Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686

Complaint

The Accident Rehabilitation and Compensation Insurance Corporation ("ACC") forwarded to the Commissioner details of the services the consumer, Mrs A, received from the providers, Dr B and Dr C. The complaint was that:

- *In March 1996 Mrs A first presented to Dr C, a general surgeon, with a lump in the right breast. Investigations showed the lump was cancerous and on 2 April 1996 Mrs A underwent a lumpectomy and excision of her right axillary nodes. Histology showed a poorly differentiated carcinoma with lymph node involvement. Mrs A underwent a post-operative course of chemotherapy and radiotherapy to the breast.*
- *In November 1996 at a routine follow-up visit to Dr C, Mrs A was found to have a small mobile lump in the inferior aspect of the right breast. A fine needle biopsy of this lump showed malignant cells. On 28 November 1996 she underwent a mastectomy. This histology showed ductal carcinoma.*
- *In January 1997 Mrs A was referred to Dr D, a plastic surgeon, for reconstruction of the right breast. This procedure was performed on 9 August 1997 and involved the insertion of a silicone/saline implant.*
- *While under the care of Dr E, a medical oncologist, in late September 1997, Mrs A noticed a lump lateral to the breast reconstruction and Dr E did a fine needle aspiration (FNA) from the area.*
- *The FNA was reported at a public hospital by Dr B on 25 September 1997. The report stated that there were malignant cells present.*
- *Dr E referred Mrs A back to Dr C for an assessment. A subsequent CT of her chest, abdomen and pelvis showed no recurrence of the cancer.*
- *On 9 October 1997 Mrs A underwent a wide excision of the area. During this procedure it became evident that the lump was on the port site for the silicone/saline implant. Because the FNA had been reported as definite malignant cells Dr C continued to excise the port site and surrounding tissue.*
- *Subsequent histology reports showed no evidence of any further tumour.*

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Complaint *continued*

- *The FNA reported on by Dr B was referred to Dr F, a city based pathologist, for a second opinion. His review of the FNA found that the cellular population present were histiocytic or myofibroblastic in type and that the appearances were suggestive in type of reaction to a breast prosthesis. Dr F found no evidence of malignancy.*
- *Mrs A now requires either a further port prosthesis so that the implant can be inflated or the insertion of a new implant.*

Investigation Process

The complaint was received on 28 July 1998 and an investigation into Dr B's report on Mrs A's fine needle biopsy was commenced on 21 September 1998. On 17 March 1999 the investigation was extended to include Dr C's subsequent actions. Information was obtained from:

The Consumer	Mrs A
The Provider / Pathologist, Public Hospital	Dr B
The Provider / General Surgeon	Dr C
Reconstructive and Cosmetic Surgeon	Dr D
Visiting Medical Oncologist, Public Hospital	Dr E
General Practitioner	Dr J
Customer Services Officer, Public Hospital	Ms K
Chief Executive, Public Hospital	Mr L
Practice Nurse for Dr D	Ms M

Other doctors referred to in this report:

City-based Pathologist	Dr F
Medical Oncologist	Dr G
Consultant Physician	Dr H
Visiting Radiation Oncologist	Dr I
Independent cytopathologist	Dr N
Independent cytopathologist	Dr O
Independent pathologist	Dr P
Independent breast surgeon	Dr Q
Pathologist, Public Hospital	Dr R
Pathologist, ACC	Dr S

Relevant clinical records were obtained and viewed along with Mrs A's pathology slides. Expert advice was obtained from an independent breast surgeon and an independent pathologist.

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Information Gathered During Investigation

In March 1996 Mrs A, who was aged 33, was referred to Dr C, a general surgeon, following the discovery of a lump in her right breast. Dr C saw Mrs A in his private practice. Dr C noted, on close questioning, that the lump had probably been present for more than a year. He performed a fine needle aspiration biopsy ("FNA") on the lump. (During an FNA a long hollow needle is inserted into the lump to remove fluid. It provides information on the cells of a tumour or cyst and is useful for excluding the presence of malignant cells in the breast.) The FNA revealed that malignant cells were present. On 2 April 1996 Mrs A underwent a lumpectomy (where the lump and surrounding breast tissue are removed) and dissection of the axillary (armpit) nodes. Histology of the lump revealed a Grade 3 infiltrating ductal carcinoma and secondary spread to two out of six lymph nodes. Mrs A was referred, through the publicly funded health system, to Dr G, a medical oncologist, for chemotherapy. Dr H, a consultant physician, supervised Mrs A's chemotherapy, which was completed in June 1996. Mrs A was then referred to Dr I, a visiting radiation oncologist, for subsequent radiotherapy, which was completed on 14 August 1996.

On 18 November 1996 Mrs A consulted Dr C as part of a routine follow-up. Dr C's examination revealed a mobile lump on the periphery of Mrs A's right breast. Dr C performed an FNA on the lump. Examination of the sample revealed further malignant cells and a simple mastectomy was carried out on 28 November 1996. Histology showed a ductal carcinoma in situ (non invasive cancer).

On 21 January 1997 Dr C wrote to Dr D, a reconstructive and cosmetic surgeon, requesting that he discuss the possibility of breast reconstruction surgery with Mrs A.

On 27 March 1997 Mrs A was reviewed, through the publicly funded health system, by Dr E, a visiting oncologist at the public hospital. Following examination Dr E wrote to Dr J, Mrs A's general practitioner, advising "*no evidence of recurrence on examination of the chest wall or abdomen*".

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Dr E also recorded in his letter to Dr J:

> "[Mrs A] *remains in remission from her previous breast carcinoma. I intend to supply her with more information about options for breast reconstruction and review her in this clinic in three months' time to make sure there is no evidence or relapse of her primary breast cancer.*"

On 26 June 1997 Mrs A was again reviewed by Dr E. Clinical notes recorded:

> "*Physical Examination: This is normal apart from slight tenderness to the left of the lower end of the sternum.*
> …
> *Assessment:* [Mrs A] *is probably in remission from her previous breast cancer and I do not believe there is any clear evidence that her current pain heralds bone relapse, but* [the radiologist] *has suggested some further plain x-rays to look at this area more closely and these will be requested.* [Mrs A] *is planning to go ahead with her reconstructive surgery in the next two months and providing the above investigations are normal I think this is a reasonable approach. …*"

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

On 4 July 1997 Mrs A consulted Dr D, in a private capacity, about reconstructive surgery. Dr D advised Mrs A about the different prostheses available (Fisher Expander, saline and gel filled). They settled on a combination of gel and saline because it provided the best feel and shape and required only one surgery to complete. There was some discussion about an implant with an integral valve but those implants are tissue expanders only and are not permanent so Mrs A would have required two surgeries. Clinical notes recorded:

> *"Second appointment for right breast reconstruction. I think we will go for a McGhan style 150 combination saline and gel filled expanding implant which would save her having two operations. This implant works as an expander and as a permanent implant. Item No: 27150231 for a 230 – 250 cc implant. We need to know the cost of this. $2,200.00.* […] *to write to* […] *with costs for surgery.*
>
> *I have given her an estimate of costs, roughly equivalent to a bilateral breast reduction. Surgery would probably take about 3-3½ hours to do the latissimus dorsi flap and place the implant and adjust it. I will do an accurate quote later.*
>
> *Left breast measured today as well as the right chest area. Left breast volume about 250 cc. Skin ellipse removed from right side is probably 13 cm by 8 cm, so a similar amount of tissue would be needed to be replaced with the skin flap. The pectoral and latissimus muscles both function well, so I think there should be no danger in doing a latissimus reconstruction even although she has had radiotherapy in the right axilla.*
>
> *Booked for 9 August 1997."*

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Dr D wrote to Mrs A on 17 July 1997 indicating:

> "*Following our consultation on 4 July 1997 the following is an estimate of costs for doing a Latissimus Dorsi muscle and skin flap reconstruction for your right breast. The expanding implant cost $2,200.00 but it can be used as a permanent implant, which would save two operations.*
>
> *Following would be the costs for the surgery. Overnight stay in hospital, $290.00 for a single room, theatre fee 3½ hours $1416.00, consumables $525.00 approximately, anaesthesia $800.00, Surgery $3,950.00, follow up $50.00 per visit, plus cost of injections $20.00 each to inflate the implant. I understand you have booked for 9 August 1997.* [Ms M] *my secretary … will contact you with an appointment to see me when I am in* [your city] *next for final discussions measurements etc.*
>
> *Please find enclosed a blood test form to get a full blood count and a coagulation screen which you could have done* [in your city]. … *They would send the results to me.*"

Dr D performed Mrs A's reconstructive surgery on 9 August 1997. On the morning of 10 August 1997 he explained to Mrs A that the operation had gone well "*and reconfirmed the fact that* [he] *had used the expanding combination gel/saline implant*". Dr D stated:

> "*She was thus aware before her surgery that this is what we were doing and I reconfirmed the fact that this had been done the morning after surgery. I understand from conversations that she maintains that she did not remember that she had an implant with an external valve even though she had this in writing and that I explained this to her post operatively. She seemed to be quite lucid post-operatively and I was not under the impression that she would not remember what I was telling her. …*"

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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Mrs A alleged that the prosthesis she discussed with Dr D on 4 July 1997 was not that which was subsequently inserted. She said he showed her a picture of a prosthesis without cords, which had the port site "*on top*" and "*in the chest part*" rather than on the side. Mrs A did not recall Dr D discussing the location of the port site with her post-operatively.

