

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

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

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**SUBMISSIONS MADE ON BEHALF OF  
DR MICHAEL BOTTRILL**

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Counsel respectfully submit:

**Term of Reference One**

*1. To determine whether there has been an unacceptable level of under-reporting in consequence of mis-reading and/or mis-reporting of abnormalities in cervical smears in the Gisborne region.*

1.1 The elements of the Committee’s task are to determine:

?? Whether there was under-reporting

?? If so, whether the “level” was “unacceptable”

?? Was the under-reporting, if found, and unacceptably so, consequent on

misreading and/or

misreporting

1.2 That there was under-reporting is evident. All laboratories experience under-reporting. Whatever definition of the phrase “false negative” is adopted, such phenomena are world-wide.

1.3 It is submitted that in the context the word “level” was apparently intended as a short-hand expression to denote the ratio between the occurrence of actual abnormalities on smears

read in a laboratory (this applies here because for practical purposes there was only one for Gisborne) and the reporting of those abnormalities as such. This begs the question, however, as to what standard of reporting qualifies. A smear demonstrating invasion may be reported as high-grade; this may be regarded as an example of under-reporting but is of no consequence to the management of the patient, who is referred for examination. On the other hand, the same degree of error, for example reporting a low-grade smear as normal, may have a flow on effect where two low grades ought to result in referral. For the evidence on this topic, and a suggestion that the simple ratio approach is crude, I refer to:

?? Skegg: Brief paragraphs 58 - 66, evidence transcript A887 1-27, A888 10-16

1.4 In any individual case the patient may understandably regard under-reporting to any degree as unacceptable to her. This is demonstrated by Patient One, whose fourth smear is said to have shown invasion but was reported as high grade for referral, resulting in prompt reference for colposcopy.

?? Transcript A19 1-10

1.5 A subjective point of view may also be taken by the pathologist under review. In the present case, Dr Bottrill accepted twice that so far as he was concerned his level of under-reporting was unacceptable.

?? Transcript B3079, 3081

1.6 No exploration of the basis of this followed. Clearly he found his under-reporting unacceptable at a personal level. He did not relate this either to the consequences or to any comparison with his colleagues or to any other comparator. The evidence does not therefore greatly assist the Committee in its task.

1.7 Expert evidence was given not only by Professor Skegg (paragraph 3 above) but also by Dr McGoogan at length:

?? Transcript A1068, A1092 - A1112

Dr Farnsworth took a more robust approach.

?? Transcript B1870 – B1871

1.8 Essentially the question is ideally to be determined on statistical grounds, having regard to the established consequences. If this turns out not to be possible (at the time of writing this remains unknown, Ruling 12 refers) then Dr McGoogan would accept what was described as a common-sense approach.

1.9 In the last resort the Court (or Committee) may determine an issue of negligence, if the body of opinion relied on is not capable of withstanding logical analysis:

?? Bolitho v City and Hackney Health Authority [1997] 4 All E.R. 771 HL

- 1.10 The analogy is far from exact, but in the event Professor Skegg does not complete his project, there is authority and evidence (viz.: Dr McGoogan) for the Committee to decide the issue.
- 1.11 It is submitted that the Sydney re-read does not materially assist, because its results challenge other laboratories, which brings up a question of New Zealand standards overall, in respect of which there is no evidence. The Otago/Northland/Bay of Plenty review may provide sufficiently reliable data, but this again remains as at the date of writing to be seen. Dr Farnsworth has no knowledge of other New Zealand standards.
- 1.12 Accordingly the essential question in my submission remains at this point in time unresolved, although there is evidence which the Inquiry may elect to accept.
- 1.13 The issue of mis-reading or mis-reporting can be shortly settled. Dr Bottrill set a high level of reaction to the presence of abnormal lesions on smears. His false positive rate indicates that he was generally correct when reporting high grade.

?? Transcript page B1857

Mis-reporting was put forward as a possible reason for the under-call on patient One's second smear.

?? Transcript A20

Clerical errors of one kind or another are a hazard to be guarded against, but there is no evidence of their reoccurrence

in Gisborne Laboratory. It follows that under-reporting resulted from mis-reading.

2. ***“If you determine that there has been an unacceptable level of under reporting, to identify the factors that are likely to have led to that under- reporting”***

There have been a number of factors referred to during the course of the Inquiry, which have been identified as potentially leading to, either cumulatively or on their own, to under-reporting in the Gisborne region. These factors, and their influence on any level of under-reporting, will be discussed below:

1. *Sole pathologist conducting primary screening and assessment of abnormalities.*

- 1.1 Prior to Dr Bottrill’s retirement in March 1996, he had practiced in the Gisborne region for nearly 30 years. He had opened his own laboratory in 1967, and commenced his practice there full-time from 1974. After 1974, there were a number of pathologists employed at Gisborne Hospital, and the evidence shows that there was a good level of interaction between the pathologists at Gisborne Hospital, and Dr Bottrill.

