

High

Court Adam Ross Penny Andrews

Under the Health and Disabilities Services Act 1993

*in the matter of* The Ministerial Inquiry into the Under-Reporting of  
Cervical Smear Abnormalities

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STATEMENT OF EVIDENCE OF dr bruce montgomerie duncan

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Dated

2000

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## STATEMENT OF EVIDENCE OF dr bruce montgomerie duncan

**Background and qualifications**

- 1 My full name is Bruce Montgomerie Duncan. I am a medical practitioner, qualifying in medicine (MChB) in 1981 from Aberdeen University, United Kingdom. My postgraduate qualifications include membership of the Royal College of Practitioners, UK (MRCGP) 1987; the Diploma in Child Health (RCP, London), 1987; a Masters Degree in Community Health (MSc) from Edinburgh University (UK) in 1991; and membership of the Faculty of Public Health Medicine (of the Royal College of Physicians, London), 1993.
- 2 I am currently employed as Clinical Director of Public Health, Tairāwhiti Healthcare Limited ("THL"). I have been in this position since September 1997. Prior to my appointment at THL I was a specialist in Public Health Medicine in Stirling, Scotland, from 1993 to 1997.
- 3 As Clinical Director of Public Health, I am accountable for activities of the Public Health Unit ("PHU") in Gisborne. The PHU is part of THL. The role of clinical director has changed over the period since 1997. From early 1997 until September 1997, there was no Clinical Director or public health physician in the PHU following the departure of the previous Medical Officer of Health. The Medical Officer of Health role was provided from Waikato and continues to be until I obtain my specialist registration later this year. The managerial roles have also changed over this period, with the accountability for the PHU transferring, during 1998, from the Service Manager (a role which no longer exists) to the Clinical Director.
- 4 From 1993 to 1997, I was as specialist in Public Health Medicine in Central Scotland. As part of the role, I was responsible in 1996 and 1997 for the purchasing of cervical screening services for the area.
- 5 This statement has been prepared in response to a request from Ms Hanne Janes, counsel assisting the inquiry, in a letter to me dated 14 January 2000.

**Assistance in preparing statement**

- 6 In preparing this statement, I have been assisted by three other THL staff members, namely Ms Jan Ewart, Ms Judy Wilson and Miss Missie Winiata.
- 7 Ms Jan Ewart is a Registered Nurse and Midwife with post-basic diplomas

in Nursing and Health Administration. In February 1996 Ms Ewart was employed as the Manager of the Cervical Screening and Sexual Health Programmes. From April 1996 that role was extended to all personal health services within the PHU. Ms Ewart completed the theoretical component of the non-medical smear-taker training with the Family Planning Association (“FPA”) in Wellington in early 1996.

- 8 Ms Wilson is a Registered Nurse and Midwife. She has been employed as co-ordinator of the Tairawhiti part of the National Cervical Screening Programme (“NCSP”) since 30 March 1999. From 1993 until February 1999, Sharon Reid was the co-ordinator.
- 9 Ms Missie Winiata (Health Promotion Certificate, 1997) was employed as Educator for the Tairawhiti CSP from 1993 to 1999. In 1999 she took on the role of Special Circumstance Support Person for those affected by the cervical smear mis-reads.
- 10 In this statement, I will refer to the “Tairawhiti office of the NCSP”. This is the regional arm of the National Cervical Screening Programme (“NCSP”). Its staff are employees of THL and the office runs as part of THL. Their primary relationship, as far as the NCSP and its database are concerned, is with the NCSP itself.

### **Overview of the National Cervical Screening Programme in Tairawhiti**

#### ***(i) Introduction of the programme***

- 11 I have been asked to comment on the introduction of the NCSP in the Tairawhiti region. The NCSP was introduced in 1991. None of the current staff, including myself, was employed at Tairawhiti at that time. As a result, we are unable to comment on this particular matter. The co-ordinator at the time of the NCSP introduction was Leanne Penney, currently with the Health Funding Authority (“HFA”) in Auckland.

#### ***(ii) Contract and policy***

- 12 The PHU runs the Tairawhiti regional office of the NCSP through a contract with the HFA. The NCSP requirement definition of 1996/97 for cervical screening (Midland Health) remains the current contract guideline, having been ‘rolled over’ since that date.
- 13 Two further documents, the Policy for National Cervical Screening 1991 (updated in 1993) and 1996, define the national policy with regard to the NCSP.

