

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

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

STATEMENT OF EVIDENCE OF

DR BRIAN JOSEPH LINEHAN

MEDLAB HAMILTON AND MEDLAB GISBORNE

I, BRIAN JOSEPH LINEHAN of Hamilton, Managing Director, state:

1. I am the Managing Director of Medlab Hamilton Limited, and also the Managing Director of Gisborne Medical Laboratories Limited. The latter company was incorporated on 27 February 1996 in order to purchase the assets of Gisborne Laboratories Limited, which took effect on 4 March 1996.
2. The laboratory operation owned by Medlab Hamilton Limited was begun in 1951 as the private pathology practice of Dr Marcus Fitchett. He was joined in 1955 by Dr Geoffrey Fairbrother and the practice became known as Fitchett and Fairbrother. In 1966 Dr Ash Symmans joined the practice and it then became known as Fitchett, Fairbrother and Symmans. I joined the practice in 1971 and we changed the name to Hamilton Medical Laboratory. More recently, in 1996 the partnership was corporatised and became Medlab Hamilton Limited ("Medlab Hamilton"). That is the name and legal entity under which it now operates. Medlab Hamilton is a privately owned, pathologist operated medical laboratory.
3. Gisborne Medical Laboratory Limited ("Medlab Gisborne") was also formed as a private limited liability company in 1996 and operates under the trading name of "Medlab Gisborne". It is a separate entity from Medlab Hamilton but has similar shareholders and is, for practical purposes, operated as if it were a subsidiary of Medlab Hamilton. The Laboratory Manager for Medlab Gisborne reports to top management of Medlab Hamilton and senior specialist staff at Medlab Hamilton exercise a supervisory role over appropriate areas of Medlab Gisborne. In particular the Quality Manager at Medlab Hamilton is responsible for quality matters at Gisborne. A number of the tests referred to Gisborne laboratory are sent on to Hamilton.
4. The automated equipment at Gisborne is on-line to the main computer in Hamilton and test results can be reported electronically directly into the requesting doctors practice computer or they may be printed out as hard copy written reports which are then distributed either by

courier or post. The written reports for doctors in the Gisborne area are printed in Gisborne and distributed from there.

QUALIFICATIONS AND EXPERIENCE

5. I am a registered medical practitioner, vocationally registered by the New Zealand Medical Council as a pathologist, and I practice as a chemical pathologist but with much of my time involved with managerial duties.

6. My qualifications are:
 - MB ChB (University of Otago) 1961
 - Diploma of Obstetrics (University of Auckland) (Dip.Obst) 1964
 - Fellow of the Royal College of Pathologists of Australasia (FRCPA) 1971

7. After obtaining my Undergraduate qualifications in medicine I worked for the then Auckland Hospital Board in its various hospitals, including National Women's Hospital where I obtained a Diploma in Obstetrics. In 1968 I took up a position as Resident Pathologist at Sydney Hospital and in 1971, after completing all the examinations for my FRCPA I took up a partnership at Hamilton Medical Laboratory. Shortly after starting in Hamilton I also took up a part-time position as a consultant chemical pathologist at Waikato Hospital. I resigned from that position in 1993 so that I could better cope with my other duties. In 1982, with the retirement of Dr Fairbrother, I became the Managing Partner (and subsequently Managing Director) of the Hamilton laboratory.

8. My training in pathology included training and examinations in four main branches of pathology - histology, haematology, microbiology and chemical pathology. My training in histology did not include cytology. I understand that the situation changed subsequent to my time as a pathology trainee. At that time cytology was considered something special and not normally included with histology training.

9. After qualifying in pathology, and although trained in the four main branches, I specialised in chemical pathology. This was partially out of personal preferences, and partially because that was the area of major need at Hamilton Medical Laboratory when I joined the practice. I have never practised as a cytologist.
10. For my generation of pathologists and for those qualifying earlier than I did, cytology was a sub-specialty where knowledge and training had to be acquired largely through personal initiative. It was not part of the training that was automatically acquired through participation in the usual histology or anatomic pathology training schemes. For example, during my time at National Women's Hospital as a pathology registrar in 1964 (subsequent to my time on the clinical teams) I received no training at all in cytology. The cytology department was separate from the laboratory and under the direction of a specialist whose principle training had been in the clinical area. Cytology was not considered necessary for our pathology examinations in histology.
11. I understand that those pathologists who did acquire skills in this area did so as a result of personal initiatives by attendance at specialised conferences and seminars, visiting laboratories in various parts of the world where cytology techniques were practised, viewing scientific literature and other voluntary initiatives. At the time I qualified in pathology there was no recognised qualification or experience in cytology that was considered necessary before a pathologist could practice as a specialist pathologist in anatomic pathology.
12. Other professional positions which I have held, or continue to hold, include:-
- Chairman of the NZ Medical Association (NZMA) 1996-1998
 - Chairman of the Ethics Committee of the NZMA 1998-Present
 - President of the New Zealand Society of Pathologists 1980
 - Examiner in Chemical Pathology for RCPA 1970s
 - Consultant Advisor in Pathology to the Minister of Health 1970s

- Chairman of International Accreditation NZ (IANZ/Telarc) 1987-98
- Chairman of Medical Professional Advisory Committee of
IANZ/Telarc 1979-Present

13. With regard to Telarc/IANZ, I was Chairman of the whole organisation for 9 years and I am still a member of the Telarc Council. Around 1980 I was appointed Chairman of the newly formed Medical Registration Advisory Committee of Telarc - a special committee of Telarc set up to institute and oversee a voluntary programme for the accreditation of medical laboratories. This programme has continued to develop until now when virtually all medical laboratories in New Zealand (the exceptions being a few small hospital laboratories) are accredited by the organisation now known as IANZ. I believe I have had a significant influence in achieving this result and the associated increase in standards and performance that flow on from accreditation. I still hold the position of Chairman of the Committee (now known as the Medical Professional Advisory Committee - MPAC) which oversees the medical accreditation programme.