?? Dr Bottrill brief of evidence paragraph 8

?? Dr Bottrill brief of evidence paragraph 18

?? Dr Bottrill brief of evidence paragraph 57 and 58

1.2 Cytology in Gisborne was read both at Dr Bottrill's laboratory and Gisborne Hospital laboratory. Throughout the time period 1967 to 1989, there was no trained cyto-screener in Gisborne. This meant that both Dr Bottrill, and any pathologist who conducted cytology work at Gisborne Hospital (if they chose to) did so both at a primary screening level, and at a cytopathology level. In about 1989 one of the hospital staff trained in cytotechnological diagnosis, although that person was the only cyto-technician in Gisborne during Dr Bottrill's time of practice.

?? Dr Bottrill brief of evidence paragraph 31.

1.3 Despite that cyto-screener's training, it appears from Mr Morris's evidence, that Dr Padwell, when undertaking a locum for Dr Bottrill in 1993, performed home screening in relation to the cervical cytology that was accepted by Dr Bottrill's laboratory. There is also evidence that despite the existence of a cyto-screener that she only performed some of the cyto-screening during the time that he was working with Dr Padwell. It is possible, taking into account Mr Morris' evidence, that Dr Padwell and the cyto-screener took turns at doing the primary screening.

?? Transcript pages B2909 to 2910

There is no evidence of any of the pathologists who routinely assisted Dr Bottrill as locums (while they were employed at the hospital), advising him of any concerns regarding the role of acting as a primary screener.

1.4 There were significant developments in cytology between the time of Dr Bottrill's commencement of practice in Gisborne, and the mid 1990's. Dr McGoogan in particular described the development of primary screeners in the United Kingdom and Scotland. She advised the Inquiry that it used to be quite common for medical practitioners to function as primary screeners, particularly in Scotland in the 1950's where there was a well organized screening programme

?? McGoogan transcript A1018 lines 5-14.

1.5 Dr McGoogan went on to say in answer to a question from Professor Duggan regarding the training undertaken by pathologists in primary screening at this time *"If you are asking me do any pathologists undertake primary screening then the answer is probably yes, a few do. But here we must be careful about our definition of primary screening, by primary screening I mean they are the first individual to look at the slide"*

?? Transcript A1018 17-22

It appears from the evidence therefore, that in the United Kingdom at this time, there are still pathologists who undertake primary screening.

1.6 Dr Teague, also commented on the development of cytopathology, but in a New Zealand context. Dr Teague described the situation in cytology as having *"evolved and that some pathologists took a particular interest in cytology, some of those people did do some primary screening, but as far as I*

*know in most laboratories there were cyto-technologists or cyto-screeners who did most of the primary screening.”*

?? Transcript B1240 22-25

- 1.7 Dr Teague’s evidence was that in 1990 – 1996 he personally would have had less of a problem with a pathologist doing primary screening than he would have with the unavailability of another person re-screening cervical cytology.

?? Transcript B1512

He indicated that there was a period in New Zealand in which pathologists quite commonly conducted primary screening and further stated that he believed that that was a common practice in the 1980’s or beforehand. In particular Dr Teague’s evidence was:

*“In fact all sorts of people were screening smears I would suggest. I’m not suggesting it was optimal but it certainly happened, and it’s the point at which that transition to more current or modern practices occurred and I believe in most practices that would have occurred prior to the 1990’s.”*

?? Transcript B1513 - 1514

- 1.8 It is submitted that it is particularly important to look at the question of primary screening, in the New Zealand context. Dr Beer gave evidence particularly relating to the availability of cyto-technologists in New Zealand. He advised the Inquiry that since 1985 in New Zealand there had been difficulty in obtaining qualified cyto-screeners. That difficulty extended into the year 2000. Dr Beer acknowledged that his laboratory

(Medlab Bay of Plenty) had had difficulty attracting qualified cyto-technologists to both Tauranga and Rotorua, and that in more isolated areas than this, there would be a greater difficulty still in attracting cyto-technologists.

?? Transcript B1093 line 13 to 1094 line 7

- 1.9 Dr Beer stated that there was at present no organized programme of training or education of cyto-screeners, and that laboratories were responsible for the training of such screeners.

?? Transcript B1081 line 24 to 1082 line 2

It is submitted that the problem of attracting screeners to more isolated rural areas was illustrated particularly with reference to Gisborne. Dr Bottrill in his brief discussed the shortage of cyto-technologists between 1990 and 1995. An advertisement had received no response (Brief paragraph 31). Dr Beer's evidence that cyto-technologists were largely trained in their own laboratories would not have been of any assistance in Dr Bottrill's case.

- 1.10 The evidence does not conclusively point to Dr Bottrill being the only pathologist conducting primary screening in New Zealand during the time period 1990 to 1996. On the basis of the "DuRose" study, the HFA were not able to exclude the possibility that another pathologist/s had been conducting either routine or non-routine primary screening.

?? Transcript B2123 lines 9-19

1.11 It was accepted by Dr Bottrill that it would have been preferable to have had a primary screener. There is no issue here.

