# **Report on Opinion - Case 97HDC9370**

Complaint	<ul> <li>The Commissioner received a complaint from a consumer about the services provided by the provider, a Surgeon. The complaint is that:</li> <li>In mid-October 1997, during a surgical procedure to remove a single enlarged lymph node in the right axilla the provider also removed other lymph nodes despite specific instructions from the consumer not to do so.</li> <li>Since the removal of the lymph nodes the consumer has experienced ongoing problems including only partial movement of her right</li> </ul>
Investigation	arm, pain, swelling and numbness. The Commissioner received the complaint on 22 October 1997 and an investigation was undertaken. Information was obtained from:
	The Consumer The Provider, a Surgeon A Physiotherapist The consumer's medical records were obtained and the Commissioner sought professional advice from a breast surgeon.
Outcome of Investigation	The consumer had a motor vehicle accident when she was 19 years old, which resulted in an abnormal chest wall. When she was 26 years she had implants to both breasts. These required replacement in June 1993. Since this time the consumer has required regular ultrasound surveillance of her breasts.
	In October 1995 the consumer suffered a fall, bruising her arms and upper chest. When the pain persisted she consulted her Breast Surgeon, who referred her to another Breast Surgeon in late December 1995. The second Breast Surgeon referred her for ultrasound investigation because the consumer was concerned that she might have an implant rupture. The ultrasound revealed a large node in her right axilla. The second Surgeon concluded that the implant had not ruptured. The consumer discussed her treatment options with her Breast Surgeon and they decided to leave the node and continue ultrasound surveillance. At that time there was no family history of breast cancer.

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Outcome of Investigation, continued	In early March 1996 the consumer underwent a MRI examination of her breasts at a Radiology Centre. This report stated: <i>"The nodular mass lesion in the right axilla at the edge of the</i> <i>implant has an appearance strongly suggestive of a silicone</i> <i>granuloma or silicone with enlarged lymph nodes."</i>
	Four weeks later, at the end of May 1996, the first Breast Surgeon undertook an exploration of the consumer's right breast and took a biopsy of the breast capsule. The Breast Surgeon's report states:
	"Within the fibrous tissue there are a number of clear spaces, some of which contain retractile foreign material consistent with silicone. There is no evidence of malignancy."
	In early October 1996 the first Breast Surgeon faxed the MRI report on the consumer's breasts to a General Practitioner. In his covering letter he stated:
	"I biopsied an area of thickened capsule, but did not find anything significant."
	In late September 1997 the consumer saw a Breast Physician at a specialist clinic for ultrasound following a referral from the first Breast Surgeon. The investigation confirmed $a$ 3–5 millimetre non-specific mass suggestive of a solid lump. The Breast Physician asked the consumer to return the following week to see the provider, who is the subject of this investigation, in order that the best possible course of action could be planned.
	Nine days later, in early October 1997 the consumer consulted the provider. On examination the provider told her that the lump could be cancerous and the only option was to remove it surgically for histological examination. He explained that if he found it was cancerous he would proceed to book her for further operations. The consumer refused further surgery. She explained to the provider that she had six operations on her breasts, she also knew about the lymph node and did not want any more operations. Furthermore, she did not intend to have any treatment if he found that she had breast cancer. The consumer explained that her sister was diagnosed with breast cancer in August 1996. She stated that she

could not endure the treatments that her sister had had to endure.

continued

Surgeon

# Report on Opinion - Case 97HDC9370, continued

**Outcome of** The consumer again explained that she knew about the enlarged lymph nodes and did not want any of these lymph nodes removed only the Investigation, lump/mass. The provider explained that he would perform the surgery under local anaesthetic, remove the mass and she would return to work the following day. The consumer rang the provider to discuss the situation again before she consented to the surgery. According to the consumer, the provider did not explain the surgery, post-operative risks or complications.

> In the provider's letter of that day to the first Breast Surgeon and General Practitioner, the provider noted:

> > "She is not keen to have any further surgery, but in view of the rather suspicious feeling to this lymph node, I think we should proceed to excise this and I have made arrangements to do so under local anaesthetic plus sedation at the [...] Surgical Centre forthwith."