**PURCHASE OF GISBORNE LABORATORIES LIMITED
OF GISBORNE LABORATORIES LIMITED**

14. As Managing Director of Medlab Hamilton, it was part of my strategic plan to look for commercial opportunities to expand the business and services of the company.
15. In January 1996 I received a telephone call from Mr Graham Reeve, then Manager of Gisborne Laboratories Limited. Mr Reeve asked me whether Medlab Hamilton would be interested in purchasing Gisborne Laboratories, which was jointly owned by Mr Reeve and Dr Michael Bottrill. Mr Reeve indicated that they had previously been negotiating with Tairawhiti Healthcare but negotiations had come to a standstill and they were seeking an alternative purchaser.
16. In January 1996, I travelled to Gisborne and spent a day with Mr Reeve and Dr Bottrill. Negotiations were commenced and carried on until an Agreement for Sale and Purchase

was signed, to be effective from 4 March 1996. A copy of that Agreement is produced as **BJL/MEDH/0001**, although with the commercially sensitive information deleted.

17. I emphasise that Medlab Hamilton did not purchase the existing company and its liabilities. A new company - Gisborne Medical Laboratory Limited - was formed and the new company purchased the assets (but not the liabilities) of the old laboratory company. Nearly all of the staff were re-employed by the new company.
18. When we took over Gisborne Laboratories Limited a number of changes were immediately instituted. All histology specimens and cytology slides, as well as other selected tests, were sent by courier to Medlab Hamilton. This was done on a daily basis by overnight couriers. We did not retain the ability to process histology and cytology in Gisborne. This decision was made because we believe that better quality could be achieved by processing both types of specimens in Hamilton as part of a much larger operation where all of the quality control checks were already in place and the Pathologists were able to give each other mutual support.
19. Prior to Medlab taking over the laboratory Quality Assurance programmes used by Gisborne included:
 - Murex General Chemistry Programme for Biochemistry analytes only.
 - The Abbott Haematology QC Programme associated with the Cell Dyn Haematology Analyser.
 - The IANZ (then TELARC) SCAP Programme for coagulation testing (this programme was discontinued in the early 90's).
20. Quality Assurance programmes, similar to those employed in Hamilton, were immediately introduced to Medlab Gisborne and we started to prepare the laboratory for IANZ/Telarc accreditation.

21. Medlab continued to use the Murex and Abbott programmes after taking over the laboratory and introduced the following additional programmes:
- Unity QC Programmes for internal QC monitoring from Biorad with an external component,
 - RCPA Haematology QAP - a branch programme covering all general Haematology rather than just the Cell Dyn.
 - NIPS (National Immunohaematology Proficiency Survey) for blood grouping.
 - Reintroduced the SCAP Programme.
 - Regional QC group participation in Biochemistry, Haematology and Microbiology.
 - Participated in an exchange of material between Medlab Hamilton and Medlab Gisborne from RCA Programmes in general Chemistry.
 - Exchange of Microbiology assessments between Medlab Hamilton and Medlab Gisborne.
22. After taking over the Gisborne Laboratory we found that there was a considerable amount of work to be done in order to achieve accreditation. The accommodation was relatively cramped (and still is although plans are now underway to extend the building). The equipment was adequate and functioning but we found that calibration was required. The microscopes were all functioning adequately but needed servicing, in particular the microscope used by Dr Bottrill was in good condition and is currently being used in the Haematology section. Dispensing pipettes had not been serviced or their calibration checked. Documentation of method procedures was virtually nonexistent so we had to introduce all the documentation required for a modern quality manual including documentation of all the methodologies and job descriptions together with formal staff continuing education and competency logs.
23. We also computerised Medlab Gisborne. Automated equipment was placed "on line" to the main computer in Hamilton and computer-generated reports replaced the old photocopied

reports.

INVOLVEMENT OF DR BOTTRILL AT MEDLAB GISBORNE OF DR BOTTRILL AT MEDLAB GISBORNE

24. Immediately after we took over the Gisborne laboratory, Tairawhiti Healthcare (the unsuccessful contender for the purchase of the laboratory) launched a very aggressive marketing campaign to try and capture the community laboratory market in Gisborne. They spent a considerable amount of money on newspaper advertisements and senior hospital executives visited the general practitioners. Part of their marketing strategy was to portray the new purchasers of the laboratory as "out-of-towners" and they urged doctors to support their local hospital. They were successful to the extent that they immediately captured almost half of the market. We have had to work very hard to recover that market. However, we have now been successful in achieving a market share equivalent to what it was prior to our takeover in Gisborne, and we are gratified that the reason cited by doctors who have changed back to Medlab Gisborne from Tairawhiti Healthcare is one of quality and service.
25. The aggressively competitive attitude of Tairawhiti Hospital Laboratory prevented the type of arrangement which is very common in this country whereby a Pathologist (or other Specialists) can work in the hospital environment but also have a part-time position in private. In fact this intense competition which appears to have been fostered by the health reforms has, in my view, been to the detriment of the general public in that it makes the traditional and expected, collaboration between doctors and health institutions much more difficult.
26. Dr Bottrill called into the laboratory from time to time, especially immediately after Medlab's purchase of the laboratory, but his visits were almost entirely of a social nature although, I understand that he did give the staff flu injections. Mr Reeve, who in the old laboratory was responsible for the general laboratory operation, was called upon a couple of times to assist with the servicing of equipment.

