Chapter 5 LAW AND REGULATION

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INTRODUCTION

The great leap in knowledge of human genetics over the last two decades has had major impact on human assisted reproductive technology (ART)[1] that consequently has attracted special regulatory controls throughout the world.[2] Genetic science and ART have intersected and given rise to the term 'reprogenetic'.[3] The extensive scope for medical[4] benefits as a result of emerging reprogenetic technologies, such as preimplantation genetic diagnosis (PGD), is compelling. Prospects raised by the myriad possibilities of reprogenetics explain why many societies and governments perceive a need for special controls, and provide impetus for jurisdictions to determine their respective legal and policy positions. The provision of ART in the human health context is distinctive from the provision of many other medical services which do not have specific and extensive regulatory frameworks surrounding their provision.[5] PGD is a technique used in ART and provides huge potential for medical benefit but, given the possibility of indiscriminate implementation, has been seen to require limitation.

This chapter of the report is in two parts. The first part describes and analyses the New Zealand framework for regulating PGD and focuses on the Guidelines on Preimplantation Genetic Diagnosis which was developed by the National Ethics Committee on Assisted Reproductive Technology and the recently enacted Human Assisted Reproductive Technology Act 2004. In addition, medico-legal obligations imposed on providers in New Zealand which are relevant in the assisted reproductive technology (ART) context will be discussed. This part also provides an in-depth analysis of the approach of the United Kingdom to regulating PGD, followed by a description of the United States regulatory position which provides a comparison to the other regimes that have adopted facilitative approaches.

The second part provides comparative analyses of how PGD is regulated in New Zealand, the state of Victoria and the UK – these are countries which have taken a broadly similar facilitative approach by opting for the adoption of legislative frameworks that delegate a range of decision-making powers to statutory bodies

PART A: REGULATORY MODELS

1 NEW ZEALAND

The legislative model which permits the use of PGD in New Zealand may best be described as a skeleton framework. While the parameters regulating the use, manipulation and storage of embryos are found in the Human Assisted Reproductive Technology Act (the HART Act) 2004, no specific provisions exist in regard to PGD, apart from a prohibition on the use of PGD for non-medical sex selection. However, the Act delegates a policy-making role to an Advisory Committee and creates an Ethics Committee which is responsible for approving applications in accordance with policy made by the Advisory Committee for procedures which include PGD. The Act also provides a mechanism by which certain procedures may be declared to be 'established procedures' on the basis of the Advisory Committee's recommendation. Once an assisted reproductive procedure is declared to be an 'established procedure' by Order in Council, the procedure ceases to be a regulated procedure and does not require Ethics Committee approval pursuant to the Act. PGD in restricted circumstances has recently been declared to be an established procedure.[6]

Prior to the enactment of the HART Act, the Minister of Health requested the National Ethics Committee on Assisted Human Reproduction (NECAHR) to promulgate guidelines for the safe and ethical use of PGD. A period of research and public consultation ensued. These Guidelines have since been designated as interim Advisory Committee Guidelines under the interim provisions provided in the HART Act 2004. The Guidelines specify what applications of PGD may be carried out with the approval of the Ethics Committee, specify further prohibited applications of PGD, and also set out information and counselling requirements for providers.[7]

Consequently, PGD in New Zealand is regulated under the HART Act, by the Order in Council which lists the categories of PGD that are established procedures, and by the interim Guidelines. Whilst the Guidelines remain effective for the next three years, the Advisory Committee will assume responsibility for their revision before the interim period expires.[8]

The following provides an analysis of the development of law in relation to ART and PGD in New Zealand. The *Guidelines on Preimplantation Genetic Diagnosis,* which provide an essential backdrop to the New Zealand policy on PGD under the HART Act 2004, will be discussed first and then followed by the HART Act 2004. The underlying philosophy of the Act, an overview of the substantive provisions of the Act in relation to PGD, the obligations placed on PGD providers and the implications of the regulatory framework for New Zealand will be examined.

1.1 THE NECAHR GUIDELINES

In June 2003 (more than a year before the enactment of the HART Act 2004), the Minister of Heath approved in principle the provision of PGD services in New Zealand, subject to NECAHR developing guidelines for the safe and ethical use of the procedure. NECAHR commissioned the Cochrane Menstrual Disorders and Subfertility Group for the New Zealand Guidelines Group which produced the report "A Systematic Review of the Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis" to provide clinical evidence base for the draft guidelines.[9]

The reviewers in that report concluded:

> *PGD is a promising approach but it is important not to overstate its potential. There is no reliable evidence as yet that it improves reproductive outcomes, even though diagnostic process itself appears to be reliable with low risk of error. Moreover there is a wide range of hereditary abnormalities and PGD currently applies to a relatively small number of them. There is currently insufficient evidence to support the use of PGD for aneuploidy screening except in the context of a controlled study. Only long-term ongoing follow up of children born after PGD can provide data on its safety and effectiveness as new clinical protocols emerge and new technologies are developed.*[10]

The reviewers suggested several modifications to the proposed Guidelines. These included that PGD for familial single gene disorders, sex linked disorders and familial chromosomal disorders should only be permissible when there was a 'high risk of severe abnormality'. A definition of what constituted "severe" was included. It was defined as: where the disorder is lethal in

childhood or early adulthood; or where physical abnormalities are likely to result in painful disability without options for effective treatment; or where developmental abnormalities are likely to result in a child/adult unable to function independently and participate in normal life. It was also recommended that aneuploidy screening should only be permitted in the context of a controlled research protocol. These proposed modifications were not adopted by NECAHR in the approved Guidelines.

The proposed guidelines for PGD formulated by NECAHR were disseminated in October 2004 (and, as it turned out, the month before Parliament passed the HART Act) to fertility clinics, District Health Boards, professional organisations, consumer groups, government agencies and interested individuals for public consultation. Public meetings throughout the country were also held in order to hear oral submissions.

The revised guidelines were approved by the Minister of Health and released in March 2005. The *Guidelines on Preimplantation Genetic Diagnosis*[11] reflect significant change from those proposed in the draft document, both in terminology and with regard to when PGD may be performed, and in some procedural requirements.[12]

With the enactment of the HART Act, references to NECAHR should now be read as referring to the newly established Advisory Committee or Ethics Committee where appropriate.

The approved Guidelines contain five sections. For ease of reference, a copy of the Guidelines is attached in Appendix 2 of this section of the report. The first category covers clinical applications of PGD which may be carried out without NECAHR approval, and which have since been declared to be established procedures. These applications of PGD may now be carried out as a matter of course in New Zealand. The second involves PGD with HLA tissue typing, which now constitutes a regulated activity under the Act, requiring prior ethical approval before it can be carried out. The third section sets out the prohibited uses of PGD under the Guidelines, whilst the fourth deals with information and counselling requirements. The last section sets out the procedural obligations for the providers of PGD services.

1.1.1 SECTION 1: USES OF PGD NOT REQUIRING NECAHR APPROVAL – NOW ESTABLISHED PROCEDURES

Section 1 of the Guidelines sets out the criteria for permissible PGD in the case of familial single gene disorders, for sex determination in prescribed circumstances of familial sex-linked disorders, and for familial chromosomal disorders. PGD is also permitted in this category for aneuploidy screening in the case of non-familial chromosomal disorders associated with advanced reproductive age or infertility.

The Guidelines provide that PGD may be performed where familial single gene disorders have been identified in the family or whanau *and* there is a 25% or greater risk of an affected pregnancy. The same criteria are applied to performing PGD for sex determination where familial sex-linked disorders have been identified in the family/whanau but no specific test for the particular mutation that causes the disorder is available. The restriction that there must be no specific test available for the particular sex linked disorder prevents the occurrence of sex-selection where a familial sex-linked disorder exists but it is possible to reliably test for the

mutation.[13] If this requirement did not exist, sex selection could occur which would involve systematically discarding male embryos, although 50% of the embryos would be unaffected. In the case of familial chromosomal disorders, the disorder must have been identified in the family/whanau. However, it is the last criterion set down in the Guidelines for each of these three categories of familial disorders that requires mention.

The final criterion for permissible PGD in these categories is that there is 'evidence that the future individual may be seriously impaired as a result of the disorder'. In contrast, the proposed Guidelines sought to authorise PGD when there was 'a high risk of serious abnormality'.[14] Whether 'serious abnormality' and 'serious impairment' differ in a real sense is debatable, but the change is likely to reflect a move to more disability-sensitive language. There is no longer any reference to a 'high risk', but mere evidence of potentially serious impairment will suffice. This would indicate that the threshold for permissible PGD without NECAHR approval has been significantly reduced.

Another notable change in the approved Guidelines in these clinical categories is the omission of the requirement that 'the option of prenatal testing alone is unacceptable to the couple'. The implication of the proposed provision was that prenatal testing was to be considered as a first option, and only when it was an unacceptable primary clinical course of action for the proposed parent(s) should PGD be considered. Under the approved Guidelines, there is no such limitation.

The restrictions on the use of PGD for familial chromosomal disorders and screening for aneuploidy have been significantly loosened in the approved Guidelines. It had been originally proposed that approval for PGD for familial chromosomal disorders must be sought from NECAHR. Each application would then be considered on a case-by-case basis. PGD in these circumstances could only be carried out where there was a high risk of serious abnormality and the option of prenatal testing alone was unacceptable. The approved Guidelines no longer require such approval to be sought, and permit PGD where the disorder has been identified in the family/whanau and there is evidence that the future individual may be seriously impaired as a result of the disorder.

Similarly, it had been proposed that PGD for aneuploidy screening required NECAHR approval on a case-by-case basis. The approved Guidelines authorise PGD for non-familial chromosomal disorders (aneuploidy testing) where the woman is of advanced reproductive age or has had recurrent implantation failure or recurrent miscarriage.[15]

The Guidelines do not provide a definition of serious impairment. Rather, they provide that 'it is the responsibility of PGD providers, in collaboration with a clinical geneticist, to determine whether a disorder is likely to be serious in the offspring'.

On the face of it, the professionals have a broad mandate to determine what constitutes a disorder that could cause serious impairment in a future child, and the likelihood of that happening.[16] The fact that clinicians determine the *likelihood* of a disorder manifesting in prospective offspring is generally unproblematic, but determining what constitutes a serious disorder is less straightforward. Objective and subjective factors may influence whether a condition is perceived as serious or not. Considerations such as the likelihood of the disease

manifesting in the offspring and the age at which it may present, and the possibilities of prevention and therapy are objective considerations. Subjective considerations encompass the experience of the prospective parents in relation to the condition.[17] It could be claimed that by leaving such decisions in the hands of the treating clinicians, rather than in those seeking the procedure, PGD cannot be represented as providing greater autonomy and reproductive freedom.[18]

An alternative proposition supporting clinicians deciding whether a disorder is likely to be serious is that it is possible that consumers may attempt to compel a provider to perform PGD for a monogenic or chromosomal disorder that has relatively little impact on the future individual.[19] However it is likely, and desirable, that in clinical practice these decisions will be made in collaboration with the intending parents. A related issue concerns the extent to which a physician has an obligation to perform PGD in cases he or she considers morally questionable.[20]

There are major implications in changing the wording from a 'high risk of serious abnormality' to 'evidence that the future individual may be seriously impaired' in relation to single gene disorders. The group of genetic disorders which may be brought within the category of single gene disorders which may cause serious impairment is extremely wide. It could be, and is likely to be, interpreted by providers as including late onset susceptibility disorders. A late onset susceptibility disorder is still a single gene disorder, but is a single gene disorder with reduced penetrance. Such disorders may be tested for without recourse to the ethics committee in New Zealand.

An example of a late onset, lower penetrance disorder is the BRCA 1 or BRCA 2 mutation. Carriers of the mutation have a 60-90% risk of developing cancer of the breast or ovary compared with a 10% risk in the general population. There is, however, no certainty of developing cancer - only a risk. A carrier of the mutation may never in fact develop cancer, or even if they do, may live several decades before the first symptoms of disease appear. However, it is doubtful that new therapeutic developments will be available for the next generation of BRCA mutation carriers that could significantly improve prevention, morbidity and mortality from BRCA-related forms of cancer.[21]

PGD for BRCA mutation has not yet been licensed in the UK. Researchers are soliciting the opinions of women carrying the mutation in regard to the effect their carrier status has on reproductive choices, and whether they would consider PGD if it was available.[22] The Human Fertilisation and Embryology Authority (HFEA) recently announced that it has been carrying out a scientific review on disorders where the genetic conditions were not fully penetrant. This includes conditions such as inherited breast cancer or inherited ovarian cancer, and hereditary non polyposis colon cancer. The views of the public are currently being sought on the appropriateness of offering PGD to screen out such disorders.[23]

At the end of 2004, the HFEA evoked sharp criticism from some groups when it agreed to licence a clinic to test embryos for familial adenomatous polyposis coli, a genetically inherited form of colon cancer which manifests in childhood or adolescence. It was alleged that the HFEA was making decisions behind 'closed doors'.[24] This type of criticism is significant, as there is no requirement in the HFE Act that the HFEA carry out consultation prior to

determining licensable activities.[25] Yet, there seems to be an implicit assumption on the part of both interest groups and Ministers of Parliament that policy decisions extending the use of PGD must occur in line with public input.[26]

The provision of PGD for all of the late onset, lower penetrance conditions mentioned above may be carried out as a matter of course in New Zealand as an established procedure. The Guidelines require that the single gene disorder must have been identified in the family/whānau; that there is a 25% or greater risk of an affected pregnancy; and simply that there is evidence that the future individual may be seriously impaired as a result of the disorder.

It is doubtful that NECAHR, when formulating the Guidelines, intended this as a consequence of the wording change. Rather, their intention was to make the threshold lower as it was often difficult for clinicians to predict whether there was a high risk of serious disorder when a disorder could be mild or severe depending on the expressivity of the mutation in question.[27]

The decision to provide PGD is essentially left up to the clinician involved. In this respect, the provision of PGD in New Zealand for single gene disorders where there is evidence that it may cause serious impairment in the 'future individual' (not 'child') is very broad. This has occurred, not only without public consultation and debate on the issue, but, in all likelihood, without advertence to the implications of the wording change in practice.

1.1.2 SECTION 2: USES OF PGD REQUIRING NECAHR APPROVAL – NOW REGULATED BY THE ADVISORY COMMITTEE AND ETHICS COMMITTEE

As mentioned above, the NECAHR Guidelines now constitute Guidelines promulgated by the Advisory Committee (i.e. ACART). In the context here, any reference to NECAHR should be read as referring to the Ethics Committee on Assisted Reproductive Technology (ECART), established under the HART Act 2004, which has the function of reviewing of applications.

The Guidelines require that proposed PGD for HLA tissue typing must be submitted to NECAHR for ethics approval on a case-by-case basis. However, the wording of the approved Guidelines differs in two potentially important respects from that in the proposed document. The Guidelines set out criteria in relation to both the live child who would be the recipient of tissue donation and to the embryo. In regard to the affected child, it remains a requirement that the disease suffered must be a single gene disorder or a familial sex-linked disorder, and the planned treatment for the affected child will only utilise the cord blood of the future sibling. In addition, the approved Guidelines require that 'no other possibilities for treatment or sources of tissue are available'. This could be a more stringent requirement than that of the proposed guidelines which required only that 'all other possibilities for treatment and sources of tissue for the affected child have been *explored*'. However, in practical terms the distinction may only be superficial.

It is the restrictions relating to the embryo that potentially extend the scope of permissible PGD in relation to HLA tissue typing. Whilst it remains a requirement that the embryo will be a sibling of the affected child, it is no longer a requirement that the embryo be 'at risk of being affected by the condition affecting the existing child', but that it is at risk of being affected by a 'familial single gene disorder or a familial sex-linked disorder for which a PGD test is available'.

While this may extend the scope to a small extent, the normative framework which permits PGD with HLA tissue-typing requires that there are therapeutic indications for the embryo to justify embryo biopsy. This departs from the approach of the United Kingdom.

There is a major anomaly apparent in the HLA tissue typing Guidelines. The Ethics Committee may not approve HLA tissue typing for a sibling in need of stem cells unless the sick sibling is suffering from a genetic disorder. This is so even when performing PGD as an established procedure to diagnose a familial single gene, chromosomal or sex linked disorder in the embryo is clinically indicated, and the HLA tissue typing is merely an additional procedure. However, in the case of an affected child who is suffering from a genetic condition, which the prospective embryos are not at risk of inheriting, HLA tissue typing may be performed regardless of whether the embryo is at risk of inheriting the same condition as the sick sibling, because HLA tissue typing is an 'add on' and not the primary reason for the tissue typing.

It is unlikely that this anomaly is intended. Reportedly, NECAHR had intended to permit HLA testing to be carried out as an 'add on' when the potential embryo was at risk from a genetic condition for which a test was available.[28] The intention was to permit HLA tissue typing as long as there was a medical indication to justify performing an embryo biopsy. This anomaly could be easily rectified by simply requiring that the affected child be suffering from a condition which is severe or life-threatening.

In summary, the New Zealand guidelines prohibit PGD for third party benefit in the absence of a risk to the embryo of a genetic disorder for which there is a test available. Although the normative framework is permissive, at this point it only permits therapeutic applications of PGD.

A compelling argument has been made that performing PGD to HLA tissue type an embryo could be more easily ethically justified than simply performing PGD to test for the presence of genetic conditions.[29] This argument is necessarily based on the premise that embryo biopsy in the course of PGD does not expose the embryo to significant harm. It follows that as PGD is not in itself a cure, but simply a selection procedure; the embryo is selected because of genetic characteristics it already had. Hence, the benefit in terms of 'best interests' for a particular child born from PGD in this context is its existence, rather than a genetic disorder free state. Without PGD, the chances are that the particular child would not have been born. In this way, PGD does not benefit the child in the sense that it prevents the child from having a serious disease, although the parents benefit significantly from having a healthy child rather than a child suffering from a genetic disorder. In the case of HLA tissue typing, PGD is carried out for a purpose that clearly affects another person; namely, the sick sibling.

In comparison, PGD to select against genetic disease is carried out for reasons other than those which affect another person; namely, simply to create a person without a genetic disease rather than to cure a person with a genetic disorder. The point made here is that in the context of PGD for tissue typing, there is an extra person in the equation who benefits from the procedure apart from the parents, and that is the sick sibling.[30] It is notable that the HFEA in the UK now permits PGD to tissue type for sick siblings as a stand-alone procedure when there is no heritable genetic risk to the embryo.

It is a mandatory requirement under the approved guidelines that the Ethics Committee fully considers the health and wellbeing of the family/whanau when it receives an application for approval to perform HLA tissue typing.

1.1.3 SECTION 3: PROHIBITED USES OF PGD

The approved Guidelines prohibit PGD for social or non-medical reasons. Altering the genetic constitution of an embryo is also prohibited, although it should be noted that the HART Act 2004 does not go that far.[31] PGD is prohibited under the Guidelines for any reasons other than those specified in sections one and two above.

Selection of an embryo with a genetic impairment seen in a parent is not permitted. Hence deaf parents may not choose to select an embryo that carries the genetic mutation that encodes for deafness. In some quarters, this has been described as 'decisional asymmetry', where medical selection may only be used when it prevents the disorder, rather than selects for it.[32] The argument raised by people who are themselves deaf and who wish to raise a deaf child is that deafness may be life-enhancing. Being deaf may provide a person with a sense of community, language and culture.[33] Such parents may believe that they are acting in their child's best interests; that by producing a child who is not deaf, the child may feel like an 'outsider' – part neither of the deaf nor the hearing community. However, the implications of this provision in the Guidelines go further than this dilemma.

Consider the following clinical scenario. Theoretically, a couple may undergo PGD for cystic fibrosis combined with aneuploidy screening because of advanced reproductive age. Only a limited number of eggs are produced, and the only one which is not affected with cystic fibrosis is affected with Down's syndrome. The Guidelines would not prevent a couple from choosing to implant an embryo with Down's syndrome, as neither of the parents is affected with the disorder. It is unclear whether the purpose of the section is to prevent the selection of embryos with disabilities, and whether a doctor would feel it would be ethically wrong to implant the embryo. This difficulty is amplified by the fact that it is generally not considered ethically wrong for a woman to carry a pregnancy to term in the knowledge that the baby has Down's syndrome.

Similarly, it is possible that a couple may go through PGD only to find that all of the embryos are affected with the disorder being screened for. Their choices in this situation are to go through IVF again, or go through IVF again using donor gametes, to give up, or to conceive a pregnancy naturally taking the risk that a resulting child may be affected. If the couple decide that they do not wish to go through IVF again, and they do not want to use donor gametes, they may wish to implant the embryos, in the hope that the expressivity of the disorder in the resulting child will only be mild.[34] However, this appears to be precluded under the Guidelines, which may in fact limit some reproductive choices. This is an area that needs to be clarified for both prospective parents and providers before such a situation arises.

It may, of course, be inaccurate to describe PGD as providing greater autonomy and reproductive freedom to couples. The Guidelines provide that in the clinical circumstances of familial single gene disorders, familial sex-linked disorders and familial chromosomal disorders, 'it is the responsibility of PGD providers, in collaboration with a clinical geneticist to determine

whether a disorder is likely to be serious in the offspring'.[35] This puts the responsibility for decision-making squarely in the hands of the clinicians prior to the performance of PGD.

1.1.4 SECTION 4: INFORMATION AND COUNSELLING

Clauses 9 and 10 of the Guidelines deal with information disclosure and informed consent. There are extensive information requirements on providers who must *ensure* those seeking PGD are given all of the information relevant for informed decision-making with regard to IVF and PGD procedures, including risks and alternatives as well as information regarding the background and experience of the clinic and clinicians. Success rates of the procedure, both in general terms and at the clinic, must be disclosed, as well as the alternatives to PGD.

Providers must give genetic and clinical information regarding the specific disorder/infertility and the likely impact of the disorders on those affected and their families/whanau prior to obtaining consent from those seeking PGD. Information about treatment, counselling and the extent of community and social support must also be imparted.

The disclosure to consumers of the availability of prenatal testing following successful implantation is now a mandatory requirement under clause 10 of the interim Guidelines,[36] as is the fact that under the Guidelines, providers are required to supply information for the Advisory Committee's annual report.

Counselling requirements for people with familial disorders and those with non-familial disorders have been distinguished in the approved guidelines. Providers must ensure that those seeking PGD for familial disorders receive genetic and psychosocial counselling from qualified counsellors trained in genetic counselling. Counselling must be culturally appropriate and include consideration of the nature of the disorder and its likely impact on the offspring and family, and the availability of treatment. The family/whanau experience of the genetic disorder, the range of alternatives to PGD and the subsequent decision-making processes, and the possible implications of undertaking PGD must be canvassed. Counselling for non-familial disorders must also be culturally appropriate, include consideration of the range of alternatives to PGD as well as the subsequent decision-making processes and the possible implications of undertaking PGD.

What is noticeably absent from the counselling requirements is that which appeared in the proposed guidelines. It had been proposed that genetic counselling must include a discussion of 'the potential difference in moral status afforded to an embryo compared with a foetus, and the implications this may have for choosing between using PGD to select against an embryo, or termination of a pregnancy following prenatal diagnosis'. The omission is arguably appropriate as it may seem coercive.

Additionally, it is no longer a requirement that counselling specifically include a discussion of the way in which genetic testing of embryos may impact on those who are already living with the condition that is being selected against.

1.1.5 SECTION 5: PROCEDURAL REQUIREMENTS

Section 5 of the Guidelines sets out the procedural requirements necessary for providers wishing to perform PGD. A more permissive approach was adopted in the approved Guidelines in relation to specific tests but procedural requirements were made more stringent.

All clinics wishing to provide PGD must be accredited by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia.[37] In addition, clinics must meet any requirements of RTAC regarding the provision of PGD, which effectively endorses the RTAC Code of Practice as the current standard for fertility service providers.

The Guidelines require that clinics must apply to NECAHR for approval to provide PGD using the generic 'innovative treatment' application form. This requirement does not apply in the context of PGD uses that have since been declared to be 'established procedures' because they may now be carried out by fertility services as a matter of course. However, clinics seeking to perform PGD in conjunction with HLA tissue typing must apply to the newly established Ethics Committee on Assisted Reproductive Technology (ECART).

The application for 'Ethics Approval of an Innovative Treatment' requires extensive information under six headings. The first requires general information. This includes information such as where and when the procedure is to occur, and the qualifications and experience of the principal medical specialists and all other medical specialists involved in the procedure. The second part of the application requires a description of the specific aims and an explanation of the scientific basis of the treatment, An explanation. of the proposed protocols and procedures involved must be provided.

The third part deals with consumer issues. The procedure for obtaining informed consent from clients for all aspects of the treatment must be outlined. Information regarding counselling arrangements, including the professional training of counsellors, as well as their availability before, during and after the project and fees and arrangements for their payments must be provided. The next part of the innovative treatment application form requires an explanation by the applicant of the risks and benefits of the treatment for all people involved, including a potential child. This includes the physical and psychological risks and/or side effects to all those involved. This is followed by part 5 which requires the applicant to provide an explanation of what they consider to be the ethical issues involved in the treatment, and how these issues have been addressed. Additionally the applicant must explain how any cultural issues in relation to the project have been addressed. The last part requires details of the measures taken for protection of information and record keeping.

An annual report from each clinic approved to perform PGD must be submitted to NECAHR under the Guidelines. The report must include information about the number of PGD procedures carried out for familial disorders and the genetic condition tested for in each procedure. The report must also detail the number of PGD procedures carried out for non-familial disorders, and the medical indications leading to the use of PGD. The outcomes of each procedure (to be reported in the following year), including results from any subsequent genetic testing must be provided. Similarly, any ethical issues that have arisen during the course of treatment, and any issues that have emerged during counselling that could have long-term impact on the offspring and their family/whanau must be described.

Since the establishment of the Advisory Committee on Assisted Reproductive Technology (ACART) under the HART Act 2004, NECAHR is no longer the body to whom fertility services must provide annual reports. Under the new regulatory scheme, ACART will request information regarding PGD treatment cycles from clinics at the end of each financial year. A summary of the data collected will be included in ACART's Annual Report to the Minister of Health.

1.1.6 LEGAL STATUS OF THE GUIDELINES

At any time during the interim period of three years after the enactment of the HART Act 2004, the Minister of Health may require ECART to treat specified provisions of any document as interim guidelines issued by the Advisory Committee for the purposes of the Act.[38] As explained at the beginning of this section, the Minister has approved the NECAHR Guidelines as interim Guidelines under the HART Act.[39] They are effective until 21 November 2007, unless revoked sooner.[40] This means the Guidelines have to be reviewed or new guidelines have to be formulated before that date.

The Guidelines have legal force in several ways. In particular, sections of the Guidelines dealing with information and counselling and the procedural requirements are effectively standards of good practice. They may be taken into account in any investigation involving a provider and a consumer under the Code of Rights. The effect of Right 4(2) of the Code is that services, which include fertility services and diagnostic services, must be provided in compliance with legal, professional, ethical, and other relevant standards. As the single source of guidelines for providers of PGD in New Zealand, the guidelines would be most persuasive in any investigation of a breach of a consumers' rights under the Code.

Performing PGD outside the limits of the Guidelines would mean that the activity is an assisted reproductive procedure as defined and regulated under the HART Act 2004. If PGD is performed outside the boundaries of the Guidelines without following the process set out in the Act - that is, without ethics committee approval - then the person performing the procedure commits an offence and is liable to conviction or fine not exceeding $50 000.[41] Because of this indirect legal force, the Guidelines are analogous to delegated legislation.[42]

The parameters set by the Guidelines were adopted by the HART Act 2004.

1.2 THE HART ACT

1.2.1 BACKGROUND

This section provides an analysis of the HART Act, including the history prior to enactment, and the framework that has been established for regulating assisted reproductive procedures, including PGD, in New Zealand.

The first attempt to introduce legislation regulating reproductive technology and research in New Zealand was made in 1996 via a Private Members Bill introduced into Parliament by Labour MP, Dianne Yates. The Human Assisted Reproductive Technology Bill was unanimously sent to the Health Committee in 1997, where it remained. In 1998 a Government Bill was introduced to Parliament, in the form of the Assisted Human Reproduction Bill. The Government Bill in the name of National MP Doug Graham contained substantively similar subject matter to the Yates Bill, but recommended a different structure for decision-making. The Government Bill delegated ethical oversight to NECAHR rather than utilising a licensing regime as proposed in the Yates Bill. [43]

In April 2003, the HART Bill became the subject of Supplementary Order Paper No.80. The HART Bill as amended by Supplementary Order Paper No.80 (HART SOP) contained substantial amendments to the Bill introduced by Dianne Yates.[44] The basis for the amendments were 'to reflect changes in technology and scientific knowledge since the bill was developed, and to fit within the current legislative framework for the health sector'.[45]

Significantly, the HART SOP removed the provisions providing for a licensing authority which had been proposed in the Yates HART Bill, providing instead for a ministerial advisory committee to provide advice, develop guidelines and monitor established procedures. It also provided for mandatory ethics review of all applications of assisted human reproductive procedures or research that were not established procedures.

Effectively faced with a third bill on ART, the Health Select Committee called for submissions on issues covered by both the private Yates Bill and the Government Bill, as well as the HART SOP.[46] The Committee presented its report in August 2004, recommending significant amendments to what was, for ease of reference, referred to as the Human Assisted Reproductive Technology Bill.

The Health Select Committee recommended several amendments to the HART SOP. One amendment of particular note was that the proposed principle that the health and well-being of children born as a result of assisted human reproduction should be 'paramount' in all decisions about procedures, should be replaced with the words 'an important consideration'.[47] Other recommendations involved strengthening the consultation requirements of ACART prior to providing significant advice to the minister, or before issuing guidelines.

The Health Committee stated specifically in relation to PGD that 'we expect the advisory committee, in considering pre-genetic [sic] diagnosis, to ensure decisions are made for medical rather than social reasons'.[48] However, this was not formalised in the Bill itself.

The genetic basis of characteristics such as intelligence, height, hair and eye colour is not yet well understood, and is likely to involve multiple genes. It has been said that:

> *Popular accounts of PGD assume that it will eventually be used to select for such non-medical traits as intelligence, height, sexual orientation, beauty, hair and eye colour, memory, and other factors. Because the genetic basis of those traits is unknown, and in any case is likely to involve many different genes, […] it is unrealistic to think that non-medical screening […], with the possible exception of perfect pitch, will occur anytime soon.*[49]

The Health Committee recommended that the Advisory Committee be required to provide specific scientific and ethical analysis prior to recommending to the Minister that a procedure be declared to be established. The HART SOP removed the provision for a licensing authority and licensing regime for assisted reproductive services, which was proposed in the original Yates HART Bill. Instead, fertility services were to be regulated under the same Act which regulates other health service providers: the Health and Disability Services (Safety) Act 2001. This proved to be a highly contentious issue. The Health Committee reported that they had examined regulatory approaches taken in other parts of the world, particularly Australia, the United Kingdom and Canada, which have licensing systems, in considering the most appropriate system that 'fits the New Zealand health structure'. Issues such as accreditation of fertility services were also considered. In defence to criticisms of the Human Assisted Reproductive Technology Bill, the Chairperson of the Health Select Committee stated:

> *I believe it is robust, because we had to construct it in the context of our health system. New Zealand is not Canada, the United Kingdom, or Australia. We have a health and disability sector here that takes a safety and quality approach. We could not have a licensing regime and think that just by bringing accreditation to the licensing of clinics, we would have a robust system. So we must remind ourselves that this bill is reflective of the current health environment in which we all work.*[50]

The Health Committee acknowledged that 'decisions about human reproduction can have an intergenerational impact, so it is important that decision-making in this area is accompanied by a robust system for ethical decision-making. Our recommended amendments explicitly allow for public input into establishing that ethical framework, to ensure that guidelines are set that meet public expectations'.[51] The Committee acknowledged that the amendments proposed a less prescriptive approach than the other jurisdictions considered.

On the third reading of the Bill in Parliament, Dianne Yates stated that the bill posed as many problems as it answered.[52] Of concern was the fact that the revised bill left decision-making regarding some highly controversial technologies (including PGD) to a Ministerial Advisory Committee which would formulate 'mere guidelines and not regulations'.

Green MP Sue Kedgley, deputy chairperson of the health committee that considered the Bill, was perhaps the most critical of it, saying:

> *Regrettably, the Government has taken what was a really impressive bill – Dianne Yates' member's bill – that would have set up a good regulatory regime similar to one that exists in England, Canada, Australia, and other jurisdictions, and gutted it to such an extent that this legislation sets up one of the weakest, most permissive regulatory regimes for assisted*

human reproductive technologies in the world – a regime that relies on guidelines, rather than regulation, and a regime that bypasses Parliament completely and delegates policy-making in that highly contentious, ethical minefield area to a committee of unelected and unaccountable experts meeting behind closed doors.[53]

The Greens claimed that by setting up a framework by which policy on significant and potentially contentious issues was to be made in a committee that is not directly accountable to Parliament, the Bill breached the well-established parliamentary principle that matters of policy and substance should be dealt with by Parliament.[54]

The Human Assisted Reproductive Technology Act was finally enacted in November 2004, after eight years.[55] Within seven months of the Bill being enacted, PGD in restricted circumstances was declared to be an established procedure.

1.2.2 PHILOSOPHY OF THE HART ACT

The normative framework of the HART Act 2004 in relation to PGD is permissive in part and facilitative. It creates a framework for decision-making by a statutory body, rather than prescribing regulations in terms of procedures. Nowhere in the Act is it specified that PGD must be limited to therapeutic uses, and only one clinical application of PGD, sex selection, is expressly referred to in the Act. While the Act sets limits in terms of prohibited assisted reproductive procedures, it does not prohibit the conduct of research. So, for example, genetic modification of gametes or embryos is not forbidden; it is only the implanting of them into a human being that is expressly prohibited. Hence, there is considerable scope for the creation of guidelines by the Advisory Committee in relation to assisted reproductive procedures including PGD and human reproductive research.

The first purpose declared in the Act is to 'secure the benefits of assisted reproductive procedures, established procedures and research for individuals and society in general'. This is to be achieved by 'taking appropriate measures for the protection and promotion of the health, safety, dignity, and rights of all individuals, but particularly those of women and children, in the use of procedures and research'.[56] The Act sets out other purposes which are to 'provide a robust and flexible framework of regulating and guiding the performance of assisted reproductive procedures'[57] and to prohibit the performance of assisted reproductive procedures (not being established procedures) without ethical approval,[58] as well as prohibiting unacceptable reproductive procedures or research.[59]

The Act sets out several principles that all persons exercising powers or performing functions under the Act *must* be guided by. These include the principles that the health and well-being of children born as a result of an assisted reproductive procedure is an important consideration, in all decisions about that procedure;[60] that the 'human safety, and dignity of present and future generations should be preserved and promoted;'[61] and that 'while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the *use* of these procedures'.[62]

The last-mentioned criterion signals that provisions must be made to protect the health and well-being of women who undertake assisted reproductive procedures or established procedures. It should not be taken to indicate that concern for the health and well-being of women is of greater importance than other interests when making decisions about procedures.

These principles clearly indicate that there are competing interests to be assessed and balanced in relation to assisted reproductive procedures or research, including the health and well-being of a potential child, and the health and well-being of women undergoing treatment. However, no interest is absolute.

Additional principles require that the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect,[63] and that the needs, values, and beliefs of Māori in particular should be considered and treated with respect.[64] This latter provision is distinctive in terms of health law by providing for the needs, values and beliefs of Māori in the principles section of the Act. This has no counterpart in other primary health legislation.[65] For example, the Health and Disability Commissioner Act 1994, possibly the most important piece of health law in New Zealand, does not expressly refer to Māori at all.[66] The original principle provided in the Yates Bill referred to the 'principles of the Treaty of Waitangi'.[67] The Select Committee recommended that it be amended as it was 'unclear how service providers, Māori and the courts would interpret the Treaty of Waitangi in this context'. The Committee was of the opinion that it may be more appropriate to amend the provision to recognise instead the specific cultural concerns of Māori, such as whakapapa, mauri, and genetic ownership and control of genetic information.[68]

The removal of the paramountcy principle in relation to the welfare of the child born as a consequence of an assisted reproductive procedure signals that the interests of those seeking assisted reproductive procedures may be an equally important consideration, as is the human health, safety and dignity of present and future generations. The Health Select Committee drafted the amendment to the paramountcy principle for the following reasons. It has been established that the health risks to children born as a result of assisted human reproduction are generally higher than children who are conceived naturally. Procedures might not be approved if they involved any health risks over and above those associated with natural conception if the health and well-being of children born as a result of an assisted reproductive procedure or established procedure had to be the paramount consideration.[69] The Government obtained a Crown Law legal opinion which advised that conferring paramountcy on the health and well-being of any child born as a result of ART could leave the Government open to litigation if a child was harmed by an assisted reproductive procedure.[70]

However, many submissions to the Health Select Committee on the HART SOP welcomed the paramountcy principle. A submission from the New Zealand Fertility Clinic drew attention to the fact that a paramountcy clause could be used as grounds to refuse providing fertility treatment in rare cases to a parent or parents that were 'unable to meet the minimum requirements of a safe, nurturing environment'.[71] However, the legal position in relation to 'fitness to parent' concerns is not clear, and has been the cause of considerable debate in the United Kingdom.[72]

Article 12 of the European Convention on Human Rights provides that 'men and women of marriageable age have the right to marry and to found a family, according to national laws governing this right'. The Convention has been incorporated into domestic law in the United Kingdom by the Human Rights Act 1998 (UK); no similar provision exists in New Zealand domestic law. Whilst the state should not prevent a person from having a child under international human rights jurisprudence, this is not absolute and even recently a New Zealand Court has been prepared to countenance limiting that right in the case of a woman suffering from mild intellectual disability.[73] In most jurisdictions, guardianship rights may be suspended or extinguished in extreme cases where children are at risk. The question arises whether a provider may refuse to provide fertility services on the grounds that the child would be at risk.[74]

The common law position in relation to intervening in 'at risk' pregnancies against the wishes of a competent pregnant woman is that to do so is an invasion of the woman's physical integrity and autonomy.[75] In the review of the Human Fertilisation Act 1990 (UK) recently undertaken by the House of Commons Science and Technology Committee it was considered that it would be an infringement of liberty for the State to prevent fertile individuals from having a child in circumstances where there were fitness to parent concerns. In their opinion the same course of action should be followed in the case of children born as a result of ART as those born by natural means whereby social services are notified of an at risk pregnancy.[76] However, there would seem to be a distinction between not interfering in an established pregnancy, and being compelled to provide ART. A provider in this situation may discuss with the patient the reasons for not wishing to provide treatment and refer on, or may take the approach adopted by the House of Commons Select Committee.[77]

It is possible that lowering the threshold for permissible intervention by removing the paramountcy provision in relation to a child born as a result of ART may result in alternative tests which may be used to judge whether a procedure should be permitted other than the more restrictive best interests test. A clinical example of this may arise with tissue typing. This involves performing PGD to determine the compatibility of embryos as potential stem cell donors for siblings suffering from life-threatening haematologic diseases.[78] The procedure has evoked controversy in that it is not *prima facie* in the best interests of the future child to be exposed to PGD where there is no genetic risk to the embryo.[79] Justifications that have been raised for performing the procedure on the grounds of best interests include arguments such as that it is better for the child to be born in this manner than not be born at all, or that it will be better to be born and grow up with a live sibling than into a family that is bereaved. However, when it is required that the health and well-being of a child born as a result is an 'important consideration', there is far greater flexibility to employ a test such as the 'reasonable parent' test which permits wider motives to be taken into consideration, as long as the procedure is not clearly against the interests of the potential child.[80]

The reality that assisted reproduction involves balancing interests and incurs additional risks, some of which are already known, but some of which may not be known for many years, is relevant to the following principle expressed in the Act. It provides that 'no assisted reproductive procedure should be performed on an individual and no human reproductive research should be conducted on an individual unless the individual has made an informed choice and given informed consent'.[81]

In summary, the underlying philosophy of the HART Act appears to be to secure the benefits of ART for individuals whilst providing a framework to protect and safeguard the health, safety, dignity and rights of all individuals, including the perceived wider interests of society.

1.2.3 CATEGORIES OF ASSISTED REPRODUCTIVE PROCEDURES

The Act sets up three distinct categories of assisted reproductive procedures: those which are prohibited, those which are regulated, and those which are declared to be established procedures. An assisted reproductive procedure is defined in section 5 of the Act, which provides:

> *In this Act, unless the context otherwise requires, – assisted reproductive procedure or procedure*
>
> *(a) means a procedure performed for the purpose of assisting human reproduction that involves-*
>
> *(i) the creation of an in vitro human embryo; or*
>
> *(ii) the storage, manipulation, or use of an in vitro human gamete or and in vitro human embryo; or*
>
> *(iii) the use of cells derived from an in vitro human embryo; or*
>
> *(iv) the implantation into a human being of human gametes or human embryos; but*
>
> *(b) does not include an established procedure.*

Hence, PGD falls within the scope of an 'assisted reproductive procedure' unless it is declared by an Order in Council to be an established procedure.

