UNDER	**THE HEALTH AND DISABILITY SERVICES ACT 1993**
IN THE MATTER	**OF THE MINISTERIAL INQUIRY INTO THE UNDER-REPORTING OF CERVICAL SMEAR ABNORMALITIES**

STATEMENT TO THE GISBORNE CERVICAL SCREENING INQUIRY

THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA

(i)

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1. INTRODUCTION

.1 The Royal College of Pathologists of Australasia “RCPA” would like to provide the following submission to the Gisborne Cervical Cancer Inquiry.

1.2 The College is supportive of the initiative and provides this submission in order to provide information to the inquiry on the role of the College in relation to the practice of pathology, particularly cytopathology, in general and specifically in the New Zealand system. In order to provide this information this submission will outline, the structure and role of the College in general, the College’s involvement in the Gisborne issue to date and some specific issues the College considers to be significant in relation to the problem for which the inquiry was called.

2. OVERVIEW OF THE COLLEGE

2.1 The College of Pathologists of Australia was incorporated under the *Companies Act, 1936* on 10 April 1956. In 1970 it received Royal assent to change its name to The Royal College of Pathologists of Australia. In January 1980 the College became the Royal College of Pathologists of Australasia in recognition of the increasing number of Fellows in New Zealand.

2.2 The New Zealand Society of Pathologists (NZSP) was founded in 1948 and came to have strong links with the Royal College of Pathologists of Australia after that was established. Gradually over the years the functions of the two organisations merged and in 1995 by mutual agreement between the two organisations the Society ceased to exist as a separate organisation and most of its functions were taken over by the College.

2.3 The College operates in accordance with its Memorandum and Articles of Association.

2.4 The principal object for which the College was established is:

To promote the study of the science and practice of Pathology in relation to medicine; to encourage research in pathology and ancillary sciences, to bring together pathologists for their common benefit and for scientific discussions and demonstrations; and to disseminate knowledge of the principles and practice of pathology in relation to medicine by such means as may be thought fit.

2.5 The College is a not-for-profit organisation with its Council as its Board of Directors.

2.6 Attachment 1 details the structure of the College including the Committees which oversee the various functions and roles of the College.

3. THE ROLE OF THE COLLEGE

3.1 The College fulfils a range of roles for its Fellows and Trainees, which could be broadly defined in the following areas:

- Training and Examinations (see paragraph 5),
- Continuing Professional Development (see paragraph 6),
- Professional Practice Standards (see paragraph 7),
- Government Relations (see paragraph 8).

4. THE ROLE OF OVERSEAS COLLEGES IN CERTIFICATION OF SPECIALISTS

The College has caused inquiries to be made to ascertain overseas practice in the qualification and on-going certification of pathologists.

4.1 United Kingdom

4.1.1 The College is responsible for certifying medical practitioners as Fellows after completion of specialist training and examination.

4.1.2 The General Medical Council (GMC) is responsible for issuing doctors with a licence to practice, i.e. “Certification”.

4.1.3 The GMC is presently devising a programme that requires all doctors including pathologists to be reassessed every five years with the onus being on the doctor to show he/she is practising in accordance with defined guidelines.

4.1.4 The intention of the GMC is to have this process introduced by 2002.

4.1.5 The College provides voluntary education programmes and conferences.

4.2 United States of America

4.2.1 The College is not responsible for certifying medical practitioners as members.

4.2.2 Examination for entry is by the American Board of Pathologists.

4.2.3 Certification is the responsibility of the American Board of Pathologists.

4.2.4 There is voluntary recertification available.

4.2.5 Continuing medical education is provided by agencies including the College of American Pathologists. Attendance is voluntary.

4.3 Canada

4.3.1 There is variation between Provinces. However, in 1992 the Federation of Medical Licensing Authorities Canada recognised the need for an integrated approach to monitoring doctors on a regular basis. The model was developed in 1996.

4.3.2 The Royal College of Physicians and Surgeons is responsible for setting entry levels for membership of pathologists.

4.3.3 The RCPSC commenced a maintenance of competence programme in 1995 which initially had a 50% participation rate.

4.3.4 The College now offers a 400 hour programme. Participation is voluntary but non satisfactory compliance will result in loss of Fellowship.

4.4 **Australia**

4.4.1 The practices vary between States.

4.4.2 Two states have separate specialist registers.

4.4.3 The Royal College of Pathologists of Australasia is responsible for setting the entry level for medical practitioners to become Fellows.

4.4.4 The College offers voluntary continuing medical education. Certificates are issued periodically to members as evidence of participation.

5. TRAINING AND EXAMINATIONS

5.1 In accordance with Article 5 of the Memorandum and Articles of Association of the College, Fellowship of the RCPA requires a recognised medical degree, an application to the Board of Censors to determine training and examination requirements, four or five years of supervised accredited training, success in examinations carried out by the Board and acceptance by Council that the individual is suitable to be a Fellow.

5.2 The Articles have provision for Fellowship for pathologists who have trained or worked in pathology for five years or have been engaged in a form of medical practice related to pathology for periods aggregating up to eight years, rather than undergoing prospective training. The College now requires all applicants for Fellowship to undergo a formal examination before being offered Fellowship. The Board of Censors determines, based on previous training and examinations, which RCPA examinations the candidate must undertake.