27. Both Dr Bottrill and Mr Reeve were very concerned at the reduction in our work volumes and offered to do whatever they could to assist, and so it was mutually agreed that we list Dr Bottrill's name as one of the associated pathologists on the Medlab Gisborne stationery. Dr Bottrill was considered a very respected, senior pathologist and we thought that his association with the new Medlab Gisborne would be an advantage. He agreed to be associated with the new laboratory but only in a nominal way because he wished to retire from active work. No fees were paid to Dr Bottrill and he was not actually required to do anything other than promote our interests among the local doctors. From the time of taking over the laboratory all histology and cytology was sent on to Hamilton and no facilities for processing histology and cytology were retained at Gisborne. Consequently, Dr Bottrill did not do any histology or cytology at Gisborne after we took over the operation in March 1996.
28. I was aware about that time that a patient had made a claim on ACC regarding a misdiagnosis, but that did not raise any concerns regarding his professional reputation or the overall quality of his work. Many very reputable doctors have had such claims made against them, and there was no reason for the new owners to become involved in a matter that dated from the period prior to purchase.
29. Until the matter received widespread publicity in the national media, I had no evidence that there was any concern about Dr Bottrill's cytology. This would have been about April 1999.
30. Towards the end of 1998 Dr Bottrill requested that his name be removed from Medlab stationery. This request was conveyed to me by the staff at Gisborne and it was my understanding that it arose simply because Dr Bottrill felt that the original purpose of having his name associated with the lab had now been served. I was not (and am not) aware of any other reason as to why he may have wished to be disassociated from the laboratory. For our part we had no reason at all to be concerned with his involvement with the lab nor had we any concerns about his past work.

31. Also, Dr Bottrill's name was listed as one of the supervising pathologists in the contract Medlab Gisborne signed with the Health Authority. There was no operational significance in this as actual supervision was provided by the various pathologists in Hamilton who supervised their own appropriate sub-specialty and, in the case of histology and cytology, all of this was located in Hamilton and in charge of the Hamilton histopathologists. However, when we signed the contract we felt it appropriate to list all the pathologists, who might be involved or associated with the laboratory and consequently, included Dr Bottrill's name. A copy of the contract with Midland RHA is produced as **BJL/MEDH/0002**.
32. I emphasise, Dr Bottrill was not able to and did not produce or supervise the production of any histology or cytology reports after Medlab Gisborne took over the operation. We included his name to the contract for the reasons mentioned above and it added justification for our decision to include his name on the stationery. At the time, it seemed a very unimportant issue and, in fact, we forgot about it to the extent that even after we agreed to remove Dr Bottrill's name from laboratory stationery we did not remember to notify the HFA that he should no longer be listed as a supervising pathologist. Formal notification was, however, eventually given to remove his name from the list on 3 June 1999 when the names of other pathologists who had since joined Medlab were added. A copy of the letter of notification is produced as **BJL/MEDH/0003**.

IANZ/TELARC ACCREDITATION

33. Telarc was established by Act of Parliament in 1972 as a user-funded statutory body tasked with the promotion and recognition of laboratories meeting international standards of quality management and technical performance. In July 1997 Telarc changed its name to International Accreditation New Zealand ("IANZ") and split off a wholly owned subsidiary company, Telarc Limited, which was given the responsibility for the certification function (eg, ISO 9000 certification). IANZ continued to be responsible for laboratory accreditation.

34. I must emphasise, however, that although IANZ is a Crown Agency it is not a regulator. While regulators can require accreditation, this is not the role of IANZ and nor should it be their role. Any compulsory aspect of accreditation has to come through other agencies, eg, via HFA or Government.
35. In 1979, Telarc introduced its accreditation programme for medical testing laboratories under the management of the first programme manager, Kevin Cooper, and under the overall direction and guidance of the Medical Testing Registration Advisory Committee (MEDRAC), which I chaired. Prior to this, one laboratory (Waikato Hospital) had applied for and been granted registration under the chemical/biological field of laboratory testing. The MEDRAC Committee, made up of 10 pathologists, laboratory scientists and specialist physicians, established and published the provisional accreditation criteria for the medical testing programme, which is produced as **BJL/MEDH/0004**, and by February 1981 over 20 medical laboratories were working towards registration. Over the years that initial provisional criteria has been considerably refined and developed.
36. Laboratories accredited by Telarc/IANZ comply with stringent requirements in relation to the calibration of test equipment, competence and training of laboratory staff, test method verification and practice, and a range of other functional and quality management criteria. The quality management criteria are currently defined in the IANZ document *New Zealand Code of Laboratory Management Practice*, which embodies the requirements of the International Standards Organisation - ISO 9002 and ISO Guide 25. This is the document currently used as the standard for accrediting medical laboratories in New Zealand. A copy is produced as **BJL/MEDH/0005**.
37. I believe that in 1990 there were 23 accredited medical laboratories. By 31 December 1996, 54 laboratories had gone through the process and completed their requirements for registration with Telarc/IANZ. As at 29 February 2000 I understand there were 67 operating medical laboratories that had achieved accreditation.
38. The IANZ programme for the accreditation of medical laboratories is based on the

principles of peer review. The standards included in the IANZ documents are those promulgated by relevant professional bodies, eg, the Royal College of Pathologists of Australasia ("RCPA"), and the accreditation procedure is carried out according to an ISO (International Standards Organisation) guideline - ISO Guide 58. A generic ISO guide for the accreditation of laboratories, ISO Guide 25, is being rewritten as a specific standard for the accreditation of medical laboratories. This work has been carried out by an international committee of ISO - TC212 - and I am the New Zealand representative on that committee. I have submitted a current draft copy as **BJL/MEDH/0006**, which I expect will become the standard for accrediting medical laboratories throughout the world.

