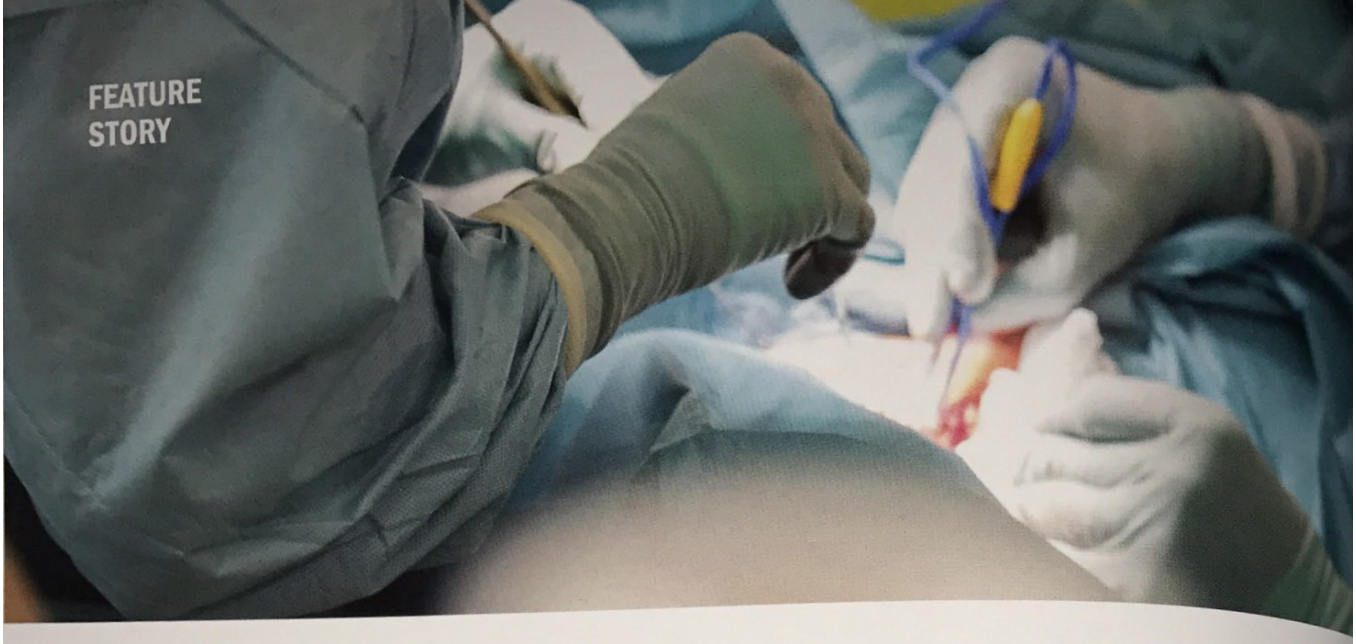

woman died from uncontrolled blood loss following a liposuction procedure to source ASC. This intervention to treat Alzheimer's disease was considered experimental. The coroner found that the cosmetic surgeon's performance was poor and resulted in the woman's death. In his report, the coroner commented that the treatment 'has some of the troubling hallmarks of 'quack' medicine: desperate patients, pseudo-science and large amounts of money being charged for unproven therapies". The coroner recommended that the Therapeutic Goods Administration (TGA) and the NSW Ministry of Health "consider how best to manage and regulate the provision of 'experimental' or 'innovative' medical or surgical procedures that have not yet been approved following clinical trials or other recognised peer-reviewed evaluation processes."[2]

Clearly, these stem cell treatments (for harvesting, cell preparation and subsequent injection) need to be provided in appropriate facilities. However, from the information provided by the majority of local clinics, it is uncertain whether the stem cell procedures are provided in appropriately accredited surgical facilities, and if all cell manipulations are undertaken in accredited laboratories where there are appropriate quality control standards. It appears some treatments are provided in an office-based environment, which in certain instances is not regulated. In a similar manner, the location of cell processing is often not clear, but should be undertaken in an appropriately accredited laboratory.

As recommended by the National Stem Cell Foundation of Australia and Stem Cells Australia:

"Any manipulation of cells, even if they come from you, carries risk of infection and other complications. They should be prepared in an accredited laboratory, where there are exacting quality control standards independently verified, or using a device that has been approved by regulators such as the TGA (page 12)".[3]

Who regulates stem cell treatments in Australia and New Zealand?

So why are these unproven and potentially dangerous therapies allowed to happen on our patch? Put simply, regulatory issues for the oversight of stem cell treatments remain a problem both locally and internationally due to the complexity of the cells themselves, the variety of ways in which they are used and manipulated.

In Australia, the TGA is responsible for the regulation of all medicinal products, including human cells and tissues, which include certain stem cell treatments. The Australian Regulatory Guidelines for Biologicals outline the legal arrangements in Australia for the supply and use of human cell and tissue-based therapeutic goods. Certain stem cell treatments that require processing, such as haematopoietic stem cells transplant for disorders of the blood and immune system, fall under the oversight of, and are approved by, the TGA.

However, many autologous stem cell treatments are not regulated by the TGA. These treatments would be considered 'medical practice' and are excluded from regulation under the Therapeutic Goods (Excluded Goods) Order No. 1 of 2011.[4] The definition of excluded treatments is "human cells that are collected, processed and returned to the same patient, in a single course of treatment while under the clinical care