Dr D wrote to Dr C on 11 August 1997 detailing the surgical procedure. He noted, in the final paragraph:

> "*Post Op to be nursed in a semi sitting position with pillows under the right shoulder. IV antibiotics, ie Augmentin for 48 hours. Post-operative* [Mrs A] *did extremely well, was mobilized Monday morning. No saline has been injected into the implant yet. The filling port is in the right lateral chest, one can start injecting this at her next post op visit in* [her city]."

Mrs A was reviewed by Dr C on 26 August 1997. He found no evidence of recurrent disease.

Mrs A was reviewed by Dr E on 25 September 1997. Mrs A told Dr E that there was a small lump on the right side of her ribs. Dr E performed an FNA on the lump. Mrs A recalled Dr E informing her that he had had trouble getting cells so she should not be surprised if Dr C requested another biopsy in two weeks' time.

The FNA was examined by Dr B, a pathologist at the Public Hospital.

Dr B's report dated 26 September 1997 recorded:

> "*Specimen Type: FNA chest wall.*
>
> *Clinical Notes:*
> *Previous Ca* [cancer] *breast (poorly diff* [differentiated], *ER-). New nodule below recent reconstruction.*

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Microscopy:
The aspirate contains several scattered single cells and noncohesive groups of neoplastic cells. The cells are medium sized with pleomorphic oval nuclei with coarse schromatin. Many multinucleated cells are present.

FNA Nodule Chest Wall:

MALIGNANT CELLS PRESENT
- these would be consistent with metastatic breast carcinoma."

Dr B was unaware of Mrs A's breast implant prior to examining the FNA. Her diagnosis of malignancy was based on Mrs A's history of breast cancer, the development of a new nodule and the presence of very atypical cells in the aspirate. Dr B stated that there can be unusual reactions near breast implants and that cells near breast implants may mimic carcinoma cells. Because she had no information about the breast implant, and in view of the history supplied to her, Dr B took those cells to be malignant.

Ms K, Customer Services Officer at the Public Hospital, advised that the hospital did not, and does not, have written protocols in place with respect to FNAs.

Dr E telephoned Mrs A on the afternoon of 25 September 1997 and informed her that she had cancer. He advised her to make an appointment with Dr C and indicated that he had telephoned Dr C to advise him of the result.

Dr E also informed Mrs A that he had telephoned Dr D, as she had an appointment with him that evening to have the implant enlarged. Dr E told Mrs A there was no need to keep the appointment as Dr D would be unable to enlarge the implant if she required further surgery.

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Dr E was of the opinion that Dr D should have been aware that he was treating Mrs A and that he would have expected Dr D to have sent him a copy of his operation note which detailed the location of the port site. Had Dr E known, in September 1997, that Mrs A's lump was the port site for the implant he would have asked Dr D to review Mrs A, but would not have done an FNA, and would not then have received the information telling him that malignant cells were present. Dr E had not seen many ports in that position and, as most consumers know where their port is, there is not usually "*that degree of uncertainty*". Dr E stated that "*this complaint is an unfortunate mix of public and private treatment and we need to ensure that information is provided and followed up*".

Dr D did not forward the operation note to Dr E. According to the operation note, copies were forwarded to Dr C and Mrs A's general practitioner.

Mrs A advised:

> "*On my husband's prompting I went to* [Dr D's] *rooms for my appointment at 7.15pm and talked to the nurse* [Ms M] *as to whether it was any use for me to see* [Dr D]. *I advised her that I was told I had a tumour on my ribs below the prosthesis and she went and talked to him as he was in one of the rooms working on a patient. …*"

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Dr D had a brief consultation with Mrs A on the afternoon of 25 September 1997 but did not keep a written record of it. Mrs A told him she had a lump under her breast and he told her she should, in that case, go back to Dr C. He said:

> *"When she came to see me on 25 September 1997 I knew that I had put it in writing to her [what type of breast implant we were using] and that I had reconfirmed it post-operatively that we had used this implant. I had also told her post-operatively that the filling dome for the implant was in the right axilla just to the side of the breast that she would be able to feel this there and that in fact her bra strap would probably cover it and hide it. As I knew I had discussed this with her when she came into my rooms and told me that she had a lump under her breast below the breast this was obviously a different site and it was an area where there had been some dense scarring and this was an area that I biopsied during the operation because I didn't like the look of it. I did not know at this stage that she could not remember what I had told her post-operatively about the type of implant she had and where the filling dome was sited. … Because I knew* [Dr C] *had this information and because I knew how I had told* [Mrs A] *this information when she said that the lump was under or below her breast I immediately assumed that this was a separate site that she was talking about and as I was busy operating my conversation in the corridor with her was brief, I still had sterile gloves on, I did discuss with her whether or not I should look at her but I decided not to because she was going to see her surgeon again the next day to have the matter attended to. Normally we leave the general surgeons to attend to matters of breast cancer. …"*

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Mrs A consulted Dr C on 26 September 1997. Dr C located a 2cm hard mass fixed to Mrs A's chest wall lateral to the lower edge of the breast reconstruction. Mrs A expressed concern about the implant as it had been inserted just seven weeks previously and she did not want it ruined. It was agreed that any decision about further surgery would be made when the results of a CT scan scheduled for the following week were to hand.

Dr C wrote to Mrs A's general practitioner following the consultation. He noted:

> "*Further to discussion on* [Mrs A] *yesterday, I saw her today. She certainly has a hard mass a little inferior to the breast reconstruction. It measures about a centimetre or slightly more in diameter and is not attached to skin, but certainly attached to the muscle deeply. I have had quite a discussion with* [Mrs A], *and advised her to have this excised, because of its deep extension, I would prefer to do this in the hospital. She is very reluctant to have a further general anaesthetic as the breast reconstruction has 'knocked her around'. She is also very concerned that she has breast cancer elsewhere, and wishes to make no plans until she has had her CT, which is next Tuesday. I think that this is the first evidence of recurrent disease, as the breast specimen in November of last year, showed features consistent with ductal carcinoma in situ, although the Pathologists were reluctant to be definite, and felt that the distinction between that diagnosis and cellular atypia due to radiation was difficult to make. I plan to see* [Mrs A] *next week to discuss the CT results, and will keep you informed. "*

The CT report on Mrs A's chest, abdomen and pelvis dated 1 October 1997 recorded:

> "*Right sided breast prosthesis noted and no specific complications seen or signs of tumour recurrence locally ….*
>
> *Thus, previous right mastectomy and no metastases noted*."

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Mrs A consulted Dr C on 3 October 1997 to receive the results of the CT scan. Dr C informed her that the tests were negative but advised her that she still required surgery on the tumour. The surgery was performed on 9 October 1997. Dr C advised that during surgery he became aware that the lump being operated on was the port site for the enlargement of Mrs A's breast implant. He noted:

> "*Before the situation was irreversible, I contemplated the options and decided to complete the excision in view of the fact of the positive cytology.*"

Histology of the specimen removed during surgery showed no evidence of a tumour.

Mrs A advised:

> "*After surgery at midday* [Dr C] *came into my room and advised me that he had removed the port to my prosthesis … and that it was stitched to my muscle and he advised us that he realised that it was the port to the prosthesis before he had gone too far and could have closed me up, but said that he talked to the theatre staff and decided to go ahead and remove the port site and surrounding tissue. I was very upset as the prosthesis had not yet been enlarged and could not be now and that I had gone through more surgery and anguish for nothing and that I would have more surgery in front of me because of the damage done.*"

Mrs A consulted Dr C on 16 October 1997 to receive the biopsy results. She stated:

> "*He had not received them. He advised me that he had in his notes a letter from* [Dr D] *advising him of the port site and where it was.*"

Mrs A consulted Dr D on 21 October 1997 to see if he could repair her implant. He told her he might be able to attach another port if there was enough tube left, otherwise the implant would have to be completely replaced.