39. I believe that since the introduction of an accreditation system for New Zealand medical laboratories, there has been a steady and very significant improvement in the quality of work performed by those accredited laboratories. However, it must be remembered that accreditation does not, and cannot, provide a guarantee that every result from a laboratory is a correct result. Human error is still possible and, indeed, inevitable. Accreditation, however, does ensure that a laboratory has appropriately trained staff, well maintained equipment and recognised methods and procedures in place so that it is not only capable of producing good quality results, but the opportunities for error are reduced to a minimum. What that minimum is, is generally a reflection of the "state of the art" at any particular time, and is constantly improving. Participation by a laboratory in the accreditation scheme is a way of ensuring that the laboratory is involved in a programme which results in continuous improvement and will raise the level of performance of that laboratory well beyond the minimum level that was necessary to achieve accreditation in the first place.
40. Medlab Hamilton was the first community laboratory to achieve accreditation, in New Zealand and this occurred on 9 September 1981. Because of my involvement with Telarc/IANZ and Medlab Hamilton's long commitment to accreditation and quality, it was my desire to bring the same standards to Medlab Gisborne. Consequently, an application for accreditation was made soon after we took over the laboratory. In fact this turned out to

be a re-activation of an earlier formal application made by the previous owners of the laboratory on 27 June 1994.

41. Accreditation takes a significant commitment from the laboratory and a major effort is required both professionally and economically to achieve the necessary standards. Responsibility for guiding Medlab Gisborne through this process was the responsibility of Medlab Hamilton's full-time quality assurance manager, Greg Scheurich, who spent months of work, both in Hamilton and in Gisborne, supervising the process and assisting the Gisborne staff with the necessary documentation and training. To do this he was able to draw on both the experience and documentation from Hamilton and so the process was faster than if Gisborne had had to achieve accreditation entirely on its own. Even so, it was over a year before Medlab Gisborne was granted accreditation on 3 December 1997 (Accreditation number 668).
42. The process of gaining accreditation usually takes a laboratory from 6 - 24 months depending on their state at the time of application. Sometimes a poorly prepared laboratory may take over two years. In the early years, after the establishment of the programme, availability of Telarc assessors may also have contributed to a delay.
43. After obtaining accreditation, a laboratory is audited annually by IANZ staff (surveillance visit), with a full peer review by a team of pathologists and medical scientists taking place every four years (reassessment visit). During these assessments, quality assurance is stringently reviewed as part of the ongoing commitment to quality improvement.
44. Since our purchase of Gisborne Laboratories Limited, there has been ongoing regular contact between Medlab Hamilton and Medlab Gisborne by telephone, e-mail, and facsimile, and visits to Gisborne. I personally visit Medlab Gisborne 3 or 4 times each year and other Pathologists visit 2 to 3 times each year. During these visits a Pathologist (and other staff) not only make a point of visiting the laboratory but also visiting the local GP's and Specialist's. This is part of our QA programme as it provides an opportunity for feedback from the local doctors with regard to any problems that might be occurring, and also to

establish a personal relationship to facilitate their easy communication by telephone for pathology consultations. Greg Scheurich, who is in charge of quality assurance, spends time carrying out an internal audit each year as well as extended time prior to the IANZ external audit each year. In addition, most of the departmental managers visit Gisborne from time to time and Gisborne staff visit Hamilton on a planned basis as part of their continuing education programme.

45. Last year, approximately 42 "person days" from Medlab Hamilton staff were spent in Gisborne. In addition, a number of Gisborne staff spent time in Hamilton for training purposes. Usually this was in periods of 1-2 weeks at a time. This amounted to approximately a further 28 "person days" last year.
46. Medlab Hamilton, and now Medlab Gisborne, have competence logs for all staff and these are assessed annually and reviewed by supervisors. They also have job descriptions and other documentation which is part of the quality manual.
47. Histopathologists working at Medlab Hamilton have been involved in the RCPA Quality Assurance Programmes from around the time they first became available. These programmes involve receiving slides from the College, examining them and reporting the diagnosis to a central collating agency, organised by the RCPA, and subsequently receiving the reports which compare each individual pathologist's diagnosis with the consensus view. Initially all the pathologists at Medlab Hamilton were working part-time at Waikato Hospital so there they received and reported the QAP slides at the hospital. Since 1991, however, when we started to employ pathologists who were not simultaneously working at Waikato Hospital, Medlab Hamilton has been enrolled separately in the RCPA programmes to ensure that all Medlab anatomic pathologists participated in the programme.⁴⁷

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48. Quality Assurance programmes in the other disciplines have been available for a long time. For example, Quality Assurance programmes in chemistry were in place when I joined the laboratory in 1971. Since then these programmes, which have been available from different sources, have grown in sophistication and importance. The programmes now being used by Medlab, and most laboratories in New Zealand, are those produced by the RCPA. Medlab's performance in these programmes has always been good. On occasions we have been the best laboratory in the country and also within the top 100 laboratories in the world (see **BJL/MEDH/0007**). It is important to record that more recent survey reports do not give "league tables". Our results have, however, always been satisfactory. Performance in the histology and cytology programmes has always been more than satisfactory.
49. Gisborne's results in the QAP surveys are now also among the best in the country (see **BJL/MEDH/008**).
50. Currently, Medlab's Quality Assurance programmes are being extended to include more focus on staff and their performance (and well-being) through an additional programme being introduced as Investors in People and also promoted by IANZ. This programme originated in the U.K.

