamentary draughtsman considered there was any doubt, a specific amendment to the Act should be enacted.

Screening Register:

296. Turning to the Screening Register, the difference between the parties relates to the effect of s.74A of the Health Act. At para 34, the Crown Law Office in its opinion of 23 August 2000 has concluded that it is doubtful whether regulations could be made under s.74A(7) that would permit clinical audits. That is because, a clinical audit would not constitute a “study” of cancer, (see also para 121 of that opinion).
297. So, the issue is whether the release of data to enable an essential clinical audit to be carried out is best achieved by regulation or outright amendment of s.74A. That is a matter for the parliamentary draughtsman.
298. Dr Medley referred to a recent enactment in Victoria where there is a link between the two registers annually (B2705). This is Part III of the Cancer Act 1958, a copy of which is in the materials to accompany these submissions. See particularly ss 60(1A), 61B and 62(5)(ca). That may well be a valid legislative solution. See also the observations of Ms Coney, that from a consumer perspective, there would be no objection to the linkage (B2820-1).

299. Another mechanism would be for the patient's consent to an audit to be sought and obtained at the time of registration of cancer to the Cancer Registry – on the basis that it would perhaps create unjustified alarm to seek a specific consent at the time of smear taking.

Recommendations: National Audit

300. Future studies of this kind should be regarded as audit not research; ethics consent would not then be required.
301. The Committee should recommend legislative amendment particularly for s74A; this must be dealt with as a matter of urgent necessity;
302. With regard to the audit which has already been contracted to the Otago University, and which must be expedited before any legislative change could reasonably be expected to be implemented, the Committee should recommend:
- 302.1 The study should be regarded as audit, not research; ethics consent would not then be required. If the parties are unable to accept this advice, then they should be urged to agree that the privacy issue be submitted to the Privacy Commissioner under s.54 of the Privacy Act, and that they will abide his decision which should be sought urgently.
- 302.2 It is permissible for data from the Cancer Register to be released, pursuant to the law in its present state, and that should occur. Those participating in the project will thereby have it within their means to consult patients or their advisors to obtain consent, enabling access to the Screening Register and to relevant medical records.
303. A related issue is the effectiveness of the Kaitiaki Regulations. I support the recommendations of the Cancer Society in that regard.

Other aspects of monitoring/evaluation:

304. The HFA is involved in various projects, which if established will enhance monitoring and evaluation. They include:

304.1 Policy and quality standards for the NCSP (Peters Exhibit 40).

304.2 Evaluation and monitoring plan including proposed national indicators (Peters Exhibit 42).

304.3 Establishing of independent monitoring group (Peters Brief I, paras 137-143; Peters Brief II, paras 15-19; Peters Affidavit, para 11).

304.4 Information management sub project – (Peters I, paras 159-163, Peters Brief II, paras 20-22).

304.5 National public health/health promotion plan for the NCSP (Peters Brief I, para 152-158; Peters Brief II, paras 23-27, and see particularly JMP/HFA/0044).

304.6 Annual statistical reports (Peters Brief I, paras 189-196; Peters Brief II, paras 34-36, and see particularly JMP/HFA/0047).

305. It is to the credit of the HFA team under Dr Peters that these initiatives have been undertaken, and pursued with vigour; however, there are a number of matters that have emerged in the evidence, and which should be the subject of recommendations from the Committee. They are:

305.1 Implementing of plans: Dr Peters indicated that it was hoped the various plans would be implemented by 30 September (B220). Whilst it is acknowledged that those involved with the screening programme have had much to contend with this year, every effort must be made to meet that timeframe. Dr Peters also indicated that compliance with quality standards would not

be assessed for some time. There was a suggestion that it could take about 12 months (her evidence was given on 4.7.00) to get the screening qualitative monitoring flowing (B207, B213). It would take this long, because time was needed to set up the measures.

Whilst it is correct that the structures being established at present must be set up properly, it must also be acknowledged that, in the meantime, the programme proceeds unmonitored. Some sporadic forms of review have been undertaken in the last 12 months, particularly in connection with this Inquiry, but there has been no overall measured monitoring, and that must be introduced urgently.

From the Committee's point of view, therefore, by the time it reports to the Minister, the plans and monitoring should have been finalised and in place.

305.2 Contractual issues: An issue arises as to the contractual position in the meantime, and whether there is any commitment by the laboratories to the draft plans. (See Mellor II, paras 28-38, and the settlement letter at TM/HFA/89). Clause 3 of the Agreement provides:

“That the following standards are incorporated as requirements on each lab.

(a) Draft cytology standards 2000

(b) National Quality standards for medical laboratories 1997

and such are variations to the above standards as are from time to time approved and agreed to by the parties.”

As was discussed during the hearing (e.g. B2548-9), there is the first problem of a draft document being incorporated. Did the

parties intend it to be incorporated only as a draft, or does it have unconditional status; secondly, there is the fact that the parties have to agree the inclusion of any subsequent variation to those primary documents.

It is said that as part of a national laboratory strategy, all labs will be required to meet a single nationally consistent contract, which is “currently being negotiated” (Mellor II, para 37). That is apparently occurring in the context of an Advisory Group.

Again, the timing of these developments is uncertain, and needs to be the subject of a specific timeframe. Assuming the finalising of the standards in question by the end of September, it is submitted those contracts should be in place by end December 2000.