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Dr C wrote to Dr D on 28 October 1997 summarising the events following Mrs A's reconstruction on 9 August 1997:

> *"I saw* [Mrs A] *on 26th August which was shortly after her reconstruction. She had taping over the wounds, was still a little tender but on examination I could find no evidence of recurrent disease and I was not aware of a mass lateral to the reconstructed breast. However, this may have been difficult because of her tenderness and the taping.*
>
> *She saw* [Dr E] *a month later, on Thursday 25th September, and at that time was aware of a lump in the right lateral chest wall. He described this as a subcutaneous nodule and did a FNA on the area which showed positive cytology. He contacted you as you were seeing* [Mrs A] *on the same day and that evening at our Breast Meeting, he told me about the situation and asked me to see* [Mrs A]. *I saw her the following day, Friday, and found a 2cm hard mass fixed to the chest wall, lateral to the lower edge of the recently reconstructed breast. She told me that she had turned up for her appointment with you the previous day but because this had been shown to be recurrent tumour you had cancelled her appointment and in fact she never saw you, but only saw* [Ms M]. [Mrs A] *was very reluctant to have any further surgery because she had had an unpleasant experience with her anaesthetic in* […] *and was somewhat unhappy with the care at* [the private hospital]. *We decided to await the CT scan the following week which proved to be clear and I persuaded her to be admitted for a wide excision of the mass.*
>
> *I did this on the 9th of October and became aware during the procedure that in fact this was the port for the prosthesis. Before the situation was irreversible, I contemplated the options and decided to complete the excision in view of the fact of the positive cytology. I ligated the tubing leading to the prosthesis.*

Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

The histology has shown no evidence of tumour in the resected specimen. The port site has been recovered and is being held by the pathologist for me to collect. They wonder whether it has been damaged in taking sections close to it. [Dr R] *has reviewed the original cytology and is convinced that it does show malignant cells.*

Throughout this [Mrs A] *has always stated that she was under the clear impression that she was having a prosthesis with an implant that would be sited superiorally but I do note in your letter of 11th August the filling port is in the right lateral chest. …*"

Mrs A consulted Dr C on 24 October 1997. She stated:

"*We received the results of the tissue.* [Dr C] *told us it was all clear, there was no sign of cancer but that it could have been in another part of the tissue that was not tested.* [Dr C] *gave us the option of having the biopsy retested at another Laboratory.*
…
I later rang [Dr C's] *surgery and asked his receptionist to advise him that we would like a second opinion on the biopsy and tissue.*"

Dr C advised ACC:

"*At my request the Pathologist referred the FNA for a second opinion to* [Dr F] *in* [a city]. *His report stated that they would interpret the cellular population as histiocytic or myofibroblastic in type, the appearances being suggestive of tissue reaction to prosthesis. He did not feel the changes were consistent with recurrent neoplasia.*"

Dr D wrote to Dr C on 23 November 1997. He advised:

"*Thank you for your letter of 28th October 1997 outlining your version of the amazing events leading to the excision of the filling dome of her breast reconstruction implant.*

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

I have had a long discussion with Mr and [Mrs A] *today and as a result of that discussion I have recorded extensive notes about the sequence of events leading up to this happening. I am more than a little surprised to say the least that neither you nor* [Dr E] *telephoned me directly to discuss the mass on the chest wall. In the letter I wrote to you post-operatively it stated quite clearly that the filling dome was in the right side of the chest and I obviously don't need to labour this point any further. You also stated that the CT scan was clear. I had a phone message from* [Dr E] *stating that there were some suspicious cells but this was relayed through two different people and I have not received a copy of the pathology report from the original FNA cytology nor from the subsequent excision biopsy. You do state in your letter that this was negative which is hardly surprising.*

These filling domes are made of quite dense silicone rubber and they have a metal backing plate to them so it is not surprising [Dr E] *had difficulty biopsying it with a needle.*

I did actually tell [Mrs A] *that she had a filling port on the right side of her chest. I remember telling her this quite clearly on my first post-operative visit in* [the private hospital], *however she may still have been under the influence of her anaesthetic, although she didn't appear to be to me at the time, but she doesn't remember my saying that to her.*

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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

I did actually see [Mrs A] *on Thursday 25th September and had a discussion with her about what was going on. I did not examine her because she said that there was a cytologically proven tumour which she was going to have excised and that it was in the scar under the breast. As the filling dome was not buried under scar but was under clear tissue in the side of the chest, and as I had already biopsied myself some dense scar tissue at the lower part of the breast, which was shown to be fibrous tissue with histiocytic infiltration, I assumed that this was possibly the area concerned. As I knew I had told* [Mrs A] *there was a filling port and where it was I assumed, incorrectly, that she had remembered this. At this stage I didn't know that she thought she had a different type of implant despite our pre-operative discussions.*

On this basis I didn't see there was much point in examining her. I accepted the issue as it stood at that stage, was sympathetic towards her and as she said she was arranging to have the area excised I agreed that this should be done. I did not realise at this stage that there was considerable doubt as to whether there was actually any malignant material there or not. The phone message I got later suggested that there were suspicious cells although she told me that there were malignant cells so that again obviously some confusion between what [Dr E] *thought and what the patient thought ….*"

Mrs A was informed of the second pathology opinion when she saw Dr C on 28 November 1997.

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Dr C telephoned Mrs A on 2 December 1997. Mrs A recalled the conversation as follows:

> "*He advised me that he had received a letter from* [Dr D] *and proceeded to question me about what* [Dr D] *and I had talked about. He stated I never told him that I had talked to* [Dr D] *(I presumed he meant on the night I was misdiagnosed (25 September 1997)). I said I did not see him for a consultation – I had an appointment with him and that I was advised by* [Dr E] *that I did not need to see him and that he had rung both* [Dr C] *and* [Dr D]. *I did go and see* [Dr D's] *nurse and talk with her*."

On 23 April 1998 Dr D replaced the port under local anaesthetic. This procedure was unsuccessful and Dr D replaced the implant on 18 January 1999.

Dr C recalled that:

> "[Mrs A] *was quite adamant both prior to this procedure and subsequent to it, that the prosthesis that she had chosen with* [Dr D] *had the port site situated superiorally in the breast. This was also confirmed by* [Dr D's] *nurse who was present when I talked to* [Mrs A] *after the operation.* [Dr D] *is also quite adamant that he told* [Mrs A] *that the port was out laterally and he did in fact record this in his operation note.*
>
> … *The confusion over where the patient felt that the port site was placed has been the main contributory factor*."

Dr C advised that the name of Dr D's nurse, present when he spoke to Mrs A after the operation, was Ms M.

Ms M disputed being present during any discussion between Mrs A and Dr C about the location of the port site, or present during any other discussion between them.

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Dr B / Dr C
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Opinion – Case 98HDC16686, continued

Information Gathered During Investigation *continued*

Mrs A denied telling Dr C where the port site was. She advised that all she knew about the reconstruction surgery was that the implant had to be filled.

The matter was referred to the ACC Committee on 17 March 1998 for consideration. The Committee discussion recorded:

> "…
> *The slides of the FNA have been reviewed by an independent pathologist,* [Dr F]. *He describes the slides as 'cellular population present were histiocytic or myofibroblastic in type – appearances were suggestive of a tissue reaction to a breast prosthesis'. The slides were reviewed independently by two further cytopathologists* [Drs N and O] *who came to an identical conclusion.* [Dr F] *did not indicate in his letter that the material was either unusual or difficult to interpret.*
>
> *The pathologist member of the Committee states that the dangers of misdiagnosing some reactive processes as carcinoma are well known to pathologists experienced at interpreting fine needle aspirates from the breast. Where active process is common, particularly fat necrosis can at cytological examination mimic some forms of carcinoma. However, a pathologist experienced at interpreting fine needle aspriation specimens should normally be able to recognise this. It is the opinion of this Committee, therefore, that the reporting pathologist should reasonably be expected to distinguish between a reactive process and the recurrence of carcinoma. The histopathology report of the specimen collected on 25 September 1997 clearly states there was a previous carcinoma of the breast and that this was a new nodule below recent reconstruction. The histopathologist* [Dr B] *knew therefore that this breast had undergone breast reconstruction.*

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Information Gathered During Investigation *continued*

The view of this Committee is that the Pathologist should have been able to distinguish between a reactive process and the recurrence of carcinoma. [Dr B] *did not and in failing to do so there was a negligent failure to diagnose under s 5(7) of the Act. …"*

Independent Advice to Commissioner

The following expert advice was obtained from Dr P, an independent pathologist:

"Two cytology slides were submitted to me: Labelled 97/00.8235

My report: *Occasional clumps of cells with occasional single cells are seen. There is some loss of mutual adhesion in the cells within the clumps but the cells have generally uniform nuclei which are similar to the nuclei seen in the single cells and in the occasional multinucleate cells seen. Occasional spindle shaped cells with elongate nuclei are present. Single cells have moderate amounts of pale cytoplasm.*
No malignant cells are present.