The provider performed the surgery eight days later. The consumer was so anxious that she asked the anaesthetist to give her a general anaesthetic. At surgery the provider found:

> "the mass was not one lymph node, but a number of lymph nodes making a collective mass. This surgical procedure was uncomplicated and the enlarged and quite pathological looking lymph node mass was excised. [The consumer] gave me absolute and unequivocal permission to remove the mass in the axilla."

Following the procedure the provider told her that he had removed the lump and a couple of lymph nodes. He did not advise her that she could require physiotherapy and that an expert physiotherapist was available at the Clinic. The consumer was shocked because she had not consented to removal of the lymph nodes.

When the consumer objected to the extent of the surgery the provider advised that:

> "She had been made aware of my opinion that this mass needed to be totally removed following which it would all be examined, as was the case. She was made aware of the fact that this mass was going to be removed by myself at surgery. Her only reluctance was in relation to having a further surgical procedure and she sought opinions elsewhere as to whether or not this mass needed removal."

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Outcome of Investigation,	Several months later the consumer's general practitioner informed her that the lump was in fact a number of lymph nodes.
continued	In his letter of December 1997 to the ACC Medical Misadventure Unit, the provider advised that: "With respect to her management it is medico-legally indefensible to leave giant large lymph nodes without a diagnosis. As the histology notes state these lymph glands were more than enlarged they were quite massive. As such the differential diagnosis of a malignant process was entertained and could not be excluded without surgical excision."
	The operation note reports: "the patient had a mass measuring 1.5 x 2 cm in the right axilla. The findings: a 3cm lymph node was excised; diathermy was used to control the bleeders. Implants and histology was made of the lymph nodes which looked too large, benign and multiple possibly secondary to previous surgery with silicone granulamas."
	Five days after surgery the consumer consulted the Breast Physician who
	advised: "Four lymph nodes were removed at the time of the surgery, all of which were clear. [The consumer] does comment that she has had some numbness in the armpit and down the arm. I have explained to [her] that this is most likely nerve damage and I would expect some improvement with time but there may be some permanent sensory loss which women usually adjust to with time".
	In early November 1997 the consumer consulted the first Breast Surgeon. He reported that: "[The consumer] came to see me because she was concerned about the axillary and the brachial fascia contraction which is occurring following recent excision biopsy of the three lymph
	nodes, which I understand from her were not malignant. I have reassured her that no surgery is indicated to free this tightness at this stage and instead she should start gently stretching up the arm."
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Outcome of Investigation, continued	On this same day, the consumer filed a complaint with ACC for medical misadventure against the provider. In response to investigation by the Medical Misadventure Unit, the provider advised the Unit in his letter of December 1997 that: "I have not seen her subsequent to surgery, but I understand that she now complains of tethering of the axillary tissue to the surrounding skin. A way to minimise the shoulder problems is to have urgent and accurate physiotherapy and indeed we have at [this] Centre a physiotherapist who is expert in this field. I would suggest in the first instance that this patient should perhaps see a physiotherapist and specifically our physiotherapist."
	"With respect to the neuropraxis the lymph glands are close to the intercostobrachial nerve and it may be that they have been bruised or traumatised at the time of lymphatic resection. This is a complication of lymph node dissection, and a well recognised one. It is sometimes not possible to completely remove the lymph glands and not traumatise the nerves as they are closely proximated. Once again as I have not seen her at follow up, I cannot comment further except to state that this should get better over a period of time or perhaps weeks or months. This patient had large lymph nodes, had surgical resection of them and I believe has not suffered any medical misadventure which is untoward, unexpected or will not improve in time."
	In early June 1998 the physiotherapist reported that: "[The consumer] has been receiving treatment for right cervical spine and right arm pain following breast surgery in November 1997. Over the last two months [the consumer] has developed a swollen/painful right thumb and hand. This is corresponded with an increase in her neck and arm symptoms and an increase in workload at work."
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Outcome of Investigation, *continued*  "On examination the right thumb is swollen and tender around the first MCP joint and thenar eminence and there is defuse swelling on the dorsum of the hand. [The consumer] has a downwardly rotated right scapula, over active levator scapula sternocleidomastoid muscles, a tender – swollen C5-C6 facet joint, and a tight median nerve (-30 degree upper limb tension test). There is general weakness of the rotator cuff on external rotation 4-/5. There has been no trauma to the thumb or hand, and I feel these symptoms could be a result of a lymphodema from removal of the lymph nodes or thoracic outlet syndrome associated with the median nerve/C5-C6 restriction."

