8 January 2004

Mrs A
Consumer

Dear Mrs A

Complaint against Dr C / Dr B / A Medical Laboratory

Thank you for your thoughtful response of 6 November 2003 to my provisional opinion. In your letter you stated that you accept that Dr B and the medical laboratory (the laboratory) did all they could to provide you with a service with care and skill, but you remain concerned that Dr C, pathologist, did not provide you with services of an appropriate standard.

Your complaint of 12 June 2002 was that the laboratory did not provide you with services of an appropriate standard. The two pathologists working for the laboratory, Dr C and Dr B, who were involved in the reading of your histology specimens taken in April 2000, were notified of your complaint on 7 March and 15 May 2003 respectively. In your complaint you alleged that:

- Dr B misdiagnosed the biopsy sample taken from your right breast on 13 April 2000 when she reported on 1 May 2000 that the specimen "may represent a complex sclerosing lesion".
- Dr C misdiagnosed the biopsy sample taken from your right breast on 27 April 2000, when he reported on 28 April 2000 that the specimen was a "probable complex sclerosing lesion".
- Dr C misdiagnosed the biopsy sample when he reported in the laboratory's Supplementary Report, dated 2 May 2000, that "there is no evidence of malignancy".

I have carefully considered your letter and sought further clarification, on the points you raised, from my independent expert, Dr Tie. You asked that I consider the following issues:

"1. What did [Dr D, the public hospital's pathologist who reviewed the biopsy sample in August 2001] see that [Dr C] did not?
2. Why didn't Dr Tie see [Dr D's] report?
3. Was it reasonable for [Dr C] to make a definitive statement that there was no evidence of malignancy?
4. What relevance did the absence of a residual or recurrent tumour a year later have to Dr Tie's findings?
5. Did [Dr C] really provide me with services of an appropriate standard?"

Dr Tie was asked to review his original advice in light of your questions and he was provided with a copy of Dr D's report which was not included in the clinical records and documents he initially reviewed. Dr Tie responded as follows:

> "I note the comments made in the review report from [Dr D]. Its contents do not change my advice. I note that other opinions were taken during the review, which would be expected in the circumstances.
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> The absence of residual or recurrent tumour did not influence my conclusions about [Dr C's] interpretation of [Mrs A's] histology. On balance, the reviewing pathologists favoured carcinoma. Histopathology depends on subjective interpretation, and in certain areas of practice, is subject to variation. The fact that [Dr C] has made a conclusion which, on review, is disagreed with by a majority, does not of itself indicate an unacceptable standard of practice. Consistency in diagnosis is what pathologists strive for. An expectation of perfect consistence is not realistic however, and underlines the importance of realising that opinions of histopathologists are not black and white test results. There are cases in which a non-malignant diagnosis made by a consensus of multiple pathologists is proved wrong by subsequent events."

You will appreciate that this is a complex matter. I have endeavoured to provide you with the information for you to understand why, although Dr C and Dr D reached different conclusions, I consider that Dr C did provide you with a service that was appropriate. My final opinion is set out below. As your complaint stemmed from your participation in the national breast cancer screening programme, I have forwarded a copy of this letter to the Manager of the National Screening Unit. I will also send an anonymised copy of the report to the Royal College of Pathologists of Australasia.

I remain of the view that Dr C, Dr B and the laboratory did not breach the Code of Health and Disability Services Consumers' Rights (the Code). In reaching this decision I considered information from you; Dr C, pathologist; Dr B, pathologist; the Director of Clinical Services at the medical laboratory; Professor E, consultant breast and general surgeon; and the Clinical Leader of the breast screening programme. Your ACC file and copies of the original breast core biopsy report from Dr B and the subsequent hookwire biopsy report by Dr C were obtained. As noted above, I also obtained advice from an independent pathologist, Dr Andy Tie, who was sent your breast tissue biopsy slides to review.

