

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

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

EVIDENCE OF CHRISTOPHER PHILIP MULES

HEALTH FUNDING AUTHORITY

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BRIEF OF EVIDENCE OF CHRISTOPHER PHILIP MULES

I, **CHRISTOPHER PHILIP MULES** of Cambridge say:

1. My full name is **CHRISTOPHER PHILIP MULES**. I reside in Cambridge. I am a consultant in the health sector.

EMPLOYMENT HISTORY

2. I was employed by the Midland Regional Health Authority Establishment Board from September 1992 and then by Midland Regional Health Authority ("Midland") from 1 July 1993. On 2 July 1997 Midland was disestablished and all assets and liabilities were transferred to the Transitional Health Authority ("THA"). The region for which Midland was responsible is now a locality for which the Health Funding Authority ("HFA") has responsibility. The HFA replaced the THA on 1 January 1998.

At Midland I was employed in the following positions:

- a. From September 1992 to March 1994, as General Manager - Planning & Development I was responsible for strategic and business planning, needs assessment, service specification, and communications.
- b. From April 1994 to February 1996, following a management restructuring, as General Manager, Family Health Services I was responsible for purchase of primary care and related services (including general practice, pharmaceuticals, and laboratory, maternity, child health, women's health and dental

health services), together with public health services from July 1995.

- c. From February 1996 to July 1996, I was General Manager, Strategic Projects.
 - d. From July 1996, I was Chief Executive of Midland until 1 July 1997.
 - e. I was Regional Manager of the THA from July until November 1997.
3. Since then I have been employed in London by a United Kingdom based marketing services company. I returned to New Zealand in December 1999 and am currently a consultant in the health sector.

SCOPE OF EVIDENCE

4. In this evidence I will provide the Inquiry with an overview of the relevant history of Midland and the THA. My evidence includes observations which are not made from my first-hand knowledge. In preparing this Brief of Evidence I have reviewed a number of HFA (Midland) files and discussed matters with other former employees of Midland and the THA.

BACKGROUND

5. Prior to the creation of RHAs I was the General Manager of the Bay of Plenty Area Health Board. In that capacity I was involved in the health reform process. I undertook work for the Health Reforms Directorate of the Department of Health (which later became the Ministry of

Health) which was responsible for developing the policy relating to the establishment of the RHAs, and the National Interim Provider Board which was responsible for the restructuring of Area Health Boards (“AHBs”) to Crown Health Enterprises (“CHEs”).

6. The health reforms were driven primarily by recognition of the need for greater accountability to consumers and to the public for expenditure and quality. Although the AHBs were accountable for their expenditure and quality, and were required to provide services within capped budgets, other publicly funded health and disability service providers were generally not accountable in this way.
7. One of the major health policy challenges was how to gain control of expenditure in the so-called demand-driven areas of general practitioner services, maternity services, pharmaceuticals and private laboratory services which essentially operated on a fee for service basis and which were experiencing significant growth in expenditure. This uncontrolled growth in turn created difficulties in making policy decisions as to where funds for health and disability services should be directed.
8. It was perceived that this funding difficulty would only worsen as the capacity of the health and disability system to deliver services continued to increase with technological developments. The public purse did not have the capacity to support continued unplanned growth in expenditure, and it was concluded that an agency was needed to gain control of expenditure growth, and work with communities to make the necessary resource allocation decisions.
9. Concurrent with this focus on financial matters, there was an equal focus on encouraging providers to be accountable for service quality in terms of both responsiveness to the needs of their patients/clients, and for the technical aspects of their services.

10. This was embodied in the so-called “*purchaser/provider split*”, which allowed providers (including CHEs) to concentrate on efficient and effective service delivery while purchasing agencies (the four RHAs and, until 1995, the Public Health Commission) were able to make resource allocation decisions and encourage improved accountability for both quality and efficiency through contractual relationships with providers.

FRAMEWORK FOR LABORATORY SERVICES INHERITED BY THE RHAs

11. When Midland became fully operational (from 1 July 1993), public laboratory services (primarily relating to testing for inpatients and outpatients) were provided in the Midland region by six CHEs - based in Hamilton, Tauranga, Whakatane, Rotorua, Gisborne and New Plymouth. Further public laboratory services were provided by CHEs in Auckland and elsewhere for complex, unusual and expensive diagnostic tests that were not on the laboratory benefits schedule (and hence private laboratories could not claim payment for them) and which were not and/or could not be performed in Midland’s region. I discuss the laboratory benefits schedule later in my Brief.
12. Private laboratory services were provided in Midland Health’s region by six providers – based in Hamilton (2), New Plymouth, Gisborne, Rotorua and Tauranga. Further private laboratory services for patients residing near the borders of Midland Health’s region were provided by laboratories in Auckland. By “*private laboratory services*” I mean the providers were not publicly owned (that is, they were not owned by the Government), although the bulk of their revenues were derived from public funds. Private laboratories refer to themselves as “*community*

laboratories” (and I refer in my Brief to the private laboratories in the Midland region as “the Providers”).

13. The Providers had developed to meet the increased demand for pathology services which could not be handled by the hospital (or public) laboratories. Providers grew and became very significant businesses, with the most of their work originating with general practitioners and private specialists. The Providers were generally owned by pathologists, some of whom were also likely to have part-time positions in public laboratories.
14. The total national spending on private laboratory services when the RHAs were established was approximately \$160 million.
15. The Providers operated on a fee for service basis, claiming from the Health Department’s Benefits Payments Office in accordance with a “*schedule*” that listed the tests for which payment could be claimed. The amount of the payment was prescribed in the schedule alongside each test, together with certain restrictions.
16. The level of fee for each test had been set historically. Since that time technology had changed and in many cases the fees paid for each test no longer bore a direct relationship to the unit cost of providing the test. Payments for some tests were probably too high in relation to costs, while others may have been too low.
17. The Department of Health’s fee for service arrangements were enshrined in regulations made pursuant to the Social Security Act 1964.
18. The schedule was referred to in the regulations and was revised from time to time by the Minister of Health both in terms of the tests included within the schedule and the level of the fees paid to the

Providers in respect of those tests. I produce a copy of the schedule which was in force when the health reforms were given effect as **CM/HFA/0001**.

