



6 June 2005

Productivity Commission Circular  
Impacts of Medical Technology in Australia

**Progress report submission – Re. Xenotransplantation section, pp. 234-235.**

Thank you for the opportunity to submit a response to the 'Impacts of Medical Technology in Australia' Progress Report.

This letter briefing outlines current advances in xenotransplantation, as relevant to pages 234 and 235 of the report.

As an international company, Living Cell Technologies (LCT) has kept up to date on progress in the xenotransplantation field in the USA and Europe. In recent years, new scientific information has been published. LCT wishes to make available this information and its own information and perspective.

**LCT's approach to xenotransplantation**

In assessing xenotransplantation, LCT urges attention specifically to the transplantation of animal cells from high health status pigs that are not genetically modified and a treatment regimen that does not require the use of toxic immunosuppressive drugs. Animal cell transplantation is feasible whereas whole animal organ transplants remain a remote potential. The features of LCT's approach to xenotransplantation are summarised below.

**Animal cell and not organ transplant**

LCT is developing pig cells for the treatment of neurological diseases such as Huntington's Disease, Stroke and Motor Neuron Disease, Diabetes and other metabolic disorders. LCT is not engaged in whole animal organ transplants.

Cell transplants have important advantages over the use of whole organs in terms of safety, morbidity and ease of administration.

**No genetic modification**

Objections to the use of genetically modified animals are not relevant to LCT's approach. LCT considers the use of animal cells that are not genetically modified as an advantage.

For example, in the event of a virus leaving a transplanted pig cell, the offending virus is coated with a film of pig cell material. This is recognised as foreign and thus rejected by the recipient's intact immune system. Viruses exiting a cell that has been genetically modified to be free of pig antigens may not be as easily recognisable as foreign or eliminated by the recipient's immune system.

**No immune suppression**

LCT's product does not require the use of toxic immune suppressive drugs. An intact immune system and natural resistance to infection in the human recipient is a critical safety factor.

**Use of high health status pigs**

LCT has access to pigs of very high health status. LCT's pig herd has very low copy numbers of porcine endogenous retrovirus (PERV) and do not produce infectious PERV particles. Recent scientific data has led to significantly less concern about the transmission of PERV to transplant recipients. There is now evidence for the subcutaneous injections into humans of PERV present in unheated pig clotting factor VIII since 1984. LCT concurs with the assessment on the safety of xenotransplantation by the US FDA, National Institutes of Health USA and Juvenile Diabetes Research Foundation.

**Closed herd**

Pigs that are a source of cells for human therapeutics are bred in specialised facilities. This prevents the potential spread of infection between species such as birds to pigs.

**Animal welfare**

Pigs as source animals are bred and maintained according to Animal Ethics guidelines and in conditions more 'humane' than pigs bred for food. Pigs are isolated from other herds but not from each other.

**US Food and Drug Administration (FDA)**

The FDA guidelines for xenotransplantation describe safety measures in detail and LCT expects to meet safety requirements.

**Clinical trials**

LCT's present products are improved from previous prototypes and ready for human trials in early 2006 for type 1 diabetes. Long term survival of cells is possible as demonstrated by the retrieval of live cells from the abdominal cavity of a xenotransplant recipient 9 years after transplantation. Data from an early study is to be published in a major European journal. LCT has published the long term follow-up of patients who have received xenotransplants and has not been able to show evidence of transmission of PERV or other pig viruses (18 patients followed up to 9 years after transplant).

LCT's other products are being developed for neurological diseases such as huntington's, stroke and motor neuron disease.

I trust that this updates you on current progress and development in the field of xenotransplantation and live cell therapy.

Should you require any further information, please do not hesitate to contact me.

I look forward to receiving further updates and viewing the final report.

Yours sincerely

**Paris Brooke**

General Manager

**Living Cell Technologies Ltd**