The consumer has continued to experience problems. She has extensive pain and swelling of her right arm extending to her fingers, neck and face. She finds it difficult to write and is not able to maintain employment to her satisfaction. She now wears a full arm-length elastic sleeve to control the swelling. These on-going treatments have been at considerable expense, the elastic sleeve alone cost \$185.00.

The Commissioner consulted a breast surgeon to advise on:

- Whether it was necessary to remove the total lumps/mass for diagnostic purposes.
- If was it possible to remove the lump/mass independent of the lymph nodes or were the lymph nodes incorporated in the mass.
- Whether the consumer's post operative course comes within that expected type of surgery.

The Commissioner's advisor initially addressed two questions:

- Did the consumer receive the operation that she consented to?
- Did she receive an adequate explanation of the possible adverse effects of the operation?

## Report on Opinion - Case 97HDC9370, continued

In addressing the specific issues, the Commissioner's advisor stated:

"[The provider] states that he removed the lump, it could be felt in its entirety. The lump consisted of a mass of lymph nodes and although there was a good deal of evidence to suggest this prior to the operation, the precise nature of the lump only become certain at the time of the operation."

"[The consumer] clearly had not been led to expect this and was distressed when told that four lymph nodes had been removed. It is difficult to judge the adequacy of this aspect of the consent without having a transcript of the discussion, but it is apparent that [the consumer's] expectations differed significantly from [the provider's] and that there was a fairly large communication gap between the two parties. The aspect of consent relating to complications seems even less satisfactory and with no evidence presented to suggest that the complications of this procedure had been discussed. Not all of the reported complications can readily be attributed to the surgery performed but some for example local numbness and tingling are common consequences of axillary surgery. This aspect at the very least could have been included in the informed consent process. All in all, the process of obtaining informed consent appears on the evidence presented, to have been barely adequate."

"The evidence from the MRI scan and a number of clinical assessments suggests the final histological diagnosis but I would agree entirely with [the provider] that the only way of excluding malignancy was certainly to excise the lump. Fine needle aspiration or other form of needle biopsy would not have been appropriate in the presence of breast implants."

The Commissioner's advisor also noted that as the lump/mass seemed to have been made up entirely of a collection of lymph nodes, the lump mass could not have been removed independently of the lymph nodes because the mass incorporated the lymph nodes.

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**Outcome of** 

continued

Investigation,

## **Report on Opinion - Case 97HDC9370, continued**

Outcome of Investigation, *continued*  "[The consumer] clearly has more problems, more severe ones and for a longer duration than could be considered 'normal'. However the problems are all common and there is nothing to suggest that the surgery was performed other than competently. [The consumer's] final complaint about non referral to physiotherapy at [the Clinic] is almost certainly the result of her decision to seek help elsewhere after her surgery and [the provider] cannot be blamed directly for this."

The Commissioner's advisor summarises his impressions from the documents provided by stating that the quality of the informed consent was below the expected level but that other aspects of the management appear to have been satisfactory.

# Report on Opinion - Case 97HDC9370, continued

Code of Health and Disability Services Consumers' Rights *RIGHT 4 Right to Services of an Appropriate Standard* 

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

#### RIGHT 6

Right to be Fully Informed

- 1) Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive, including -...
  - b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;

#### RIGHT 7

Right to Make an Informed Choice and Give Informed Consent.

- 1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.
- 7) Every consumer has the right to refuse services and to withdraw consent to services.

#### **Report on Opinion - Case 97HDC9370, continued**

Opinion:In my opinion the provider breached Right 6(1)(b), Right 7(1) and RightBreach7(7) of the Code of Health and Disability Services Consumers' Rights as<br/>follows.