19. The arrangements for quality standards and monitoring were essentially self imposed by laboratory service providers through their professional and business representative bodies. I believe the Department of Health did not have systems in place to monitor or audit the quality of the services provided, nor in fact the schedule payments made for laboratory services.
20. Membership of the Association of Community Laboratories (“ACL”) was available to private laboratories and the ACL had ethical rules regulating the conduct of its members. A requirement of those ethical rules was that members be accredited (or have applied for accreditation) by TELARC or an equivalent accreditation body and that the accreditation body monitored the quality of the systems used by the Provider. I produce a copy of the ACL Ethical Rules as **CM/HFA/0002**. Those Ethical Rules were adopted by ACL on 25 March 1993 and amended on 11 August 1994.
21. Pathologists (including those working in both private and public laboratories) required specialist recognition by the Medical Council of New Zealand (“MCNZ”). They could be members of the Royal College of Pathologists in Australasia (“RCPA”) and/or the New Zealand Society of Pathologists (“the Society”). These bodies regulated the professional standards of their members.
22. I understand that some quality standards were developed by the Department of Health in conjunction with the Cytology Liaison Committee for laboratories performing cervical screening services as part of the National Cervical Screening Programme (“NCSP”). The NCSP is discussed in more detail later in my evidence.

THE STATUTORY FRAMEWORK

23. The Health and Disability Services Act 1993 as originally enacted (“the Act”) provided for the creation of RHAs to perform the function of purchasing health and disability services in accordance with Funding Agreements entered into between the Crown and the RHAs. The sections of the Act I refer to below are set out in the terms they were originally enacted and which were current during my employment by Midland.
24. The Act required the Minister of Health to notify the RHAs of the Crown’s objectives and to enter into Funding Agreements with the RHAs. The RHAs were required to purchase health and disability services to meet the Crown’s objectives to the extent enabled by the Funding Agreements. The scope of services purchased by Midland and the other RHAs included:
- a. Personal Health Services: Primary Care Services; Pregnancy and Childbirth Services; Dental Health Services; Primary Diagnostic; Therapeutic and Support Services; Secondary and Tertiary Medical Services; Secondary and Tertiary Surgical Services; Mental Health and Drug and Alcohol Services;
 - b. Disability support services;
 - c. From 1996 onwards, public health services.
25. Section 19 of the Act provided that the RHAs should:

“... purchase services only from persons who maintain standards (including ethical standards) that the purchaser considers appropriate for those services.”

26. Section 22(2) of the Act provided that:

“Each purchaser [RHA] may from time to time-

- (a) Negotiate and enter into purchase agreements containing such terms and conditions as may be agreed; and*
- (b) Monitor the performance of each purchase agreement”.*

27. Midland and the other RHAs were subject to onerous statutory obligations to consult. Section 34 of the Act provided that:

“Every regional health authority shall, in accordance with its statement of intent, on a regular basis consult in regard to its intentions relating to the purchase of services with such of the following as the authority considers appropriate:

- (a) Individuals and organisations from the communities served by it who receive or provide health services or disability services:*
- (b) Other persons including voluntary agencies, private agencies, departments of State, and territorial authorities.”*

28. The Minister of Health issued annual Policy Guidelines for RHAs which set out the Crown’s objectives and the principles to be applied to purchase decisions as required by Section 8. Those principles are:

- a. Equity;
- b. Effectiveness;
- c. Efficiency;
- d. Acceptability;

- e. Safety; and
 - f. Risk management.
29. Midland developed annual purchasing plans in response to the provisions of the Act and the Policy Guidelines. These purchase plans were then approved by the Minister and Ministry of Health and relevant sections of these were incorporated in the Funding Agreements as schedules. The annual Funding Agreements created contractual obligations for the RHAs in relation to purchase decisions.
30. Midland's total budget for the year ending 30 June 1995 was approximately \$900 million. The budget for laboratory services purchased from Providers was approximately \$25 million or 2.7% of the total.

FUNDING AGREEMENT PROVISIONS RELATING TO LABORATORY SERVICES

31. The 1993/1994 Funding Agreement essentially required Midland to maintain the laboratory services which were available in 1992/1993. I produce an extract from the 1993/1994 Funding Agreement as **CM/HFA/0003**.
32. The 1994/1995, 1995/1996 and 1996/1997 Funding Agreements essentially required Midland to purchase laboratory services which were to be available within certain distances and to be provided free of charge. I produce an extract from the 1994/1995, 1995/1996 and 1996/1997 Funding Agreements as **CM/HFA/0004** to **CM/HFA/0006**.