- 14 The revenue from the HFA contract forms a guide to staff levels for the Tairāwhiti regional office of the NCSP. The PHU employed one full time co-ordinator/systems analyst and one half-time data entry clerk directly to run the regional NCSP, with a half-time health educator and a fifth-time smear-taker (until May 1999). Since May 1999, additional staff have been employed to cope with the additional demand arising out of the HFA investigation.
- 15 The role of the local Co-ordinator is to operationalise and co-ordinate the NCSP at the local level. THL supports the NCSP through accommodation, line management and general support infrastructure. The local co-ordinator (together with the other 13 regional coordinators) meets with the national programme coordinator (Jane McEntee) and national programme manager (Julia Peters) on a regular basis, currently twice yearly.

***(iii) Education and information – interest groups and interested groups***

- 16 The educator makes contact with various groups to offer education sessions. Examples include training groups, Maori Women's Welfare League, Country Women's Institute, community health committees, Maori Health League, Pacific Island Groups and workplaces. The educator works closely with other PHU staff, for example, occupational and public health nurses who have well-established links with groups and workplaces.
- 17 Education sessions are arranged from these contacts or on request. Sessions are held, as much as possible, in places suitable to the women involved.
- 18 The content of these sessions stresses the important part women play within the family/whānau and how the cervical smear is a part of making sure that women remain healthy. The sessions involve explanations regarding who should have a smear and demonstrations (using the model supplied in the Ministry of Health ("MoH") kit). It is always emphasised to the women that the NCSP is a *screening* programme and that there will be a small percentage that could potentially be read inaccurately.
- 19 The MoH information kits were initially generic but later included Maori-specific and Pacific Island people-specific material. These kits are the main resources used at the education sessions. All written or audio-visual material is produced nationally.

- 20 It has been difficult to get into some areas to provide education, for example, accessing educational institutions. As the Tairāwhiti area has a high uptake of women on the NCSP register (currently 94% of eligible women are registered), we have been trying in recent years to reach areas where under-represented groups may be, looking at other strategies including working a lot closer with other providers of health care.

***(iv) Training/qualification of smear-takers***

- 21 People wishing to become 'non-medical' smear-takers attend a course run by polytechnics or the FPA. All non-medical smear-takers in the Tairāwhiti area are registered nurses. Until 1996, smear takers were required by legislation to be approved by the MOH.
- 22 The current national guidelines (for smear takers) have been under review since 1996. Locally, all non-medical smear-takers are invited to ongoing education.

***(v) Publications/policies/guidelines issued to smear-takers***

- 23 As part of the FPA or polytechnic smear-takers courses people are issued with detailed material on all aspects of cervical screening. Copies of national policies, guidelines and publications including pamphlets are also issued.
- 24 A minimum of one annual update is held in the region, facilitated by the local co-ordinator. Both medical and non-medical smear-takers are invited to participate in these information sessions. Sessions held over recent years have included laboratory updates and colposcopy, national co-ordinator visits and updates on national issues.

***(vi) Steps taken to inform the public***

- 25 National, regional and local promotion has occurred in September of each year. National promotion included television advertising, newspaper articles, tee-shirts and NCSP endorsement on products such as pens, combs, and notepads. These promotions were intended to remind women of the importance of regular smears and the importance of being on the NCSR. In Tairāwhiti, promotion has also occurred through local groups, for example, Korikori Tinana (a line-dancing group) and with a touch rugby team.
- 26 Static displays, pamphlets and posters are distributed through as many venues and sites as possible, including the Citizens Advice Bureau, libraries, educational institutions, hospitals and general practitioners'

(GPs) surgeries.

- 27 Radio interviews and sessions are done on Ngati Porou and Turanga FM and there is other media exposure, especially during National Cervical Screening Awareness weeks. Newspaper articles are also done on an *ad hoc* basis.

**The status of the register relating to the Tairawhiti region now, including both cytology and histology results**

**(i) Overview**

- 28 The Tairawhiti CSP has the third highest enrolment coverage (95%) of the 14 regional sites. There are around 11,300 women enrolled from an eligible population of 11,900. Eligible women are women aged 20-69, excluding women who have had total hysterectomies for benign disease. There are a further 700 women enrolled from outside the age group 20-69. Our five-year coverage rate (those women who have had a smear within the last five years) is the highest in the country at 89%. Our population is approximately 45% Maori and 55% non-Maori. The effect of the current investigation has been to increase the enrolment and coverage on the NCSP.
- 29 In the months following the problem being identified, the Tairawhiti office of the NCSP worked with Di Best of the HFA to review the accuracy of the Tairawhiti data, set out above, on the national database.