5.3 The College allows training and examination in the following sub-disciplines of Pathology:

- Anatomical Pathology (slanted examinations in Forensic Pathology, Cytopathology, Paediatric Pathology and Neuropathology are available)
- Chemical Pathology
- General Pathology
- Genetics
- Haematology
- Immunology
- Microbiology

5.5 In addition the College offers diplomas in Cytopathology, Forensic Pathology and Forensic Medicine.

6. CONTINUING PROFESSIONAL DEVELOPMENT

6.1 The College has since formation played a major role in assisting Fellows to continually develop their knowledge and skills in relation to the professional practice of pathology.

6.2 The College's role as it is defined in its Memorandum and Articles of Association is to assist Fellows to participate in continuing education (and the related issues of medical currency and competency) with the primary responsibility for doing so resting with the individual pathologist.

6.3 At present, verification (credentialing) of pathologists after initial registration by the Medical Council is primarily a matter for employers. Revalidation of pathologists is presently being developed by the Medical Council.

6.4 This development arises from the new Medical Practitioners Act 1995, which this College anticipates will be detailed in full in the submission of the Medical Council.

6.5 Bearing these points in mind, for many years the College has provided support to Fellows to maintain currency by providing education sessions, an annual scientific meeting, a College journal and a network of colleagues to exchange ideas and developments.

6.6 The need for all specialist medical practitioners to keep up-to-date with developments in their specialty and to maintain their skills is greater today than ever with the growth in technical and scientific progress.

6.7 While the majority of members have used College activities to enhance their skills and education, the practice now adopted is for this activity to be formally documented and quantified.

6.8 To respond to this need and to assist Fellows with this requirement the College established a Continuing Professional Development Programme (CPDP) in 1996. The CPDP was officially launched in September 1996 and made available to Fellows in January 1997. The Programme is based on self-directed learning through the documentation of educational activities in a learning Diary.

6.9 The CPDP is a development of continuing medical education in Australia and New

Zealand. The Programme has taken as its starting point, the continuing education model MOCOMP, developed by the Royal College of Physicians and Surgeons of Canada.

6.10 At the heart of the CPDP is the principle that new learning is most relevant for the professional if the acquisition of new knowledge, skills or attitudes enhances his or her ability to solve problems in the workplace. The stimulus for this learning lies in the challenges of everyday practice. This approach recognises and emphasises the individual nature of the learning interests and needs of the practising professional.

6.11 The Programme is voluntary with over 820 College Fellows, Affiliates and Trainees registered. This represents one third of the College's Fellowship. The RCPA is presently undertaking an active campaign to encourage all College members to participate.

6.12 The College has 218 Fellows in New Zealand and 112 participants in the CPDP programme, a participation rate of 51%.

6.13 Many Fellows indicate that while they may not formally participate in this programme they are actively involved in continuing education.

6.14 The College, like most medical Colleges in the world, is currently considering and supporting the issue of revalidation of its Fellows. Revalidation will involve not only continuing education but also assessment of competence of Fellows. This initiative is being progressed in New Zealand at a faster rate than in Australia at present, with the Medical Council of New Zealand moving towards compulsory revalidation by July 2001.

7. PROFESSIONAL PRACTICE STANDARDS

7.1 General Issues

7.1.1 The College has been actively involved in assisting with the setting of standards for laboratory practice and providing Fellows with a means to test the quality of their practice.

7.1.2 Within Australia, the College was an active participant in working with government to establish the National Pathology Accreditation Advisory Council (NPAAC) in 1979. This Committee is still in operation and the College has three nominees on the Committee.

7.1.3 NPAAC advises the Commonwealth, State and Territory Health Ministers on matters relating to the accreditation of pathology laboratories. NPAAC plays a key role in ensuring the quality of Australian pathology services, and is responsible for the development and maintenance of standards and guidelines for pathology practices. NPAAC is made up of representatives from all States and Territories, nominees from peak professional bodies and the Department of Health and Aged Care.

7.1.4 While NPAAC provides the standards for laboratory practice the actual accreditation process is carried out by NATA/RCPA a joint initiative between the College and the National Association of Testing Authorities.

7.1.5 In Australia to obtain a Medicare Benefit for pathology the laboratory must be accredited under the NATA/RCPA scheme. In accordance with the NPAAC Standards mentioned above, 'Laboratories must be enrolled, participate and remain in an external quality assurance programme (QAP) complying with NPAAC criteria'. The RCPA QAP Pty Ltd programmes comply with this criteria.

7.1.6 The College has been active in developing external Quality Programmes in Pathology. As far back as 1970 the College undertook Laboratory Proficiency Surveys. These gradually evolved into Quality Assurance Programmes in the major disciplines of Pathology. In 1988 the College handed the management of these external Quality Programmes to RCPA Quality Assurance Programme Pty Ltd. There has been a formal Quality

Assurance Programme in Cytopathology since 1989 with preliminary surveys introduced in 1987. New programmes are developed in association with the College's Quality Assurance Scientific and Education Committee.

7.1.7 The College is aware that the RCPA QAP Pty Ltd has been asked to provide data directly to the Inquiry on the general performance of laboratories from Australia and New Zealand in Quality Assurance Programmes. The RCPA QAP Pty Ltd also has Performance Standard data available from Australian laboratories.