1.2.3.1 Prohibited Activities

The Act has adopted the widespread prohibition against permitting a human embryo to develop outside the body of a human being beyond fourteen days after its formation. Criminal sanctions apply for any breach of this provision.[82] However, research on embryos is not expressly prohibited although it is limited by the fourteen day rule.

The Act prohibits the sale or purchase of human embryos or gametes.[83] This effectively sets the bar against potential exploitation of women in particular, with implications not only at a national level but also on a global level. The potential for a global fertility industry is best illustrated by a newspaper article in 2004 which revealed that the UK Human Fertilisation and Embryology Authority intended to visit a Romanian clinic in order to monitor the purchase of human ova from women by UK clinicians. The procedure of egg recovery is invasive, requiring hyper-stimulation with gonadotrophins prior to egg pick up, and carries risks such as ovarian hyperstimulation syndrome. While the HFEA was in no sense involved in the transactions, observers were purportedly shocked that the HFEA 'tacitly approved this commodification and globalisation of tissue in the form of the cross-border trade in ova'.[84] Whilst the New Zealand regulatory approach may be described as a permissive regime, this does not extend to permitting the commercialisation of gametes or embryos.

Prohibited activities which carry a penalty of either imprisonment for a term not exceeding five years or a fine not exceeding $200 000, or both, are listed in schedule 1 of the Act.[85] Other prohibitions in the Act carry lesser penalties, and concern prohibiting the development of embryos beyond fourteen days,[86] storage of in vitro embryos and gametes,[87] obtaining gametes from minors,[88] and advertising for illegal activities.[89]

Of direct relevance to PGD is section 11, which places restrictions on the sex selection of human embryos. Section 11(1) provides:

> *No person may, for reproductive purposes, -*
>
> *(a) select an in vitro human embryo for implantation into a human being on the basis of the sex of the embryo; or*
>
> *(b) perform any procedure, or provide, prescribe, or administer any thing in order to ensure, or in order to increase the probability, that a human embryo will be of a particular sex.*

A person who breaches this section is liable to either imprisonment for up to one year, or a fine of up to $100 000, or both.[90] However, the statute provides a lawful excuse if sex selection was undertaken to prevent or treat a genetic disorder or disease.[91]

Section 11 is drafted extremely broadly. Whilst section 11(1) (a) relates directly to PGD, it is assumed that section 11(1)(b) is intended to cover techniques such as sperm sorting, which allows parents to select the sex of their child prior to conception,[92] or to new techniques which may be developed in the future. However, the provision is drafted so broadly that a person who, for example, consults a homeopath for homeopathic remedies to increase their chances for a child of a particular sex, could render the homeopath liable to prosecution under the Act.[93] Whilst this is most unlikely, the question whether this particular section was a proportionate response to concern relating to sex selection is begged.[94]

1.2.3.2 Regulated Activities

The Act sets up two types of bodies: an advisory committee which is responsible for creating policy, and an ethics committee which facilitates the implementation of that policy. The adoption of a split regulatory framework instead of a central regulatory body has been criticised on the basis that it goes against an international trend which perceives that the creation of a single body creates greater consistency, provides greater accountability, and therefore increases the ability to foster public confidence.[95] However, the National Ethics Committee on Assisted Human Reproduction (NECAHR), which had previously been responsible for establishing guidelines, and for reviewing and approving assisted reproductive procedures and assisted reproductive research, was supportive of the creation of two bodies. In a submission on the HART SOP it was stated:

> *As a Ministerial Advisory Committee, NECAHR currently develops policy and guidelines on assisted human reproduction as well as giving ethical approval on individual applications. This dual role has become increasingly difficult for NECAHR as the number of issues it is being required to consider is increasing in number and complexity. NECAHR supports the separation of the development of policy and guidelines from the ethical approval process.*

The New Zealand National Advisory Committee on Health and Disability Support Services Ethics (NEAC) also endorsed the separation of policy and development of guidelines from the operational work of reviewing particular proposals for similar reasons.[96] Whilst the framework clearly has the support of two of the major ethics bodies of New Zealand, it could be argued that the issue is one of resources, rather than that a split regulatory body is the most desirable option in itself. However, the policy-making role undertaken by the Advisory Committee requires a high level of skill and experience. The ability for the Advisory Committee to concentrate only on creating policy is an appropriate utilisation of expertise. Being able to focus on policy increases the efficiency of the policy-making process. These are compelling reasons in favour of the division of roles between the two bodies.

1.2.3.2.1 ECART

The Act provides that assisted reproductive procedures may only proceed with the prior written approval of the ethics committee,[97] which may give an approval subject to any conditions it thinks fit to impose.[98] The ethics committee may not give an approval unless it is satisfied that the activity proposed to be undertaken under the approval is consistent with relevant guidelines or relevant advice issued or given by the advisory committee.[99] If there are no relevant guidelines or advice, the ethics committee may not approve an assisted reproductive procedure or human reproductive research until such time as the Advisory Committee formulates them. The ethics committee is therefore restrained by the parameters set by the Advisory Committee.[100] The ethics committee has the power to cancel an approval, either in whole or in part, in certain circumstances.[101]

The Minister of Health is responsible for designating an ethics committee as the relevant ethics committee for the purposes of the Act.[102] Section 27(3) provides:

> *(3) In designating a committee under this section, the Minister*
>
> *Must ensure that the committee-*
>
> *(a) complies in its composition with any applicable standard governing ethics committees determined by the national advisory committee appointed under section 16(1) of the New Zealand Public Health and Disability Act 2000.*

The national advisory committee appointed under section 16(1) is the National Advisory Committee on Health and Disability Support Services Ethics, more commonly referred to as 'NEAC'. There is one national set of standards for ethical review in New Zealand, which is the Operational Standard for Ethics Committees.[103]

The Operational Standard requires that an ethics committee should include a minimum of 10 persons, half of whom should be lay members, including a lay chair.[104] There must be a lawyer and a person with expertise in ethics, and at least two Māori members with an awareness of te reo Māori and an understanding of tikanga Māori.[105] The Operational Standard also provides that it is important that the committee's composition include individuals possessing knowledge and understanding of consumer and community issues and perspectives. Each committee should have a composition tailored to provide it with appropriate medical, scientific, clinical and research expertise to enable it to ethically review the majority of the proposals coming

before it. In addition to the requirements prescribed by the applicable standard, the HART Act requires that the ethics committee includes one or more members with expertise in assisted reproductive procedures; and one or more members with expertise in human reproductive research.[106]

However, the Terms of Reference for the Ethics Committee provide that ECART must consist of not fewer than 8 and not more than 12 members. This sets the minimum number of members lower than that required by the Operational Standard. It could be claimed that if ECART is constituted with only 8 members, as it currently is, it is improperly constituted under the HART Act 2004.

Section 27(4) of the Act provides:

> *The committee designated under this section is subject to any applicable ethical standards determined by the national advisory committee appointed under section 16(1) of the New Zealand Public Health and Disability Act 2000.*

This appears to state that the designated ethics committee is subject to the Operational Standard. [107] Chapter 6 of the Standard sets out the procedure for committee meetings, and provides that every question before any meeting shall be determined by consensus decision-making. Using a consensus approach requires a process of discussion and debate leading to a decision, rather than by a process of formal vote casting. A proposal will only be approved when every member is willing to allow the proposal to proceed. On this approach a single settled and consistent objection to the proposal will necessitate further discussion or review.

Curiously, the Terms of Reference for the Ethics Committee on Assisted Reproductive Technology provide that while a consensus position should be achieved where possible, where that is not possible, a vote shall apply with a two-thirds majority required for decision-making.[108] The Terms of Reference also provide that should a member or members wish to abstain from some or all of the decision-making process because of strong moral or religious reasons the abstentions shall not affect the approval process. Given that ECART must work within guidelines and on advice from ACART it seems that they do not have a great deal of discretion in their decision-making ability. It is therefore unclear why a Health and Disability Ethics Committee must reach a consensus decision, yet ECART only requires a two thirds majority to determine issues.

Additionally, it is unclear whether the decision-making parameters in the Terms of Reference are valid in view of the requirements of section 27(4) of the HART Act 2004. The Terms of Reference provide that ECART must operate in accordance with the following specified criteria. ECART must perform its duties in accordance with: the HART Act and any other enactment; the ECART terms of reference; any guidelines or advice issued by ACART or transitional guidelines gazetted by the Minister of Health under section 79 [sic] of the Human Assisted Technology Act;[109] and in accordance with Chapters 1-4 of the Operational Standard. It is stated that 'on any point of conflict, the guidelines issued by ACART will have precedence over the Operational Standard'.

However, on a plain reading of the statute the Minister *must* ensure that the committee complies in composition with the standard, which is set out in chapter 6 of the Operational Standard. This chapter is precluded from the Terms of Reference. Similarly, the Act provides that the designated ECART *is subject* to the standard. These are mandatory provisions, not discretionary provisions. It is submitted that if ECART is not constituted according to, and does not follow the procedures set out in the Operational Standard, then ECART will be acting *ultra vires*. Any decision may then be challenged by judicial review on the grounds that it is procedurally invalid.

The HART Act and the Terms of Reference are silent on review or appeal rights of an applicant whose proposal is declined. The Operational Standard provides that committees have an obligation to review a previous decision to grant or decline ethical approval of a proposal when new information relevant to that decision arises.[110] The Operational Standard also provides for a second opinion process, which could be undertaken either by the ethics committee or the applicant. Where the application is a research proposal, or any proposal has a research element, second opinion requests should be referred to the National Ethics Committee or the Health Research Ethics Committee. It is stated that 'principles of natural justice underlie the second opinion process'.[111]

In contrast the HART Act merely provides that, in carrying out their functions, ECART may consult with any persons who, in the opinion of the committee, are able to assist it to perform its functions.[112] ECART must forward research reports to ACART, along with comments or requests for advice that the ethics committee considers appropriate. Yet there is no mechanism providing for natural justice, whereby an applicant may appear before ECART, nor is there any mechanism to appeal against a decision of ECART. This is a substantial barrier to ECART achieving transparency and fairness, and may affect public confidence in the decision-making process. Whilst judicial review may be brought on either substantive or procedural grounds against a decision of ECART, it is costly and time consuming.

1.2.3.2.2 ACART

The Minister of Health is responsible under the HART Act for establishing the Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research, (ACART). The Advisory Committee must consist of not fewer than 8 and not more than 12 members,[113] at least half of whom must be lay persons.[114] There must be one or more members with expertise in either assisted reproductive procedures, human reproductive research, ethics, or relevant areas of the law.[115] Additionally, there must be one or more members with expertise in Māori customary values and practice and the ability to articulate issues from a Māori perspective, and one or more members with the ability to articulate issues from a consumer perspective.[116]

Significantly, the Advisory Committee must also include one or more members with the ability to articulate the interests of children, who must either be the Commissioner for Children, or be a representative or employee of the Commissioner.[117] This may ameliorate the dilution of the principle in the Act relating to the health and well-being of children born as a result of an assisted reproductive procedure or established procedure by providing such children with a voice on the Committee.

Appointing a diverse range of persons contributes to the ability of the Advisory Committee to be perceived as capable of engaging in legitimate, democratic decision-making. ACART must follow an extensive consultative process in the formulation of guidelines or advice, in an attempt to engage in inclusive and widespread debate with the public. This kind of engagement with the public has been referred to as 'biomedical diplomacy'.[118] However, there are procedural concerns relating to the decision-making processes which may undermine ACART's ability to follow a transparent policy-making path.

Whilst the composition of the Advisory Committee is specified in the Act, the Act confers on the Committee complete freedom to regulate its procedure in any manner that it thinks fit.[119] There are no guidelines for decision-making processes, such as whether consensus or unanimity is required. A simple majority may be all that is required to introduce guidelines and advice. The Terms of Reference for ACART state that every question before any meeting shall generally be determined by consensus decision-making. Where a consensus cannot be reached a simple majority vote will apply. In such circumstances, the Chairperson shall have the casting vote. Whilst consensus decision-making may be the ideal, it is the process and robustness of the decision-making that is the essential factor. Residual disagreement may be inevitable, but is not necessarily a sign of failed deliberation.

Decisions made by the Advisory Committee must be made in accordance with the principles as stated in the Act.[120] The Terms of Reference outline the role and functions of ACART.[121] These include the heading 'Duties and responsibilities of a Member', under which it is stated

> *This section sets out the Minister of Health's expectations regarding the duties and responsibilities of a person appointed as a member of ACART. This is intended to aid members of ACART by providing them with a common set of principles for appropriate conduct and behaviour and serves to protect ACART and its members.*
>
> *As an independent statutory body, ACART has an obligation to conduct its activities in an open and ethical manner. ACART has a duty to operate in an effective manner within the parameters of its functions as set out in its Terms of Reference and in accordance with the HART Act.*

It is stated that members should have a commitment to work for the greater good of the committee. The Terms of Reference require that members perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest and, additionally, that '[p]roper observation of these principles will protect ACART and its members and will ensure that it retains public confidence'.

The Terms of Reference notes that members attend meetings and participate in committee activities as independent persons responsible to ACART as a whole. Members are not appointed as representatives of professional organisations and/or particular community bodies. This is pertinent to the justifiable requirement that ACART should not assume that a particular group's interests have been taken into account simply because a member is associated with a particular group. In addition, such a requirement is necessary where members must be prepared to think and reason beyond partisan viewpoints. If not, decision-makers would be unable to engage with, and analyse issues beyond, the perspective of their own particular groups.

It is a requirement that the chair of ACART must ensure that the agenda and minutes are published on the internet as soon as possible after they are confirmed by the members of the committee. This has not been achieved by NECAHR, where although there were three meetings in the year ending 2005, the last minutes posted were December 2004. It is unclear whether ACART meetings will be open to the public.

Of great significance are the duties the Terms of Reference impose on ACART in relation to information. Whilst members are free to express their own views within the context of committee meetings, members must publicly support a course of action decided by ACART. If unable to do so, members must not publicly comment on decisions.

Such a provision has a counterpart in the Constitutional Convention enshrined in the *Cabinet Manual*. This convention requires that once Cabinet makes a decision, then (except in some coalition governments when 'agree to disagree' processes have been established) Ministers must support the decision, regardless of their personal views and whether or not they were at the meeting concerned.[122]

Whilst this may be justified in terms of Cabinet decision-making, it is a far greater leap to justify it in terms of an Advisory Committee. The legitimacy of the Advisory Committee's decision-making in terms of transparency and accountability may be better served by providing the reasons for ACART decisions, and the competing perspectives that it took into account. It may be useful to report whether the particular decision was made by unanimity, consensus or simple majority. This would show that 'conclusions are based on conscientious and intelligible moral thought'.[123] This is no more than our judiciary do when providing majority and dissenting decisions in the courts.[124]

Providing reasons for decision-making was achieved to an extent by NECAHR when they published the approved Guidelines on PGD. In the introduction it was stated that:

> *During the consultation period a diverse range of views was expressed on assisted human reproductive technologies, genetic testing, and the moral status of the embryo, as well as on PGD. These ranged from strong support of the guidelines to total rejection of all reproductive technologies, including PGD. The pluralistic nature of New Zealand society means that universal agreement on the use of PGD was not a possibility. In revising the guidelines following the public consultation, NECAHR took account of all the submissions and focused on the strength of the arguments with regard to particular clauses in the guidelines, rather than on the number of stakeholders for or against them.*

Concerns of disability groups were also specifically addressed:

> *Concern has been raised that PGD discriminates against people with disabilities, and promotes the view that the birth of people with disabilities should be prevented. However, it is important to distinguish between 'disability' and 'people with disabilities', and that selecting against embryos with disabilities does not necessarily imply that those with disabilities are living lives that are either less valuable or less meaningful.*

It has been noted that there was no explicit mention of Māori values in the NECAHR Guidelines.[125] A greater explanation for the substantive provisions and the reasons for allowing or limiting specific aspects of PGD would enhance future policy created by the Advisory

Committee. This should include an explanation of the scientific evidence, particular ethical strands of argument, (for example reproductive autonomy is an ethical strand which should be considered as well as the moral status of the embryo) and the underlying principle used to determine the particular policy.

The functions of the advisory committee include guideline development and the provision of advice to the ethics committee, and the review of such guidelines and advice.[126] The Advisory Committee must also provide advice to the Minister on issues arising out of assisted reproductive procedures or human reproductive research.[127] This includes, but is not limited to, advice as to whether –

(i) the Act or any other Act should be amended to prohibit or provide for any kind of assisted reproductive procedure or human reproductive research:

(ii) on the basis of the information, assessment, advice, and ethical analysis required under section 6(2)(a) to (d), any kind of procedure or treatment should be declared to be an established procedure:

(iii) whether any established procedure should be modified or should cease to be an established procedure: [emphasis author's]

(iv) whether a moratorium should be imposed on any kind of assisted reproductive procedure or human reproductive research:

(v) regulations should be made under section 76 of the Act to regulate the performance of any kind of assisted reproductive procedure or research.[128]

It is a particular strength of the HART Act that it provides ACART with the flexibility to advise whether certain procedures should be revoked from the established procedure category. This mechanism enables ACART to respond quickly to any health concerns that may arise as the procedures are increasingly implemented and more medical and scientific knowledge becomes available.

In addition, there is a provision under the Act to effectively 'buy time' when there is a need for the Advisory Committee to develop guidelines, or to provide advice to the Minister. In these circumstances, the Minister may recommend the passing of an Order in Council declaring a particular assisted reproductive procedure or human reproductive research to be subject to a moratorium for up to eighteen months.[129] During this time, the ethics committee must not consider or grant a request to approve a proposal for that form of procedure or research.[130] This prevents any particular assisted reproductive procedure or human reproductive research from taking place until formulation of guidelines or advice occurs following due process under the Act.

Of great relevance is the requirement that the advisory committee *must* monitor the application, and health outcomes, of assisted reproductive procedures *and established procedures;* and developments in human reproductive research.[131] Hence there is an emphasis on safety and accountability, which covers all assisted reproductive procedures and research, including established procedures. However, the Act does not specify in what way the oversight is to occur. Nor does it provide specifically that medium and long-term outcomes must be monitored. This is a substantial gap, given that some adverse developmental side effects may only become apparent as a child grows up.

The Advisory Committee is required to provide the Minister with information, advice, and if it thinks fit, recommendations regarding specified assisted reproductive activities, including the selection of embryos using preimplantation genetic analysis.[132]

1.2.3.2.3 Statutory Obligations of the ACART

(a) Barometer of Public Opinion

The Advisory Committee may only issue guidelines if interested parties and members of the public have been given a reasonable opportunity to make submissions on a discussion paper or on an outline of the proposed guidelines.[133] The Advisory Committee is statutorily obliged to take those submissions into account.[134] After receiving a copy of the guidelines, the Minister must table them in the House of Representatives, but does not need the approval of the House for them to come into effect.[135]

Similarly, for specified instances of assisted reproductive research and ART (including selection of embryos using PGD), the Advisory Committee must call for and take into consideration submissions before giving significant advice to the Minister.[136] This requirement effectively ensures that the committee assesses the barometer of public opinion prior to issuing guidelines or providing significant advice to the Minister, but does not mean that views expressed will necessarily be accommodated.[137]

Whilst undertaking consultative measures to determine public opinion is traditionally viewed as engendering public trust, it must be recognised that reliance on quantification of the dominant opinions from public consultations which are 'often based on an unrepresentative sample, limited analysis, and attenuated moral discussion' places demands on resources, and of itself does not necessarily create legitimate and fair policy-making.[138]

(b) Duty to Consult

Before the Advisory Committee gives advice to the Minister or issues guidelines to the ethics committee, it must consult on the proposed advice or guidelines with any members of the public or any other person or group 'that the committee considers appropriate' and with appropriate government departments and agencies.[139] Although some may hold cynical views of the consultation requirement, seeing them simply as a form of window dressing, the Court of Appeal has declared that consultation provisions impose real obligations. In *Wellington International Airport Ltd v Air New Zealand*[140] the Court considered what was required by a duty to consult. McKay J observed, 'consultation does not require agreement between the parties, but requires more than mere notification'.[141] Lord Morris of Borth-y-Gest said:

> *The requirement of consultation must never be treated perfunctorily or as a mere formality. The local authority must know what is being proposed. They must be given a reasonably ample and sufficient time to express their views or to point to problems or difficulties: they must be free to say what they think.*[142]

In addition, before the advisory committee issues guidelines to the ethics committee, it must consult on the proposed guidelines with the Minister of Health.[143] It is implied in effect that the Minister is the final arbiter on the guidelines, although there is no statutory right of veto,

nor is there a requirement that the Minister must approve the guidelines or the advice of the ACART. However it is difficult to envisage the Minister tabling guidelines in Parliament that he is strongly opposed to, given his political vulnerability. In this way the Minister wields considerable power. This is compounded by the fact that appointments to the Advisory Committee are made and terminated by the Minister.[144]

In summary, there are significant fetters on the activities of the Advisory Committee in terms of the extensive requirement to consult widely prior to establishing guidelines or giving advice. However, there is a shortfall in achieving legitimate decision-making by virtue of the lack of independence from the Minister of Health, and a lack of transparency in the decision-making process. Reasons ought to be given as to how decisions are made in order to legitimate the decision-making process and policy recommendations.

There is no appeal process under the Act. Decisions of ACART may be subject to judicial review on grounds either of procedural or substantive invalidity. However, this process is costly. It is possible that complaint to the ombudsman may be utilised as a vehicle for review.[145]

1.2.3.3 ESTABLISHED PROCEDURES

As indicated above, ACART may advise the Minister of Health that certain assisted reproductive procedures should be declared by Order in Council to be established procedures. This has the effect that those procedures may be carried out without recourse to the jurisdiction of ECART and ACART. The Governor-General may make an Order in Council on the recommendation of the Minister, who may request the Order on the basis of advice received from ACART.[146] However, ACART must still monitor the outcomes of established procedures, and may recommend to the Minister that an established procedure should cease being an established procedure.

In tendering advice to the Minister that an assisted reproductive procedure should be declared to be an established procedure, ACART must provide the Minister with a report that sets out scientific and ethical analysis relating to the procedure, and whether, in its expert opinion, the Minister should recommend that the assisted reproductive procedure or treatment be declared an established procedure.[147]

In April 2005 the Director-General of Health, Dr Karen Poutasi, advised the Minister of Health of a list of procedures which should be declared to be 'established procedures'.[148] Under the interim provisions of the Act, the Director General of Health is deemed to be the Advisory Committee for the nine months following the date on which the HART Act receives Royal assent.[149] Surprisingly, PGD in circumstances covered by Section 1 of the NECAHR Guidelines was included in the list of proposed established procedures. Consequently, PGD for familial single-gene disorders, familial sex-linked disorders, and familial chromosomal disorders which were within the criteria set out in section 1 of the Guidelines became established procedures. So too was PGD for non-familial chromosomal disorders associated with advanced reproductive age or associated with infertility.

This was surprising on several fronts. First, in almost all jurisdictions that allow PGD, the practice is still being considered experimental, due to ongoing scientific uncertainty.[150] This had been emphasised in the "Systematic Review of Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis" which recommended a cautious approach because the 'evidence on the effectiveness and long term safety of PGD is currently limited and inconclusive'.[151] It may have seemed reasonable to wait for the newly established ACART to make recommendations involving PGD.

The Order in Council was passed with urgency to enable fertility services to continue to provide routine services after the date that the HART Act provisions regulating assisted reproductive procedures became effective. The procedures at issue needed to be declared to be established; if not, they would each need to have ethical approval before they could be undertaken. While this is understandable in the case of IVF and other routine procedures, it is more difficult to justify PGD on that basis that it had never been performed in New Zealand and as such was not a routine procedure. The Minister stated that 'the proposed established procedures do not differ from the status quo, and are not likely to be controversial'.[152]

Although the decision may have seemed precipitous, due process in making the Order in Council was followed under the Act. In accordance with section 6(2)(a)-(d) of the Act, the Director-General commissioned a report from an Advisory Group (AGART) to review the risks and benefits associated with specific assisted reproductive procedures, and the acceptability of those risks.[153] This differed from the *Systematic Review of the Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis* in that it covered a range of ARTs.

AGART convened in 2004 to provide the Director-General of Health with advice on the risks associated with ART and an assessment of those risks. The group met three times and based their recommendations on systematic reviews carried out by the New Zealand Guidelines Group including the *Systematic Review* and literature searches and updates carried out by New Zealand Health Technology Assessment.[154]

The Terms of Reference for the Advisory Group on Assisted Reproductive Technologies required the group to undertake:

- An in-depth assessment of the possible health risks to children and the mother, including intergenerational health risks, associated with ART. The assessment will take account of current research data and knowledge on health risks associated with these procedures and of gaps in the basic science of human fertilisation and sperm selection, and hereditable traits linked to sub-fertility.
- An assessment of the level of elevated risk of adverse health outcomes for children, the mother and subsequent generations associated with the use of ART:
    - focusing on those procedures currently available in New Zealand or likely to be available in the near future,
    - an assessment of whether the level of risk associated with each of those procedures is acceptable,
      recommendations on whether those procedures should be approved as 'established procedures' for the purposes of the HART Act 2004.

- Broad scientific advice on monitoring and research needs in relation to ART (retrospective or prospective), including surveillance, epidemiology and data collection. This will involve providing advice on:
    - the usefulness of the data currently collected by fertility clinics in terms of assessing the health risks associated with particular ART and on what, if any, additional information is needed
    - management of the information (eg, governance arrangements, anonymisation of data)
    - what, if any, research could usefully be undertaken in New Zealand, including long term follow-up of ART children

AGART considered the risks associated with procedures available in New Zealand at that time,[155] and also considered the risks associated with procedures which they considered were likely to be, or may be, available in the near future. This included PGD, use of thawed ovarian tissue, and in vitro maturation within IVF or ICSI.

The Advisory Group concluded that, although there were clearly some risks associated with PGD, these risks were not markedly higher than the risks associated with IVF and therefore the risks associated with PGD were acceptable.

The Minister was subsequently advised by AGART that the risks associated with PGD fell within an acceptable level for New Zealand because the risks were not raised above those risks for IVF alone, and PGD offered potential benefits for those who were genetically predisposed to having a child with a serious disorder. However, where there is no infertility or genetic risk to the embryo, the risk/benefit ratio is significantly altered.

AGART noted in its report that fertility clinics collect information on all babies born as a result of ART – including pregnancy and birth outcomes, mode of delivery, birth status, birth weight, gestational age, plurality, perinatal mortality, congenital malformation and maternal morbidity. Providers obtain information by following up both the lead maternity carer and the patient after the due date of birth of any assisted pregnancy. The information collected is fed into the Australia and New Zealand Assisted Reproduction Database (ANZARD), and is used for three purposes:

- Generation of the National Perinatal Statistics Unit (Australia) annual report
- Generation of summary data reports for the Reproductive Technology Accreditation Committee (RTAC), which is responsible for accrediting fertility clinics in both Australia and New Zealand
- To provide fertility clinics with regular internal reports of their outcomes for comparison with Australia and New Zealand-wide norms.

ANZARD includes information about treatment methods and PGD, as well as details of pregnancy and birth outcomes, including mode of delivery, birth status, birth-weight, gestational age plurality, and prenatal mortality. Congenital malformation and maternal morbidity is self reported by patients. All data is reported on an anonymised basis.

ANZARD is useful in terms of providing information relating to perinatal and maternal health outcomes but there is a gap in that congenital malformations are not reported by fertility clinics. AGART recommended that fertility clinics should collect and report to the Ministry of Health the NHI number of all infants born as a result of ART so that it may be linked with the New Zealand Birth Defects Monitoring Programme and matched against the NZ Birth Defects Register. However, not all health outcomes will be picked up as birth defects, such as some epigenetic disorders. Nor are medium- or long-term data collected.

It was stated that the concern expressed internationally about the outcomes for children born as a result of ART was shared by the Ministry of Health. The Ministry is to examine the possibility of 'matching data and putting in place systematic monitoring of health outcomes for children born as a result of assisted reproductive procedures. This is likely to include discussions with fertility clinics, seeking advice regarding any privacy issues and assessing the suitability of the Birth Defects Monitoring Programme.'[156] This is an issue of great importance which needs to be addressed with some urgency.

The Ministry of Health intends to periodically match the NHI number of babies born from assisted reproductive procedures with the Birth Defects Monitoring Programme. Although theoretically the data could be matched to any Ministry of Health database which also has the National Health Index number, no other matching is intended.[157]

Access to fertility services for the performance of PGD is significantly limited for many people by virtue of the cost involved. It has, however, been announced that public funding for up to two cycles of PGD for couples at risk of transmitting serious genetic disorders will be made available.[158] The funding does not cover PGD to screen for aneuploidy. It is expected that around 40 couples a year will be able to access funding through the District Health Boards.[159]

In Australia, PGD costs about $1700 on top of an IVF cycle and there is no Medicare rebate for PGD.[160] Although there is no overall NHS funding for PGD in the UK, Guidelines for Commissioners of NHS services were released in 2002.[161] These guidelines recommend that individual cases should be considered by commissioners for NHS funding. It was recommended that two to three cycles would increase the chance of a successful pregnancy and make the most cost-effective use of genetic probe development. However this is only a guideline, and does not translate to what is occurring in practice.[162] Hence, New Zealand is the only jurisdiction under study that has made specific Government funding available for PGD.

1.2.4 SUMMARY

The Human Assisted Reproductive Technology Act 2004 provides a skeleton framework which prohibits certain specified assisted reproductive procedures and uses, and confers authority upon an Advisory Committee (ACART) to determine the finer details of permissible and impermissible assisted reproductive activities. Assisted reproductive procedures are regulated by Guidelines crafted by ACART and applied by an Ethics Committee (ECART) that is also appointed under the Act. Some assisted reproductive procedures avoid regulation where there are sufficient grounds to have them declared to be established procedures. The Act adopts a facilitative regulatory approach. The Act provides a flexible and potentially permissive regulatory framework for the provision of PGD in New Zealand, whilst prohibiting PGD for social sex selection.

Analysis of the interim Advisory Committee Guidelines has revealed several ethical issues which may pose difficulties for both providers and consumers of PGD. Should a prospective parent be limited in their choice of available embryos, and seek to implant an affected embryo in the hope that the expressivity of a disorder is low, or on the basis that having a disabled child is better than no child at all, it is possible that a breach of the Guidelines may occur with the consequences of rendering the provider liable to a fine under the HART Act. There is no process whereby a provider could get immediate direction when faced with such a situation, although they could apply to the Ethics Committee for clarification of the Guidelines. This grey area needs to be addressed before such a clinical scenario arises.

An Order in Council has recently been passed declaring certain applications of PGD to be established procedures. It is notable that the application of PGD for single gene disorders in the established procedures category is very broad. On the face of it, PGD to detect low penetrance single gene disorders may be carried out as an established procedure. This potentially covers late onset disorders such as Alzheimer's disease and susceptibility disorders such as BRCA 1 and 2 or familial adenomatous polyposis coli. It is most unlikely that NECAHR intended this consequence when drafting Category 1 of the Guidelines. It is equally unlikely that the Director General of Health intended this consequence when recommending the passing of the Order in Council which made Category 1 of the Guidelines established procedures. There needs to be clarification of this issue so that providers and consumers may operate in an area of certainty, and without fear of sanctions.

PGD in conjunction with tissue typing remains a tightly and conservatively regulated 'assisted reproductive procedure' under the Act. The parameters of permissible HLA tissue typing are problematic on several counts. The drafters have gone beyond their jurisdiction in requiring an assurance that the planned treatment for the affected child will utilise only the cord blood of the future child. Medical procedures carried out on a live child are covered by established principles of health care law, and it is not within the remit of a policy-making body to attempt to predetermine those issues. In addition, the HLA Guidelines encompass a structural anomaly. An embryo may be tested for HLA compatibility as an add-on procedure if an embryo biopsy is indicated to test for the presence of a genetic disorder, but this may not be carried out 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. Again, it is unlikely that 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 such a wide range of PGD is permitted as an established procedure.

At this point, 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.[163] 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. In this way, there is also a permissive aspect to the Act.

On the face of it, while the Act is permissive, it is far from conferring on the Advisory Committee unfettered and arbitrary decision-making power. The New Zealand framework provides significant flexibility which is moderated by public consultation requirements under the Act and sets limits by prohibiting sex selection of embryos. Decisions must be made in accordance with the principles expressed in the Act. These principles tend towards balancing competing interests, while protecting the health and well-being of stakeholders.

However on deeper analysis, 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, the members are restrained from commenting publicly indicating any disagreement with policy decisions. However, it may increase transparency and public confidence in the legitimacy of the Committee if decisions are accompanied by reasoned analysis of the decisions, including the scientific basis, the differing perspectives taken into account, and the number of members in favour or against decisions that are made.

There are strong grounds to believe that the decision-making process set out in the Terms of Reference for ECART is *ultra vires.* The Act provides that the ethics committee is subject to the *Operational Standard for Ethics Committees.* The Ministers' 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 ECART open to challenge by way of judicial review on the grounds of procedural invalidity.[164] In addition, the Act requires that the Minister must ensure that the committee complies in its composition with the Operational Standard. The Standard requires a minimum of 10 members. However, the Ethics Committee Terms of Reference provide for 8 members as a minimum, and it is currently constituted with 8 members. It is therefore possible that ECART is not legally constituted under the Act.

There are no rights of appeal from the decision of an Ethics Committee or the Advisory Committee.[165] This is a barrier to the Act achieving a 'robust' framework. Whilst ECART may seek or receive advice from ACART, they cannot be compelled by a claimant to do so. Judicial review is available, but it is expensive and time consuming.

Finally, 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 was not put in place before PGD was declared to be an established procedure.

In passing the Act, the New Zealand legislature has rejected a trend seen in other jurisdictions which have opted for a licensing system with one statutory body responsible for creating both policy and assessing applications. One motivation for this is clearly that the system New Zealand has adopted is a cost-effective and efficient option.[166] The fact that PGD has been declared to be an established procedure in certain specified circumstances adheres to the principle of imposing the least necessary regulatory intervention, and reduces the number of applications from consuming ECART time and money.

There is little doubt that the HART Act 2004 was a necessary legislative initiative. The framework sets up an affordable, efficient, responsive process, and is supported in health and safety aspects by other health law initiatives. However, it will be the fine-tuning of the work of the Advisory Committee that will dictate the success of the regulatory scheme in terms of being seen to be making policy in a transparent, fair and legitimate manner.

1.3 OBLIGATIONS ON PROVIDERS – THE MEDICO-LEGAL CONTEXT

1.3.1 STATUTORY OBLIGATIONS UNDER THE HART ACT

All New Zealand fertility clinics have been accredited by the Reproductive Technology Accreditation Committee (RTAC), which is the accreditation body of the Fertility Society of Australia, for the last decade and a half. This external professional oversight of fertility services has been accepted on a voluntary basis by fertility service providers in New Zealand.

The HART Act 2004 deems fertility services as coming within the definition of specified health or disability services under the Health and Disability Services (Safety) Act 2001.[167] The purpose of the HDS(S) Act is to:

(a) promote the safe provision of health and disability services to the public; and

(b) enable the establishment of consistent and reasonable standards for providing health and disability services to the public safely; and

(c) encourage providers of health and disability services to take responsibility for providing those services to the public safely; and

(d) encourage providers of health and disability services to the public to improve continuously the quality of those services.[168]

Under section 9 of the HDS(S) Act, a person providing fertility services must be certified by the Director-General to provide health care services of that kind, meet all relevant service standards, comply with any relevant conditions to which the person was subject by the Director-General, and must comply with the HDS(S) Act.

There are no specific standards for fertility services currently in New Zealand. The Ministry of Health hopes to have a standard published by Standards New Zealand in early 2007.[169] Until such time as the Minister approves specific standards for providing fertility services,[170] providers are deemed to comply with the HDS(S) Act[171] if the provider complies with specified criteria. The provider needs to be certified by the Director-General of Health, must comply with any standards approved by the Director General of Health under the HART Act, and must have been the subject of an audit report by an approved organisation and that report must be given to the Director General within 5 days that it is received by the provider.[172]

The Director-General has approved the RTAC to audit the provision or likely future provision of fertility services in New Zealand in the interim period.[173] The RTAC Code of Practice has been approved as the standard for providing fertility services in the interim period.[174] The Terms of Reference for RTAC require them to visit centres using ART to assess compliance with the Code. Accreditation (with or without conditions) may be granted to centres for up to three years. The RTAC Code of Practice[175] provides guidelines relating to staff and resources, patient information, consent, laboratory services, treatment methods, record keeping, ethics and research, quality control and accreditation. In relation to laboratories, the Code of Practice provides that both biochemistry/endocrinology and andrology laboratories must be accredited by the Australian National Association of Testing Authorities or the New Zealand equivalent to the ISO 17025 guidelines.[176]

As well as setting out standards, the Code of Practice makes recommendations for patient management. It states that the objective of ART should be the live birth of a single healthy child. For this reason, RTAC requests that all ART programs make every reasonable effort to reduce multiple pregnancy.[177] Some of the language in the Code of Practice is expressed in terms of requesting, not requiring. However, requirements for laboratory services and qualifications of laboratory personnel, record keeping, and information provision contain mandatory standards.

The HDS(S) Act provides the Director-General of Health with the authority to cancel the certification of a provider.[178] In addition, cessation orders may prohibit the provision of services if the Director General is satisfied that the provision of services by the provider or under the provider's control does not comply with certification and standards requirements, or services are being provided in an unsafe or unsanitary manner.[179] Closing orders may also be made.[180] A cessation or closing order may be revoked by the Director-General if she is satisfied that the reasons for which it was issued no longer apply, it is unlikely those reasons will apply again in the short term, and there are no other reasons that would justify the issue of a cessation order or a closing order in respect of the person or place concerned.[181] An appeal process is provided under the Act against a cancellation or certification.[182]

Consequently, the provisions of the HART Act have essentially provided the legal requirement for clinics to be accredited and to adhere to standards, given statutory reinforcement to voluntary professional self-regulation, and provided civil sanctions for non-compliance. The Act has created new synergy by combining elements from both professional self-regulation and government regulation.

The fact that accreditation of services is carried out by an Australian professional body may be criticised on the grounds that this important role should not be delegated to an offshore organisation. However, this may enable inspections to be more objective than if carried out by New Zealand fertility providers, who would have to inspect their colleagues, with whom they may be competing for business.

The health and disability infrastructure in New Zealand, which provides a framework for safety and accountability, and which can be extended to cover fertility services, is a compelling argument against adopting the licensing approach taken by other jurisdictions.

1.3.2 OTHER OBLIGATIONS ON PROVIDERS

Prior to the introduction of the HART Act 2004, fertility services did not operate in a legal vacuum, nor are they only subject to the requirements of the HART Act since its enactment. There are significant relevant additional regulatory measures affecting health providers in the New Zealand medico-legal context. These include consumer protection law in the form of the Health and Disability Services Consumers' Code of Rights, professional disciplinary proceedings under the Health Practitioners Competence Assurance Act 2003, compensation for treatment injury pursuant to the Injury Prevention, Rehabilitation and Compensation Act 2001, civil claims for wrongful birth or wrongful life, and actions in criminal negligence. The following is a brief discussion of how these discrete areas of law may impact upon fertility providers. It is not intended to go into these in detail, which would require a far greater analysis, but rather to outline the potential issues that may arise in theory. Close analysis of these issues will be carried the project progresses.

1.3.2.1 The Common Law and Negligence

In a common law claim for damages on the grounds of negligence it is necessary to prove several fundamental requirements. These are that the practitioner owed the plaintiff a duty of care; that the practitioner breached the duty of care owed; that the plaintiff suffered compensable damage; and the damage suffered by the plaintiff was caused by the practitioner's breach of the duty of care that he/she owed a plaintiff.

Common law claims for negligence in New Zealand have been circumscribed by the statutory compensation regime. However, negligence is still relevant for the purpose of the Code of Consumers' Rights, and for allegations of professional misconduct. Significantly, both the Code of Rights and disciplinary law have dispensed with the requirement to establish harm arising from alleged negligence. Because of this, the mere evidence of negligence may suffice to constitute a breach of the Code, or to satisfy a professional misconduct charge, without any evidence that the breach was causative of harm on the part of the plaintiff. In this way, negligence is still a live issue in New Zealand.