MEDLAB GISBORNE'S INVOLVEMENT IN THE HFA'S RESPONSE TO DR BOTTRILL'S APPARENT UNDER-REPORTING OF CERVICAL SMEARS

Gisborne's Involvement in the HFA's Response to Dr Bottrill's Apparent Under-Reporting of Cervical Smears

51. When Medlab Hamilton took over Gisborne Laboratory Ltd, we also took over all the medical records that were present in the laboratory. This included the reports and slides from recent years - approximately since 1990. While very recent reports were filed within the building all the reports and slides from more than a year or so earlier were filed in boxes in a shed adjacent to the laboratory buildings. Over the years there had been deterioration in the condition of the outer storage boxes, although the slides and inner boxes were generally in good order. However, the Manager at Gisborne Medlab, Janet Wilson, has informed me that the flooding around the time of Cyclone Bola meant that some boxes and slides were ruined and had been discarded. There was no requirement at that time to keep slides "forever" and the oldest slides were discarded as space was needed for more recent ones.
52. As is common practice, all the glass slides had been identified with a number that had been etched onto their surface. With the system in place before we took over the laboratory, this number was recorded on the request form. The laboratory copy of the report (which also had the cytology number on it) was then stapled to the original request form before filing alphabetically in the current year's files. Consequently, in order to locate the slides pertaining to a particular patient it was necessary first to know the patient's name and approximately when the smear had been collected. The request/report form could then be located in the alphabetical file for the appropriate year. From that report the number of the slide was able to be obtained and used to locate the slide which was filed in another box in numeric order. Consequently, the location of a particular patient's slide was rather a time-consuming process that had to be carried out by someone who knew what they were doing. In practice, this was (and is) the senior staff at Gisborne - usually the Manager.

53. In approximately April 1999, the HFA approached Medlab Hamilton regarding the re-screening of slides. Medlab Hamilton in turn advised Medlab Gisborne on 7 April 1999 that there was likely to be an HFA audit of the cervical smear slides and that the laboratory records and slides would need to be removed.
54. At our request, the HFA provided a letter of indemnity protecting Medlab from any liability once the records and slides had been removed from the Gisborne laboratory premises. A similar letter was requested when the HFA wished to remove the histology records and slides from the premises. Copies of these letters are produced as **BJL/MEDH/0009**.
55. Subsequently, the HFA contacted Janet Willson, the manager of Medlab Gisborne, and arranged to collect certain laboratory records, cervical smear slides and then later, the histology slides and reports. This was in order for the HFA to be able to organise the re-screening of cytology tests taken from 1991 to 1996 and breast histology from 1989 to 1996 which had been carried out by Dr Bottrill.
56. In the course of this Inquiry our staff at Medlab Gisborne, and to a lesser extent, Hamilton, have spent many hours locating slides and assisting HFA representatives in this process, as well as following up on correspondence and other communications. This has been an enormous task for the small number of overworked staff who have had to deal with the issues. It has been unpaid work and generally unappreciated, although we were gratified to receive official acknowledgement and a letter of thanks from the Health Funding Authority (“HFA”). This is produced as **BJL/MEDH/00010**. Also, a letter to The Editor of the Gisborne Herald paid tribute to the assistance provided by Medlab Gisborne staff in the course of this investigation. A copy is produced as **BJL/MEDH/00011**.
57. All lawful requests for patient reports or slides have been dealt with promptly by Medlab staff and all responses were well within the minimum period of time prescribed by the Privacy Act.

58. Medlab has also responded to all requests for other patient information. To the best of my knowledge, all information relevant to this inquiry has been disclosed.
59. Throughout the whole exercise Medlab has been very concerned for the women affected. We have been concerned, not only for those who may have been specifically affected by an error in laboratory reporting, but also for all those women who have been unnecessarily alarmed by the enormous publicity generated by the affair.
60. Consequently, while we have had no involvement in, or responsibility for, the alleged under-reporting of cervical smears in Gisborne, we have contributed an enormous amount of time in endeavouring to assist resolving the issues.
61. The Sydney laboratory contracted to re-screen the cervical slides by the HFA re-numbered the slides in such a way that the old Gisborne Laboratories Ltd numbering system was obscured. Medlab Gisborne is now concerned that this re-numbering may make it difficult to reconcile our laboratory records, once they are returned by the HFA, with the re-read slides. This may be of importance should there be any legal proceedings resulting from the HFA's re-screening programme, or other requirements to revisit the slides. This problem will be much worse when our present senior staff are no longer available e.g. when they leave.
62. At the present time the slides have been returned by the HFA, but the laboratory records have not. Medlab Gisborne is therefore not currently able to reconcile the slides and the records. It is anticipated that the records will be returned once the HFA have collated and analysed all of the results.
63. We would like to acknowledge the excellent co-operation and working relationship which developed with the HFA personnel, in particular, the Gisborne Co-ordinator, Marie Burgess. It was as a result of her recommendation that the Christchurch laboratory which was contracted to re-screen the breast histology did not obscure the original numbering

system.