7.1.8 Many laboratories in New Zealand participate in the RCPA Quality Assurance Programme Pty Ltd, Quality Assurance Programmes. Many also participate in the College based Surgical Pathology New Zealand (SPANZ) slide circulation programme for anatomical pathologists.

7.1.9 The NPAAC Requirements for Gynaecological Cytology also detail requirements for internal quality control programmes. These state that laboratories be able to demonstrate:

7.1.9.1 A system of follow-up for correlating the results of gynaecological cytology with relevant histopathology;

7.1.9.2 A system for evaluating screening performance;

7.1.9.3 A review of past negative cytology smears from patients with current abnormal cytology/histology.

7.1.10 In addition to the formalised external quality assurance programmes, and such internal quality control programmes as above some practices do undertake further activities to monitor and improve quality. The format of these measures will vary depending on the nature of the practice. Examples of other quality activities that practices may undertake include:

7.1.10.1 A formal review session with multiple practitioners involved at a combined meeting;

7.1.10.2 The circulation of case material or a selection of cases to be re-read by other practitioners;

7.1.10.3 The double sign out of malignancy reports;

7.1.10.4 Review of cases by international experts.

7.2 **College involvement with Accreditation within New Zealand**

7.2.1 Accreditation is also now compulsory in New Zealand if a laboratory is funded by the Health Funding Authority on a fee for service basis, a requirement that only came into effect in the mid nineties with the changes to New Zealand health funding.

7.2.2 Part of the IANZ (International Accreditation New Zealand) requirements is for laboratories to participate in external quality assurance programmes such as the RCPA QAP Pty Ltd or equivalent.

7.2.3 Unlike Australia, IANZ sets the standards for accreditation as well as undertaking the inspections. IANZ has a Medical Testing Professional Advisory Committee which provides advice on professional issues in relation to standards and accreditation. The College has one representative on this Committee.

7.3 **Specific Requirements for Cytology Accreditation**

7.3.1 In Australia during 1997, the National Pathology Accreditation Advisory Council (NPAAC) published a document on 'Requirements for Gynaecological (Cervical) Cytology'.

7.3.2 This document details the minimum acceptable standard for laboratories in Australia, which perform gynaecological cytology and is the guideline NATA/RCPA use when accrediting laboratories. Of note, it specifies that laboratories must participate in internal and external quality assurance programmes and provide a framework of what is appropriate.

7.3.3 In New Zealand, for laboratories to be able to participate in the National Cervical Screening Programme in accordance with section 4.2 of the National Cervical Screening Programme Policy Statement 1996, they must

be accredited with TELARC, which is now IANZ or International Accreditation New Zealand. IANZ is in the process of developing specific guidelines for cytology at present.

7.4 **Qualifications to Undertake Gynaecological Cytology**

7.4.1 The (Australian) National Pathology Accreditation Advisory Council's (NPAAC's) document 'Requirements for Gynaecological (Cervical) Cytology' is a relevant reference on this issue.

7.4.2 This states that for a Pathologist to practice in the area of gynaecological cytology he or she needs to be a Fellow of the Royal College of Pathologists of Australasia or shall hold an equivalent qualification. In addition, the pathologist shall be skilled in interpreting the cytology and histology of gynaecological specimens and demonstrate appropriate training and experience. The document states that appropriate training is *"appropriate training in general or anatomical pathology preferably with a further qualification such as the Fellowship of the International Academy of Cytology or the Diploma in Cytopathology from RCPA".*

7.4.3 Persons currently being examined for Fellowship of the College in Anatomical or General Pathology undergo a substantial testing of their competence in Cytopathology, including Gynaecological Cytopathology. The College considers that this is a sufficient qualification to practice in the sub-specialty. The College since 1973, has offered examination for Fellowship in Anatomical Pathology slanted towards Cytopathology. This examination is considered appropriate for those Fellows with a particular interest in Cytopathology or who are contemplating a career specifically in Cytopathology. Qualification in this sub-specialty however, is not a requirement for most contemporary day-to-day practice of pathology.

7.4.5 In addition, the College developed the Diploma in Cytopathology in 1996 to provide a qualification for persons who have been Fellows for some time and whose professional practice had developed to include a major interest in Cytopathology.

7.5 **Conduct of Pathology Practice Code of Ethics By-law**

7.5.1 The Council of the College has approved the following principles governing the conduct of Pathology practice:

7.5.1.1 The fundamental objective of the practice of Pathology is to promote the welfare of patients in terms of maintenance and restoration of health.

7.5.1.2 Fellows engaged in the practice of Pathology should be guided by the same ethical considerations, as are practitioners in other areas of medicine. For these purposes the College follows the Australian Medical Association Code of Ethics (Revised November 1995). Copies of this document are available from the College on request.

7.6 **College Ability to Expel or Discipline Fellows**

7.6.1 The Memorandum and Articles of Association of the College have provision for termination of membership of Fellows in certain circumstances.