305.3 Volumes: Dr Peters has developed a discussion paper on this matter (JMP/HFA/0041). As the paper itself discloses, the topic has had a vexed history. CSLAC recommended to TELARC, on 15 August 1999, a maximum number of slides (Glackin Vol 4, Tab 18, page 21). That recommendation found its way into the CSLAC recommendations of May 1991 (Boyd Vol 5, Tab 22). It was not until the Expert Meeting of 13 May 1998 (Glackin Vol 16, Tab 76), that a figure for minimum volumes was finally accepted for New Zealand. Dr Boyd agreed that the best part of 8 years was an unacceptable length of time for implementation of this criteria (A556-A559).

The issue appears to be the willingness of pathologists to accept a limitation which could affect their economic viability.

The HFA has attempted to deal with the issue on a consensus basis (B218, and B220/17). But Dr Peters agreed that it was definitely time to set the standard and “bite the bullet”, although she was concerned with regard to the situation concerning hospital laboratories.

We have seen other examples in the chronology of the consensus approach being attempted, which has resulted in standards not being finalised or set. Examples are TELARC accreditation, and the failure of the Royal College to ratify the draft Sax standards (Sax brief, para 53). The track record of the profession is such that it cannot be relied on voluntarily to commit to standards of this nature; self interest has too often prevailed. Accordingly, the Committee should recommend that if, following consultation by September 2000, there is still no consensus, a standard should be imposed.

There is an allied issue, namely the number of laboratories which should process cervical cytology. Professor Skegg questioned the wisdom of having smears examined "*in about 20 separate laboratories*" (Brief, paras 50, 51).

Evidence was placed before the Committee of large pathology operations such as Sonic Health Care Limited (PM/HFA/0028 – profile of Sonic). On page 147, the laboratory throughput of the five laboratories involved is given. Clearly these are substantial operations, with an impressive standard procedure, and a detailed QA process including a QA team (Pages 176-185).

Professor McGoogan also outlined the essentials in a competent cytopathology laboratory (McGoogan brief, para 79-94, see especially, paras 85-87). As at February 2000, she was Patient Services Director, Pathology, Lothian University Hospitals NHS Trust (EM/CA/001). In evidence, she spoke of the various practices adopted in what is plainly a substantial laboratory (A1081/1-15, A1090/16, A1093/11-19, A1113/16, A1124/25). As one would expect, substantial laboratories are more likely to commit to, and uphold proper quality assurance. She referred to an Audit Commission Report, which concluded the funding of small laboratories was an inefficient use of the resources available (McGoogan Brief, para 168).

Given the effect which Gisborne events have had on public confidence with regard to medical laboratories, it is submitted consideration should be given by the National Screening Programmes Unit to limiting the letting of contracts for cytology to laboratories in each of the main centres only. The days of small laboratory practices, undertaking a modest throughput of cytopathology, are past. As for hospital cytopathology, if a given hospital lab will not maintain a throughput sufficient to meet minimum volumes criteria, there is an issue as to competence to do such work and it should be contracted out to a lab familiar with such work.

305.4 Proposed National Indicators: One of these is the number of A1 smears in the HSIL category (Page 15 of 27, Proposed National Indicators, Tab 42, Peters). Professor Skegg discussed the relevance of age standardised death rate per 100,000 when compared with other OECD countries (B2431-3). The question arose as to whether the .5% benchmark which is the same as the Australian measure (GVW/CA/006, page 315) is appropriate, given an age standardised death rate for Australia of 2.7, and for New Zealand 4.2. This is a matter that needs to be revisited.

305.5 Annual statistical reports: The importance of these has already been stressed. Witnesses were asked to comment on the utility of including, as an aspect of such reports, tables in the form referred to in the European Guidelines (Skegg, B2389-2393; Cox B2509-2527, Peters B3437-B3449).

In light of the advice given to the Committee, therefore, data of this nature should be included in future statistical reports.

305.6 Independent Monitoring Group: Professor McGoogan spoke of regional Quality Assurance teams (A1031, A1089-1090) which ensure that the local programme within the region meets quality standards (see also EM/CA/004). The need to monitor all

aspects of the programme, as to quality was stressed. The terms of reference for the Independent Monitoring Group need to ensure quality control of all aspects of the programme. In the UK, quality is the personal responsibility of the regional directors of public health (McGoogan, B1090/3). Allowing for population differences, there should be an equivalent role in New Zealand; it is submitted there should be a national QA Co-ordinator, personally responsible for quality assurance at all levels of the programme.

305.7 Funding: A theme already identified, in the history, is resource constraints (para 104 ff, supra). Dr Peters was optimistic that funding would be available, for example:

- ?? to establish the independent monitoring body (B204/16).
- ?? a substantial budget has been put in for screening programme and most of it approved (B229/11).
- ?? \$2m included in budget for all developmental work over the next year, including, funding of upgrade work (B237).
- ?? With adequate resources, the unit can carry out the work that needs to be done (B276/8).

Dr Poutasi was asked to confirm what level of commitment the Ministry would be able to give. It was pointed out that there had been a significant increase to \$1.633m in the current financial year (JP/HFA/0052); she stated that if such expenditure was necessary to secure adequate quality and monitoring, then such funding had to be made available (B4098/24). She said that, *“whatever resources are necessary to secure an effective programme will be applied”*. (B4099). A related issue is to ensure there is an adequate mix of in-house expertise (CSAC Report 1994, Glackin Vol 7, Tab 35, page 13, Poutasi, B4092-3, B4097-8).

No doubt there has been substantial focus on the programme, and the need to upgrade it, as a result of the Gisborne tragedy. The issue is not what will happen in the balance of the current financial year, or even the next financial year; the issue is whether the substantial funding necessary to maintain a successful programme indefinitely will be available. The recommendation from this Committee must be that the Government has to be prepared to commit substantial funding to the screening programme for the foreseeable future.

Unless that commitment is given, the Programme should be discontinued.

