Choosing Genes for Future Children

REGULATING PREIMPLANTATION GENETIC DIAGNOSIS

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PRINCIPAL INVESTIGATOR: PROFESSOR MARK HENAGHAN

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Te Kaupapa Rangahau Ira Tāngata
Law, Ethics and Policy for the Future

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FOREWORD

Early in my tenure as President of the Law Commission, Lynda Hagen and then Trustees of the New Zealand Law Foundation called to discuss the possibility of a major project centred on the Human Genome Research and its core unifying factor for all humanity. Their object was awesome. Their determination was inspirational. The credentials of those they proposed to involve were impressive. Although firmly based in New Zealand and engaging locally, the concept envisaged international as well as interdisciplinary collaboration.

Because of the size and scope of the exercise, the Trustees responsibly first undertook a thorough and comprehensive assessment of the idea following which the commitment to the three-year project was made.

The concept at its inception was, and always will be, visionary. It deals with issues which are evolving and emerging by the day. Its concern is not merely with the advances made by science, but the implications, at all levels and in all aspects of human endeavour, of those changes.

I have been fortunate to be one of those invited to be part of an ongoing Advisory Review Committee. From time to time, we receive reports on what is being achieved, offer suggestions from the experience of our varied backgrounds and are available as a general sounding board.

As was the case with the original brief, the Review Committee has remained committed to the demand that this project must add value to what is being done elsewhere around the world but remain reflective of the particular environment within this country.

Although it is early days, we are persuaded that the confidence which the Law Foundation placed in the principal investigator, Professor Mark Henaghan, and the extraordinarily impressive team that he has built up around him, has been well placed. We have seen the difficulties of embarking on a task which breaks new ground, the frustrations of finding that extensive work which has been undertaken is being replicated elsewhere and the demand of ensuring that anything produced must stand up to rigorous peer analysis but at the same time be capable of being understood and evaluated by any informed reader.

I am reminded of the words by Thomas Jefferson which appear across the gate of the University of Virginia "For here we are not afraid to follow truth wherever it may lead." It is in that spirit that this professional, responsible and sensitive inquiry is being undertaken. There are no hidden agendas. There are no preconceptions. There are issues which impinge upon everyone of us within the community that demand serious and thoughtful consideration.

New Zealand cannot divorce itself from global advances. Barriers of time and space are history. As a society we must understand what is being achieved abroad and be prepared for its implications for good and ill within our own country.

This project is an important vehicle to extend our knowledge and understanding and to help prepare us for whatever the future will demand. There are seldom right or wrong responses in any absolute sense. Judgment will need to be made, balance achieved and mutual respect fostered. The work of our researchers can assist significantly in providing the data and possibilities for responsible and responsive decisions to be taken.

J Bruce Robertson
Judge's Chambers
Court of Appeal
Wellington

FROM THE NEW ZEALAND LAW FOUNDATION

This three-year research project is groundbreaking for New Zealand and it has the potential to touch the lives of every New Zealander. The New Zealand Law Foundation is delighted to have been the catalyst for such important research and to see the publication of the first report from the project.

At the start of the new millennium, the Law Foundation took the initiative to explore significant areas where it appeared that the development of the law may well be lagging behind developments in technological advancement.

After extensive analysis, the Law Foundation identified an urgent need to research the law relating to biotechnology and more particularly reproductive technologies.

Scientific advances around the world had resulted in rapid progress in gene technologies. New and fundamental questions were being raised about the essence of life, humans and human nature. The ability to alter the building blocks of life was being acquired and developed in an environment of uncertainty in relation to ethics and law. The Law Foundation recognised that while the science supporting biotechnology was well developed, the pace of change often rendered current law and regulation inapplicable or irrelevant and denied communities the opportunity to debate and research the consequences of that science.

The Law Foundation saw the opportunity to assist the nation to navigate through this potential minefield by commissioning this independent, international study – **The Human Genome Research Project, Te Kaupapa Rangahau Ira Tāngata: Law, Ethics and Policy for the Future**.

This research is an important step towards ensuring the law in New Zealand is well positioned to meet the legal and ethical challenges arising from gene biotechnology. It is crucial that the debate is well informed. The Human Genome Research Project will assist that process.

These challenges are international and the Law Foundation is convinced that a global, inter-disciplinary approach is required. While the project will determine the effect of rapid advancement in gene technologies on New Zealand law, the debate must be wider to include scientific, medical, ethical, cultural, economic and philosophical perspectives.

The Law Foundation chose the Otago Law Faculty under the leadership of Professor Mark Henaghan to head this research in New Zealand, and linked it with recognised national and international leaders in these fields to enhance the focus and add the expertise necessary for a project of this kind. While the focus is New Zealand, the findings will have relevance to other legal systems.

An important aspect of the project is that it is independent. This will no doubt add weight to the findings and recommendations.

Finally, it is important to acknowledge the efforts of two Law Foundation personnel. The first is past Chair Gray Cameron for his leadership at the inception of this project.

The second is Executive Director Lynda Hagen. Lynda's vision identified New Zealand's need for this project. Her determination ensured the Foundation Board also understood this need. Her dedication to this project has been outstanding and the Board is truly grateful to Lynda for her exceptional efforts in ensuring this project reached fruition.

James Johnston
Chairman
New Zealand Law Foundation

PREFACE

> *"[T]he human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity."*
>
> Article 1 of the Universal Declaration on the Human Genome and Human Rights

The New Zealand Law Foundation Trustees and their Executive Director, Lynda Hagen, had the vision that the emergence of genetic technologies in medicine would pose new challenges for current and future regulatory frameworks, and that thoughtful, strategic and balanced scholarly work by a team of scholars would help inform policy and the law for New Zealand both now and into the future.