**(ii) Cytology results**

- 30 A long standing problem with obtaining laboratory results without the accompanying request form and the lack of histology was compounded by the increased workload after April 1999. Di Best and Judy Wilson met with Janet Willson of Medlab Gisborne, and Brian Morris and staff of the Gisborne Hospital Laboratory. Both laboratories were happy to co-operate with change, despite these changes in practice resulting in some increased workload.
- 31 The primary change that resulted from these meetings was that the Tairawhiti office of the NCSP now receives, on a daily basis, the copy of the smear laboratory request form. Prior to this, smears (with the request form) were sent to the appropriate laboratory (Medlab Hamilton from Medlab Gisborne, and Medlab Central from Gisborne Hospital). The smear would be read and over the next two to four weeks, the results and the top copy of the pink laboratory request form would be returned to our office for processing. Generally, the forms would be returned first and then the results on disk, although

sometimes they would come together or request forms would arrive after the results. We felt that changing the system would be much safer for the following reasons:

- it would allow the office to immediately update a woman's details;
  - if a result did not arrive to match a request form, we would be aware of this (prior to this it was very difficult to identify missing smear results), and therefore could request the result from the laboratory or smear-taker.
- 32 Most importantly, both local laboratories had agreed that they would hold the smears until a smear history could be supplied. The smear-history would go with this smear to the appropriate laboratory and would provide the cytologist with previous smear results – vital information particularly for those women with abnormal histories. The delay in sending the smears to either the Hamilton or Palmerston North laboratory would have been at most, only one day. There would also be a much closer working relationship with both laboratories.
- 33 In March 1999 there were a number of smear results (approximately 200) in a “hold” file that were unable to be processed due to missing forms. Working in conjunction with the smear-takers in May and June, the missing information was obtained allowing these results to be posted on the NCSP register. Since that time, there are rarely more than 5-6 results in the hold file and results are reviewed and dealt with monthly.
- (iii) Histology results**
- 34 The NCSP register should receive all (cervical and endocervical) histology results except for those women who have chosen to “opt-off”. In May 1999 it became apparent that large numbers of these results were missing. Di Best obtained and processed approximately 1,500 missing results with the assistance of the hospital laboratory. We also initiated a system with both laboratories such that a photocopy of the histology request form would be sent to our office (the forms are collected on a daily basis together with the cytology forms).
- 35 Until mid-November 1999, Gisborne Hospital had a resident pathologist, but the Hospital did not have the necessary software to supply the results to the Tairawhiti office of the NCSP on disk. As a result, on a monthly basis, the laboratory would send the hard copy of the results to the local site. These would be collated by the Tairawhiti office and then sent to Wellington for coding and entering on the NCSP register.

This system remains in place and works well. Since mid-November 1999, histology from Gisborne Hospital has been sent to Medlab Central in Palmerston North. Our histology results are not sent on disk.

- 36 In this region a very small amount of histology is done privately. Historically, this histology was read by Medlab Hamilton and was processed via the Waikato CSP. This was because of the small number of results (estimated to be 20-30 per year). The Tairawhiti office of the NCSP is working with Medlab Hamilton to develop a process to ensure that results come to Tairawhiti.

**Changes made to the NCSP in the Tairawhiti region as a result of the experience following the re-reading of Dr Bottrill's smears**

- 37 The first impact was the change in guidelines (from the HFA - 2 smears post Dr Bottrill), and many of the phone calls we had from women and smear-takers dealt with these new recommendations. As these guidelines are not national guidelines, the recall date for those women has to be manually amended where appropriate. Recall systems were developed by the Tairawhiti office of the NCSP and smear-takers, particularly in the PHU clinic.
- 38 For those women identified in the re-read and also enrolled on the NCSP, Tairawhiti office of the NCSP receives a copy of the letter to the smear-taker. This information is processed to the NCSP register. Judy Wilson also works with Missie Winiata in assisting women requesting more information about cervical screening and to review their smear histories. The Tairawhiti CSP also monitors referral and attendance at colposcopy.
- 39 From July 1999, Tairawhiti office of the NCSP began supplying Gisborne Hospital with smear histories for all women attending for colposcopy.

**The events leading up to the discovery of the problem relating to Dr Bottrill's reading of cervical smears, and subsequent actions taken by THL**

***(i) Awareness of the alleged problem***

- 40 In early April 1999, I became aware of a potential problem affecting cervical smears. The first indication of a potential problem was to Judy Wilson, Programme Co-ordinator. She was contacted by a colleague in Auckland (Tracy Monehan – Operations Manager, Auckland CSP), asking whether she had received a copy of a letter from the solicitor in the Auckland case (Mr S Grieve) where a woman

was suing a pathologist over the consequences of a series of under-reported slides. At that contact, Judy Wilson was able to ascertain that the case involved Dr Bottrill. Up to that point, I was not aware that a court case in Auckland related to Gisborne.