EFFECT ON COMMUNITY LABORATORIES OF THE GISBORNE INQUIRY

EFFECT ON COMMUNITY LABORATORIES OF THE GISBORNE INQUIRY

64. Over the last few years, and especially since this issue of cervical smears in Gisborne became a matter of national news media attention, histologists and cytologists throughout the country have become extremely sensitive about their reporting. I have found that some are reluctant to have anything to do with work from Gisborne and those that do endeavour to have all their opinions checked by at least one other pathologist. Quality assurance procedures in screening have been stepped up and the amount of time spent in re-screening (and checking) has increased considerably. The number of histology slides referred for consultant opinion, including specialist overseas consultants, has increased considerably. In Medlab it is now approximately 30 per month, only a few years ago it would have been in the order of a few per year. The overall effect of this is that productivity, measured in terms of the number of reports per unit of professional time and dollar cost, has decreased considerably (or conversely the cost of producing each report has increased considerably).
65. The extra costs that are particularly associated with increased quality in Cytology include extra technologists time in screening slides, extra senior technician's time spent checking slides screened by someone else, extra time by the Pathologist spent checking the slides screened by technicians, extra time spent by Pathologists's getting second opinions, extra time locating and examining previous cervical smears and any relevant histology, and demands from anatomic pathologist's for increased remuneration as recognition of increased stress and increased likelihood of being involved in disciplinary or legal actions as a result of error. All of these factors combine to make anatomic pathology service very costly and relatively much more expensive than it was only a few years ago.
66. In our laboratory the number of slides screened by the primary screener has dropped from

about 80 per day in 1993 to 40 per day or less currently. In addition, the checking procedures have increased considerably. In 1993, 10% of the slides were randomly selected for re-screening, but now all slides are re-screened (including all normals) by a second screener although the second screen is somewhat more rapid than the first. All abnormal or questionable cells are identified and marked for subsequent checking by a senior cytotechnologist and, if confirmed to be abnormal, passed on to a pathologist for further checking and reporting. This process is according to the guidelines published by the Advisory Committee on Cytology. All of this means that productivity is now about half or less than what it was a few years ago.

67. Also the enormous publicity generated by this enquiry is adding considerably to the professional stress placed upon pathologists. Anatomic pathologists, in particular, feel they are under a national spotlight and every diagnosis could be the subject of a future court case. As medicine is not an exact science and an anatomic pathology diagnosis is, essentially, an opinion, most anatomic pathologists consider the pressure they are currently placed under quite unreasonable. The effect of this on recruitment and retention of pathologists should not be underestimated.

SUBMISSIONS AND RECOMMENDATIONS

Small Laboratories

68. Medlab's philosophy regarding the operation of smaller laboratories is that it is extremely difficult, if not impossible, to run a small laboratory in complete isolation and still achieve acceptable levels of quality and professional service. It is our belief that small laboratories need to have a close association with a larger laboratory so that they can share in the quality assurance programmes, continuing education, peer review, support and supervision by senior specialised technologists, scientists and pathologists. All of this flows from the association of having a critical number of professionals working together. In more practical terms, and with reference to cervical screening, I believe that unless a laboratory is examining a certain minimum number of slides per year it should send the work elsewhere. Various figures have been published and, I am sure will be available to the inquiry, but, in my opinion, I believe that it should be about 20,000 per year.
69. Also I believe it is dangerous for a pathologist to work in professional isolation. The two major public concerns relating to Pathology - Gisborne and Waunganui - both involved Pathologists who either for geographical or for personal reasons worked in professional isolation. I believe the same factors are true in other branches of medicine. With particular regard to pathology I consider it most important that a Histopathologist should have easy access to colleagues so that slides can be easily referred for another opinion. If a Pathologist is geographically isolated then this sort of consultation can only occur by physically sending the slides to another laboratory and so the threshold for this to occur will be much higher than if such referrals can occur within the same building. Sub-specialisation (i.e. specialising in a particular branch of anatomic pathology e.g. gynaecological pathology, or bone pathology etc.) now make such referrals a lot more important than in previous years. The current extent to which sub-specialisation is now the norm in a modern laboratory requires a pathologist to have easy access to colleagues in other sub-specialties.

70. On the other hand, this does not mean that small laboratories (e.g. by working closely with a large laboratory) are not capable of achieving excellence or, conversely, the quality of large laboratories can be taken for granted, or that either the public or private sector has a monopoly on quality. It is, perhaps, worth remembering that the whole issue of cervical screening, as a matter of public interest and concern, began in a major public hospital considered a centre of excellence.
71. Quality can be achieved in any laboratory by an ongoing commitment to the process but does require certain prerequisites. This may include minimum volumes of work or associations with a larger laboratory. And we should remember that even with a good quality system in place mistakes will still occur.

Shortage of Pathologists

72. There is also, in my view, a serious shortage of pathologists in New Zealand. This is particularly noticeable in anatomic pathology. As the Director of a major laboratory I am particularly aware of that shortage at the moment. In my view a major cause of that shortage is the current structure of the public hospitals. In practice, all young doctors seeking training in pathology have to secure a registrar training position at a public hospital. With the focus on business objectives that has been characteristic of the public hospital system over the last few years, registrar training posts are often seen as expensive luxuries which do not contribute to the short term profitability of the laboratory and hospital. Consequently, the number of training posts available for pathology registrars has been, in my view, insufficient in recent years to maintain an adequate supply of suitably trained pathologists.
73. Added to this is the fact that overseas posts for pathologists are often more attractive, both financially and professionally, than those available in New Zealand, and we have a situation which is rapidly approaching crisis point.