That vision led to the creation of the **Human Genome Research Project, Te Kaupapa Rangahau Ira Tāngata: Law Ethics and Policy for the Future**, based at the University of Otago and sponsored by the New Zealand Law Foundation.

The goal is to discuss options for legal, ethical and regulatory policy that will be adopted not only in New Zealand but internationally. Policy development and law reform need to address new knowledge and the implications resulting from advances in genetic technology that can be complex and made more challenging by a number of factors, for example: the speed of discoveries in new understandings and applications; the plurality of opinions, attitudes and perceptions; the importance for scientists and clinicians to conduct research and undertake innovations; market pressures and consumer demands coupled with an increasing degree of global connectedness; and evolving social expectations and norms.

To encourage wide-ranging analysis and reflection as much as possible, the Project has been designed to be interdisciplinary and international. In comparison with international initiatives in this area, this project is unique in having such a full array of perspectives – all focusing on the same issues at the same time.

The Principal Investigator of the Project is Professor Mark Henaghan, Dean of the Law Faculty at the University of Otago.

The full-time researchers on the Project cover the disciplines of:

- Science (Dr Genevieve Matthews),
- Māori knowledge (Danny Tuato'o, Victoria Guyatt, Sacha McMeeking),
- Ethics (Dana Wensley, Dr Mike King, Helen Davidson), and
- Law (Jeanne Snelling, Deborah Lawson).

Collaborators from overseas for the Project include:

- Institute of Law and Ethics in Medicine at the University of Glasgow in the United Kingdom (Director: Professor Sheila McLean), and
- Stanford Centre for Biomedical Ethics at Stanford University in the United States of America (Associate Director: Associate Professor Mildred Cho).

Senior Investigators for the Project are:

- Professor Donald Evans, Director of the Bioethics Centre, University of Otago,
- Professor Stephen Robertson, Paediatrics and Child Health, Department of Women's and Children's Health, University of Otago,
- Dr Ian Morison, Biochemistry Department, University of Otago,
- Dr Tony Merriman, Biochemistry Department, University of Otago,
- Bevan Tipene-Matua, Director of Māori Research and Development, Christchurch Polytechnic Institute of Technology,
- Professor Nicola Peart, Law Faculty, University of Otago,
- Professor Grant Gillett, Bioethics Centre, University of Otago, and
- Dr Nicki Kerruish, Paediatrics and Child Health, Department of Women's and Children's Health, and the Bioethics Centre, University of Otago.

Richman Wee, formerly of the Health Research Council of New Zealand, manages the Project.

The Project has an Advisory Review Committee (ARC) which is coordinated by Dr Bruce Scoggins, CEO of the Health Research Council of New Zealand. ARC members comprise:

- Professor Ingrid Winship of Genetic Health Services Victoria, Royal Children's Hospital Melbourne,
- Justice Michael Kirby of the High Court of Australia and chair of the International Bioethics Committee Expert Group on the Universal Declaration on Bioethics and Human Rights,
- Emeritus Professor Colin Mantell, formerly Tumuaki and Head of Department for Māori and Pacific Island Health, Faculty of Medicine and Health Services, University of Auckland, and
- Justice Bruce Robertson of the New Zealand Court of Appeal and former President of the New Zealand Law Commission.

The Project has contact with the Ministry of Health, the Advisory Committee for Assisted Reproductive Technology (ACART) and the Ethics Committee for Assisted Reproductive Technology (ECART) set up under the Human Assisted Reproductive Technology Act 2004, the National Screening Unit, and the Bioethics Council.

The direction of the Project emerged from a three-month scoping exercise that was undertaken in the summer of 2003: *The Regulatory Implications of the Human Genome Project for New Zealand, Phase 1*, involving Professor Mark Henaghan, Professor Donald Evans, Dr Tony Merriman, Dr Ian Morison, Bevan Tipene-Matua, James Dann, Katie Elkin, Claire Gallop, Matthew Gillett, Mereana White, and discussions with ARC.

In 2004, Dana Wensley was funded by the New Zealand Law Foundation and prepared a report on the *Acceptable Limits of Reproductive Genetics: A Discussion of Ethical Principles and Regulatory Mechanisms of Control* (July 2004). The aim of the report was to identify commonly held ethical principles and legal mechanisms for control that have been developed in other jurisdictions. Dana Wensley's report showed the dichotomy between the fundamental right of reproductive freedom and society's interest in ensuring that technology is not used in a manner that is unacceptable or which may cause harm to society in general is not as simple as it seems. Our views about how far the right to reproductive autonomy extends are coloured by our views of how private uses of genetic technology affect society in general. The report touched on a few of the wider implications of genetic decision-making, such as the effect on the family, the parent-child relationship and the community of people with disabilities. That report was written just before New Zealand passed the Human Assisted Reproductive Technology Act 2004 (the HART Act).

In 2005, Kirsty Dobbs, a summer research scholar on the Project, produced a background paper on comparative legal approaches for preimplantation genetic diagnosis.

This first major report from the Project, after six months of a fully assembled team of researchers working together, critiques and communicates a wide range of issues and concerns about PGD from a variety of perspectives. This report will be built on in other reports that will follow as a result of ongoing work arising from the Project. In the spirit of open inquiry and thinking we will, if necessary, revise and adjust the findings of this report in subsequent reports in the light of further reflection, insight and research.