?? Transcript page B3092 lines 20 –22

He further expressed the view that he had always hoped that the two laboratories in the city could be reunited because he thought that they would then provide a much more efficient and better way of dealing with the work load. To do this, he had always given the pathologists at the Hospital a small amount of routine cytology, to encourage them to remain.

?? Transcript B3058 lines 5 - 12

1.12 Dr Bottrill's evidence further was that he had always performed his services in the best way that he could, under the circumstances in which he found himself. At the time, he was not aware of inadequacy of his training for the task of primary screening. This was never remarked on by any colleague, except to the extent this was implicit in Dr Teague's 1995 suggestion.

?? Transcript B3090 lines 12 – 15

?? Dr Bottrill brief paragraph 43

## 2. Training

2.1 Dr Bottrill qualified MB CHB (1953 Birmingham) and at the time of his retirement was a fellow of the Royal College of Pathologists of Australasia (1973).

?? Brief Dr Bottrill paragraph 3

2.2 Dr Bottrill's training is set out in paragraph 5 of his brief of evidence. Essentially he studied for four and a half years in pathology, from March 1957 to September 1961. He had, during that time, the opportunity to study gynaecological cytology with the specialist at the women's hospital in Leeds, on a part-time basis for a period of three months. He then recommenced reading gynaecological cytology in 1967 at Gisborne Hospital. He had by that time, had regular contact with Dr Williams, a pathologist at Auckland Hospital, who has been described by Dr Bottrill as the "leading light" in the formation of the New Zealand Society of Cytology.

?? Brief of evidence of Dr Bottrill paragraph 15

2.3 It is submitted therefore that when Dr Bottrill recommenced reading cervical cytology smears in 1967, he had had the same, if not more, training than many of his colleagues. This was confirmed by Dr Bottrill in his evidence (transcript B3086) where he said that his three month part-time in exfoliate cytology would have been three months longer than any of his contemporaries who trained at the same time. He also confirmed that training for cytology did not exist in the 1950's.

2.4 Professor Davies, the President of the Royal College of Pathologists of Australasia confirmed (transcript B1183 lines 10 and 11) that cytology did not have the prominence in the late 50's to early 60's that it has now. He also referred to two possible episodes in which Dr Bottrill could have undergone

training in cytopathology; firstly under Professor Lumsden when doing morbid anatomy and histology and possible secondly when referring to his experience with Dr Goldie at St James Hospital.

2.5 Professor Davies' evidence, it is submitted, was also of assistance in relation to the training that was available for a pathologist wishing to specialize in gynaecological cytology offered by the College. His evidence ( page B1185 lines 15-24) were that there were currently courses available, the most comprehensive being run by the Victoria Gynaecological Cytology Service. The course offered was a two week residential course which from time to time some pathologists in Australia attended.

2.6 The examinations in pathology offered by the College in the 1970's were also discussed. In particular it has been noted that there was an examination slanted towards cytopathology available from 1973, the year that Dr Bottrill obtained his fellowship. Professor Davies' evidence on this point was that the broader anatomical pathology examination (that Dr Bottrill sat) coincided with the introduction of the slanted examination, and may suggest that cytopathology was in the minds of the Board of Censors at that time, as something to be looked at for people doing anatomical pathology. The fact that Dr Bottrill did not sit the slanted examination, did not mean that he did not have some component of cytopathology in his examination

?? Transcript B1188 lines 20-24

2.7 Professor Davies rejected the idea that an applicant for a fellowship who was practicing in gynaecological cytology or intended to do so would be required by the College to sit the examination of anatomical pathology slanted towards cytopathology. He rejected this on the basis that there was a component of cytopathology in the special anatomical pathology examination and also in the tissue pathology component for general pathology, whilst acknowledging that the training and examination was not as detailed as in the slanted examination. In particular, Professor Davies noted as follows:

*“The slanted examination and indeed the diploma which is mentioned are things that were developing particularly for those pathologists who wished to perhaps take a career in something like a very large cytology service such as the Victorian Gynaecological Cytology Service.”*

?? Transcript B1189 – 1190 line 11

2.8 Indeed Dr Linehan confirmed that Dr Bottrill in not sitting the fellowship in anatomical pathology slanted towards cytopathology would have been in the company of most pathologists practicing cytopathology at that time. He stated:

*“Only those who qualified subsequent to that time would have taken that option. I can’t think of any that I know who would have actually re-qualified under those criteria.”*

?? Transcript B3825 lines 1–8

2.9 Dr Teague's view was that at present in New Zealand if a person was to specialize in gynaecological cytology and make that a major part of their practice then they would want to get specialized training in that area. The centre that currently provides the most training for New Zealand in the area is the Victorian Gynaecological Cytology Service, which runs residential courses of up to two weeks duration.

?? Transcript B1251 lines 4-14

It is still not a requirement however to hold a specialized fellowship qualification in order to read cytological smears.

?? Transcript B1251 lines 22-25

The evidence from Dr Teague was that in addition to the slanted examination of the College a diploma in cytopathology was available after the completion of a fellowship, or there was a qualification available to become a fellow of the International Academy of Cytology.

