

# **Brief of Evidence for the Ministerial Inquiry into the Under-reporting of Cervical Smear**

## **Abnormalities in the Gisborne Region**

**Dr Annabelle Farnsworth**

### **INTRODUCTION**

1. I am the Director of Cytopathology at Douglass Hanly Moir Pathology Pty Ltd. I have been practising as a Cytopathologist for just over 15 years and have both my Fellowship of the International Academy of Cytology and also the Diploma of Cytopathology from the Royal College of Pathologists of Australasia. I am the Chair of the Quality Assurance Working Group convened by the National Advisory Committee for the Federal Cervical Screening Program. I am appointed as the Pathology Advisor to the National Cervical Screening Program and also to the New South Wales State Women's Cancer Screening Advisory Committee.
2. A detailed Curriculum Vitae has been provided to the Inquiry as Exhibit TM/HFA/0028. My report on the re-reading has already been provided to the Inquiry as an attachment to the HFA's Interim Report of 6<sup>th</sup> March, 2000 and this evidence expands on my previous report (TM/HFA/0085).
3. Douglass Hanly Moir Pathology is a large privately owned pathology laboratory situated in North Ryde, Sydney. The Cytology Department of Douglass Hanly Moir examines approximately 150,000 Pap smears annually and has a cytology screening staff of approximately 40 qualified Cytologists and 6 cytopathologists. The laboratory also processes approximately 20,000 non-gynaecological specimens annually. The laboratory is a wholly owned subsidiary of Sonic Healthcare Ltd, a publicly listed company which currently owns pathology practices both on the east coast of Australia and in New Zealand. Details of Sonic Healthcare have also been provided in Exhibit TM/HFA/0028.

## **ENGAGEMENT OF DHM**

4. In mid-May of 1999 I received a phone call from Dr Norman Fitzgerald inquiring as to whether this laboratory would be interested in re-reading a large number of Pap smears. Although there had been some vague discussion in pathology circles about a particular court case in New Zealand involving alleged misreading of Pap smears, I was unaware of any other details related to the request for re-reading of Pap smears. Dr Fitzgerald informed me at the time that he had spoken with Dr Gabriele Medley from the Victorian Cytology Service who had declined the invitation to participate in the re-reading but suggested he call me. I did express at that time an interest in undertaking the re-reading but initially thought that we could use some of the automated screening devices that we have in the laboratory to speed up to the process. The logistics of re-reading large numbers of Pap smears from another country were quite daunting given that this laboratory was already very busy and there was not an excess number of staff available.
5. I was then contacted by Mr Jim DuRose from the Health Funding Authority (HFA) who further raised the question of re-reading a large number of Pap smears under contract to the HFA. It was made quite clear at that time that the re-reading would need to be done manually and not involve any automated screening devices.
6. After I discussed the matter with my Chief Executive Officer, Dr Colin Goldschmidt, a decision was made to undertake the re-screening exercise but to distribute it through the five Sonic laboratories. At that time Sonic Healthcare had no commercial interests in New Zealand but owned a large laboratory situated in the west of Sydney, Barratt & Smith, a laboratory in Adelaide, Clinpath, a laboratory in Canberra, Capital Pathology, and a laboratory in the southern part of New South Wales, Southern Pathology. It was felt that with these five different

laboratories and over sixty Cytologists all together, the re-screening exercise could be manageable.

7. Before any further discussions could happen, Mr Jim DuRose from the HFA came to visit and meet with us at Douglass Hanly Moir on 4<sup>th</sup> June, 1999. At this time he outlined the brief of what would be required for this re-reading exercise and we outlined to him our proposal to use the five Sonic Healthcare Laboratories.
8. The logistics of transporting slides to and from Gisborne were discussed as was the need to transfer the results electronically to enable linkage with the New Zealand National Cervical Screening Register (NCSR). The meeting was quite fruitful. A formal tender document was required. I understand that other laboratories were invited to participate in the re-reading but declined. The DHM tender document and contract with the HFA have already been produced to the Inquiry as Exhibit TM/HFA/0028.

#### **AUSTRALIAN QUALITY ASSURANCE AND ACCREDITATION REQUIREMENTS**

9. All five Sonic laboratories engaged in the re-reading exercise complied with all applicable Australian QA and Accreditation requirements. I will first provide a glossary of the appropriate bodies involved with QA and Accreditation in Australia.

##### **NATA**

##### **National Association of Testing Authorities**

- A private organisation which does all different types of testing, not just medical.

##### **NPAAC**

##### **National Pathology Accreditation Advisory Council**

- A peak Commonwealth Government advisory body which draws membership from the pathology industry and Government.
- Develops the standards in conjunction with all stakeholders to which laboratories are inspected.