1.3.2.2 Code of Consumers' Rights

The purpose of the Health and Disability Commissioner Act 1994 is expressed as being:

> *to promote and protect the rights of health consumers and disability services consumers, and, in particular, to secure the fair, simple, speedy, and efficient resolution of complaints relating to infringements of those rights.*[183]

This objective is achieved through the promulgation of a Code of Rights pursuant to the Health and Disability Commissioner Act, and the establishment of a complaints process to ensure enforcement of those rights.[184] A consumer of fertility services is a consumer under the Code of Health and Disability Consumers' Rights.[185] The rights provided under the Code may be described as generic rights, and include the following:

1	the Right to be Treated with Respect,
2	the Right to Freedom from Discrimination, Coercion, Harassment, and exploitation,
3	the Right to Dignity and Independence,
4	the Right to Services of an Appropriate Standard, (this includes the right to have services provided with reasonable care and skill and to have services provided that comply with legal, professional, ethical, and other relevant standards)
5	the Right to Effective Communication,
6	the Right to be Fully Informed,
7	the Right to Make an Informed Choice and Give Informed Consent,
8	the Right to Support
9	Rights in respect of teaching and research and
10	the Right to Complain.

Right 4 effectively provides a right to non-negligent care. The Code is distinctive in providing an avenue for complaint, investigation and the imposition of limited sanctions without any requirement that the alleged negligence caused actual damage to the consumer. Hence, the Code provides an avenue for redress where negligence has occurred in the absence of harm suffered by the complainant.

These rights would cover any procedures carried out on a consumer of fertility services, and potentially any procedure performed on their gametes. However, it is unlikely that the Code would apply to an embryo. Gametes are derived from a 'consumer' and a 'health care procedure' includes any health treatment, examination, health research or health service administered to, or carried out on or in respect of, any person by any health care provider. Procedures performed in relation to gametes may therefore be services performed 'in respect of' a consumer. It is likely that a technician or embryologist in a lab would come within the definition of a 'health care provider' as contained in the Health and Disability Commissioner

Act 1994.[186] However, it is unlikely that an embryo would come within the definition of a 'health care consumer' under the Act'.[187] As an embryo is perceived to have an independent moral status from a parent, but does not have any legal status as a person, any procedure is unlikely to be deemed to be carried out 'on or in respect of a health care consumer'. Hence there is scope for protection of fertility service consumers under the Code, but it is unlikely that the Health and Disability Commissioner has direct jurisdiction over PGD procedures on embryos under the Code of Rights.

There is also a duty under Rights 6 and 7 of the Code to inform, and to obtain informed consent. The Code augments the interim Guidelines, providing a complaints process for breaches. For example, a provider is required under the Guidelines to supply the patient with specific information.[188] If this does not occur, then a claim may be brought under the Code for breach of the Right to be informed.[189]

1.3.2.3 Professional Disciplinary Law

The Health Practitioners Disciplinary Tribunal was established on 18 September 2004 pursuant to section 84 of the Health Practitioners Competence Assurance Act 2003 (HPCA).[190] The Tribunal hears and determines disciplinary proceedings brought against health practitioners.[191] Professional misconduct is defined in the HPCA Act as:

> (a) … any act or omission that, in the judgment of the Tribunal, amounts to malpractice or negligence in relation to the scope of practice in respect of which the practitioner was registered at the time the conduct occurred; or
>
> (b) … any act or omission that, in the judgment of the Tribunal, has brought or was likely to bring discredit to the profession that the health practitioner practised at the time the conduct occurred.[192]

The definition of professional misconduct in s101(1)(a) of the HPCA Act refers to professional misconduct as meaning malpractice or negligence in relation to the way a health practitioner discharges his or her professional responsibilities. Subsection 101(1)(b) categorises acts or omissions that do, or are likely to, bring discredit to the practitioner's profession, regardless of whether the acts or omissions in question occurred in relation to the practitioner's 'scope of practice', as professional misconduct.[193]

In the first hearing reported under the new legislation it was declared unlikely that the legislature intended that all of the criteria required by the common law to establish negligence would need to be proven in the prosecution of health practitioners. The inquiry to be undertaken in a matter before the Tribunal was whether the practitioner's acts or omissions fell below the standards reasonably expected of a health practitioner in the circumstances of the person appearing before the Tribunal. Whether or not there was a breach of the appropriate standards is to be measured against the standards of a responsible body of the practitioner's peers.[194] This approach, it was said, 'avoids the need for prosecuting authorities to prove damage'.[195]

It was stated that the test as to what constitutes professional misconduct involves a two step process. The first step involves an objective analysis of whether or not the health practitioner's acts or omissions in relation to his or her practice can be reasonably regarded by the Tribunal

as constituting: malpractice; or negligence; or otherwise meets the standard of having brought, or was likely to bring discredit to the practitioner's profession. The second step of the process requires the Tribunal to be satisfied that the health practitioner's acts or omissions require a disciplinary sanction for the purposes of protecting the public and/or maintaining professional standards and/or punishing the health practitioner.

Hence, a practitioner may be liable for a finding of professional misconduct in the event of negligence when his or her act or omission falls below the standard reasonably expected of a health practitioner in the circumstances of the person appearing before the Tribunal. It is not necessary to prove damages, but the Tribunal must be satisfied that disciplinary sanctions are required in order to protect the public, to maintain professional standards or simply to punish the health practitioner.

1.3.2.4 Injury Prevention, Rehabilitation and Compensation Act 2001

Accident Compensation legislation was first introduced into New Zealand in the 1970s.[196] Historically, it provided cover for personal injury arising from medical misadventure which occurred as a result of medical error or medical mishap as defined in the Act. As of 1 July 2005, the medical error and medical mishap provisions have been replaced with personal injury caused by treatment (treatment injury).[197] The Act bars court proceedings for damages arising directly or indirectly from personal injury that is covered by the scheme.[198]

Treatment injury is defined as personal injury that is suffered by a person seeking treatment from one or more registered health professionals, or receiving treatment from or at the direction of one or more registered health professionals, that is caused by treatment.[199] Treatment includes;

(a) the giving of treatment,
(b) diagnosis of a person's medical condition,
(c) a decision on the treatment to be provided (including a decision not to provide treatment),
(d) a failure to provide treatment or to provide treatment in a timely manner,
(e) obtaining, or failing to obtain, a person's consent to undergo treatment, including any information provided to the person to enable the person to make an informed decision on whether to accept treatment
(f) the provision of prophylaxis
(g) the failure of any equipment, device or tool used as part of the treatment process …
(h) the application of any support systems, including policies, processes, practices, and administrative systems, that-
    (i) are used by the organisation or person providing the treatment;
    (ii) directly support the treatment

Treatment injury does not include personal injury that is a necessary part or ordinary consequence of the treatment taking into account all the circumstances of the treatment, including the person's underlying health condition and the clinical knowledge at the time of the

treatment.[200] Treatment injury does not include personal injury that is wholly or substantially caused by a person's underlying health condition,[201] or that is a result of a person unreasonably withholding or delaying consent to treatment.[202] There is no cover if personal injury is solely attributable to a resource allocation decision.[203] Nor does the fact that the treatment did not achieve a desired result, of itself, constitute treatment injury.[204]

Treatment injury includes personal injury suffered by a person as a result of treatment given as part of a clinical trial where the claimant did not agree in writing to participate in a trial. Cover for treatment injury will also arise where an approved ethics committee gave approval for a trial, being satisfied that the trial was not to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled.

Where personal injury occurs, for which there is cover under the IPRC Act, it is still possible that exemplary damages may be obtained where the actions of the practitioner constitute 'outrageous' conduct, and other legal consequences do not adequately express the court's disapproval of the practitioner's conduct.[205] Whilst the IPRC Act 2001 applies to consumers of fertility services, there is great uncertainty at to its relevance in the context of wrongful birth or wrongful life claims which may potentially be brought against fertility providers by parents of a disabled child or by a disabled child themselves.

1.3.2.5 Wrongful Birth

Wrongful birth actions involve a claim brought by a parent or parents who argue that, but for another person's negligence, their child would not have been conceived or born. This could arise in the case of a provider failing to advise the risk of illness, or failing to advise a couple to undergo prenatal diagnosis after PGD, or failing to interpret correctly the results of a procedure such as PGD. Where a breach of the duty of care is alleged, it may be claimed that the parents have been deprived of an opportunity to not proceed with implantation or pregnancy. Damages may be sought in respect of the distress occasioned by the parents in respect of the existence of the disability in the child, and for the extra costs involved in raising such a child. In New Zealand such claims are complicated by the Injury Prevention Rehabilitation and Compensation Act 2001. As already discussed, the IPRC Act bars court proceedings for damages arising directly or indirectly from personal injury that is covered by the scheme. This excludes the ability for a civil claim to be brought against a person when the cause of action involves personal injury caused by treatment (treatment injury).[206]

It has been held in the High Court that conception, pregnancy, and childbirth could not be considered to be a personal injury to the mother when they occurred as a result of a natural or gradual process.[207] However, it is plausible that conception through IVF could be construed as a personal injury if negligence occurred in the course of the procedure, as it is more difficult to construe it as a natural or gradual process.[208] If this is accepted, an IVF/PGD parent would not be able to bring a civil claim for wrongful birth because of the statutory bar which excludes a person from bringing an action for personal injury covered by the Act.[209]

If, on the other hand, wrongful birth cases are held to be outside the IPRC Act scheme, a provider may become liable in a civil claim for negligence resulting in wrongful birth. In PGD cases, the issue becomes one of wrongful selection of an embryo, or a missed chance of terminating a pregnancy on the basis of prenatal diagnosis.

In *Cattanach* v *Melchior*,[210] the High Court of Australia held that the costs of rearing a healthy, but unplanned, child were recoverable. The United Kingdom has recently followed a different path based on policy grounds.[211] These grounds were the incalculability in monetary terms to the parents of the benefits of the birth of a healthy child, the sense that it would be morally offensive for the parents to recover these costs, and that society would regard it so. In *Rees* v *Darlington Memorial Hospital NHS Trust*,[212] the House of Lords reaffirmed that such costs are not recoverable, nor are the extra costs of raising a healthy child where the parent is disabled.[213] However, where the pregnancy has resulted in the birth of a disabled child, there may be a greater chance of damages being recovered.[214] If a wrongful birth action in the context of an assisted reproductive procedure is held to be outside the IPRC Act in New Zealand, it remains to be seen which common law approach our courts adopt.

1.3.2.6 Wrongful Life

A claim for wrongful life could be brought by a child born as a result of PGD if a test is undertaken to exclude a disorder, but it is negligently reported. Another possible avenue in which it may arise is the situation where although no negligence was involved, a test was read as a false negative but the woman was not advised to undergo prenatal testing. In the event that the child is born with the disorder for which PGD was carried out, it could be argued that had the mother been informed that the embryo carried that specific mutation, or that she should undergo prenatal testing in the second circumstance, she would not have had the embryo implanted, and the child would not have been born. A claim in negligence may also arise if a provider has failed to advise of a genetic risk to a prospective embryo.

The basis for a wrongful life claim is often said to be a claim by the child that he or she would have been better off if he or she had never been born.[215] Claims for wrongful life have evoked different judicial responses throughout the world.[216] There have not been any successful actions brought on the grounds of wrongful life in New Zealand.[217]

In a case heard in the New York Supreme Court, parents and their child who had cystic fibrosis sought to bring a medical malpractice action against a hospital, medical centre and physician.[218] It was alleged that the defendants failed to warn a couple who were undertaking IVF with donor ova that the donor was a carrier of cystic fibrosis. As the father was unknowingly a carrier of the genetic mutation also, the child subsequently born inherited cystic fibrosis. It was made clear in the Supreme Court that rights of recovery did not exist for a child's birth with cystic fibrosis or for parents for emotional distress.[219] However, a right of recovery for pecuniary expense for the infant's care and treatment could be available. Claims for gross negligence or fraud in failing to prevent the conception of child with cystic fibrosis could be brought, although causation issues would raise some difficulties for the claimants.

A case of wrongful life was recently heard in the Australian High Court.[220] This is the first time the High Court of Australia has been asked to address the issue of wrongful life. The case involved two people, in one case an adult and in the other a child, who were seeking compensation for their disabilities which were allegedly caused by the negligence of doctors. Each has significant disabilities and will require care for the rest of their lives. In one case a doctor failed to diagnose rubella early in the mother's pregnancy. In the other case an IVF

clinic failed to properly advise parents of the risk of an inherited clotting disorder. The NSW Court of Appeal decided in a 2-1 judgment to reject the medical negligence claims of the two claimants.[221] The case then went on appeal to the High Court. The case was heard by the full court of the High Court on 10 November 2005, but the judgment is yet to be released.

The French courts bucked the trend of rejecting wrongful life claims on public policy grounds, becoming the first European jurisdiction to allow an action for wrongful life.[222] In addition, a strong argument for reconsidering and allowing wrongful life actions in the form of 'diminished life' actions has recently been made.[223]

The areas of wrongful life and wrongful birth are extremely complex. The above has been intended to merely provide an overview of the potential of these claims. It is not in any way a full analysis of the issues and will be canvassed in greater detail in a later report.

1.3.2.7 Crimes against the Person – Criminal Negligence

The Crimes Act includes several provisions which may be relevant in the context of providing fertility services. Section 155 of the Crimes Act 1961 imposes a legal duty on every one who undertakes (except in case of necessity) to administer surgical or medical treatment to have and to use reasonable knowledge, skill, and care in doing any such act.[224] Anyone who omits to discharge that duty without lawful excuse is criminally liable for the consequences. Section 156 of the Crimes Act 1961 provides that everyone who has in his/her charge or under his/her control anything whatever, whether animate or inanimate, or who erects, makes, operates, or maintains anything whatever, which, in the absence of precaution or care, may endanger human life is under a legal duty to take reasonable precautions against and to use reasonable care to avoid such danger. A person who omits without lawful excuse to discharge that duty will be criminally responsible for the consequences.

However, these legal duties are subject to an important qualification, by virtue of an amendment to the Crimes Act in the 1990s. Section 150A was inserted by the Crimes Amendment Act 1997 after the sustained and effective lobbying of a coalition of medical bodies.[225] As a result of the amendment, liability for criminal negligence will only accrue if in the circumstances of the particular case, the omission or neglect is a major departure from the standard of care expected of a reasonable person to whom that legal duty applies in those circumstances.[226] Although prosecutions under the Crimes Act 1961 are rare, they are still possible.[227]

1.3.3 SUMMARY: THE MEDICO-LEGAL CONTEXT

Fertility service providers are subject to professional and legal oversight in a number of ways. For the purposes of the Code of Consumers' Rights, there is no requirement for the provider to have caused harm to be guilty of a breach, although the sanctions available under the Code are relatively modest. Causation of harm is not a prerequisite to a finding of professional misconduct under the HPCA Act 2003, but the tribunal must be satisfied that the health practitioner's acts or omissions require a disciplinary sanction for any of the following purposes: protecting the public, maintaining professional standards or punishing the health practitioner. Whilst the IPRC Act 2001 cushions a provider from claims in negligence by providing cover for treatment injury and placing a statutory bar on proceedings arising out of personal injury for which a claimant has cover under the Act, exemplary damages are available when a practitioner is guilty of 'outrageous' conduct. It is unclear whether the IPRC Act 2001 prevents a claim for wrongful birth in New Zealand in the context of ART. If it does not, it is similarly unclear whether policy concerns would override a Court's willingness to allow a wrongful birth action in New Zealand. Whether civil claims for wrongful life should be permitted is a strongly contested issue in other jurisdictions. Again, there are complex issues involved which have mitigated against allowing such claims in other countries. Criminal sanctions exist where negligence, which is a major departure from the standard of care expected of a reasonable person in those circumstances, causes bodily harm or death.

2 THE UNITED KINGDOM

The United Kingdom's approach to regulating the use of PGD has been described as 'one of the most liberal regulatory mechanisms in the world'.[228] It is difficult to consider the legislative approach of the United Kingdom to the regulation of reproductive technologies without first taking into account the political context. The predisposition of the United Kingdom is heavily geared towards scientific freedom.[229] In a Foreword to the Government White paper, *Our Inheritance, Our Future,*[230] Tony Blair wrote:

> *Our country has a remarkable scientific tradition. The extraordinary achievements of Newton, Darwin and a host of other eminent scientists have both greatly increased the understanding of our world and improved the quality of life for everyone.*
>
> *Our record continues to be outstanding; with just one per cent of the world's population, we receive nine per cent of scientific citations. Nowhere has this record been more notable in recent decades than in bio-science and bio-technology.*
>
> *The discovery in Britain of the structure of DNA 50 years ago – perhaps the biggest single scientific advance of the last century – marked the beginning of a golden age of bio-science in Britain which continues today. It is likely to have as big an impact on our lives in the coming century as the computer had for the last generation.*
>
> *The more we understand about the human genome, the greater will be the impact on our lives and on our healthcare …*

> *I am proud to know that much of this ground-breaking work is already taking place in our country. I am also absolutely determined that the National Health Service should be able to respond to these advances so the benefits of genetics and the more personalised and improved healthcare it will bring are available to all.*
>
> *It means we must prepare now for the future. We must invest in research and research facilities to drive further discovery …*[231]

It is apparent throughout the White Paper that there is a very strong desire to harness new genetic technologies in the United Kingdom, and to be world leaders in this area. Notably, some of the world's 'firsts' in ART and genetic science were British. The first test tube baby in the world was Louise Brown who was born in Britain in 1978, and the first cloned mammal was a British sheep called Dolly. This scientific drive is accompanied by initiatives aimed at increasing public awareness and understanding of issues raised by genetic technologies, and engaging the general public in consultation on certain topics.[232] The Government established the Human Genetics Commission in 1999 to provide expert advice on human genetics and the relevant social and ethical issues arising from them.[233] The hope is that these mechanisms will enable the Government to ensure that 'its regulatory framework around genetics and health anticipates and reflects public concerns'.[234]

The following discussion seeks to provide a brief background to the introduction of the HFE Act 1990 and an outline of the relevant substantive provisions of the Act. A description of how PGD came to be a licensable activity, as well as the legal challenge to the HFEA's decision to allow licenses for HLA tissue typing will be set out. The current content of the Code of Practice in relation to PGD will then be outlined. Excerpts of the relevant parts of an in-depth review of the HFE Act by the House of Commons Science and Technology Committee will be provided. This section will conclude with the Government proposals for change to the current system.

2.1 BACKGROUND TO THE HFE ACT 1990

In 1982 the Committee of Inquiry into Human Fertilisation and Embryology was set up by the government under the chairmanship of Dame Mary (now Baroness) Warnock.[235] The Committee's terms of reference were:

> *to consider recent and potential developments in medicine and science related to human fertilization and embryology; to consider what policies and safeguards should be applied, including consideration of the social, ethical and legal implications of their developments; and to make recommendations.*

The Warnock Report was released in 1984. In 1987 the Government White Paper, *Human Fertilisation and Embryology: A Framework for Legislation* was published after consultation on the Warnock report.[236] A major focus of the Warnock report was on embryo research, which inevitably led to great discussion as to the moral status of embryos. A key conclusion of the Warnock Committee was that the human embryo had a special status, entitling it to 'some protection in law'.[237] After six years and much political debate after the Warnock Report was released, the HFE Act was passed.

The HFE Act has been described as a pragmatic response to the public anxieties evoked by the ability to create in vitro human embryos and the related potential for embryonic use, manipulation and research. Ethical concerns for the embryo and the perceived need to protect the public were central to the Act which, it has been said, is evidence of the intention of the British Parliament to facilitate research and progress by legitimating such research with regulation.[238] 'Britain opted for a limited and pragmatic regulation of research and treatment focusing on ensuring public accountability on the part of both researchers and clinicians, facilitating medical and scientific progress and largely skating over fundamental questions of reproductive choice'.[239] The price of the British 'realpolitik' has been described as a lack of a single coherent philosophy underlying the regulatory regime.[240]

2.2 THE HFE ACT 1990

The construction of the Human Fertilisation and Embryology Act 1990 is vastly different to that of the New Zealand Act. The Human Fertilisation and Embryology Act 1990 contains few express prohibitions, and delegates considerable decision-making power to the Human Fertilisation and Embryology Authority (HFEA). The Authority is an independent arm's length body under the patronage of the Department of Health.[241] The Act provides the basis for a system which authorises the HFEA to deal with the regulatory aspects of certain artificial reproductive procedures and research.[242]

The purpose of the Act was to regulate the creation and use of human embryos outside the body, to prohibit certain practices in connection with embryos, and to establish and empower the HFEA to grant licenses for otherwise prohibited activities. There is an absence of any principles set out in the Act itself. The HFE Act should be read with the Warnock Report and the subsequent Government White Paper.

The HFE Act sets out certain prohibitions in connection with embryos[243] and sets up a licensing authority,[244] the scope of whose power includes granting licences, authorising activities in the course of providing treatment services,[245] storage[246] and research.[247] The HFEA is responsible for maintaining a code of practice for the proper conduct of activities carried on in pursuance of a licence under the Act.[248]

Activities for which the HFEA may grant treatment licences are set out in clause 1, schedule 2 of the Act, which provides:

> 1 (1) A licence under this paragraph may authorise any of the following in the course providing treatment services-
>
> (a) bringing about the creation of embryos in vitro,
>
> (b) keeping embryos,
>
> (c) using gametes,
>
> (d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose,
>
> (e) placing any embryo in a woman…

(3) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services.

'Treatment services' for the purposes of the Act are defined as 'medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children'.[249] Licences for treatment under paragraph 1 of schedule 2 may be granted subject to conditions specified in the licence, including the manner of the performance of activities referred to in sub-clause (1) above.[250]

The Act sets out the conditions of every licence for treatment.[251] It is provided that 'a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth'.[252]

The HFE Act permits the Secretary of State to make regulations for any purpose for which regulations may be made under the Act.[253] This effectively permits amendments to be made to the Act in the form of regulations. However, certain regulations may not be passed unless a draft has been laid before and approved by a resolution of the House of Parliament.[254] Parliamentary scrutiny involves either an affirmative resolution of any proposed change, or in some cases negative resolution.

Scrutiny of secondary legislation by negative resolutions involves regulations being lodged in the office of the clerk of each House. The regulations will come into force 40 days after lodging if they have not been made subject to a resolution for annulment passed in either the House of Commons or the House of Lords. The less rigorous safeguard of negative resolution by the House concerns any additional functions to be undertaken by the HFEA,[255] the composition of the HFEA licence committees,[256] changes in licensing procedure,[257] any proposed increase or decrease in the permitted period for the storage of eggs or embryos,[258] and any changes in the information which the HFEA is obliged to disclose to an applicant under s31 of the Act.

Parliamentary scrutiny and affirmative resolution are necessary for making regulations which would add to the activities involving keeping or use of an embryo that are to be prohibited under the Act.[259] Similarly, any proposal relaxing regulations prohibiting the storage or use of gametes[260] or adding to the practices which may be authorised in a treatment licence[261] must be subject to an affirmative resolution of the House of Parliament. The statutory instrument will not take effect until approval occurs in Parliament by affirmative resolution.

In 2001, section 3 of the Act was extended by regulations to allow the HFEA to grant licences for research to be undertaken on human embryos in order to increase knowledge about the development of embryos, about serious disease and to enable the knowledge derived to be applied in the development of treatments to combat serious disease.[262] Embryonic research had previously been restricted to research involving infertility, congenital disease, miscarriage, contraception or the detection of genetic or chromosomal abnormalities.[263] This regulation has opened the door to stem cell research, distinguishing the UK regime as amongst the most liberal in Europe.

2.3 THE HFE ACT AND PGD

It is apparent from the relevant sections of the HFE Act set out above that the Act does not expressly provide for the licensing of PGD. However, the Act provides a mechanism for passing regulations to extend the list of activities for which treatment licences may be given. Such regulations would require the affirmative resolution of the House of Parliament, as already discussed. Significantly, regulations were not utilised to mandate the licensing of clinics for PGD when applicants first approached the HFEA for a licence to carry out PGD. Instead, the HFEA took the approach that the Act implicitly authorised them to license clinics to provide PGD services.

The Authority assumed jurisdiction over PGD on the following grounds. The HFE Act explicitly permits research on embryos, and the possibility of developing methods for detecting gene or chromosome abnormalities in embryos prior to implantation was recognised at the time of enactment. This was supported by the fact that a clinical trial undertaken at the time to develop PGD for a life-threatening sex-linked disorder had occurred. The HFEA was therefore of the opinion that the Act implicitly supported the licensing of PGD for severe or life-threatening disorders, and it was consequently within their mandate to create policy in the area.[264] Currently eight clinics are licensed in the UK to carry out PGD for specific medical conditions.[265]

The HFEA is responsible for maintaining a Code of Practice for the proper conduct of activities carried on in pursuance of a licence under the Act. It is also responsible for issuing guidance to fertility clinics which may supplement the Code of Practice at relevant times.[266] In August 1999, the HFEA issued an interim licensing guidance for PGD via letter from the Chief Executive, which included guidelines for the licensing of embryo biopsy practitioners. In November 1999, after the release of the interim guidance, the HFEA and the Advisory Committee on Genetic Testing (ACGT) then issued a consultation document on Preimplantation Genetic Diagnosis. When the Human Genetics Commission (HGC) was formed a month later in December, it took over the consultation from the ACGT.[267] A joint HFEA and HGC working party was established in late 2000 to analyse the responses and to formulate recommendations to the HFEA. [268]

The consultation document did not directly address the question of Preimplantation HLA tissue typing. However, interim guidance for the use of PGD with tissue typing where there was a genetic risk to the embryo was announced by the HFEA in November of 2001. This guidance was in contrast with an opinion provided by the HFEA Ethics Committee which was in favour of permitting preimplantation tissue typing in the absence of a heritable condition.[269] The ethics committee opinion addressed three issues in relation to preimplantation tissue typing.

- Is PGD with HLA typing compatible with the 'welfare of the unborn child?'
- Is licensing PGD with HLA typing compatible with the public good?
- Can morally significant criteria be found to demarcate 'acceptable' and 'unacceptable' reasons for the conception and selection of embryos?

The committee believed that consideration of the welfare of the child should not be restricted to a narrow legal perspective, but should include the wider question of the putative child's actual moral, psychological, social and physical welfare.[270] The ethics committee believed that in this context arguments based on eugenics were irrelevant, as the explicit purpose of the treatment is to cure a particular condition. The committee favoured a 'principle of constrained parental decision-making when deciding whether a child should be conceived and selected to provide donor tissue for an affected sibling'. The constraints involved exhausting other avenues of tissue, or treatment, and the condition suffered by the existing child needed to be severe or life-threatening. The ethics committee believed that the technique should also be available where a sibling suffered from a life-threatening but non-inherited condition. The opinion of the ethics committee was not adopted by the HFEA, which took a more restrictive approach. A material reason given for the more restrictive approach was the lack of evidence relating to the effects of embryo biopsy.[271]

When the HFEA agreed to license PGD with tissue typing in 2002 for a couple whose child was suffering from the genetic disorder beta thalassaemia, judicial review proceedings were brought by the lobby group CORE.[272] It was claimed that the HFEA had no power to issue a licence that permitted the use of PGD with HLA tissue typing to select between healthy embryos. The HFEA was also strongly criticised by the House of Commons Select Committee on Science and Technology at that time.[273] The basis of the Select Committee criticism was that the decision to allow tissue typing occurred in the absence of public consultation on the issue, and went significantly further than PGD which was carried out in the interests of the future child itself:

> *The HFEA's decision to allow tissue typing in conjunction with preimplantation genetic diagnosis went beyond the scope of its own public consultation. It is vital that the public are taken along with decisions of such ethical importance.*[274]

In 2003, a decision of the High Court in relation to the legality of the HFEA decision to license tissue typing cast a shadow of doubt on whether it was within the statutory authority of the HFEA to confer licences on clinics to perform PGD simpliciter.[275] However, Lord Phillips MR subsequently confirmed in the Court of Appeal in an obiter dicta statement that the HFEA did have the authority pursuant to the HFE Act to issue licenses for PGD.[276] This view was clearly persuaded by the fact that not adopting this interpretation of the Act 'would render unlawful a practice which has been carried on for over a decade and which is patently beneficial'.[277]

The HFEA revised the interim guidance on PGD via Chair's Letter in May of 2003.[278] The revised guidance was incorporated into the 6th edition of the Code of Conduct which included a chapter dedicated to PGD, for the first time. The guidance did not include guidelines on HLA testing because of the uncertainty surrounding the legality of the procedure.[279]

After the *Quintavalle* case had been successfully appealed to the Court of Appeal, the HFEA decided to review its tissue typing policy. The Ethics and Law Committee were responsible for the review. The HFEA adopted the recommendations, extending its policy on HLA tissue typing in July of 2004 to permit HLA tissue typing in the case of siblings with sporadic disease, as well as in heritable disease cases.[280] The following provides a review of the details of the case, and provides a discussion of the scope of the HFEA's authority under the HFE Act 1999. The requirements of the HFEA Code of Conduct will then be set out.

2.4 HLA TESTING – THE QUINTAVALLE JUDGEMENTS

The precursor to the *Quintavalle* litigation began in September 2001 when an IVF service provider sought a ruling from the HFEA as to whether they could apply for a licence to permit the clinic to carry out tissue typing for a couple whose child was suffering from a genetically inherited blood disorder, beta thalassaemia. The authority decided in principle to allow HLA Tissue Typing, but only where PGD was already necessary to avoid passing on a serious genetic disorder. Licences for tissue typing were to be assessed on a case-by-case basis, and would only be granted subject to the following conditions:

(a) the condition of the affected child should be severe or life-threatening, of a sufficient seriousness to justify the use of PGD;

(b) the embryos should themselves be at risk of the condition affecting the child;[281]

(c) all other possibilities of treatment and sources of tissue for the affected child should have been explored;

(d) the techniques should not be available where the intended recipient is a parent;

(e) the intention should be to take only cord blood for the purposes of the treatment;[282]

(f) appropriate counselling should be given to the parents;

(g) families should be encouraged to take part in follow-up studies;

(h) embryos should not be genetically modified to provide a tissue match.

Josephine Quintavalle[283] sought and obtained permission to seek judicial review of the HFEA's decision announced on 13 December 2001 to award a licence to treat the Hashmi family. She challenged the decision on the ground that the HFEA had no power to issue a licence that permitted the use of HLA typing to select between healthy embryos. Her challenge succeeded in the High Court.

There were two issues canvassed in the High Court. The first was whether genetic analysis of a cell taken from an embryo involved the 'use of an embryo'. If the question were answered in the affirmative, then a licence would be required. If it did not, then no license would be necessary. The second issue argued was whether genetic analysis for the purpose of tissue typing was 'necessary or desirable for the purpose of providing treatment services'. The claimant argued that the purpose of tissue typing could not be said to assist women to carry children, and could not come within the definition of treatment services.

Maurice Kay J applied a literal and restrictive approach. He found it inconceivable that Parliament would have intended to leave an issue such as tissue typing outside the ambit of the Act, as it of necessity constituted 'use' of an embryo. Tissue typing therefore could only be performed in pursuance with a licence. In regard to the argument framed in the alternative he held that tissue typing of an embryo had no impact on the ability of a woman to carry the embryo after implantation, and could not be said to be 'necessary or desirable for the purpose of assisting women to carry children'. In the context of whether the activities in the course of treatment were 'designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose', Maurice Kay J was of the opinion that 'suitable' meant only that the embryo would be viable. That would constrain

the use of PGD for some genetic conditions which do not affect the viability of the foetus. This had significant consequences for the scope of permissible PGD as many genetic disorders do not impact on the viability of a foetus. As the purpose of tissue typing was to ensure tissue compatibility with a sibling it was not for the purpose of assisting women to carry children and therefore did not constitute 'treatment services'. Hence, tissue typing was not an activity for which the authority was entitled to grant a licence under paragraph 1(1).

Permission was given for the Authority to appeal the decision. Concerned that the High Court judgment had wider implications, in particular that it put in doubt the legitimacy of the use of PGD to diagnose genetic disorders in general, the Secretary of State for Health sought and obtained permission to intervene to support the Authority's appeal.

The appeal was upheld in the Court of Appeal.[284] The Authority accepted in the higher court that embryo biopsy involved the 'use' of an embryo, and therefore a licence was required to authorise the procedure pursuant to section 3(1)(b). The Court of Appeal accepted that the Authority could only issue a licence for 'treatment services' involving the use of an embryo where it appeared to the authority to be necessary or desirable for the purpose of 'assisting women to carry children' and when the activities in the course of the treatment were 'designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose'.

However, it was held that treatment for the purpose of 'assisting women to carry children' was not restricted only to that which would assist a woman in the physical process of conceiving and producing a child. Treatment for the purpose of 'assisting women to carry children' was capable of embracing IVF treatment designed to ensure that a child would not suffer from genetic defects *or* would possess stem cells matching that of a sick or dying sibling where concerns about the characteristics of any child conceived would otherwise inhibit or prevent a woman from bearing a child. In those circumstances PGD with tissue typing in the course of the treatment services could be said to be an activity designed to secure that the embryo was 'suitable for the purpose of being placed in a woman'.

On these grounds, the Court held that the Authority was entitled to conclude that the Act authorised it to licence IVF treatment with PGD for the purpose of tissue typing, subject to such conditions it considered appropriate.

It was noted by Lord Phillips MR that enabling such a choice to be made in regard to characteristics of embryos through PGD raised difficult ethical questions as to whether and for what purpose such choice should be permitted. He stated that these decisions had been placed in the hands of the Authority.[285] Lord Justice Schiemann went further, stating that the decision of the Authority did not mean that parents had a right to IVF for social selection purposes.[286] However, it is still implicit in his judgment that the Authority had the power to mandate social selection procedures, should it choose to do so.

The decision of Mance, LJ provides a greater depth of reasoning, making a distinction between performing embryo biopsy for trivial preferences, and performing it in the face of compelling medical situations. He determined that the circumstances of the Hashmi's (the family concerned) lay conceptually between the two poles of 'good medical reasons' for tests, and testing for 'purely social reasons'. In his opinion they:

lie closer in spirit in my view to the former pole than to the latter. There are here good medical reasons for screening any embryo, although they do not relate to any future child's health. The concerns to which the authority's decision and the licence for Mr and Mrs Hashmi are directed are anything but 'purely social', relating as they do to the health of a sibling and the well-being of the whole family.[287]

Undeterred, Josephine Quintavalle took an appeal to the House of Lords.[288] Again it was held that IVF treatment was a medical service provided for the purpose of assisting a woman to carry a child within the definition of treatment services in section 2(1) of the Act. Performing HLA typing constituted an activity 'in the course of' providing that IVF treatment within section 11(1) provided it was an activity falling within the meaning of a practice to determine whether embryos were 'suitable' for the purpose of being placed in the woman and appeared to the authority 'necessary or desirable', within paragraph 1 of schedule 2. PGD and HLA typing could lawfully be authorised by the authority as activities to determine the suitability of the embryo for implantation within the meaning of paragraph 1(1)(d) of Schedule 2 to the 1990 Act.

It was held that the term 'suitable' in paragraph 1(1)(d) fell to be construed in the context of the scheme of the 1990 Act and the background against which it had been enacted. In this way, the House of Lords applied a purposive approach. It was held that Parliament had intended to define the licensing power of the Authority in broad terms and to entrust it to decide which practices were ethically acceptable, subject to the prohibited matters in section 3(3) of the Act and Parliament's regulatory powers. The concept of suitability was broad enough to include suitability for the purposes of the particular mother. Parliament had not intended to confine the Authority's powers to unsuitability on grounds of genetic defect; the limits of permissible embryo selection were ultimately for the authority to decide.

Brown LJ stated:

In the unlikely event that the authority were to propose licensing genetic selection for purely social reasons, Parliament would surely act at once to remove that possibility, doubtless using for the purpose the regulation making power under section 3(3)(c). Failing that, in an extreme case the court's supervisory jurisdiction could be invoked.[289]

Although the HFEA has the power to license clinics to perform PGD for social reasons, this does not mean that it will of necessity do so. Although sex selection is not illegal in the United Kingdom, the HFEA has refused to license the use of PGD for sex selection for non-medical reasons. The UK Parliament has acted in the past to curtail what it perceives to be undesirable scientific developments, for example with the enactment of the Human Reproductive Cloning Act 2001 which bans reproductive cloning in the UK.

The purposive approach employed by the Law Lords may have superficial appeal, particularly if one thinks that the decision was defensible, but the process employed by the Lords is less convincing on close analysis. Applying a purposive approach involves determining whether:

> *…when a new state of affairs, or a fresh set of facts bearing on policy, comes into existence, the courts have to consider whether they fall within the Parliamentary intention. They may be held to do so, if they fall within the same genus of facts as those to which the expressed policy has been formulated.*[290]

It may be argued that both deselecting embryos carrying genetic abnormalities to avoid the transmission of serious heritable disease, and deselecting embryos on the basis that they will not provide a tissue match for an existing sick child, realise benefits that are not directly attributable to the particular embryo that is selected. PGD to test for genetic disorders is generally accepted on the basis that it is in the interests of the 'future child'. However, the only benefit to the embryo which is found to be free of heritable disease is the fact that it is selected for implantation.

Both procedures are carried out for broadly therapeutic reasons; in one case to avoid disease, the other in an to attempt to cure disease suffered by a third party. However, the procedures have been perceived as being vastly different.[291] The initial performance of PGD to test for heritable conditions did not provoke a legal challenge by CORE. It was only when preimplantation tissue typing was proposed that judicial review was sought. There is merit to the view that on closer examination, there is not such a great distinction between the two procedures. Neither test provides direct benefit to the particular embryo on which the procedure is carried out. It is simply a greater stretch to conceptualise this when, in the case of tissue typing, the procedure seems only to be undertaken in the interests of a third party.

The point being made is that the challenge to the Authority's jurisdiction may have been more properly made at the point when it sought to license clinics to perform PGD. It was by no means clear that the Authority had the discretion to license clinics to perform PGD. The ground on which the HFEA based their decision to issue licences for PGD was not firm, albeit a pragmatic and reasonable activity.

In addition, the HFE Act provides the machinery to add, by way of regulations, to the purposes for which licences may be given. Yet this process was not utilised. Further, the interim guidelines were introduced prior to any consultation being completed. What the Hashmi case highlights is that when legislation is drafted in neutral terms and the regulatory purpose is very broad, interpretive flexibility may mean that available formal regulatory responses are spared. Consequently any decisions made can give rise to challenge. It has been cautioned that 'the legal community, with its tendency towards gentle incrementalism, is not particularly well-equipped to handle any kind of [genetic] revolution.'[292] Arguably, the *Quintavalle*[293] case is evidence of incrementalism occurring in law.

Ironically, the Chair of the HFEA commented when giving evidence to the Science and Technology Committee that the problems that the Authority experienced with PGD arose from the fact that PGD was not expressly provided for in the legislation. She advocated that in reviewing the legislation, Parliament set out specifically the acceptable parameters of embryo selection, as it had done in relation to embryo research in the 1990 Act.[294]

2.5 THE HFE ACT AND THE CODE OF PRACTICE

The HFE Act 1990 requires that the HFEA give guidance to licensed centres about the 'proper conduct of activities carried out in pursuance of a licence'.[295] The guidance is primarily contained in the HFEA's Code of Practice. Consultation is required on the Code of Practice with any persons the Secretary of State requires it to consult with, and any other persons it considers appropriate.[296] Approval of the Code must be gained from the Secretary of State. The Code of Practice is not legally binding, but it may give grounds to a licence committee to refuse a licence if it is not observed.[297] Policy decisions may also be conveyed apart from the Code via letters from either the Chair or the Chief Executive of the HFEA. Interim licensing guidance for PGD and guidelines for embryo biopsy practitioners were the subject of a letter from the Chief Executive in 1999. Consultation only ensued after the guidelines were sent out.

The composition of the Authority is set out in Schedule 1 of the Act. Regulations passed in 1991 prescribe the composition and procedures of the HFEA licence committees and the appeals procedure.[298] Members have historically been appointed to the Authority by the Secretary of State. They are now appointed by the NHS Appointments Commission, which reduces the political influence over appointments.[299] The Chair and deputy chair must be lay persons (not medically qualified or engaged in IVF treatment or research) and a majority must be lay members.[300]

The Code of Conduct which accompanies the Code of Practice sets out seven principles of public life.[301] It is stated in the introduction to the Code that the object of the HFEA Code of Practice is 'wider than to secure the safety or efficacy of particular clinical or scientific practices. It is concerned with areas of practice which raise fundamental ethical and social questions'.