?? Transcript B1252 lines 1-4

2.10 It is submitted that it is apparent that the qualifications discussed by Dr Teague, are not requirements in the year 2000, for the practice of cytopathology. Dr Beer, a pathologist practicing in the cytopathology area confirmed that currently, in the year 2000:

*“I think New Zealand has something like 7 pathologists who have the post-graduate qualification of the fellowship in the International Association of cytopathology, and I'm not sure of*

*the number who have the Royal College of Pathologists post-graduate qualification. The remainder of the pathologists working in this area have the fellowship and the Royal College of Pathologists of Australasia and it is now being recognized by most in this area that they should be looking towards attaining a post-graduate qualification such as that offered by the diploma offered by the College or by the International Association of Cytology”*

?? Transcript B1082 lines 4-12

- 2.11 It is submitted that Dr Bottrill’s qualifications that were held at the time that he read cervical cytology, were those held by his peers, and it is only relatively recently pathologists are looking towards attaining a post-graduate qualification in cytopathology. Dr Bottrill’s training and practical experience in cytopathology, it is submitted, was standard in a doctor of his time of qualification and training.

3. *Appropriate continuing education*

- 3.1 No New Zealand pathologist gave evidence of any formal structured continuing medical education available in New Zealand. Dr Bottrill’s evidence was that he was a member of both the New Zealand Society of Pathologists, and the Society of Cytology. He was, as has previously been stated, a fellow of the Royal College of Pathologists of Australasia.
- 3.2 The burden of continuing medical education in this area appears to have been taken up by the Society of Cytologists,

which was formed in the late 1960's by Dr Stephen Williams and Dr John Sullivan. Dr Bottrill was invited to join and while the Society did not involve anything mandatory, annual meetings of a scientific nature were held and in addition there were sporadic meetings when overseas visitors were in New Zealand.

?? Dr Bottrill brief paragraph 15

3.3 Dr Bottrill's evidence was that for the first 10 years in the 70's and 80's he attended all of the Society's meetings. After 10 years he started going on alternate years.

3.4 Dr Bottrill was a regular attendee of meetings of the New Zealand Society of Pathologists. His evidence was that he regularly attended functions and meetings of that organization, initially annually and later approximately every two years depending on where the meetings were held.

?? Dr Bottrill brief paragraph 13

3.5 Annual meetings were also held of the North Island division of that Society, which he attended regularly. In addition to this continuing medical education, Dr Bottrill at paragraph 56 of his brief of evidence set out other attendances including:

1. Attendance at local post-graduate meetings of about 6-8 per year.
2. Attendances at conference and workshops relating to cytology and histology – attendance of cytology sessions of the College meetings at a rate of approximately every two years from 1968 to 1993.

3. Attendance in 1993 at the conference in Mexico of the World Association of Societies of Pathology (W.A.S.P)

4. Attendance in 1995 of W.A.S.P conferences in Auckland.

3.6 Dr Bottrill also gave evidence that he spent some time each week in the library at the Gisborne Hospital, reading on general pathology topics, relevant to his practice.

3.7 Dr Beer confirmed that he had personally met and talked with Dr Bottrill at some of the New Zealand Society of Pathologists meetings. Dr Beer confirmed that Dr Bottrill was a reasonably regular attendee of the local meetings, and he had not seen any change in attendance and interest between 1991 to 1996, although he did notice that Dr Bottrill did suffer some ill health

?? Transcript B1057 lines 3-15

3.8 The conferences available for the period 1990 – 1996 that could be regarded as providing continuing education nationally were listed by Dr Teague as

- the annual meeting of the New Zealand Society of Cytology,
  - the annual meeting of the New Zealand Society of Pathology,
  - occasional meetings of the College in New Zealand and
  - a North Island Pathologist meeting held annually.
- Attendance at those meetings were confirmed by Dr Teague as being those that would qualify for mention

to Telarc if Telarc were checking ones continuing education.

?? Transcript B1235 line 20 – page 1236 line 15

Dr Bottrill’s evidence was that he attended those meetings regularly, and during the 80’s and 90’s on a bi-annual basis. There is no contrary evidence.

#### 4. Telarc Accreditation

4.1 Dr Bottrill was clear that cost was not an important consideration to Dr Bottrill in the pursuit of Telarc accreditation. It is submitted that the clear evidence (transcript B3059 lines 24-29) was that the question for him was what he saw as a gigantic amount of work involved in the organization and documentation of the organization of his laboratory.

4.2 Dr Bottrill could recall discussions with Dr Linehan in relation to Telarc accreditation of pathologists throughout New Zealand. Dr Bottrill’s view was:

*“... I felt that the accreditation system, although obviously a good thing, was of very limited use to a very small laboratory like mine, mainly because Telarc concentrates so very much on documentation”.*

Despite holding this view, Dr Bottrill was aware of the requirement by ACL, for its members to be applying for and

obtaining Telarc accreditation, and he and his laboratory manager, Mr Reeve, put that process in train.