Overview

This investigation concerns the service provided to you by two pathologists employed by the medical laboratory. You underwent a routine screening mammogram on 3 April 2000. As a result of an abnormal finding in the upper outer quadrant of your right breast, a core biopsy was taken on 13 April. The biopsy specimen was sent to the laboratory on 13 April where it was read by Dr B. Dr B recommended further investigation and on 27 April a hook wire biopsy specimen was taken from your right breast. The additional biopsy was sent to the laboratory and read by Dr C. Both Dr B and Dr C reported that the abnormality in your right breast was a complex sclerosing lesion, and was not indicative of carcinoma. The pathology information and your

clinical picture (which included the mammogram) was reviewed by a multidisciplinary breast screen panel and you were referred back to your general practitioner for routine follow-up.

In July 2001 you were referred to a medical service by your general practitioner for routine breast screening. The biopsy specimens taken in April 2000 were reviewed as part of the screen. The review of the specimens found a Grade 1 infiltrating ductal carcinoma. You had a partial mastectomy and axillary node dissection on 13 September at a public hospital and were referred for follow-up radiotherapy.

Background

Core biopsy – 13 April 2000
On 3 April 2000 you underwent a routine screening mammogram at a specialist breast examination service which revealed an abnormality. You were examined by a breast physician, who found an area of thickening in the upper outer quadrant of your right breast. The breast physician explained the assessment process to you and obtained your written consent to allow the assessment process to proceed. On 13 April additional mammographic views and ultrasound guided core biopsies were taken. Dr F performed the biopsies. The biopsies were sent to the laboratory for reading.

Dr B was the pathologist who reported on the initial core biopsy taken from your right breast on 13 April 2000. The breast biopsy specimen she reported was a core biopsy taken from the right upper outer quadrant of the breast.

Dr B informed ACC that she considered the possibility of a malignant lesion. She said: "It can be difficult to differentiate these benign ducts from a well differentiated carcinoma without the assistance of immunohistochemistry." She said that when the special immunohistochemistry staining test was applied she interpreted them as positive, which placed the lesion in the benign category and representative of a complex sclerosing lesion.

Because the lesion was complex and histologically difficult to determine, a follow-up hookwire localisation and biopsy was recommended.

Hookwire biopsy – 27 April 2000
You underwent a D wire insertion excision biopsy at a surgical centre on 27 April, which was also performed by Dr F. The biopsy specimen was sent to the laboratory for reading and reporting. Dr C, pathologist, read the specimen and reported his findings on 28 April.

Dr C stated:

> "There is one area of increased fibrosis with groups of distorted ducts. … [I] feel that the appearances are compatible with a complex sclerosing lesion. Immunohistochemical stains to confirm the presence of intact myoeothilieum in the distorted ducts will be done and an addition report will be issued as soon as possible."

Dr C's supplementary report issued on 2 May 2000 stated that the stains confirmed his original diagnosis and that there was no evidence of malignancy. Dr C informed me:

> "I think it is evident from my initial report that I was not entirely confident of the diagnosis without obtaining confirmation from appropriate immunohistochemical stains. After examination of those stains on May 2nd 2000 I concluded that the appearances were compatible with a complex sclerosing lesion and issued the supplementary report."

Follow-up
On 11 May, in accordance with the specialist breast examination service's normal protocol, your histology and films were reviewed at a multidisciplinary meeting involving a radiologist, breast physician, surgeon and pathologist. The meeting agreed that the clinical and imaging features of the lesion in the upper outer aspect of your right breast were "concordant with the histological finding of a complex sclerosing lesion".

A letter was written to your general practitioner, Dr G, to inform him of the results of the investigations and to recommend that he refer you for a routine screen in one year.

In July 2001 Dr G referred you to an alternative breast screening service for a mammogram. The clinical examination at that time was normal, and the x-ray showed no evidence of malignancy.

Professor E, consultant breast and general surgeon, stated that it is normal procedure at the alternative breast screening service to review the radiology and histology findings of patients who have a history such as yours, at the weekly multidisciplinary meeting. At the meeting on 7 August 2001, the team was advised that your original histology, which had been reviewed by Dr D, consultant pathologist at the public hospital, showed a Grade 1 infiltrating ductal carcinoma, 9mm in size.