In framing the Code of Practice, the HFEA has been guided both by the requirements of the HFE Act and by:

1	The respect which is due to human life at all stages of its development
2	The right of people seeking assisted reproductive treatment to proper consideration of their request
3	A concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved and
4	A recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge.[302]

It is stated in the Code of Practice that the HFEA acknowledges that these considerations may sometimes conflict and has sought to reconcile them in a way which is both practicable and in accordance with the spirit and intentions of the HFE Act. The HFEA's aim is to support the best clinical and scientific practice, while guarding against the undoubted risk of exploitation of people at a time when they may be particularly vulnerable'.[303]

The sixth edition of the Code of Practice included preimplantation testing for the first time. Chapter 14 of the Code deals with preimplantation testing. The Code distinguishes preimplantation screening from preimplantation diagnosis.

2.5.1 LICENSING REQUIREMENTS

The Code of Practice sets out licensing requirements for 'Preimplantation Testing'. A clinic may only carry out testing for the genetic conditions, chromosomes or traits (or combinations of these) and use those specific tests (or combination of tests) that are listed in the preimplantation testing Annex to their licences or approved by a licence committee in any particular case. Until very recently every clinic was required to submit a fresh application to the HFEA every time they wished to test for a new condition, and for each new test they wished to use. This is in stark contrast to the system set up in New Zealand.

In January of 2005, the HFEA announced a new policy to streamline the approval of applications for preimplantation genetic diagnosis.[304] Under the new guidelines, if a clinic with proven expertise in performing embryo biopsies, applies for a licence to carry out screening for a particular condition, which is already being carried out successfully in another clinic – such as screening for sickle cell anaemia, cystic fibrosis and Duchenne's muscular dystrophy, the HFEA will approve the application without having to go through the full HFEA licence committee process, providing the same technique and methods are used. Suzi Leather, Chair of the HFEA said:

> *PGD is now an established technique for screening embryos which has been carried out under HFEA scrutiny for several years and we have assessed all the relevant evidence gathered over this time.*
>
> *We have decided that whilst PGD is a specialised procedure, which can only be carried out by a qualified embryo biopsy practitioner, it should be straightforward for those clinics with a proven track record in the appropriate techniques to be able to carry out screening for any of the conditions currently approved.*
>
> *This will streamline the system, cutting down on bureaucracy and speeding up the approval process which will benefit both the patients who benefit from this treatment and the clinicians treating them.*

Less common specialised applications of PGD still require consideration by an HFEA licence committee on a case-by-case basis.[305] It is significant that the HFEA is now providing patients with the opportunity to give evidence to the HFEA face to face should they choose to do so.

Where clinicians wish to test a single embryo for more than one genetic condition or trait an application must be made to the HFEA for each specific combination of tests that is proposed, regardless of whether the centre is already licensed to use each of the tests individually. It is hard to see the justification for this requirement when running more than one test does not necessitate biopsying more than the usual one or two blastomeres, and there is no increased physical risk to the blastocyst or embryo.

The Code contains a provision that seems common-sense that it is not apparent why it was necessary to include it. It is to the effect that embryos which have been biopsied, or resulting from gametes which have been biopsied, may not be transferred with any other non-biopsied embryos in the same treatment cycle. To do so would risk the birth of a child suffering from a disorder that PGD had been performed to prevent. The Code prohibits the use of PGD, or the use of information derived from tests on an embryo, for sex selection of embryos.

The HFE Act requires that records must be kept as a condition of all licences, and enables the HFEA to specify the manner in which and for how long records are kept.[306] The HFEA is required by the Act to maintain a confidential register of information about donors, patients and treatments provided by licensed centres. It was set up in 1991.

2.5.2 ACCREDITATION

Sections 17(1)(b) and (d) of the HFE Act 1990 state that it is the duty of the person responsible to secure that proper equipment and suitable practices are used in the course of the activities carried out pursuant to licences.[307] The Code of Practice requires that all genetics laboratories used for Preimplantation Testing are expected to be Clinical Pathology Accreditation (CPA) accredited (or equivalent) or at least be working towards CPA, with accreditation to be completed within five years.[308] It is curious that in the Report of the Science and Technology Committee, it was reported that the CPA scheme does not accredit embryology laboratories as the field is considered too controversial.[309]

As part of its inspection process, the HFEA has taken on the inspection of all technical aspects of assisted conception, including clinical and laboratory processes. Inspections cover record-keeping, conditions for the storage and disposal of licensed material, suitability of staff, equipment and working practices.[310]

2.5.3 STAFF QUALIFICATIONS

Section 17(1)(a) of the Act confers on the authorised person responsible under the licence the duty to secure that the 'other persons to whom the licence applies are of such character, and are so qualified by training and experience, as to be suitable persons to participate in the activities authorised by the licence'. The Code does not go much further than this, except to provide that it 'is expected that a multidisciplinary team will be involved in the provision of the PGD service, including reproductive specialists, cytogeneticists and molecular geneticists. This team is expected to maintain close contact with the primary care physician or the referring clinician, and treatment is expected to encompass continued support of patients following PGD'.[311]

At the beginning of the Code of Practice, guidance is provided as to what certain phrases signify. The words 'expected to' or 'expected that' indicate what is to be regarded as the proper conduct of licensable activities or as suitable practice within licensed centres. Any departure from the Code of Practice may be taken into account by the HFEA and could result in the revocation of a centre's licence.[312]

2.5.4 COUNSELLING

Section 13(6) of the Act provides that 'a woman shall not be provided with any treatment services […] unless the woman being treated and, where she is being treated together with a man, the man has been given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and has been provided with such relevant information as is proper.' It is significant that the Code does not impose mandatory counselling requirements on providers. This is in contrast to the New Zealand position, where under Guidelines, providers 'must ensure' that people seeking PGD for familial disorders receive

genetic and psychosocial counselling from qualified counsellors trained in genetic counselling. Psychosocial counselling is mandatory when PGD is sought for non-familial disorders.[313]

The Code sets out that people seeking treatment are expected to have access to both clinical geneticists and genetic counsellors, and that ideally, people seeking treatment are expected to be referred to the treating centre by a Regional Genetics Centre. However, all of those seeking treatment are expected to be known to an accredited clinical geneticist.[314]

2.5.5 PATIENT INFORMATION

The requirement of information provision is expressed in terms of what is *expected* to be provided to patients. It is explained that when 'expected' is used in the Code, it indicates what is to be regarded as the proper conduct of licensable activities or as suitable practice within licensed centres.[315] In contrast, the equivalent New Zealand Guidelines declare that the provision of specified information is a mandatory requirement.

It is expected that reference will be made to the experience of the clinic carrying out the procedure. Information is expected to include:

(i) Genetic and clinical information about the specific condition

(ii) Its likely impact on those affected and their families

(iii) Information about treatment and social support available and

(iv) Where the family has no direct experience of the condition, the testimony of families and individuals about the full range of their experiences of living with the condition.[316]

It is also expected that the possible outcomes of genetic testing and their implications will have been fully explored with those seeking treatment prior to PGD being undertaken.

2.5.6 CLINICAL DECISION-MAKING – THE WELFARE OF THE CHILD

A peculiar aspect of the HFE Act is the requirement in section 13(5) in regards to the welfare of the child. Section 13(5) provides;

> *A woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who might be affected by the birth.*

The HFEA provides guidance to clinics on how to make a 'welfare of the child assessment' on individuals or couples seeking licensed treatment in Part 3 of the Code of Practice. Fertility clinics are expected to take into account a number of factors which could have an impact upon the welfare of the child who might be born as a result of treatment. Clinics are also expected to write to the individual's or couple's general practitioner (GP) to ask whether, from the patients' medical records, the GP has any reason to believe that any child resulting from the treatment might be at risk. The patient has to give permission for the fertility clinic to approach the GP. The clinic might also ask patients to fill in 'child welfare' forms or have a special interview with them.

The Welfare Provision has proved to be a contentious aspect of the HFE Act. The HFEA recently undertook a consultation as to how the application of the welfare of the child could be improved.[317] The Consultation document asked whether taking account of the welfare of the child who may be born as a result of treatment and any other child who may be affected should remain an HFE Act obligation on fertility service providers. It was concluded that:

> *The involvement of a medical team in assisted conception means that certain third parties have some responsibility towards the child to be born. However, the importance of patient autonomy means that clinics should only refuse to provide treatment where there is evidence that the child is likely to suffer serious physical or psychological harm.*[318]

The HFEA has now released revised Guidance on how to interpret the welfare of the child provision under section 13(5) of the HFE Act 1990.[319] The Code provides that the decision to undertake PGD is expected to be made in consideration of the unique circumstances of those seeking treatment, rather than the fact that they carry a particular genetic condition. It is stated that the indications for the use of PGD are expected to be consistent with current practice in the use of prenatal diagnosis. The crux of decision-making differs in a major way under the Code of Practice as compared with the Guidelines in New Zealand. The Code provides:

> *It is expected that PGD will be available only where there is a significant risk of a serious genetic condition being present in the embryo. The perception of the level of risk by those seeking treatment is an important factor in the decision-making process. The seriousness of the condition is expected to be a matter for discussion between the people seeking treatment and the clinical team.*[320]

Further information that is *expected* to be considered when deciding the appropriateness of PGD is:

(i) The view of the people seeking treatment of the condition to be avoided
(ii) Their previous reproductive experience
(iii) The likely degree of suffering associated with the condition
(iv) The availability of effective therapy, now and in the future
(v) The speed of degeneration in progressive disorder
(vi) The extent of any intellectual impairment
(vii) The extent of social support available and
(viii) The family circumstances of the people seeking treatment

2.5.7 ANEUPLOIDY SCREENING

Aneuploidy screening is dealt with separately from PGD in the Code of Practice. After referring to paragraph (1)(d)[321] of Schedule 2, the Code sets out the only categories of patients for whom it is *expected* aneuploidy screening will be used:

(i) Women over 35 years of age

(ii) Women with a history of recurrent miscarriage not caused by translocations or other chromosomal rearrangements

(iii) Women with several previous failed IVF attempts where embryos have been transferred, or

(iv) Women with a family history of aneuploidy not caused by translocations or other chromosomal rearrangements.

Information that is *expected* to be imparted includes reference to the process, procedures and risks involved in undertaking IVF and biopsy procedures. Reference is expected to be made to the experience of the clinic in carrying out the procedure. Patients are expected to be also informed in writing:

(i) That embryos that have been biopsied may not be suitable for cyopreservation and use in subsequent treatment cycles

(ii) That the more tests that are used to examine the chromosomes, the greater the likelihood of finding chromosome abnormalities (whether they are biologically significant or not), and thus the lower the chance of finding suitable embryos for transfer

(iii) Of the procedure to be followed in the case of a diagnostic failure

(iv) That there is no guarantee against a miscarriage occurring despite preimplantation aneuploidy screening being performed

(v) The patients are recommended to undergo prenatal screening

(vi) Of the financial costs of treatment

(vii) Of the possible emotional burden should a successful pregnancy not result following PGS for aneuploidy

These information requirements are materially different from those required under the NECAHR interim Guidelines.

2.6 ACCESS TO ART

The National Institute for Clinical Excellence (NICE) has recently published guidelines on Fertility.[322] In regards to IVF, it was recommended that, subject to specific criteria, women should be offered three cycles of IVF on the public NHS service. The secretary of State has responded that he wished the NHS to work towards full implementation of the NICE guidelines.[323] Funding of IVF cycles in the UK varies widely from region to region, with some regions providing no funding for IVF.[324]

2.7 REFORM

Although the HFE Act has generally withstood the test of time well given the massive leap in technological capacity since its inception, recent legal challenges have highlighted a gap between the ambit of the Act and new technology or new applications of established technologies.[325] While none of the legal challenges has been successful, there have been calls for reform of the UK system from many corners.[326] Economic forces and a wish to reduce what some see as a bureaucratic and expensive system are factors driving reform. Changing societal attitudes are also drivers for change.

Lord Winston has been a strong critic in regard to regulation; even more so since his retirement from clinical medicine:

> *I am not opposed to regulation. But in the modern UK healthcare system there are now quite enough safeguards without the HFEA. The authority is not a great British success. And it is a costly body: the HFEA charges Hammersmith about 30 000 pounds annually for its licence. These costs inevitably are passed to the patients who already pay large sums for their treatment.*[327]

The HFEA is funded in part by grant and in part by licence fees. In 2003-2004 the amount obtained by grant was around 4 million, while revenue from fees was 3.5 million. Currently research license fees are set at 200, with the intention being to increase them to up to 6000. The leap is justified by the expensive nature of administering research licences. If they are to be administered more efficiently, with fewer delays for the researchers, more staff are required, creating more expense.[328]

The HFEA has been criticised for a lack of transparency and public consultation.[329] It has been claimed that the methods of licensing and inspection are unduly expensive and duplicative.[330] A recent report released after incidents at an NHS hospital found several areas of concern in regard to the licensing activities of the HFEA.[331]

Fertility expert Lord Winston has claimed that by employing clinicians or scientists working in clinics as part-time inspectors for the HFEA, rather than employing a full-time salaried inspectorate, a possible conflict is created. As the clinics are largely privately funded, the inspectors are competing practitioners and scientists.[332] However it has been indicated by the Chair of the HFEA that they will be moving to an in-house inspectorate.[333]

Two major reviews of the HFE Act have recently been undertaken. The House of Commons Science and Technology Select Committee announced their decision to undertake a review of the Act in October 2003. The Select Committee carried out the review for two main reasons. Firstly, that it was necessary to 'reconnect the Act with modern science' and secondly, that the Department of Health approach of keeping the Act 'under review' was inadequate given the rapid pace of medical and scientific advance and the legal challenges to the HFEA's jurisdiction.[334]

Following this, the Department of Health announced its intention to review the Act in January 2004, for which public consultation closed in November 2005.[335] The Science and Technology Select Committee report was released in March 2005, with a Government response published in August 2005.[336]

2.7.1 REPORT OF THE HOUSE OF COMMONS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY

The Report from the Science and Technology Committee is impressive by virtue not only of the depth and breadth of the review, but also because of the wealth of information obtained in the oral and written evidence provided to the Committee.[337] The Report concludes with a 'blueprint for a legislative and regulatory system fit for purpose in the 21st century'.[338]

The terms of reference were extremely wide. They included the following:

Table 1: Inquiry into Human Reproduction and the Law: Terms of Reference

a) To consider a) the balance between legislation, regulation and reproductive freedom; b) the role of parliament in the area of human reproductive technologies; and c) the foundation, adequacy and appropriateness of the ethical framework for legislation on reproductive technologies.	
b) To consider the provisions of the Human Fertilisation and Embryology Act 1990 in the context of other national and international legislation and regulation of medical practice and research.	To include related legislation such as the EU human tissue directive, and law covering human rights, surrogacy, adoption and abortion. To include relevant declarations and statements by international bodies. To compare the safety and welfare provisions of the Human Fertilisation and Embryology Act 1990 with those that cover other areas of medical practice.
c) To consider the challenges to the Human Fertilisation and Embryology Act 1990 from a) the development of new technologies for research and treatment, and their ethical and societal implications and b) recent changes in ethical and societal attitudes.	To include new areas of research, treatments and interventions, such as cloning, cell nuclear transfer, transplants of ovarian and testicular tissue, embryo splitting, selection of genetic characteristics (including sex selection), stem cell therapy and the use of immature gametes.
d) To consider the composition, expertise and approach of the Human Fertilisation and Embryology Authority, its code of practice, licensing arrangements and the provision of information to patients, the profession and the public.	

The overall tone of the report by the Science and Technology Committee was one of terse criticism. The philosophy apparent in the report was that if the HFEA wished to curtail some aspect of ART, then there should be good evidence to justify the restraint.[339]

> *Legislation should reflect the fact that assisted reproduction is now a standard clinical procedure and its focus should be on improving clinical standards and ensuring safety. Intending parents should be able to seek appropriate services, subject to the professional regulation of safety and quality. This would ensure that reproductive decisions remain primarily in the private domain, governed by professional ethics and the law of consent. However, legislation will be needed to offer appropriate protection for the human embryo and to accommodate status and other legal issues.*[340]

Not surprisingly, the opinions of the Committee members were not unanimous. Five of the eleven members disagreed with the main report.[341] The minority view was that the majority had adopted an 'extreme libertarian position'. They believed that the report did not reflect the legitimate role for the state and regulation to play.[342]

The Select Committee began its report by considering the status of the embryo. The gradualist approach taken by the Warnock committee was endorsed.[343] The Committee believed this position recognised the special status of the human embryo, while at the same time respected the legitimate interests of intending parents and the wider society. However the Committee noted that in the context of treating infertility by IVF, an activity which is for the most part a widely accepted and positively perceived intervention, the principal issue was not the status of the embryo but rather the 'rights' or interests of individuals to have assistance in reproducing.

By adopting an approach consistent with the gradualist approach, the Committee accepted that assisted reproduction and research involving the human embryo both remained legitimate interests of the state. Reproductive and research freedoms must be balanced against the interests of society, but 'alleged harms to patients or society need to be demonstrated before forward progress is unduly impeded'. [344]

Whilst assuming a libertarian stance, the majority advocated increased governmental oversight. The majority felt that the HFEA should not be developing policy, but rather overseeing technical standards and quality management.[345] It was pointed out that section 8 of the HFE Act set out the HFEA's role as an advisory body. This involved keeping under review information about: embryos and any subsequent development of embryos; the provision of treatment services and activities governed by this Act; and advising the Secretary of State, if asked, about those matters. These functions are distinct from its regulatory functions and the dual role, in the opinion of the Select Committee, is problematic. While under the regulatory role it must discharge its duties according to the Act, the Advisory role challenges it to find fault with the legislation on behalf of the Government.[346] It was acknowledged, however, that the HFEA had little choice but to develop a policy function given its brief, but a strengthened role for Parliament was called for.[347]

Significantly, the Select Committee observed that the 'reasons for which PGD is licensed, if at all, are some of the most challenging facing the review of the HFE Act.'[348] The Committee referred to the Nuffield Council on Bioethics' 2002 report on genetics and human behaviour, in which a description of the libertarian view of selection was provided:

> *The main argument in favour of the permissibility of selection is that there is a legitimate exercise of individual liberty. There is, quite generally, a strong presumption in favour of the exercise of individual liberty wherever its exercise does not conflict, directly or indirectly, with the legitimate interests of others.*[349]

The opposing view is expressed as the intuitive objection to prenatal selection, which is that it is 'interfering with nature'. The Code of Practice states that indications for the use of PGD are expected to be consistent with the current practice in the use of prenatal diagnosis. The Select Committee was of the view that applying a gradualist approach, an embryo at five weeks demanded less respect than a foetus at nine weeks gestation. The argument was also raised that the two procedures could not be equated because of the fact that in terms of the foetus, regard must be paid to the interests of the woman who was carrying the child.

The Code of Practice criteria for licensable PGD require a significant risk of a serious genetic condition. Whilst the application of the criteria is straightforward with serious disorders that are fully penetrant, it is more problematic when the expression of the gene is not 100%, or when there were available treatments. The Committee stated that:

> *We have concerns about the criteria imposed by the HFEA. PGD is limited in that it can only be used to screen out disorders and thus it cannot be used to create 'designer babies'. We see no reason why a regulator should seek to determine which disorders can be screened out using PGD. Nevertheless, clinical decisions should operate within clear boundaries set by Parliament and informed by ethical judgements.*[350]

In relation to preimplantation HLA tissue typing, the Committee was of the opinion that there were no compelling reasons for a statutory authority to make judgements on whether or not a family could seek preimplantation tissue typing, provided they fell within parameters set by Parliament.[351]

Towards the end of the report the Committee stated that 'We remain convinced that a larger role for our democratically accountable Parliament would give the public greater confidence that the big ethical issues of the day are being given adequate attention.'

The House of Commons Science and Technology Committee considered the issue of people going abroad for treatment that is unavailable in the UK, and in so doing engaging in 'reproductive tourism'. It was concluded that attempts to curtail reproductive tourism would not be justified by the seriousness of the offence and, moreover, would be impossible to enforce.

The Government has agreed with the House of Commons Committee that attempts to control reproductive tourism would be extremely difficult and probably not justified.[352] However, a recent report by the Human Genetics Commission stated 'we recommend that the HFEA should explore ways in which clinics in the UK can be prevented from preparing or otherwise colluding with individuals intent on seeking treatments which are permissible abroad, but prohibited within the UK.[353]

2.7.2 PROPOSED CHANGES

The Government Response to the Report from the House of Commons Science and Technology Committee was published in August 2005.[354] It was agreed that it would be preferable for revised legislation to set out the parameters for PGD more clearly. The Government indicated it would seek wider public views on the boundaries of acceptable uses of PGD and tissue typing, and on the appropriate scope and nature of regulatory intervention.[355]

The Government has indicated that the current model of regulation, in which Parliament determines prohibitions and parameters within which an independent statutory authority licenses activities is sound and should continue.[356] However, this was subject to the following:

> *… the Government also accepts that legislation should be more explicit and provide Parliament with greater powers to debate and amend the law. In particular, the Government accepts the need to clarify the extent of any policy-making role of the regulator.*

The HFEA provided a model for the Human Tissue Authority which was recently established under the Human Tissue Act 2004. Although the HTA Act regulates gametes and embryos,[357] it excludes gametes and embryos outside the human body. Hence, prenatal genetic diagnosis comes within the jurisdiction of the Human Tissue Authority, whilst PGD is regulated under the HFEA. Although the HTA has a separate legislative mandate, the two authorities are to be merged to create a single body.

In 2004 the Department of Health conducted the Arm's Length Bodies Review, with the aim of achieving economic savings and streamlining the work of such bodies.[358] The Report said that the HFEA would be dissolved by April 2008 and merged into a new body called the Regulatory Authority for Fertility and Tissue. This new body would regulate assisted reproduction, embryo research and the use of human tissue. The UK Government has since announced its intention to replace the HFEA and the Human Tissue Authority (HTA) with a single authority responsible for the regulation of assisted reproduction, embryo research and the use of human tissue. This would require primary legislation and would be known as the Regulatory Authority for Tissue and Embryos (RATE). The new authority will be responsible for overseeing the requirements of the EU Tissue Directive.[359]

It is the intention of the Government that new legislation which will establish the Regulatory Authority for Tissue and Embryos (RATE) and disestablish both the HFEA and HTA will be effective by April 2008.[360] It is intended that 'this legislation will set out the policy in relation to human tissue and embryos and assisted reproduction clearly and comprehensively. It will also give Parliament a greater role in keeping the law up to date through means of secondary legislation. The policy-making role of the new Authority will therefore be limited'.[361]

It is proposed that RATE will be headed by a lay chairperson, and have substantial lay representation among its membership. Although the exact functions of the new body will depend in part on the outcome of the public consultation, the Government has provided an outline of the functions the new body will carry out. These are very similar to those currently carried out by the HFEA.[362] RATE will be an executive non-departmental public body. Its primary function will be to consider applications for licences to undertake those activities which Parliament decides should be subject to licensing. It will be funded principally from fees levied on licence-holders. To support its licensing function, RATE will be responsible for regular inspections of premises where licensable activities are carried on, and will issue codes of practice giving guidance to persons undertaking those activities within its remit.

Both the HFEA and the HTA currently have statutory functions, including monitoring or reviewing developments relating to the activities within their remits, and providing advice to the Secretary of State where appropriate or where asked to do so. It is believed that a similar 'advisory' function would be appropriate for RATE. It is also proposed that legislation will set out requirements for consultation and approval of codes of practice. It was agreed by the Government that 'so far as possible clinical decision-making should be left to patients and professionals, that professional regulation is essential and that Parliamentary oversight should be strengthened'.[363]

The Government has sought the opinions of the public on the guidance given to fertility clinics by the HFEA regarding how to implement the welfare of the child provision.[364] The Government consultation is also canvassing views on whether legislation should set out the general criteria under which embryo screening and selection can be undertaken. Should there be a prohibition on deliberately screening in, or selecting for impairments or disabilities – as opposed to screening out, or selecting embryos free from such impairments? Should the authority to decide and license uses remain with the statutory regulator in accordance with general criteria set by Parliament, or should it be a matter for patients and clinicians, within the legal limits set by Parliament? The Government is also seeking views on sex selection for non-medical reasons.

The UK Government has included in its consultation the issue of whether legislation should define a formal role for the professional bodies in advising RATE on the content of technical standards for assisted reproduction and embryo research. These standards would be required to conform to the quality and safety requirements of the EU Tissue Directive.

The new licensing authority will be able to revoke or vary licences if necessary in response to regulatory breaches. Where less serious breaches occur which do not justify the withdrawal of a licence, less severe sanctions may be a more proportionate response. The aim is to ensure compliance in an environment which encourages the improvement of standards and systems. To this end the Government is seeking views on what sanctions should be available to the regulator to ensure conformity with regulations.

2.8 SUMMARY

The United Kingdom was one of the first jurisdictions in the world to introduce legislative initiatives in the field of ART. The legislative regime introduced certain prohibitions in relation to embryos and gametes, and delegated considerable power to the statutory body created under the Act, the Human Fertilisation and Embryology Authority. The HFEA has been described as operating within one of the most liberal laissez-faire schemes in Europe.[365] The Authority has complete discretion to determine the permissible limits of PGD.

When analysing the regulatory model that has been put in place in the United Kingdom, it is impossible to ignore the political drive to harness the benefits of new genetic technologies and to remain at the forefront of scientific endeavour. However, this is balanced by significant attempts on the part of the Government to set up means of engaging and educating the public in relation to genetics and relevant ethical and social issues. It should also be noted that while the HFEA has an extremely wide discretion conferred under the HFE Act, there is an unwritten rule that public consultation must occur prior to developing significant new policy. There is evidence of a strong commitment to deliberative democracy. It is therefore ironic that the HFEA put the cart before the horse when they developed their interim policy on HLA tissue typing, and suffered political and public backlash as a result.

The HFE Act has been at the heart of intense criticism in the last two years in particular. The most extensive critique of the Act has been carried out by the House of Commons Science and Technology Committee. An essential point made by the Committee was that assisted reproduction is now an established standard clinical service. The focus therefore, should be on improving clinical standards and ensuring patient safety. Alarmingly, the House of Commons review highlighted inadequacies in quality assurance and safety aspects in regard to licensing inspections.

Another theme of the review was that reproductive decisions should remain primarily in the private domain, governed by professional ethics and the law of consent. The reviewers felt that it was inappropriate for a statutory regulator to determine the permissible parameters of PGD. In their view, clear boundaries should be set by Parliament, and be informed by ethical judgments.

It appears, from the Government response to the House of Commons Science and Technology Committee Report, that the status quo will be maintained. However, a new Authority, the Regulatory Authority for Tissue and Embryos will be established under new legislation to carry out the functions that have, up until now, been carried out by the HFEA.

3 UNITED STATES

The following provides an overview of the United States position.[366] Detailed analysis of countries that have dissimilar regulatory systems is not the aim of this report but the regulatory system in the United States provides a valuable reference point when the broadly similar approaches of the New Zealand, UK and Victoria approaches are considered.

3.1 CURRENT US REGULATION

3.1.1 FEDERAL REGULATION

Currently, there is no federal regulation that directly addresses the use of PGD technology. Because regulation of medical practice is usually determined at the state level, there are only a handful of established federal agencies that could possibly impact current laws at the federal level with respect to PGD.[367] The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) as well as the Center for Medicare and Medicaid Services (CMS) are the only three governmental agencies with this potential.

3.1.1.1 Centers for Disease Control and Prevention (CDC)

According to the 1992 Fertility Clinic Success Rate Reporting Act (FCSRA), IVF clinics must report a number of statistics to the Society for Assisted Reproductive Technologies (SART) annually.[368] Reported information includes initial diagnoses leading to treatment, how many IVF cycles are performed, how many embryos were transferred per cycle, and the ultimate success rate of pregnancies and live births.[369] Currently, clinics are not required to

report any data on the use of PGD. If clinics were required to report these numbers, however, it would be much more clear what methods are being used, in which cases, on whom and how often. Currently, there is no method of systematic collection of this information in the US.

3.1.1.2 Food and Drug Administration (FDA)

This federal agency usually exercises regulation over drugs, devices and some uses of human tissue, all of which apply to IVF in some respect. In the case of PGD, laboratory instruments used in the process of genetic testing can fall under the jurisdiction of the FDA. However, genetic tests, which are used by most US clinics, do not fall under FDA oversight.[370] The Genetics and Public Policy Center reports that "given the existing confusion about FDA's jurisdiction over genetic testing in general, there is uncertainty regarding its authority to regulate PGD tests."[371] Therefore, the FDA does not currently regulate the use of genetic devices for PGD, or exercise explicit authority over the technology. However, they could potentially influence regulation of PGD in specific areas.

3.1.1.3 Center for Medicaid and Medicare Services (CMS)

The primary contribution that CMS has made to regulation in the area of reproductive technology is the Clinical Laboratory Improvement Amendments of 1988, more commonly referred to as CLIA. The objective of the CLIA program is to ensure the quality of laboratory tests.[372] According to CLIA, a clinical laboratory can be defined as a laboratory that analyzes material "derived from the human body" for the purpose of providing "information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."[373] Whether clinics performing IVF and PGD should be considered clinical laboratories, as CLIA defines them, is an unresolved question. There is concern that including PGD in the scope of CLIA would necessarily commit CMS to consider the embryo as a human being. In the future, if PGD is found to fall within the scope of CLIA it could subject the process of genetic testing to much stricter regulations and federal inspections.[374] This would ensure quality with respect to the use of PGD and also provide valuable information as to the exact details of PGD use in the United States.

3.1.2 STATE REGULATION

State regulation, like federal regulation, does not exist for preimplantation genetic diagnosis. There are a few areas where there is potential for laws and guidelines, but such opportunities have not been adopted by any US states. Some state laws exercise regulation over assisted reproductive procedures, but in general, fertility clinics do not operate under strict state oversight. There are no laws that address PGD technology explicitly. As discussed earlier, some states do exercise power in relation to insurance coverage mandates, but these address infertility benefits in the broader sense and do place any requirements on coverage of PGD.

Future state regulation of PGD technology could take many different forms. The state of New York, for example, "is in the process of developing standards for laboratories that will include oversight of the genetic tests associated with PGD."[375] In 1999, the CDC published the *Implementation of the Fertility Clinic Success Rate and Certification Act of 1992: A Model*

Program for the Certification of Embryo Laboratories, which was a Notice of "model certification program requirements, including definitions, administrative requirements, and embryo laboratory standards.[376] Although this model was created to be implemented at the state level, more than 6 years after its conception it has not been used by any state. Despite the fact that almost no state regulation exists today, there remains potential for the construction of state regulation that will lead to meaningful oversight of PGD technology.

3.2 COURT ACTION

As the use of PGD increases, there will almost certainly be an increase in the incidence of court action surrounding the application and acceptability of different uses of PGD. Often, "standards developed through case law frequently influence legislative action or become a de facto policy by themselves."[377] In the United States there has been only one notable court case with regard to PGD specifically. The case, *Paretta v. Medical Offices for Human Reproduction*, which is relevant to wrongful life claims, has been discussed above at 1.3.2.6.

3.3 STANDARDS OF PROFESSIONAL ORGANISATIONS

Currently, the American Society for Reproductive Medicine (ASRM) is the only professional body in the US that has taken an explicit position on preimplantation genetic diagnosis. This organisation has published on the potential benefits and value of PGD as well as the guidelines concerning the use of PGD for non-medical sex selection. In 2004, the ASRM published a paper entitled *Preimplantation Genetic Diagnosis,* in which the Practice Committee recommended:

> *PGD appears to be a viable alternative to post-conception diagnosis and pregnancy termination. … It is imperative that patients be aware of potential diagnostic errors and the possibility of currently known long-term consequences on the foetus of the embryo biopsy procedure. … and PGD should be regarded as an established technique with specific and expanding applications for standard clinical practice.*[378]

The Ethics Committee of the ASRM published another document entitled "Sex Selection and Preimplantation Genetic Diagnosis" in 2004 to address the the possibility of expanding the use of PGD to non-medical sex selection. The Ethics Committee formally recommends that, "preimplantation genetic diagnosis used for sex selection to prevent the transmission of serious genetic disease is ethically acceptable" while other uses of PGD "should not be encouraged."[379] Although the recommendations of professional organisations are not legally binding and membership of these organisations is voluntary, these guidelines carry significant weight in the medical community. Because of this, these professional organisations could potentially play a significant role in influencing the direction of development of PGD technology. Other US organisations include The Society for Assisted Reproductive Technology (SART), the College of American Pathologists (CAP), and the American College of Medical Genetics (ACMG). These professional societies have not published clinical guidelines addressing the details of PGD use although they may well do so in the near future.

It is difficult to report accurately how many PGD procedures occur in the United States annually, or even the exact number of clinics that use this technology. Because the statistics are so few in the United States in this relatively new area of reproductive medicine, analysis

is conducted on worldwide scale. An article published in 2005 in the journal of *Gynecologic and Obstetric Investigation* entitled "Preimplantation Genetic Diagnosis: The Earliest Form of Prenatal Diagnosis" reports that in ten years there have been only 6,000 PGD cycles even attempted, resulting in only about 1,000 PGD pregnancies.[380] Currently, the European Society of Human Reproduction and Embryology (ESHRE) states that there are 97 clinics worldwide performing PGD in a number of different countries including the US, the UK, Spain, Israel, Belgium, and Australia.[381] ESHRE reports that the United States alone has 19 clinics; a number significantly greater than any other individual country. These US clinics operate all over the country in many different states including, but not limited to, California, New York, Texas, Connecticut, and Massachusetts.

3.4 ACCESS

Because PGD first requires IVF, the entire process can be extremely expensive for couples. On average, the cost of IVF is between $10,000 and $12,000 with an additional $2,500-$4,000 for preimplantation genetic diagnosis.[382] The natural question is how couples can pay for this medical service since many people do not have sufficient monetary resources to cover the procedure on their own.

3.4.1 INSURANCE COVERAGE

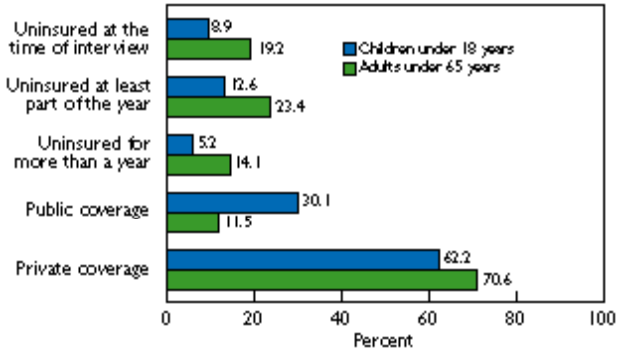
In the United States, many people are insured in some form or another by their employer or through the policy of a family member. The United States Census Bureau broadly classifies health insurance coverage as private or government coverage. In addition:

> *Private health insurance is coverage by a plan provided through an employer or union or purchased by an individual from a private company. Government health insurance includes the federal programs Medicare, Medicaid, and military health care; the State Children's Health Insurance Program (SCHIP); and individual state health plans.*[383]

These two categories will be distinguished here as public and private insurance coverage. Federal law states that coverage provided by private insurance is not subject to insurance regulation by states. This fact complicates federal and state regulation of health benefits offered to insured Americans because many insurers are exempt from state mandated policy. In the six-month period from January to June 2005, the National Health Interview Survey (NHIS) of the Centers for Disease Control (CDC) reports 19.2 % of Americans between the ages of 18-64 were uninsured at the time of the interview, and that of those insured, 70.6% of Americans in the same age group were covered by private insurance policies and only 11.5% had public insurance coverage.[384] The following chart is taken from this CDC report.

Figure 2. Percentage with health insurance coverage under 65 years of age, by type of insurance and age group: United States, January-June 2005.

Data Source: Family Core component of the 2005 National Health Interview Survey. The estimates for 2005 were based on data collected from January through June. Data are based on household interviews of a sample of the civilian noninstitutionalized population.



According to this recent data, a significant number of Americans would not have access to guaranteed insurance coverage of PGD even if it were state mandated. More generally, analysis of state-mandated insurance coverage of infertility treatment demonstrates that there is no systematic regulation of coverage for reproductive technology. This includes not only PGD, but IVF, diagnosis and diagnostic tests, gamete intrafallopian transfer (GIFT), medication, etc. A non-profit organisation called the InterNational Council on Infertility Information Dissemination (INCIID) publishes an updated review of state mandates with regard to insurance coverage of infertility treatment. Currently, 13 states have individual state mandates for insurance coverage with respect to infertility. To illustrate the variance in state policy, a summary of state mandates from Arkansas, California and Connecticut follows:[385]

3.4.1.1 Arkansas

In Arkansas, state law requires insurance providers to cover the cost of *in vitro* fertilization if the couple meets the necessary conditions. These conditions include a history of unexplained infertility for two or more years, infertility due to a specific condition, including a requirement that either the patient or the spouse is a policy holder and that the patient's eggs will be fertilized only with sperm from the spouse. Under this law, HMO's are not required to comply with this mandate. Insurance providers may also place a lifetime ceiling limit on the infertility treatment at $15,000.

3.4.1.2 California

In the California Health and Safety Code, Section 1374.55, infertility is as "the presence of a demonstrated condition recognized by a licensed physician and surgeon as a cause of infertility; or the inability to conceive a pregnancy or carry a pregnancy to a live birth after a year or more of sexual relations without contraception."[386] Some insurers are required to provide a number of diagnostic procedures and treatments under this mandate. Treatments under this mandate include diagnosis and diagnostic tests, surgery, medication and gamete intrafallopian transfer. However, IVF is specifically excluded from the list of required treatments. In California, many insurers are not required to offer any coverage of infertility treatment, but they must inform employers what coverage is or is not available. If coverage is available, employers can then choose whether or not they provide the coverage to employees. In California, therefore, many IVF procedures are not covered by insurance policies.

3.4.1.3 Connecticut

In 2005, the Act Concerning Health Insurance Coverage for Infertility Treatment and Procedures passed in the state of Connecticut. Here, Connecticut defines infertility as a "condition of a presumably healthy individual who is unable to conceive or produce conception or sustain a successful pregnancy during a one-year period."[387] Although couples are subject to some limitations and requirements, the act requires the coverage of "medically necessary expenses of the diagnosis and treatment of infertility, including, but not limited to, ovulation induction, intrauterine insemination, *in vitro* fertilization"[388] as well as a number of different procedures. Some procedures such as IVF are limited to cases where all other less expensive methods have been exhausted.

In addition to these three states, 10 other states, including Hawaii, Illinois, Maryland, Massachusetts, Montana, New York, Ohio, Rhode Island, Texas, and West Virginia have enacted state mandates regarding infertility and assisted reproductive technology. Each state's laws can widely differ with respect to specific requirements, limitations and given definitions of infertility, diagnosis and treatment.

Insurance coverage cannot be depended upon to provide an adequate or sufficient method for helping couples in need pay for infertility treatment. Coverage of PGD is even more difficult because it is not formally included in any state mandates. In medically necessary cases, a fertility clinic can appeal on behalf of a patient to the insurance company by writing a convincing letter. Couples can also write appeals to insurance companies with a heartfelt explanation of why they need PGD to ensure the absence of a serious genetic condition for their child. Anecdotal evidence from fertility clinics and online message boards suggest that if coverage is granted, it is most often the result of written appeal.

As is often the case with relatively new technology in the medical field, access to PGDis limited to the very few who can pay large sums of money for the services. The Genetics and Public Policy report concludes that:

> *for insurers, the question of whether to cover any medical procedure or test primarily comes down to an analysis of the potential costs and benefits of coverage. A cost-benefit analysis of PGD would have to take into account the cost of the underlying IVF, the embryo biopsy and genetic testing. It is not clear whether any health insurer in this country has undertaken a formal cost-benefit analysis of PGD for inherited genetic disorders.*[389]

Until this economic analysis occurs, insurance companies are not likely to include policy regarding PGD in infertility plans, and access to the technology will remain restricted.

3.4.2 ALTERNATIVES TO INSURANCE COVERAGE

Although the following alternatives are certainly not ideal, they do provide an option for couples who are denied insurance coverage for the use of PGD or for those who are not insured at all. The first option is seeking financial aid from the fertility clinic itself. This could take the form of discounts for couples that fit a certain low economic profile, or long- term payment plans. However, even a significant discount on a $16,000 procedure could far exceed what many people are able to pay. Payment plans, on the other hand, seem like a more viable option. A somewhat controversial practice is offering discounts if patients are willing to donate their eggs for other couples' use. The controversy here exists because some argue that this option is coercive and takes advantage of the desperation of financially disadvantaged couples.

When examining the insurance coverage of infertility treatments as well as the limited alternatives to insurance, it becomes quite clear that access to PGD technology faces severe financial restrictions. Until insurers are willing to pay for IVF and PGD, in whole or in part, the access to this potentially beneficial technology will remain limited to a small number of people in the United States.