305.8 Other aspects of evaluation: Doctors Cox and Richardson identified, in 1997, 15 matters for evaluation (Glackin, Vol 9, Tab 47, page 4). Three only were implemented. Some others may have been overtaken by HFA initiatives. The balance, however, should be implemented.

LOCATION OF PROGRAMME: CANCER CONTROL STRATEGY

306. In the interests of continuity of the significant work which has been undertaken in the last 18 months, it is accepted that the only realistic option for the immediate future of the programme, is for it to be transferred to the Ministry of Health, upon the dis-establishment of the HFA. Indeed, it appears all the relevant decision making to achieve such an end has already been taken (Lambie Brief, para 86 and 87, JP/HFA/050, notes B3924).
307. It would appear that the current staff will thereby continue their present functions (Peters Brief II, Para 28-33). It is important, at this point in the life of the programme, not to disrupt the significant initiatives which are being undertaken at present.
308. There is, however, a wider question for the medium term, which needs to be addressed now. That is the question of whether the screening programme should reside in a stand alone agency, in the context of an overall cancer control strategy.
309. The original advice from the Porirua Workshop was that an executive group with decision making power, be formed to control the programme, and allocate funding to the Area Health Boards. (Boyd, Vol 3, Tab 14). This 1998 advice was not accepted by the Minister (Boyd 151-3).
310. Much later, Dr Peters has identified a separate entity as an option for cervical and screening programmes (JMP/HFA/0031). This was discussed in evidence (B243-237). Dr Peters agreed that there were "advantages in terms of sustainability" (B245-6); that it would put it in a better position and make it less immune to more general changes within the health system which might be driven by political concerns or general theories about health delivery (B245/13).

311. Professor Skegg saw such a model as preferable originally, and preferable now; the Ministry of Health he said is not an ideal place in which to place responsibility for a programme like this; further, Advisory Committees are often ignored (A900-1).
312. Dr Cox considered that there was a need for stricter adherence to the WHO guidelines for the organisation of an effective screening programme, and that the central office of the programme should no longer be in the Ministry of Health (Brief, para 247). He was concerned that the programme was returning to the Ministry of Health, because he was not confident the culture of the organisation had changed (B2620).
313. Ms Marshall thought there should be a separate agency (Brief, para 134).
314. Ms Coney, expressing a similar view, said she was “nervous verging on desperate” about the programme returning to the Ministry of Health (B2744). A stand alone agency would be a visible identification of expertise, and would permit separate accountability (B2744).
315. All these witnesses considered that there was a need for a cancer control agency for New Zealand, which would reside in a separate agency:
- 315.1 Skegg DCS/CA/008 – “Need for a National Cancer Control Strategy in New Zealand”, NZMJ.
- 315.2 Cox Brief, para 253-7; B2551-2556
- 315.3 Skegg, A901, A979-982
- 315.4 Marshall Brief, para 130-134
- 315.5 Coney B2744/17
- 315.6 Handiside Brief, para 49
- 315.7 Peters, B251-254.

316. The overall history of this issue is contained in the NZMJ article; there was some action in 1994 and 1995, which resulted in the Ministry of Health issuing “Cancer Control Services in New Zealand: Developing a National Implementation strategy” (see also newsletter of March/April 1994, SC/WHAT/008, page 464).
317. Dr Poutasi stated that the government’s health strategy, which is a draft at present, “signals a significant commitment” to cancer control. She also agreed that screening programmes should be part and parcel of an overall cancer strategy (B4093-5).
318. It is not the Ministry’s position, however, that such strategy should be undertaken in a separate agency, as recommended by Professor Skegg, Dr Cox, Ms Marshall and Ms Coney.
319. The Cancer Society is plainly in support of such an initiative (see opening statement of Society, B2460), and its submission will develop the need for such in greater detail.
320. Another important component in a cancer strategy is the Cancer Register, which is only in a “marginal state of health” (Skegg A901-24). There is a risk of the breast screening programme getting into the same problems as were discussed in this Inquiry (Skegg A901). Indeed during the Inquiry, there were media reports of a significant problem with the administration of the Dunedin Breast Screening Programme.
321. In New Zealand, according to the NZMJ article:

“Cancer is increasing as a major cause of disability and disease in the community. Currently cancer is the leading cause of death among both non Maori and Maori and is the main cause of premature death representing 24% and 39% of person-years of life lost for males and females respectively. About 15,000 New Zealanders develop cancer and about 7,700 die from it each year. By 2005 it is projected that 21,400 will develop and

7,800 die of cancer each year in New Zealand. This projected 42% increase in cancer incidence and 27% increase in cancer deaths, demands a strategic response by central government.”

322. There is a distinct risk that this Inquiry will result in some of the more pressing aspects of the NCSP being addressed, but other important adjuncts of cancer control, such as the Cancer Register and the Breast Screening Programme, not receiving the attention which they require.

323. This Committee, therefore, should make a strong recommendation that the Minister liaise with the National Cancer Control Steering Committee (Cox Brief, para 17), so as to provide adequate formal support and resources for the implementation, in the near future, of all aspects of a co-ordinated Cancer Control Strategy, including the establishment of a separate agency within which the screening programmes should be located. Professor Skegg and Dr Cox urged consideration of the Australian models, and these should be considered (Skegg, A859, Cox B2551-2).