Mark Henaghan
June 2006

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Chapter 1 MAIN FINDINGS

Preimplantation genetic diagnosis (PGD) is publicly funded in New Zealand from 2006. PGD poses a range of issues that have ongoing significance for other later emerging applications of genetic technologies arising from the sequencing of the human genome. The idea of the 'designer baby' is the most publicly proclaimed outcome of new developments in genetic medicine.

Professor Gareth Jones cites the following as examples of how the public imaginations and fears are fed.[1] The first is from a hoax website:

> "*Dear Prospective Parent*
>
> *Thank you for considering GenoChoice to plan the future well-being of you and your family. My name is Dr Elizabeth Preatner, a prenatal geneticist and embryologist here at GenoChoice. Using our state-of-the-art technologies, you can quite possibly ensure that your child's life may be free of such diseases as cancer, Alzheimer's, and heart disease – as well as conditions like obesity, aggression, and dyslexia. And you can even specifically choose genes that may determine favorable characteristics in your child*".[2]

The second is from Joel Garreau:

> "*We are at a turning point in history. For millenniums our technologies … have been aimed at modifying our environment. Now, for the first time, our technologies are increasingly aimed inward – at altering our minds, memories, metabolisms, personalities, and progeny. This is not some science fiction future. Inexorable increases in ingenuity are opening vistas, especially in what we may call GRIN – genetic, robotic, information and non – technologies*".[3]

Professor Jones also cites the German philosopher, Jurgen Habermas, who views PGD as being:

> *"based on a judgment of the quality of a human being and therefore expresses a desire for genetic optimisation. An act that in the end leads to the selection of a healthier organism issues from the same attitude as a eugenic praxis".*

Professor Jones argues persuasively that distinctions between medical therapy and enhancement, normality and abnormality, health and disability, are not clearly defined. They change over time and between societies – "all of us, when compared with our forebears, are enhanced". He emphasises that "what is lacking from so much debate in this area is a lack of what is or is not scientifically feasible … there are differences of kind between PGD and designing the perfect baby".

The title of our report: *Choosing Genes For Future Children – Regulating and Preimplantation Genetic Diagnosis* has been carefully selected We want the report to be accurate about what is being done. It is possible, using PGD, to choose that a baby will not have genes for a particular genetic disorder.

There is no societal unanimity on the answers to the ethical and moral questions that are raised by the use of PGD. When artificial insemination was first possible, a Royal Commission was set up in the United Kingdom to see whether it should be made a criminal offence. Now the technology is widespread throughout the world. Our society places high value on individual choice and autonomy, yet there are times when individual choice and autonomy are perceived to harm the community as a whole – at which point that is reached is rarely a matter of common agreement.

The Hippocratic Oath, which states "I will follow treatments which according to my ability and judgment I consider for the benefit of my patients and abstain from whatever is harmful", does not provide all the answers to the complexities of the issues that PGD raise. The concepts of "benefit" and "harm" are not neutral and depend very much on the perspective of whoever is looking at them.

It would be too simplistic if the choice were between either opting for a broad-brush approach of greatest caution reinforced by State control until such time as we have foreseen and tested all the possible risks and concerns of the use of PGD, or an ultra-liberal approach of non-interference until it is clearly proven there are risks and harms that everyone agrees upon.

In the past, both such approaches have led to negative consequences in particular contexts. For example, in the 1930s in the United States of America, over 20,000 people who the United States government believed were "undesirables" were sterilised against their will as a precaution against them having children. The case of *Buck* v *Bell* [4] in 1924 concerned three generations: a mother Emma Buck, her daughter Carrie Buck, and a granddaughter Vivian Buck who lived in a "colony for epileptics and feeble-minded" in Virginia. Emma Buck's sister Doris was also part of the case. They were all deemed to be mentally defective by an IQ test (the Binet test). Vivian was only seven months old at the time of "testing" but was reported to have a "look" about her which was not quite "normal". This was sufficient evidence to convince Justice Oliver Wendell Holmes in the United States Supreme Court to declare "three generations of imbeciles are enough".

Doris and Carrie were duly sterilised. The upshot of the 1924 decision in *Buck* v *Bell* was that by 1931, 27 other States enacted sterilisation laws to prevent the "undesirable classes" from reproducing. The laws provided for the compulsory sterilisation of certain classes of people thought to be insane, feeble-minded or epileptic, habitual criminals and moral perverts. Vivian, Carrie Buck's daughter, went through second grade at high school where her teachers reported her to be very bright. Doris Buck was never told the real nature of the operation; simply that it had been for a burst appendix. David Galton[5] says that when Doris Buck learned the truth she said: "I broke down and cried. My husband and me wanted children desperately. We were crazy about them. I never knew what they'd done to me." The individual is harmed in the mistaken belief the State will benefit.

At a similar time in the United States, in 1932,[6] the individual unregulated choices of medical researchers had a massive impact on 400 African-Americans who had signs of syphilis in the infamous Tuskegee Syphilis Study. The 400 African-American research subjects were observed for 40 years to see how syphilis progressed in them. They did not know the nature of the experiment nor were they told after 1945 that penicillin could treat their condition. By 1955,

one-third of the research subjects were dead from syphilis. In the 1970s, this public health scandal was brought to light when medical papers were published about the experiment. A civil rights action was filed against the United States Public Health Service and was settled out of court for more than US$9 million. It took until President Clinton's presidency for an apology to be issued on behalf of the US Government to the surviving victims. The freedom of the researchers to research as they saw fit led to cruel and inhumane harm to the subjects of the research.