?? Dr Bottrill brief paragraph 47

This involved meetings with Mr Walker of Telarc in 1993 and 1994.

?? Dr Bottrill brief paragraph 47

Those meetings were handled predominantly by Mr Reeves. Despite these meetings, and correspondence between Mr Walker and Mr Reeves, at no stage was Dr Bottrill advised of Mr Walker's view of Gisborne Laboratory's standards as now expressed to the Inquiry.

?? Transcript B3105 line 18 - 26

Nevertheless Ms Janet Wilson and Mr Reeves began to formulate documentation that provided a basis for manuals for Gisborne Laboratory.

?? Linehan supplementary exhibit no. 12 pages 1-63.

That document was assessed by Dr Linehan, as being part of the effort by Gisborne Laboratory before Medlab Gisborne took over the laboratory, to achieve accreditation with Telarc.

?? Transcript B2837 line 20 - 23

- 4.3 In relation to applying for Telarc accreditation after the purchase of Gisborne Laboratory by Medlab Hamilton, Dr Linehan said it was desirable to have uniformity between Medlab Hamilton and Medlab Gisborne

?? Transcript B2838 lines 4 -6

4.4 Dr Bottrill's own evidence was that he personally commenced some work towards documentation that would be necessary for Telarc accreditation in the areas of cytology and histology, which included documentation of descriptions of methodology used in those areas.

?? Dr Bottrill brief paragraph 48

4.5 It is submitted that in any event it was clear that Gisborne Laboratory took steps designed to initiate and progress achievement of Telarc accreditation, even if there was not a complete understanding of that requirement. In particular, Mr Walker's evidence regarding the state of the laboratory is not supported by any other witness. Dr Linehan's view of Mr Walker's evidence was that Mr Walker must have confused the visits that he undertook at the laboratory when making his brief of evidence. Further it was clear from Mr Walker's evidence that he took no notes in relation to this visit.

?? Transcript B2838 lines 8-10

4.6 The purchases of capital items before and during the Telarc accreditation process prior to the sale of the laboratory demonstrate the maintenance of standards.

?? Transcript B2838-2839

4.7 In common with many of his colleagues, Dr Bottrill's laboratory was not accredited in 1993 or 1994. Dr Beer accepted under cross-examination, that as at the time that the

Association of Community Laboratories required its members to be registered, there were 18 community laboratories in existence, and of those only 9 were registered with Telarc for cytology testing.

?? Transcript B1048-1049

4.8 Dr Beer also advised the Inquiry that many laboratories in 1994 were concerned about the time frame that had been set by ACL for Telarc registration, and that the date for the achievement of Telarc registration was viewed as flexible by the Association of Community Laboratories.

?? Transcript B1049 21-26

4.9 It is submitted that the study conducted by the Health Funding Authority of laboratories' current and previous practices, shows that despite most of those laboratories being Telarc registered during the appropriate time periods, there were still laboratories that had made significant errors either in coding, or in under calling cervical cytology. It was also clear from Mr du Rose's evidence that this had occurred despite Telarc accreditation, and had only been picked up by the HFA study.

?? Transcript B2132 lines 17-24

## 5. Quality Assurance participation

5.1 Dr Bottrill was aware that from the mid 80's the introduction of a quality assurance programme into cytology began being

discussed by the Royal College of Pathologists of Australasia. It is clear also from his evidence that he viewed participation in informal meetings with other pathologists regarding interesting or difficult slides as a form of quality assurance.

?? Dr Bottrill brief paragraph 44

The process began with informal meetings with Dr Williams, Dr Flora Smith and the registrars at National Women's or Auckland Hospital when he commenced employment in Whangarei in 1966. It is clear that these informal meetings with colleagues were a part of his practicing life, and continued in Gisborne when a pathologist was available at the hospital.

?? Dr Bottrill brief paragraph 57.

5.2 By the early 90's Dr Bottrill had received opinions from his colleagues who had taken part in the College programme and were not enthusiastic in relation to it.

?? Dr Bottrill brief paragraph 44.

Those views of the programme (that it was not suited to New Zealand pathology, and that the results took too long to get back), were confirmed by Dr Teague in his evidence

?? Transcript B1482

Dr Teague agreed that there were two deficiencies with the programme. The first identified deficiency was that the Bethesda Code did not match the Australian system that was utilized in the programme and the second was that the results

took so long in coming back that some pathologists were of the view that they had lost their currency and practical value. Dr Teague's evidence also was that he became a representative on the Committee of the College programme in 1994, and that the problems with the programme were resolved by late 1994 or early 1995.

?? Transcript page B1482

5.3 Dr McGoogan also noted in her evidence that the introduction of quality assurance programmes in England had not been universally accepted by colleagues, and noted that in fairness, in the late 1980's and early 1990's many pathologists did not see the need to participate regularly in external quality assurance schemes.

?? Transcript A1128

5.4 Dr Bottrill has noted that cost was not a factor for him in joining the programme, but noted that his belief held at the time was that he would not have obtained the same immediate practical benefit that colleagues working in larger laboratories had in participating in the programmes.