3.5 SUMMARY

In the US, there is a lack of direct regulation concerning PGD. While current regulatory mechanisms can be stretched to encompass PGD technology and providers, such an approach seems to be inadequate and there is an inherent lack of control and monitoring. The current general system of oversight raises concerns over the acceptable uses of PGD, its safety, accuracy, effectiveness and accessibility. It has been observed that "[t]here are… neither governmental nor nongovernmental guidelines regarding the boundary between using PGD in efforts to produce a disease-free child and using it in efforts to select genetic traits that go 'beyond therapy' – that is, traits that are useful to older siblings or simply desirable to the would-be parent."[390] In such an open market, "there is a clear tendency to expand the application of PGD beyond the scope of clearly and narrowly defined medical purposes of detecting embryos that will suffer from a disease or severe handicaps".[391]

The current ambit of unregulated PGD technology in the U.S. is extensive – preimplantation genetic diagnosis includes:

~ testing for severe heritable genetic diseases/disorders

~ testing for sex-linked diseases (therapeutic sex selection)

~ testing for late onset diseases

~ testing for complex diseases (multi-factoral, predisposition, susceptibility diseases) where the risk of disease development is largely unknown

~ aneuploid screening (testing of embryos for aneuploidies to help improve the success rate (implantation rate) of IVF, particularly in women of advanced maternal age)

~ testing for carrier status

~ HLA tissue matching (to create a stem cell donor for an existing child) and

~ "social sexing" (non-therapeutic sex selection).

The above applications of PGD are permissible and not against the law. This represents a truly 'open market', with no legal impediments to PGD use and subject only to scientific boundaries and limits. In 2004, the President's Council on Bioethics concluded that PGD is "essentially unmonitored, unstudied, and unregulated."[392]

Access to this technology is a very important social consideration given that the process of IVF and PGD is expensive. In the US, having health insurance does not necessarily mean coverage of infertility treatment or genetic testing. In fact, many policies do not even cover IVF. It is also important to note that many Americans do not even have health insurance. The consequence of the high out-of-pocket expense is that only those people who can pay for the procedure have access to the technology. In addition to the issue of economic inequality, it is also important to consider the societal cost of putting resources toward this very complicated and expensive procedure. Redirecting funds and staff away from the basic health needs of millions of Americans could be controversial in the future as PGD becomes more common.

PART B: A COMPARATIVE ANALYSIS OF FACILITATIVE REGIMES

1 INTRODUCTION

This section of the report provides an analysis of PGD and compares the regulatory responses of NZ, Victoria and the UK.

It has been said that, at its simplest, PGD regulation can be distilled as involving choices along two axes: who regulates and under what normative framework.[393] The normative framework may be permissive or restrictive. An intermediate model distinguishes between medical and non-medical uses of PGD, balancing the individual social benefits of PGD against its perceived individual and social harms.[394] There may also be a mix, for example, permission subject to a particular qualification such as adherence to specific licensing requirements. Sanctions may also reflect certain values and may be criminal or administrative in nature.

The response to the regulation of PGD throughout the world has been predictably varied. However, most jurisdictions have implemented some form of regulatory control. The spectrum of control runs from a virtually free market system that is regulated only by professional self-regulation and the particular criminal or civil system of that jurisdiction, such as in the United States.[395] In these jurisdictions, reproductive autonomy and scientific freedom take precedence. Further along the spectrum are facilitative regimes which create broad legislative frameworks that delegate a range of decision-making powers to a statutory body, such as those in New Zealand, the Australian State of Victoria and the United Kingdom. Narrower frameworks create restrictive legislation, where, although some forms of PGD are permitted, the acceptable use of PGD is specified as precisely as possible. Examples of such legislation is that enacted in France and the Netherlands.[396] At the end of the spectrum are those jurisdictions which completely prohibit PGD, such as Italy and Germany.[397] Travelling to another country to obtain treatment, often referred to as 'reproductive tourism,' is the only option for persons seeking PGD in these latter countries.

Regardless of the framework adopted, a necessary precursor to creating a regulatory framework is clarity as to why regulatory 'interference' is required, what consequences are to be avoided, and how best to achieve the regulatory objective. It is also essential to determine the requirements for legitimate and fair law making in the face of extensive diversity of opinion.[398]

In a liberal democracy, good legal policy should be guided by an ideal of democratic theory. This means that legal policy on ethically controversial issues should be based on norms which represent an intersection amongst competing ethical positions. Hence the challenge for policy makers is to identify, prioritise and balance a competing and complex range of ethical beliefs.[399] Decision makers must seek to achieve 'regulatory legitimacy' in the absence of a consensus view. To do this requires promoting a sense of connection between the stakeholders and the regulation itself. There is a need and precedent for community participation in debate. In addition, the law must be responsive to evolving technologies.[400]

Legislators must balance competing views on the moral status of the embryo, and determine what compromise is required to enable medical benefits to accrue to society whilst avoiding what may be, to many people, socially unacceptable practices. How they do this will be reflected in the policy created and the degree to which it is permissive or restrictive.[401] When regulators are pressed to defend the legitimacy of their position, it might not be so much a matter of justifying its general orientation (for prohibition or permission) as its fine-tuning.

The first reported clinical application of PGD occurred in 1990, when it was used to sex select an embryo to prevent the transmission of an X-linked heritable condition.[402] In the same year, the United Kingdom established a regulatory framework for human assisted reproductive technology and associated reprogenetic technologies with the enactment of the Human Fertilisation and Embryology Act 1990. The United Kingdom was one of the first jurisdictions to enact legislation after the State of Victoria introduced the first legislation in 1984.[403] This section of the report will analyse these legislative and policy frameworks in relation to PGD, and to consider the distinguishing aspects of New Zealand's policy choices.

This analysis will concentrate on the Victorian and UK systems because they sit in a similar position on the regulatory range as New Zealand. The process of determining the respective policy positions, and the strengths or weaknesses of the different systems will be reviewed with the aim of evaluating the regime established in New Zealand. It is not proposed to go into detail in respect of countries that have strongly prohibitive legislation, or countries that have no regulatory controls, unless they add to the analysis of the jurisdictions to be examined. A table setting out the range of possible responses to the regulation of PGD and the implications of those choices adopted by various countries is provided in the appendix of this part of report.

The Human Assisted Reproductive Technology Act 2004 does not exist in a legal vacuum, but sits within a broader context of health law in New Zealand. It is therefore proposed to consider other aspects of health law that will impact on this area in New Zealand.

2 WHY REGULATE?

The UK House of Commons Science and Technology Committee stated, in a recent review of ART, that 'the philosophical view that individuals should have the right to make private choices – such as reproductive decisions – free from the scrutiny of the state" can be traced to John Stuart Mill who said:

> *The only purpose for which power can be rightfully exercised over any member of a civilised community, against his will, is to prevent harm to others. The only part of the conduct of any one, of which he is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign.*[404]

It follows that the starting point in any discussion of law which seeks to curtail aspects of individual choice is to determine the basis for intervention. Rationales which are often used to justify regulating new reprogenetic technologies such as PGD include:

- ~ the need to determine parameters in regard to creating, manipulating and destroying embryos,
- ~ the prevention of treatment or research excess in a vulnerable patient population;
- ~ minimising risk to prospective children and future generations; and
- ~ preventing harm to women.

PGD necessarily involves the creation and wastage of embryos which are not suitable for implantation. Policy choices, which may or may not involve specific legislative frameworks, inevitably require placing a value on the status of the embryo which is at the centre of all debates involving reproductive technology. Yet the moral status of preimplantation human embryos is highly contested. At one end of the debate are those who believe that an embryo has the moral status of full personhood, and should accordingly be protected.[405] An intermediate position would assert that the embryo gradually acquires greater moral status as it develops. Applying this gradualist approach, a developing foetus would be accorded greater moral status than an early embryo. The gradualist approach gives some explanation for the various restrictions relating to the use of embryos, which arise, for example, the appearance of the primitive streak at fourteen days is often taken to prescribe acceptable limits for embryo research. Equally, the point at which a foetus becomes potentially viable influences the lawfulness of termination. At the other end of the debate, the position taken is that the embryo is no more than a collection of cells, albeit with the potential to develop into a human being.[406]

One factor which must be taken into account when regulating PGD is achieving, at the least, consistency with the law in relation to abortion, which has already placed a value on the moral status of the embryo. Reproductive autonomy is emphasised in abortion law where a pregnancy may be terminated on the basis of prenatal testing. This reflects reproductive choice as a high-end value. If the abortion framework in a jurisdiction is essentially permissive, this will have implications for the lawful parameters of PGD.

Concerns for the health and safety of the children born as a result of PGD, and the women undergoing the procedures, have been part of the drive to impose regulatory restraints on PGD. Until very recently, PGD has been described as an 'experimental procedure'.[407] It is not difficult to find instances of treatment or research excess in New Zealand, or in other countries.[408] Most jurisdictions have experienced instances in their history where medical treatment or research excess has caused extreme harm to specific populations.[409] In reprogenetics, the stakes are high. Third parties are involved in the form of the putative child to be born and some reprogenetic interventions may have intergenerational effects.

In the United States it was recently reported that experimental reprogenetic techniques have been rapidly introduced onto the market 'without sufficient prior animal experimentation, randomized clinical trials, or the rigorous data collection that would occur in federally funded studies.'[410] One study reported an experimental technique that had assisted twenty women to achieve a pregnancy. The women had previously been unable to conceive as the

result of defects in their eggs' cytoplasm, or 'ooplasm'. Transplantation was performed and healthy ooplasm from donor eggs was injected into the defective eggs. The transplant entails the transfer of genetic material from one egg to the other, as the ooplasm contains minute organelles called mitochondria, and each mitochondrion contains a small loop of DNA. In this way, the resulting child receives a genetic contribution from three different persons. Because mitochondrial DNA is maternally inherited, if the resulting child is female she will pass on to her child the genetic contribution of both her mother and the female ooplasm donor. The researchers announced that they had achieved the first successful 'germ-line modification' and that it had resulted in apparently healthy babies.[411] Alarmingly, ooplasm transplantation was advertised on the Internet before the United States Food and Drug Administration intervened to collect information and conduct hearings on the safety and efficacy of the technique.[412] Like many reproductive procedures, the long-term effects of the intervention are not known.[413]

Because of the lessons learned by past research and treatment excesses, and the novel problems raised by reprogenetics, limits are perceived to be required to balance the benefits available to society against the putative risks from the excesses of science. However, the risks associated with PGD are not known to be substantially higher than those associated with IVF. A recent review carried out in New Zealand, "Systematic Review of the Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis", reported that PGD does not increase obstetric or neonatal complications above those which occur with IVF alone.[414] While the incidence of major birth abnormalities is about 3.8%, similar to that reported with IVF,[415] there are suggestions of an increased incidence of rare epigenetic disorders in babies born as a result of reproductive techniques such as IVF and ICSI.[416] This could also apply to infants born following PGD.

Although the risks involved in PGD are not higher than those linked to IVF, there are established risks associated with IVF. The New Zealand Advisory Group on Assisted Reproductive Technologies (AGART) found that singleton children born as a result of IVF are more likely to be born early, be of low birth weight and have poorer neonatal health outcomes than naturally conceived children.[417] The risk of preterm delivery for singletons conceived as a result of IVF is around twice that of natural conception. Neonatal, perinatal and infant mortality rates are twice as high for babies conceived by IVF as for natural conceptions.[418] Whilst these risks were found to be acceptable in the case of infertility, the ratio of risk to benefit may alter when there is no infertility or medical indications for the performance of PGD.

The argument for regulating PGD is often phrased in terms of setting 'appropriate limits', yet there is much debate as to where the permissible limits should be drawn. Most people would understand, even if they would not agree with, a decision conscientiously taken to undergo PGD to test for the presence of a chromosomal disorder such as Down Syndrome or the Fragile X gene. But where then is the line to be drawn: 'At gender selection? To exclude homosexuals? To favour the tall, the blonde, or the beautiful? To exclude a propensity to obesity or a potential for ugliness?' [419] Hence, the issue for decision makers is not only whether the law should be involved, but if it should, where the limits of permissible PGD should be drawn.

3 EXPECTATIONS OF REGULATION – REALISM OR IDEALISM?

Epithets such as 'designer babies' and 'eugenics' are often used in relation to preimplantation genetic technology. To a large extent, such labels are neither accurate, nor are they helpful.[420] The impetus for the initial use and subsequent development of the technology has been to provide better options for avoiding the transmission of serious heritable disorders and to increase the chances of successful implantation for subfertile patients.[421]

However, possible extensions of the technology have evoked concern. Should testing for susceptibility disorders, where there is no certainty that a genetic condition will develop and where an individual may live many years before the onset of symptoms, be available? Should it be permissible to test for late onset disorders? Should PGD be used to determine if an embryo possesses the same tissue type as a sick sibling and could therefore be a potential tissue donor of umbilical cord stem cells? The prospect that the technique may be used to select embryos for non-medical indications, such as physical characteristics, has provoked the strongest controversy.[422] In this latter category sex selection is the only realistic current prospect.[423]

Particular challenges are presented when regulating in this area where views may be polarised and morally or politically charged, and where the science is complex and rapidly evolving. In determining the parameters of legislation, legislators cannot solely rely on public consensus, as there may in fact never be one.[424] The rate of scientific advance means that the law must be sufficiently flexible to cope with changes. Similarly, views held by the public may also change with time, as interventions come to be perceived as more mainstream, and technology improves.[425]

In order to deal with these challenges, creating legislation which delegates decision-making authority to a regulatory body has been the approach of many jurisdictions to regulating ART and PGD. This includes New Zealand. In these circumstances, certain values may appear to be in conflict. These bodies are generally set up as statutory authorities that are independent or one step removed from government. Depending on the particular regulatory framework involved, such bodies may effectively be creating quasi-law. This role may clash with the view that it should be Parliament that determines the lawful parameters of ART.

The need for legislation to be flexible so that it does not quickly become obsolete when technological advances occur may also attract the criticism that regulatory powers conferred on a statutory body are too broad and are not sufficiently certain. Finally, answers to difficult questions are expected quickly, often under significant time pressures.[426] The expectations placed on such bodies are high.

Regardless of the specific characteristics of the approach taken to regulating ART, there are accepted principles which must underpin any regulatory initiative for the regulatory scheme to be perceived as legitimate by stakeholders and the general public. The regulatory framework must be proportionate to the perceived harms or risks posed to justify the imposition of regulatory limits. When it is determined that regulation is necessary, regulatory measures should be kept to the minimum required in order to achieve the regulatory objective. Regulators should have clear lines of accountability. In particular, this requires that they justify their decisions, and are subject to public scrutiny. There should be accessible, fair and

effective complaints and appeals processes. There should be 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. Finally, regulation must be sufficiently targeted to achieve its objective.[427] By observing these principles, it is hoped that regulation is perceived to be legitimate in a pluralist society where views of the public may be very divergent. While such regulatory measures will not be universally endorsed by people who may either be opposed to certain practices, or those who oppose regulatory interference, the regulatory process will at least meet the minimum standards of legitimacy.

In addition to these principles, it may be added that the regulatory framework in New Zealand should provide for the incorporation of Māori values.[428] A pragmatic requirement is that the regulatory structure that is put in place is cost effective, both for the bodies that oversee the regulation and the providers delivering the service.

4 REGULATORY APPROACHES – THE SPECTRUM

Although this analysis is focused on the regulatory approaches adopted by New Zealand, the United Kingdom and the State of Victoria, these regulatory schemes are by no means representative of other jurisdictions. Not every jurisdiction has adopted legislative frameworks, and not all that have resemble those adopted by the jurisdictions under study in this analysis. Whilst, most jurisdictions have implemented some form of regulatory control, the means of regulating vary widely.

At one end of the spectrum are jurisdictions such as the United States, which operate in a virtually free market system that is regulated only by professional self-regulation and the criminal or civil law system of that particular jurisdiction. In such jurisdictions, reproductive autonomy and scientific freedom appear to take precedence.[429] Other jurisdictions – such as the UK, Victoria and NZ – have opted for facilitative regimes which create broad legislative frameworks that delegate a range of decision-making powers to statutory bodies. More restrictive frameworks create legislation with narrower scope, where although some forms of PGD are permitted, acceptable uses of PGD are specified as precisely as possible. This may be seen in the legislative instruments of France and the Netherlands.[430] At the end of the spectrum are those jurisdictions which completely prohibit PGD, such as Italy and Germany.[431] Reproductive tourism is the only option for persons seeking PGD in this last-mentioned category.

New Zealand has only recently passed legislation dealing with ART after a legislative process that took eight years.[432] The analysis that follows will focus on countries that sit in a position similar to NZ on the regulatory spectrum. This section will not go into detail about countries that have strongly prohibitive legislation or those which have an absence of direct regulatory controls. A table setting out the range of possible responses to the regulation of PGD and the implications of choices adopted by various countries is provided in Appendix 1.

5 COMPARATIVE ANALYSIS: NZ, VICTORIA AND THE UK

New Zealand, the United Kingdom, and the Australian State of Victoria have all adopted broadly similar regimes to regulating ART, which includes PGD. Each of the three jurisdictions has enacted an overarching statute which regulates ART, and creates a statutory body to facilitate the administration of the Act. Although the structures are similar, there are key differences. The following analysis seeks to analyse:

- ~ the underlying purpose or philosophy of each Act,
- ~ who is responsible for decision-making in relation to PGD under the respective regulatory regimes and how decisions are made,
- ~ the permissible limits of PGD in each jurisdiction,
- ~ mechanisms to ensure the safe provision of fertility services,
- ~ provisions for administrative fairness and appeals, and
- ~ regulatory legitimacy and the HART Act 2004.

By making comparisons with the United Kingdom and Victorian, it is hoped to identify the distinctive aspects of the New Zealand system.

5.1 BACKGROUND – REGULATORY FRAMEWORKS

In contrast to the other jurisdictions studied in this report, Australia does not have one central statute regulating ART.[433] Specific statutes regulating ART have been passed in Victoria, South Australia and Western Australia.[434] For the purpose of this report, an in-depth analysis of the Victorian system will be made.

The state of Victoria, Australia was the first jurisdiction in the world to pass legislation in the area of ART when it enacted the Infertility (Medical Procedures) Act 1984. The Act was essentially based on a 'criminal model'.[435] It was repealed in 1995 with the passing of the Infertility Treatment Act 1995 (Vic), which adopted a licensing approach in contrast to the earlier criminal approach. The current Victorian Act, sets out definitive principles of the Act, provides certain prohibitions, and delegates power to a statutory body, the Infertility Treatment Authority, to administer the Act. The Infertility Treatment Act 1995 (Vic) provides for the regulation of infertility services through the licensing and approval of places and practitioners by the Infertility Treatment Authority.[436]

The legislative approach to ART adopted by the United Kingdom in 1992 differs markedly from that first enacted in Victoria in 1984. Instead of a criminal system, the UK opted for a licensing system, an essentially 'civil' model of regulation.[437] The Human Fertilisation and Embryology Act 1990 (UK) sets out specific prohibitions in relation to embryos and confers power on the Human Fertilisation and Embryology Authority to authorise embryo research, treatment services and the storage of embryos through a licensing system.

New Zealand has adopted a slightly different system. The New Zealand Human Assisted Reproductive Technology Act 2004 (HART Act) has introduced a framework that declares certain assisted reproductive procedures to be prohibited, and creates two distinct decision-

making bodies.[438] These two bodies have clear remits - an Advisory Committee on Assisted Reproductive Technology (ACART) is responsible for creating policy in accordance with the principles and requirements set out in the Act - and an Ethics Committee on Assisted Reproductive Technology (ECART) is responsible for facilitating the implementation of that policy. Whilst the HART Act incorporates a health and safety framework for performing assisted reproductive procedures, it does not set up a licensing system, in contrast to the UK and Victorian legislation.

5.2 UNDERLYING PHILOSOPHY/PURPOSES/OBJECTIVES OF THE ACTS

In the area of rapidly advancing biomedicine, it is essential to have a clear understanding of the underlying philosophy of the Act which establishes the particular regulatory framework. When science points in one direction, but compelling arguments point in another, decision-makers are thereby able to justify their decisions on the basis of the underlying philosophy of the Act and the regulatory objective.

The philosophy underpinning the New Zealand HART Act is apparent in the provision that sets out the first purpose of the Act. The overarching purpose is to:

> *secure the benefits of assisted reproductive procedures, established procedures and human reproductive research for individuals and for society in general by taking appropriate measures for the protection and promotion of the health, safety, dignity, and rights of all individuals, but particularly those of women and children, in the use of these procedures and research.*[439]

Hence, the intention of the Act is to obtain the benefits of assisted reproductive procedures not only for individuals, but also for society in general. It seeks to do this by creating a framework to protect and safeguard the health, safety, dignity and rights of all individuals, especially women and children, in the use of assisted reproductive technology and research. This protective purpose is ambiguous. While, at first, it seems to encompass the wider effects of assisted reproductive technology on society in relation to benefits, it then seems to limit the protective purpose to the individuals accessing the technology. Another interpretation of the purpose section of the Act is that the benefit to society is conferred by ensuring that individuals can access assisted reproductive technology safely.

Although the primary purpose of the Act appears to be about securing the 'benefits of assisted reproductive procedures', the underlying philosophy of the HART Act does not appear to be a libertarian one which places foremost priority on reproductive autonomy.[440] The Act contains rigid prohibitions on sex selection, and also places prohibitions on the commercial supply of human embryos or gametes, and commercial surrogacy arrangements.[441] It seems that the underlying purpose intended by the legislature is to balance the securing of benefits for individuals within the perceived wider interests of society.[442]

Providing a robust and flexible framework for regulating and guiding the performance of assisted reproductive procedures and research is expressly declared as another central purpose of the Act.[443] This is achieved by conferring decision- making authority on ACART subject to certain restraints. The Act sets out principles which guide all persons exercising powers

or performing functions under the Act. These include the principles that the health and well-being of children born as a result of an assisted reproductive procedure is an 'important consideration' in all decisions about that procedure;[444] that 'human health, safety, and dignity of present and future generations should be preserved and promoted;'[445] and that 'while all persons are affected by assisted reproductive procedures and established procedures, women, more than men, are directly and significantly affected by their application, and the health and well-being of women must be protected in the *use* of these procedures'.[446] These principles clearly indicate that there are competing interests to be assessed and balanced in relation to assisted reproductive procedures or research. However, no particular interest is accorded primacy.

Additional principles require that the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.[447] In particular section 3(f) provides that the needs, values, and beliefs of Māori should be considered and treated with respect.

In summary, the general philosophy underlying the purposes and principles of the New Zealand Act is closely akin to the ethical principle known as an 'ethic of care'.[448] Traditionally associated with feminist thought, the ethic of care seeks to balance the principles of individual autonomy, equality, respect for human life and dignity, protection of the vulnerable, appropriate use of resources, accountability, and individual and collective interests. An ethic of care is also the underlying principle in the Canadian legislation.[449]

The Victorian Infertility Treatment Act 1995 sets out that two of its seven purposes are 'to regulate the use of IVF … and to establish the Infertility Treatment Authority'.[450] Clearly, the overriding purpose of the Victorian statute is to prescribe limits, and to set up a body to enforce those limits. Section 5 outlines guiding principles which must be given effect in administering, or carrying out functions or activities under the Victorian Infertility Treatment Act 1995. These principles are set out in descending order of importance, with the interests of the person born or to be born as a result of treatment of paramount concern. This is a high order criterion. Neither the New Zealand nor United Kingdom adopt the paramountcy principle in their regulatory frameworks. This principle is followed by the principle that human life should be preserved and protected, and the interests of the family should be considered. The interests of the infertile couple in fulfilling their desire to have children is included, but is accorded least priority.[451]

There are several characteristics of the IT Act that distinguish the Victorian legislation in the context of this discussion. The first is the fact that the IT Act has clearly ascribed paramountcy to the welfare of the prospective child. However, this principle may raise tensions with aspects of reproductive technology where the interests of the future child require balancing against uncertainty as to risk, and with the interests of other individuals. It is also unusual that the interests of the family should precede those of fulfilling an infertile couple's desire to have children. Without a couple, there is no family to consider. In addition to these distinguishing aspects of the legislation, the Victorian legislature attempted to prescribe very narrowly those who could access ART. Section 8 of the Act specifies who is eligible for treatment. It essentially provides two pathways to treatment, either infertility, or the risk of transmission of a heritable condition.

Section 8 provides:

8. Persons who may undergo treatment procedures
   (1) A woman who undergoes a treatment procedure must -
      (a) be married and living with her husband on a genuine domestic basis; or
      (b) be living with a man in a de facto relationship
   (3) Before a woman undergoes a treatment procedure-
      (a) a doctor must be satisfied, on reasonable grounds, from an examination or from treatment he or she has carried out that the woman is unlikely to become pregnant from an oocyte produced by her and sperm produced by her husband other than by a treatment procedure; or
      (b) a doctor, who has specialist qualifications in human genetics, must be satisfied, from an examination he or she has carried out, that if the woman became pregnant from an oocyte produced by her and sperm produced by her husband, a genetic abnormality or a disease might be transmitted to a person born as a result of the pregnancy.

Although section 8(1) of the Act refers to a woman who is married or in a *de facto* relationship, marital status is no longer a ground for preventing access to ART, as long as other statutory requirements are met. It was held in the Federal Court that requiring a woman be married or in a heterosexual *de facto* relationship in order to access infertility treatment was inconsistent with the Federal Sex Discrimination Act 1984. This rendered the state law invalid.[452] However, the access requirements which limit treatment to persons requiring assisted reproductive procedures services for 'infertility' are still problematic for single or lesbian women. There is no definition of 'infertility' under the Act, so it is unclear whether it would encompass social infertility, where for example a lesbian woman 'is unlikely to become pregnant' because her partner is female, or clinical infertility whereby physical characteristics such as endometriosis exist causing infertility. The ITA has directed their clinics that unmarried women must be assessed as clinically infertile to be able to access infertility treatment.[453] This prevents lesbian or single women who are not suffering from clinical infertility accessing ART in the State of Victoria.

Limiting access to persons requiring treatment for infertility, or to those who are at risk of transmitting a genetic disorder to their child produces incongruous results. For example, a single or lesbian woman could access ART on the basis of a genetic disorder, or under the infertility provision because she is sufficiently old to be categorised as infertile, but if she is not assessed as clinically infertile, or at risk of transmitting a heritable condition, then treatment under the Act is precluded.[454] The irony is that in the case of single women or lesbian women who are not experiencing infertility, the fact that they are capable of transmitting a genetic disorder provides them with a pathway to fertility services they would not otherwise have.

The access requirements of the Act have been criticised as producing unfair and irrational results, and lacking a clear policy basis.[455] It has been observed that the Act 'clearly' enshrines a regulatory framework which expresses a community view about who should receive treatment, how children born of the procedures should be treated and the status of the human embryo.[456]

It has been said, although disputed, that the interests of the Catholic Church are reflected in the legislative framework.[457] One commentator has noted that there are limitations to the ability of the Victorian system to monitor and review community attitudes and responses to the development of the technology, and propose modifications to the regulatory framework because of the difficulty of amending the Act.[458] Yet all these criticisms of the Infertility Treatment Act 1995, described as a prescriptive regime which delegates minimal discretionary power to the statutory body, belie the fact that the Authority permits a greater range of PGD than that currently permitted in the United Kingdom or New Zealand.

The provisions of the Act do not specify what is considered to be a 'genetic abnormality or a disease'. It is this absence of a rigid definition that makes the Victorian legislation facilitative, as opposed to restrictive.[459] The only direct reference to PGD in the Act relates to sex selection.

Unlike the New Zealand and Victorian legislation, there is a noticeable absence of any express guiding principles in the United Kingdom's Human Fertilisation and Embryology Act 1990.[460] However, the Act should be read with the Warnock report.[461] The legislation sets out certain limits of assisted reproductive technology and research,[462] and establishes a licensing authority which may issue licenses for treatment, and research.[463] However, the Act prohibits the provision of treatment pursuant to a licence unless 'account has been taken of the welfare of any child born as a result of treatment (including the need of that child for a father), and of any other child who may be affected by the birth'.[464] There are several broad objectives underlying the HFE Act 1990: flexibility, safety and the welfare of the next generation.[465]

In summary, the New Zealand HART Act seeks to provide a means for the provision of ART within a flexible protective framework, which arguably includes consideration of the wider interests of society, and which does not prioritise the interests of any particular stakeholder. In contrast, the Infertility Treatment Act 1995 (Vic), is more prescriptive, prioritising the interests of the person to be born as the paramount concern. It also limits who may access ART.

The United Kingdom's HFE Act creates the most permissive and potentially liberal framework, delegating considerable discretionary authority to the HFEA. It has been said that the HFE Act is evidence of the intention of the British Parliament to facilitate research and progress by legitimating such research with regulation.[466]

5.3 NEW ZEALAND

5.3.1 WHO REGULATES?

Having analysed the underlying philosophy of the respective Acts responsible for the regulatory frameworks of the jurisdictions under study, it is proposed to determine who in fact makes decisions in relation to PGD, and what are the current permissible parameters in the respective jurisdictions.

The HART Act 2004 provides a skeleton framework whereby certain 'assisted reproductive procedures' and research are expressly prohibited,[467] others are regulated by a statutory body, and those which are declared to be 'established procedures' are excluded from the regulatory regime.[468] A commitment to imposing the minimum regulation necessary is achieved by the mechanism available to declare certain procedures to be established.[469]

The only provision in the HART Act which expressly refers to PGD provides that no person may select an embryo on the basis of sex unless it is to prevent or treat a genetic disorder or trait. A policy-making role is designated to ACART, – subject to specified requirements, for procedures which include PGD. ACART is responsible for the development of guidelines and the provision of advice to ECART, and the review of such guidelines and advice.[470] ACART must also provide advice to the Minister on relevant issues.[471] This includes advice as to whether an assisted reproductive procedure should be declared to be an established procedure.

Effectively, ACART is responsible for determining the boundaries of permissible PGD in New Zealand, although it is subject to certain restraints. ACART may only issue guidelines if interested parties and members of the public have been given a reasonable opportunity to make submissions on a discussion paper or on an outline of the proposed guidelines.[472] ACART is statutorily obliged to take those submissions into account.[473] After receiving a copy of the guidelines, the Minister must table them in the House of Representatives, but the guidelines do not need the approval of the House.[474] However, the Health Committee can, under Parliamentary rules, choose to undertake an inquiry into the guidelines.

Similarly for specified instances of assisted reproductive research and assisted reproductive technology, which include selection of embryos using PGD, ACART must call for and take into consideration submissions before giving significant advice to the Minister.[475] This requirement effectively ensures that the committee assesses the barometer of public opinion prior to issuing guidelines or providing significant advice to the Minister, but does not mean that views expressed will necessarily be accommodated.[476]

Before ACART gives advice to the Minister or issues guidelines to the ECART it must consult on the proposed advice or guidelines with any members of the public or any other person or group 'that the committee considers appropriate', or with appropriate government departments and agencies.[477]

The HART Act provides that assisted reproductive procedures may only proceed with the prior written approval of ECART.[478] An assisted reproductive procedure is defined in section 5 of the Act. An assisted reproductive procedure:

(a) means a procedure performed for the purpose of assisting human reproduction that involves-
    (i) the creation of an in vitro human embryo; or
    (ii) the storage, manipulation, or use of an in vitro human gamete or and in vitro human embryo; or
    (iii) the use of cells derived from an in vitro human embryo; or
    (iv) the implantation into a human being of human gametes or human embryos; but
(b) does not include an established procedure.

Effectively, if an application of PGD has not been declared to be an established procedure, it constitutes a regulated activity under the Act. ECART may not give approval unless it is satisfied that the activity proposed to be undertaken under the approval is consistent with relevant guidelines or relevant advice issued or given by ACART.[479] If there are no relevant guidelines or advice, the ECART may not approve an application until such time as the ACART formulates them. ECART is therefore tightly constrained by the parameters set by ACART.[480]

The Act provides a mechanism by which certain procedures may be declared to be 'established procedures', or cease to be an established procedure, on the basis of ACART's recommendation. Once an assisted reproductive procedure is declared to be an 'established procedure' by Order in Council, the procedure ceases to be regulated under the Act.[481] PGD in restricted circumstances has recently been declared to be an established procedure.[482]

Whilst Parliament has provided a prohibition on sex selection, it is essentially the Advisory Committee on Assisted Reproductive Technology which determines the permissible limits of PGD in New Zealand. However, ACART is constrained to act in accordance with the principles declared in the Act, and is statutorily required to engage with the public and interested parties prior to formulating policy.

5.3.2 PERMISSIBLE LIMITS

The current regulatory framework in New Zealand has established three categories of PGD: PGD which is statutorily prohibited; PGD which is regulated under Guidelines promulgated by the Advisory Committee and which requires Ethics Committee approval; and PGD which has been declared to be an established procedure by Order in Council.

In regard to PGD which is prohibited, section 11 of the HART Act provides:

Restrictions on sex selection of human embryos

(1) No person may, for reproductive purposes, -

(a) select an in vitro human embryo for implantation into a human being on the basis of the sex of the embryo; or

(b) perform any procedure, or provide, prescribe, or administer any thing in order to ensure, or in order to increase the probability, that a human embryo will be of a particular sex.

Breach of this section attracts a hefty penalty, with a person liable to either imprisonment for up to one year, or a fine of up to $100 000 or both.[483] However, a lawful excuse will be available if sex selection was undertaken to prevent or treat a genetic disorder or disease.[484]

Whilst section 11(1)(a) relates directly to PGD it is assumed that section 11(1)(b) is intended to cover techniques such as sperm sorting,[485] or to new techniques which may develop in the future, that allow parents to select the sex of their child prior to conception.

Section 11(1)(b) is drafted extremely broadly. The provision is drafted so widely that a person who consults, for example, a homeopath for homeopathic remedies to increase the chances of conceiving a child of a particular sex, could hypothetically, result in the provider breaching

section 11(1)(b). Throughout history people have practised sex selection. Reportedly the Greeks thought that tying off the left testicle would produce a male because the male determining sperm were derived from the right testicle.[486] Section 11(1)(b) is possibly one of the better examples of regulatory overkill in current New Zealand legislation. It begs the question whether the extremely broad prohibition on sex selection is commensurate with the putative risks or harms arising from sex selection.

The prohibition on non-medical sex selection sends a strong signal that the intended normative axis for regulating PGD in New Zealand is strictly therapeutic. It is noteworthy that the only high order criterion relevant to PGD in the Act relates to sex selection. PGD for selection of non-medical traits, which is arguably one of the most contentious aspects of PGD, is not expressly prohibited under the Act.[487]

The prohibition on sex selection was not in the HART Bill as amended by Supplementary Order Paper No 80 initially. It was added by the Select Committee in response to concerns that New Zealand was being more permissive than other jurisdictions.[488] The current policy in relation to sex selection appears to be based broadly on perceived 'social acceptability' – an intellectually and ethically dubious concept, and one which has not been used to determine the acceptability of other medical practices.[489] Perceived societal disapproval of certain practices does not necessarily mean that those practices should be prohibited.[490]

5.3.3 ESTABLISHED PROCEDURES

A recently passed Order in Council[491] declared certain categories of PGD to be established on the basis of advice received by the Minister of Health from an Advisory Group on Assisted Reproductive Technologies and a systematic review undertaken by the New Zealand Guidelines Group.[492] In her subsequent report to the Minister of Health on established procedures, the Director-General of Health stated; 'current evidence indicates that the risks associated with PGD are not markedly higher than those associated with IVF or ICSI,' and the 'risks associated with PGD fall within an acceptable level for New Zealand, because the risks are not raised above those risks which exist for IVF alone'. In this context, PGD offers potential benefits for those who are genetically predisposed to having a child with a serious disorder.[493]

The Order permits the use of PGD as an established procedure for non-familial chromosomal disorders (aneuploidy screening) without regulatory restraint where the woman is of advanced reproductive age, or has suffered from recurrent implantation failure or recurrent miscarriage.[494]

PGD may be performed as an established procedure for familial single gene disorders which have been identified in the family or whanau and where there is a 25% or greater risk of an affected pregnancy. The same criteria are applied to performing PGD for sex determination where familial sex-linked disorders have been identified in the family or whanau, but no specific test for the particular mutation that causes the disorder is available. The restriction prevents the performance of sex-selection where a familial sex-linked disorder exists, but it is possible to diagnose the particular mutation.[495] In the case of familial chromosomal disorders, the disorder must also have been identified in the family/whanau.

The final threshold criterion for PGD involving familial single gene disorders, familial sex-linked disorders and familial chromosomal requires that there be 'evidence that the future individual may be seriously impaired as a result of the disorder'.

In contrast, the proposed threshold set out in a consultation document prior to the established procedures order sought to authorise PGD when there was 'a high risk of serious abnormality'.[496] There is no longer any reference to a 'high risk', but mere evidence of potentially serious impairment will suffice. This would indicate that the threshold for permissible PGD without approval has been lowered from that originally proposed.

The Order in Council does not provide a definition of serious impairment. However, the Interim Guidelines on Preimplantation Genetic Diagnosis, since incorporated as ACART Guidelines, provide that 'it is the responsibility of PGD providers, in collaboration with a clinical geneticist, to determine whether a disorder is likely to be serious in the offspring'.[497] On the face of it, clinicians have a broad mandate to determine what constitutes a disorder that could cause serious impairment in a future individual, and the likelihood of that happening.[498]

The fact that clinicians determine the likelihood of a disorder manifesting in prospective offspring is generally unproblematic, but determining what constitutes a serious disorder is less straightforward.[499] It could be claimed that by leaving such decisions in the hands of the treating clinicians, rather than in those seeking the procedure, PGD cannot be represented as providing greater autonomy and reproductive freedom.[500] However it is likely, and desirable, that in clinical practice these decisions will be made in collaboration with the prospective parents.

The group of genetic disorders that may be brought within the category of 'single gene' disorders which may cause 'serious impairment' in an individual is extremely wide. It could be, and is likely to be, interpreted by providers as including late onset and reduced penetrance disorders. An example of a late onset, lower penetrance disorder is the BRCA 1 or BRCA 2 mutation. Carriers of the mutation have a 60-90% risk of developing cancer of the breast or ovary compared with a 10% risk in the general population. There is no certainty of developing cancer, only a significant risk. A carrier of the mutation may never in fact develop cancer, or even if they do, may live several decades before the first symptoms of disease appear. However, the only fool-proof prophylaxis for carriers of the mutation is double mastectomy, a radical and mutilating surgical procedure. It is thought to be doubtful that new therapeutic developments will be available for the next generation of BRCA mutation carriers that could significantly improve prevention and morbidity and mortality by BRCA-related forms of cancer.[501]

The provision of PGD for late onset, lower penetrance conditions such as BRCA 1 and 2, or familial adenomatous polyposis coli,[502] may potentially be carried out as a matter of course in New Zealand under the established procedure category. The decision to provide PGD is essentially left up to the clinician involved. In this respect, the provision of PGD in New Zealand for single gene disorders where there is evidence that the mutation may cause serious impairment in the 'future individual' (not 'child') could be readily accessible, being made at the point of patient-doctor contact. It is comparatively broad in relation to the current policy of the HFEA. PGD for BRCA mutation has not yet been licensed in the UK, but is permitted in the State of Victoria.

The Human Fertilisation and Embryology Authority (HFEA) has only recently undertaken a review to determine if testing for susceptibility conditions should be permitted in the United Kingdom.[503] In contrast, there has not been any public consultation undertaken in New Zealand as to whether PGD should be extended to select against embryos with genetic mutations which cause late onset disorders or which increase the risk of developing a disease later in life.

The potentially broad approach in relation to single gene disorders in the established procedure category is in contrast with the prohibitive policy in the HART Act in relation to sex selection, and the restrictive approach to HLA testing under the Interim ACART Guidelines. It should be noted that the current Guidelines were created prior to the newly established ACART being appointed.[504]

The only application of PGD which is currently within the remit of ECART as a regulated activity is PGD carried out in conjunction with human leukocyte antigen (HLA) tissue typing. HLA tissue typing involves testing embryos to determine compatibility as stem cell donors for siblings suffering from life-threatening diseases. This may arise when a child is suffering from disorders such as neoplastic[505] or congenital diseases which affect the formation of blood cells and/or the immune system. In these cases, transplantation of haematopoietic stem cells such as cord blood or bone marrow is currently the best course of treatment for the affected child.[506] Where there is no HLA identical donor available in the family, PGD can be used to select an embryo that is HLA identical.[507] The procedure has evoked controversy, particularly where the affected child is not suffering from a genetic disorder, and there is no genetic risk to the embryo to medically justify an embryo biopsy.[508]

Interim Advisory Committee Guidelines on PGD require that proposed PGD for HLA tissue typing must be submitted for ethics approval on a case-by-case basis. The Guidelines provide criteria for decision-making by the ethics committee.[509]

Provisions which specifically relate to the affected child provide that tissue typing may only be carried out when the disorder suffered by the live child is a familial single gene disorder or a familial sex-linked disorder. This eliminates any application in the case of an affected child who is suffering from a sporadic disease, or a non-genetically transmitted disease.[510] In addition, the planned treatment for the affected child must only involve utilising the cord blood of the future sibling. This last provision is problematic. Medical procedures carried out on a live child, such as the aspiration of bone marrow for the purpose of transplantation, are covered by established principles of health care law. It is not within the remit of a policy-making body on assisted reproduction to attempt to predetermine those issues. The final criterion provides that no other possibilities for treatment or sources of tissue should be available.