In New Zealand, in 1987, the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters (the Cartwright Inquiry) found that an experimental research programme conducted by Dr Green in the 1960s and 1970s at the National Women's Hospital in Auckland resulted in inadequate treatment for many women.[7] The research involved withholding conventional treatment from patients with carcinoma in situ of the cervix in order to study the natural course of the disease. About 40 of the women patients eventually developed invasive cancer.

The best way to develop good regulatory policy is to consider as many viewpoints as possible in a fair and even-handed manner. The final decision to regulate or not is for the government to consider, decide and act. Our task is to present the viewpoints and regulatory options with compassion and to analyse them as best we can without bias. Our hope is that the tone of this report will, at the very least, enable readers to empathise with interests and concerns that go against their own interests and concerns. For a community to work through potentially deeply divisive issues, it is crucial that an attitude of seeing the concerns of others in their best light is cultivated. This is not the same as giving up one's own values and committing to the values and beliefs that give a particular concern force. Dr Anthony T Kronman has said:

> *"Only the person who has surveyed, with sympathetic detachment, the conflicting interpretations that different members of his community offer of its goals is in a position to say whether his own preliminary views should be revised and to make an informed choice among the alternatives before him".*[8]

There is an incommensurable diversity of human goods and no overriding objective criterion to definitively rank them. If there are no rational grounds for insisting that one view of the good is superior to those of others, then forced suppression of a particular belief or practice leads to the loss of something humanly valuable.

The investigators and researchers working on this Project do not represent any particular political party, religion, belief or government policy. They are all independent and diverse thinkers who bring to the Project a spirit of open inquiry and empathy for different viewpoints and dispassionate (as is humanly possible) analysis.

THE SCIENCE AND CLINICAL UTILISATION OF PGD

PGD was developed as an alternative to prenatal diagnosis for couples who were at risk of passing inherited diseases to their children. With prenatal testing utilising chorionic villus sampling (CVS) or amniocentesis, diagnosis is undertaken when pregnancy is already established. If the foetus is affected then parents may consider whether to continue with the pregnancy or to terminate it. Hence, when compared with prenatal diagnosis, PGD substantially minimises or avoids the need for termination.

Research in the UK on PGD began in the mid-1980s to help couples who wished to have diagnosis for inherited disease before embryo implantation instead of during pregnancy. Preimplantation testing techniques were not new then but had been carried out on non-human embryos since 1968 and were used routinely in the context of animal husbandry to breed animals of the preferred sex.[9]

The first successful human pregnancies using PGD were reported in 1990 for various X-linked or sex-linked disorders (where males, not females are affected) with the selection of female embryos for implantation. This was followed by the report in 1992 of a live birth after utilising PGD selection against cystic fibrosis, which is an autosomal disease where both copies of a gene are non-functional.[10]

By 2000, PGD had been used in the UK to test for a range of disorders caused by a single gene, e.g. beta-thalassaemia, sickle cell anaemia and muscular dystrophy, and for chromosomal abnormalities, e.g. Down, Turners and Edwards syndromes.[11]

PGD involves the creation of embryos, embryo biopsy, analysis of one or two biopsied cells, and transfer of unaffected embryo(s) to establish pregnancy. PGD incorporates the use of IVF technology as part of the process.

Embryos are created by injecting a single sperm into each oocyte to achieve fertilisation. This technique, intracytoplasmic sperm injection (ICSI), is used in the majority of cycles of PGD, to avoid contaminating sperm interfering with the PCR analysis.

After fertilisation, embryos are cultured and then embryo biopsy carried out. This involves taking one or two cells from an embryo, two to four days after fertilisation. In some instances, polar body biopsy, involving the analysis of polar body cells resulting from oocyte development, is used. The polar bodies give an indication of the genetic composition of the egg. Polar body biopsies are used in countries where embryo biopsy is prohibited.

Single cell diagnosis is then performed using the polymerase chain reaction (PCR) or fluorescent *in situ* hybridisation (FISH), depending on the disorder being diagnosed.

PCR is the exponential amplification of a specific region of DNA and is used to analyse small changes in DNA in a single gene. Each new mutation requires the development of a new PCR test. In addition, because it is such a sensitive technique and because the target is so small, contamination has to be carefully avoided. A technique called whole genome amplification (WGA) is a way of increasing the amount of template for the PCR reaction from just one copy of the genome to many. PCR is also hampered by a phenomenon known as 'allele dropout' (ADO) or 'preferential amplification' which happens when an allele being examined fails to

amplify. In a carrier, for example, only the normal or only the affected allele is amplified rather than both alleles equally. Analysis of areas either side of the mutation (also using PCR) control for this phenomenon.

FISH is used to analyse chromosome numbers and gross abnormalities and for sex selection mainly for X-linked disorders. It can easily be used for non-medical sex selection, the use of which is illegal in NZ currently.

PGD started with the purpose of identifying embryos that have the genetic mutations for serious, life threatening conditions. PGD can also be used to help women with a history of recurrent miscarriages or of advanced maternal age to reduce the rate of miscarriage. Embryos are biopsied and screened for changes in chromosomal numbers (aneuploidy[12]) and only those embryos with a normal number of chromosomes are transferred. This is by far the most common use of the technology according to recent figures[13] but this use of the technology is not publicly funded in New Zealand. On the basis of what is presently known in terms of the science and technological ability, screening for aneuploidy is not sufficiently determinative of a guaranteed outcome.

