Report on Opinion - Case 98HDC15901

Complaint	The Commissioner received a complaint about the services provided to the consumer by the general practitioner. The complaint is that:
	 The fat atrophy in the consumer's neck and back as a result of steroid injections administered in mid-October 1996 is considered to have been due to a failure by a registered health professional to observe a standard of care and skill that was reasonable in the circumstances. The general practitioner did not advise the consumer that a possible side effect of the steroid injections was fat atrophy.
Investigation	The Commissioner received the complaint from the Medical Misadventure Unit of the Accident Rehabilitation and Compensation Insurance Corporation ("ACC") on 6 July 1998 and an investigation was undertaken.
	Information was received from:
	The Consumer The General Practitioner/Provider
	The consumer's medical records were obtained and reviewed. Information was also received from a pharmaceutical company.
Information Gathered During Investigation	The consumer has suffered from severe migraine from her early teenage years. These migraine headaches have been particularly difficult to control and she has used a large range of medication, including opiates. In 1995 the consumer became dependent on opiates and required treatment for her dependence. During October 1996 the consumer suffered with particularly severe migraines, which did not respond to <i>emigran</i> , <i>digesic</i> (a painkiller) and <i>voltaren</i> (an anti-imflammatory).
	In mid-October 1996 she consulted a general practitioner. The general practitioner was reluctant to use opiates, and <i>pethidine</i> (a painkiller), which had been used in the past, left the consumer feeling anxious and depressed. At this consultation the consumer complained of severe headaches, and neck and shoulder pain which plagued her on a daily basis.
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Information Gathered During Investigation, *continued* On examination the general practitioner found cervical dysfunction with a tense trapezius muscle and several trigger points. The general practitioner believed his options for treating the consumer's migraine were limited and decided to inject *kenacort A10* (an anti-inflammatory), one quarter of an ampoule into each of four trigger points. The general practitioner advised the Commissioner that:

"I did not consider the risk of fat and muscle atrophy as relevant, because of the low dose and the fact that [the consumer] was so distressed. I felt that I had to give her treatment urgently.

Referral to other treatment providers or specialist was not an option. The treatment was effective, in that it brought relief and was repeated by me [in early] November 1996.

In early February 1997 the consumer returned to the general practitioner with fat atrophy indentations on her neck and shoulder, which were immediately recognised by the general practitioner as the effect of his injections of *kenacort A10*. He immediately supported the consumer's application to the Medical Misadventure Unit at ACC. He has taken full responsibility and expressed sincere regret at this mishap.

The fat atrophy caused severe indentations on the consumer's neck and shoulders, some of which are visible above the neckline of her dresses. The consumer consulted a plastic surgeon who advised the ACC:

"[The consumer] first consulted me [in late] April 1997 on the recommendation of her general practitioner [the second general practitioner], to discuss treatment for fat atrophy depressions on the back of her neck ... [The plastic surgeon] confirmed that there were four depressions on the right side of the back of her lower neck, the right suprascapular region and the left suprascapular region. Each of these measured about 2cm x 3cm and were up to 1cm deep. They were conspicuous when wearing an ordinary low cut dress."

Treatment

"The only appropriate treatment to improve these depressions was fat grafting ...

... The procedure involved aspirating fat cells from her abdomen, centrifuging them to aspirate out the fluid component and then aspirating of the oil component...

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Information Gathered	This left viable fat cells, 2ml of which were injected into three of the depressions, one of the depressions was more shallow and being
During	covered by hair was not treated.
Investigation,	
continued	The initial improvement is gratifying but not all the fat injected will survive and she may need further treatment."

The ACC Committee noted that:

"... [W]hilst this is a general practice procedure it is generally only carried out by a practitioner who has particular skills in administering Kenacort, and the Committee has considerable concerns about the result of this particular administration of Kenacort series."

New Ethicals November 1997 (p.211) advises:

"[K]enacort may be administered 1mg intradermally ... Adverse Effects as local atrophy (usually temporary)."

The medical information manager at the pharmaceutical company, the distributor of *kenacort*, advised:

"For Intradermal administration, the initial dose of triamcinolone acetonide will vary depending upon the specific disease entity being treated but should be limited to 1.0mg (0.1 mL) per injection site, since larger volumes are more likely to produce cutaneous atrophy. Multiple sites (separated by one centimetre or more) may be so injected ... such injections may be repeated, if necessary at weekly or less frequent intervals."

The manager also advised the Commissioner that the consumer's reaction was unusual given that only a quarter of the recommended dose was administered.

The general practitioner administered .25mg into four different sites on the consumer's shoulders and neck on two occasions.

The consumer is now being treated by a neurologist for her migraine headaches.

Report on Opinion - Case 98HDC15901, continued

Code of Health and Disability Services	RIGHT 4 Right to Services of an Appropriate Standard
Consumers' Rights	 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 –
	 <i>An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;</i>
Opinion: No Breach	In my opinion the general practitioner did not breach Right 4(2) of the Code of Health and Disability Services Consumers' Rights.
	The consumer was suffering a particularly severe bout of migraine headaches and the general practitioner was very limited in the choice of medications available to the consumer. He considered the possible benefits of <i>kenacort A10</i> to be greater than the likelihood of adverse reaction. The general practitioner administered a quarter of the maximum dose. The injections were far enough apart, in terms of frequency, to comply with the recommendations of the manufacturer. In my opinion the general practitioner's administration of <i>kenacort</i> complied with professional standards.

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Opinion: Breach	In my opinion the general practitioner breached Right 6(1)(b) of the Code of Health and Disability Services Consumers' Rights.
	The general practitioner stated that he did not advise the consumer about the possible risk of muscle or fat atrophy before he injected her with <i>kenacort A10</i> . He considered that the dose would be so small that it would not cause that localised reaction. In my opinion he should have informed the consumer of the possibility of this adverse event and not informing her of this risk was a breach of her rights under the Code of Rights.
Actions	• I recommend that the general practitioner write a letter of apology to the consumer for breaching the Code of Rights. This letter is to be sent to the Commissioner who will forward it to the consumer.
	• I have received an "Adverse Event" form from the pharmaceutical company. I request that the general practitioner return the completed form to the drug company at his earliest convenience.
Other Actions	A copy of this opinion will be sent to the Medical Council of New Zealand.