74. Some years ago there was a large section, headed by Dr George Salmond, in the then Department of Health concerned with medical workforce planning. This section was disbanded and does not seem to have been replaced, although I understand the present Government is relooking at this issue.
75. I believe it is essential for Government to address medical workforce planning issues and, in particular, workforce planning for pathology as a matter of urgency.
76. Similarly there is also a shortage of trained technical screening staff in cytopathology. I believe the reasons for this also need to be addressed as a matter of national urgency.

Advisory Committee on Pathology Services

77. It is my belief that Government needs easy and regular access to expert advice on matters relating to pathology. This could be achieved by the establishment of an Advisory Committee, say, a National Advisory Committee on Pathology Services, which would have the responsibility to advise Government on all matters relating to pathology services. Such committees have existed in the past and I was a member of one - The Consultant Advisors in Pathology - which existed in the 1970s. As far as I am aware it was never formally disbanded but it simply stopped meeting. I believe the committee served a useful purpose and more than justified its existence. One of its recommendations was that Government should endorse the concept of Telarc/IANZ accreditation for medical laboratories. This recommendation was adopted and was, I believe, a very important factor in ensuring that the present accreditation scheme was generally accepted, although it was originally voluntary.
78. If such a committee is re-established I also think it is important that it should be given sufficient status and authority that its advice is not easily discarded or ignored. For example, when hepatitis C testing became available, various professional bodies, including the NZMA, recommended that hepatitis C testing be introduced for routine testing of blood for transfusion purposes. This advice was not accepted, although it could be argued that

subsequent events proved that it should have been.

79. The mere availability of expert advice e.g. from professional bodies or advisory committee's, does not mean that it will be accepted. In fact in my experience, it is very likely to be rejected as simply representing 'vested interests'.
80. In her evidence earlier in this inquiry Dr McGooghan expressed disbelief that advice from a formal advisory committee system could be disregarded and said that it was "unthinkable" in UK practice for this to occur.
81. The role of such a committee could also include the endorsement and ratification of IANZ standards for accreditation {cf NPAAC (National Pathology Accreditation Advisory Committee) ratification of NATA (National Association of Testing Authorities - Australian equivalent of IANZ) Standards in Australia}.
82. If such an Advisory Committee is re-constituted, I believe it should include at least four pathologists, one from each of the major sub-specialities (Anatomic Pathology, Haematology, Microbiology and Chemical Pathology) and two should be from the public sector and two from the private sector. This is the minimum number of pathologists necessary for the committee to have credibility with regard to technical/professional matters.
83. It is also essential that an advisory committee of this nature should be adequately resourced with sufficient funds to meet on a regular basis and have access to secretarial and administrative support. Without this, and the authority and status referred to above, a committee is not able to function effectively and becomes little more than window dressing.

Role of the Profession

84. The view has been expressed that the medical profession should have done more in ensuring

quality service from its members. Since the enactment of the recent Medical Practitioners Act which came into force on 1 July 1996 the New Zealand Medical Council has had the power to require evidence of competence from doctors renewing registration. I understand that the Medical Council is performing this function by requiring participation in the various college continuing education programmes. For Pathologists this is the RCPA continuing professional development programme (CPDP) which is available to all Pathologists whether or not they are members of the RCPA.

85. The old Medical Practitioners Act also gave the Medical Council power to discipline doctors (including removing their name from the register) but, in practice, this was confined to cases of a disciplinary nature or when there was evidence of incapacity on health grounds rather than incompetence alone.
86. It is my belief that the Medical Council operating under the present act will be a lot more active in requiring evidence of competence. Doctors are being held accountable for their professional conduct.
87. The ability of the profession's Ethics Committees to control the conduct of members has been extremely limited since the enactment of the Commerce Act. Shortly after the enactment of this act the Commerce Commission demanded copies of all NZMA central and district ethical committee's minutes and correspondence and, while I do not recall all of the details, I do remember that the NZMA was required to change a number of its ethical rules. Perhaps even more important than the actual requirements and prohibitions of the Commerce Commission regarding the functioning of the NZMA's ethics committee's was the message sent to doctors acting on those committees. In effect the message was "society (or at least the Commerce Commission) was not interested in self regulation which it sees as anticompetitive and you will end up in serious trouble if you do anything which the Commerce Commission thinks you should not do". When the NZMA endeavoured to have meetings with the Commerce Commission to establish exactly what the Commerce Commission considered was, and what was not, acceptable the Commerce Commission would not agree to such a meeting. Shortly afterwards District Ethics Committee's were

disbanded and the Central Ethics Committee has largely confined itself to giving advice. Consequently the ability of the profession to enforce ethical matters or address breaches of ethics which in themselves do not constitute an offence under the Medical Practitioners Act, is now very limited.

88. I would suggest, however, that the most effective method of ensuring laboratories are accredited (and this now includes ensuring that the pathologists are involved in the RCPA CPDP) is for the HFA, or Ministry of Health, to require and enforce accreditation as part of its contract with all laboratories. This should apply to hospital as well as community laboratories.
89. Draft Standards drawn up by a group consisting of representatives from the RCPA, IANZ and HFA have never been finally accepted mainly, I understand, because the HFA would not accept the same standards had to apply to all types of testing, including those performed outside laboratories (near patient testing). The standards included in the Midland RHA contract with Medlab Gisborne (**Appendix 5**) are still specified as "draft". (See exhibit **BJL/MEDH/0002**).