PGD has subsequently been used to select a tissue-matched or HLA compatible embryo for the purpose of having a child who will be a match for an existing sick sibling for a stem cell transplant from the umbilical cord.

In 1997, a PGD consortium was formed as part of the European Society of Human Reproduction and Embryology (ESHRE) to undertake long-term study of the efficacy and clinical outcomes of PGD. The ESHRE PGD Consortium started collating data from 25 centres (increasing to 66 centres by 2005) from Europe and six other countries and on referrals, cycles, pregnancies and babies born after PGD. Reports have been published in 1999, 2000, 2002 and 2005, covering data up to 2002.[14]

Recognising variations in local or national regulations and specific laboratory practices, and acknowledging that differences will remain with regard to the ways in which PGD is practised, the ESHRE PGD Consortium recently provided guidelines in the hope that higher quality overall and standardisation of PGD can be achieved by building consensus opinion within the PGD community on best practices based on available evidence.[15]

A study of the past 12 years of data from the world's three largest PGD centres, comprising 4748 PGD attempts and 754 successful pregnancies, led to the conclusion that PGD is safe.[16]

PGD is not yet a widely used procedure but seems likely to become more popular both as people become aware of its availability and as the number of conditions for which testing is available expands. New Zealand is unique amongst countries offering PGD services, given its commitment to funding the full cost of up to two cycles of IVF/PGD for people who use PGD to test for serious inherited genetic disorders. This funding includes the costs of the IVF treatment that must accompany PGD.[17] While the embryo biopsy can now be performed in New Zealand, many of the tests are conducted on a contracted-out basis at Monash IVF in Australia. Monash IVF is contracted to provide tests for five major conditions[18] and also offers aneuploidy screening – any testing beyond these can be done on a case-by-case basis.

The question of whether or not New Zealand develops a full capability for this technology is likely to be dependent on the actual and projected uptake by the population. PGD is a highly specialised technique and requires skilled personnel. Staff competence and skill maintenance will be vital to the provision of this service in order to maximise safety and efficiency, yet New Zealand has challenges to overcome, for example, in terms of offering competitive and attractive remuneration by comparison with other countries. It has been noted, for instance, that "New Zealand has traditionally had difficulty recruiting and retaining geneticists, mainly because of professional isolation."[19]

MĀORI PERSPECTIVES ON PGD

Māori are the tangata whenua – the indigenous people of New Zealand. The Treaty of Waitangi 1840, a treaty signed between Māori chiefs and representatives of the British government, and the principles of the Treaty create and continue to re-create the unique relationship between the Crown and Māori in New Zealand.[20] Māori concerns about PGD hinge partly on the concern that the principles of the Treaty may have been undermined by the Human Assisted Reproductive Technology Act 2004 (the HART Act) and the Guidelines on Pre-implantation Genetic Diagnosis (the Guidelines) in that neither the legislation nor the Guidelines make express reference to the Treaty of Waitangi, nor do they provide sufficiently adequate account of the ethical basis for how culturally-based decisions may be undertaken or implemented consistent with tikanga Māori.

The HART Act does, however, state that the needs, values and beliefs of Māori should be considered and treated with respect, and that the different ethical spiritual and cultural perspectives in society should be considered and treated with respect.

Cultural values that underpin a Māori way of being and the place of Māori in the universe are established by virtue of their whakapapa (genetic inheritance). The authority of a group to make collective decisions about the best interest of its members, individual autonomy, or self-governance, is based on the ability of a group to govern themselves. Ultimately, Māori acknowledge that an individual has a right to use PGD, but the collective asserts its authority to protect its whakapapa – as a taonga under Article II of the Treaty of Waitangi.

A pioneering study of ethical, spiritual, cultural and social issues pertaining to pre-birth genetic testing from a Māori perspective was carried out by the Māori research team collaborating with this project. The study involved in-depth interviews with a range of Māori participants. No single Māori view on the potential risks and benefits of pre-birth genetic testing is offered although strong patterns of agreement on aspects of the potential risks and benefits emerged. There was general agreement that PGD has the potential to do more good than harm for Māori communities. There was also general agreement and concern that Māori may not have equity of access to PGD. The most pressing concern for Māori is working at the balance between individual and collective rights to the use of PGD and creating an environment where this can happen.

A cultural decision-making framework based on tikanga Māori to help with assessing the risks and benefits of PGD in a culturally appropriate way is proposed.[21] The framework provides

a position for assessing a situation or event that challenges thinking and values, using key concepts (such as tapu, mauri, take, utu, whanautanga, manaakitanga, mana, tika and noa)[22] relating to tikanga Māori.

Respect for cultural priorities is an extremely important consideration in the regulation of genetic services in New Zealand. A role of any regulatory regime is therefore to support the expression of tikanga Māori in the modern world, enabling the present generation of Māori to reproduce according to the spiritual and philosophical understandings of their ancestors

ETHICAL PRINCIPLES

The fact that embryos are specifically created for selection in the use of PGD entails their possible rejection. This, rather than the PGD activity itself, is thought by some to be objectionable as it is said to instrumentalise embryos. Equally, other arguments are used by opponents of PGD, for example that it may have negative effects on resultant children and that there may be risks to the child's physical and/or emotional status. The emotional risks would be the hardest to quantify but some believe that the power of choice put into the hands of parents by PGD could alter the parent/child relationship fundamentally from one of unconditional love to one dictated by the realisation (or not) of specific 'designer' expectations.

There are a number of arguments against PGD. One of them is the 'Playing God' objection which is examined from the Christian viewpoints, and from the secular standpoint in terms of interfering with the natural order.