?? Dr Bottrill brief paragraph 44

5.5 It is also apparent from Dr Bottrill's letter to Mr Malpass dated 24 August 1994 (Mules volume 2 exhibit 21) that he saw the liaison between himself and Gisborne Hospital Laboratory pathologists as a form of quality assurance, although on an informal basis. Dr McGoogan, who gave her evidence prior to Dr Bottrill's evidence, identified this aspect as a possible

misunderstanding by Dr Bottrill as to the purpose of external quality control programmes.

?? Transcript A1129

5.6 It is submitted that until early 1995, and following the involvement of Dr Teague in the College Quality Assurance Programme, the programme was not well adapted for New Zealand conditions, and that that aspect affected pathologists' participation in the programme.

6. *Health*

6.1 Dr Bottrill has identified his major health problem as being a coronary artery bypass operation which was performed in 1990. The only after effect that Dr Bottrill was conscious of following that operation, was a deterioration in his short term memory. Because of this short term memory deterioration he, appropriately, it is submitted, developed a system of writing reminder notes for himself, and gave up forensic pathology which he felt required him to have an immediate past memory of an autopsy.

?? Dr Bottrill brief paragraph 59

6.2 In a discussion with the Chair he said that he thought it was possible that his bypass operation had led to a potential deficit in concentration, but there is no evidence before the Inquiry of that. He had a full medical examination prior to his resumption of work in 1990, and was confirmed fit to work.

His view was that in retrospect, prior to 1990 he had had no problem because he had been practicing for 25 years and if local doctors were concerned at the failure of diagnosis of cervical cancer then he expected he would have either indirectly or directly some feed back.

?? Transcript B3081

?? Transcript B3082

7. Quality Control Measures

A.

(i) 10% rapid re-screening

7.1 Over the relevant time period Dr Bottrill randomly re-screened 10% of his cervical cytology. This was a practice that was adopted by many of the laboratories participating in the Health Funding Authorities review of cervical cytology practice in New Zealand community laboratories 1990 – 1999. In the first time period 13 of the 17 laboratories participating in cervical cytology practiced random 10% re-screening. This has declined to approximately 8 in the 1994 – 1995 period. It became less favourable as a quality control measure in 1996 – 1998 period with three laboratories conducting random 10% re-screening, and by January to October 1999 only one laboratory was conducting 10% random re-screening.

?? JD/HFA/001 page 14

7.2 The 10% random re-screening appears to have declined over the years in favour of the 100% rapid review, which was being conducted by 15 of the 17 laboratories by 1999.

7.3 Therefore over the time period that Dr Bottrill practiced, at least half of the laboratories practicing were re-screening on a 10% random re-screening basis. This is the practice that Dr Bottrill adopted, it is submitted, in line with those of his colleagues. Unfortunately, because of Dr Bottrill's position as the primary screener, it meant that the slides were not being re-screened by a different person. Dr Teague however noted that there was some statistics to show that if the same person re-screened a slide, they may get a different answer. This would be a small benefit arising from the 10% rapid re-screen process, if used in Dr Bottrill's laboratory.

?? Transcript B1512

(ii) Records

7.4 Dr Bottrill's evidence was that by 1992 his computer records were such that he could bring up patient reports for that year by name, but he could not access other reports while doing a particular report. That was done by searching the data base.

?? Dr Bottrill brief paragraph 36.

Dr Bottrill did not routinely review every patient's previous smear history, when reading a new smear.

?? Transcript B3129 lines 9 – 15

He did however keep a card index system for abnormal cytology and was able, if faced with an abnormal smear, to access that from the card index system, or the computer.

?? Dr Bottrill brief paragraph 41

?? Brief of evidence Eleanor Jane Vertongen

Mrs Vertongen's case shows that Dr Bottrill referred Mrs Vertongen following two low grade findings; such referral must result from the ability of Dr Bottrill to review previous abnormal cytology.

(iii) Biopsy cytology correlation

7.5 Dr Bottrill's evidence in this regard was that he did not routinely receive histology results unless he performed the histology himself. When he did the histology he kept a record on the abnormal card index of high grade and cancerous lesions.

?? Transcript B3098 lines 5-20

Dr Bottrill confirmed that after the advent of the Privacy Act, which was interpreted extremely rigidly by the Hospital authorities, it was very difficult to get any histology information about their patients.

?? Transcript B3099 lines 6-14

B. External Peer Review

7.6 Dr Bottrill's evidence, as covered in a discussion regarding quality assurance programmes, was that he had throughout the course of his career used informal meetings between pathologists as a form of peer review. During this time period, there were three pathologists working at Gisborne Hospital (Dr Singh, Dr Chan and Dr Padwell) with whom Dr Bottrill interacted on a regular basis (daily in many instances) while they were present at the Hospital. While this interaction lessened with Dr Padwell, Dr Bottrill's evidence was that he maintained professional contact with Dr Padwell during his employment.