A histopathologist at the public hospital noted:

> "[Dr D] interpreted the sections as showing a grade 1 infiltrating carcinoma in-situ. … [Drs …] and I also reviewed the sections and favoured infiltrating ductal carcinoma over a benign lesion. … The delay in treatment has not worsened the prognosis because there was no residual tumour left behind in the breast. … This is a very low grade tumour. The prognosis is excellent. It is accepted that low-grade infiltrating carcinomas can be very subtle and immunoperoxidase stains can be open to varying interpretation."

Professor E met with you on 28 August 2001 to inform you of the review findings and discussed your treatment options. You were admitted to the public hospital on 13 September for hookwire guided right breast wide local excision, plus axillary node dissection. The procedure was uncomplicated.

On 18 September Professor E wrote to Dr G:

> "I carried out a re-excision of [Mrs A's] previous operative site and an axillary dissection. … I am pleased to say that no residual cancer was found. She did have sclerosing adenosis and a small focus of atypical ductal hyperplasia. None of the axillary lymph nodes which were examined contained tumour. I saw her later at the Clinic and gave her this good news."

Professor E referred you for follow-up radiotherapy, which is a normal part of management after local excision of a breast cancer.

Dr B's response

Dr B informed me that she is an affiliate member of the Royal College of Pathologists of Australasia and participates in both the general and Breast Quality Assurance programmes.

Dr B informed ACC:

> "I was the reporting pathologist on the initial core biopsy. The biopsy showed a difficult interpretive lesion with atypical features. The differential diagnoses included a malignant lesion, which was excluded on the basis of positive myoepithelial immunohistochemistry. However, with the presence of atypia (reported as atypical duct hyperplasia) and a complex sclerosing lesion/radial scar, which are reported in the literature to be associated with a higher incidence of malignancy, excision is the appropriate management. This was instituted.
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> …
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> The staining was equivocal and I interpreted them as positive. … On review, these stains were interpreted as negative and changed the diagnosis to a well differentiated adenocarcinoma."

Dr C's response

Dr C is a Fellow and Founder Member of the Royal College of Pathologists (UK) and an affiliate of the Royal College of Pathologists of Australasia.

Dr C informed me:

> "On review of the sections again in late August 2001 after they were returned from [the public hospital] to this laboratory it was evident that the special stains were equivocal. On the H & E sections I think the distinction between the two suggested diagnoses is very difficult and that differences of opinion between pathologists are likely in this case."

The Director of Clinical Services at the medical laboratory supported Dr C's comments, and stated that the laboratory has a quality assurance programme which includes a daily review of all breast pathology by the four pathologists involved in reporting breast material at the laboratory. A proportion of these slides is also subject

to external review by an outside pathology group in another city as part of the laboratory's external quality control.

Relevant Code Provisions

RIGHT 4
Right to Services of an Appropriate Standard

1) *Every consumer has the right to have services provided with reasonable care and skill.*

Commissioner's Opinion

Dr B

Specimen taken on 13 April 2000
Dr B was the reporting pathologist on the initial core biopsy taken from your right breast by Dr F on 27 April 2000.

The core biopsy specimen was difficult to interpret. Dr B considered the possibility of cancer, but as it is sometimes difficult to differentiate between non-malignant and malignant tissue without the assistance of special tests she decided to proceed with a special immunohistochemistry staining test. My independent expert advised that in many core biopsies immunostaining would not be required, but in this case it was essential.

When Dr B applied the staining tests she interpreted the results as negative for malignancy. As a result Dr B interpreted your breast lesion as a benign complex sclerosing lesion and not cancer. However, because the lesion was found to be complex and difficult to determine, Dr B recommended that Dr F follow up his initial biopsy with a more specific hookwire biopsy.

My independent expert informed me that Dr B's report was "clear and comprehensive and reflects careful consideration" of the biopsy specimen. He said:

> "The distinction between sclerosing adenosis/complex sclerosing lesion, atypical ductal hyperplasia and infiltrating carcinoma is a common and well recognized area of difficulty histological diagnosis. Interpretation of conventionally stained … sections is often adequate, but use of immunohistochemical stains is becoming increasingly routine."