There is a plurality of Christian views of PGD ranging from the conservative proscriptive position to the modern facilitative position of engaging with God in His creative activity. The conservative view holds that to engage in PGD is to reject God's image in His creation; it is to reject human life as a gift and transform it into a humanly designed product. Each of these undermines the dignity of human beings and their unconditional worth. This is, however, a minority view. The modern facilitative view is that people are seen as co-creators with God to realise the existence of a better world. On this basis PGD, is not ruled out per se but is limited to applications which are 'good'. The challenge lies in identifying which applications are 'good'.

A difficulty with the 'Playing God' objection is the level of uncertainty attaching to Christian views because of the wide range of views about God and the Christian moral order. These make the objection equivocal. Furthermore, the Christian justifications for intervening in human life in many areas, including modern medicine, to avoid agonies being suffered by people, make it inconsistent to avoid by means of PGD the intractable and unbearable suffering brought about by serious incurable genetic disorders.

Secular substitutes for the Playing God criticism of PGD take the form of claiming that it amounts to an unnatural intrusion into procreation and therefore is an invitation to risks such as reduction in biodiversity. This criticism is countered, first, by an appeal to the fact that interference in breeding over centuries has not had this effect and, second, that the small numbers involved in PGD could not produce such an effect. The claim that interference

with nature entailed by PGD would produce a slippery slope to eugenics is an empirical claim which lacks evidence in that other similar reproductive technological innovations have been successfully regulated by public consensus.

The conservative view of the embryo as having the full moral status of a person proscribes PGD. On the other hand, the liberal view that no moral status is accorded to the embryo or foetus places no barriers on what should be done to them. Between these views, the moderate view sees the developing embryo and foetus as growing in moral status throughout gestation and calls for limits to the use of PGD but not its proscription.

The wide and differing range of views held by the general public on the status of the embryo and foetus cannot be ignored. New Zealand legislation already permits abortion and PGD on limited grounds, and so does not reflect the conservative view of the foetus although the limits imposed might be construed as opposing a completely liberal view. There are no conclusive arguments, nor is there any crucial evidence, which can resolve the differences in views from various accounts of the status of the human embryo and foetus. The question of whether PGD should or should not be permitted is ultimately not usefully addressed by seeking an answer to the question of the status of the human embryo or foetus.

The moderate or 'gradualist' approach to the human embryo – an approach that sees the embryo as more than a mere collection of cells, but as less than a full person – is adopted in this report. This approach requires that the embryo of the human species is worthy of respect at all stages, but that certain interventions/treatments may be permissible at certain stages, with the limits of permissibility narrowing as the embryo/foetus nears maturity.

Selecting embryos on the basis of their genetic status is a matter of considerable concern for many people – particularly those speaking for the disability rights community. Attitudes vary as to whether or not the availability of PGD to screen out genetic conditions will result in disrespecting people with disabilities or whether this use of PGD sends out a eugenics signal. For some, it is inevitable that the ability to choose to discard affected embryos means that those currently living with the relevant condition are disrespected; that their lives are regarded as less worthy. There is a lack of empirical evidence to support one case or the other.

Proponents of PGD contend that it is the disability and not the disabled that we are seeking to avoid. On this argument, there need be no negative impact on those living with disability.

Equally, the eugenic argument is asserted strongly by some, while others would distinguish individual rights to make choices from the state-sponsored eugenic programmes which were in place in the United States and, most especially, Nazi Germany in the early parts of the 20th Century. For example, the House of Commons Select Committee on Science and Technology took issue with the negative connotations of the word 'eugenics', saying:

> *"If ensuring that your child is less likely to face a debilitating disease in the course of their life can be termed eugenics, we have no problems with its use: state programmes that impose a genetic blueprint are another matter. They should be outlawed as part of any regulation of assisted reproduction. Use of the word eugenics must not be used as an emotive term of abuse to obscure rational debate".*[23]

Discussions about these issues in New Zealand are emerging. The New Zealand Organisation for Rare Disorders is open to the use of emerging genetic technologies for parents to choose to avoid the birth of children with disabilities. For the Crippled Children's Society, their focus has been to consider changing their constitution to emphasise that they celebrate the lives of people with disabilities.

The place of people with disabilities and the impact of clinical advance on their position is sometimes seen to be somewhat marginalised, and surely deserves special protection. New Zealand does not have a Disability Rights Commission (as, for example, the UK does) although it has a Minister for Disability and an Office for Disability Issues. Additionally, even with a number of statutes relevant in this area (the New Zealand Bill of Rights Act 1990, Human Rights Act 1993, and Health and Disability Commissioner Act 1994), New Zealand has no body directly responsible for issues that fall under the category of promoting good relations between people with disabilities and their communities.[24]

The bioethical analyses are informed by the Universal Declaration of Bioethics and Human Rights (UDBHR)[25] which significantly focuses on the inter-relationship between bioethics and human rights, and helps shape thinking and reflection for both the process of developing policy and determining the content of policy. At the heart of the ethical analysis of PGD is the tension between, on one hand, individual freedom and privacy to make reproductive choices and, on the other hand, social solidarity and responsibility to ensure that human dignity is not eroded or undermined.