THE REGISTERS

324. Evidence was given concerning the ability of the screening register and the cancer register to operate efficiently.

Screening Register

325. As already observed, the HFA has been running an IM sub project (Peters Brief II, paras 20 and 21, JMP/HFA/057).
326. That project has identified a number of key issues. It states (page 4 of Exhibit), that the next steps are to:
- 326.1 Address and resolve laboratory reporting issues;
 - 326.2 Identify minimum practices and document the role and scope of the regional sites;
 - 326.3 Clarify and document the acceptable activities outside the scope of basic regional site services to enable particular regional sites to meet regional needs.
 - 326.4 Review service requirements and current funding mechanisms.
327. In the course of their oral evidence, Dr Peters and Ms Matchem identified five particular issues with the register (Peters B3412-4, Matchem B3585-8). They are:
- 327.1 Data quality from the laboratories
 - 327.2 Inconsistency in regional site practices

327.3 Register not a population based register, but a utilisation register.

327.4 Absence of colposcopy assessment data.

327.5 Linkages with other registers, particularly Cancer Register.

328. Ms Matchem also identified “vulnerabilities” (B3580, transfer of data from lab to register, data from lab is not accurate, timeliness of data). It was suggested and she agreed that there are no present means of quality controlling laboratories, and that these issues are proceeding on trust; with the consequence that 25% of data is missing. The evidence has also indicated significant delays in the provision of histology (see para 79 ff above). Even now results are being sent in hard copy, not disk (JMP/HFA/0048).

329. Ms Matchem was asked to comment on the possibility of persons working in the regional centres being employees of the central body, rather than the regional body (B2583). She agreed that this would certainly create more control over what happened within the regional site, and consideration should be given to this possibility.

330. It would appear that Dr Peters and her team are alert to these issues, and the recommendation from the Committee should be that the present initiatives be maintained. The print out problem mentioned at para 42, supra, needs also to be dealt with.

The Cancer Register

331. Professor Skegg was critical of the state of this register, which he described as an essential tool for monitoring the cervical screening programme. He said it was in a “fairly marginal state of health”; in his view it was poorly funded, and receives a low priority within the functions of the National Health Information Service. The register needs to be headed, he said, by a medically qualified person, preferably an epidemiologist (A901-2).
332. An indication of personnel involved in administering the register is set out in the front of Exhibit PSC/MOH/004; the Team Leader (who Professor Skegg said was not a “medical person”, A902) resigned three months ago (B3598/26).
333. In evidence, there was evidence of problems of delay (Cancer New Registrations and Deaths 1996, produced in the year 2000, PSC/MOH/004). Dr Peters referred to the two registers being “out of synch”. (Although, as to this see Mr Fraser’s evidence, B3616-8 – it appears the provisional data is more up to date, B3621).
334. Fundamentally, the issue, as Professor Skegg stated, is resources – more staff (B3622-3).
335. Given the critical role which the Cancer Register plays in monitoring and evaluation, it is essential that the priority to be given to upgrading NZHIS work, and that medical leadership by an epidemiologist, be provided.

MANAGING INCIDENTS

336. Mr Du Rose spoke of a “draft protocol” to deal with future incidents (B2087).
337. It would appear, however, that this was “transitional” only.
338. This issue needs to be dealt with properly, and the programme can no doubt benefit from the UK Guidelines of November 1999 (EM/CA/002).
339. The Committee should recommend prompt development of similar guidelines.

DISTRICT HEALTH BOARDS

340. There are clearly some difficult structural issues which will require careful resolution, with the inception of 22 District Health Boards (Peters B3417-21).
341. The possibility, yet again, of split accountabilities and fragmentation could well arise.
342. There are various issues:
- 342.1 Contractual relations, for example with laboratories: will these be between the National Screening Programmes Unit (of the Ministry) (JMP/HFA/050, page 8), and the providers, with funding to be via that Unit which is preferable; or will, as the overall DHB model apparently supposes, the contractual arrangements be via the DHB and provider? (According to the explanatory note of the New Zealand Public Health and Disability Bill, *“DHBs will fund or provide services for geographically defined populations and will be responsible for public hospitals and other related services which are currently owned by HHSs. Many of the HFA’s current responsibilities for needs assessment and funding of services will transfer to DHBs. The Ministry of Health will continue with its current functions and, in addition, will be allocated some of the roles of the HFA and CCMAU (Health)”*).

342.2 A second issue is that already raised in the context of registry issues (para 329 above). Will regional co-ordinators be employed in DHBs or by the National Screening Programme Unit? The present position is that regional co-ordinators are the employees of Health and Hospital Service. That raises accountability issues for the national programme as well as quality assurance and “control” issues (B3582).

343. Again, there is the problem of attempting to “superimpose” the programme on an existing structure; a stand alone agency might well deal with problems of this nature. In the meantime, there is potential for significant dysfunction. The Committee must recommend that specific attention be given to these issues so that the problems which have occurred in the past, particularly those which occurred in the last major restructuring in 1993, do not recur.

344. It is worth mentioning a related issue for the future, which is competence of practitioners. Over the last 12 months, the HFA/Ministry of Health have been sponsoring a major initiative relating to the credentialling of medical practitioners. “Credentialling” is described as:

344.1 Initial credentialling – verification of past qualifications, experience and record; initial allocation of the privileges/definition of scope of practice.

- 344.2 Ongoing (periodic) review of credentials – verification that clinical practice since the previous view meets professional standards; review of privileges/redefinition of scope of practice.
345. A working party has considered a framework for credentialling over the past 12 months, and a discussion document will emerge shortly (and prior to the hearing of submissions).
346. Whilst the processes, which counsel understands are still being developed, can be made to work in an institutional environment, (because credentialling can be built into relevant employment contracts and such institutions are able to establish appropriate structures for carrying out credentialling), a more difficult question applies in respect of a sole practitioner, such as Dr Bottrill. In a credentialling regime, there is no employer to carry out “initial credentialling” or “ongoing credentialling”.
347. This matter is raised in the present context, because the Gisborne tragedy highlights issues relating to the competence of sole practitioners.
348. The recommendation from the Committee should be that in the development of credentialling concepts, particular attention must be given to the position of sole practitioners.