SECTION 51 NOTICES

33. The health reforms aimed to change the basis for purchasing of health and disability services to utilise purchase agreements (contracts) to encourage greater accountability for use of public funds in providing efficient and high quality services. However, in order to preserve continuity of services RHAs used Section 51 of the Health and Disability Services Act 1993 to issue Notices to providers stating the terms and conditions under which they were entitled to receive payment for services rendered. If after a notice was given a provider claimed for payment then the provider was deemed to have accepted the terms and conditions of the Notice.
34. The Section 51 Notices were intended to operate only as a transitional device until such time as more appropriate contracts for service could be negotiated. This intention was documented in the Policy Guidelines eg. page 22 of the 1994/1995 Policy Guidelines:
- “RHAs should work towards developing proposals to replace section 51 notices when they expire.”*
35. I produce a copy of the 1994/1995 Policy Guidelines as **CM/HFA/0007**.
36. Section 51 Notices were issued to pathologists who were operating private laboratories at 1 July 1993 when the RHAs assumed responsibility. The Notices were generic, that is they were consistent nationally.
37. The laboratory Notice issued by Midland (and the other RHAs) substantially reflected the prevailing regulations that governed the provision of private laboratory services under the Department of

Health, with some changes to reflect the requirements of the new legislation and the Funding Agreement between the RHA and the Minister of Health. This enabled the status quo to prevail during the transition to purchase agreements allowed by Section 22 of the Act. I produce a copy of the covering letter and the Section 51 Notice which was sent to pathologists as **CM/HFA/0008** and **CM/HFA/0009** respectively.

38. A Section 51 Notice was sent to Dr Bottrill who was the pathologist at the Gisborne private laboratory which was called Gisborne Laboratories Limited (“GLL”).
39. The schedule attached to the Section 51 Notice was the same schedule as applied under the regulations, except I believe that subsidy levels had been increased uniformly by 5% by the Minister of Health in the final review under the old regulations. The schedule included cytological examination of cervical smears with a fee of \$16.50 per examination.
40. Under the Section 51 Notice payments to pathologists were to be made by Health Benefits Limited (“HBL”), a company jointly owned by the four RHAs, that was formed when the RHAs took over the Benefits Payments Office from the Department of Health. The Board of HBL comprised the Chief Executive Officers of each of the four RHAs, together with an external chairman.
41. HBL undertook monitoring of claims for payment by providers.
42. The Section 51 Notice allowed for pathologists intending to provide laboratory diagnostic services to do so by notifying the RHA in accordance with clause 5 of Schedule 3. All that was required by the notification provisions was an indication of the intended place of practice and the date from which the pathologist intended to start

practice. Once that information was received the RHA would issue the pathologist with a claim number to be used on all claims to HBL. This information was already known to the RHA for existing providers.

43. Section 51 Notices were essentially introduced to enable the current situation to continue. The concluding sentence in the covering letter under which the Section 51 Notice was sent to pathologists (CM/HFA/0007) read:

“In summary this section 51 notice reaffirms that it is ‘business as usual’ from 1 July 1993.”

44. The only quality requirements were that the pathologist be registered under Section 39 of the Medical Practitioners Act 1968 as a specialist pathologist; and that appropriate equipment was available to be used in the laboratory. In issuing Section 51 Notices, Midland and the other RHAs therefore relied on professional qualifications and self-regulation to maintain standards.

45. GLL was a member of ACL and Midland relied on that membership and the obligations under ACL’s ethical guidelines.

46. Dr Bottrill was a Fellow of the RCPA and Midland relied on that membership and the professional standards imposed by that membership.

47. The Section 51 Notice did allow the Board of the RHA to refuse to give recognition to a pathologist under clause 3 of Schedule 2 having regard to:

“3.1.1 The personal qualifications of the applicant and an assessment of the apparatus and equipment available for his or her use, made with reference to the standards for registration by TELARC or a similar certifying authority; and

3.1.2 *Any considerations that in the opinion of the Board of the Regional Health Authority would make the recognition of the applicant contrary to the public interest.”*

48. I deal with the application of this clause later in my Brief.
49. Any complaint or dispute arising in relation to any benefits, fees or subsidies could be referred to an Advisory Committee constituted under clause 6 of Schedule 3 of the Section 51 Notice. The Midland Health Pathology Advisory Committee was never required to consider any complaints or disputes.

RHA LABORATORY SERVICES PURCHASING STRATEGIES

50. As noted above, one of the many tasks of Midland identified in the purchase plans and Funding Agreements was to address the issues of expenditure and quality which existed in the private laboratory area, in order to assure service quality and enable services to be provided within Midland’s finite budget. The 1994/1995 Policy Guidelines provided at page 21:

“Control of growth in demand-driven expenditures is of paramount importance. When RHAs are unable to make savings in this area of currently uncapped growth, there will be pressure on the RHA resources for other services.”

51. The cost to the public purse of Provider services had been escalating due to:
- a. Fee increases to schedule tests;
 - b. Addition of new tests to schedule; and
 - c. Growth in the volume of services demanded and provided.

52. During 1993 and 1994 discussions within Midland took place regarding the rapid growth in spending on Provider services. Figures made available to Midland by HBL suggested that cumulative annual growth was around 12% per annum, making private laboratory services one of the fastest growing areas of expenditure for the new RHA. Midland's laboratory expenditure per capita was higher than that of the other RHAs and was increasing at a higher rate.
53. At that time the RHAs generally operated independently (particularly with respect to contracting as the Commerce Act governed our activities) and Midland determined that it needed to consider new purchasing arrangements for these services that would ensure its financial and quality risks were managed in accordance with its statutory obligations and the requirements of its Funding Agreement with the Minister of Health.
54. Midland recognised two aspects to controlling expenditure - demand side (relating to the requests made for laboratory services) and supply side (relating to the payments made for laboratory services).
55. Midland implemented strategies intended to address the demand side issues – for example, by providing general practitioner groups with the opportunity to manage budgets for the laboratory tests they ordered. This was encouraged by the Minister as documented in the Policy Guidelines eg. page 22 of the 1994/1995 Policy Guidelines:
- “The Government expects that RHAs will use a variety of approaches to contracting with general practitioners, including budget-holding.”*
56. Midland actively pursued development of budget holding, and by the 1995/96 year 25% of the approximately four hundred general

practitioners in the Midland region were participating in some form of budget holding for laboratory services.