LAW

The assessment of legislative frameworks in this report is based on principles which are most likely to enable regulatory initiatives to be accepted by the general public as legitimate. These principles require that the regulatory framework must be proportionate to the perceived harms or risks posed to justify the imposition of regulatory limits. Regulators should have clear lines of accountability, in particular, their decisions must be justified and be subject to public scrutiny. There should be accessible, fair and effective complaints and appeals processes. Consistency in administering the regulation and in the regulation itself, and transparency in terms of what the regulatory objective is, and the legal obligations of those being regulated are essential. Finally, regulation must be precisely targeted to achieve its objective.

In comparison to other regimes with similar regulatory structures, New Zealand is unique in that the HART Act establishes two statutory bodies with clear remits. New Zealand has therefore departed from the international trend of having one statutory authority that both creates and implements policy. Instead there are two bodies: an advisory committee which creates policy, and an ethics committee which assesses individual cases against the advisory committee's guidelines. The main benefit of this structure is that focusing solely on policy increases the efficiency of the Advisory Committee's policy-making process, both in terms of time and the expertise of those creating policy.

New Zealand is different from the jurisdictions used here as comparators in that it has essentially de-regulated some aspects of assisted reproduction. The UK Human Fertilisation and Embryology Authority[26] is presently arguing for more rather than less inclusive regulation.

The mechanism governing 'established procedures' in the HART Act allows certain procedures to be carried out without external scrutiny and indicates to that extent a commitment to imposing only such regulatory restraint as is seen to be necessary. The fact that it is an offence to perform an established procedure unless the provider is certified under the Health and Disability Services (Safety) Act 2001 shows there is emphasis on ensuring that appropriate clinical standards are observed and patient safety is maintained. A further difference in the New Zealand legislation is that it has not adopted a licensing system. Instead, it has built on existing health and safety requirements, making certification under the Health and Disability Services (Safety) Act 2001 a statutory requirement and providing civil sanctions for non-compliance. There is no explicit provision allowing for conscientious objection within the regulatory framework for PGD that recognises circumstances where a segment of providers and the public may not wish to be involved because of, for example, religious or personal moral beliefs.[27]

There is as yet no provision for applicants to appear before the Ethics Committee when presenting their case (a right which has recently been made available in the United Kingdom). This may perhaps be an unfortunate omission, particularly as the Ethics Committee exercises the function of applying policy and making decisions affecting individual citizens coming before it. Allowing an explicit process that provides the opportunity for applicants to speak to their case would render decisions more transparent, and build more confidence and trust in the process. There is no right of appeal from a decision of the Ethics Committee – such a right exists in both the UK and the state of Victoria.

The report identifies issues of inconsistency in the legislation and policy development within the context of the legislation. The creation of a category of 'established procedures' reflected an apparent desire not to regulate unnecessarily, yet it is arguable that the outright ban on non-medical sex selection is unnecessarily rigid, particularly as public and other attitudes can and do shift rapidly. The 'established procedures' category is potentially broad enough to capture late-onset and susceptibility disorders, such as those involving BRCA1 and BRCA2 mutations which are transmitted in an autosomal dominant pattern in families. Carriers of the mutations have a 60% to 90% risk of developing breast cancer, compared with a 10% risk in the general population. This may not have been intended but the wording of 'serious impairment' is broad enough to cover this situation. The determination of 'serious impairment' under the 'established procedures' category is solely a medical one at present in New Zealand. By way of contrast in the UK, the determination is made in collaboration with the family who have a say into the decision about PGD use.

Selection of embryos with a genetic impairment seen in a parent is prohibited by the Guidelines. The implication of this, by contrast, is inconsistent with prenatal testing where parents can choose to continue with the pregnancy when aware of genetic impairment in a foetus.

The Guidelines which set out the lawful parameters of PGD in conjunction with HLA tissue typing are problematic on several fronts. The Guidelines require that the planned treatment for the affected child will utilise only the cord blood of the future sibling. Yet medical procedures carried out on a child, such as bone marrow donation, do not come within the jurisdiction of the policy-making body under the HART Act 2004. In New Zealand, medical procedures carried out on a child are covered by other established healthcare law and principles.

The effect of the Guidelines is that an embryo may be tested for HLA compatibility as an add-on procedure if embryo biopsy is indicated to test for the presence of a genetic disorder in the prospective offspring. However, tissue typing may not be carried out as an additional procedure if the affected child is suffering from a non-genetically heritable condition, regardless of whether embryo biopsy is indicated to test for the presence of a familial single gene or familial chromosomal disorder in the embryo. It is unlikely this was an intended consequence by those responsible for the Guidelines. The anomaly may be easily rectified by requiring only that the affected child is suffering from a severe life-threatening condition. Regulating HLA tissue typing so narrowly is in tension with the minimal evidence of risk to the embryo, particularly when a wide range of PGD uses are already permitted as established procedures.

All of the policy formulated via and pursuant to the Act has been based purely on therapeutic applications of PGD technology. Although there has been an intention expressed by the Select Committee that PGD should not be used for selection of non-medical traits, this has not been expressly stated in the Act. While the prohibitions in Schedule One of the Act prohibit reproductive research, they do not prohibit the conduct of non-reproductive research which may be permitted should the Advisory Committee promulgate guidelines.[28]

The terms of reference provided by the Minister for the Advisory Committee evoke some concerns. Decisions of the Advisory Committee may be made by simple majority vote. This may be criticised by some but it is the robustness of the debate that is important. Understandably, perhaps, the members are restrained from publicly expressing any disagreement with policy decisions. It would increase transparency, and thereby promote public confidence in the legitimacy of the Committee and the process, if decisions of the Committee were accompanied by reasoned analysis of the decisions reached, including the scientific basis, the differing perspectives taken into account, the number of members in favour or against (or abstaining from) decisions that are made, and the opportunity for dissenting individual members to record and append their comments to the final decision of the Committee.

