Dear Professor Holloway

Consultation on Living Cell Technologies’ Application to Conduct a Xenotransplantation Clinical Trial

Thank you for your email of 14 July 2008 requesting my submission on Living Cell Technologies’ application to conduct a xenotransplantation clinical trial.

Background
In 2005, the Bioethics Council sought public comment on xenotransplantation. As part of this consultation, the Bioethics Council released a discussion document entitled The Cultural, Spiritual and Ethical Aspects of Xenotransplantation: Animal-to-human Transplantation to provide information about the nature of xenotransplantation and the cultural, ethical and spiritual questions it raises.

On 18 May 2005, I responded to the Bioethics Council by providing a submission on the broader issues of xenotransplantation. I attach a copy of my submission for your information. You will note that I commented on the following issues:

- the role of the Health and Disability Commissioner;
- the application of the Code of Health and Disability Services Consumers’ Rights (the Code) to xenotransplantation research and therapy;
- spiritual and cultural perspectives on xenotransplantation;
- weighing the interests of the individual against those of the public;
- informed consent; and
- regulation of xenotransplantation.

Since the Bioethics Council’s consultation in 2005, Living Cell Technologies has applied to conduct a clinical trial of pig cell transplantation in New Zealand. The Gene Technology Advisory Committee assessed the proposal and concluded that there was sufficient evidence that the proposed therapy was safe and had the potential to be effective to allow the trial to proceed. Northern X Regional Ethics Committee then assessed the proposal and approved the clinical trial, subject to the Minister of Health addressing
certain issues. The Minister of Health has now asked the National Health Committee to provide him with independent advice on Living Cell Technologies’ application.

My response
I remain very interested in the issues around xenotransplantation and I commend you for consulting widely on this application. However, I believe it would be inappropriate for me to provide a submission on this clinical trial application.

My role is to promote and protect the rights of consumers who use health and disability services, including those who participate in research. I have jurisdiction to assess and resolve complaints alleging a breach of the Code. I am required to carry out this function impartially and with an open mind. This could be open to challenge if I had commented on a specific clinical trial application.

I would, however, be interested in reviewing any reports that are published as a result of this consultation.

Yours sincerely

Ron Paterson
Health and Disability Commissioner