In respect of the embryo, the Guidelines state that it must be a sibling of the affected child, and be at risk of being affected by a 'familial single gene disorder or a familial sex-linked disorder for which a PGD test is available'. This provision has been broadened from that originally proposed in a previous consultation document, which required that the embryo be 'at risk of being affected by the condition affecting the existing child'.[511] This has extended the scope of permissible HLA tissue typing to a small extent, while maintaining the normative framework which permits PGD with HLA tissue-typing only when there are therapeutic indications for

the embryo to justify a biopsy. In this way, the New Zealand guidelines prohibit PGD with HLA testing for third party benefit in the absence of a risk to the embryo of a genetic disorder for which there is a test available.

There is a distinct structural anomaly in regard to the HLA guidelines, which may produce bizarre results. This anomaly may be best explained by a clinical example. Consider the scenario where there is a genetic indication to test an embryo for a heritable condition, such as cystic fibrosis, and the parents also wish to carry out tissue typing because a sibling is suffering from a non heritable medical condition that could be cured by a stem cell transplant, such as a life-threatening blood condition. The ethics committee would be unable to approve the application to perform HLA testing in conjunction with PGD because the sick sibling is not suffering from a familial single gene disorder or familial sex linked disorder, as required by the guidelines. This is so even though the PGD may be carried out as a matter of course as cystic fibrosis comes within the established procedures category. However, it seems that NECAHR, which was responsible for formulating the guidelines, had intended to permit HLA testing to be carried out as an 'add on' when the potential embryo was at risk from a genetic condition for which a test was available.[512] Clearly, the framers wished to permit HLA tissue typing as long as there was a medical indication to justify performing an embryo biopsy, and this anomaly is unintended. It could be easily rectified by simply requiring that the affected child be suffering from a condition which is severe or life-threatening.

As already clearly established, the New Zealand Guidelines restrict HLA tissue typing unless there is a genetic risk to the embryo. However, a compelling ethical argument has been made for performing HLA tissue typing as a stand alone procedure when there is no risk of a heritable genetic disorder being transmitted to the embryo. This argument compares the ethical basis for performing PGD to detect genetic anomalies, against HLA tissue typing to determine donor compatibility.[513] This argument is necessarily based on the premise that embryo biopsy in the course of PGD does not expose the embryo to significant harm.

The restrictive approach which limits HLA tissue typing in New Zealand to circumstances where the live sibling is suffering from a genetic condition departs from the current approach of the United Kingdom.[514] Such a restrictive approach is surprising, considering the approach taken in regard to PGD as an established procedure.

The rationale since given for declaring PGD to be an established procedure in specified circumstances is that the risks associated with PGD were not markedly higher than those associated with IVF or ICSI, and could be justified in the case of serious heritable genetic disorders. Given the underlying philosophy of the Act and the level of risk associated with PGD, it is very difficult to reconcile the more restrictive aspects of the regulatory framework.

The final criterion for ECART when deciding whether to permit PGD with HLA tissue typing stipulates that the health and well being of the family/whanau must have been fully considered. It is unclear why the same risks which attach to PGD in the case of single gene or chromosomal disorders may not be justified when balanced against the benefits to seriously ill children, their families and society in general in the case of preimplantation HLA tissue typing.

The implication of the current policy is that it is better for a child not to be born at all, than to be born partly as a result of a parental wish to provide a tissue donor for an existing child. However, the 'protection and promotion of the health, safety and dignity and rights' of New Zealanders may be better achieved by permitting parents to demonstrate to an ethics committee why they should be able to access PGD to perform HLA tissue typing when they have a seriously ill child.

In summary, the rigid statutory prohibition on non-medical sex selection and the very restrictive policy in relation to HLA tissue typing indicates that the normative axis for PGD in New Zealand currently is very narrowly restricted to therapeutic indications for serious heritable genetic diseases. The restrictions on HLA typing seem difficult to justify on the basis of the underlying philosophy of the Act, and the risks associated with embryo biopsy. In contrast, the established procedures category is much more expansive.

5.4 VICTORIA

5.4.1 WHO REGULATES?

The Infertility Treatment Act 1995 prescribes who may access fertility services, sets out definitive principles underpinning the Act, provides certain prohibitions, and delegates power to a statutory body, the Infertility Treatment Authority, to administer the Act. The Victorian legislation is prescriptive and is said to delegate much less discretionary power to the ITA than occurs under the UK legislation.[515] It has been said that the Victorian legislation is the starkest example of capture by a particular group, where the predominant interests of the Catholic Church are reflected in the legislative framework.[516] Yet ironically, in the context of PGD, some provisions appear to be broader than the current New Zealand policy.

PGD is permitted in accordance with guidelines produced by the ITA, which are bound to limit PGD to circumstances where it is used to avoid the transmission of a genetic disorder. Hence, there is no room for the ITA to extend PGD to applications for social selection.

The Infertility Treatment Act 1995 (Vic) provides for the regulation of infertility services through the licensing and approval of places and practitioners by the Infertility Treatment Authority.[517] A licence authorises the performance of the activities specified in the licence at the premises identified in the licence.[518] The Authority has published two PGD policies; one governs the use of PGD for genetic testing and the other covers genetic testing combined with tissue typing.[519]

5.4.2 PERMISSIBLE LIMITS

As in New Zealand, sex selection is prohibited under the Infertility Treatment Act 1995 (Vic) unless it is necessary for the avoidance of a genetic abnormality.[520] Unlike the New Zealand Guidelines, there is no restriction in the ITA guidelines that sex selection may only occur in the absence of a specific genetic test for the particular sex-linked disorder for which an embryo is at risk of inheriting.

The IT Act does not specify what is to be considered a 'genetic abnormality or disease'. The ITA guidelines provide that PGD will only be utilised for those disorders which 'will significantly adversely affect the health of a person who may be born'.[521] Responsibility for determining what is a genetic abnormality or disease lies with a doctor with specialist qualifications in human genetics. The Act therefore imposes the responsibility for gate-keeping on the specialist doctor.[522] This is the same approach taken by the New Zealand Guidelines.

The ITA policy sets out a list of ethical questions that arise in the context of genetic testing, which take into consideration the principles as set out in section 5 of the Act. These are:

- whether the interests of the person born are universally met through the application of PGD and genetic testing;
- whether it is ethically appropriate to discard embryos with a carrier status, and whether this is consistent with the guiding principles of the Act;
- the extent to which these considerations are viewed in the context of the interests of the family, as outlined in the guiding principles of the Act;
- the use of PGD for conditions of different severity or impact on quality of life is not morally similar. The level of risk of transmission, the degree of abnormality and the family's experience and perception of abnormality are important considerations;
- there is a broader public policy issue about the way in which genetic testing of embryos may impact on people who are already living with a condition which is being selected against;
- for people seeking to utilise PGD, there may be a different moral status afforded to an embryo as opposed to a foetus. Therefore the decision to select against an embryo is different for them, from the decision to terminate a pregnancy. Further, the likelihood of success of this option will vary, particularly for the older mother who is likely to produce fewer embryos, and where genetic testing may further reduce the number of available embryos.

It is significant that the ITA expressly states that whilst applications of PGD for the purposes of genetic testing must be guided by the current practice in relation to Prenatal Diagnosis, and guided by the Policies of the Human Genetics Society of Australia, it is recognised that there may be a greater range of indications where PGD may be considered. This includes selection against carrier embryos. Such cases must be reviewed on their individual merits in terms of the clinical and ethical considerations, by the clinicians involved and the couple seeking treatment. This statement is significant in providing that there may be more clinical indications for performing PGD than prenatal screening, and that decisions must be made in conjunction with the couple involved. It is evidence that the ITA is clearly applying a gradualist approach to the embryo, whereby it accrues greater status and rights as it develops, and an embryo is accorded less moral status than a developing foetus. It goes further than the parameters provided by both the New Zealand and United Kingdom frameworks. This is so even though the guiding principles of the Act are more restrictive than those of the New Zealand Act and United Kingdom Acts. The broader approach to permissible PGD is reflected in the following policy adopted by the ITA.

A list of conditions for which PGD may be carried out which do not require application on a case-by-case basis is provided by the Authority.[523] The first category permits testing for chromosomal imbalances where there has been recurrent implantation failure, recurrent miscarriage, the woman is of advanced maternal age, there is a previous history of foetal aneuploidy, or if the parents are known *carriers* of chromosomal rearrangements. The second category includes known carriers of chromosomal rearrangements, specified X-linked conditions and carriers of those X-linked disorders, and specified single gene disorders. Significantly, BRCA1 is included in the category of single gene disorders, so PGD for BRCA1 may be carried out without notification to the ITA. As already discussed, testing for BRCA1 is not universally permitted. It is a late onset disorder which is not fully penetrant. There are other disorders in the list, which indicate that the ITA has adopted a broad approach to permissible disorders for which PGD may be carried out.[524] Any other applications of PGD must be approved by the Authority on a case-by-case basis. These include:

(a) testing for autosomal recessive conditions where it is proposed to identify and select against carrier embryos, in addition to testing for the condition;

(b) exclusion testing where a person is at risk of an autosomal dominant condition but does not wish to undertake direct testing;

(c) conditions where there is a higher incidence in one sex, but there is inconclusive genetic evidence about the transmission of that condition, eg autism, Asperger's syndrome. In this context, clinical evidence, family history and peer-reviewed evidence to support the application must be presented to the Authority.

(d) HLA tissue typing with PGD of a causative gene is also considered on a case-by-case basis.

These categories go significantly further than those established in New Zealand. Testing for carrier status has not been addressed in the current NZ guidelines, nor have categories (b) and (c). Performing PGD in categories (a) and (c) is unlikely to be permitted under the current established procedures category in New Zealand. Being a carrier of an autosomal recessive condition is unlikely to constitute potentially serious impairment in the future individual. Yet many parents may reasonably wish to select against carrier embryos so that future offspring do not have to face the same difficulties in their child-bearing years. This is an area that needs to be addressed by the New Zealand ACART. The United Kingdom has not provided any guidance as to whether parents may select out carrier embryos in the Code of Practice. However, a recent report published by the UK Human Genetics Commission has recommended that parents should be able to choose which embryos they wish to have implanted when there are both carrier and unaffected embryos suitable for implantation available.[525]

The Established Procedures category declared under the HART Act only covers Mendelian and X-linked conditions by virtue of the requirement that there must be a 25% or greater chance of transmitting the genetic disorder. It is unclear that category (c) would fall within the 25% threshold. The New Zealand Ethics Committee would be unable to adjudicate on any applications made to perform PGD in these categories in the absence of Guidelines released by the ACART. This is a possible area for guideline development in the future.

The ITA assesses applications for compliance with the Act, including whether the appropriate counselling information and consent procedures have been undertaken.[526] A comprehensive medical report is required. After approval by the Authority, ethics committee approval may still be required in certain categories. This includes the use of PGD to select against carrier embryos where there is an autosomal recessive genetic condition, or in circumstances where the clinician or clinic is of the opinion that although a procedure is lawful, it requires consideration of the ethical implications of the specific case history. Ethics committee approval is also required in the case of HLA tissue typing.

As already indicated, the Infertility Treatment Act 1995 (Vic) permits access to ART where there is a risk of a genetic abnormality or disease being transmitted to a prospective child. The use of PGD for non-medical sex selection is expressly prohibited under the Act, even though sex selection for non-medical indications could not come within the access criteria as set they are out in the Act. The Infertility Treatment Authority has, under the discretion conferred on it, articulated the threshold for permissible PGD.

Analysis of the Infertility Treatment Authority policy in relation to PGD has highlighted areas that are not yet addressed by the current New Zealand guidelines. This includes whether carrier testing and selection against embryos that are carriers of a specific mutation is permissible, and whether sex selection may be carried out when there is a familial history of a particular disorder, but for which there is inconclusive evidence that the condition is genetically inherited. It is expressly stated that the indications for PGD may go beyond those for PNT. There is some irony in the fact that the Victorian policy, which is promulgated under an Act known for its restrictive policy and 'catholic capture', has extended the permissible limits of PGD beyond that of prenatal testing in contrast to the UK and New Zealand.[527]

The ITA policy governing HLA tissue typing diagnosis[528] is necessarily limited to circumstances where there is a genetic risk to the embryo. This is because the access provisions under the Act require that, except in the case of infertility, treatment may only be used if a genetic abnormality or a disease might be transmitted to a person born as a result of pregnancy.[529] Hence, the ITA is prevented from extending tissue typing to circumstances where there is no genetic risk to the embryo unless there is an amendment to the statute.[530]

The ITA policy on HLA tissue typing provides that PGD and HLA tissue typing are not explicitly prohibited by the Infertility Treatment Act 1995 provided that the applied techniques do not infringe any prohibition imposed by the Act.[531] It is acknowledged that the intention of the Act is generally that the interests of the person born or to be born are paramount. It is stated that the use of PGD and HLA typing can be seen to be consistent with the guiding principles of the Act, as every effort is made to both save an existing life and create a new life. However, it is stated that it is clear that the application of the technology in this way is novel, and raises many ethical and social considerations beyond the immediate interests of the couple seeking the procedure, or the terminally ill child. For this reason, the Authority has imposed a number of conditions on its use. An overriding condition of the ITA is that each application will be dealt with on a case-by-case basis.[532] In relation to the affected child, the genetic disorder suffered must be severe or life-threatening.

Each application to the Authority must provide an outline and evidence of the genetic condition that the embryo is to be tested for; the clinical circumstances in relation to the use of the procedure; the current prognosis of the living child; the nature of the procedure proposed in relation to the child who is to be born (ie cord blood or bone marrow); the likely effect of cord blood or bone marrow transplantation with HLA matched blood or bone marrow on the future prognosis of the affected child; and whether alternative treatments to PGD and HLA have been investigated and/or utilised. There must be confirmation from a specialist geneticist that all reasonable efforts have been made to identify alternative forms of treatment for the sick child.

In addition, evidence must be provided to the Authority that the patient has been comprehensively advised of: the risks associated with IVF treatment for the woman and the PGD procedure for the embryo; the chances of producing an embryo that is unaffected by the genetic conditions and tissue typed; the likely success rates of achieving a pregnancy; and any alternatives to treatment.

The ITA policy provides that the Authority will only consider applications to harvest cord blood or bone marrow and further provides that 'the harvesting of non-regenerative organs is not acceptable'. This last statement is a timid representation of the position at law. It is most unlikely that there could be any justification at common law that would enable a parent to provide a proxy consent for the removal of a non-regenerative organ from their child for donation to another child.[533] To be lawful, such a procedure must be in the 'best interests' of the donor. If a child donates a non-regenerative organ, such as a kidney, they are exposed to significantly increased health risks in the future, and thus it would be very unlikely to be legally justifiable. It is most unlikely that any surgeon would agree to carry out such a procedure.

The procedure is only available if the primary recipient is a sibling, although if a relative suffers from a similar genetic condition, it is the prerogative of the parents to decide if cord blood or bone marrow may be donated. The Authority reviews all applications on a case-by-case basis, but the final decision rests with the ethics committee at the institution where the procedure is being undertaken.

Key considerations, which must be brought into an ethical consideration of an application by an ethics committee, and which are covered in counselling include:

(i) the motivation and level of understanding of the parent in seeking to have an additional child. If this motivation is solely for the purposes of furthering the interest of an existing sibling, then this may raise concerns. However, if the child is wanted for his/her own worth, then this may be justifiable. The Authority's ethical advice highlights the difficulty of identifying the motivation for parents, faced with a terminally ill child, and a desire to complete their family;

(ii) the issues which may arise where the birth of a child does not resolve the genetic condition for the existing sibling;

(iii) the status of the child within the family and the relationships, which grow, with the growth of all children within the family.

It is significant that the ITA countenances the future use of bone marrow, which goes further than the current New Zealand Guidelines where it is a requirement that 'the planned treatment for the affected child will utilise only the cord blood of the future sibling'. However as already discussed, the New Zealand restriction exceeds the jurisdiction of a regulatory body, as the donation of bone marrow from a living child is governed by general principles of medical law.

5.5 THE UK

5.5.1 WHO REGULATES?

The Human Fertilisation and Embryology Act 1990 contains few express prohibitions, and delegates considerable decision-making power to the Human Fertilisation and Embryology Authority (HFEA). The Act empowers the HFEA to act as licensing authority for the purposes specified in the Act.[534] The Authority is responsible for maintaining a code of practice for the proper conduct of activities carried on in pursuance of a licence under the Act.[535]

There is no express reference to PGD in the HFE Act. However, the Act prohibits the creation, keeping or use of an embryo except in pursuance of a licence.[536] The HFEA may grant licences approving activities in the course of providing 'treatment services'.[537] 'Treatment services' for the purposes of the Act are defined as 'medical, surgical or obstetric services provided to the public or a section of the public for the purpose of assisting women to carry children'.[538] Activities for which treatment licences may be given are set out in paragraph 1, Schedule 2 of the Act.

Paragraph 1 of Schedule 2 provides:

1-(1) A licence under this paragraph may authorise any of the following In the course of providing treatment services-

a. bringing about the creation of embryos in vitro,

b. keeping embryos,

c. using gametes,

d. practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose,

(e) placing any embryo in a woman…

The foregoing is limited by the restraint on the HFEA's power contained in clause 3:

(3) A licence under this paragraph cannot authorise any activity unless it appears to the Authority to be necessary or desirable for the purpose of providing treatment services.

Licences for treatment made under paragraph 1 of schedule 2 may be granted subject to conditions specified in the licence.[539] The Act sets out conditions of every licence for treatment.[540] One such condition provides that 'a woman shall not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for a father), and of any other child who may be affected by the birth'.[541]

Although the Act does not provide expressly for the licensing of PGD, the HFEA took the approach that the Act implicitly authorises them to license clinics to provide PGD services.[542] This was despite the fact that the HFE Act provides a mechanism via regulation for adding to the practices which may be authorised by the Authority in a treatment licence.[543] However, regulations were not utilised to mandate the licensing of clinics for PGD when applicants first approached the HFEA. The HFEA has been approving licences for PGD since 1999, and licences for HLA tissue typing since 2001.

When the HFEA approved a licence in 2001 permitting HLA tissue typing to be performed in conjunction with PGD, the scope of the Authority's discretion became the subject of legal challenge.[544] It was claimed that the HFEA had no power to issue a licence that permitted the use of HLA tissue typing to select between healthy embryos. The case was initially successful in the High Court. However, it was confirmed in the Court of Appeal and subsequently in the House of Lords that the Authority has the power to issue licences for PGD and HLA tissue typing under the Act.[545]

Consequently, PGD may be licensed by the HFEA as a practice designed to secure that 'embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose'. The Court of Appeal has held that treatment for the purpose of 'assisting women to carry children' is not restricted only to that which would assist a woman in the physical process of conceiving and producing a child. It is capable of embracing IVF treatment designed to ensure that a child will not suffer from genetic defects or will possess stem cells matching that of a sick or dying sibling where concerns about the characteristics of any child conceived would otherwise inhibit or prevent a woman from bearing a child. The House of Lords has affirmed that PGD and HLA tissue typing may be authorised by the HFEA as activities to determine the suitability of the embryo for implantation.[546] On their analysis, the concept of suitability in paragraph 1(1)(d) fell to be construed in the context of the scheme of the 1990 Act and the background against which it had been enacted. It was held that Parliament had intended to define the licensing power of the HFEA in broad terms and to entrust it to decide which practices were ethically acceptable, subject to the prohibited matters in section 3(3) of the Act and Parliament's regulatory powers. The term 'suitable' was broad enough to include suitability for the purposes of the particular mother. Parliament had not intended to confine the HFEA's powers to unsuitability on grounds of genetic defect; the limits of permissible embryo selection were ultimately for the HFEA to decide.

Despite the wide discretion conferred on the Authority, the HFEA is not free to act arbitrarily, at least not without attracting criticism. The HFEA was soundly rebuked by the House of Commons Science and Technology Committee after releasing its interim policy on HLA testing.[547] The policy permitted HLA testing to be performed in conjunction with PGD when there was risk of transmission of a genetic disorder. The House of Commons Select Committee stated that the decision to allow tissue typing in conjunction with PGD occurred in the absence of public consultation on the issue, and went significantly further than PGD which was carried out in the interests of the future child itself. The decision went beyond the scope of the HFEA's public consultation on PGD and it was 'vital that the public are taken along with such matters of ethical importance'.[548]

Similarly, in 2004 the HFEA evoked sharp criticism again when it agreed to grant a licence to a clinic to test embryos for familial adenomatous polyposis coli (FAP), a genetically inherited form of colon cancer which usually manifests in early adolescence or early adulthood.[549] Prior to this, licences had been approved only for genetic disorders that invariably led to untreatable conditions, or those affecting children. It was alleged that the HFEA were making decisions behind 'closed doors'.[550]

This type of criticism is significant, as there is no requirement in the HFE Act that the HFEA carry out consultation prior to determining whether licences should be granted.[551] Yet, there seems to be a presumption on the part of the Government, the public and interest groups that policy decisions in the United Kingdom, which appear to extend the use of PGD, must occur following public input. Such consultative work has been essential to the perceived legitimacy and acceptance of the decisions of the HFEA by both the public and by Parliament.

The United Kingdom's approach to regulating the use of PGD has rightly been described as 'one of the most liberal regulatory mechanisms in the world'.[552] Although the HFEA has the power to license clinics to perform PGD for social reasons, it does not mean that it will necessarily do so. Sex selection is not illegal in the United Kingdom under the HFE Act, although the HFEA has refused to license the use of PGD for sex selection for non-medical reasons. But should they wish to, it is clearly within their mandate. It is undoubtedly the HFEA who set the permissible limits of PGD in the United Kingdom.

Changes to the UK system are imminent. The British Government has announced its intention to replace the HFEA and the Human Tissue Authority (HTA) with a single authority responsible for the regulation of assisted reproduction, embryo research and the use of human tissue.[553] This will require primary legislation and will be known as the Regulatory Authority for Tissue and Embryos (RATE). The new authority will be responsible for overseeing the requirements of the EU Tissue Directive.[554]

5.5.2 PERMISSIBLE LIMITS

The HFEA Code of Practice sets out licensing requirements for what is referred to as 'preimplantation testing'.[555] The Code states that 'it is expected that PGD will be available only where there is a significant risk of a serious genetic condition being present in the embryo'. The perception of the level of risk by those seeking treatment is an important factor in the decision-making process. The seriousness of the condition is expected to be a matter for discussion between the people seeking treatment and the clinical team.[556] Aneuploidy screening guidance is similar to that of both NZ and Victoria.[557]

The HFEA Code of Practice states that indications for the use of PGD are expected to be consistent with current practice in the use of (post-implantation) prenatal diagnosis.[558] Concern has been expressed about whether this is the appropriate benchmark;[559]

> *..the basis for the comparison is that both PGD and PND have at the least theoretical risks attached to them but to apply the same clinical indications to both is only justified if these risks are equivalent. The HFEA surveyed the scientific literature on the risks associated with embryo biopsy in relation to its policy review on preimplantation tissue typing. It*

cited two studies and reported that 'These studies showed consistently that the sample of children studied did not show a significant increase in incidence of serious abnormalities at birth, or, where information was available, at 1 and 2 years of age. Nevertheless, there are as yet no long-term follow-up studies of PGD offspring available'.[560]

The House of Commons Select Committee on Science and Technology concluded that applying a gradualist approach to the status of the embryo would suggest that a 5-day old embryo should be accorded fewer rights or less respect than a developing foetus. Paradoxically, there is a divergence between the protection afforded to an embryo created in vitro before it is implanted and one at a later stage of development under the current HFEA Code of Practice.

The irony of the PGD – PNT dichotomy was made obvious in evidence given to the House of Commons Select Committee. A couple, whose application to the HFEA to undertake PGD with HLA tissue typing was declined on the basis that their sick child was not suffering from a genetic condition, reported that they were initially advised to undergo amniocentesis and termination if the foetus was not a tissue match.[561] The HFEA has subsequently reviewed HLA tissue typing guidelines, and tissue typing may be performed regardless of whether there is a risk of transmission of a genetic disorder.

As observed by the Royal Society of Edinburgh,[562] restricting PGD to serious genetic conditions might mean that the (arguably) ethically less troubling option of non-implantation would be subject to more rigorous controls than the (arguably) more troubling ethical option of pregnancy termination following prenatal diagnosis.[563] In New Zealand, the Guidelines simply state that PGD is an alternative to prenatal diagnosis, and is distinguished from it by the stage at which decisions have to be made: at the embryonic rather than the foetal stage.[564]

Apart from FAP, the HFEA has not yet permitted licences to test for late onset susceptibility conditions, such as inherited breast cancer or inherited ovarian cancer.[565] The HFEA has announced that it had been carrying out a scientific review on disorders where the genetic conditions were not fully penetrant. This includes conditions such as BRCA 1 and 2, and hereditary non polyposis colon cancer. The views of the public are currently being sought on the appropriateness of offering PGD to screen out such disorders.[566] Researchers are soliciting the opinions of women carrying the mutation in regard to the effect their carrier status has on reproductive choices, and whether they would consider PGD if it was available.[567] It is likely that the HFEA will approve licences for BRCA testing in 2006.[568] Although the UK system is comparatively permissive, such consultation has been important in the HFEA maintaining the confidence of the public.

UK clinicians face more bureaucracy than their Antipodean counterparts in providing PGD services. Until very recently, every clinic was required to submit a fresh application to the HFEA each time they wished to test for a new condition, and for each new test they wished to use. Each application requires the payment of a fee to the HFEA.[569] A licensed clinic may only carry out testing for the genetic conditions, chromosomes or traits (or combinations of these) and using those specific tests (or combination of tests), that are listed in the preimplantation testing annex of their licences, or that have been approved by a licence committee in any particular case. This is in stark contrast to the system in New Zealand.

In January 2005 the HFEA announced a new policy to streamline the approval of applications for PGD.[570] If a clinic, with proven expertise in performing embryo biopsies, applies for a licence to carry out screening for a particular condition, which is already being carried out successfully in another clinic, such as screening for sickle cell anaemia or cystic fibrosis, the HFEA will approve the application without having to go through the full HFEA licence committee process, provided that the same technique and methods are used. Less common specialised applications of PGD still require consideration by an HFEA licence committee on a case-by-case basis.[571]

The Human Fertilisation and Embryology Act has been described as a pragmatic response to the public anxieties evoked by the ability to create in vitro human embryos and the related potential for embryonic use, manipulation and research.[572] In defence of the lack of clearly articulated principle, it has been observed that 'issues involving perplexing cocktails of ethics, law and public morality have been resolved in a manner which has served private access to assisted conception services whilst maintaining broad public support for this provision. Indeed, the lack of any dogmatic stance has allowed the development of liberal policy without causing widespread offence or opposition'.[573] However as science advances and ethical debates intensify, the need for a central philosophy or principle becomes more and more apparent.

5.6 THE SAFE PROVISION OF FERTILITY SERVICES

Ensuring that the health and safety of both the persons accessing fertility services and the embryos produced as a result of assisted reproductive procedures are protected to the highest standard possible is a major factor in gaining public confidence in any regulatory framework.[574]

The licensing approach followed by Victoria and the UK was rejected in New Zealand. Instead, the HART Act 2004 provides that fertility services are deemed to come within the definition of specified health or disability services under the HDS(S) Act 2001.[575] Under section 9 of that Act, a person providing fertility services must be certified by the Director-General of Health to provide fertility services, meet all relevant service standards, comply with any conditions to which the person was subject by the Director-General, and operate in compliance with the HDS(S) Act.

There are no specific standards at present for fertility services in New Zealand.[576] Until such time as the Minister approves specific standards for providing fertility services,[577] providers are deemed to comply with the HDS(S) Act[578] if the provider complies with specified criteria. The provider must be certified by the Director-General of Health, have been the subject of an audit report completed for the purposes of accreditation by an organisation approved by the Director General of Health, and must comply with any standards approved by the Director General under the HART Act.[579]

The Director-General has approved the Reproductive Technologies Accreditation Committee (RTAC) of the Fertility Society of Australia to audit the provision or likely future provision of fertility services in New Zealand in the interim period[580] until the fertility service standards are notified. The RTAC Code of Practice has been approved as the standard for fertility services in the interim period.[581]

The provisions of the HART Act have essentially provided a legal requirement for clinics to be accredited and to adhere to standards, putting what was occurring on a voluntary professional self-regulatory basis on a statutory footing and providing civil sanctions for non-compliance. In essence, the New Zealand regulatory framework has built on existing institutions for health and safety, as well as requiring standards to be formulated which are specific to the New Zealand context. It is a positive aspect of the New Zealand approach that it incorporates both professional self-regulation and government regulation within the statutory framework.

In New Zealand, ACART is charged with monitoring the application, and health outcomes, of assisted reproductive procedures and established procedures; and developments in human reproductive research in New Zealand.[582] This requirement places an emphasis on safety and accountability, which covers all assisted reproductive procedures and research, including established procedures. However, the Act does not specify in what way the oversight is to occur. Nor does it provide specifically that medium and long-term outcomes must be monitored.[583] The interim Guidelines require that fertility clinics provide an annual report detailing the number of PGD procedures carried out for familial and non-familial disorders, and the genetic or clinical indications for the use of PGD. A follow-up report is required detailing the outcomes of those procedures. Currently, all embryo biopsy carried out on behalf of New Zealand consumers is carried out at Monash IVF, in the State of Victoria.[584]

The Infertility Treatment Act 1995 (Vic) provides for the regulation of infertility services through the licensing and approval of places and practitioners by the Infertility Treatment Authority. Section 93 of the Act stipulates that certain activities may not be performed unless they are performed at a place which is licensed.[585] A licence authorises the performance of the activities specified in the licence at the premises specified in the licence.[586] Section 106 of the Act confers power on the Authority to impose conditions on licences.

The ITA has produced a policy document which sets out the conditions required to be met in order to obtain a licence.[587] Failure to comply with these conditions can result in revocation of the licence or an order for compliance. [588]

The licensed centre must be accredited with the Australian Council on Healthcare Standards. In addition, the licensed centre must be accredited by, or be in the process of seeking accreditation from, the Reproductive Technology Accreditation Committee. All diagnostic laboratories used by the licensed centre must be accredited with National Association of Testing Authorities (NATA). Failure to comply with the terms of the licence carries a penalty of 240-penalty points or 2 years' imprisonment.[589] In all cases of PGD, licensed places are required to report annually the number of applications used for genetic testing, and the types of indications for which it is used. Licensed places are required to notify the Authority of any applications of PGD which have not previously arisen. The Authority is responsible for carrying out a yearly audit to ensure that the policy meets the requirements of the Guiding Principles of the Act.

In the United Kingdom, the HFE Act 1990 provides that it is the duty of the person responsible to ensure that proper equipment is used, and that suitable practices are used in the course of the activities carried out pursuant to licenses.[590] The HFEA Code of Practice requires that all genetics laboratories used for preimplantation testing are expected to be Clinical

Pathology Accreditation (CPA) accredited (or equivalent) or at least be working towards CPA, with accreditation to be completed within five years.[591] It is curious that in the Report of the Science and Technology Committee, it was reported that the CPA scheme does not accredit embryology laboratories as the field is considered too controversial.[592]

The HFEA has taken on the inspection of all technical aspects of assisted conception, including clinical and laboratory processes. Inspections cover record keeping, conditions for the storage and disposal of licensed material, suitability of staff, equipment and working practices.[593] Significantly, the inspection processes have come under attack by the very people being inspected. The HFEA inspection process was described by the Association of Clinical Embryologists as being inadequate to amount to accreditation for two reasons. Firstly, the time spent was insufficient, and secondly the inspector training was inadequate or inappropriate. The Association stated that there was no observation of practice, and no time to obtain evidence that people were actually doing what they said they were doing. Compared with other laboratory accreditation systems, the time spent with a practice was so small as to be valueless. The group advocated that accreditation be a prerequisite to licensing.[594] On the instigation of the HFEA, a group of professionals began working together to develop Standards for Assisted Conception Units in 2004, which would provide the basis for accreditation, reflecting a move away from a system of licensing to accreditation.[595]

This would seem to be a good example of a case where those being regulated are alienated by the requirements of the regulatory body, in this case on the grounds that the inspection process does not meet the standards of professional self-regulation.

The health and disability infrastructure in New Zealand, which provides a framework for safety and accountability, and which can be extended to cover fertility services, is a compelling argument against adopting the licensing approach taken by other jurisdictions.

5.7 ADMINISTRATIVE FAIRNESS AND APPEALS

In liberal democracies such as the countries being reviewed in this analysis, it is important that a regulatory process is perceived as being fair and transparent by those affected by the regulatory framework, as well as imposing a degree of accountability on the part of decision makers. Provisions for natural justice and an appeals process go some way to meet these criteria.

However, there is an absence of any explicit provision for natural justice or an appeal process in the New Zealand system. The terms of reference for ECART are silent as to whether applicants appear before an ethics committee. The framework does not provide in any way for an appeal from a decision of ECART. By allowing applicants to state their case to them, the legitimacy of the ethics committee structure is strengthened. This is affirmed by the experience of the HFEA, which now permit applicants to appear before licence committees.

When an application on behalf of the Whitaker family was made to a licence committee to carry out HLA tissue typing on embryos to determine donor suitability for a child who was suffering from Diamond Black Fan Anaemia, the HFEA rejected the application. The condition had not been inherited from either of the child's parents, as neither was a carrier of the disease; rather the condition was a sporadic mutation. The application was rejected on the basis that

the tissue typing procedure would be carried out solely to find a tissue match, and not to diagnose a genetic condition. The Whitaker family was not permitted to appear before the HFEA to argue their case.[596] However, it is significant that the HFEA now intends to provide applicants with the opportunity to give evidence to the HFEA licence committee face to face should they choose to do so.[597]

As yet, there have been no indications from the New Zealand ECART as to whether applicants will have the opportunity to attend meetings. The argument in favour of allowing applicants to make a case to the ECART is strengthened by the fact that the ECART is not responsible for the policy which is formulated by ACART, they simply administer it. Hence, permitting applicants to appear will not impact on policy formation, but may influence the way that policy is interpreted.

It is important, as a matter of administrative law, that an appeals process is put in place for applicants who have been denied approval by the ECART. Applicants who have been denied approval to perform PGD-HLA, or any new application, should have an avenue to have their claim reconsidered. This could be performed by a subcommittee of ACART.

Although decisions of ACART and ECART may be subject to judicial review on grounds of either substantive or procedural invalidity, this process is time consuming and costly. It is possible that a complaint to the ombudsman may be utilised as a vehicle for review.[598]

In contrast, section 149 of the Victorian Infertility Treatment Act 1995 provides an appeal mechanism to the Administrative Appeals Tribunal under the Act where an application is declined by the Authority.[599] Appeals may only be made by a person aggrieved by the decision of the Authority.[600]

In the UK, the HFEA is required to establish Licence Committees to discharge the Authority's functions relating to the granting of licences under the Act.[601] The Human Fertilisation and Embryology (Licence Committee and Appeals) Regulation 1991[602] sets out the composition and procedure of Licence Committees. A licence committee must have five members.[603] If a licence is approved, the centre will be informed and the procedure may be carried out. If a licence committee refuses a licence application, the applicant may appeal under section 20 of the Act.

An Appeal Committee consists of at least five members of the Authority.[604] An appeal is by way of rehearing by the Authority. Any member who took part in the initial licence committee work is disqualified from sitting on the appeal.[605] The appellant is entitled to appear or be represented, as are the members of the licence committee.[606] The HFEA is precluded from taking into account anything adduced by a member of the public, other than the grounds for his or her original complaint.[607]

5.8 REGULATORY LEGITIMACY AND THE HART ACT

Sue Kedgley, Deputy Chair of the Health Select Committee responsible for the HART Bill stated in Parliament at the time of the third reading of the HART Bill:

> *Regrettably, the Government has taken what was a really impressive bill – Dianne Yates' member's bill – that would have set up a good regulatory regime similar to one that exists in England, Canada, Australia, and other jurisdictions, and gutted it to such an extent that this legislation sets up one of the weakest, most permissive regulatory regimes for assisted human reproductive technologies in the world – a regime that relies on guidelines, rather than regulation, and a regime that bypasses Parliament completely and delegates policy-making in that highly contentious, ethical minefield area to a committee of unelected and unaccountable experts meeting behind closed doors.*[608]

It is doubtful whether such stinging criticism is warranted. As already discussed, the HART Act designates the outer limits of ART and research by providing express prohibitions for some assisted reproductive procedures and research.[609] Section 11 of the Act has entrenched the prohibition against PGD to determine sex for non-medical reasons as well as precluding a person from performing any assisted reproductive procedure or providing, prescribing or administering any thing in order to increase the likelihood that an embryo will be of a particular sex. The particular section is somewhat over zealous, potentially prohibiting a wider range of activities than it needs to.

The underlying philosophy of the HART Act 2004 cannot be described as liberal, in contrast to the UK Human Fertilisation and Embryology Act 1990. The UK Act has virtually authorised unfettered decision-making by the HFEA in regard to PGD and HLA tissue typing. Because of the broad discretion conferred on the HFEA, mechanisms present in the Act which would have provided Parliamentary oversight when extending the procedures for which licences could be given, such as PGD in conjunction with HLA tissue typing, were not invoked.

However, the New Zealand Act has successfully achieved a flexible regulatory framework in relation to PGD, with the exception of sex selection. The regime is significantly less liberal than the United Kingdom. However, a particular strength of the New Zealand framework is the ability for assisted reproductive procedures to be declared to be 'established' on the basis of scientific and ethical analysis provided by ACART. Such a mechanism enables regulators to impose the least necessary regulatory intervention when there is no evidence that regulatory oversight is required. There is also a safeguard provided under the Act in that ACART may provide the Minister with advice as to whether any established procedure should be modified or should cease to be an established procedure.[610]

The structure set up by the UK HFE Act 1990 has often been referred to as a system worthy of emulating,[611] and much may be learned from the rich history of the Act and the HFEA since its inception. However, the Human Fertilisation and Embryology Act has been the subject of several legal challenges over its fifteen years of existence.[612] It has been at the heart of intense scrutiny and debate in the last two years in particular. It has been claimed that the HFEA method of licensing and inspection of clinics is unduly expensive and duplicative.[613] Alarmingly, the House of Commons review highlighted inadequacies in quality assurance and

safety aspects in regard to licensing inspections carried out by the HFEA. In contrast, the New Zealand system is not overly bureaucratic, in terms of health and safety, and does not impose additional costs on providers above those that they have been incurring on a voluntary basis prior to the legislation being enacted.[614] In addition, New Zealand is the only jurisdiction of those reviewed which has made state funding available for use of PGD.

Decisions of the HFEA have allegedly lacked transparency and initial public consultation before permitting HLA tissue typing and in extending PGD to test for susceptibility to childhood cancers such as familial adenomatous polyposis.[615] It is clear that although the HFE Act 1990 confers enormous discretion on the HFEA, decisions which appear to be have been made arbitrarily and that are disconnected from public input impact negatively on whether policy is perceived as legitimate by the public, by professionals and the Government.

The New Zealand HART Act requires that the public be given an opportunity to make submissions on proposed guidelines in relation to PGD. This attempts to ensure 'deliberative democracy' as a part of the regulatory process. Such consultation attempts to ensure that it is not medical or scientific utility alone that is taken into account in decision-making, but the perceived impact of the activity by the public.

In addition, ACART must consult with interested parties and members of the public that they consider are appropriate. Yet for policy to be seen as democratic and legitimate, genuine engagement with stakeholders and the public in general must go further than this. The need for the existing policy, effectively 'inherited' by the newly appointed ACART, to be reviewed goes hand in hand with a need to ensure that both the ACART and ECART discharge their statutory duties in such a way that enables them to create and apply policy legitimately, openly and fairly.