?? Dr Bottrill's brief paragraph 57

7.7 These daily visits, and consultations with any resident pathologist at Gisborne Hospital were confirmed by Mr Morris in his evidence.

?? Transcript B2904 - 2905

7.8 While Dr McGoogan did not regard these collegial interactions as any useful quality review process, she did note at page A1131 that it was an admirable practice to discuss a difficult slide with another pathologist who has a special interest in that area. She also noted that such discussions could refine a pathologist's diagnostic abilities.

7.9 In summary, Dr Bottrill may have misconstrued or misunderstood the nature of his reviews and liaison with pathologists at Gisborne Hospital. The fact however that he did so on a regular basis, it is submitted, shows that he was open to assistance and interpretation, and enthusiastic in this regard. The basis for this interaction was historical, and part of his desire for the two laboratories to be united.

8. Summary of evidence in relation to Terms of Reference 2

8.1 The possible contributory factors have been identified as follows:

8.1.1 No cytologist/screener and no other cytopathologist

It is submitted that this, while not the only contributing factor, was one of the two major contributors.

8.1.2 Training

As there is no identifiable difference between Dr Bottrill's training and that of his contemporaries, this is not a significant factor.

8.1.3 Continuing Medical Education

This was participated in by Dr Bottrill; there does not appear to be any significant issue here.

8.1.4 Telarc accreditation

With respect to the evidence of the two Telarc representatives, I do not see this as establishing that

Telarc accreditation would of itself have made a significant difference. It may have highlighted the lack of a screener/second pathologist. It would have involved exterior quality control, which is a major factor, but it is not Telarc's function to provide that control.

#### 8.1.5 Quality Assurance

The lack of an external quality assurance programme is the second major contributor.

#### 8.1.6 Health

Whether Dr Bottrill's bypass in 1990 had effects more extensive than the perceived deterioration in short-term memory is not established. It is not apparent that any investigation carried out now could be of assistance to establish whether or not this was a factor. It can be raised only as a possibility.

#### 8.1.7 Quality Control

##### A. Internal

Dr Bottrill's re-screening was in accordance with standards at the time. His internal record keeping was in order; he could track patients through.

?? Transcript B3128

Regrettably, his computerized records appear to have been discarded.

?? Transcript B2945

## B. External

External quality control was practiced as Dr Bottrill described.

?? Brief of evidence Dr Bottrill paragraph 57

As far as it went, it was no doubt useful. It is of lesser significance than the lack of an external quality assurance programme.

## 9. Conclusion

9.1 It is submitted that Dr Bottrill acted in good faith throughout. He honestly believed in the quality of the service he provided to the people of his district over 30 years. Other than in the area of cytology 1990-1996 that quality is not in issue.

9.2 Many desiderata have been raised in hindsight. None were apparent as anything more than desirable refinements at the time. No compulsion for any different or improved methodology existed. Most importantly on this topic, Dr Bottrill can now be seen to have practiced in a situation where the extent of the perils, if known, were not appreciated, by himself or by most others. Had this not been the case, it is reasonable to assert that he would have been alerted.

3. *“If you determine that there has been an unacceptable level of under-reporting, to satisfy yourselves whether or not this was an isolated case rather than evidence of a systemic issue for the National Cervical Screening Programme.*

3.1 Assuming that TOR 1 has been determined accordingly, the Committee must satisfy itself whether or not this was an isolated case rather than evidence of a systematic issue for the NSCP.

3.2 In the context of submissions on behalf of Dr Bottrill, it is not my task to review the systemic issues with the NCSP administration that occupied most of the time of this Inquiry. I take this question, in this context, to require you to determine whether there were unacceptable levels of under-reporting in regions other than Gisborne where the women have considered their health to be protected by the NCSP.

3.3 In my submission, as at the date of writing, this issue remains open. It is certainly a possibility, but it remains unresolved. In preliminary submissions at the opening in Auckland of the Inquiry on 19 November 1999, I said , inter alia:

*“The Sydney figures are therefore startling in that they find nearly twice as many high grade lesions as any New Zealand community laboratory. It is to be noted that Dr Bottrill’s laboratory was not the lowest reporting laboratory in terms of percentages.”*

3.4 This in fact may have under-stated the proportion. The du Rose study has not alleviated the cause for concern. The review of Northland and Bay of Plenty, using Otago as a

control, will, it is to be hoped, enable the report with reference to TOR 3 to be settled.

**4. *“To identify changes already made to legislation, to laboratory or other processes, or to professional practices to address the risks of under-reporting of abnormalities in cervical smears”.***

4.1 This term of reference principally relates to the changes in the powers of the Medical Council upon the enactment of the Medical Practitioners Act 1995. The Medical Council’s new power to review a doctor’s competence is established by that Act (Sections 60-65). It provides wide powers for the Council to review the competence to practice of any medical practitioner who holds an annual practicing certificate whether or not there is reason to believe the practitioner’s competence may be deficient

?? See also Georgina Jones brief paragraph 105

4.2 Such powers are wide ranging, and if used effectively by the Council, can increase either in individual cases, or in groups, the competence of practitioners involved in any particular specialty. Section 62 provides that from time to time the Council can set or recognize competence programmes in respect of specific classes of medical practitioners. It is not merely a mechanism for reviewing an individual practitioners practice.