- 41 That same week, a number of requests came to the Tairāwhiti office of the NCSP for cervical smear histories. The requests for histories came through local Cancer Society staff. Jan Ewart and I discussed the requests with Janice Hobbs, and explained that clear authority would be needed from the patients concerned before we could release the information.
- 42 These events gave rise to a series of informal meetings between Judy Wilson, Jan Ewart and myself. There were a number of further contacts with the Cancer Society and also with local GPs involved in identified cases. These meetings, both formal and informal, led to the view that there was a potential problem with cervical cytology. At that time we could identify four women (including the case in Auckland), in whom there was either a known under-reporting of cervical cytology or in whom there was a suspicious smear history. All the cases involved had a common feature: that Dr Bottrill's laboratory had read the smears. Around that time, we also became aware of Dr Bottrill's previous appearance before the New Zealand Medical Council.
- 43 I discussed the PHU's concerns with senior management, including THL's Chief Executive Officer in the first half of April 1999.

**(ii) Action taken by THL**

- 44 On 16 April 1999, I spoke to the New Zealand Medical Council (Frank Linehan and Lynn Urquhart) and to the MoH (Dr Bob Boyd). The contacts were made to inform both bodies about the above concerns, and also for advice about appropriate action. The advice from the New Zealand Medical Council and the MoH was to contact both the Health and Disability Commissioner's Office ("HDC") and the HFA.
- 45 The HDC was contacted that day and on 19 April 1999 (Peter Williamson). There has been no further contact from that office.
- 46 I contacted Jane MacEntee (NCSP) of the HFA on 16 April 1999 and she indicated that Tracy Mellor (HFA, Quality and Audit) was leading the process and was therefore the person to contact. Tracy was subsequently contacted on 19 April 1999.

- 47 On 19 April 1999, I had a telephone conversation with Ms Mellor outlining our concerns. It was clear that there was already some activity on the part of the HFA. They were aware of the Auckland court case and seemed to be aware of Mr Grieve's letter (referred to above). Ms Mellor indicated that the HFA was actively determining how to tackle the problem and that a proposal would be completed shortly.
- 48 At that point I had significant doubts about cervical smear reporting from Dr Bottrill's laboratory. I was forming the view that a re-read could become necessary. I formed this view for a number of reasons. Any reassurance of people (that there were no systematic errors) would be impossible without some measure of performance. In addition, if there had been systematic under-reporting, reviewing all the slides offered the best opportunity to change the health outcomes for women of this area. I was also aware of previous screening failures overseas, where re-reading was the chosen method of review.
- 49 The important issue was the need to determine whether the cases brought to my attention represented a systematic failure of screening. The alternative explanation was that we were finding the small number of women who do not benefit from the NCSP.
- 50 In reviewing the screening histories of the women brought to my attention, it was clear they had all had regular smears; their risk of developing cervical cancer should have been small. A collection of four such women led to the suspicion that there was a systematic error. We also had identified a number of women who had the apparent sudden development of a high-grade smear despite a history of normal smears. While not unknown, this, coupled with the four cases above, also suggested an under-reporting.

***(iii) Continuing activity since 19 April 1999***

- 51 I spoke with clinical colleagues, contacting all general practices on 21 and 22 April 1999. The issue of a potential systematic failure was raised with senior medical staff at Gisborne Hospital on 21 April 1999 (see below).
- 52 Following 19 April 1999, there was a series of telephone contacts with Tracy Mellor to discuss the HFA proposal to investigate the alleged failure of the laboratory. Tracy Mellor came to Gisborne on 26 April 1999.
- 53 At that 26 April meeting the HFA Project Manager, Marie Burgess, was

brought in. Three local GPs were also asked to join to provide local advice. The meeting discussed the recall of women not having had a smear since March 1996, the potential re-read of Dr Bottrill's work and the formation of an expert group to advise the HFA.