Article 57 (b) currently states:

> *"If he has been convicted of an indictable offence wherever occurring, he has been struck off the register of medical practitioners in any jurisdiction as a result of disciplinary proceedings, he is found to be guilty of scientific fraud or if by resolution of the Council passed by a majority of at least two-thirds of the whole number of members of the Council or their substitutes it be declared that his conduct has been prejudicial to the interests of the College or that they are of the opinion that his professional or personal conduct is or has been such that he is not a fit and proper person to be a Fellow of the College and it be resolved that his membership be terminated provided that 28 days notice of such meeting of the Council and its purpose shall have been sent to such member and that he shall have been given the opportunity of stating his case to the Council;"*

7.6.2 The component of the Article that *"he has been convicted of an indictable offence whenever occurring, he has been struck off the register of medical practitioners in any jurisdiction as a result of disciplinary proceedings, he has been found to be guilty of scientific fraud or if"* was inserted into the Articles in 1998.

7.6.3 The other circumstance where the membership of a Fellow can be terminated is in relation to non-payment of subscriptions.

7.6.4 There is no other provision available to the College under the present Articles in relation to disciplinary action or termination of Fellowship.

7.6.5 It is important to note that terminating the membership of a Fellow currently does not automatically prevent a person from practising medicine, in general, or prevent them practising pathology as a specialist. The conduct that led to the termination of Fellowship may warrant attention of the relevant Medical Board/Council but a second action by the relevant registration authority is necessary in order to have any effect on that individual's right to practice.

8. GOVERNMENT RELATIONS

The College has a role in relation to liaising with governments on issues relating to the professional practice, medical economic and other medico-political issues.

8.1 Australia

8.1.1 In Australia the College has a close working relationship with the Commonwealth Department of Health and Aged Care. This relationship is fostered at many levels. In addition to the National Pathology Accreditation Advisory Council mentioned above there are the following forums for discussion and collaboration:

8.1.2 **Pathology Consultative Committee (PCC)** . PCC is the peak Australian Government Committee that deals with Pathology issues. One of its major roles is to oversee the development of the Pathology Agreement. This agreement is an agreement where the profession and government work together to ensure the growth in pathology test utilisation is appropriate within a capped fee for services funding environment. In addition part of the agreement involves the introduction of new standards for accreditation of collection centres and also the development of guidelines and other quality initiatives to ensure the quality use of pathology in Australia. Members are drawn from the College, the Australian Association of Pathology Practices (AAPP), the Health Insurance Commission (HIC) and the Department of Health and Aged Care (DHAC).

8.1.3 **Pathology Services Table Committee (PSTC).** The Pathology Services Table (PST) of the Medicare Benefits Schedule lists the pathology tests for which Medicare benefits are available, their Schedule fees and conditions for use. The Government is advised on the composition of the PST by the Pathology Services Table Committee that includes experts in pathology from private industry and public hospital practices. The Committee keeps the Table under review to ensure that the services, fees and conditions for use are appropriate, and consults with professional and other expert groups on these issues.

8.1.4 **PCC/PSTC Statistics Subcommittee** . This Committee is a Subcommittee of PSTC and PCC and analyses Pathology related Medicare data to identify

trends in utilisation. This Committee has a major role in assisting the monitoring of the Pathology Agreement in terms of growth in services and the quality use of pathology.

8.2 **New Zealand**

8.2.1 In New Zealand the College has had limited involvement with the government agencies in recent times. It now restates its offers to work collaboratively on issues in relation to pathology.

8.2.2 The College has provided advice to the New Zealand Health Funding Authority in relation to issues of training and competency of Fellows through consultations with the Clinical Training Agency (CTA), on matters related to post entry clinical training specifications, which form part of the contracts with providers. It would be highly desirable for the College and the New Zealand Health Funding Authority to establish a closer working relationship in other areas, such as the College has in Australia with the Commonwealth Department of Health and Aged Care. The College has welcomed the recent request to provide nominations for an Advisory Group for Public Health Screening Programmes.

8.2.3 It would be helpful for the Health Funding Authority to look more at the emerging concept of clinical governance and to seek to engage professional bodies such as the RCPA in provision to Government of timely professional advice in the relevant areas of expertise on an ongoing and properly resourced basis. In the College's view this would make the College and its knowledge and expertise available in a formal way.

9. GENERAL ISSUES IN RELATION TO CERVICAL CYTOLOGY IN NEW ZEALAND

9.1 Cervical Screening

The National Cervical Screening Programme (NCSP) was launched in 1990 and 14 regional sites became operative in 1991. The 14 separate registers of databases were reconfigured into one central register during 1996/97. In 1998 the responsibility for the National Cervical Screening Programme and the Register transferred from the Ministry of Health to the Health Funding Authority. Currently 90% of adult NZ women participate in the programme.

9.2 When the screening programme was set up TELARC/IANZ accreditation was not compulsory in New Zealand laboratories nor was participation in external quality assurance programmes (QAPs).

9.3 Despite this laboratories became accredited and involved in external QAPs. There was strong support for laboratories that were involved in the NCSP to be accredited and involved in external QAPs. As mentioned previously the 1996 National Cervical Screening Programme Policy detailed this requirement.

9.4 Up to mid 1998 there were four principal categories of abnormality used in New Zealand for the reporting of cervical smears. These were:

1. Normal
2. Atypical Squamous Cells of Uncertain Significance (ASCUS)
3. Low grade squamous intraepithelial lesion (LSIL)
4. High-grade squamous intraepithelial lesion (HSIL)
5. Invasive cancer.