57. Midland also recognised that (on the supply side) pathology and laboratory services required review and the prices to be paid for schedule tests were likely to need adjustment.
58. On 23 July 1993 I wrote to stakeholders in the Midland region advising them that a review would be undertaken. I produce a copy of my letter as **CM/HFA/0010**. I produce a list of the stakeholders to whom it was sent as **CM/HFA/0011**.
59. At the time Midland was addressing these issues, we did not have any specific concerns about the quality of Provider services but did have general concerns that the Section 51 Notices did not provide an appropriate framework for emphasis on quality improvement and monitoring. The Policy documents stated that this was to be encouraged by the RHAs eg. page 36 1994/1995 Policy Guidelines:
- “RHAs are to encourage the providers they enter into purchase arrangements with to participate in quality improvement processes which are culturally effective. This may include accreditation.”*
60. Midland believed this could be better addressed in contracts for service than in revision of Section 51 Notices.
61. Midland developed a generic approach to quality improvement which formed part of its contracting strategy. That approach was to require providers to develop quality improvement plans. This approach is described in an attachment to the 1994/1995 Cervical Screening Service Requirement Definition which is produced later in my evidence as **CM/HFA/0037**.

62. For those reasons Midland was eager to move from Section 51 Notices to the negotiation and implementation of contracts with each provider.

TRANSITION FROM SECTION 51 NOTICES TO CONTRACTS WITH INDIVIDUAL LABORATORIES

63. Mr Kirk Wakem was responsible for managing Midlands' transition from purchasing of laboratory services using Section 51 Notices to the implementation of individual contracts with the Providers.
64. Mr Wakem was responsible for developing and issuing proposal papers from Midland for consultation with the Providers and other interested parties, and for conducting negotiations with the Providers to achieve the implementation of individual contracts reflecting the principles as outlined in the Funding Agreement. The majority of the consultations and negotiations were with ACL which represented the interests of the six Providers who were all members of ACL.
65. From the outset of the project ACL interposed itself between the Providers and Midland, which made it difficult to develop a clear picture or understanding of the circumstances of individual laboratories. An example of this arose during an initial analysis of laboratory services carried out for Midland by Deloitte Touche Tohmatsu ("DTT"). A questionnaire was sent to the Providers. The ACL responded on behalf of the Providers and indicated that it would provide Midland with only aggregated results.
66. Initial consultation led to a meeting between ACL and Midland on 28 February 1994 when objectives to guide further consultation and contracting were agreed. I produce a copy of the list of agreed objectives as **CM/HFA/0012**. Those objectives were:

- “(i) *Ensure that appropriate high quality services are available throughout the region.*
- (ii) *Purchase laboratory utilisation levels consistent with high quality requirements and cost efficiency within a capped budget for the RHA as a whole.*
- (iii) *Manage expenditure on laboratory service [and] transfer [any] savings as an outcome of this management into other health services.*
- (iv) *Develop a process [and] manage the volume of tests as an outcome of benchmarking laboratories and GP/Specialist referral rates, together with appropriate education programmes to encourage the levels of laboratory tests to be at an ‘optimum’ level.*
- (v) *Develop purchasing strategies that ensure a competitive market and competitive prices driven by providers of laboratory services.*
- (vi) *Develop in the medium term fund holding schemes (or in the short term incentive schemes for optimal testing) for primary and specialist outpatient services, and continue use of laboratory – inclusive contracts for hospital services.”*

67. A protracted period of consultation and negotiation followed. The obligation to consult was taken seriously by Midland. Midland prepared issues and directions papers and received submissions from interested parties including ACL. ACL was essentially opposed to the development of a contestable market and made every effort to protect the commercial interests of its members. It was this issue of contestability that was a major factor in delays to implementation of contracts. ACL made a number of Official Information Act requests which were complied with. ACL made a complaint to the Ombudsman which led to an inquiry. ACL also threatened litigation on a number of occasions and I understand some of those materialised with proceedings being issued against Midland and the HFA.

68. The Providers were not opposed in principle to the quality standards requirements proposed by Midland. The major issues which required resolution before the Providers would agree to enter into contracts were economic rather than related to quality.
69. Midland had no reason to question the quality of the services it was purchasing but was, as mentioned earlier in my Brief, trying to encourage a commitment to quality improvement by Providers.
70. The early discussions between ACL and Midland regarding quality standards contributed to the initiative to develop national quality and service standards for medical testing laboratories. The development of the standards is discussed by Sylvia Sax in her Brief of Evidence.
71. As a result of considering the ACL submissions on Midland's proposals, we decided that the basis for contracting which would be most acceptable to the Providers was a restricted market based on efficient pricing (to be determined using an Efficient Pricing Exercise ("EPE")).
72. Midland then negotiated with ACL the terms and conditions upon which a contract on the basis of a restricted market would be acceptable to the Providers and a contract proposal was developed.
73. The ACL confirmed its understanding of the proposal in a letter to Mr Wakem dated 26 August 1996. I produce a copy of that letter as **CM/HFA/0013**. That letter refers to an EPE at paragraph 4. The proposal was approved by Midland's Executive Management Team ("EMT").