EDUCATION/INFORMATION ISSUES

349. Ms Coney advised the Committee as to the education resources for women (Brief, para 228 ff).
350. She had the impression that of the various resources available over the years, these were not explicit about limitations of cervical screening or benefits (B2759).
351. That impression is confirmed by the evidence of the women themselves in this Inquiry – see paras 38-40, supra.
352. The HFA has recognised the importance of education, and has undertaken a “public health sub project” (Peters I, para 145 ff), which included the production of resources, and training.
353. Ms Coney (Brief, para 209) spoke of the recent literature review prepared by Women’s Health Action.
354. The evidence in this hearing has shown that these are vital initiatives, and the Committee should stress to the Minister, the significance of them.
355. It is in that context that the Committee should also strongly endorse the factors referred to at para 50 of this submission.

CONSUMER MATTERS

356. Ms Coney stressed the importance of consumer representation (Brief para 142 ff). The consumer's role is that of advocate (B2785).

357. This important participation was highlighted in the Cartwright Report itself, where there was the following recommendation in respect of a cervical screening programme:

“The Minister of Health should establish a group representative of a wide range of women health consumers and appropriate health professionals, including representatives of cytology, pathology, colposcopy, and nursing personnel” (Report of the Cervical Cancer Inquiry 1988, page 209).

358. There is a helpful description of the role of consumer in the WHO publication “The World Health Report 2000” (available at www.who.int/whr/2000). A relevant extract is included in Counsels' materials. The real point that is being made in this extract is that patients are at the centre of health services. A health system must therefore revolve around the patient/consumer.

359. Principle 7 of the recent “7 Fundamental Principles”, published by the Minister of Health in “The New Zealand Health Strategy”, June 2000 is:

“Active involvement of consumers and communities at all levels.”

360. That principle is described in the following terms:

“Principle 7 identifies the need to have consumers and communities involved in decisions that affect them. This process should also seek to ensure that services fully reflect the needs of individuals and communities at all levels of the health sector.” (available at www.moh.govt.nz/primarycare.html).

361. It is plain from the history that consumers not being used to the extent that was advocated at the outset.

362. As will be submitted below, there is an ongoing role for advisory committees, and it is vital that consumer representation be included on those committees, contrary to the position that has occurred in the past. (Coney Brief, para 156).

363. The Committee must recommend that such a failure must not recur.

ADVISORY GROUP COMMITTEES

364. The failures in the present history of the Advisory Committees has already been discussed (para 159 ff, supra).
365. Professor McGoogan discussed the UK model (948, 1002-4, 1134-5).
366. It would appear that the importance of such input is recognised at present, in that there is at present, a Public Health Screening Advisory Committee to the HFA (Cox Brief, para 11), for the Tairāwhiti situation a separate Advisory Committee (Mellor Brief, para 32 following), and another again for the Du Rose study (De Rose Brief, para 73 following).
367. It would appear that the New Zealand concept of an “Advisory Committee” is more akin to a “working party” in the UK. That is because the Committee advises the relevant health body, not the Minister.
368. In many respects, the role has been to supply expertise which the Ministry of Health has not itself employed.
369. Whilst there is a higher level of expertise involved in running the programme, now, than was the case hitherto, it is submitted the correct balance should be:
- 369.1 The National Screening Programme’s Unit should be staffed by persons having the correct mix of expertise (for example as advised by CSAC in the 1994 report, Glackin Vol 7, Tab 35,

page 13). Skills in the fields of medicine, epidemiology, public health statistics, computing and cytology are required. The NSW programme is a good example (Wain, B1941-4). Dr Poutasi confirmed that the Ministry would be making skills in those fields available for the future leadership of the programme (B4093). But Advisory Committees should not be required to supply the day to day expertise which the programme requires.

369.2 Advisory Committees can offer objective advice from a neutral quarter, uninfluenced by political or management influence. Above all, consumers must be represented on the Advisory Committee. A role which has not been possible hitherto is the watchdog role. The advice of such a Committee is entitled to respect, and should be accepted.

370. One of the problems of the past was the fact that the Minister was not correctly advised as to relevant circumstances. So:

370.1 Information from the Expert Group was not accurately or properly conveyed, by the Department of Health to the Minister. (e.g. Coney Brief, para 94).

370.2 The Minister was incorrectly advised in 1993 that TELARC accreditation was compulsory.

370.3 The Minister was not given the full picture at the time of the review of accountabilities, and did not anticipate the strong

adverse reaction that would be received from a number of quarters, including the Advisory Committees.

371. Given such a history, an Advisory Committee for the Cervical Screening Programme should be maintained, and should be accountable to, and report to, the Minister so as to balance advice received from the Ministry or officials.

ETHICS COMMITTEES

372. Ms Coney was of the view that Ethics Committees had had a rather “checkered history”. They have suffered from the reform process in the same way as the NCSP itself had, through a lack of oversight, lack of evaluation, and lack of training (Coney, B2751-2).
373. She acknowledged researchers’ disquiet about Ethics Committee, as well as disquiet from a community perspective.
374. She commented on the lack of any evaluation of Ethics Committees, and proposed a review of what they approve and turn down (B2822).
375. The related issue is the need for a National Ethics Committee, perhaps within the office of the Health and Disability Commissioner to give it independence, stability and focus around health consumers rights (B2752). Until a short time ago, there was a national Ethics Committee, but only the Minister could refer matters to it.
376. The particular example of the screening programme has thrown up some additional issues, which need also to be reviewed. For example in the case of national audit, there are the following points to note:
- 376.1 There needs to be a clearer distinction in the relevant guidelines as to the difference between audit (particularly for the purposes of monitoring and evaluation), and research.
- 376.2 There is a distinction to be noted between informed consent and privacy (see submission of Privacy Commissioner, para 28).