9.5 A comparatively small number of low-grade abnormalities progress to high-grade status. Less than 1% of all smears reveal high-grade SIL. Without intervention high-grade SIL can lead to invasive cancer, a process which may take some years.

9.6 A fifth category, ASCUS? HSIL (“atypical squamous cells of uncertain significance unable to exclude high grade squamous intraepithelial lesion”) was added as an additional coded report option in about June 1998. ASCUS is the lowest level of abnormality in the reporting system apart from clearly benign or reactive changes. Such a result would lead to further patient testing.

9.7 With the present technology the result of testing is based on a subjective microscopic evaluation of the specimen by one or more observers. There is an internationally acknowledged rate of about 5-10% of "false negative" reporting of high-grade laboratory smear tests due to failure to recognise the abnormal cells in the smear. A recent published study (May 1999) which examined the characteristics of false negative cervical smears concluded that such smears were quantitatively different from true positive cervical smears. In addition abnormalities may not be detected where the abnormal cells while present in the patient are not contained in the sample on the slide being read.

9.8 This statement is generally supported and is derived from a Consensus Statement developed at the NCI/NIH Consensus Development Conference on Cervical Cancer held in Bethesda, USA in 1996.

"The majority of the cervical cancers go through a well defined pre-invasive stage. Pap smears are highly effective in screening for pre-invasive lesions, however a single test has a false negative rate of approximately 20%. One half of the false negatives are due to inadequate specimen sampling, and the other half are attributed to a failure to identify the abnormal cells or to interpret them correctly."

9.9 In a population where HSIL is present in 1 in every 100 women having a cervical smear (prevalence of 1%), on the basis of the statement in section 9.8 above, for 1000 women 10 will have HSIL. This will go undetected in one woman because cells are not present in the sample and in another because the cells while present will go undetected by testing as currently practised with the other 8 being recognised. In practice these numbers will vary with the actual prevalence of HSIL in the relevant community.

9.10 Usually HSIL develops into invasive cancer relatively slowly. In consequence, repeat testing at regular intervals reduces the risk of this condition being undetected.

10. LEGISLATIVE REQUIREMENTS

10.1 In New Zealand there are two legislative requirements with which laboratories must now comply in relation to Cervical Screening.

10.2 The first relates specifically to the Screening Programmes and is covered by Section 74 A of the *Health Act 1956* (as amended). In summary, the Act specifies that a laboratory must forward cervical cytology and histology results to the National Cervical Screening Register unless the specimen is accompanied by a written objection.

10.3 The other legislative requirement relates to the *Cancer Registry Act 1993 and Cancer Registry Regulations 1994.* In summary, a person in charge of a laboratory is required to send a report to the Director General of Health when *"a cancer test indicates the presence of cancer in any person (including a deceased person"*.

11. QUALITY CONTROL IN CYTOLOGY

11.1 Up to the mid 1990s a commonly used quality assurance measure involved full re-screening of between 5-10% of smears classified as “normal”. However statistical analysis found this did not provide an adequate rate of detection of “false negatives” leading to an insufficient level of protection for patients.

11.2 From the mid-90s onwards most laboratories began a rapid (30-60 second) re-screening of all negative slides which improved the detection rate of false negatives. In addition there is now also an examination of comparative reporting by all laboratories testing for the National Cervical Screening Register, which enables comparison between laboratories in a diagnostic category. Most computerised laboratories also review their own in-house reporting statistics.

11.3 International Accreditation New Zealand (IANZ – formerly TELARC) now accredits and registers reporting laboratories in cytology which ensures they comply with acceptable quality practices.

12. CYTOLOGY REVIEW PANEL

12.1 In 1994 the Association of Community Laboratories, with support from the RCPA and the NCSP established protocols to set up a Cytology Review Panel to review gynaecological cytology slides to provide evidence when a laboratory's reading of smears was brought into question.

12.2 All laboratories which participated did so on a basis common to many quality assurance activities that their identity would be kept confidential. The process involves five laboratories out of a panel of eight each being circulated with 10 cytology slides, all of which are routine cervical smears originally examined by the laboratory under scrutiny. Amongst those 10 slides is the case under review from a medico-legal perspective.

12.3 The slides are re-screened by each of the laboratories, simulating normal screening conditions as far as possible.

12.4 The review process is initiated by contacting one of the panel laboratories. The panel laboratory contacted may coordinate the exercise and collate the review findings. Neither that laboratory nor the laboratory under scrutiny may take part in the review and any panel laboratory that has previously reviewed the slides is similarly disqualified. These measures are part of the review protocol and are intended to eliminate review bias to the extent possible. As mentioned, availability for the panel is conditional on protection of identities of the participating laboratories. Confidentiality is essential, as:

12.4.1 It is the best means of ensuring that the readings are carried out in an environment as close as possible to that which exists in day-to-day practice;

12.4.2 It reduces the incentive for reviewing laboratories to have a higher index of suspicion than would exist in day-to-day practice for fear of the consequences that arise from reviewing potentially contentious slides;

12.4.3 The laboratories participating in the review do so because they are motivated to participate in reviews that are carried out in the fairest and most reliable way possible. Non-preservation of the laboratories' confidentiality would be a considerable disincentive to involvement.