In order to achieve regulatory legitimacy, policy must be perceived by the public as being legitimately made, regardless of their views at to the appropriateness of the policy.[616] It is essential that ACART obtains robust, non-partisan scientific evidence, and it is well informed of competing moral views, and the merits of those moral views. In a pluralistic society, it is important that policy makers, who are essentially creating quasi-law, are perceived to be listening to all (reasonable) voices in the debate. As McCarthy says:

> *An ongoing, and perhaps permanent, feature of free societies is that reasonable people disagree on basic values. In such conditions, there are really only two choices. One is to have a society in which whichever interest group happens to achieve the balance of power gets to force its values on others who can reasonably disagree with those values. The other is to have a society in which value disputes are resolved in a way in which no one can reasonably reject.*[617] *(emphasis added)*

This is particularly so when some groups may feel excluded from the composition of ACART. A diverse composition is generally viewed as enhancing deliberative democracy. Yet there is no one on the ACART who subscribes to the view that embryos deserve full moral status. Interest groups who hold such views may subsequently feel disenfranchised. It should be documented, when policy is released, how such different views were considered, but most importantly, they must be acknowledged.

In the absence of reaching a consensus view on policy issues, ACART is to determine questions by simple majority vote.[618] This has raised alarm in some quarters. However, the real issue is not whether consensus is reached in decision-making; rather it is the robustness of the debate and the range of views considered. This should be reflected in the reasons given for policy decisions. Providing information as to whether a decision was made unanimously, or whether it was a split decision may also demonstrate transparent and open decision-making, which may enhance how ACART processes are perceived. Objective transparency is a key means of engendering public trust.[619]

CONCLUSION

The New Zealand HART Act seeks to provide a means for the provision of ART within a flexible protective framework. The Act does not prioritise the interests of any particular stakeholder, but arguably requires consideration of the wider interests of society in regards to assisted reproductive procedures.

The New Zealand HART Act may, like the United Kingdom's HFE Act, be similarly described as a pragmatic response to the public and political concerns evoked by the use of reprogenetic technologies such as PGD. Social sex selection has been statutorily prohibited as a result of a last minute amendment to the HART SOP, inserted to avoid allegations of comparative permissiveness. In all other respects, the Act confers on ACART the role of balancing individual rights and public policy in the area of preimplantation genetic diagnosis. This is subject to constraints which require ACART to act in accordance with the principles declared in the Act, and to engage with the public and interested parties prior to formulating policy.

With the exception of sex selection, the regulatory framework for PGD as it stands now was essentially determined prior to ACART being appointed. There is much for the ACART to address. The established procedures policy does not define a familial single gene disorder, which may create some uncertainty as to the ambit of permissible PGD in New Zealand. On a plain reading of the Order in Council, late onset and low penetrance conditions are included as established procedures. By encompassing late onset and low penetrance conditions, the established procedures category extends PGD beyond the scope of public consultation carried out.

This wide scope of permissible PGD which does not require external oversight by ECART is also in tension with the rigid prohibition in relation to sex selection, and the restrictive policy in regard to HLA tissue typing. The HLA policy restricts tissue typing to situations where embryo biopsy for a genetic condition is clinically indicated, and HLA tissue typing is an add-on to the primary procedure. This mandates revision of the Guidelines, which restrict tissue typing to cases where the sick child is suffering from a genetic disorder. If embryo biopsy is indicated, then it becomes irrelevant whether or not the sick child is suffering from a genetically heritable disorder. For this reason, the Guidelines should be amended to require simply that the affected child be suffering from a condition which is severe or life-threatening. There is also a need to determine whether the current restrictive HLA policy is justifiable. The 'protection and promotion of the health, safety and dignity and rights' of New Zealanders may be better achieved by permitting parents to make a case to the ethics committee for HLA tissue typing as a stand alone procedure.

The comparison with Victoria has also highlighted gaps in the current regulatory framework. Victorian Guidelines permit the use of PGD to select against carrier embryos in certain circumstances. The Infertility Treatment Authority will also consider applications to perform PGD where there is a higher incidence of a condition in one sex in a particular family, but there is inconclusive genetic evidence about the transmission of that condition. The policy developed by the ITA has resulted in a comparatively liberal approach to the conditions which PGD may be used to detect. This is notable for two reasons. Firstly, the Infertility Treatment Act 1995 (Vic) is widely perceived as a non-liberal piece of legislation. Secondly, the liberal policy has been created without undertaking public consultation and has seemingly not attracted criticism from either the public, or the Victorian Government, in contrast to the experience of the United Kingdom

The success of the ACART will depend in large part on how it undertakes its policy-making role in the future. The Committee will be judged on whether its policies can be justified on the basis of the underlying principles of the Act, whether they are proportionate to perceived risks, are consistent, and transparently made. It is important that ACART obtains robust, non-partisan scientific evidence. In addition, ACART must be well informed on competing moral views. The competing moral views that have been taken into account by ACART should be documented alongside policy that is released.

It is a concern that the New Zealand regulatory framework does not make any provision for natural justice or an appeal process. The success of ECART's deliberations rests on whether they are perceived to be conducted fairly and transparently. Both the Victorian and United Kingdom regimes provide appeals processes, and the HFEA now permit applicants to appear before them. It is important that these matters are addressed by ACART and ECART as a matter of administrative fairness.

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APPENDIX I

Models of Regulation for PGD (Lexi Neame, Poster Presentation, ITA, Melbourne, Victoria, Australia, 2004)

	Professional Guidelines	Facilitative Legislation	Restrictive Legislation	Prohibitive Legislation
Method of regulation	Voluntary peer review process	Legislation and delegation to statutory body	Comprehensive legislation	Legislation banning procedures
Rationale	Reproductive rights Individual autonomy Scientific freedom	Need to monitor developments in technology Need to prohibit certain uses of technology	Circumscribe the use of PGD Prevent its expansion beyond limited parameters	May be related to religious, cultural or historical considerations
Characterised by	Variable compliance with professional guidelines Use of PGD for wide range of indications, including non-medical ones Pioneering new developments in the technology Contested applications	Broad legislative framework Use of gatekeeper function Tendency towards permissiveness Established clinical indicators for PGD	Narrow legislative frame – statutory provisions that are as precise as possible in specifying acceptable indications for PGD Case-by-case assessment, which leads to high levels of bureaucratisation No distinction between clinical and experimental indications for PGD	*Express prohibition:* direct legal injunction against PGD *Effective prohibition*: secondary requirements that render the status of PGD unclear, or prevent licensing by the relevant agency, or prohibit research on embryos, or research that is not for the benefit of the embryo
Potential outcomes	Social sex selection Preimplantation HLA High levels of innovation	Regulation is adaptable – new technologies are subject to significant oversight, with a view to becoming clinical practice	Genetic testing but no aneuploidy or vice versa No medical sex selection Very limited indicators Case-by-case approval for all PGD Framed in research protocols	No PGD Reproductive tourism Performed illegally
Criticisms	Individual interests of professionals and/or prospective parents override public concerns	May be perceived as increasingly permissive	Inflexible regulatory processes Ill equipped to integrate scientific and technological developments into regulation May be experienced as arbitrary May not distinguish between clinical practice and experimental procedures	Limits the reproductive options of people at risk of transmitting a genetic condition
Jurisdictions	USA; New South Wales and Queensland, Australia; India	UK; Victoria, Australia; Canada; New Zealand	France; Slovenia; Netherlands	Italy; Germany; Austria; Switzerland; Ireland

APPENDIX 2

GUIDELINES ON PREIMPLANTATION GENETIC DIAGNOSIS[620]

SECTION ONE

Uses of PGD not requiring NECAHR approval - Now Established Procedures

Familial Single Gene Disorders

1. PGD for familial single gene disorders may be carried out where:
   1.1 the disorder has been identified in the family/whānau and
   1.2 there is a 25% or greater risk of an affected pregnancy and
   1.3 there is evidence that the future individual may be seriously impaired as a result of the disorder.

Familial Sex-linked Disorders

2. Sex determination for familial sex-linked disorders may be carried out where:
   2.1 the disorder has been identified in the family/whānau and
   2.2 there is a 25% or greater risk of an affected pregnancy and
   2.3 no specific test for the particular mutation that causes the disorder is available and
   2.4 there is evidence that the future individual may be seriously impaired as a result of the disorder.

Familial Chromosomal Disorders

3. PGD for familial chromosomal disorders may be carried out where:
   3.1 the disorder has been identified in the family/whānau and
   3.2 there is evidence that the future individual may be seriously impaired as a result of the disorder.

Non-familial Chromosomal Disorders Associated with Advanced Reproductive Age

4. PGD for non-familial chromosomal disorders (aneuploidy testing) may be carried out where:
   4.1 the woman is of an advanced reproductive age.

Non-familial Chromosomal Disorders Associated with Infertility

5. PGD for non-familial chromosomal disorders (aneuploidy testing) may be carried out where:
   5.1 the woman has had recurrent implantation failure or recurrent miscarriage.

Determination of a Serious Disorder

6. It is the responsibility of PGD providers, in collaboration with a clinical geneticist, to determine whether a disorder is likely to be serious in the offspring.

SECTION TWO

Uses of PGD requiring NECAHR approval – Now Regulated by the Advisory Committee and Ethics Committee

PGD with Human Leukocyte Antigen (HLA) Tissue Typing

7. HLA tissue typing in conjunction with PGD must be submitted to NECAHR for ethics approval on a case-by-case basis and may only be carried out where:

Affected Child

7.1 the affected child suffers from a familial single gene disorder or a familial sex-linked disorder and

7.2 no other possibilities for treatment or sources of tissue are available and

7.3 the planned treatment for the affected child will utilise only the cord blood of the future sibling and

Embryo

7.4 the embryo will be a sibling of the affected child and

7.5 the embryo is at risk of being affected by a familial single gene disorder or a familial sex-linked disorder for which a PGD test is available and

Family/Whānau

7.6 the health and wellbeing of the family/whānau has been fully considered.

SECTION THREE - PROHIBITED USES OF PGD

8. PGD may not be carried out for the following:

8.1 social reasons, including sex selection

8.2 to alter the genetic constitution of an embryo

8.3 to select embryos with a genetic impairment seen in a parent

8.4 any reason other than those specified in sections one and two.

SECTION FOUR - INFORMATION AND COUNSELLING

INFORMATION

9. Providers must ensure that those seeking PGD are given all of the information relevant for informed decision-making, and this must include reference to the following:

9.1 the processes and procedures associated with IVF and PGD

9.2 the risks associated with the procedures

9.3 the background and experience of the clinic and clinicians

9.4 the success rate of the procedure, both in general, and at that particular clinic

9.5 the alternatives to PGD.

10. Providers must ensure that those seeking PGD are given all of the following information prior to giving consent:
    10.1 genetic and clinical information about the specific disorder/infertility
    10.2 the likely impact of the disorder/infertility on those affected and their families/whānau
    10.3 information about treatment, counselling, and the extent of community and social support available
    10.4 the availability of prenatal testing following successful implantation
    10.5 NECAHR's requirement for providers to supply information for the Committee's annual report as specified in guideline 17.

Counselling for People with Familial Disorders

11. Providers must ensure that those seeking PGD for familial disorders receive genetic and psychosocial counselling from qualified counsellors who are trained in genetic counselling.

12. Counselling must be culturally appropriate and include consideration of the following:
    12.1 the nature of the disorder, its likely impact on the offspring and family/whānau and the availability of treatment
    12.2 the family/whānau experience of the genetic disorder
    12.3 the range of alternatives to PGD and subsequent decision-making processes
    12.4 the possible implications of undertaking PGD.

Counselling for People with Non-familial Disorders

13. Providers must ensure that those seeking PGD for non-familial disorders receive psychosocial counselling from a qualified counsellor.

14. Counselling must be culturally appropriate and include consideration of the following issues:
    14.1 the range of alternatives to PGD and subsequent decision-making processes
    14.2 the possible implications of undertaking PGD.

SECTION FIVE - PROCEDURAL REQUIREMENTS

Accreditation

15. All clinics wishing to provide PGD must be accredited by, and meet any requirements regarding the provision of PGD of, the Reproductive Technology Accreditation Committee of the Fertility Society of Australia.

NECAHR Approval

16. All clinics wishing to provide PGD must apply to NECAHR for approval using the innovative treatment application form.

Annual Reporting

17. Each clinic that is given approval to perform PGD must submit an annual report to NECAHR, which will include:
    - 17.1 the number of PGD procedures carried out for familial disorders, and the genetic condition for each procedure
    - 17.2 the number of PGD procedures carried out for non-familial disorders, and the medical indications leading to the use of PGD
    - 17.3 the outcomes of each procedure (to be reported in the following year), including results from any subsequent genetic testing
    - 17.4 any ethical issues that have arisen during the course of treatment
    - 17.5 any issues that have emerged during counselling that could have long-term impact on the offspring and their family/whānau.

APPENDIX 3

MAIN FEATURES OF THE HART BILL, ASSISTED HUMAN REPRODUCTION BILL, HART SOP, HART ACT 2004

HART Bill: (Yates) (Licensing, prevent commercialisation, require record keeping)

- Establishment of a Human Reproductive Technology Authority, that would grant licences for treatment fertility services, the storage of embryos, and research
- Prohibited a range of AHR procedures including; cloning, implanting a non human embryo in a woman and a human embryo in an animal, germ line genetic modification, sex selection, and the use of eggs from human foetuses
- Prohibited payment in connection with human embryos and gametes, surrogacy arrangements, and child, body part or foetuses
- Provided a record-keeping scheme relating to AHR treatments, and an information-keeping scheme for donor offspring

Assisted Human Reproduction Bill

- Expands role of NECAHR, review ART proposals, develop protocols and guidelines for providers on ART procedures and techniques, advise the Minister on issues
- Prohibited cloning of humans, fusing of animal and human gametes, implantation of animal or human embryos into the opposite species, use of human cells to develop procedures or techniques for undertaking any of these activities

HART SOP:
Retains certain features of the HART Bill

- Regulatory framework for assisted reproductive procedures and human reproductive research – removed licensing regime for fertility providers
- Principles to guide those operating under the legislation, with the interests of a child born as a result of assisted reproductive procedures being paramount in decisions about the use of such procedures
- Allowed for certain procedures to be declared 'established procedures'
- Established a ministerial advisory group to give advice, develop guidelines for ethics committee(s) established under act
- Provides for regulations to be made by on recommendation of Minister
- Removed prohibition on germ line genetic modification, sex selection, mandatory genetic screening, the use of eggs from foetuses, and non-reproductive cloning. Requires MAC to give advice to Minister before applications relating to these activities could be considered for ethical approval

- Protection against the commercialisation of surrogacy, embryos and gametes
- Prohibitions relating to particular activities including reproductive cloning, and the implantation of an human embryo in an animal or vice versa
- Creates a duty to stop an embryo developing beyond 14 days outside a human body
- A record keeping regime, and provisions for access to information about donors and donor offspring
- Regulation of fertility service providers under the HDS(S) Act.

HART Act (modifications by health committee)

- Additional purpose: bill intended to protect and promote the health, safety, dignity and rights of all individuals, particularly women and children, in the use of assisted reproductive procedures and reproductive research
- Additional purpose statement about the intention of the legislation to secure the benefits of assisted reproductive procedures and human reproductive research
- Additional principles: 'human health, safety, and dignity of present and future generations should be preserved and promoted', 'women, more than men, are directly and significantly affected by the application of assisted reproductive procedures *and established procedures*, and the health and well-being of women must be protected in the use of these procedures
- Amended the principle that a child's health and well-being born as a result of assisted human reproduction should be 'paramount' to 'an important consideration'
- Amended functions of advisory committee to include giving advice on whether a moratorium should be imposed on any assisted reproductive procedure or human reproductive research and whether regulations should be made
- Strengthened requirements to be met before an assisted reproductive procedure can be declared an established procedure by requiring that the advisory committee must, before providing advice to the minister, furnish information about the procedure or treatment, an assessment of known risks and benefits, an assessment of whether that risk is acceptable, and an ethical analysis
- Strengthened advisory committee guideline process by requiring the committee to consider public submissions before issuing guidelines
- Guidelines to be presented to the House of Representatives (does not require approval of the House)
- Strengthened advisory committee duty to consult before providing significant advice to minister
- Additional prohibition against the genetic modification of gametes and embryos for reproductive purposes

- Permitted sex selection if the purpose was to prevent or treat a genetic disorder. Restricted any action that would ensure, or increase the probability that an embryo would be of a particular sex unless to prevent or treat a genetic disorder
- Removed proposal in the SOP that additions to the list of prohibited actions be allowed to be made by order in council, on recommendation of Minister, commencing only with approval of house, now requires amending legislation (but what about removing from list, isn't that the greatest concern?)

ENDNOTES

1 *In this report 'assisted reproductive technology' is referred to only in relation to human assisted reproductive technology.*

2 *The State of Victoria, Australia, was the first to enact legislation in 1984 with the enactment of the Infertility (Medical Procedures) Act 1984. It included a strict regime of regulation based essentially on criminal penalties, prohibiting experimental procedures which had not been reviewed by the Standing Review and Advisory Committee on Infertility. This was followed by legislation introduced in South Australia, (Reproductive Technology Act 1988), the UK, (Human Fertilisation and Embryology Act 1990) and later Western Australia, (Human Reproductive Technology Act 1991 (WA). See Chalmers, D., 'Professional Self-Regulation and Guidelines in Assisted Reproduction' (2002) 9 JLM 414- 420.*

3 *Reproductive genetics, also increasingly referred to as 'reprogenetics', is the merging of two distinct sciences: human assisted reproduction and human genetics. For an article discussing the social and practical harms that result from the 'pathologization' of traits in the context of regulatory models, see 'Regulating Preimplantation Genetic Diagnosis: The Pathologization Problem' 118 Harvard Law Review 2770-2799, (2005).*

4 *There is much debate as to what term should be used to describe embryo selection on the basis of therapeutic grounds. See 'Regulating Preimplantation Genetic Diagnosis: The Pathologization Problem' 118 Harvard Law Review 2770-2779, (2005) It is argued that labelling a PGD decision 'therapeutic' immediately pathologizes the trait at issue, thus harming people with that trait, constraining reproductive choices surrounding it, and ossifying negative social attitudes toward it. It is difficult to see how this may be avoided.*

5 *Exceptions to this are medical services such as abortion, or the provision of mental health services. When it was suggested in the United States that an oversight mechanism should be introduced for assisted human reproductive technology, reproductive technologists argued that they should not be singled out for regulations that do not apply to other areas of medicine. See ISLAT Working Group, 'ART into Science: Regulation of Fertility Techniques' (1998) 281 Science 651.*

6 *See Human Assisted Reproductive Technology Order 2005, 2005/181, effective from 22 August 2005.*

7 *See HART Act 2004, s83(2).*

8 *Section 83(1) of the HART Act 2004 provides that the interim period ends three years after the Act receives the Royal Assent. Hence the interim period will expire on 21 November 2007.*

9 *Marjoribanks et al, Systematic Review of the Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis (PGD), Advice for the National Ethics Committee on Assisted Human Reproduction and the Ministry of Health, September 2004.*

10 *Marjoribanks et al, Systematic Review of the Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis (PGD), Advice for the National Ethics Committee on Assisted Human Reproduction and the Ministry of Health, September 2004, 4.*

11 *These approved guidelines will be referred to as the 'Guidelines' whilst the proposed guidelines sent out for public consultation will be referred to simply as the proposed guidelines.*

12 *There are other changes in terminology which, although important, will not be analysed, as the focus here is on the changes which increase the scope of authorised PGD. (Eg, where 'family' appears in the Proposed Guidelines, it has been changed to 'family/whanau' in the Approved Guidelines).*

13 *Take for example haemophilia A and B which is a sex linked heritable condition. It is not permitted to sex select against this diseases, as it is possible to reliably assess the mutation in the FVIII or FIX genes. Abstracts – 6th International Symposium on Preimplantation Genetics 2005, Oral Presentation)-33.*

14 *This is consistent with the terminology used in the HFE Act 1990 which provides that there must be a 'significant risk of a serious genetic condition'.*

15 *It has been reported in the United States that PGD is most commonly used to detect aneuploidies. See Reproduction and Responsibility: The Regulation of New Biotechnologies, The President's Council on Bioethics, Washington, DC, March 2004, Chapter 3, available at http://www.bioethics.gov (accessed on 15/8/2005).*

16 *Note that there are two ways of interpreting this provision. The first is that it relates to the degree of likelihood of the disorder manifesting itself in the offspring being determined by clinicians. The other is that it leaves the question of whether a disorder is a serious disorder up to clinicians.*

17 *Leschot, N., Cobben, J. and Brocker-Vriends, A., 'Case I: Prenatal Testing for Hereditary Breast Cancer' in Galjaard, H. and Noor, L. (eds) Prenatal Testing, New Developments and Ethical Dilemmas, Amsterdam, Royal Netherlands Academy of Arts and Sciences, 2004, 21.*

18 *Draper, H. and Chadwick, R., 'Beware! Preimplantation Genetic Diagnosis May Solve Some Old Problems But It Also Raises New Ones' in McLean, S.A.M. (ed) Genetics and Gene Therapy, Aldershot, Ashgate 2005, 351.*

19 *Possible examples of single gene disorders that have (arguably) little impact on the quality of life of an individual include: colour blindness (monogenic sex-linked disorder), and male pattern baldness (major cause is a single dominant autosomal gene).*

20 *For example, the Contraception, Sterilisation and Abortion Act 1977, cl 46 permits a provider to refuse to perform an abortion on the grounds of conscience. This has been exercised recently in New Zealand with some providers in the Waitemata Health Board area refusing to perform late second semester terminations on mental health grounds. The Health Board has consequently funded women going to Australia for terminations. See http://www.nzherald.co.nz/category/story.cfm?c_id=204&ObjectID=10372135*

21 *Leschot, N., Cobben, J, and Brocker-Vriends, A., op cit.*

22 *Tilstone, C., 'UK Clinicians to Screen for BRCA Mutations' 6 Lancet Oncol 358 (2005).*

23 *See Press Release, 11 August 2005, 'Should Embryo Screening Help Parents Prevent Passing on a Wider Range of Inheritable Diseases?' available at http://www.hfea.gov.uk/PressOffice/Archive/1123751318 (accessed on 6/09/2005)*

24 *See Leading Edge, 'Screening for Disease: How Far is Too Far?' 4 Lancet Neurology 1, (2005).*

25 *Id. 'In defence of the HFEA's decision, each licence application is peer reviewed by experts in PGD and the disease in question, and the disease in question, and several important factors are taken in to consideration. For example, is there a treatment available for the disease, or is one likely to be developed in the near future? Does the disease strike early in life or is onset in adulthood? Does the disease cause substantial suffering? Although answers to these questions are not clear-cut, they provide an ethical framework for HFEA's decision-making. The authority approves licences for PGD on a case-by-case basis.'*

26 *This is affirmed by the criticism of the HFEA by the House of Commons Science and Technology Committee in relation to the release of the policy on preimplantation HLA testing in 2002.*

27 *Personal communication via letter, Kathy Spencer, Deputy Director-General, Sector Policy Directorate, Ministry of Health, 20 December 2005.*

28 *Personal communication via letter, Kathy Spencer, Deputy Director General, Sector Policy Directorate, Ministry of Health.*

29 *Devolder, K., 'Preimplantation HLA Typing: Having Children to Save Our Loved Ones' 31 J Med Ethics 582 (2005).*

30 *Devolder goes so far as to say 'in my opinion, this makes the moral case for PGD for HLA typing even stronger than the moral case for PGD for selection against genetic disease'. See Ibid, at p. 583.*

31 *Schedule 1 of the HART Act 2004 simply prohibits the implanting into a human being a genetically modified gamete, human embryo, or hybrid embryo.*

32 *'Regulating Preimplantation Genetic Diagnosis: The Pathologization Problem' 118 Harvard Law Review 2770-2779, at p. 2779, (2005)*

33 *Draper and Chadwick, loc cit., at p. 349.*

34 *Single gene disorders may have variable expressivity which influences the nature and severity of the phenotype. For example Marfan Syndrome occurs as a result of a mutation in the gene for fibrillin, which affects the connective tissues of the body. The organs primarily affected are the skeletal system (long, thin extremities and fingers, lax joints, bony deformities of the spine and sternum), the eye (severe nearsightedness and dislocation of the lens), and the heart (valvular incompetence, widening of the root of the aorta, and sometimes dissection of the aorta and sudden death). Variable expressivity means that an individual with Marfan syndrome may have involvement of only two of all three major systems, and the severity of the manifestations may vary widely. See Gelehrter, T., Collins,F. and Ginsburg, D., Principles of Medical Genetics (2nd ed), United States, Williams & Wilkins, 1998, at p. 29.*

35 *Section 1, clause 6.*

36 *It is reported that many people who have undergone PGD decline prenatal testing as they are reluctant to risk their pregnancy. See Kalfoglou, A., 'PGD Patient's and Providers' Attitudes to the Use and Regulation of Preimplantation Genetic Diagnosis' 11 RBM Online 486, 49, (2005). Laver et al, 'Preimplantation Genetic Diagnosis: Patient's Experiences and Attitudes, 17 Hum Rep 2464, at p. 2467, (2002). See also Marjoribanks et al, Systematic Review of the quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis (PGD) Advice for the National Ethics Committee on Assisted Human Reproduction and the Ministry of Health, prepared by the Cochrane Menstrual Disorders and Subfertility Group (CMDSG) for the New Zealand Guidelines Group, September 2004 at p 24.*

37 *RTAC adopted the National Health and Medical Research Council guidelines, see p 12 Reprogenetics, Whose Rules Apply*

38 *Human Assisted Reproductive Technology Act 2004, s83(2). This requirement should be published in the Gazette. See Human Assisted Reproductive Technology Act 2004, s83(3).*
39 *See New Zealand Gazette, No. 123, 11 August 2005, 3010.*
40 *See Human Assisted Reproductive Technology Act 2004, s83(1).*
41 *See Human Assisted Reproductive Technology Act 2004, s16(2). However the fine is greater if sex selection is carried out in breach of section 11 of the Hart Act 2004.*
42 *See Skene, L., 'Why Legislate on Assisted Reproduction?' in Freckleton I and Petersen, K., (eds) Controversies in Health Law, Sydney, Federation Press, 1999 266, at p. 270. The author described a regulatory regime similar to that set up in New Zealand, a 'statutory body could be established with broad powers to advise government on issues arising from time to time in reproductive technology and to develop and oversee a code of practice or licensing system, which is in effect a form of delegated legislation'. The Green party was also of the opinion that the Guidelines would have a similar status as delegated legislation; 'These 'guidelines' will not only set out policy on a wide range of assisted reproductive procedures: they will be in reality binding legal instruments, or a form of delegated legislation, that will determine which assisted human reproduction procedures or research may be approved by the ethics committee.' Report of the Health Committee, Human Assisted Reproductive Technology Bill, 6 August 2004, 14.*
43 *Three years earlier in 1995, an Officials' Committee was established to make recommendations to the Government on the implementation of the Ministerial Committee on Assisted Reproductive Technologies Report, entitled Assisted Human Reproduction - Navigating our Future (MCART, 1994). MCART, which had been appointed by Justice Minister Mr Graham, had recommended establishing a Council of Assisted Human Reproduction, with a role to advise ministers, develop policy and assist in the preparation of Codes of Practice and Guidelines. However the Officials' Committee recommended that policy development and codes of practice could be taken on by NECAHR. One of the reasons given for this preference was 'the cost to the taxpayer'. See Coney, S. and Else, A., Protecting Our Future, Auckland, Women's Health Action, 1999, at p. 27.*
44 *This Bill will be subsequently referred to as the Human Assisted Reproductive Technology Bill, as amended by Supplementary Order Paper No. 80, 2003.*
45 *Report of the Health Committee, Human Assisted Reproductive Technology Bill, 6 August 2004, 195-2.*
46 *Because of the lapse of time since submissions were received on the Human Assisted Reproductive Technology Bill (Yates), the Assisted Human Reproduction Bill and the introduction of the Supplementary Order Paper, the health committee returned submissions received by previous Health Committees, and invited submitters to resubmit. Seventy nine submissions and 25 form submissions on the HART Bill and SOP were received.*
47 *However, this may have been moderated to an extent by a later amendment to the section dealing with the composition of the advisory committee. The amendment required that one or more members with the ability to articulate the interests of children be included on the advisory committee, and who must, at the time of his or her appointment, hold the office of children's commissioner or be a representative or employee of that office.*
48 *Report of the Health Committee, Human Assisted Reproductive Technology Bill, 6 August 2004, 195-2, 10.*
49 *Robertson, J., 'Extending Preimplantation Genetic Diagnosis: Medical and Non-Medical Uses', 29 Journal Med Ethics, 213, (2003).*
50 *Steve Chadwick, Chairperson Health Committee, Hansard, HART Bill third reading, 16846, 10 Nov 2004.*
51 *Report of the Health Committee, Human Assisted Reproductive Technology Bill, 6 August 2004, 195-2, 2.*
52 *Hansard, Human Assisted Reproductive Technology Bill, third reading, 10 Nov 2004, 16832.*
53 *Hansard, Human Assisted Reproductive Technology Bill, third reading, 10 Nov 2004, 16839.*
54 *Report of the Health Committee, Human Assisted Reproductive Technology Bill, 6 August 2004, 14. Although the Greens voted in support of the Act, it was on the basis that it provided some safeguards, and prohibited the worst excesses of assisted human reproductive technology, specifically the genetic engineering of humans and the sex selection of embryos other than for serious genetic disease.*
55 *The legislative history of the Bill: Introduction and First reading (195-1) 27 June 1996; Second Reading 23 April 1997; HART Bill as Amended by Supplementary Order Paper No, 80 2003, 29 April 2003; Reported from Health Committee (Bill 195-2) 6 August 2004; Consideration of report, 25 August 2004; Committee of the whole House (Bill 195-3), 6, & 20 October 20004; Assented to as Act 2004 No 92, 21 November 2004.*
56 *Human Assisted Reproductive Technology Act 2004,s3(a).*
57 *Human Assisted Reproductive Technology Act 2004, 3(d).*
58 *Human Assisted Reproductive Technology Act 2004, s3(e). Other purposes not mentioned infra are (c) to prohibit certain commercial transactions relating to human reproduction: (f) to establish a comprehensive information-keeping regime to ensure that people born from donated embryos or donated cells can find out about their genetic origins.*
59 *Human Assisted Reproductive Technology Act 2004, s3(b).*
60 *Human Assisted Reproductive Technology Act 2004, s4(a).*
61 *Human Assisted Reproductive Technology Act 2004, s4(b).*
62 *Human Assisted Reproductive Technology Act 2004, s 4(c). This principle was drawn from the Canadian legislation. See Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee' POL (04) 147, 21 June 2004, p. 6.*

63 *Human Assisted Reproductive Technology Act 2004, s4(g).*

64 *Human Assisted Reproductive Technology Act 2004, 4(f).*

65 *Although it should be noted that the New Zealand Public Health and Disability Act 2000 sets out mechanisms to enable Māori to contribute to decision-making on, and to participate in the delivery of, health and disability services in order to recognise and respect the principles of the Treaty of Waitangi, and with a view to improving health outcomes for Māori. See New Zealand Public Health and Disability Act 2000 s4, and Part 3. See also section 4 of the Hazardous Substances and New Organisms Act 1996 which provides that the purpose of the Act is to 'protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms'. Matters relevant to the purpose of the Act are set out in section 6. This sets out mandatory considerations that all persons exercising functions, powers and duties under the Act shall take into account, and includes (d) The relationship of Māori and their culture and traditions with their ancestral lands, water, sites, waahi tapu, valued flora and fauna, and other taonga.*

66 *However, the Act provided for the promulgation of a Code of Rights for health consumers and disability service consumers under section s. 20(1) of the Health and Disability Commissioner Act 1994. The Act specified certain rights of health consumers and obligations of health care providers that should be provided for in the proposed Code of Rights to be drafted pursuant to the Act. In particular, it specified that regulations should provide for rights and duties in relation to 'the provision of services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups. See Health and Disability Commissioner Act 1994, s20(1)(c)(iii). The subsequent Code included in Right 1(3) that "every consumer has the right to be provided with services that take into account the needs, values and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Māori".*

67 *See Human Assisted Reproductive Technology Bill, 195-1, s3(f).*

68 *See Cabinet Education and Health Committee, 'Assisted Human Reproduction' EHC (01) 28, 7 June 2001, p 10. Released Under the Official Information Act.*

69 *See Report of the Health Committee, Human Assisted Reproductive Technology Bill, 6 August 2004, 195-2, 5.*

70 *See Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee' POL (04) 147, 21 June 2004, p4. Released under the Official Information Act. It was noted in this document that Crown Law advised that the word 'paramount' in the principle on the health and well-being of children; created structural difficulties for the operation of the Act; gives rise to an increased risk of Crown liability; and creates a conflict between this principle and the new purpose of securing the benefits of assisted reproductive procedures. In this context the individuals being protected under the Act are not only those persons seeking PGD or the child produced by the assisted reproductive procedure or established procedure, but also the professionals performing the procedures, the statutory advisory committee and ethics committee, and the Government.*

71 *The New Zealand Fertility Clinics submission was made by all New Zealand Assisted Reproductive Technology clinics.*

72 *See Human Reproductive Technologies and the Law, House of Commons Select Committee on Science and Technology, Fifth Report of the 2004-2005 Session, HC 7-1, at p. 49.*

73 *See X v Y [2004] 2 NZLR 847, alt cit K v R, KR v MR. This case involved a 29 year old woman who had a rare congenital disorder called Partial Trisomy 8. She suffered from a mild intellectual disability, developmental delays and certain physical characteristics unique to Partial Trisomy 8. KR had been receiving regular contraceptive injections but became pregnant after stopping the injections. KR wanted to give birth and raise a child. KR's father had been appointed as her welfare guardian under s 12 of the Protection of Personal and Property Rights Act 1988. He applied to the Family Court under s 10 of the Act for orders that the pregnancy be terminated and for KR's sterilisation. A conference was convened by the Family Court under s 66 of the Act. The Court heard evidence and reports from MR, a consultant psychiatrist and KR's medical practitioner. The Family Court had directed that the medical evidence should address KR's capacity and the least restrictive outcome for her having regard to the welfare of the subject person and the extent of the incapacity of the person to make informed decisions in relation to his or her welfare. It was held that an approach that rested on the welfare principle and the statutory criteria precluded a rule that sterilisation could never be ordered for contraceptive purposes. To read such a rule into the Act was to determine in the abstract that sterilisation could never be the least restrictive outcome that was appropriate having regard to the person's degree of incapacity and circumstances.*

74 *It has been reported that in some Australian clinics assisted reproductive procedures have been refused on fitness to parent grounds. In a study of 15 clinics in New South Wales and Victoria it was reported that although it was unusual for clinicians to view a patient as unfit to parent, there were cases in which clinics refused treatment on these grounds. These refusals were based upon reports from child protection authorities or family services. One clinic had declined to treat a patient with a severe physical handicap who was not seen to be able to cope with a child. See Petersen, K., Baker, H. Pitts, M and Thorpe, R., 'Assisted Reproductive Technologies: Professional and Legal Restrictions in Australian Clinics' 12 JLM 373, at p. 382, (2005)*

75 *See St George's Healthcare NHS Trust v S [1999] FAM 26, 50, CA; Re MB (Medical Treatment) [1997] 2 FLR 426, CA.*

76 *See Human Reproductive Technologies and the Law, supra cit, at p. 49.*

77 *Right 4(2) of the Health and Disability Services Consumers' Rights Code provides that every consumer has the right to have services provided that comply with legal, professional, ethical and other relevant standards. Relevant ethical standards include the New Zealand Medical Association Code of Ethics, (March 2002) which provides that 'Doctors have the right, except in an emergency, to refuse to care for a particular patient. In any situation which is not an emergency, doctors may withdraw from or decline to provide care as long as an alternative source of care is available and that the appropriate avenue for securing this is known to the patient'. Coles Medical Practice in New Zealand. Wellington: Medical Council of New Zealand, 2005, at p 43 states that 'a doctor may only decide to discontinue seeing a patient when there is a breakdown in the patient-doctor relationship such that the doctor is rendered incompetent to treat the patient'. The Code of Rights provides that a doctor will have a defence to an alleged breach of the Code if the doctor can show that he or she took 'reasonable actions in the circumstances' which encompasses 'all relevant circumstances'. See Paterson, R., 'Calling it Quits – Ending a Doctor-Patient Relationship' New Zealand Doctor, at p 14 (15 June 2005).*

78 *Eg diamond blackfan anaemia, acute myelocytic anaemia, and other leukaemias.*

79 *Three main arguments against allowing PGD with tissue typing in these circumstances are that (i) the saviour sibling is used as a commodity, (ii) the slippery slope argument that allowing such a practice may lead to the creation of 'designer babies', (iii) child welfare argument according to which saviour siblings may be physically and/or psychologically harmed. See Sheldon, S. and Wilkinson, S., 'Should Selecting Saviour Siblings be Banned?' 30 J Med Ethics, 533, (2004).*

80 *For a discussion of justifications for minors as donors for siblings, see Thomas, C., 'Preimplantation Testing and the Protection of the 'Saviour Sibling' 9 Deakin L Rev 119, at p. 136, (2004).*

81 *Human Assisted Reproductive Technology Act 2004, s4(d). There are three further principles, 4(e) donor offspring should be made aware of their genetic origins and be able to access information about those origins: 4(f) the needs, values, and beliefs of Māori should be considered and treated with respect: 4(g) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.*

82 *Human Assisted Reproductive Technology Act 2004, s9. Sanctions for breach of this section include either a conviction and imprisonment for a term not exceeding two years, or a fine not exceeding $100 000, or both. Further, any provider and person responsible for an activity approved by an ethics committee who fails to take all practicable steps to ensure that the development of in vitro human or hybrid embryos beyond the specified time does not occur is liable to a fine of $50 000.*

83 *Human Assisted Reproductive Technology Act, s13(1) (2). No person may give or receive, or agree to give or receive, valuable consideration for the supply of a human embryo or human gamete. The Act also prohibits commercial surrogacy arrangements. See Human Assisted Reproductive Technology Act, s14.*

84 *Dickenson, D. 'Human Tissue and Global Ethics' 1 Genomics, Society and Policy 41, (2005). See also Report on the Human Fertilisation and Embryology Authority's Review of Sperm, Egg and Embryo Donation in the United Kingdom, (Seed Report) October 2005, at p. 18.*

85 *These activities include artificially forming, for reproductive purposes a cloned embryo or a hybrid embryo; implanting into a human being a cloned embryo, an animal gamete or embryo, a hybrid embryo; implanting into an animal a human gamete or human embryo, or a hybrid embryo; implanting into a human being a genetically modified gamete, human embryo, or hybrid embryo; implanting into a human being gametes derived from a foetus, or an embryo that has been formed from a gamete or gametes derived from a foetus.*

86 *Human Assisted Reproductive Technology Act 2004, s9.*

87 *Human Assisted Reproductive Technology Act 2004, s10.*

88 *Human Assisted Reproductive Technology Act 2004, s 12 prohibits obtaining or using a gamete from an individual who is under 16 years, unless it is obtained or used to preserve the gamete or to bring about the birth of a child that was, in the reasonable opinion of the person, likely to be brought up by the individual from whom the gamete was obtained.*

89 *Human Assisted Reproductive Technology Act 2004, s 15.*

90 *Human Assisted Reproductive Technology Act 2004, s11(2).*

91 *Human Assisted Reproductive Technology Act 2004, s 11(3). Note that there could be a lawful excuse under this section, but may still be breach of the established procedures order which preclude sex selection to avoid a sex-linked genetic disorder when there is a test available for that particular mutation. See Human Assisted Reproductive Technology Order 2005, 181.*

92 *Sperm sorting allows a parent to choose which sperm is to be used to fertilise an oocyte, and thus the sex of the resulting embryo. Each single spermatozoa carries either an X or Y chromosome, which will determine the sex of an embryo should fertilisation occurs. As the oocyte carries only X chromosomes, if the successful spermatozoa carries a Y chromosome a male individual will result (XY), whereas if the spermatozoa carries an X chromosome, a female will result (XX).*

93 *Throughout history people have attempted sex selection. Reportedly the Greeks thought that tying off the left testicle would produce a male because the male determining sperm were derived from the right testicle. Other methods based on the positioning and timing of intercourse, or special diets have been claimed as influencing sex of offspring. See Liao, S., 'The Ethics of Using Genetic Engineering for Sex Selection' 31 J Med Ethics 116, at p. 116, (2005).*

94 *In the UK, a consultation carried out in 1993 indicated that 93% of 165 respondents were against allowing PGD for non-medical sex selection. In 2003, that percentage had dropped to 69%. This illustrates that public opinion is fluid, and may change over time. See Report on Human Reproductive Technologies and the Law, House of Commons Select Committee, supra cit, at p. 155*

95 *See Davidson, H., 'Embryonic Stem Cell Research' Dissertation Submitted in partial fulfilment of the requirements of the degree of Master of Bioethics and Health Law, University of Otago, October 2003, 128.*