4.3 The areas relating to the ability of the Medical Council to deal with the health of practitioners have also been enlarged. The part of the Act in relation to health (Sections 76-82) give the Council wide powers to order medical examinations in relation to matters where there is a suspicion that fitness to practice either in a physical or mental capacity may be effected.

?? Brief Georgina Jones paragraph 81

4.4 It is submitted that these powers, particularly in relation to the ensuring of competence, are capable of having a significant impact upon the levels of competence achievable by the medical profession.

5. *“To identify other changes agreed to be implemented , either by the Government or by professional organizations, that will further address any risks of under-reporting of abnormalities in cervical smears”.*

5.1 No submissions are here offered.

6. *“To consider all relevant proposals that could ameliorate any risks of under-reporting or abnormalities in cervical smears and identify whether these are covered by 4. or 5. above and whether further changes are needed.”*

6.1 From the point of view of Dr Bottrill, the approach to this issue starts with the position in which he finds himself:

- He was trained and qualified in accordance with the standards of his time both in pathology in general and cytology in particular.
- He provided to Gisborne a cytology (and general pathology) service of which there was no contemporary criticism and which has not now been shown to be deficient.
- From 1990/91 the evidence suggests that his powers of detection of high grade lesions , or of reporting them, were not adequate. He had no clue to alert him of this until, at the earliest, 1995 and no knowledge of the state of affairs now alleged until 1999.

6.2 It follows that the imposition of compulsory external quality review is the major factor likely to prevent recurrence. The recognition of the risks of a one-person operation leads in turn to the guidelines for minimum and maximum numbers to be read by screeners and pathologists.

**7. *“To comment on any other issue the Inquiry Team believes to be of particular relevance”***

7.1 Screening is designed to identify those cases where active management is indicated. For a screener to produce a report

which improves the condition or lessens the potential danger to patients two condition external to the work of the person reporting must be met.

7.2 Firstly, the patient must be screened in good time, and sufficiently regularly. The disfavour with which the programme has been regarded in some quarters may result from genuine concerns relating to its efficacy compared with other demands on funds. The question of where the NCSP should stand in priority or otherwise to other healthcare concerns could not be fully examined within the Terms of Reference.

7.3 Secondly, reports requiring action in respect of individual patients need to be acted upon, and the patients need to understand their condition. It would be tedious to list all the examples of patients saying that they did not know, or were not told, but two examples may illustrate:

Mrs Vertongen: Dr Bottrill recommended referral; she did not know and it did not happen.

?? Transcript B3044

Mrs Tombleson: Believed, apparently incorrectly, she had cancer.

?? Transcript A36

7.4 The issue, simply put, is that the NCSP cannot be reviewed in isolation. The Inquiry may be of assistance in restoring it to its proper place in the scheme of healthcare in New Zealand. The Inquiry will further promote the cause of education relative to women's health.

8. ***“To make recommendations, consistent with section 4 (a) of the Health and Disability Services Act 1993, as to any future action the Government or its agencies should consider taking.”***

8.1 I have received on behalf of Dr Bottrill the claims for ACC cover made by women who believe they have suffered medical misadventure for which they request cover.

8.2 S4(a) Health and Disability Services Act 1993 refers to the best care and support for those in need of health and disability services.

8.3 Many women whose smears have been under-reported may undergo procedures which would otherwise not have been necessary. Some may die. ACC is appropriate to provide support for those entitled to cover who suffer financially. Without financial loss, the independence allowance provided under Part 4 Schedule 1 Accident Insurance Act 1998 may be seen as inadequate.

- 8.4 Given the present political commitment to the restoration of lump sums, the topic may not be of major importance to the Inquiry. But if injured patients cannot sue, they must be adequately compensated. The Inquiry touched from time to time on the benefits of common-law accountability. The difficulties here are manifold and the subject of extensive literature.
- 8.5 One benefit of the no-fault system is that a publicly accountable body becomes aware of medical misadventure, and has power to act on it. The Gisborne problems would therefore have come to light as illnesses repeatedly occurred following normal smears. Patient One was the first, and one case clearly did not raise alarms. But several claims could be expected to be another matter.
- 8.6 The UK inquiries (Inverclyde, Kent and Canterbury) occurred in a common-law setting, but were not initiated consequent on litigation. It is submitted that there is no evidence before the Inquiry that a common-law system in New Zealand would have caused the problems to have come to light earlier than was the case.
- 8.7 The Inquiry may on this basis, reaffirm the suitability of the ACC system for New Zealand conditions, subject to its provision of adequate compensation for those who do not necessarily suffer financially, or whose quality of life is affected by the cause of their entitlement to cover and corresponding inability to sue.

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Counsel for Dr Bottrill  
5 September 2000