**HIC****Health Insurance Commission**

- The government department within the Department of Health & Aged Care Services which funds Medicare. It funds Pap smears as well as GPs, specialist consultations.

**RCPA**

- Royal College of Pathologists of Australasia.

**MEDICARE**

- The universal government funded health insurance system. Patients can claim for the cost of Pap smears or clinical services where a bill has been issued. The doctor or pathology laboratory can claim in bulk directly from the government, if the patient assigns the benefit; no bill is issued to the patient under these circumstances.

**THE NATIONAL  
CERVICAL**

- A federally funded initiative which co-ordinates the national program for the prevention of cervical cancer. It is administered within the population

**SCREENING  
PROGRAM**

- health (public health) division of the Department of Health & Age Care. It advises and directs the program as a public health initiative, eg it funds national recruitment programs, audits, cost-effectiveness and general outcomes of the program. It has in the past been involved and is still involved in developing quality standards in conjunction with NPAAC.

- Each of the five Sonic laboratories are accredited by the HIC. To claim medicare benefits, a laboratory has to be accredited. The main criteria for accreditation is that they have to be enrolled in an approved external quality assurance program. The HIC has to have proof of enrollment (usually a certificate issued by the Quality Assurance Program) submitted annually. The name of the Supervising Pathologist and staff qualifications need to be supplied. The laboratory must also be registered with NATA. This accreditation became compulsory in the late 1980's.
- The only external quality assurance program available in Australia for cervical cytology is that run by the Quality Assurance Program of the RCPA.

- Each of the laboratories is registered for gynaecological cytology by the National Association of Testing Authorities / Royal College of Pathologists of Australasia (NATA / RCPA). Specific guidelines for cervical cytology were first introduced in 1993. These were revised and became requirements in 1997. The NPAAC requirements for laboratories performing cervical cytology are presented as attachment AF/HFA/0001.
- Laboratories are inspected to guidelines and requirements developed by the National Pathology Accreditation and Advisory Council (NPAAC). These guidelines cover all aspects of laboratory function and include staffing, reporting, health and safety, and quality assurance measures.
- The NATA/RCPA inspection and registration process occurs every three years. It was first introduced in 1987. If a laboratory is inspected and found not to comply with the requirements, a quality improvement process is initiated. If the laboratory after some time fails to comply, NATA may notify the HIC and Medicare payments can be withheld.

### **RE-READING LOGISTICS AND METHODOLOGY**

10. The logistics of shipping over 20,000 slides to and from Gisborne, New Zealand to North Ryde in Sydney was a daunting task. The actual procedures have been outlined in Tracy Mellor's evidence but points of note were:

- That all the slides needed to be shipped from Gisborne to Douglass Hanly Moir in North Ryde.
- Each slide was unpacked with the corresponding request form. The slides were not labelled with the patient's name but rather the original Gisborne laboratory identifying number was etched with a diamond pencil. This was checked against the request form. If

there were any discrepancies which were rare, contact was made with the organisers, Marie Burgess, for clarification. A Douglass Hanly Moir identification number was then issued. A barcoded label with the identifying number was attached to the slide which was then used throughout the re-read. I am entirely confident that each slide has been correctly logged in and the result has been issued for the correct women.

- We then distributed them amongst our other four laboratories. They then read and reported the slides and returned them to Douglass Hanly Moir. We then returned them to Gisborne.
- We had had a lot of experience with shipping slides previously between Australia and Hong Kong and we used the same specially designed boxes that had been used previously.
- The HFA required the re-reading to be done quickly. They gave us a deadline of Christmas 1999 to finish the re-reading exercise. One thousand two hundred (1,200) Pap smears per week were shipped from Gisborne and read per week by the combined Sonic group laboratories. The work was divided unevenly amongst laboratories but as Douglass Hanly Moir is by way the largest laboratory with the greatest resources but in all, Douglass Hanly Moir ended up reading approximately just over 50% of the Pap Smears, the others being distributed amongst the other laboratories.

11. It was a requirement of the HFA that the reading of the Pap smears be done manually and using normal quality assurance measures. Initially there was some discussion as to whether we should be doing rapid re-screening which is currently done in New Zealand. This is not a quality assurance measure that has been introduced at Sonic. I do not believe that it has any great scientific validity. The HFA was happy that we use our normal quality assurance measures within the laboratories.