Opinion: *The smears are representative of a foreign body reaction which is seen in the presence of foreign material and could be related to a reconstruction site or an implant.*

The specific standards which apply to the FNA examination of breast lesions:

(a) The pathologist must have adequate training and experience in cytopathology and in histopathology.

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Opinion – Case 98HDC16686, continued

Independent Advice to Commissioner *continued*

(b) There must be a quality control system in place with:
1) review of slides by another pathologist.
2) correlation of all cytology with histology.
3) review of previous cytology and histology from the breast lesions previously reported as malignant, to check whether the suspect cells in the slide under review have a similar appearance to the previously reported cells.
4) The pathologist is under an obligation to secure 'all relevant clinical information' before reporting an FNA …
5) If there is the faintest doubt the slide should be reported as equivocal and a repeat FNA or a core biopsy should be requested!

In the circumstances of this patient there was no great urgency and thus the above steps would have not occasioned undue delay.

Was the diagnosis of malignancy reasonable in the circumstances?

1. [Dr B] *did not obtain 'all relevant clinical information' prior to reporting although* [she] *was told that there was a 'previous carcinoma and the nodule was below a recent reconstruction'.*

2. *A prudent pathologist would have obtained a history of two previous FNAs from carcinomas, a history of chemotherapy and radiation and breast implant.*

3. *Even the history stated should have alerted* [her] *to the possibility of a foreign-body reaction.*

4. *A prudent pathologist would have reviewed the previous FNAs and histology in conjunction with the submitted FNAs and would have compared the relevant cells.*

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Opinion – Case 98HDC16686, continued

Independent Advice to Commissioner *continued*

5. [Dr B] *is 'unsure' whether the slides were seen by another Pathologist.* [She] *is surely aware that:*
'If it is not written it did not happen!'

6. [Dr B] *correctly reported multinucleate cells present. Such cells, if malignant epithelial cells, are rare in breast malignancy and I have seen multinucleate malignant epithelial cells only once in the thirty years I have been reporting breast cytology (they may occur in sarcomas of the breast).*

The presence of these cells and of single histiocytic cells should have enabled the pathologist to have made a correct diagnosis.

No mistakes are acceptable on FNA specimens of breast lesions and should not occur!

For the reasons outlined I do not consider [Dr B's] *diagnosis reasonable in the circumstances and in fact represents a major error which a prudent pathologist would not have made. …*"

The following expert advice was obtained from Dr Q, an independent breast surgeon:

"*Your request for a report focuses on* [Dr C's] *advice to* [Mrs A] *and the performance of the operation. However another issue that has contributed largely to the present situation is the report from the pathologist at* [the public hospital] *suggesting that malignant cells were present in the lump that was removed in October 1997. The histology of this tissue indicated there was only benign tissue around the expander portal. A subsequent review of the fine needle aspiration taken from that area was reported as being benign by a pathologist in* [a city] *who reviewed the histology. Without this report it is most unlikely that* [Dr C] *would have proceeded in the way that he did.*

Continued on next page

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Independent Advice to Commissioner *continued*

An important issue which relates to [Dr C's] *action is the siting of the tissue expander portal. Tissue expanders have two types of portal, one that is built into the upper front part of the tissue expander and the other which is attached to the expander by a length of tubing, this type can be positioned anywhere that the operating surgeon thinks will provide ready access. A lateral position is however generally the most convenient. There is no doubt that* [Dr D] *states in his operation note that the portal is placed 'in the right lateral chest'.* [Dr C] *clearly did not see this prior to performing the surgery. When I read* [Dr D's] *report I, in fact, read it four times before I found this comment which was in the very last sentence of the report. This was somehow not where I expected to find it. The situation was also made more complex by* [Mrs A] *apparently telling* [Dr C] *that the portal was placed superiorly and* [Dr D's] *nurse also apparently told* [Dr C] *the same thing. My expectation would be that* [Dr C] *did not seriously consider that the lump on the side of* [Mrs A's] *breast was in fact a portal. It is a relatively easy thing to recognise by palpation if you think of it and when you have dealt with a large number of these. I would not expect* [Dr C] *to have had much experience of patients undergoing this sort of surgery and I think that his non-recognition and indeed* [Dr E's] *non-recognition of the lump as a portal is not unreasonable.*

The next issue is what should he have done at the operation when he realised that the lump was a portal. If he had been operating simply to remove a lump then the answer would have been very clearly to leave well alone. The situation was made much more complex than that by the existence of an unequivocally malignant fine needle aspiration report from this region. I think this left [Dr C] *with very little option but to do a relatively wide excision of the area in question. It would be very difficult to do this without removing the portal. Again this is a very unusual situation and although I have done many of these operations I have not met the situation that existed in this case, where a fine needle aspiration from a portal site showed malignant cells.*

Continued on next page

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Independent Advice to Commissioner *continued*

In answer to your specific questions:

What are the specific standards that applied and were they followed?

I think the most important standard in this situation is to give adequate treatment for a supposed cancer recurrence. I don't think that anything less than an excision of the area from which the fine needle aspiration was obtained would give information that could exclude a cancer recurrence. In my view all other aspects follow the need for adequate anti cancer treatment. If [Dr C] *had done a more limited procedure and found no tumour tissue there would have been still uncertainty about whether he had missed it and that in fact there was tumour still present. There were undoubtedly failures in communication between the various health professionals involved in this case and this is highlighted particularly by the situation in which* [Dr C] *found himself operating on an area unaware that a tissue expander portal was present.*

[Comment on] [Dr C's] *conclusion that the port site of* [Mrs A's] *breast implant was located superiorly.*

It was not correct but not unreasonable in the light of being given specific information to that effect both by [Mrs A] *and by* [Dr D's] *nurse. Clearly if* [Dr C] *had read the operation record from* [Dr D] *carefully enough he would have extracted the information. An alternative might have been to discuss with* [Dr D] *the positioning of the port if he was in any doubt about its position.*

Was* [Dr C's] *decision to perform surgery on the 9th October 1997 reasonable in the circumstances?

My view to that is a very simple yes. It would have been untenable to have left this area unoperated on after obtaining a report of malignant cells on fine needle aspiration. It would be impossible to be certain that there was not a small deposit of cancer tissue present unless the area was excised completely.

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Independent Advice to Commissioner *continued*

Was* [Dr C's] *decision to continue with a wide excision reasonable in the circumstances?

The answer to this is really the same as [above] *that the only way of excluding cancer being present was to remove all the tissue in the area for histological examination. The incorrect fine needle aspiration result undoubtedly triggered the sequence of events which led to* [Dr C] *performing the operation that he did.*

Any other matters relevant to the standard of care provided by* [Dr C]*?

Breast cancer management is very much a multi disciplinary activity which requires effective coordination between the health professionals involved. In this instance [Mrs A] *received advice from a General Surgeon, Radiation Oncologist, a Medical Oncologist and a Plastic Surgeon with all the associated supporting staff contributing to her care. The communication was by letter and by telephone but ultimately proved inadequate particularly with regard to the siting of the portal.*

Conclusion

My view is that [Dr C] *did not breach the* [Code] *and the only criticism I could make of his actions was to fail to see the penultimate line in* [Dr D's] *operation record. Even if he had been aware of the presence of a lateral port he may well still have had no option but to perform the operation that included removal of the portal.*

This case illustrates the vital importance of accurate cytopathology and the unfortunate consequences that can follow from an inaccurate report. It also illustrates the importance of effective communication between health professionals."