12.4.4 This protocol which basically establishes a blind comparative analysis process is in patients' best interests and allows the establishment and monitoring of realistic standards.

12.4.5 While the identity of participating laboratories can be made confidential under the provisions of the Medical Practitioners Act 1995, Quality Assurance Activities, it has never been suggested that test data should be similarly treated.

12.4.6 The test data is not treated as confidential. It is made available. This is an added safety measure for patients.

Without this protection, laboratories would not participate, as it is likely that variation will occur in reviewing as it is does in the normal screening process. Any review bias in this arrangement tends to favour a greater likelihood of over-reporting of abnormalities.

12.5 The provisions of the Medical Practitioners Act 1995: Quality Assurance Activities allow for protection of information obtained or generated in the course of a defined quality assurance activity. Ministerial approval is required for this. The College has made application to the Minister for declaration of the Cytology Review Panel as a quality assurance activity under this provision.

12.6 It is relevant that protection sought under the Act is not for the information generated in the review process, but solely in respect of the identities of participating laboratories.

13. COLLEGE INVOLVEMENT WITH GISBORNE CYTOLOGY

13.1 The Inquiry will know that between 1990 and 1994 Gisborne pathologist Dr Bottrill under-read four Pap smears from a patient whose name was suppressed and shall be referred to as “Patient A”. She subsequently developed invasive cancer of the cervix, which led to major surgery and radiotherapy.

13.2 College records show that Dr Bottrill qualified in medicine in 1953, and studied pathology for five years from September 1957 to September 1961 in the United Kingdom. He came to New Zealand in 1961, and practised in general pathology before establishing a laboratory in Gisborne in 1967. The Royal College of Pathologists in the United Kingdom was not established until 1962, after he left the country.

13.3 He became a Fellow of the Royal College of Pathologists of Australasia (RCPA) by oral and practical examination in 1973.

13.4 Dr Bottrill retired from practice in 1996.

13.5 Dr Bottrill’s slides in relation to this case were subjected to the Cytology Review Panel process referred to previously and the information was used in the ensuing court case.

13.6 The College received a letter dated 29 March 1999 from Mr Stuart Grieve QC counsel for Patient A. This was the first formal correspondence the College had received on this matter. The letter referred to both the patient and pathologist by name only. There was a reference to this letter in the media in the Sunday Star Times on 26 September 1999 stating that the College had forwarded a copy of this letter to Dr Bottrill’s solicitor. The College did not take the action alleged.

13.7 The letter was sent by Mr Grieve QC to a number of organisations including the Health and Disability Commissioner, the Health Funding Authority, Cervical Screening Authority, Minister of Health, Medical Council of New Zealand and National Women’s Hospital. The letter referred to Mr Grieve’s view that the slides of other patients of Dr Bottrill should be re-read.

13.8 The College viewed these concerns seriously and immediately made inquiries.

13.9 On the 21 April 1999 the College replied to Mr Grieve using information provided to it at the time from an adviser to the National Cervical Screening Programme relating to Dr Bottrill's performance and using the 1998 RCPA/QAP Pty Ltd Annual Report on Performance Standards in Australian Laboratories in relation to Cervical Cytology reporting.

13.10 From the data from the National Cervical Screening Programme provided at the time, Dr Bottrill's performance was not considered to be significantly different from other practices of comparable size and range in key parameters. The letter stated that using the RCPA/QAP Pty Ltd Performance Standard data (only collected in Australian Laboratories at this stage) the recommended standard for a laboratory is that not less than 0.5% of cervical smears are reported as high grade abnormalities. Dr Bottrill's practice at the time fell into this range being close to the national aggregate of 0.77%.

13.11 In the College's response it was stated that there is a known rate of incidence of high grade abnormalities that will be missed of the order of 10 to 20%. The background to these figures was discussed previously in this submission.

13.12 The College received another letter from Mr Grieve dated 28 April 1999 seeking further clarification of issues. The College did not have further information to add at that time.

13.13 On April 29, 1999 the Health Funding Authority issued a press statement saying that prior to going to court neither the High Court nor the Medical Practitioners Disciplinary Committee "found any evidence that the pathologist was any more inaccurate than others." In this statement any patients who had had a Pap smear read as normal by a Gisborne pathologist between 1991 and 1996 and had not had a repeat smear since were encouraged to attend for a repeat smear.

13.14 The Medical Council has among its powers one to require medical practitioners, including pathologists, to undertake rigorous competency reviews and/or assessment of health. From time to time the College has assisted the Medical Council in matters, including disciplinary matters, to enable issues of concern involving pathologists to be addressed.

13.15 The College had no formal notification of concerns about Dr Bottrill. As a result of inquiries made, the College has since learned that some College members were

aware of the disciplinary charges.

13.16 The College would not hesitate to refer concerns about a member to the Medical Council. The College is not and has never been the body to which:

13.16.1 Complaints about a pathologist are made. Complaints were made to the Secretary of the Practitioners Committee under the Disciplinary Practitioners Act 1968 and now to the Health and Disability Commissioner.

13.16.2 Information about medical error or mishap or poor outcomes is communicated. The Accident Compensation Corporation Medical Misadventure limb is the organisation that receives claims, initiates investigations and in some cases refers concerns to other agencies.