12. The method used to examine each of the NZ slides was as follows:

- A Cytologist screened the slide. This means that they examined every cell on the slide by moving the slide through their microscopic field of vision in a logical grid like pattern. If an abnormality is detected these cells are marked. The slide is then re-examined by another Cytologist. If the smear is still considered abnormal, it is then seen by a Cytopathologist. The final report is then issued.
- If no abnormal cells are identified the cytologist issues the report.
- At Douglass Hanly Moir Pathology we use targeted re-screening. This means that if there is an abnormal history eg. bleeding, discharge or there is a previous known abnormality then the slide is completely re-screened by a second Cytologist. This occurs even if the first Cytologist has not found an abnormality.
- The other quality measures that are used are those required by NPAAC. They include complying with the performance standards, checking each screener's performance, and reviewing all negative smears from a subsequently detected abnormality. They are as outlined in the NPAAC document (Exhibit AF/HFA/0001).

13. It is important to note that both the reading and reporting was done without any prior knowledge of the results that had been previously issued. Only the original request form was sent with each of the Pap smears. The details from this request form were entered electronically into our system as per normal and any clinical history on the original request form was recorded in the patient's file, which is our normal procedure.

14. The reporting terminology that we used is the Australian modified Bethesda system. This is different to the New Zealand reporting system, which is the Bethesda system. Because we

wanted to approximate as close to normal reading, it was not feasible to teach the cytologists a slightly different reporting system. They therefore reported as they would normally do and there was an electronic matching system developed by Douglass Hanly Moir (under contract from the HFA) whereby the results were electronically translated from the Australian modified Bethesda system to the New Zealand Bethesda reporting system. This was checked multiple times and the results are correct. Our own internal checks of reporting correlate with that reported by the HFA in their interim report TM/HFA/0085. The reported rates of abnormalities in our analysis are per slide, not per case or per patient. It is important to note that all slides were reported separately, even if two slides per the same patient were in the same box.

Within our normal laboratory system, analysis are issued every six months which give a breakdown of a referring practitioner as results accompanied by a breakdown of the laboratories overall Pap Smear results. This same program was able to be utilised to look at the results of the re-read slides. This gave us a breakdown of the results for each diagnostic category.

15. Our reporting system is such that once a patient has been logged into the system, all their results are kept together and therefore during the re-screening process, women who had repeat smears over the period of time had their results collated as we went through the re-screening exercise. We were aware that a number of women had a number of Pap smears during that time.
16. Each week a floppy disc of results was returned to the New Zealand National Cervical Screening Register as per the HFA contract. We also re-packaged and returned all material including the original request forms and all slides to Gisborne. Hard copies of results in our terminology were also issued and sent. They could be used for double-checking purposes. We currently have our own record of all the reports. These are kept under security and are

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

### **OUR APPROACH TO THE RE-READING**

17. My understanding after much discussion with both Jim DuRose and Norman Fitzgerald was that the principal purpose of the re-reading exercise was for the women of the Gisborne Region who had had Pap smears.

18. At the beginning of the exercise we held a days briefing for other laboratories involved in the process. At this time, we had an educational session on the type of appearances that we anticipated seeing. The type of appearances that we anticipated were the normal appearances that are reported everyday in our laboratories. We were also aware of the problems with false negatives and the more difficult appearances that have been discussed in Professor Euphemia McGoogan's Brief of Evidence. These were also appearances we anticipated seeing. As described by Professor McGoogan, these appearances can be difficult. I was in fact concerned that we might have overlook some abnormalities. We notified our medical indemnity insurers before commencing the project to cover us accordingly.

19. We also trained the cytologists from the other laboratories on our computer system, which was electronically available to them at the distant sites. They reported the Pap smears into our system as has previously been described. All the results from all the laboratories were collated electronically as if having been read in one laboratory, and returned to New Zealand as has been previously described.

### **SLIDE QUALITY AND RESULTS OBTAINED**

20. Jim DuRose had arranged for the first 100 slides to be sent as a trial box of slides to test out the logistics of the process. We were anxious to find out in the condition of the slides. We did not

know whether they would need re-staining, re-cover-slipping and how they would be presented. We did not know how the request forms would appear. We were surprised by the good quality of the stain and there were no slides that needed re-staining.

21. A large number of them needed re-cover-slipping however. In at least 50% of them the cover-slip covered approximately 75% of the material and we undertook this re-cover-slipping process quite extensively. We use a 50 x 24mm cover-slip whereas the cover-slips used were either 38 or 40mm x 22mm in length. We did not measure them. The material to be examined is visible with the naked eye. If there was a significant amount of material not covered by the original cover-slip we covered it. There were occasional slides, of the order of 5-10 (the actual number was not recorded) in total that were cover-slipped on the wrong slide. These needed to be re-cover-slipped to be examined.
  
