SUBMISSION TO THE REVIEW OF THE GENE TECHNOLOGY SCHEME BY THE LEGISLATIVE AND GOVERNANCE FORUM ON GENE TECHNOLOGY

29 SEPTEMBER 2017

Introduction

I thank the Legislative and Governance Forum on Gene Technology for the opportunity to contribute to the review of the National Gene Technology Regulatory Scheme.

I consider that the Scheme has made valuable contributions to the safe development of gene technology in Australia and internationally.

I contributed to the Technical Review of the Gene Technology Regulations in December 2016 and May 2017. I now submit the following additional proposals for consideration under this Review:

1. **Suggestions for modifications to the Gene Technology Regulations**
   I suggest that improvements to definitions in the Regulations would help clarify how techniques and organisms may be regulated as technology advances. For example:
   a) Replacement of the term 'foreign nucleic acid' by 'gene technology' in item 1 of Schedule 1 could assist with regulating new technologies that do not introduce nucleic acids from other organisms.

   b) Widening the scope of item 2 of Schedule 1 by adding '*An organism, cell, tissue'* to the existing definition of what is not a GMO, which currently is:
   'A whole animal, or a human being, modified by the introduction of naked recombinant nucleic acid (such as a DNA vaccine) into its somatic cells, if the introduced nucleic acid is incapable of giving rise to infectious agents.'

   c) Appropriate use of a caveat such as *'provided it is unlikely that there will be increased capacity to cause harm'* (e.g. as a result of the modification) in conjunction with definitions that exclude techniques or organisms from additional risk management (e.g. use of naked nucleic acids or cells derived from iPSCs)

2. Suggestions regarding the interface with other regulatory schemes

Therapeutic products and clinical trials in Australia are covered by Human Research Ethics Committees and the TGA. They are also likely to be subject to the requirements of other regulatory agencies in other jurisdictions (such as the FDA, MHRA or EMEA). Classifications in one jurisdiction may affect conduct and marketability in others and harmonisation is vital to reducing barriers. Two areas for consideration in these regards are:

a) Triaging clinical trials involving GMOs
Consideration could be given to whether or not ethics and TGA review are sufficient (without necessarily requiring a separate application to the OGTR) for risk managing clinical trials in Australia involving gene or cell therapies using conventional means that have a history of safe use with respect to persons handling the GMO and the environment. The roles of patient safety and international experience would be part of such considerations.

b) *Taking account of the effect of Australian regulatory systems on international activities*
Classification or review under one regulatory system may pose risks for others. For example, a formal exempt classification of a clinical trial or the use of a therapeutic GMO under the Australian Gene Technology Regulatory Scheme may pose issues in other jurisdictions in relation to conduct or marketing. The exempt classification requires that a GMO is not intentionally released although the risks are considered negligible. In the clinical trial or therapeutic context this may be an impediment. Suggestion 2 a) above may assist in this regard.

Conclusion

I submit the above in my capacity as an individual and look forward to participating in the next phases of this important Review.