Informed consent is needed where proposed treatment, even if skilfully performed, carries a “material” risk, so that a patient has a right to be informed of those risks. Privacy, on the other hand has to do with disclosure of information.

376.3 Guidelines for the Ethics Committee, on privacy issues, should be consistent with the Health Information Privacy Code. In an audit case, consideration will need to be given to Rule 11(1)(c), and Rule 11(2)(h). In the latter instance, the prerequisite is whether it is not desirable or practicable to obtain authorisation from the individual concerned. That creates a presumption of authorisation; arcane distinctions as to whether that authorisation be obtained by a register as against an internationally respected epidemiologist should not impede important audit.

376.4 If it is not possible to obtain consent, considerable assistance may be derived by guidelines which have been developed in Australia, “Guidelines under Section 95 of the Privacy Act 1988”, and which, at s.3 contains an excellent set of criteria to be used in determining the public interest in the protection of privacy, as against the public interest in proposed research. Those guidelines are commended for consideration. (See also with regard to the Australian position, the recently released, “Statement on Ethical Conduct in Research involving Humans 1999”, National Health and Medical Research Council and

“Accessing Patients’ Records without individual consent for Epidemiological Research” [2000] Journal of Law and Medicine, 76, included in Counsel’s materials).

377. Accordingly, it is submitted the Committee should recommend that the work of Ethics Committees should be reviewed:

377.1 an evaluation of their work to date should be carried out;

377.2 there should be training for Committee members;

377.3 there should be established a National Committee, in the office of the Health and Disability Commissioner (not within the Ministry, as is proposed upon the dis-establishment of the HFA) to which an appeal or complaint may be taken from a Regional Committee to enable review of decisions; further, an issue having national implications, such as the Cox/Richardson study, should go to a national body, and not to a regional committee. This would promote consistency.

377.4 Guidelines for Ethics Committees should be reviewed, as above; a Ministry of Health review of the National Standards was to have been released in May 2000, and has not yet emerged. It should take into account the issues which have arisen during the Inquiry.

LEGISLATIVE ISSUES

378. Submissions have already been made concerning the release of data from the Cancer Register and the Screening Register, and the need for legislative amendment.
379. There are other legislative changes requiring consideration. The most significant of those are the proposed amendments to the Medical Practitioners Act 1995, as described by Dr Boyd (Brief, 169-171). A consultation document has been produced (GRB/MOH/0034).
380. The Medical Council's response is at MAHB/MCNZ/0015, page 45.
381. It would appear that the Ministry has independently expedited consultation of this issue, but support for those initiatives should be given by the Committee.
382. There are three particular matters which are raised:
- 382.1 The introduction of provisions under which doctors would report an incompetent colleague would be, prima facie, a welcome amendment to the Medical Practitioners Act 1995. However, such a provision which encourages, or even requires, doctors to report on incompetent colleagues needs to be accompanied by clear guidelines to doctors as to when and how they should respond to problems they encounter. Introduction of a provision permitting reporting, without explicit guidance, will simply cause problems.

The General Medical Council in the UK has issued comprehensive guidelines on referral by doctors of incompetent practitioners to the GMC. These provide a step by step procedure for doctors to follow when confronted with problems. They state clearly what kind of matters should be reported, and what kind of matters are outside the GMC's power to investigate. Although there is no statutory provision in the UK governing the reporting of incompetence, the Court of Appeal has in the past held that GMC guidelines represent the law (**W v Edgell** [1990] 1 All ER 835 – the rules are set out at pages 843-4).

382.2 The second matter relates to findings of medical error or mishap. In the consultation document, it was suggested that such findings would be reported by the ACC to the Medical Council (Boyd Vol 5, Tab 34, page 2-3, para 4).

The Accident Rehabilitation and Compensation Insurance Act 1992, s.5(10) contained such a mechanism. For reasons which are not apparent, this reporting provision was not repeated in the Accident Insurance Act 1998 when it was enacted.

The proposed mechanism, as referred to in the discussion paper, would again have the ACC advise the Medical Council of such cases, but not the Health and Disability Commissioner.

The Health and Disability Commissioner is now required to deal with complaints, inter alia, of medical error and mishap, in the first instance, not the Medical Council.

Accordingly, the Corporation should refer cases of medical error and mishap not only to the Medical Council, but to the Health and Disability Commissioner.

382.3 It is proposed that the Medical Council itself (rather than the Medical Practitioners Disciplinary Tribunal, which is the position under the Medical Practitioners Act at present), has the power to suspend, “*where there are reasonable grounds to believe a doctor poses risks to the public*”. The alternative (reference to a Complaints Assessment Committee, for investigation and ultimate placing of a charge before the Medical Practitioners Disciplinary Tribunal, which only then considers the possibility of suspension), can take a considerable period of time. It is important that the Medical Council has this right, subject to practitioners’ rights of natural justice.

383. Consideration may need to be given to the possibility of lab reviews (of the Du Rose kind) being gazetted as a quality assurance activity under Part VI of the Medical Practitioners Act 1995, so as to maximise co-operation of labs in reviews which might otherwise be perceived as self-incriminatory.

384. A related issue is a possible Health Professional’s Competency Assurance Bill. It is understood that such a Bill is mooted wherein all

regulatory statutes governing health professionals, including doctors, nurses, dentists, occupational therapists and midwives will fall under this regime. The individual statutes, affecting those professions, will be repealed, and each profession will be the subject of its own Regulations.