Cost of Quality

90. Public expectations for quality in the health service are now extraordinarily high, and in my view, often exceed the capabilities of medical science. Unlike other branches of science, medicine is not an exact science and failures of the system to deliver outcomes up to expectation will always be present. Quality, in terms of outcomes, is, however, constantly improving and will come about from a number of factors, including developments in technology but, in a laboratory they will often be achieved by the establishment of effective Quality Assurance Programmes. This will include measures covering everything from staff training and management systems through to product checking. All of these things are covered in IANZ accreditation, but they all cost money and add to the final cost of

producing a laboratory report. This is seldom acknowledged by funders or purchasers of health services. I feel that often there is a naive belief on the part of government and its agencies that better quality health services will occur if only health professionals would "take more care", or "not be negligent".

91. While it is certainly true that failure in healthcare delivery will occur from culpable medical error, and there will be some gain in the quality of health delivery if these errors are eliminated, but overall far greater improvements in health delivery will be achieved if the average standard of practice of all health professionals is improved just a little. This is the main objective of a quality system and, I believe, this is what it does achieve. But at a cost. In our laboratory the technician time involved in screening cervical smears has more than doubled since 1992. Other costs including reagents, have also increased. While some of these have been due to "normal" increases in costs, a very large proportion has been due to the extraordinary costs associated with increased demands for quality. For example, smertakers now often send in two slides from each patient in an endeavour to ensure they have not missed the lesions. Currently, we average 1.3 slides per patient. Checking procedures now include the full screen by one cytotechnologist, then each slide is "step screened" (a more abbreviated screening process). In addition, suspicious slides are shown to a senior cytotechnologist and anything considered abnormal is referred on to the pathologists. As well as the screening procedures there is considerable extra work involved in checking previous slides and in complying with the various requirements of the National Cervical Screening Programme. All of these factors result in a considerable increase in the time (and cost) involved to process a single patient.
92. Failure of the funding authority to recognise the increased costs in providing laboratory services means increased pressures on laboratories to achieve efficiencies where ever they can be found. Taking short cuts in quality procedures is an easy way to reduce laboratory costs and, like cutting costs by not paying insurance premiums, may not lead to any immediate problems or be immediately apparent.

93. Unless laboratory services are adequately funded and this includes recognising increased costs due to increased quality requirements, it is inevitable that there will be an almost irresistible temptation to reduce costs by reducing quality measures.

Cost of Competition

94. The health reforms initiated by the previous Government produced an environment which stimulated and encouraged competition in the health industry. I understand that this was with the intention that competition would lower prices as it does in some commercial activities although how this was to be achieved with a fixed schedule of prices is not clear. Competition, however imposes considerable extra costs on a laboratory and this is particularly evident in the cost of collection services where competition can force one laboratory to match the service provided by a competitor even though a logical assessment of the medical requirements might see even one collection facility as excessive. This adds unnecessarily to the cost of laboratory services and means that less money is available for other functions such as providing quality. Also, one way or another, these costs are eventually met by the taxpayer.
95. Prior to the abolition of the old Department of Health, entry into the community pathology market was at the Minister's discretion and entry was regulated to meet the perceived needs of a given area. In this way excess capacity and unhelpful competition was avoided.
96. It is my opinion that competition and market forces are not good methods for providing effectiveness and efficiency in the health industry. I believe medicine functions more effectively in a co-operation rather than in a competitive environment.

HFA and Quality

97. Since the mid 1970s, I have been involved at different times and to a variable extent in

negotiations with government and its agents concerning the funding of community laboratory services. In the 1970s and 80s I was a member of a committee of the New Zealand Society of Pathologists which represented the community laboratories in negotiations with the then Department of Health and, in more recent years, I was a representative as one of the laboratories in negotiations with Midland Regional Health Authority, and its subsequent evolution as the Regional Branch of the Transitional Health Authority and later the Health Funding Authority.

Government has always paid lip service to the concept of purchasing on the basis of both quality and price. The Midland Regional Health Authority contract for the Purchase and Provision of Medical Laboratory Services for the period beginning 1.11.96 states:

" E16 National Medical Laboratory Quality and Service Standards

National medical laboratory quality and service standards currently being developed will become part of this Contract and will be attached as Appendix 5 to the Contract on their completion." (See exhibit **BJL/MEDH/0002**)

These standards were never formally adopted.

98. The very recent (14.03.00) amendments to that contract in the Midland Region has an addition regarding quality in cervical screening and an increase in the fee. But over the approximately 25 years that I have had contact with government negotiators on this issue, I cannot recall any other instance where there was an acceptance that quality had a price which needed to be identified and recognised in fee negotiations. Always there was the assumption that no matter how low the fees were kept, quality would still be maintained and could be taken for granted. I do not think this is either logical or practical.
99. It is my view that government and its various agencies have purchased laboratory services on the basis of price alone and have paid only lip service to quality-until some disaster becomes public knowledge. I believe that quality should become in practice, as it is in theory, a major criterion by which the government purchases laboratory services. This

needs to be recognised, both in the negotiated fee structure and in the insistence of accreditation which ensures that recognised standards are in place.

- 100. Agreed standards, including ethical standards, should be enforce.

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Brian Joseph Linehan

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Date