THE ESTABLISHMENT OF CONTRACTS

74. An offer to enter into contracts with the Providers was made by Midland on the basis of a proposal approved by the Midland Board following the discussions with the Providers.
75. I produce a letter dated 28 November 1996 as **CM/HFA/0014**. This letter contained an offer based on the following components:
- a. Three year contract.
 - b. An increase of 2.5% to the prices in the schedule subject to the proviso that an EPE be carried out.
 - c. Fifteen tests added to the schedule.
 - d. Mechanism for considering additions/deletions to the schedule.
 - e. Introduction of a utilisation review programme substituted for a previously considered risk-sharing arrangement proposed by ACL.
 - f. Inclusion in the contract of the new laboratory information system requirements, business rules, HBL audit protocol, and the national medical laboratory quality and service standards.
76. The offer was accepted by all of the Providers. I produce copies of the letters of acceptance as **CM/HFA/0015**. The letter of acceptance from Medlab Hamilton Limited refers to offers and contracts plural. This is because Medlab Hamilton Limited had recently acquired ownership of GLL and contracts for both were sent to the Medlab Hamilton offices.

77. A formal contract document was prepared. The contract was submitted to the Midland Board of Directors for approval under cover of a memorandum dated 9 December 1996. I produce a copy of that memorandum as **CM/HFA/0016**. Once approved the contract was sent under cover of letter dated 23 December 1996 which stated:

“The contract is in line with the offers noted to you in our letters dated 28 November 1996 and 6 December 1996.”

78. I produce a copy of that letter addressed to Diagnostic Laboratory Limited as **CM/HFA/0017**. A letter in identical terms was sent to each Provider.

79. These contracts were executed by the parties in or about February and March 1997. The contracts were generic. I produce a copy of the contract with Medlab Gisborne Limited as **CM/HFA/0018**. I understand that Dr Bottrill retired following the sale of GLL to Medlab Gisborne Limited and before the contracts which replaced the Section 51 Notices were entered into.

80. The contract provided for quality issues. The section headed “*Service Specifications*” (Section E) noted:

“EO2 We wish to purchase community laboratory diagnostic services that:

- a. Provide patients with the best quality and most cost effective services based on established professional standards and codes of practice.*
- b. Ensure patient and staff safety.*
- c. Provide rapid results of laboratory tests and specialist pathology advice to Referring Practitioners.”*

81. It was agreed at clause E15:

“E15 We will purchase only those tests for which you have TELARC (or equivalent) accreditation and subsequent TELARC registration. You must ensure that any test which you do not provide must be subcontracted to a laboratory which has TELARC (or equivalent) accreditation and TELARC registration for that testing.

You must notify us within 48 hours if you or your subcontractor are denied TELARC accreditation and registration or if, for any reason, you or your subcontractor’s TELARC accreditation or registration is suspended.”

82. At clause E16:

“E16 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.”

83. Appendix 5 of the contract set out the draft national quality and service standards for medical testing laboratories (which are discussed in the Brief of Sylvia Sax). Midland wanted to stress the intention to include these standards as a contractual requirement as soon as they were complete.

84. The contract provided that Midland would only purchase tests for which the Provider had TELARC (or equivalent) accreditation.

85. Section F of the contract stated:

“SECTION F: ORGANISATIONAL QUALITY STANDARDS

This section describes the quality standards which you must meet when providing all of the services covered by this Contract. You will perform all services covered by this contract in accordance with:

- (a) the terms and conditions of your Telarc (or similar) accreditation;*

- (b) *the provisions of the Health and Disability Commissioner Act 1994 and the Code of Consumer Rights and Responsibilities issued under that Act;*
- (c) *all other relevant statutes, regulations and bylaws and with generally accepted standards for quality and safe practice.”*

REGIONAL LABORATORY QUALITY PRACTICES

86. Following the media publicity about the pathology problems at Good Health Wanganui (which was in the Central RHA’s region) in June 1994, Midland considered more closely the quality of the laboratory services it was purchasing and sought to identify the professionally instituted quality strategies that laboratories had in place.
87. On 17 August 1994 Dr Paul Malpass (Midland Advisor: Surgical Services) wrote to all organisations undertaking histopathology in this regard. I produce a copy of that letter as **CM/HFA/0019**. I produce a list of the recipients of that letter as **CM/HFA/0020**.
88. In respect of the laboratories in Gisborne, no response was ever received from Tairawhiti Healthcare Limited (“Tairawhiti”) although we knew that its laboratory was TELARC registered. I produce a copy of the response received from GLL as **CM/HFA/0021**. At that time, Dr Bottrill informed Midland, GLL had applied to TELARC for registration.
89. A memo was sent to me on 28 September 1994 discussing the responses. The memo noted that the response from GLL was judged to be unsatisfactory by Mr Neil Woodhams (General Manager, Hospital & Specialist Services for Midland) and Dr Malpass. I produce a copy of that memo as **CM/HFA/0022**.

90. Although GLL's response was deemed by Mr Woodhams and Dr Malpass to be unsatisfactory, Dr Bottrill had informed Midland that the laboratory was in the process of seeking TELARC registration as required by the NCSP Policy. The division of responsibility between the RHAs for laboratory standards and the MoH for quality issues relating to the NCSP are dealt with later in my Brief at paragraph 115
91. Similarly, Midland had no reason to believe that GLL was not operating within the terms of the Section 51 Notice in respect of service quality. Residents of the Midland region could (and did) raise with Midland any concerns about the quality of the services they received from contracted providers through face-to-face contact with a member of our staff (a number of whom who were based locally) or through telephone or mail. Similarly, service providers could (and did) advise Midland of any concerns they had about other providers. In addition, we contracted with the Health Consumer Trust to provide a complaints investigation and dispute resolution service throughout our region. Another avenue for receiving complaints was the management staff or Board members of Midland's joint venture with the Iwi of Tairawhiti. I am not aware of any complaints received about Dr Botrill or GLL arising through any of these mechanisms during my time with Midland that would have allowed Midland to refuse recognition in the way contemplated by clause 3 of schedule 2 of the Section 51 Notice (set out at paragraph 48 of my Brief).
92. Midland therefore had no specific cause to question the competence of Dr Bottrill. The local doctors ordering diagnostic tests from GLL (primarily general practitioners and private specialists) were in the best position to consider the appropriateness of his work. We received no complaints from them or their patients, nor from the pathologist or cervical screening manager at Tairawhiti Healthcare.