#### **Right 6(1)(b)**

The consumer was not fully informed about her impending surgery. The provider advised the consumer that the only way to obtain a definitive diagnosis of the lump was to excise the lump itself. The provider's mind was clearly on excluding a diagnosis of cancer but that was not the consumer's intention. The provider was aware of the number of operations the consumer had had on her breasts and her reluctance to have further surgery. He was also aware of her intention to refuse cancer treatment should this become necessary. The provider did not explore other options with the consumer.

I do not accept that the provider explained the surgery to the consumer adequately. In my opinion removal of a lymph node could reasonably be contemplated in a surgical procedure to remove an axillary mass. However, the consumer made it known to the provider that she did not want lymph nodes removed. In the light of this information the provider should have explained that surgery to remove the mass was likely to also include removal of one or more lymph nodes. This is information that the consumer could reasonably have expected to receive in determining whether to consent to the procedure.

I do not accept that the provider explained to the consumer the expected risks or side effects of the surgery. Numbness and tingling are commonplace with this type of surgery but the consumer was not expecting them. Furthermore removal of lymph nodes could reasonably be expected to cause some degree of swelling but this was not discussed with the consumer. It would appear that the surgery was more extensive than anticipated and that the consumer was not advised about the possibility of physiotherapy and how it could help.

The provider indicated that the consumer's surgery would be minor, would be performed under local anaesthetic and that she would be back at work the following day. The consumer has experienced considerable ongoing and unexpected problems. She has also encountered considerable additional expense. Failure to fully inform the consumer of the risks of this happening was also a breach of the Code.

### Report on Opinion - 97HDC9370, continued

Opinion: Breach, <i>continued</i>	<ul> <li>Right 7(1) and 7(7)</li> <li>Services may only be provided to a consumer if the consumer gives informed consent. In terms of the Code, informed consent is not a one-off event, but a process involving effective communication, provision of all necessary information and the consumer's freely given, competent consent. Each of these elements reflects a fundamental component of the informed consent process and they all work together to ensure valid consent.</li> </ul>
	Thus, consent is not valid unless it is given with complete understanding of what is being consented to. As discussed above, the consumer was given

what is being consented to. As discussed above, the consumer was given insufficient information on which to base her decision about removal of the mass. In my opinion, therefore, the provider failed to obtain the consumer's informed consent to its removal in accordance with Right 7(1) of the Code of Health and Disability Services Consumers' Rights.

Further, as a corollary to the right to give informed consent, every consumer has the right to refuse services. In the consumer's mind the mass was different from the lymph nodes and she made her wishes very clear to the provider that she did not wish lymph nodes to be removed. Although the provider considered that it was medico-legally indefensible to not remove the lymph nodes, it was still the consumer's right to refuse to have that done. Failure to comply with the consumer's wishes on this matter was a breach of Right 7(7) of the Code of Health and Disability Services Consumers' Rights.

# **Report on Opinion - Case 97HDC9370, continued**

Opinion: No Breach	<b>Right 4(2)</b> In my opinion the provider did not breach Right 4(2) of the Code of Health and Disability Services Consumers' Rights.
	The lump itself could not have been removed independent of the lymph nodes because the lump was in itself enlarged lymph nodes. Following the surgery the consumer has continued to experience complicated and severe side-effects. The problems that the consumer is experiencing are common to this type of surgery although the severity of her symptoms cannot be entirely attributed to the surgery. These complications need not result from incompetently performed surgery.
	The provider's purpose in performing the surgery was to exclude malignancy. He removed the lump in total to exclude this possibility. There is no evidence to suggest that this surgery was done incompetently or that it did not meet professional standards.
Actions	I recommend that the provider:
	• apologises in writing to the consumer for his breach of Right 6(1)(b) and Rights 7(1) and 7(7) of the Code of Health and Disability Services Consumers' Rights. I have received a letter of apology from the provider and have sent it to the consumer.
	A copy of this opinion will be sent to the Medical Council of New Zealand. A copy will also be sent to the Royal Australasian College of Surgeons for their information and publication.
	In accordance with section 45 of the Health and Disability Commissioner Act 1994 I will refer this matter to the Director of Proceedings.