13.16.3 Information about the performance of a pathologist or laboratory is notified. Such information is collected by TELARC (now IANZ) for laboratories that are part of the programme.

13.16.4 The body that receives or collates information on individuals being screened by cervical cytology. This is the responsibility of those managing the National Screening Register.

13.17 The College does not undertake disciplinary hearings in its own right and does not participate in disciplinary hearings under the Medical Practitioners Act 1995. Those hearings are conducted by the Tribunal established under that Act.

13.18 However, the College has voluntarily assisted these other organisations by providing expertise, mentoring and supervision when requested.

13.19 In recent weeks the new Health and Disability Commissioner has asked the College to nominate individuals with recognised expertise to provide advice to the Commissioner. The College views this as a constructive development.

14. SUBSEQUENT ACTIONS

14.1 The College's opinion was based on the information available to it at the time, which was:

14.1.1 That one patient's slides had been misread in circumstances that the Medical Practitioners Disciplinary Committee viewed as being at the lower level of misconduct.

14.1.2 That his reporting according to figures provided by the NCSP was within an acceptable range.

14.2 Following the hearing, the HFA learned of two other cases of misdiagnosis by Dr Bottrill. The HFA established a review group that included pathologist Dr Norman Fitzgerald of Dunedin. Dr Fitzgerald was appointed as an independent pathologist not as a College representative. The College Councillor Dr Andrew Tie met with Ms Tracey Mellor of the HFA.

14.3 On 8 May 1999 the Chairman of the NZ Committee of the RCPA, Dr Andrew Tie made a press statement which defended the screening programme, expressed concern at the misdiagnosed slides and supported the HFA review and recall programme.

14.4 Noting that it was not yet possible to know if there was a systemic failure of screening by Dr Bottrill, Dr Tie reiterated the limitations of current technology and said it was very sad that this had been highlighted by the personal tragedy of several patients.

14.5 On 11 May 1999 the Judge who had ordered the suppression of Dr Bottrill's name lifted the suppression.

14.6 On May 13 1999 the authority announced a $1.5m investigation in the Gisborne area, including free smears and counselling, and the rereading of all cervical smear slides from 1991 to end February 1996.

14.7 The College established a Cytology Focus Group in NZ to address the findings of the review, and there has been discussion with representatives of key quality assurance bodies within the College in Australia and the Australian National Cervical Screening Programme.

14.8 The Health Funding Authority (HFA) announced that it had contracted with a Sydney-based laboratory "to re-read 30,000 cervical smears from Gisborne."

14.9 Australia was chosen to both "maintain independence from the issue in NZ" and to minimise the impact of such a workload on the existing screening programme here. The work was to be concluded by the end of December. All women whose slides are re-read were to be contacted by the HFA. The HFA did consult with the College as how best to undertake this review.

14.10 On September 21, 1999 the HFA released the first results of the retesting, which showed that of the 4,900 slides so far re-read, 157 were considered to show high-grade abnormalities. Dr Bottrill had reported 28 of these as high-grade.

14.11 As a result the HFA set up colposcopy clinics and announced that because of the significant under-reporting of cervical slides the HFA was to review some of Dr Bottrill's histology (breast specimens).

14.12 On the same day the Minister of Health announced proposed law changes and the present Ministerial Inquiry was announced.

14.13 The Minister said that there had been a number of significant law changes and changes in practice of pathology since Dr Bottrill had retired in 1996, but *"a gap had been identified for cases before 1996."* There would be consultation with the health profession and others before the new legislation was developed, he said.

15. SUBSEQUENT STEPS TAKEN

In New Zealand the following developments have occurred:

15.1 The College is encouraging all laboratories in New Zealand to have rapid re-reading of all smears, together with directed full rescreening, rather than fully re-screening 10% of them.

15.2 Computerisation allows review of in-house reporting statistics, which is more difficult with a card system.

15.3 On-going review of accreditation and quality practices.

15.4 Heightened awareness of the risks of isolated practice.

16. FALSE NEGATIVE RATES

Despite these new strategies to reduce the false negative rate the international literature currently concludes that even with a well designed and well resourced screening process approximately 5-10% of smears containing pre-cancerous cells will be reported as normal.

17. SCREENING CYTOLOGY

17.1 The Pap smear is a screening test not a diagnostic test that involves the subjective interpretation by a cyto-technologist or a pathologist of approximately 50,000 to 100,000 cells spread on a routine glass slide. There is considerable debate among expert cyto-pathologists concerning the criteria for the categories used to report PAP smears, and the terminology used in reporting.

17.2 Further assessment either using colposcopy or histology follows the reporting of abnormal smears. As with all tests none of these techniques has a 100% sensitivity or specificity. For this reason the patient must be regularly screened.

18. SPECIFIC SYSTEMIC ISSUES IN NEW ZEALAND

18.1 There are issues in New Zealand that are evident from a systemic point of view which if addressed could help prevent those such as the Gisborne issue occurring again.

18.2 The College on the information available to it, believes:

18.2.1 The collaborative relationships the College has with the Federal Government in Australia may be a model worth consideration by the Inquiry.