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Independent Advice to Commissioner *continued*

Further advice was sought from my breast surgeon advisor in relation to the issue of communication. Dr Q provided the following additional advice:

> "*The issue that you require comment on is the exchange of information between the three specialists concerned with* [Mrs A's] *clinical care and the resulting effects on the performance of a FNA (fine needle aspiration biopsy). I think, with respect, that the question being asked is not the key question. The fundamental issue in my opinion is why did* [Mrs A] *have a marginally necessary operation which resulted in a bad outcome. I will attempt to answer both questions.*
>
> *The reason that* [Mrs A] *had the implant/expander damaged was that she had a surgical procedure (an excision biopsy) done on the region of the portal (part of the expander/prosthesis). The reason for the operation was that a positive cytology result for malignant cells (I have not seen the report) was given on an FNA specimen taken from a lump in this area. This FNA was performed by* [Dr E] *on the lump that he found while doing a follow-up check and which was judged by him to be suspicious enough to warrant a FNA. I am not critical of his decision to do this FNA although with hindsight it just might have been avoided. The problem arose because of a false positive cytology report from the laboratory on the FNA specimen. A subsequent review of the material by another cytopathologist did not confirm the presence of malignant cells. The final histopathology also showed no evidence of malignancy confirming that the FNA report was incorrect. I can go no further on this aspect of the case, if you were considering this as a possible breach, you might seek expert cytopathology advice.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Independent Advice to Commissioner *continued*

If either [Dr C] *or* [Dr E] *had recognised the lump as a buried portal, the operation to ascertain the nature of the lump might not have taken place although, as I said in my first report, once a malignant cytology report was received it would have been very difficult not to biopsy the area. Assuming that neither specialist was very familiar with tissue expander/prostheses, it might have been difficult not to advise a biopsy either by FNA or by open operation, even knowing that the portal was in that area.*

The normal way that information is relayed about the details of this type of operation, by a plastic surgeon, would be by a letter to the referring surgeon ([Dr C]*) with a copy to the GP. A copy might be sent to the oncologist but this would be unusual. If* [Dr C] *had felt that the operation record had information of unusual importance he might send a copy to* [Dr E]*, but this would again be unusual. He clearly did not think that there was a special need in this case. I would not criticise him for this. If* [Mrs A] *had had her reconstruction in the city in which she lived and had hence seen more of* [Dr D] *for filling of her expander she might just have saved the day by pointing out the site of the portal herself. This is a comment not a criticism.*

Summary
In the event, the crucial event was the false positive cytology report which triggered off the series of events that led to the unfortunate outcome for [Mrs A]. *I am not critical of the actions of* [Dr C], [Dr D] *or* [Dr E]. *This seems to be the sad story of a series of events, none of which involved significant error, leading to a bad outcome.*"

Continued on next page

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion

Mr L, Chief Executive of the Public Hospital, responded to the Commissioner's provisional opinion as follows:

> "[The Public Hospital] *does not accept the breaches found against it and* [Dr B] *and accordingly, notes the following points:*
>
> **[Public Hospital]**
>
> *1. Contrary to the Commissioner's provisional finding,* [the Public Hospital] *does have a quality assurance system in place and did so at the time of the alleged breaches. Attached is the relevant Clinical Quality Assurance policy. As you will see, there is a policy for reviewing slides by another pathologist whereby pathologists forward difficult cases for a second opinion to an independent pathologist. It is standard practice for the pathologists at the laboratory to consult each other in all unusual cases, most malignancies, suspicious and malignant FNAs. In addition, joint review sessions at a multiheader microscope occurs on a regular basis.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

2. The pathology laboratory is accredited by IANZ (International Accreditation New Zealand) and accreditation is confirmation that such reviews take place. The laboratory has been accredited since 22 October 1985. To be accredited by IANZ the laboratory must conform to the standards of the New Zealand Code of Laboratory Management Practice ('the Laboratory Code'). The Laboratory Code specifies requirements for the 'competent management of a testing laboratory' including requirements for a quality system, documentation control, laboratory quality control procedures and corrective action procedures. Laboratory accreditation is formal recognition by an independent authority that the testing laboratory is competent to carry out specific tests or types of tests. The Laboratory Code states that compliance with the requirements of the code constitutes a quality assurance programme.

3. … required by the Laboratory Code, demonstrates that the current policy and other quality assurance processes are working well. It is of note that there is no national policy or guideline to the effect; the Ministry of Health has not prescribed conditions or issued guidelines for reporting FNAs, nor has the Royal Australasian College of Pathologists.

4. The policy of pathologists forwarding difficult cases for a second opinion to an independent pathologist allows for the pathologist to use his/her clinical judgment in determining whether a second opinion is required. As stated, it is standard practice for the pathologists to consult each other in all unusual cases, most malignancies and all FNAs. In [Mrs A's] *case, a second opinion was in fact sought and obtained.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

5. *Whilst* [Dr B] *was reviewing* [Mrs A's] *cytology slides under the multiheader microscope, she showed* [Dr R] *a few selected fields under the microscope.* [Dr R] *recalls* [Dr B] *asking him, at this time, whether he remembered reviewing* [Mrs A's] *case at a previous joint review session.* [Dr R] *agreed that* [Mrs A's] *case had been the subject of a prior joint review session and* [Dr R] *recalled to* [Dr B] *that he had been the pathologist who had reported her previous cytology (*[Mrs A's] *case stood out to* [Dr R] *because she was a relatively young woman with two previous malignant breast FNAs).* [Dr R] *confirmed* [Dr B's] *knowledge of* [Mrs A's] *case including the two previous FNAs showing malignancy. On having been shown a few selected fields,* [Dr R] *concurred that the cytology* [Dr B] *was examining was highly suspicious of malignancy and did not disagree with* [Dr B's] *cytological opinion of malignancy at that time bearing in mind her previous history.*

6. *In the circumstances, it was not unreasonable for* [Dr B] *not to recall* [Mrs A's] *previous cytologies. As* [Mrs A] *was seen by* [Dr C] *in his private practice, her previous cytology slides were not immediately available at* [the public hospital] *(they are held at a private laboratory). Because she was a private patient, there was no hospital file available that documented the presence of the breast implant. And,* [Dr R] *was present when* [Dr B] *was viewing the post-implant cytology and he confirmed to* [Dr B] *that he had reported the two previous cytologies and that these showed malignancy. Even if* [Dr B] *had made such a correlation, it would merely have confirmed her diagnosis.*

Continued on next page

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

7. There is a system in place for pathologists at the laboratory to review historical reports if the patient has previously been a patient at the hospital (versus a private patient). When a specimen arrives at the laboratory a preliminary paper report is generated. Any historical anatomical pathology is indicated by the presence of a code (a 'SNOMED' code). Pathologists can then do a routine inquiry on a computer to view individual historical reports if required.

8. To require pathologists to secure 'all relevant clinical information' before reporting an FNA is not standard practice in New Zealand and, indeed, is unreasonable. This would require pathologists to telephone oncologists, surgeons and physicians, and to access and review the clinical notes in every case because they could never be certain otherwise that all relevant clinical information had been provided. Pathologists must be able to rely on the clinician providing sufficient clinical information. It is the responsibility of the clinician to obtain and clearly document clinical information and, accordingly, convey this information to the pathologist. The need for clinicians to provide detailed information is constantly reinforced by the pathologists at clinical audit review meetings.

9. Two 'independent' pathologists ([Dr F] *and* [Dr P]*) who have subsequently reviewed the cytology slides in question, had the benefit of being made aware of all the relevant clinical information, including the presence of the implant and the result of the subsequent histology. Had* [Dr B] *known about the silicone implant she is certain that her report would have been very different and would have accorded with* [Dr F] *and* [Dr P]. *That, of course, is the benefit of hindsight, something that* [Dr B] *was not privileged to have at the time.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

10. [The Public Hospital] *does not accept that it has breached the Code of Health and Disability Services Consumers' Rights in* [Mrs A's] *case. It considers that it does have adequate quality assurance systems in place, demonstrated by the pathology laboratory's track record. The evidence presented in the Commissioner's provisional opinion is incomplete and, as a result, the conclusions drawn by the Commissioner are unsound.*

[Dr B]

11. [Dr B] *is a very experienced pathologist with a proven track record. She has worked* [in Public Hospital's] *for* [many years]. *In stating that 'the pathologist must have adequate training and experience in cytology and histopathology',* [Dr P] *implies that* [Dr B] *is not adequately trained or experienced. This is untrue and very misleading and* [the Public Hospital] *requests that the Commissioner clarifies this issue.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

12. *The Commissioner's independent pathologist (*[Dr P]*) advises that a prudent pathologist would have obtained the two previous FNAs, chemotherapy, radiation and breast implant histories prior to arriving at a diagnosis, and that it was* [Dr B's] *responsibility to obtain all relevant clinical information prior to reporting on the FNAs. With respect,* [Dr P's] *views reflect the ideal world, not the reality of clinical practice. As stated, it is the responsibility of the clinician caring for the patient to provide the pathologist with all relevant clinical information. The pathologist must be able to rely on clinicians providing sufficient information. If not, all pathology work would grind to a halt whilst the pathologists chased clinicians and clinical notes to confirm that all relevant clinical information had been provided. This is particularly so in cases such as* [Mrs A's]*, where the patient is seen privately and the clinical notes containing the vital information (the presence of the implant) are held by the private clinician.*

