

National Genomics Policy Framework Project Reference Group's Submission to the 3rd Review of the Gene Technology Scheme

The National Genomics Policy Framework Project Reference Group (the Reference Group) provides the following response relating to Review Theme one – Technical issues, Finding 5 (pages 18-19) of the preliminary report, which reads:

***Finding 5** – The Review found that the Scheme was not designed to regulate humans, including those who have received or inherited germline therapies (or who have received somatic therapies that were not envisaged when the Gene Technology Act 2000 was drafted). Therefore, the Scheme is not the most appropriate means to regulate the application of human gene therapies (including any ethical, legal and social issues).*

Any consideration of whether additional regulatory oversight is needed in this area may benefit from national collaboration across the health sector, to identify the most appropriate body to undertake this work.

The Reference Group supports the finding.

Furthermore, the Reference Group notes that definition clarity is required, in order to avoid the possibility of a person who has undergone gene therapy (be it germline or somatic therapies) being considered a genetically modified organism (GMO). To address this, the Reference Group supports an amendment to the definition of a GMO in the *Gene Technology Act 2000* to ensure that human beings are not inadvertently subject to the provisions of being regulated as a GMO under that legislation.

If the above legislative amendment were to result in changes to governance arrangements to expand the scope of regulatory activity, the Reference Group would support national collaboration to identify the most appropriate form of regulatory oversight.

Attachment

Attachment A: National Genomics Policy Framework Project Reference Group membership

Attachment A

NATIONAL GENOMICS POLICY FRAMEWORK PROJECT REFERENCE GROUP MEMBERSHIP

Caroline Edwards (Chair)

Deputy Secretary, Health Systems Policy & Primary Care Group, Commonwealth Department of Health

Professor Matthew Cook

Professor of Medicine (ANU), Director, Immunology, Canberra Hospital, Director, Centre of Research Excellence in Personalised Immunology (NHMRC), ACT Health

Heather Malcolm

Senior Consultant Clinical Support, System Performance and Innovation, Northern Territory - Department of Health

Cathryn Cox

Executive Director, Health System Planning and Investment Branch, NSW Health

Dr Keith McNeil

Assistant Deputy Director General and Chief Medical Information Officer, Clinical Excellence Division, Queensland - Department of Health

Dr Janice Fletcher

Clinical Director, Genetics and Molecular Pathology, Deputy Executive Director SA Pathology, South Australia - Department of Health and Ageing

Dr Paul Fennessy

Manager, Genomics & Health Technology, Cancer, Specialty Programs, Medical Research and International Health Branch, Health and Wellbeing Division, Victoria - Department of Health and Human Services.

Dr Joy Mendel

Senior Program Advisor, Clinical Support, Principal Medical Advice Section, Acute Planning and Strategy Unit, Planning, Purchasing and Performance Group, Tasmania - Department of Health and Human Services.

Professor Hugh Dawkins

Director, Office of Population Health Genomics, Western Australia - Department of Health