18.2.2 It would be appropriate to use the medical Colleges as an overarching body to provide advice on issues. If the government requests a single professional's advice on an issue it will obtain only one personal opinion. On the other hand if a College was asked to provide an opinion on issues such as professional practice, quality or standards, it would have access to the views from multiple professionals and also a critical evaluation of current literature and contemporary standard practices. This is standard international practice.

18.2.3 The Cervical Screening Programme, while having achieved a great deal already, would benefit from greater professional input at a College level. In particular, a national cervical cancer register and a cervical cancer mortality review process are suggested as a means of continually evaluating the programme's effectiveness.

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ATTACHMENT 1

STRUCTURE OF THE ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA

1. GOVERNING BODY - COUNCIL

Council is the governing body of the College, which is elected by the Fellowship or appointed by Council. It is actively involved in setting strategic and policy directions for the College. The composition of Council is as follows:

Office Bearers:
- President
- Vice Presidents x 2
- Honorary Secretary
- Honorary Treasurer

Vice President for New Zealand

State Councillors
- Queensland
- New South Wales/ACT
- Victoria
- Tasmania
- South Australia/NT
- Western Australia

Chairmen of the Major Committees
- Board of Censors (BOC)
- Board of Education (BOE)
- Pathology Professional Activities Committee (PPAC)
- Quality Assurance Scientific and Education Committee (QASEC)

Chairman, Faculty of Oral Pathology

Temporary Members of Council *(Under Article 22)*
- Hong Kong
- Malaysia
- Singapore

2. OTHER MAJOR COMMITTEES OF THE COLLEGE

2.1 Executive Committee

The Executive Committee, a subcommittee of the Council has responsibility for operational issues for the College. It consists of the Office Bearers and the Vice-President for New Zealand. In addition, during the intervals between Council meetings, the Executive Committee may exercise such powers of the Council as Council so determines, that are necessary for the management and direction of the business and conduct of the affairs of the College.

2.2 Board of Censors (BOC)

The Board of Censors is responsible for the training and examination process for Fellowship of the Royal College of Pathologists of Australasia and for other qualifications of the College. The Board is responsible for the accreditation of laboratories for training. On behalf of the Australian Medical Council and Medical Council of New Zealand, the Board is also responsible for the assessment process for overseas-trained specialists.

2.3 Board of Education (BOE)

The Board of Education is responsible for providing advice on education issues, promoting research in pathology and raising public awareness of pathology. The BOE develops, coordinates and supports continuing education activities, such as update courses, oversees the scientific programme of the Annual Scientific Meeting and coordinates the development and publication of educational materials for internal or external distribution.

2.4 Continuing Professional Development Programme (CPDP) Subcommittee

The CPDP Subcommittee is a subcommittee of the Board of Education and is responsible for the development, promotion and evaluation of the RCPA Continuing Professional Development Programme (CPDP).

2.5 Pathology Professional Activities Committee (PPAC)

The role of PPAC is to address, develop and maintain the medico-political activities of the College through the development of relationships with Federal and State Governments, political parties and politicians and other strategic organisations within Australia.

In addition, the role of PPAC includes the development and maintenance of effective codes of practice in the various disciplines of pathology, including the appropriate ethical standards of pathology practice.

2.6 Quality Assurance Scientific And Education Committee (QASEC)

The Quality Assurance Scientific and Education Committee is responsible for providing advice on matters relating to quality in the practice of pathology. QASEC acts as a point of contact for the exchange of information regarding quality issues between the College and external bodies or agencies.

2.7 Discipline Advisory Committees (DACs)

DACs are committees in their respective disciplines established to provide expert advice to the Executive Committee. This includes:

2.7.1 advice regarding training;
2.7.2 identification of areas of concern or new initiatives which require review from a political or professional perspective.

There are nine Discipline Advisory Committees in the following areas:

Anatomical Pathology
Chemical Pathology
Cytopathology
General Pathology
Genetics

Haematology
Immunology
Microbiology
Forensic Pathology

2.8 Management Team

The activities of Council and associated Committees are supported by a team of staff headed by the Chief Executive Officer located at Durham Hall in Sydney. In addition there is a part-time Professional Administrator based in Wellington to assist the specific New Zealand Committee and Fellows.

3. NEW ZEALAND SPECIFIC COMMITTEES

3.1 Committee for New Zealand

3.1.1 The major role of the Committee for New Zealand is to monitor, consider and act on issues arising in and exclusive to New Zealand, which affect the interests of College Fellows. The Committees communicate with New Zealand government departments, political parties and other organisations whose decisions may impact upon the practice of pathology. The Committees are also responsible for providing education activities for Fellows and Trainees.

3.1.2 The Committee for New Zealand is chaired by the Vice President for New Zealand who is on the Council and Executive Committees of the College

3.2 Committee on Education and Training New Zealand

Is responsible for the Continuing Professional Development Programme in New Zealand and for overseeing the organisation of the New Zealand Annual Scientific Meeting, workshops and seminars; re-certification/revalidation issues. It is a sub-committee of the Committee for New Zealand

3.3 Committee for Pathology Practice

Responsible for general issues and representation to government and health sector agencies. This is a sub-committee of the Committee for New Zealand.

3.4 Committee For Standards And Information Technology

This Committee is responsible for professional standards and quality issues and also for issues relating to information technology. It is also a sub-committee of the Committee for New Zealand