13. [Dr P] *advises that knowledge that a patient had had a breast reconstruction should have alerted* [Dr B] *to the possibility of a foreign body reaction. This is unreasonable. Notification of breast reconstruction surgery would not automatically mean that a foreign body was present. It may well mean that only the patient's own tissue had been involved in the reconstruction, for example that a nipple had been shifted or that fatty tissue had been removed. In such cases a foreign body reaction would not be a suspected or expected finding. Again, the pathologist is dependent on the responsible clinician supplying the relevant information.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

14. It is well recognised that the management of breast cancer involves 'triple diagnosis': the clinician caring for the patient and making the clinical diagnosis must be satisfied that the clinical picture is consistent with the radiological and pathological diagnosis. Seeking the opinion of a radiologist or pathologist should involve declaration of all the relevant facts of the case by the best informed clinician looking after the patient, the offer of an opinion by the radiologist and pathologist, followed by an assessment by the clinician to ensure that all sides of the picture fit together. If there is any inconsistency between the clinical, radiological and pathological diagnosis, the clinician should plan a course of action which will clarify the problem.

15. In [Mrs A's] *case,* [Dr B's] *cytology report was but one part of this process and it is most unfair to hold her singly responsible for the very unfortunate outcome. It is apparent from the Commissioner's reporting of events that the 'triple diagnosis' did not correlate in* [Mrs A's] *case: clinical examination following* [Dr B's] *cytology report would have revealed the suspicious lump to have been close to the implant portal; and, radiological consultation (a CT scan) had not identified any malignancy. This would have been the ideal opportunity for clarification of the inconsistencies, prior to proceeding to further surgery.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

General Comments

16. *The benefit of hindsight cannot be underestimated. Whilst two pathologists have concluded that the cytology slides in question showed changes suggestive of tissue reaction to a prosthesis (versus malignancy), this is with the benefit of the full clinical picture, including the fact that there was an implant in situ and that the histology had shown no evidence of tumour in the resected specimen. At the time* [Dr B] *viewed the slides, she was not aware of the presence of an implant, and histology of the resected specimen was obviously not available to her.*

17. *The divergence of opinion clearly illustrates the fact that pathologists are human and consequently there will be differences of opinion.* [Dr P's] *comment that 'no mistakes are acceptable on FNA specimens of breast lesions and should not occur!' is completely unacceptable. Whilst this position may theoretically be very plausible, it does not reflect the reality that pathologists are human and consequently there will be differences of opinion and mistakes will be made.* [the Public Hospital] *is advised that, contrary to* [Dr P's] *view, multinucleate cells in breast cancer specimens are not as rare as his experience would suggest.*

18. [The Public Hospital] *understands that* [Dr P] *was not one of the expert pathologists recommended by the Royal Australasian College of Pathologists nor on the Commissioner's list of experts. This is inconsistent with the published policy of the Commissioner.* [The Public Hospital] *also understands that* [Dr P] *is not currently in clinical practice. By repeatedly applying ideal standards which do not reflect every day practice,* [Dr P] *brings into question the reliability of his advice.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

19. *Formal reviews of cases are regularly conducted by pathology departments. A formal review involves double blind conditions whereby a pathologist is given information on a number of cases similar in nature to the case in question. A pathologist will be presented with a tray of 5-10 slides amongst which will be the slides in question. The pathologist is asked to report on the slides as they would in a day-to-day practice.* [The Public Hospital] *requests that the Commissioner arranges for a formal review of the cytology slides reported by* [Dr B]*, with the pathologist being provided with the same information provided to* [Dr B] *and no more. A formal review would be the only fair way of assessing* [Dr B's] *diagnosis; it is the only way that the benefit of hindsight can be eliminated.*

20. [The Public Hospital] *also notes that this complaint was referred to the Commissioner from ACC and not the patient. According to* [Dr C] *the patient was absolutely adamant throughout his dealings with her that the implant port was superior and not lateral. This strongly influenced his decision to operate when she re-presented with the further lump. The patient's insistence that the port was superior played a very significant part in this unfortunate case and must be acknowledged by the Commissioner.*

21. *Finally,* [the Public Hospital] *requests that the Commissioner set out more clearly the fact that* [Mrs A] *consulted* [Dr C] *in his private practice. …*

22. [The Public Hospital] *believes that if all the relevant evidence is considered, including a truly independent pathological opinion (from a formal review), the findings of breaches by itself and* [Dr B] *will not be sustained. Further, it would be extremely concerned if the Commissioner refers this case to the Director of Proceedings on the basis of the incomplete facts set out in the provisional opinion.*"

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

Dr F responded on behalf of Dr B as follows:

"***Experience for offering this opinion:***
I am a vocationally registered anatomic pathologist practising as a surgical pathologist and cytopathologist in [a city]. *I have 10 years' experience in cytopathology and have a specialist interest in breast pathology including breast cytopathology. As such I receive a number of cases each year in consultation for other pathologists requesting my opinion in this area of practice.*

…

Details of the current case
An FNA was undertaken on the patient ([Mrs A]*) in late September 1997 by a medical oncologist (*[Dr E]*) of a lump in the right lateral breast. This lump was adjacent to the site of a previous breast reconstruction procedure undertaken in August 1997 following a mastectomy for infiltrating carcinoma of the breast in November 1996.* [Dr B] *in consultation with* [Dr R] *reported the FNA as malignant and further surgery was undertaken by* [Dr C] *in October 1997. At the time of the procedure and in light of the subsequent histological examination it became clear that the lump was associated with the port site for the breast implant and no recurrent tumour was identified in the sample.*

Shortly following this I was asked by [Dr R] *to review the FNA material together with the histology slides. I concluded that the FNA material was consistent with tissue reaction to foreign material and that there was no evidence of malignancy in either specimen.*

Independent advice has been obtained from [Dr P], *a retired* [city-based] *cytopathologist. He also concluded that 'the smears are representative of a foreign body reaction which is seen in the presence of foreign material and could be related to a reconstruction site or an implant'.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

He concluded that [Dr B's] *diagnosis represented a major error which a prudent pathologist would not have made. He based this conclusion on the following points:*

i) *'No mistakes are acceptable on FNA specimens of breast lesions and should not occur'.*

ii) [Dr B] *did not obtain all the relevant clinical information and that a 'prudent pathologist would have obtained a history of two previous FNAs from carcinomas, a history of chemotherapy and radiation and breast implants'.*

iii) *The brief history as stated to the reporting pathologist should have alerted her to the possibility of a foreign-body reaction.*

iv) *'A prudent pathologist would have reviewed the previous FNAs and histology in conjunction with the submitted FNAs and would compare the relevant cells'.*

v) [Dr B] *was unsure whether the slides were seen by another pathologist.*

vi) [Dr B] *reported the presence of multinucleated cells in the material; such cells are rare in breast malignancy.*

My opinion

I have not re-reviewed the FNA material in question on this occasion, but have referred to my notes and correspondence from the initial review in 1997/8.

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

Contrary to opinion of [Dr P], *false positive diagnoses from breast FNAs do occur and are a well described and accepted risk with the procedure. There is a significant body of published literature on this matter and when I last reviewed these studies the published false positive rates ranged from 0% to 11%. The risk of a false positive diagnosis from a breast FNA depends largely on experience and amongst experienced cytopathologists the published rates are between 1 and 2 per 1000 procedures. A meta analysis of 14 series by Feldman and Corell reported an overall false-positive rate of 0.17% (42 false-positive diagnoses in 25,180 breast FNA procedures).*

The pathologist when approaching the diagnosis of malignancy in a breast FNA material is aware that there is no single criteria which can be used as a definitive indicator of malignancy. Instead the pathologist assesses a number of criteria of malignancy and by putting weight on these different criteria will decide whether there is sufficient evidence of malignancy. If they feel that enough of the criteria are fulfilled they will make a definitive diagnosis of cancer. If there is doubt that a number of the key criteria are fulfilled a pathologist may report the material as suggestive of malignancy but not definite for malignancy. The main criteria for malignancy in the common type of breast cancer are:

i) A cellular smear;
ii) A variable cell pattern;
iii) A conspicuous loss of cell cohesion;
iv) Pleomorphic isolated single cells;
v) Single cells with retained cytoplasm and sometimes a plasmacytoid appearance;
vi) Anisonucleosis (variation in nuclear size and shape).