93. As an example of how Midland addressed quality complaints I refer to Midland's approach to a CHE following a complaint regarding the quality of a diagnosis performed by the hospital pathologist.
94. Dr Malpass wrote to the CHE seeking a response to the complaint. The CHE responded to that letter saying that an independent audit was being carried out and that other steps were being taken to deal with issues of professional competence. Following completion of the audit the CHE again wrote to Midland to advise that the audit showed that the error was isolated and that the patient's general practitioner had been notified of the error.
95. On 18 October following responses from virtually all the laboratory service providers in the Midland region to his letter of 17 August Dr Malpass sent me a further memo identifying and suggesting that quality programmes should be put in place including internal and external peer review to assure maintenance of pathologists' professional standards. I produce a copy of that memo as **CM/HFA/0023**.
96. On 25 October 1994 I wrote to laboratory providers seeking comments from them on a proposal to require them to instigate quality programmes which would include internal and external peer review. I produce a copy of that letter as **CM/HFA/0024**. I produce a copy of a list of addressees of that letter as **CM/HFA/0025**. A separate letter was sent to Tairawhiti Healthcare as no response had been received from them to Dr Malpass' letter of 17 August 1994. I produce a copy of that letter as **CM/HFA/0026**.
97. I received a number of responses to my letter. I produce copies of those responses as **CM/HFA/0027**.

98. One of the responses to my letter was from ACL. I produce a copy of that letter as **CM/HFA/0028**. In that letter ACL stated:

“There is strong support from all Association of Community Laboratory members both in the Midland region and elsewhere. All laboratories have intimated that they have in place appropriate programmes and if any formal statement is going to be made regarding the actual details of quality assurance programmes, a number of points need to be discussed fully. These include:-

- (1) *The need for all laboratories to be appropriately accredited in all departments including histopathology – this is a requirement of the ACL.*

...

- (2) *The mechanism of assessing the quality assurance programmes – there has been considerable concern expressed at the potential for constructing series of bureaucratic requirements which will not have much validity as far as quality control but will generate significant time and cost involvement. In this context, any thoughts of formally implementing requirements under an agreed variation of Section 51 should only be undertaken after extensive consultation with the current established providers, the Association of Community Laboratories as a whole, the New Zealand Society of Pathologists and the Royal College of Pathologists of Australasia.*

The Association is thus strongly supportive of the stated intent but would wish this to be only put in place after extensive consultation of all parties and a consensus agreement on what is likely to be productive and of value in quality control.”

99. I submitted a paper to the Midland Board following receipt of the correspondence identifying the themes of the responses and recommending that the issue of the quality requirements Midland should place on contracted laboratories be included in the terms of reference for the Pathology Policy Liaison Group (the establishment of which had been previously approved by the Board). I produce an extract from the Board paper as **CM/HFA/0029**. The Board approved my recommendations.

100. The Policy Group first met on 12 April 1995. Terms of reference were developed which noted that “*quality requirements within the purchasing of laboratory services*” were within the Policy Group’s domain of intent. Quality requirements were later considered on a national level with the development of national quality and service standards which is discussed by Sylvia Sax.
101. Midland was also concerned to understand the detail of what TELARC registration involved and sought information from TELARC. A letter was received from TELARC on 2 November 1994. I produce a copy of that letter as **CM/HFA/0030**.
102. TELARC explained that specific schedules for each field of medical testing including histology were in the late stages of development and “*should be available in early 1995*”.

PATHOLOGY SERVICES IN THE GISBORNE REGION

103. When the RHAs were established in 1993, laboratory testing on specimens referred by general practitioners was performed by both GLL and Tairawhiti.
104. This was an uncommon but not unique situation. Generally the larger CHE laboratories did not perform schedule tests, but some of the smaller CHE hospital laboratories chose to do so in order to maintain a critical mass of work.
105. The Gisborne region provided a relatively small market for laboratory services and the presence of two laboratories meant that both were likely to face issues of viability. An example of this has been

Tairawhiti's ongoing difficulty in recruiting and retaining pathologist staff.

106. Prior to the conclusion of Midland's laboratory contract negotiations in 1996, Tairawhiti attempted to purchase GLL. Midland was aware of this initiative and had no reason to oppose it. However, Tairawhiti was unsuccessful in its bid to purchase GLL, with private laboratory Medlab Hamilton Limited ("Medlab") concluding an agreement to purchase GLL in March 1996. As a result two laboratory contracts were issued to Medlab as discussed in earlier my Brief.
107. After Medlab purchased GLL, Tairawhiti sought to compete with Medlab and strengthen its pathology staffing by forming an alliance with Academic Pathology Limited, a subsidiary of the Christchurch Teaching Hospital. Academic Pathology Limited sought a Section 51 Notice from Midland but we did not support this.
108. A separate primary-referred laboratory services contract (similar to that used with the private laboratories) was then negotiated to enable Tairawhiti to claim payment for general practitioner-referred schedule tests performed by them. My understanding is that this contract remains in place today.