22. In the first box of slides we found a high number of high-grade smears. Initially I thought it was possibly a test to see whether we were competent at cytology and I rang Jim DuRose to let him know that we had found some high-grade lesions. We continued to find abnormalities at a rate which was quite unusual. The cytological appearances were also remarkable in the first box. The cytological appearances were those that we would normally see in classic cytology textbooks written in the 1950's and 1960's. The abnormal Pap smears showed readily identifiable highly atypical cells, many with features of keratinisation which are rarely seen today in our practice. The obviousness of the abnormal material on the abnormal slides and the actual appearances of the cells astounded us. These appearances continued throughout the whole re-reading exercise. We had not anticipated any of this.

### **SENSITIVITY / SPECIFICITY**

23. It is important also to acknowledge that cytology is a prediction, not a diagnosis and that it needs to be confirmed by colposcopy and subsequently histology. In our laboratory we have

approximately 75% confirmation of our normal high-grade lesions as being high-grade with a further 15-20% being confirmed as a CIN lesion. I do not know the confirmation rate of our calls of the New Zealand slides. It should also be kept in mind that upwards of 40% of all high-grade lesions regress.

24. All of the cytologists reading the slides and all of the pathologists were aware that these were slides from the Gisborne re-reading project. When the project was being set up we were aware of the potential criticism as to possible bias, given that we knew these slides were from Gisborne. The smears were however assessed by the normal screening protocols, and using normal cytological criteria, which are used in our laboratory. No different procedures were introduced.
25. We have our own computer program for analysing the results and were aware of the high rates of high-grades, inconclusives and low-grades that were being reported. We did not know how this correlated with the original reading of the smears. It was only when the first correlation was released by the HFA to the general public in September 1999 that we were aware of the poor correlation. At no time did we change our procedures but rather kept processing the slides by the original protocol and reading them as per our normal cytological criteria. At many times during the process I was conscious of the large numbers of high-grades we were reporting and was concerned to investigate the reasons for this.
26. All the slides were read in the normal way that Cytology is practiced. No special procedures were undertaken. The procedures that were used have been in place as long as I have been a cytopathologist (since 1985). They were readily available, anywhere in the world in the period 1991 - 1996. The cytological criteria used to report the slides are those described in classic textbooks dating from the 1950's. The abnormalities that were detected were not difficult to find. They were not found as a result of extensive searching but rather were very apparent.

There are no new cytological criteria that were used that would not have been available in New Zealand in 1991 - 1996.

27. The Australia Modified Bethesda system used by us is clearly described. There are specific appearances which are classified into different categories. The only category that may need some further explanation is the *"inconclusive high-grade to be excluded"* category. There were a large number of smears classified into this category in the re-read. This category is the same as the New Zealand *"ASCUS high grade to be excluded and colposcopy recommend"* category. This is a category used where appearances are difficult to interpret. In cervical cytology there are limits to what one can reliably predict under the microscope. As this is a screening test, the "inconclusive high grade to be excluded" category is used when a high grade lesion is suspected but insufficient criteria are present and where a colposcopy is the next appropriate test.
  
28. Included in this *"ASCUS high grade to be excluded"* category are smears with appearances which are difficult to classify. Within this category there would be a number of smears with the difficult "false negatives appearances" as has been previously described. As the recommended management with these reports is colposcopy, they were included in the initial high grade results reported to the New Zealand public. This is not usual and does not compare with the original high grade rate reported in Gisborne. Rather the comparison should be drawn between the re-read high grade rate and the Gisborne high grade rate.
  
29. At the end of the re-read I decided to photograph some of the material we were seeing. I telephoned Jim Du Rose and asked his permission to photograph some of the slides. The material was collected over one or two days and is a random sample of the type of appearances which were reported as high grade. The photographs are produced as Exhibit AF/HFA/0002. Tracey Mellor has subsequently provided me with the original results. These were not known

at the time of the re-read or the photography. I have also included photographs of Papanicolaou's original pictures of normal and abnormal cytology from 1943. I have also included a false negative case for comparison.

## LEGEND FOR PHOTOGRAPHS

- (a) Normal Squamous Cells Papanicolaou 1943
  
- (b) Abnormal Squamous & Gladular Cells Papanicolaou 1943
  
- (c) False Negative Cytology Example  
Archived Case From Douglass Hanly Moir Pathology  
**(NOT FROM THE RE-READ)**
  
- (d) 89022667 (C229-96)  
Re-read High Grade  
Original Negative
  
- (e) 89022769 (C332-96)  
Re-read High Grade  
Original High Grade
  
- (f) 89022791 (C355-96)  
Re-read High Grade  
Original Negative
  
- (g) 89022865 (422-96)  
Re-read High Grade  
Original ASCUS
  
- (h) 89022898 (C455-96)  
Re-read High Grade  
Original Negative