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

The most common causes of false positive diagnoses in breast FNAs either occur when the pathologist attempts to render a diagnosis on inadequate or poorly prepared material or when the pathologist gives an incorrect interpretation to the criteria outlined above in unusual or atypical lesions. There are a well recognised set of benign or reactive conditions that, in certain circumstances, can fulfil a number of the malignancy criteria given above. These include ruptured cyst, fibrocystic change, fat necrosis, organising haematoma, atypical fibroadenoma, gynaecomastia, inflammatory related changes including granulation tissue, pregnancy and lactational changes, papillomas, mucoele-like lesions, and changes induced by radiation/chemotherapy.

In the current case the FNA shows florid changes of inflammation caused by reaction to foreign material. This is an unusual change to see in a breast FNA sample and [Dr B] *has looked at the material and applied the standard criteria to its interpretation – in particular the material fulfilled some of the standard criteria for malignancy – namely criteria (i), (iii) and (v) as outlined above. I believe that* [Dr B] *has placed considerable weight on these criteria and has as a result tended to downplay the lack of any cytological atypia, namely criteria (ii), (iv) and (vi) which on review make this a benign sample.*

Although the size of my laboratory allows me to maintain a special interest in this sub specialty I have made, to my knowledge, two false positive diagnoses in breast FNA work over a 10 year period. In both situations these were unusual lesions and at the time I felt that there were sufficient of the criteria noted above to warrant a diagnosis of malignancy. In both situations it was a judgement call as to what degree of weighting to apply to all of the factors in the biopsy material.

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

[Dr P] *gives weight to the presence of multinucleated cells in the material.* [Dr P] *may not be aware of literature on this issue. While I agree with him that these cells are uncommon in malignant breast FNAs they are well described in this situation. A standard monograph in this area of pathology devotes two paragraphs to a description of a number of types of giant cells seen in FNAs of infiltrating ductal carcinoma of the breast.*

I agree with [Dr P] *that it is a prudent practice to obtain full details of the history and in particular to review the current material together with the previous FNAs especially as the new lesion arose adjacent to the site of the previous infiltrating ductal carcinoma. When viewed together there is a striking difference between the cytological features of the original carcinoma and the material obtained in September 1997. If the two sets of material had of been reviewed together then the error in interpretation may well have been avoided. There is a statement that advises that* [Dr B] *was present at a multidisciplinary review of the case before the final FNA was undertaken and so was fully apprised of the previous history. It is also recorded that* [Dr R] *verbally confirmed to* [Dr B] *that material from the September 1997 FNA was from the woman whose complex history they had reviewed at a previous multidisciplinary meeting.*

It is my understanding therefore that [Dr B] *did seek a second opinion on the FNA from* [Dr R]. *This was not by way of a formal request but instead she asked* [Dr R] *to look at several high power fields of the FNA. One suspects that* [Dr B], *having incorrectly interpreted the cytopathological findings was further led into a false sense of security by* [Dr R's] *informal opinion on the case.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

Conclusion

It is my opinion that a false positive diagnosis was rendered by [Dr B] *based on an incorrect interpretation of the findings in the slide. As I have indicated I feel that this is an area in which even very experienced cytopathologists may make interpretative error and as such I would strongly disagree with the opinion that this 'represents a major error which a prudent pathologist would not make'. Misinterpretation of inflammatory lesions in the breast is a well recognised and published cause of false positive diagnosis in breast FNA material. In addition, published material would not support the contention that the presence of multinucleated cells in the FNA should have enabled the pathologist to make a correct benign diagnosis.*

I believe the interpretive error was compounded by a failure to examine the previous FNA material and compare this with the current material. It would appear that many of the details of this complex case were however already known to [Dr B] *at the time she reported on the FNA material in question and that her familiarity of the case resulted in a reliance on memory rather than fresh review of all the patient's FNA material.* [Dr B] *was correct in her procedure of asking a second pathologist to look at the case; this case highlights the benefits of introducing a more formal review process.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Response to Provisional Opinion *continued*

I have described this error of the type that even the most experienced pathologist can make, in a profession where it is essential that we strive to avoid such errors the most important issue is how do we reduce the likelihood of such an error reoccurring. In my laboratory we have trialed a system of ensuring that all second opinions are formalised and signed out by two pathologists. Initially in some instances the two header microscope was used with both pathologists reviewing the material and discussing it together. What we found was that this system had the potential to influence the second pathologist's opinion which in turn had the potential to negate the benefits of a second opinion. We now prefer a system where the second pathologist looks at the material in isolation then only once he or she has reached an opinion discusses it with the other pathologist. This change to practice in my laboratory's opinion is the best way we can think of to avoid a patient suffering the same misfortune as [Mrs A]. *In saying this it must be recognised that the 'human factor' means that sometimes mistakes will happen even when multiple pathologists examine a case. These changes will be the subject of ongoing discussions with colleagues in pathology."*

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Independent Advisor's Response

Dr P responded to Mr L's advice as follows:

"*Thank you for your invitation to comment which I do thus:*

I agree entirely with your report and proposed actions.

I reject and deplore the response of the Chief Executive of [the Public Hospital] *for the following reasons:*

- *The excuses for the mistake made are quite invalid.*
- *He has misquoted me in relation to 'multinucleate cells'.*
- *The suggestion that pathologists are too busy to obtain relevant clinical information to assist them in making accurate diagnoses is quite contrary to accepted practice.*
- *Clinical information is invaluable but the final diagnosis depends on the interpretation of the appearances of the relevant cells.*
- *The co-ordination of patient's records from the private sector and the public sector is vital and is readily achievable and absence of such co-ordination places patients at risk.*
- *My views represent current clinical practice and are ideals which responsible pathologists strive for.*
- *He has not provided written evidence of a reputed second opinion. I would expect such opinion to be in writing and to confirm 'unequivocal malignancy'. Absence of such written reports implies a lack of quality control.*
- *He has not accepted that an unacceptable mistake has occurred and that a patient has suffered from that mistake. ALL pathologists make mistakes but must accept responsibility for those mistakes and thus learn valuable lessons.*
- *He does not appear to have shown any concern for the patient, and instead has tried to justify a mistake. Surely, our ultimate concerns should be for the wellbeing of our patients.*

As the question of the reliability of my advice has been raised by the C/E of [the Public Hospital] *I enclose an abbreviated CV for your information.*"

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Independent Advisor's Response *continued*

Dr P responded to Dr F's report as follows:

"*Thank you for asking me to comment on the ACC case notes and* [Dr F's] *report.*

I note that five pathologists ([Dr B]*, two Cytopathologists,* [Dr S] *from the ACC and I) are in agreement that the slide in question showed no evidence of malignancy.*

None of the pathologists in their initial reports suggest the presence of any unusual or difficult features.

The ACC committee concluded that there was 'a negligent failure to diagnose'.

[Dr F's] *second report appears to be at some variance with his original report, but after careful analysis I conclude that we agree on almost all points thus:*

1. *The obtaining of clinical details is prudent.*
2. *Review of previous material is prudent.*
3. *A second opinion should be truly independent and in writing.*
4. *We agree that mistakes do occur, but I consider that they should not occur, as other methods of diagnosis are available. (I covered reasons for mistakes in a paper I presented to the College of Pathologists as long ago as 1979.)*
5. *Giant cells are uncommon and foreign body giant cells even more so in slides of breast malignancy.*

I am at a loss to explain how [Dr F] *can report to the ACC and not mention any unusual or difficult features, and then in another report apparently make excuses for the mistaken diagnosis.*

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Independent Advisor's Response *continued*

His reasoning that this is not a 'major error' is not obvious to me.

As all pathologists agree that a mistake resulting in major surgery has been made, I have no reason to change my original report and in particular I confirm that:

'The error is a major error which an experienced pathologist should not make.'"

Code of Health and Disability Services Consumers' Rights

The following Rights in the Code of Health and Disability Services Consumers' Rights are applicable to this complaint:

RIGHT 4
Right to Services of an Appropriate Standard

1) *Every consumer has the right to have services provided with reasonable care and skill.*
2) *Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards.*

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Opinion: Breach Dr B

In my opinion Dr B breached Rights 4(1) and 4(2) of the Code of Health and Disability Services Consumers' Rights.

Rights 4(1) and 4(2)

Dr B was asked to review an FNA from a lump on Mrs A's chest wall. She was aware that Mrs A had a history of breast cancer and that this was a new lump below a recent reconstruction. While Dr B was unaware that Mrs A's reconstruction included the insertion of a breast prosthesis, I accept my independent pathologist's advice that a prudent pathologist would have obtained the two previous FNAs, chemotherapy, radiation and breast implant histories prior to arriving at a diagnosis, and that it was Dr B's responsibility to obtain all relevant clinical information prior to reporting on the FNA.