385. A consultation paper is in the course of preparation by the Ministry of Health, and is expected to be released shortly.

386. It is submitted that the specific matters raised in the discussion paper, promoting changes to the Medical Practitioners Act (Boyd, Vol 5, Tab 34), should be advanced and enacted, rather than placed on hold while a more fundamental restructuring of the regulatory process discussed, consulted and possibly implemented. It is likely that such a restructuring would take considerable time. It is important when there has been significant erosion of public confidence in the medical profession following Gisborne events; that amendments pertaining to medical practitioners are enacted promptly.

387. Counsel for the Women Affected strongly support these amendments.

388. Turning to the position of Laboratory Technologists, under the Medical Auxiliaries Act 1966, the Medical Laboratory Technologists Regulations 1989 (SI 1989/282), have been promulgated. There are two issues:

388.1 The first arises from Regulation 9, which provides that certain persons can perform medical laboratory technology; those persons include a registered medical practitioner, as of right. Dr

Boyd (Brief, para 88), noted that the regulation does not require the medical practitioner to be a pathologist and on the vocational register, but said that as from 2001 any medical practitioner carrying out this task would need to be subject to the oversight of a vocationally registered pathologist. (This issue is described more fully in Dr Baird's brief, paras 34 and 41 (c)). Providing the HFA/Ministry adopts its current policy of letting contracts only to laboratories who have supervising pathologists (until at least 1 July 2001), there would appear to be no difficulty arising from this provision.

388.2 Regulation 4 provides that the Medical Laboratory Technologists Board shall issue a manual from time to time prescribing the qualifications and training for registration. Inter alia, in the current manual, a trainee is obliged to undergo a course of training in a medical laboratory in one only of nine subjects, one of which is histology, and another of which is medical cytology. It would appear from the terms of the manual that it would be possible for a medical laboratory technologist to obtain qualification under one topic, and thereby become a registered medical laboratory technician; there is nothing in the regulations or manual, however, to prevent that technologist from practising in another field, for which he or she has not been trained. It is recommended that this issue be taken up with the Board, with a view to the lacuna being dealt with.

389. As regards laboratory assistants, Dr Boyd stated that they work under the supervision of a technologist, scientific officer, or registered medical practitioner (Brief, para 94). An issue for consideration, however, is as to proper monitoring, to ensure that lab assistants are in fact working under supervision at all times. Given the evidence which has been heard as to the difficulty of attracting staff, particularly in remote locations, smaller laboratories may well have difficulty in providing supervision when senior staff are ill, on holiday, or during weekends. Monitoring procedures should ensure proper supervision at these times.
390. The final legislative matter relates to the approval, by a Medical Officer of Health, of lay smear takers. The Health Reforms (Transitional Provisions) Regulations 1993 provided, in Regulation 4 for extension of an earlier regulation which dealt with this issue, namely Regulation 4A of the Social Security (Laboratory Diagnostic Services) Regulations 1981. That transitional provision had the effect of continuing the power to give such approvals until 30 June 1994. In 1997, the Programme Managers raised an issue as to approval of non medical smear takers (GRB/MOH/040, Boyd A531-2).
391. On the face of it, there was a hiatus after 30 June 1994. Counsel for the Ministry has advised me that there is an explanation in respect of this matter, but as yet, I have not received it. It is a loose end which needs to be resolved. The short point is, are lay smear takers subject to approval?

CONCLUSION

392. In this submission, we have not dealt with the many special, cultural and other issues which arise for Maori women and their whanau. They require special consideration by the Committee, which we are confident you will give. It is appropriate, however, for our colleague Ms Kapua to address you on those matters.
393. Although there are many concerns indeed which have been raised in this submission, we do not overlook the positives which have been achieved by the programme. They are worthy of note. Professor Skegg stated that despite many false starts and interruptions, the NCSP has achieved a great deal. There is considerably greater awareness among women and health providers of the need for cervical screening; participation is high. (Skegg Brief I, para 41 ff).
394. The 1996 policy sought to increase the proportion of eligible women enrolled and screened in the previous three years to 85% by the year 2000. According to the draft statistical report, the figure as at 31 December 1998 was 82.9% (Peters Brief II, para 36).
395. According to the draft "Progress on Health Outcome Tasks" for 1999 (DGL/MOH/0014 page 38, and Figure 1, page 39) in 1997, 73 females died from cervical cancer, the lowest since 1980. The trend has steadily declined over the interim during a period when, without a screening programme, a epidemic was expected (Cox, Skegg, GRB/MOH/039, 1986).

396. However, the programme is at a critical stage. There is a serious crisis of public confidence. It is imperative that the range of recommendations which have been advocated on behalf of the Women Affected, and which the Committee is urged to adopt, are implemented with urgency.
397. This will require a great deal of effort and allocation of resources, for the foreseeable future.
398. Unless that happens, however, the programme should be discontinued immediately.
399. It is an outrage that for the second time in 12 years, a major public review has had to be undertaken. There were high hopes that the recommendations of the Cartwright Report would result in a comprehensive and well planned programme. Had those recommendations been followed, that is what we would have had.
400. That did not occur, and that a second major Inquiry was required only 12 years later, is a serious indictment against those involved.
401. There must not be a third major scandal relating to cancer.
402. For that reason, we make a final recommendation. The Minister should appoint a person to monitor, on a long term basis, the implementing of the recommendations of this Inquiry.
403. We respectfully submit that Professor Skegg, who has plainly been a key participant in this matter throughout, and who has an outstanding

international reputation, be so appointed to report directly to the Minister from time to time as to the implementing of the recommendations of this Inquiry.

