



**Office of the
Health Complaints Commissioner
2007**

700-0511006 – A medical practitioner – an adverse outcome from a cosmetic procedure

Section 23 (1)(d) – a health service provider failed to exercise due skill; s. 23 (1)(g)(ii) a health service user was not provided – with a reasonable opportunity to make an informed choice of the treatment or services available - Investigation finalised October 2006 – Matter referred to and resolved in conciliation – Practitioner referred to the Medical Council of Tasmania

A complaint was made against a medical practitioner by a woman who alleged that she had suffered an adverse reaction to Dermalive[®],¹ a deep derma filler used in a cosmetic procedure in 2000-2001, and that the doctor at the relevant date knew or ought to have known of the risks involved and failed to warn her of the risk. In about 2004 the complainant began to experience pain and was aware of lumps having developed in the areas injected during the cosmetic procedure in 2001. She sought information from the doctor about the filler used and access to her medical records without success.

The complainant consulted Associate Professor Frank Kimble a plastics and reconstructive surgeon, who operated to remove the lumps. Further unsightly lumps emerged and the prognosis is that further surgery will be required. Mr. Kimble undertook research to establish the product used and the information provided or available at the relevant time and was of the opinion that the lumps were a late-onset granulomatous reaction following the injection of the product Dermalive[®]. He provided the complainant with a 1999 article from *Plastic and Reconstructive Surgery* April 15, 2005 titled "New-Fill Injections May Induce Late On-set Foreign Body Granulomatous".

It was suggested by the complainant that other clients of the doctor and Bioscor might have suffered similar adverse outcomes. A search conducted in the Supreme Court of Tasmania Registry and enquiries made during the investigation established that other clients had suffered a late onset granulomatous reaction as a result of Dermalive[®] being used in a cosmetic procedure and alleged that they had not been warned of the potential risks of Dermalive[®].

The conclusion was that the complainant suffered a late-onset granulomatous reaction following the injection of the product Dermalive[®] or DermaLife in a cosmetic procedure undertaken by the doctor in about January 2001. There appear to be no other cosmetic procedures undergone by the complainant which would have caused this condition and

the condition is consistent with the reported side effects of the product Dermalive®. It appears likely that this adverse reaction was caused by the product and not the technique used to inject the filler.

Regarding knowledge of the risks associated with the use of Dermalive® in 2000 – 2001 the conclusion is that the doctor knew or ought to have known of the risks involved with the use of Dermalive® and that prospective patients must be warned of that risk. At the time of the introduction of Dermalive®, it was documented that one of the potential risks was inflammatory granuloma formation and that although rare, this should be covered in any pre-operative discussion with the patient contemplating the use of the product. As stated in the product technical guidelines *“it is vital to inform the patient of the characteristics of Dermalive®, as well as its indications, particularly to the patient to be treated, its contraindications, its incompatibilities and its potential side-effects.”*

The doctor maintained that he knew of the relevant risks, warned the complainant and warned all his clients and provide the complainant with product information. The complainant states that she did not receive the patient label or the patient brochure or the information titled “Packaging insert DERMALIVE” and was not informed of the potential complications and risks or contraindications for the product’s use, its incompatibilities and its potential side-effects. Her friend who accompanied her to the appointment provided corroborating evidence. The conclusion reached is that the doctor failed to warn the complainant of potential complications and risks and a relevant risk materialized, namely late on-set granulomatous reactions causing her loss and damage.

There is a public interest issue relating to product safety as consumers, in order to give valid consent, need to be informed of any complications, contraindications and risk associated with the product and the cosmetic techniques used. It would appear that the late on-set granulomatous reactions resulting from Dermalive being used for cosmetic enhancement are not as rare as indicated in the initial research. It would appear that there is probably sufficient information now available that reputable practitioners throughout Australia would not use the product or would warn of the potential risks. Taylor Bryant were the former distributors but no longer distribute this product.

The matters was referred to conciliation for the purposes of negotiating a financial settlement to compensate the complainant for the loss and damage suffered as a consequence of the late on set granulomatous reaction associated with the product Dermalive®, about which she was not adequately warned.

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Approved for Annual Report [theme or case summary]

¹ Manufactured by Dermatech, 28 Rue de Caumartin, 75009, Paris, France