My advisor informs me that the history that Dr B was aware of should have alerted her to the possibility of a foreign body reaction. My advisor states that a prudent pathologist would have reviewed the previous FNAs and histology in conjunction with the submitted FNAs and would have compared the relevant cells. My advisor informs me that Dr B correctly reported that multinucleate cells were present in the FNA but that malignant multinucleate cells are rare in breast malignancy. The presence of these cells and of single histiocytic cells should have enabled Dr B to turn her mind to the other issues and to have made a correct diagnosis.

According to Mr L, Dr B showed Dr R "*a few selected fields under the microscope*" and asked him if he remembered reviewing Mrs A's case at a previous joint review session. Dr R confirmed Dr B's knowledge of Mrs A's case, including that the two previous FNAs had shown malignancy. He agreed that the cytology was "*highly suspicious of malignancy*". Mr L argued that, in the circumstances, it was reasonable for Dr B not to recall Mrs A's previous cytologies; the previous cytologies were not immediately available, and a pathologist should be able to rely on the information provided by the clinician. However, the clinician *did* specify that a reconstruction had taken place. This should have alerted Dr B to the possibility of an implant, and could have been confirmed by a phone call to the referring clinician.

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Opinion: Breach Dr B *continued*

Mr L further argued that "*two independent pathologists had the benefit of being made aware of all the relevant clinical information*". Clearly it was important that all the relevant clinical information be taken into account. Information about the previous cytologies, crucial to her interpretation, was accessible to Dr B. All pathologists subsequently involved in reviewing this case had access to the information and agreed that there was no evidence of malignancy.

Dr F agreed that:

> "[i]*t is a prudent practice to obtain full details of the history and in particular to review the current material together with the previous FNAs especially as the new lesion arose adjacent to the site of the previous infiltrating ductal carcinoma. When viewed together there is a striking difference between the cytological features of the original carcinoma and the material obtained in September 1997. If the two sets of material had of been reviewed together then the error in interpretation may well have been avoided.*"

He also noted that, while Dr B sought a second opinion from Dr R, it was not a formal request:

> "[O]*ne suspects that* [Dr B], *having incorrectly interpreted the cytopathological findings was further led into a false sense of security by* [Dr R's] *informal opinion on the case.*"

The fact that mistakes do occur is not in dispute. Dr P's point was that they "*should not*" occur. I am not satisfied that Dr B took reasonable steps to ensure that a mistake did not occur. In my opinion Dr B, by failing to obtain the relevant clinical information before reporting on the FNA or to consider that the cells were a foreign body reaction to Mrs A's breast implant, did not provide services with reasonable care and skill and in compliance with professional standards. I agree with my advisor's conclusion that Dr B's diagnosis represented a major error which a prudent pathologist would not have made. Dr B therefore breached Rights 4(1) and 4(2) of the Code.

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Opinion:
Breach
Public Hospital

In my opinion the Public Hospital breached Right 4(1) of the Code.

Right 4(1)

I accept the advice of my independent pathologist that specific standards which apply to the FNA examination of breast lesions include a quality control system with the following features:

> *"Review of slides by another pathologist.*
> *Correlation of all cytology with histology.*
> *Review of previous cytology and histology from the breast lesions previously reported as malignant, to check whether the suspect cells in the slide under review have a similar appearance to the previously reported cells.*
> *The pathologist is under an obligation to secure 'all relevant clinical information' before reporting an FNA …."*

The Public Hospital had no protocol in place to ensure that its pathologists obtained prior patient histories or accessed prior FNAs that were reported as malignant in order for effective comparisons to be made. In my opinion, by failing to have this system in place, the Public Hospital did not provide services with reasonable care and skill and breached Right 4(1) of the Code.

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Opinion: No Breach

In my opinion Dr C did not breach Right 4(1) of the Code.

Dr C

Right 4(1)

Dr E referred Mrs A back to Dr C following the discovery of a small lump on the right side of her ribs and after he received Dr B's report which showed that malignant cells were present in an FNA sample. Dr C located a lump fixed to the chest wall lateral to the lower edge of her right breast and, while subsequent CT results indicated no signs of local cancer recurrence, advised Mrs A that surgery on the tumour was still necessary. Dr D's operation note specified that the port site for the breast implant was lateral to the lower edge of Mrs A's right breast. I accept the advice of my independent breast surgeon that Dr C's failure to recognise that the lump was a portal site was not unreasonable in the circumstances. I also accept the advice of my independent breast surgeon that, even if Dr C had noted that this was the port site, he needed to operate in order to remove the tissue reported by Dr B as malignant. I am satisfied that, having determined during surgery that the lump was the port site for Mrs A's breast implant, Dr C had an obligation to continue with a wide excision of the area as the only way of excluding cancer. The wide excision would have been very difficult to do without removing the portal. In my opinion Dr C provided services with reasonable care and skill and did not breach Right 4(1) of the Code.

Action

I recommend that Dr B take the following actions:

- Apologise in writing to Mrs A for her breach of the Code. This apology is to be sent to the Commissioner and will be forwarded to Mrs A.

- Review her practice in light of this report.

Continued on next page

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Action
continued

I recommend that the Public Hospital take the following actions:

- Apologise in writing to Mrs A for its breach of the Code. This apology is to be sent to the Commissioner and will be forwarded to Mrs A.

- Review its clinical quality assurance policy to include protocols for obtaining the patient's history, accessing prior FNAs as comparison, and for checking results.

Other Comment

Quality assurance

I note that the Public Hospital had a quality assurance policy which stated that pathologists should forward difficult cases for a second opinion to an independent pathologist. The review by Dr R was done informally and I reiterate Dr F's advice: "*One suspects that* [Dr B] … *was further led into a false sense of security by* [Dr R's] *informal opinion on the case*".

Dr F also advised:

> "*In my laboratory we have trialed a system of ensuring that all second opinions are formalised and signed out by two pathologists. … We now prefer a system where the second pathologist looks at the material in isolation then only once he or she has reached an opinion discusses it with the other pathologist. This change to practice in my laboratory's opinion is the best way we can think of to avoid a patient suffering the same misfortune as* [Mrs A]."

I recommend that the Public Hospital consider these comments in light of Mrs A's experience and liaise with the Royal College of Pathologists of Australasia regarding implementation of this system.

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Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Other Comment *continued*

Communication between providers
I also note with concern Dr Q's comment that:

> "*Breast cancer management is very much a multi disciplinary activity which requires effective co-ordination between the health professionals involved. In this instance* [Mrs A] *received advice from a general surgeon, radiation oncologist, a medical oncologist and a plastic surgeon with all the associated supporting staff contributing to her care. The communication was by letter and by telephone but ultimately proved inadequate, particularly with regard to the siting of the portal*."

There were instances where communication between the providers about Mrs A's treatment was lacking. This lack of co-operation impacted on the quality and continuity of the care that Mrs A received. I emphasise that consumers have the right to expect that all the providers who are involved in their care communicate and co-operate with each other to ensure quality and continuity of care.

Referral by ACC
Mr L correctly pointed out that this complaint was forwarded to my office by ACC, not Mrs A. However, Mrs A was contacted by my staff on 8 September 1998, prior to an investigation being commenced. She advised at that time that she supported an investigation by the Commissioner.

Location of port site
Mr L requested that I acknowledge Mrs A's insistence to Dr C that the port was located superiorly, and that this "*played a very significant part in this unfortunate case*". While it is clear that there was ambiguity about where the port site was, I note again Mrs A's insistence that she did not know its location and did not advise Dr C accordingly.

Continued on next page

Dr B / Dr C
Public Hospital

Opinion – Case 98HDC16686, continued

Other Comment *continued*

Expert pathology advice

I reject Mr L's assertion that Dr P is not qualified to advise on the standard of skill and care reasonably expected of a pathologist in Dr B's circumstances. Dr P is a highly experienced and well qualified pathologist, and although he is not in clinical practice, and has not been nominated by the Royal College of Pathologists of Australasia as an advisor, I regard him as a suitable independent expert to advise me in this case.

Other Actions

A copy of my opinion will be sent to the Medical Council of New Zealand, the Ministry of Health and ACC.

A copy of this opinion, with identifying features removed, will be sent to the Royal Australasian College of Surgeons, the New Zealand Association of Plastic and Reconstructive Surgeons and the Royal College of Pathologists of Australasia, for educational purposes.