Based on the advice of my expert, it is my opinion that when Dr B immunostained the biopsy specimen, and recommended further examination when she found the specimen difficult to interpret, she provided you with a service with reasonable care and skill, and therefore did not breach Right 4(1) of the Code.

Dr C

Specimen taken on 27 April 2000
Dr F performed a D wire insertion excision biopsy (hookwire biopsy) on you at the Surgical Centre on 27 April 2000. The specimen was sent to the laboratory for reading and reporting.

My independent expert informed me that the processing of a hookwire specimen is similar to that of a core biopsy except that the hookwire is used to look specifically at an area of interest or suspicion. With a large specimen, sections of the specimen are selected from areas of greatest suspicion, but in smaller specimens all the tissue may be processed.

Dr C received the specimen and in his initial report of 28 April reported that there was "one area of increased fibrosis with groups of distorted ducts". He stated his opinion that the tissue he examined was compatible with a complex sclerosing lesion but, because he was not totally confident of his conclusion, he intended to perform further immunohistochemical stains to confirm the diagnosis. He reported that he would issue a further report as soon as the results of the staining were available.

Dr C issued his supplementary report on 2 May. He recorded his conclusion, after examining the additional immunohistochemical stains of the hookwire biopsy material, that it was a complex sclerosing lesion and that there was no evidence of malignancy.

My expert noted that Dr D's different interpretation of your biopsy specimen in August 2001, when she concluded that you had a Grade 1 infiltrating ductal carcinoma, was a subjective discrimination in an area where differences of opinion are known to occur.

My expert informed me:

> "This case illustrates an experience which a significant proportion of pathologists practising in surgical pathology will have during their careers. When there is a difficult threshold between a benign diagnosis and a malignant one, there are various competing influences in the pathologist's mind, including the need for accuracy for the benefit of the patient as it affects their health and longevity, the extent of the investigation and invasion patients must undergo during diagnosis, avoidance of unnecessary surgery, and the desire not to make a mistake in missing a significant diagnosis for reasons of defensive or cautious practice."

Dr Tie also stated:

> "Histological interpretation evolves incrementally as new information is incorporated into the technical and interpretative aspects of practice. … Interpretation is influenced by experience with previous cases, and is refined continually over time."

My advisor noted that histological interpretation is an area in which pathologists sometimes agree to differ in their interpretations, as your case graphically illustrates. He noted that although Dr D's interpretation of the tissue was that carcinoma was present in April 2000, the absence of either residual or recurrent tumour when you had further surgery in September 2001 might support Dr C's conclusion that the lesion was benign. My expert informed me that he has not been provided with any evidence to demonstrate that Dr C failed to follow normal practice when he interpreted your tissue specimen, or that he failed to provide you with services of an appropriate standard.

The information that has been presented and reviewed in this case is complex. I am persuaded by the observation of my expert that Dr C and Dr B practise in an environment where review of breast pathology is routinely performed and as a consequence there is a discipline of practice and constant reconsideration of clinically important decisions. The interpretation of your case was important. Dr B questioned her own interpretation, and Dr C admitted in his initial report that he was not confident of his conclusions. It is my view that it is reasonable to assume that in these circumstances Dr C would have examined the tissue samples very closely and that his final conclusions would have been well considered. Although Dr C's conclusions were later questioned by other pathologists, there were some pathologists who agreed with his interpretation of the slides. In my opinion, when Dr C read your breast biopsy specimens in April and May 2000, he provided you with a service with reasonable care and skill and therefore did not breach Right 4(1) of the Code.

I have attempted to fully and fairly investigate your complaint. I trust that you understand the reasons for my decision and hope that my investigation has answered some of your concerns.

Thank you for bringing your complaint to my attention.

Yours sincerely

Ron Paterson
Health and Disability Commissioner

Enc

cc: The Manager, National Screening Unit

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