NATIONAL CERVICAL SCREENING PROGRAMME

109. The NCSP commenced in 1990 prior to creation of the RHAs. At this time, I was Assistant General Manager – Planning & Development for Bay of Plenty Area Health Board, and was responsible for overseeing local implementation of the NCSP. Each Area Health Board (“AHB”) was charged with local programme and register management and co-ordination.
110. A Government policy document on the NCSP was issued in 1991 (“the 1991 Policy”). I produce a copy of that document as **CM/HFA/0031**.
111. Because of the nature of cervical cancer screening and treatment, many different types of service provider were involved. Key participants included general practitioners and private laboratories. At the time the programme commenced general practitioners and private laboratories were operating in an environment where they provided services on a fee for service basis, paid by the Department of Health, as I have already described.
112. There were challenges in implementing the NCSP because of the absence of any contractual relationship between the AHBs (or Department of Health) and the general practitioners and laboratories.
113. The local AHB manager responsible had strong links with the NCSP manager in the Department of Health. The local AHB manager was required to ensure that the computer systems were installed and implemented appropriately and that the correct systems and procedures were followed by the service providers. Considerable consultation with health professionals and women’s groups was undertaken by the local AHB manager to design and implement locally appropriate programmes within the national policy framework.

114. The responsibilities of the Department of Health, AHBs and the Advisory Committee are explained at page 7 of the 1991 Policy.

115. One of the aims of the NCSP was to introduce quality standards around the reading of slides by pathologists, a process that requires the pathologists to exercise their professional judgement after actually viewing the slide and cannot be automated. Those aims were explained under the heading “Laboratories” at page 5 of the 1991 Policy as follows:

“4.1.2 All cytology laboratories servicing the National Cervical Screening Programme should be registered with the Testing Laboratory Registration Council of New Zealand (TELARC) or other recognised authority. It is expected that laboratories not so registered will apply and gain such registration. A reasonable period of time will be allowed for laboratories to obtain registration. This may take up to two years.

4.1.3 The Department of Health will be responsible for confirming that those laboratories carrying out cytology screening for the National Cervical Screening Programme meet the requirements set out in 4.1.4.

4.1.4 The criteria for registration by TELARC or other recognised authority will be established by the Cytology Advisory Liaison Committee. The Department of Health will be consulted. The criteria will include:

- *reading of minimum number of smears a year;*
- *employment of adequate numbers of suitably qualified staff;*
- *maximum workload for each cytoscreener;*
- *adequate in-service education;*
- *satisfactory participation in both internal and external quality assurance procedures;*
- *provision of cytology reports to the cytology register.*

4.1.5 The Department of Health, the Cytology Advisory Liaison Committee, TELARC, and other relevant organisations will monitor standards for the training of cytology laboratory assistants.

116. To my knowledge, this was the first time that an attempt was made to have private laboratories agree with an external agency (in this case, the Department of Health) to develop and implement quality standards. How this was to be enforced in the absence of an appropriate accountability structure is unclear.
117. When the RHAs were created the NCSP had been in place for three years, during which time the AHBs had led local implementation. Providers had been brought together into a loose network, the computer systems had been installed, and a proportion of eligible women had been enrolled into the programme.
118. An updated Government policy document on the NCSP was issued in October 1993 (“the 1993 Policy”). I produce a copy of that document as **CM/HFA/0032**.
119. The responsibilities of the Ministry of Health, the RHAs, Public Health Commission, Cervical Screening Advisory Committee and the Cytology Advisory Liaison Committee are explained at page 8 of the 1993 Policy.
120. The responsibility of the Ministry of Health for introducing quality standards around the reading of slides by pathologists was continued from the role of the Department of Health in the 1991 Policy. Those aims were explained under the heading “*Laboratories*” at page 5 of the 1993 Policy as follows:

“4.1.2 All cytology laboratories servicing the National Cervical Screening Programme should be registered with the Testing Laboratory Registration Council of New Zealand (TELARC)

or other recognised authority. It is expected that laboratories not so registered will apply and gain such registration. A reasonable period of time will be allowed for laboratories to obtain registration.

4.1.3 The Ministry of Health will be responsible for confirming that those laboratories carrying out cytology screening and histology for the National Cervical Screening Programme meet the requirements set out in 4.1.4.

4.1.4 The criteria for registration by TELARC or other recognised authority will be established by the Cytology Advisory Liaison Committee in consultation with the Ministry of Health. The criteria will include:

- *reading of a minimum number of smears a year;*
- *employment of adequate numbers of suitably qualified staff;*
- *maximum workload for each cytoscreener;*
- *adequate in-service education;*
- *satisfactory participation in both internal and external quality assurance procedures;*
- *provision of cytology reports to the cytology register.*

4.1.5 The Ministry of Health, the Cytology Advisory Liaison Committee, TELARC, and other relevant organisations will develop and monitor standards for the training of cytology laboratory assistants.”

121. The Funding Agreements between the Crown and Midland Health required Midland Health to purchase primary care services including cervical cancer screening services. The requirements for purchasing cervical screening services were set out in detail in the Funding Agreements. I produce extracts from the Funding Agreements for 1993/1994, 1994/1995, 1995/1996 and 1996/97 as **CM/HFA/0033** to **CM/HFA/0036**.

122. There had been fourteen AHBs and following the health reforms, local co-ordination was continued by fourteen of the CHEs which replaced

the AHBs. The obligations for local programme and local register management and co-ordination were included in the contracts between the RHAs and the CHEs. In the Midland region, the CHEs with NCSP contracts were Taranaki Healthcare Limited, Tairāwhiti Healthcare Limited, Health Waikato Limited and Eastbay Health Limited.