There are strong grounds to believe that the decision-making process of the Ethics Committee as set out in the Terms of Reference for ECART is ultra vires. The HART Act, in effect, requires the Ethics Committee to be subject to the *Operational Standard for Ethics Committees* (the Operational Standard). The Minister's terms of reference permit decision-making on the grounds of a two-third majority, contrary to the Operational Standard which requires consensus decision-making. This leaves any decision made by them open to challenge by way of judicial review on the grounds of procedural invalidity. In addition, the Act requires that the Minister must ensure the committee complies in its composition with the Operational Standard which requires a minimum of 10 members. However, the Terms of Reference for the Ethics Committee provide only for 8 members as a minimum, and the committee is currently constituted with 8 members. It is possible, therefore, that ECART may be open to challenge as being not legally constituted under the Act.

It is a concern that, although the Advisory Committee has been given the mandate and duty to monitor the application and health outcomes of assisted reproductive procedures and research, a robust medium- or long-term monitoring system has not been put in place before, or at the same time as, PGD has been declared to be an established procedure.

There is little doubt that the HART Act 2004 was a necessary legislative initiative. The framework sets up affordable, efficient and responsive processes, and is supported in terms of health and safety aspects by other health law instruments. The success of the regulatory scheme, in terms of being seen as transparent, fair and legitimate, will be largely left to the Advisory Committee who will need to be on the constant look out for 'fine-tuning'.

New Zealand's bi-cultural identity necessitates consideration of issues emerging from the use of novel technology from at least two cultural perspectives. These may be harmonious or discordant depending on a multitude of factors, adding a level of complexity which may be less noticeable in mono-cultural societies. Social research which investigates perceptions, experiences and attitudes relating to assisted reproduction is vital to deliberation in applied ethics. Any ethical analysis and resultant policy which does not consider these would unlikely be effective or may lead to unintended consequences.

New Zealand is renowned for its thorough investigation of issues surrounding the implementation of novel technologies as was seen in the Royal Commission of Inquiry into Genetic Modification. There is, however, a comparative dearth of research investigating issues surrounding individual perceptions, experiences, and attitudes relating to new human assisted reproductive technologies.

Caution should be exercised before directly applying the findings or knowledge arising from research investigating public groups overseas to the New Zealand situation. The main concerns which have emerged from social research into PGD in other countries include, but are not limited to, its potential impact on the following: pre-natal life, children, people with disabilities, those involved in making reproductive decisions, women, men, communities, and family relationships.

The creation of fair and relevant criteria with which to evaluate public views is extremely difficult and has in the past resulted in the marginalising of relevant groups, such as children and people with disabilities. This, coupled with the consultation requirement built into the HART Act, highlights the importance of specific social and ethical research into assisted reproduction in New Zealand. Such research will greatly enhance the level of ethical debate and also the value and durability of policy and legislation in these areas.

When there are strongly held positions on either side of a debate such as there is on PGD, a common situation in a democracy is to go with the majority view. However, the meaning of democracy needs refinement and the following comment from H.L.A. Hart, the Oxford legal philosopher, gives us pause for reflection:

> *"It seems feasibly easy to believe that democratic principles entails acceptance of what may be termed moral populism: the view that the majority have a moral right to dictate how all should live … The central mistake is a failure to distinguish the acceptable principle that political power is best entrusted to the majority from the unacceptable claim that what the majority do with that power is beyond criticism and must never be resisted. No one can be a democrat who does not accept the first of these, but no democrat need accept the second".*[29]

At present, PGD has the most dramatic impact on a small minority of families. Their voices and concerns can easily be lost. This report critiques majority positions which unjustifiably or inconsistently erode family choices.

Mark Henaghan and Sheila McLean
(with thanks to Richman Wee and to all project members for their input into this chapter)
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ENDNOTES

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22 For explanation and discussion about these concepts, please refer to Chapter 3. Here, the following brief translations are offered. Tapu = sacred, restricted. Mauri = human life force. Take = case, issue, matter. Utu = compensation, cost. Whanautanga = relationships. Manaakitanga = hospitality. Mana = prestige. Tika = appropriate, correct, fair, justification, right. Noa = balance, neutrality.

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24 For an example of an alternative position, see the Equality Bill, introduced in the House of Lords on 18 May 2005, which provides that the Disability Rights Commission in the UK shall undertake a number of things in this regard. Section 10 provides that the Commission shall:
   (a) promote understanding of the importance of the fair treatment of disabled persons,
   (b) encourage good practice in the treatment of disabled persons,
   (c) work towards the elimination of prejudice against, hatred of and hostility towards disabled persons, and
   (d) work towards the elimination of the involuntary isolation of disabled persons.

25 The UDBHR was adopted by the 33rd session of the General Conference of UNESCO in October 2005.

26 Established by the (UK) Human Fertilisation and Embryology Act 1990

27 A suggestion that has recently emerged overseas in the context of a multi-cultural and multi-religious jurisdiction recognises that a segment of the medical community and the public may not wish to be involved in interventions such as PGD on the basis of religious or personal moral beliefs, and that, equally, other members of the medical community and the wider public may wish to be involved in ways that are not harmful to the moral and social fabric of society – the recommendation that followed from this was that provision be made so that no one shall be under any duty to be involved if the person has a conscientious objection: Singapore Bioethics Advisory Committee, *op. cit.*

28 This is provided in the Guidelines on PGD.

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