**(iv) Activities since 26 April 1999**

- 54 The PHU has been closely involved in the activities of the investigation since early April 1999. We have taken part in all public meetings locally. We have organised, advised and taken part in all meetings with GPs and smear-takers. The PHU has been a point of information and contact for the public as well as women affected by the mis-reading. The Unit has operated the 0800 Helpline since its inception in April 1999.
- 55 The Tairawhiti office of the NCSP has been exceptionally busy since then, providing smear histories, advice and processing results from the extra smears performed as a result of the investigation. The PHU provided the support worker (Missie Winiata) and has also administered the Special Circumstances Grant. The PHU continues to work with and support other health care providers in the area to encourage women to attend for cervical smears. THL has provided the infrastructure for the extra clinics (Dr Ron Jones being the expert colposcopist brought in to lead the process). I am (as Clinical Director of the PHU) an external appointee to the HFA's Advisory Group.
- 56 Missie Winiata was appointed co-ordinator of Support Services for the women with misread smears in July 1999. She was appointed because of her knowledge of the NCSP and the local community.
- 57 Letters were sent, telephone calls and personal contact was made with Te Runanga-O-Turanganui-A-Kiwa, Ngati Porou Hauora, Turanga Health, community groups, GPs, smeaertakers and the colposcopy specialist informing them of her appointment, what it entailed and also asking for input into how the PHU could make this position work best for the women. As a result, training needs were identified for the Kaiawhina in the Tairawhiti region. This training was put in place by the co-ordinator and the Tairawhiti office of the NCSP.
- 58 Pamphlets and posters were developed and sent to all GPs, smear-taker clinics and anywhere else that was deemed appropriate. Media releases were given to radio stations and the local newspapers in the Tairawhiti region outlining her position. Missie Winiata visited all GP

practices and clinics in the area to introduce herself, accompanied by a team from the ACC who explained the claims procedure for women with misread smears. A form was also developed to collect basic information from the women who were accessing support, advice and information. As time went on this form was amended after input from some of the women who complained that it was far too detailed.

- 59 Missie now attends regular meetings with the Provider Advisory Group and the Women's Support Group, which have been invaluable as a means of alerting her to issues that some of the women were experiencing. She has also made herself available at most of the colposcopy clinics. Missie also supported the colposcopy team in making contact with women that have not attended their appointments.
- 60 I have heard the evidence of the women affected during the inquiry, some of which has implications for THL. There seems to be a particular concern about the amount of information and follow up available to the women affected. I agree that in some cases this may have been less than ideal. THL has been in touch with those women who raised concerns.

**(v) *Non-cervical cytology issues***

- 61 Deleted.
- 62 Over the weeks of April and early May 1999, I contacted each general practice (though not every GP at that time), and spoke to most senior clinicians at Gisborne Hospital. I indicated to these persons that there were concerns about the reporting of cervical cytology. Doctors were asked to specifically inform me of any cases where there had been any under-reporting, or suspicion of under-reporting. This request was not limited to cervical cytology or histology, but included all Dr Bottrill's work.
- 63 Deleted.
- 64 I have received no other information about failures or alleged failures in Dr Bottrill's work from medical colleagues in Tairāwhiti.

**Could anything have been done to pick up the problem earlier?**

- 65 There are two issues here; what could have been done, and if something could have been done, who might legitimately have been expected to

have done it?

- 66 With the benefit of hindsight, there may have been a number of opportunities to raise the level of suspicion:

66.1 A clinical review of cases of cervical cancer should include a review of the woman's screening history. This can be performed in two main ways. The first is at the level of the clinician. The review of each case of cervical cancer, at diagnosis, should include a review of smear history. This may include a re-reading of relevant slides. However, for the clinician, a change in what is a small number of cases of a relatively rare disease may make it difficult to recognise an overall trend. For the Tairāwhiti area, there have also been a number of changes in gynaecologist since 1990, a factor which can reduce the likelihood of detecting change in infrequent events.

66.2 While a local gynaecologist could raise the issue, the second option exists to have a (confidential) system at a national level where the history of every woman with cervical cancer could be reviewed. At a national level, patterns or trends might be seen that could be precluded by the analysis of small numbers. This overview would add to the power of surveillance of smear history review.

- 67 The inquiry has highlighted the inadequacy of comparative data between laboratories and regions. In relation to high and low grade changes, the NCSP could review the proportion of high and low grades reported by laboratory (or by area, or by other variable). The comparison with other laboratories and a national standard would not tell you if a laboratory were not performing appropriately, as it might merely reflect the population presenting for smears. It would, however, indicate where further investigation might be appropriate.
- 68 There are standards of practice for laboratories available, both here and from other countries, which outline a process of quality control to reduce the risk of under-reporting of cervical cytology.
- 69 Placing the responsibility for the national NCSP in a single manager who is adequately skilled and resourced, while not necessarily being able to prevent all failures, would certainly reduce the risk of a systems failure.

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Bruce Montgomerie Duncan

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Date