404. This Committee may well be assisted by some of the conclusions of the Inverclyde Report. But it should also be noted that *“the majority of the recommendations of the Inverclyde Report were put in place within the first 24-36 months”* (McGoogan A1039/16). The Gisborne recommendations should be the subject of anticipated timeframes for implementation.

SUMMARY OF RECOMMENDATIONS

405. For convenience, a summary of recommendations referred to in this submission is given:

405.1 Clinical audit:

- ?? The Advisory Group should be convened to oversee the ongoing HFA work, and to debate whether any further evaluation of the 17 laboratories is required (para 283.2).
- ?? Clinical audit studies should be regarded as audit not research, so that ethics consent would not then be required (para 300).
- ?? The Committee should recommend legislative amendment, especially for s.74A, as a matter of urgent necessity (para 301).
- ?? With regard to the National Clinical Audit, contracted to Otago University, such study should be regarded as research. Ethics consent will not then be required. If the parties are unable to accept this advice, then they should agree that the privacy issue be submitted to the Privacy Commissioner under s.54 of the Privacy Act, and that they will abide his decision which should be sought urgently (para 302.1).

- ?? It is permissible for data from the Cancer Register to be released, pursuant to the law in its present state, and that should occur (para 302.2).
- ?? The recommendations of the Cancer Society in relation to the Kaitiaki Regulations are supported (para 303).

405.2 Monitoring and evaluation:

- ?? The plans currently being conceived should be implemented by 30 September 2000; monitoring should be in place by end 2000 (para 305.1).
- ?? Unconditional contracts, incorporating the finalised plans, should be in place by end December 2000 (para 305.2).
- ?? A standard as to minimum volumes should be fixed, by end September 2000; consideration should be given to limiting the letting of contracts for cytology to laboratories in each of the main centres only (para 305.3).
- ?? The proposed national indicator for high grades (.5%) should be reviewed (para 305.4).
- ?? Annual statistical reports should be produced, and tables incorporating the data contained in the European Guidelines included (para 305.5).

- ?? The Independent Monitoring Group should quality control all aspects of the programme. A national quality control co-ordinator should be appointed (para 305.6).
- ?? The Government should confirm that all necessary resources and an adequate mix of in-house expertise to maintain the programme successfully for the foreseeable future will be made available (para 305.6).
- ?? The matters contained in the Cox/Richardson Evaluation Plan of 1997 which have not hitherto been contracted should now be implemented (para 305.7).

405.3 The Minister should liaise with the National Cancer Control Steering Committee so as to provide adequate formal support and resources for the implementation in the near future of all aspects of a co-ordinated cancer control strategy, including the establishment of a separate agency within which the screening programme should be located (para 323).

405.4 The Registers:

- ?? Present initiatives with regard to the upgrading of the Screening Register should be maintained (para 330).
- ?? The form of printouts should be considered (para 41).

- ?? Priority should be given to upgrading NZHIS work, with the allocation of more staff resources, including medical leadership by an epidemiologist (paras 334 and 335).

405.5 Managing incidents:

- ?? There should be a prompt development of incident guidelines (para 339).
- ?? Attention should be given to any structural problems that might arise from placing the Screening Programme in the Ministry of Health, upon the dis-establishment of the HFA, so as to ensure that dysfunctional relationships do not arise; contracts should be directly between the National Screening Programme Unit and providers (paras 342 and 343).
- ?? Regional Co-ordinators should be employed by the National Screening Programme Unit (para 342.2); alternatively there should be direct accountability to the Manager of the Unit.
- ?? In developing credentialling concepts, particular attention should be given to the position of sole practitioners (para 348).
- ?? The HFA Public Health sub project should be endorsed (para 354).

- ?? The Committee should emphasise the significance of a cervical screening programme, as the only known effective preventative strategy for cervical cancer, including the fact that there are a number of known co-factors causing the cervical cancer (paras 50 and 51).

405.6 Consumer matters:

- ?? It is vital that consumer representation be included on Advisory Committees (paras 362 and 363).
- ?? An Advisory Group Committee should be maintained for the Screening Programme; the Committee should report to the Minister (para 371).

405.7 Ethics Committees:

- ?? An evaluation of the work of Ethics Committees to date should be carried out.
- ?? There should be training for Committee members.
- ?? A National Committee should be established in the office of the Health and Disability Commissioner.
- ?? The guidelines for Ethics Committees should be reviewed (para 377).

405.8 Legislative issues:

- ?? With regard to proposed amendments to the Medical Practitioners Act 1995, guidelines need to be given to doctors, when required to report on incompetent colleagues (para 382.1).
- ?? ACC findings of medical error or mishap should be reported to both the Medical Council and to the Health and Disability Commissioner (para 382.2).
- ?? The Committee should endorse the introduction of a right of suspension by the Medical Council (para 382.3).
- ?? Consideration should be given to the possibility of lab reviews being gazetted as a quality assurance activity under Part VI of the Medical Practitioners Act 1995 (para 383).
- ?? The above amendments should be expedited, and should not await the enactment of a Health Professionals Competency Assurance Bill (para 386).
- ?? The Medical Laboratory Technologists Board should be invited to consider the criteria for registration of Lab Technologists, and whether a technologist should practice in an area for which he or she has not received training (para 388.2).

?? Mechanisms for the monitoring of oversight of laboratory assistants should be introduced (para 389).

?? The position as to the approval of lay smear takers should be reviewed and clarified (para 390).

405.9 The Minister should appoint a person to monitor, on a long term basis, the implementing of the recommendations of this Inquiry (para 403). Professor Skegg is recommended. An anticipated timeframe for implementing the Committee's recommendations should be given (para 404).

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