123. Midland prepared a service requirement definition for cervical screening for 1994/1995 which was included in Midland's contracts with these CHEs. I produce a copy of that document as **CM/HFA/0037**.
124. As described in the 1993 Policy, monitoring and evaluation of the NCSP remained the responsibility of the Ministry of Health (the Department changed to a Ministry during this time), and it was the Ministry that had access to the information from the register which was the key to monitoring of laboratory service providers. Midland did not routinely receive information from the register.
125. The RHAs were required to monitor and evaluate the quality of services they purchased and provide information to the Minister of Health. The requirements were set out in the Funding Agreement and were intended to allow national monitoring and evaluation of the NCSP by the Ministry.
126. While RHAs were charged with monitoring and evaluating the quality of (among other things) smear reading services, unless we had a specific complaint or the local CHE cervical screening programme manager alerted us, we would not have had any means of identifying such quality issues in the absence of laboratory contracts with appropriate information provision.

127. For the RHAs the specific laboratory component of the NCSP was a relatively low priority because we believed that the Ministry was responsible for it.
128. Our NCSP priorities were enrolment of women, improving access to screening and treatment services, and ensuring collection and communication of data from the local programme directly to the Ministry.
129. These priorities were reflected in the contract monitoring indicators included in our cervical screening contracts with the CHEs as the local managers of the NCSP. These indicators were:
- a. Total number of women enrolled on the cervical screening register in the month;
 - b. Number of eligible women newly enrolled;
 - c. Total number of eligible woman on register;
 - d. Number of smears taken;
 - e. Number of referrals to colposcopy;
 - f. Waiting times for colposcopy.
130. An updated Government policy document on the NCSP was issued in 1996 (“the 1996 Policy”). I produce a copy of that document as **CM/HFA/0038**.
131. The responsibilities of the Ministry of Health and the RHAs are explained at page 26 of the 1996 Policy.

132. It was noted at page 20 of the 1996 Policy:

“The NCSP will also provide laboratories with an analysis of their own results in comparison to a national average on an annual basis for quality assurance purposes.”

133. It was also noted at page 29 of the 1996 Policy that one of the future developments for the Ministry of Health was to *“develop processes to monitor and evaluate ... variations in laboratory reporting practice”*.

134. The purchase of the cervical screening programme in the Midland region was the responsibility of Midland’s programme manager of women’s health, Ms Jane Hudson. Key aspects of her responsibilities were:

- a. Preparing service specifications to accompany our contracts with CHEs and local community groups, which translated the national NCSP policy and the Funding Agreement to meet the particular requirements of the Midland population. As we had a very high Maori population, strategies for encouraging their enrolment were a high priority.
- b. Supporting Midland contract managers and providers to ensure programme requirements were met, and service improvements identified.
- c. Maintaining effective links with the local CHE NCSP programme managers, the national co-ordinator in the Ministry, personnel in other RHAs responsible for cervical screening, and internally with other Midland staff concerned with purchasing colposcopy, health promotion, general practice and laboratory services.

135. The Ministry's national NCSP co-ordinator held regular national meetings with the CHE NCSP programme managers. The RHAs had a representative at these meetings (from Central RHA). In addition, the RHAs as a group met with Ministry NCSP personnel on a few occasions to talk through policy and roles/responsibilities issues. Policy developed by the Ministry's national NCSP co-ordinator had input from Midland (and the other RHAs) as part of its stakeholder consultation, and this then was documented in the Funding Agreement.
136. Ms Hudson met with the programme managers of the four contracted CHEs in our region twice each year to discuss directions, priorities and issues, in addition to the formal annual contracting meetings. She also visited each CHE annually to meet the wider staff groups involved in the NCSP.
137. The four CHEs' contractual obligations were described in the service requirement definition referred to in paragraph 116 of my evidence. In summary, these obligations were:
- a. Collection and provision of information to the Ministry of Health (through the register).
 - b. Local co-ordination of the NCSP.
 - c. Links with smear takers (general practitioners and non-medical), laboratories, the Medical Officer of Health, consumers and health educators.
 - d. Sub-contracting with local community groups for health promotion/education for particular population groups.

SUMMARY

138. Midland recognised that the laboratory Section 51 Notice gave inadequate assurance of quality, and sought to replace it with contracts. These contracts were not signed until March 1997 (back-dated to November 1996). The major reasons for the protracted development period were:
- a. Our statutory obligations to consult with affected parties on proposals to change our purchasing arrangements.
 - b. The opposition of ACL to our various proposals for change, and difficulties we experienced through 1993 and 1994 in developing an effective working relationship with ACL as the representative of the private laboratories in our region. We had little contact with the pathologists themselves, including Dr Bottrill.
 - c. The complexity of the laboratory market with its inter-related public and private components.
 - d. The difficulty we experienced in obtaining robust information from public and private laboratories, in part because of concerns about its commercial sensitivity.
139. However, despite these difficulties, Midland was the first of the RHAs to negotiate and implement enduring laboratory contracts. These contracts included Section F which brought in TELARC accreditation as a contractual requirement.
140. Registration/accreditation systems such as TELARC and ISO focus on organisational systems and processes. They do not consider the competence of individual professionals such as pathologists, which is

the domain of professional self-regulation. The project for development of national quality and service standards discussed by Sylvia Sax sought to draw together both areas.

141. The Policy Guidelines and Funding Agreements required Midland and the other RHAs to use reasonable endeavours to ensure laboratories undertaking cervical screening examinations were TELARC registered.
142. Between 1991 and 1996 the Department/Ministry of Health was responsible for laboratory quality in respect of the NCSP, covering both definition of the criteria for TELARC registration and confirmation of which laboratories were eligible to carry out NCSP screening work. The Department/Ministry also controlled the data from the NCSP register that allowed comparative monitoring and analysis of laboratory activity. Midland did not have such access.