96 *Submission of the National Advisory Committee on Health and Disability Services Ethics (NEAC) on the Hart Bill, as amended by SOP No. 80, (2003).*

97 *Human Assisted Reproductive Technology Act 2004, s16. Breach of this section carries liability for a fine of up to $50 00, s16(2).*

98 *Human Assisted Reproductive Technology Act 2004, s19(3). These may include limiting the duration of the approval; or limiting the individual or individuals on whom any assisted reproductive procedure may be performed to a particular individual or to particular individuals or to a class or classes of individuals.*

99 *Human Assisted Reproductive Technology Act 2004, s19(2).*

100 *It is stated in the Terms of Reference of the Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research that ACART should monitor the decisions of the ethics committees to ensure they fall within the guidelines as intended by ACART. If, after consideration of one of ECART's decisions, ACART considers that the decision falls outside of its guidelines, ACART should inform ECART of this.*

101 *These circumstances exist if the ethics committee is satisfied that: the conditions stated in the approval have been breached, or that the activity under the approval is inconsistent with any relevant guidelines and advice issued by the advisory committee; or is inconsistent with the description set out in the application in which the approval was sought; or breaches the Act or regulations made under the Act. Approval may also be cancelled if the ethics committee becomes aware that the activity to which the approval relates poses a serious risk to human health and safety. Human Assisted Reproductive Technology Act 2004, s22(1). If the approval is cancelled, the activity must be stopped. See s23.*

102 *Human Assisted Reproductive Technology Act 2004, s27(1). Such an ethics committee may be designated for the purposes of the section or be one that has been established for another purpose, s 27(2).*

103 *Operational Standard for Ethics Committees, Ministry of Health, (2002). It is the responsibility of NEAC to update these standards in the future, pursuant to s16 (1) of the New Zealand Public Health and Disability Act 2000.*

104 *A lay person is defined in the Terms of Reference as a person who, at no time during the person's membership of ECART or in the 3 years before becoming a member of ECART; is a health practitioner within the meaning of the Health Practitioners Competence Assurance Act 2003; or is involved in health research; or is employed by or associated with, or has a pecuniary interest in, a provider.*

105 *All members of ethics committees are expected to have knowledge of the Treaty of Waitangi and its application to ethical review.*

106 *Human Assisted Reproductive Technology Act 2004, s27(3)(b).*

107 *The Operational Standard provides guidance on a number of principles that should be considered when reviewing research proposals and applications for innovative practice. It sets out consistent operational and administrative procedures common to all health and disability ethics committees.*

108 *Terms of Reference Ethics Committee on Assisted Reproductive Technology, p7. Available at http://www.newhealth.govt.nz/ecart/about.htm*

109 *This should be section 83 of the Human Assisted Reproductive Technology Act 2004.*

110 *Operational Standard for Ethics Committees, para 274.*

111 *Operational Standard, para 286.*

112 *Human Assisted Reproductive Technology Act 2004, 28(1)(d).*

113 *Human Assisted Reproductive Technology Act 2004, s33(1)(a).*

114 *Human Assisted Reproductive Technology Act 2004, s34(5). A layperson is defined as a person who, at no time during the person's membership of the Advisory Committee or in the 3 years before becoming a member of the committee, - (a) is a health practitioner within the meaning of the Health Practitioners Competence Assurance Act 2003; or (b) is involved in health research; or (c) is employed by or associated with, or has a pecuniary interest in, a provider.*

115 *Human Assisted Reproductive Technology Act 2004, s34(4)(a) – (c).*

116 *Human Assisted Reproductive Technology Act 2004, s34(4)(d) and (e).*

117 *Human Assisted Reproductive Technology Act 2004, s34(4)(g), 34(5).*

118 *This phrase was reportedly coined by Derek Morgan, see Chalmers, D., 'Reprogenetics – Whose Rules Apply? One Day Symposium' Victoria, 2004.*

119 *Human Assisted Reproductive Technology Act 2004, 33(1)(b).*

120 *Terms of Reference, Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research.*

121 *Section 33(1)(b) of the Human Assisted Reproductive Technology Act 2004 provides that the Advisory Committee may, subject to this Act and any directions that the Minister gives by written notice to the committee, regulate its procedure in any manner that the committee thinks fit. Section 42(2)(d) requires that the Minister must present a copy of a notice giving directions as to the procedure of the advisory committee under s 33(1)(b) to the House of Representatives.*

122 *See Cabinet Manual 2001, (Cabinet Office, Department of the Prime Minister and Cabinet, Wellington, New Zealand) para 3.21.*
123 *See Liddell, K., Biolaw and Deliberative Democracy: Regulating Human Genetic Technology in a Morally Pluralist Society (D Phil Thesis, Faculty of Law, University of Oxford 2000-2003) at p. 254.*
124 *See Weed, M., 'Ethics, Regulation, and Biomedical Research' 14 Kennedy Institute of Ethics Journal 361, (2004) where it is argued that the following mechanisms increase the credibility and legitimacy of advisory bodies; legal independence from direct control by the executive or legislative, diversity of membership, provision of majority and minority reports on ethical issues, and open hearings.*
125 *McMeeking, S., 'Pre-Birth Genetic Testing and Māori' p58.*
126 *Human Assisted Reproductive Technology Act 2004, s35(1)(a).*
127 *Human Assisted Reproductive Technology Act 2004, s35(1).*
128 *Human Assisted Reproductive Technology Act 2004, s35(1)(b).*
129 *Human Assisted Reproductive Technology Act 2004, s24(1). This may be extended for 1 further period not exceeding eighteen months. Human Assisted Reproductive Technology Act 2004, s24(2).*
130 *Human Assisted Reproductive Technology Act 2004, s25. Breach of the moratorium when an ethics committee has not given approval, or has cancelled an approval, triggers a sanction of imprisonment for up to two years or a fine of $200 000 or both, Human Assisted Reproductive Technology Act 2004, s27.*
131 *Human Assisted Reproductive Technology Act 2004, s35(2).*
132 *Human Assisted Reproductive Technology Act 2004, s38(e). Also in the list are: donations of embryos; embryo splitting; gametes derived from deceased persons; requirements for informed consent; the import into, or export from, New Zealand of in vitro donated cells or in vitro donated embryos.*
133 *Human Assisted Reproductive Technology Act 2004, s36(1)(a).*
134 *Human Assisted Reproductive Technology Act 2004, s36(1)(b).*
135 *Human Assisted Reproductive Technology Act 2004, s36(3). Note that the Health Committee can, under Parliamentary rules, choose to undertake an enquiry into the guidelines.*
136 *Human Assisted Reproductive Technology Act 2004, s 39.*
137 *See Hansard, Sue Kedgley, Human Assisted Reproductive Technology Bill, 16841, 10 Nov 2004. 'This unelected and unaccountable body must go through a process of consultation. Although that is some comfort, it is, based on our recent experience, only a little comfort because all of us have written thousands of submissions to various bodies and they have completely ignored those submissions. We hope that the ministerial advisory committee will not behave like so many expert committees and ignore public submissions, but we cannot be certain of that'.*
138 *Liddell, K., Biolaw and Deliberative Democracy: Regulating Human Genetic Technology in a Morally Pluralist Society (D Phil Thesis, Faculty of Law, University of Oxford 2000-2003) at p. 268.*
139 *Human Assisted Reproductive Technology Act 2004, s41.*
140 *[1993] 1 NZLR 671 (CA).*
141 *[1993] 1 NZLR 671 (CA) 674.*
142 *Port Louis Corporation v Attorney General of Mauritius [1965] AC 1111, 1124(PC).*
143 *Human Assisted Reproductive Technology Act 2004, s41.*
144 *Human Assisted Reproductive Technology Act 2004, s34(2).*
145 *The Ombudsmen are appointed by the New Zealand Parliament. Their primary purpose is to inquire into complaints raised against New Zealand central, regional and local government organisations or agencies. They are independent review authorities and are accountable to Parliament, not the Government. An ombudsman may undertake a review of any decision or recommendation made or act done or omitted by a central or local government department or organisation which affects any person or body of persons in their personal capacity. As a statutory body under the auspices of the Ministry of Health, the Advisory Committee would come within the jurisdiction of the Office of the Ombudsman pursuant to the Ombudsmen Act 1975. After an investigation into the complaint the Ombudsman forms an opinion whether the act, omission, decision complained of: appears to have been contrary to law; was unreasonable, unjust, oppressive or improperly discriminatory; was in accordance with a rule of law or a practice that is or may be unreasonable, unjust, oppressive of improperly discriminatory; was based on a mistake of law or fact; or was wrong. An Ombudsman can also consider whether a discretionary power has been exercised for an improper purpose or on irrelevant grounds or after taking account of irrelevant considerations, or whether reasons should have been given for the decision or recommendation. Where an Ombudsman forms the opinion that a complaint has merit, it may be recommended that the department or organisation concerned take action to remedy the complaint. Although an Ombudsman has no power to force a department or organisation to accept a recommendation, most recommendations are accepted.*
146 *Human Assisted Reproductive Technology Act 2004, s6.*

147 *Human Assisted Reproductive Technology Act 2004, s6(2). In tendering advice to the Minister under this section the Advisory Committee must provide the Minister with a report that sets out the following: (a) information about the procedure or treatment; (b) an assessment, drawn from published and peer reviewed research, of the known risks and benefits to health of the procedure or treatment; (c) advice as to whether, in its expert opinion, the known risks to health of the procedure or treatment fall within a level of risk that is acceptable in New Zealand; (d) an ethical analysis of the procedure or treatment; (e) advice as to whether, in its expert opinion, the Minister should recommend that the procedure or treatment be declared an established procedure.*

148 *See Ministry of Health, Health Report, Ref No 20057668, (21 April 2005).*

149 *See Hart Act 2005, s79(1).*

150 *Knoppers, B. and Isasi, R. 'Regulatory Approaches to Reproductive Genetic Testing' 19 Human Reproduction 2695-2701, at p. 2697, (2004) 'There is also hesitation to adopt this technique because of its eugenic potential".*

151 *Marjoribanks et al, Systematic Review of the Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis (PGD), Advice for the National Ethics Committee on Assisted Human Reproduction and the Ministry of Health, September 2004, 3.*

152 *Cabinet Paper, 'Established Procedures Under the Human Assisted Reproductive Technology Act 2004,' (Office of the Minister of Health, May 2005) 1.*

153 *The Advisory Group (AGART) consisted of nine people. It included an Information Specialist Manager from the New Zealand Health Technology Group, an epidemiologist working with the Public Health Intelligence Business Unit of the Ministry of Health, a specialist in reproductive endocrinology and infertility, the Chair of NECAHR, the Chief Advisor of Pacific Health, Ministry of Health, a member of the Executive Committee of Fertility New Zealand who had conceived two children with the use of assisted reproductive technology, and a Senior Lecturer in Obstetrics and Gynaecology.*

154 *New Zealand Health Technology Assessment Group, Health Outcomes for Children Born Via Assisted Human Reproduction, Christchurch, New Zealand, (2003).*

155 *IVF, ICSI, assisted hatching in conjunction with IVF or ICSI, blastocyst culture in conjunction with IVF or ICSI, gamete intra fallopian transfer, intra-uterine insemination, cryopreservation of gametes, embryos and ovarian tissue, and use of thawed gametes and embryos.*

156 *The Minister has requested that the Ministry report back on this work by December 2005.*

157 *Personal communication, Kathy Spencer, Ministry of Health, Deputy Director-General, Sector Policy Directorate, 23 February 2006. Information requested under the Official Information Act 1982.*

158 *See Press Release, Pete Hodgson 12 December, 2005 available at http://www.beehive.govt.nz/hodgson (accessed on 14 December 2005).*

159 *Up to two cycles of state funded IVF is available in New Zealand for couples who meet specific eligibility criteria. The second cycle is only available if the first cycle is unsuccessful. See Media Release, Hon Annette King, 11 July 2004. Available at: http://www.beehive.govt.nz/ViewDocument.aspx?DocumentID=20293.*

160 *See The Australian, November 10, 2005. Story available at http://www.theaustralian.news.com.au/common/story_page/0,5744,17193883%255E28737,00.html (accessed on 14 December 2005). In Australia, there is no limit on the number of IVF treatments funded by the federal government.*

161 *See Genetics Commissioning Advisory Group, Preimplantation Genetic Diagnosis (PGD) – Guiding Principles for Commissioners of NHS Services, Department of Health, September 2002.*

162 *Funding of IVF cycles in the UK varies from region to region. In 2003 the National Institute for Health and Clinical Excellence (NICE) was commissioned to examine the provision of infertility treatment in the UK. NICE published its conclusions in guidelines entitled Fertility, Assessment and Treatment for People with Fertility Problems. It was recommended that women should be offered three cycles of IVF on the public NHS service. These are only guidelines however, and some regions do not provide any publicly funded IVF. For a table comparing the number of state funded IVF cycles in the UK with Western Europe see http://www.bionews.org.uk/commentary.lasso?storyid=2887 (accessed on 24/01/06).*

163 *This is provided for in the Guidelines on PGD.*

164 *Note that parts of the Operational Standard are to be updated by the Ministry of Health. Ethics Committees are answerable to ACART, whilst NEAC is head of regional ethics committees. The ethics structures between ACART and NEAC are completely separate, yet it would seem that the provisions of the Act incorporate the Operational Standard.*

165 *Prior to the enactment of this legislation, the Health Research Council Ethics Committee provided review of NECAHR decisions. A second opinion process from decisions of an ethics committee was also in place.*

166 *Expensive frameworks can effectively mean that it becomes a tax 'on the infertile' or, in this context, a tax on people who are capable of passing on genetic mutations to their offspring.*

167 *Human Assisted Reproductive Technology Act 2004, s 80(1).*

168 *Health and Disability Services (Safety) Act 2001, s3.*

169 *The standard will be referred to as NZS 8181:2007 Fertility Standards and Audit Workbook.*

170 *Human Assisted Reproductive Technology Act 2004, s81(6).*

171 *Health and Disability Services (Safety) Act 2001, s9.*

172 *Human Assisted Reproductive Technology Act 2004, s 81(1)(a-d).*
173 *Notice of this approval appeared in the New Zealand Gazette, No 158, Wellington, Thurs 2 December 2004, p 3925 pursuant to section 81(4) of the Human Assisted Reproductive Technology Act 2004. (Note an error in the notice, which refers to the relevant clauses as they appeared in the HART Bill, rather than as they appear in the HART Act 2004). A provider who is accredited by RTAC in the interim period is deemed to be certified for the purposes of section 26 of the HDS(S) Act 2001.*
174 *Personal communication, Tanith Robb, Policy Analyst, Ministry of Health. See Human Assisted Reproductive Technology Act 2004, s82.*
175 *The Fertility Society of Australia, Reproductive Technology Accreditation Committee Code of Practice for Centres Using Assisted Reproductive Technology, Revised April 2002.*
176 *International Accreditation New Zealand (IANZ) provides laboratory accreditation for Medical Testing in compliance with NZS/ISO 15189:2003 Medical Laboratories – Particular Requirements for Quality and Competence. This standard is based upon ISO/IEC 17025 and ISO 9001. It replaced the New Zealand Code of Laboratory Management Practice for all IANZ accredited medical testing laboratories as of 1 January 2004. ISO is the International Organisation for Standardisation, and develops international standards adopted by approximately 153 countries.*
177 *The Fertility Society of Australia Reproductive Technology Accreditation Committee, Code of Practice for Assisted Reproductive Technology Units, Revised February 2005. See also Murray A., Hutton J., Peek J., 'Responsible IVF Treatment in New Zealand is the Preferential Transfer of a Single Embryo' 118 No 1212 NZMJ (1 April 2005).*
178 *Cancellation of certification is mandatory if the Director General is satisfied that the person does not meet the relevant service standards, or if there are no longer in force service standards for providing health care services of that kind, or if the provider has asked in writing for cancellation. See Health and Disability Services (Safety) Act 2001, s30.*
179 *Health and Disability Services (Safety) Act 2001, s48(a). A cessation order may also be served if the provider or a person providing health cares services under the provider's control has at any time – been convicted of an offence against the Act, or been convicted of an offence punishable by imprisonment; or been adjudged bankrupt under the Insolvency Act 1967, or become the subject of an order under section 383 of the Companies Act 1993. See s48(b).*
180 *Health and Disability Services (Safety) Act 2001, s49.*
181 *Health and Disability Services (Safety) Act 2001, s50.*
182 *Health and Disability Services (Safety) Act 2001, s51.*
183 *See Health and Disability Commissioner Act 1994, s6.*
184 *See The Code of Health and Disability Services Consumers' Rights Regulations 1996.*
185 *A 'consumer' is defined under the Code as a health consumer or a disability services consumer. For a definition of a health consumer it is necessary to refer to the HDC Act. Section 2(1) of the Act states that a 'Health consumer' includes any person on or in respect of whom any health care procedure is carried out, and a ``Health care procedure" means any health treatment, health examination, health teaching, or health research administered to or carried out on or in respect of any person by any health care provider; and includes any provision of health services to any person by any health care provider. 'Health Services' includes fertility services.*
186 *A 'Health Care Provider' is defined in section 3 of the HDC Act 1994. It includes not only any health practitioner (s 3(h)), but also a person for the time being in charge of providing health care services within the meaning of the Health and Disability Services (Safety) Act 2001, in compliance with that Act, (s 3(a)), and any other person who provides, or holds himself or herself or itself out as providing, health services to the public or to any section of the public (s 3(k)).*
187 *A Health consumer as defined in section 2 of the Act includes any person on or in respect of whom any health care procedure is carried out. An embryo is not a person.*
188 *Guidelines on Preimplantation Genetic Diagnosis, (NECAHR, March 2005) 7.*
189 *See Right 4(2), Every consumer has the right to have services provided that comply with legal, professional, ethical, and other relevant standards and Right 6, Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive.*
190 *To date, the Tribunal has received twelve complaints against Health Practitioners, completing three hearings, all resulting in findings of professional misconduct. See http://www.hpdt.org.nz Tribunal's Statistics (accessed on 19 Sept 05).*
191 *Registered health practitioners in the fertility services context who are subject to the Tribunal's jurisdiction include: Medical Practitioners, Medical Laboratory Technicians, Medical Laboratory Scientists, Nurses.*
192 *See Health Practitioners Competence Assurance Act 2003, s101(1)(a) and (b).*
193 *See HPCA Act 2003 v Nuttall (Dec No: 8/Med04/03P, 31 March 2005, Dr DB Collins, Chair) 17. The charge 'professional misconduct' set out in the HPCA Act includes matters previously categorised as 'disgraceful conduct in a professional respect' contained in the Medical Practitioners Acts of 1995 and 1968.*
194 *See Re HPCA Act 2003 v Nuttall (Dec No: 8/Med04/03P, 31 March 2005, Dr DB Collins, Chair), citing Maynard v West Midlands Regional Health Authority [1985] 1 All ER 635 (HL).*
195 *See Re HPCA Act 2003 v Nuttall (Dec No: 8/Med04/03P, 31 March 2005, Dr DB Collins, Chair) 19.*
196 *See Accident Compensation Act 1972.*

197 *See Injury Prevention, Rehabilitation and Compensation Amendment Act (No 2) 2005, s13. The amendment was made because the medical error provision which required a finding of negligence on the part of the practitioner was inconsistent with the no-fault scheme, and contributed to an adversarial tendency in some medical misadventure claims. Additionally, the requirement that the adverse consequence be so rare as to occur in one per cent or less to suffice for medical mishap was also perceived to be confusing and arbitrary. The objective of the amendment was therefore to remove the adversarial nature of claims, to simplify and shorten the claims process, and to promote better and safer delivery of medical services by encouraging practitioners to co-operate in resolving a claim.*

198 *IPRC Act, s 317. This bar applies whether or not the claimant lodges a claim or whether entitlement is received.*

199 *It includes a person suffering an infection that is a treatment injury, who directly passes the infection on to a partner, child or third party. See the IPRC Act 32(7).*

200 *IPRC Act, s32(1)(c).*

201 *IPRC Act, s32(2)(a).*

202 *IPRC Act, 32(2)(c).*

203 *IPRC Act, 32(2)(b)*

204 *IPRC Act, 32(3).*

205 *See A v Bottrill [2002] UKPC 44, [2002] 3 WLR 1406, 1415.*

206 *For a definition of treatment injury, see Injury Prevention Rehabilitation and Compensation Act 2001, s32.*

207 *See SGB v Wairarapa District Health Board [2002] NZAR 413, Gendall J. Although this case was decided in relation to the Accident Rehabilitation and Compensation Insurance Act 1992, it is equally applicable to the current Act. See IPRC Act 2001, 26(2). 'Personal injury" does not include personal injury caused wholly or substantially by a gradual process, disease, or infection.*

208 *See Tobin, R., 'Wrongful Birth in New Zealand, 12 JLM 294, at p.300 (2005).*

209 *Injury Prevention, Rehabilitation, and Compensation Act 2001, s317(1)(a). See Harrild v Director of Proceedings [2003] 3 NZLR 289 where it was held that an injury to a foetus in utero which resulted in death as a result of medical negligence was held to be a 'personal injury' to the mother. It could be argued that in extending the approach that a mother and an unborn child became the same 'person' in the context of the ACC legislation, it could be argued that it extended to conception. The minority considered that personal injury through medical misadventure must be suffered by the person receiving treatment, which in this case, was the mother. See Tobin, loc cit, at p. 303.*

210 *(2003) 199 ALR 131.*

211 *See McFarlane v Tayside Health Board [1999] 4 All ER 961.*

212 *[2003] 4 All ER 987.*

213 *However the majority held that a conventional sum of £ 15,000 should be awarded to the claimants to mark the fact that the parents of a child born following a negligently performed sterilisation or negligent advice are the victims of a legal wrong.*

214 *See the discussion in Manning, J., 'Health Care Law: Part 1: Common Law Developments' [2004] NZ Law Review 181 regarding Parkinson v St James and Seacroft University Hospital NHS Trust [2002] QB 266. See also in support of Parkinson, Todd, S., 'Damages for Wrongful Birth' 4 NZ Law Rev 534, (2001). 'Parkinson provides for a fair and just solution to a difficult question. Distinguishing between children who are normal and children who are disabled might be thought to be invidious, but arguably the extra expenses fall outside the ordinary and inextricable calculus of benefits and burdens associated with the birth of a child. As Hale LJ observed, the analysis treats a disabled child as having exactly the same worth as a non-disabled child. It affords him the same dignity and status. It simply acknowledges that he costs more.'*

215 *In the context of these claims, the argument for wrongful life are based on the grounds that disability suffered is so great that non-existence or death is seen as preferable to life.*

216 *See Cour de Cassaton Case No 9913701. (Court upheld a wrongful life action brought by a child who suffered severe disabilities due to his mothers undiagnosed rubella infection during pregnancy cf McKay v Essex Area Health Authority [1982] 1 QB 1166 (CA) (Court of Appeal rejected a wrongful life claim brought where the medical practitioner incorrectly assured a pregnant woman that she had not contracted rubella when she had. The court held that there was no duty on the doctor to prevent the child's birth; secondly that the injuries were caused by the rubella, not the negligence of the doctor.)*

217 *See Morris, A. and Saintier, S., 'To Be Or Not To Be: Is That The Question? Wrongful Life and Misconceptions' 11 Med L R 167, (2003). Dimopoulos,P., 'The Moral Status of Wrongful Life Claims' 35 CLWR 32.1. (2003); Seymour, J., 'Actions for Wrongful Birth and Wrongful Life' 2 NZ Bioethics J 26 (2001). See Sharman, R., 'Wrongful Life Actions: The Legal and Ethical Hurdles' 9 JLM 233, (2001).*

218 *See Paretta v Medical Offices for Human Reproduction. 195 Misc. 2d 568, 760 N.Y.S. 2d 639 N.Y. Sup., 2003.*

219 *The Court relied on the decision in Becker v Schwartz 46 N.Y. 2d 401, 413 N.Y.S 2d 895, 386 N.E.2d 807 (1978) which involved a wrongful life claim. In refusing to recognise the claim in law it was declared that a child did not have a right to be born free from genetic disease. Bransten J stated in Paretta, 'Theresa, however, like any other baby, does not have a protected right to be born free of genetic defects. A conclusion to the contrary, permitting infants to recover against doctors for wrongs allegedly committed during in-vitro fertilization, would give children conceived with the help of modern medical technology more rights and expectations than children conceived without medical assistance. The law does not recognize such a distinction and neither will this Court'.*

220 *Harriton v Stephens [2005] HCA Trans 301.*

221 *See Harriton (by her tutor) v Stephens and other cases [2004] NSWCA 93. Nb the dissenting judgment of Mason P. hn X v Mutuell d'Assurance du Corps Sanitaire Francais et a (2000) JCP 2293. However, the French government subsequently passed legislation to preclude wrongful life claims. Law adopted by the French Senate on 19 February 2002.*

222 *See Mason, K. and Laurie, G., Mason & McCall Smith's Law and Medical Ethics (7th ed), Oxford, OUP, 2006.*

223 *The section includes any other lawful act the doing of which is or may be dangerous to life.*

224 *See Skegg, P.D.G., 'Criminal Prosecutions of Negligent Health Professionals: The New Zealand Experience', 6 Med L Rev, 220, at p. 244 (1998).*

225 *Crimes Act 1961, s150A.*

226 *See R v Little (Unreported HC Christchurch, T17, 01, August 16 2001, Young J). The patient suffered a cardiac arrest after a chemical facial peel. During the procedure the patient had been given significant amounts of sedative drugs, and became unconscious. The patient had not been monitored via pulse oximeter when the drugs were given. When the cardiac arrest occurred there was no emergency equipment on the premises. Although the woman died as a result of brain injury suffered during the hypoxic cardiac arrest, the Crown chose not to seek a conviction for manslaughter. The accused doctor pleaded guilty to a charge of failing to provide the necessities of life to his patient, and thereby endangering her life or permanently injuring her health. It was held that the doctor was criminally negligent in not stopping the procedure when the patient fell unconscious, and was fined $30,000.*

227 *See Henaghan, M. and Wensley, D., 'Preimplantation Genetic Diagnosis: A Discussion of Regulatory Mechanisms of Control from a New Zealand Perspective' 2 JIBL 45, at p. 48, (2005).'…only the United States provides a more 'liberal' approach to PGD than that seen in the UK'. See also Morgan, D., 'Ethics, Economics and the Exotic: The Early Career of the HFEA' 12 Health Care Analysis 7, at p. 20, (2004). 'There may be a lack of realisation that in terms of regulatory regimes the HFEA still operates within one of the most liberal laissez-faire schemes in Europe'.*

228 *Brownsword, R., 'Biotechnology and Rights: Where are we Coming From and Where are we Going?' in Klang, M. and Murray, A. (eds) Human Rights in the Digital Age, Great Britain, Glasshouse Press, 2005, at p. 230.*

229 *Government White Paper, Our Inheritance, Our Future, Cm 5791, June 2003. The Government paper details how it proposes to invest an additional 50 million pounds in England to develop genetics knowledge, skills and provision within the NHS. The Secretary of State for Health said in the foreword to the paper that 'Our vision is that the NHS should lead the world in taking maximum advantage of the application of the new genetic knowledge for the benefit of all patients'.*

230 *Ibid, para 1.*

231 *These initiatives have included the establishment of six new genetics knowledge parks. As part of their core remit, the knowledge parks are to encourage local debate about the ethical and social implications of advances of human genetics. The Progress Education Trust organises educational seminars to provide genetic education to the public, including work with schools and universities. It is also responsible for the weekly internet newsletter, Bionews.*

232 *Government White Paper, Our Inheritance, Our Future, Cm 5791, June 2003, 76. The HGC is an advisory body (but is not an arm's length body) established in the Department of Health. This public body gives Health and Science Ministers strategic advice on developments in human genetics and their impact on healthcare, and on the social and ethical issues that arise.*

233 *Id.*

234 *Department of Health and Social Security, Report of the Committee of Inquiry into Human Fertilisation and Embryology (The Warnock Report), July 1984, Cm 9314, at p. 4.*

235 *White Paper, Human Fertilisation and Embryology: A Framework for Legislation November 1987 Cm 259.*

236 *See Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, supra cit, at p. 7.*

237 *Brazier, M., 'Regulating the Reproduction Business' [1999] Med L Rev 166, at p. 172.*

238 *Brazier, loc cit, at p. 174. However the author notes that pragmatism may have its advantages.*

239 *Brazier, loc cit, at p. 166, 167. Realpolitik is defined as politics based on pragmatism or practicality rather than on ethical or theoretical considerations.*

240 *An Arm's Length body is a stand-alone national organisation, undertaking executive functions.*

241 *The underlying philosophy of the HFEA Act can be described as permissive because it provides a flexible legislative framework which permits a relatively rapid response to scientific and social developments. See Petersen, K., 'The Regulation of Assisted Reproductive Technology: A Comparative Study of Permissive and Prescriptive Laws and Policies' 9 JLM 483 (2002). The HFEA has criminal sanctions for breach but the regulatory scheme depends more upon its controls over the licensing system than upon the criminal law.*

242 *Human Fertilisation and Embryology Act 1990, s3. These prohibitions include creating, keeping or using an embryo without a licence, placing a live embryo or gametes other than human gametes in a woman. A licence cannot authorise keeping or using an embryo after the appearance of the primitive streak, placing an embryo in any animal, keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.*

243 *Human Fertilisation and Embryology Act 1990, s5*

244 *Human Fertilisation and Embryology Act 1990, s11(1)(a).*

245 *Human Fertilisation and Embryology Act 1990, s11(1)(b).*

246 *Human Fertilisation and Embryology Act 1990, s11(1)(c).*

247 *Human Fertilisation and Embryology Act 1990, 25.*

248 *Human Fertilisation and Embryology Act 1990, s2.*

249 *Human Fertilisation and Embryology Act 1990, schedule 2, clause 1.*

250 *Human Fertilisation and Embryology Act 1990, s13.*

251 *Human Fertilisation and Embryology Act 1990, s13(5).*

252 *Human Fertilisation and Embryology Act 1990, s45.*

253 *Human Fertilisation and Embryology Act 1990. s 45(3).*

254 *Human Fertilisation and Embryology Act 1990, s8(d).*

255 *Human Fertilisation and Embryology Act 1990, s9(5).*

256 *Human Fertilisation and Embryology Act 1990, s10(1)(2).*

257 *Human Fertilisation and Embryology Act 1990, s14(5).*

258 *Human Fertilisation and Embryology Act 1990, s3(3)(c).*

259 *Human Fertilisation and Embryology Act 1990, s4(2).*

260 *Human Fertilisation and Embryology Act 1990, schedule 2, para 1-(1)(g).*

261 *See the Human Fertilisation and Embryology (Research Purposes) Regulations 2001/188.*

262 *Human Fertilisation and Embryology (Research Purposes) Regulations 2001/188, s2(2).*

263 *See HFEA and ACGT Consultation Document on Preimplantation Genetic Diagnosis (November 1999) para 10.*

264 *Brownsword, R., 'Reproductive Opportunities and Regulatory Challenges' [2004] Mod L Rev 304, 305.*

265 *The HFEA may issue guidance to fertility clinics by one of three forms – a Chair's Letter, by a Letter of the Chief Executive or by Directive.*

266 *The ACGT was incorporated into the Human Genetic Commission.*

267 *See the Outcome of the Public Consultation on Preimplantation Genetic Diagnosis, Joint Working Party of the Human Genetics Commission and the Human Fertilisation and Embryology Authority, November 2001.*

268 *See Ethical Issues in the Creation and Selection of Preimplantation Embryos to Produce Tissue Donors, Opinion of the Ethics Committee of the Human Fertilisation and Embryology Authority, November 22 2001.*

269 *This wider consideration of social factors is consistent with a common law application of the best interests test in the case of an incompetent person acting as bone marrow donor for a sick relative. See Re Y (Mental Patient: Bone Marrow Donation) [1997] Fam. 110.*

270 *HFEA Report: Preimplantation Tissue Typing, 2004.*

271 *R. (on the application of Quintavalle) v Human Fertilisation and Embryology Authority [2003] 2 All E.R. 105 (Maurice Kay J) HC. Josephine Quintavalle represented the group Comment on Reproductive Ethics (CORE) whose purpose is to 'focus and facilitate debate on ethical issues arising from human reproduction and, in particular, assisted reproduction'. Absolute respect for the human embryo is a principal tenet of CORE.*

272 *House of Commons Select Committee on Science and Technology, Fourth Report, Developments in Human Genetics and Embryology, 2002.*

273 *Ibid, para 17.*

274 *R. (on the application of Quintavalle) v Human Fertilisation and Embryology Authority [2003] 2 All E.R. 105 (Maurice Kay J) HC.*

275 *R (Quintavalle) v Secretary of State for Health [2003] EWCA Civ 667, [2004] QB 168 paras 38-41. Lord Phillips of Worth Matravers MR pointed to the legislative provisions relating to issuing licences for research on embryos. Such activities included 'increasing knowledge about the causes of congenital disease' [schedule 2, paras 3(2)(b)] and 'developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation' [schedule 2, 3(2)(e)] .*

276 *[2004] QB 168, para 43.*

277 *See Chair's Letter (03)04.*

278 *See Chapter 14, Code of Conduct, 6th ed, 2003.*

279 *This new policy was officially introduced to clinics via a Chair's Letter, CH(04)05. This guidance recognises that depending on the indications for the existing child, it may be acceptable to use preimplantation tissue typing with a view to using bone marrow from the resulting child and provides detailed guidance relating to clinical decision-making and patient information.*

280 *These criteria have since been relaxed. The Authority has accepted evidence that the risk from biopsy is low, consequently embryo biopsy for the purpose of carrying out tissue typing may be performed where there is no genetic risk to the embryo.*

281 *This particular provision was removed in 2004 when the HFEA reviewed their guidance. Prior to the change, it was commented that the HFEA is guiding the regulation of reproductive technologies in a direction that does not always fit easily with the general principles of health care law as they have developed elsewhere. 'Paradoxically, it might be noted that the principle of child welfare was intended by the architects of the 1990 Act to enjoy a weaker role in the regulation of human fertilisation and embryology than in other areas of law. Yet there is little doubt that the courts would sanction the far more invasive procedure of use of bone marrow to save Charlie Whitaker, were his saviour sibling already born'. See Sheldon, S. and Wilkinson, S., 'Hashmi and Whitaker: An Unjustifiable and Misguided Distinction?' 12 Med L Rev 137 (2004). This highlights the need for policy to be developed that is consistent with existing health law.*

282 *R. (on the application of Quintavalle) v Human Fertilisation and Embryology Authority [2003] 2 All E.R. 105 (Maurice Kay J) HC.*

283 *R (Quintavalle) v Secretary of State for Health [2003] UKHL 692*

284 *[2004] QB 168 para 50.*

285 *[2004] QB 168 para 98.*

286 *[2004] QB 168, para 135.*

287 *R (on the application of Quintavalle) v Human Fertilisation and Embryology Authority [2005] 2 All ER 555 UKHL, [2005] UKHL 28, [2005] 2 WLR 1061.*

288 *Ibid, para 62.*

289 *See Royal College of Nursing of the United Kingdom v Department of Health and Social Security [1981] AC 800.*

290 *See Brownsword, R., 'Reproductive Opportunities and Regulatory Challenges' Mod L Rev 304 (2004).*

291 *Brownsword, R., Cornish, W.R. and Llewelyn, M., 'Human Genetics and the Law: Regulating a Revolution' 61 Modern Law Review 593 (1998).*

292 *[2003] EWCA Civ 667.*

293 *House of Commons Select Committee on Science and technology, Human Reproductive Technologies and the Law, Fifth Report of the 2004-2005, HC 7-II, Q 1239. Research was initially permitted for five purposes under Schedule 2, Section 3 of the Act: (a) promoting advances in the treatment of infertility; (b) increasing knowledge about the causes of congenital disease; (c) increasing knowledge about the causes of miscarriages; (d) developing more effective techniques of contraception; or (e) developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation. In 2001 the Human Fertilisation and Embryology (Research Purposes) Regulations 2001 added the following purposes; (a) increasing knowledge about the development of embryos; (b) increasing knowledge about serious disease; or (c) enabling any such knowledge to be applied in developing treatments for serious disease. These regulations allow the use of embryos for therapeutic research, including that using embryonic stem cells.*

294 *Human Fertilisation and Embryology Act 1990, ss25, 26.*

295 *Human Fertilisation and Embryology Act 1990, s26(3).*

296 *Human Reproductive Technologies and the Law, House of Commons Science and Technology Committee, Fifth Report of the 2004-2005 Session, HC 7-1, para 221, p 97.*

297 *See the Human Fertilisation and Embryology (Licence Committee and Appeals) Regulations 1991/1889. A Committee consists of six members drawn from the Authority, including a Chair. Determination by a committee to grant a licence must be made unanimously. The Secretary of State for Health exercised power conferred under s9(5), 10 and 45 of the HFE Act 1990 to pass these regulations.*

298 *Human Reproductive Technologies and the Law, HC 7-1, para 351, p 152, supra acit.*

299 *Human Fertilisation and Embryology Act 1990, schedule 1, para 4.*

300 *The seven principles of public life are; selflessness, integrity, objectivity, accountability, openness, honesty, leadership.*

301 *Human Fertilisation and Embryology Authority, Code of Practice, 6th Edition, 2003, at p9.*

302 *Human Fertilisation and Embryology Authority, Code of Practice, 6th Edition, 2003, at p9.*

303 *See HFEA Press Release, 19 January 2005.*

304 *These include licensing for new conditions; PGD with tissue typing; tissue typing on its own; testing for late onset conditions or susceptibility genes.*

305 *Human Fertilisation and Embryology Act 1990, ss 13, 24.*

306 *Human Fertilisation and Embryology Act 1990 s17(1)(b),(d).*

307 *Code of Practice, 6th Edition, 2003 para 14.11.*

308 *Report on Human Reproductive Technologies and the Law, published as the Fifth Report of the 2004-2005 Session on 24 March 2005, HC 7-1, para 366. The CPA does include andrology laboratories.*

309 *Human Fertilisation and Embryology Act 1990, s13-17.*
310 *Code of Practice, 6th Edition, 2003 para 14.12.*
311 *Code of Practice, 6th Edition, 2003, 12.*
312 *In the recent Select Committee review of the HFE Act the Committee did not see a role for legislation or regulation mandating counselling.*
313 *Code of Practice, 6th Edition, 2003 paras 14.13, 14.14.*
314 *Code of Practice, 6th Edition, 2003, 12.*
315 *Code of Practice, 6th Edition, 2003, 14.17.*
316 *HFEA, Tomorrow's Children: A Consultation on Guidance to Licensed Fertility Clinics on Taking into Account the Welfare of Children to be Born of Assisted Conception Treatment, January 2005.*
317 *See HFEA, Tomorrow's Children, November 1995.*
318 *See HFEA, New Guidance on Welfare of the Child Assessments, CH (05) 04 -2 November 2005, available at www.hfea.gov.uk*
319 *Code of Practice 14.22.*
320 *Schedule 2, Paragraph 1 (1) A licence under this paragraph may authorise any of the following in the course of providing treatment services - …(d) practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose.*
321 *NICE, Fertility: Assessment and Treatment for People with Fertility Problems, Clinical Guideline 11, February 2004.*
322 *Health Secretary Welcomes New Fertility Guidance', Department of Health Press Release 2004/0069, 25 February 2004.*
323 *For a table comparing the number of state funded IVF cycles in the UK with Western Europe see http://www.bionews.org.uk/commentary.lasso?storyid=2887 (accessed on 24/01/06).*
324 *See in particular R (on the application Quintavalle) v Secretary of State for Health, [2003] 2 AC 687, [2003] UKHL 13, in which it was claimed that organisms created by cell nuclear replacement did not fall within the definition of 'embryo' in s1(1) HFE Act 1990. The consequence of this would have been that cloning by SCNT would not have been prohibited by the Act. The claim was successful in the High Court, but was overturned in the Court of Appeal. The Human Reproductive Cloning Act, c23 has since been passed, creating an offence of placing a human embryo in a woman other than by fertilisation. See also R (Quintavalle) v Secretary of State for Health [2003] UKHL 692. Judicial Review of HFE decision to grant a license for PGD with HLA tissue typing to select between healthy embryos.*
325 *This has come from many sources, and included academics, lawyers, and clinical practitioners. See Birk, D., 'The Reform of the Human Fertilisation and Embryology Act 1990', [2005] Fam Law 563. See also McLean, S., 'Issues in Assisted Reproduction – the UK Experience' Raising the Standard: Family Law Conference (2003: Auckland, NZ) 'the growing range of topics which have reached the UK courts, and the exponential growth of development, seems likely to mandate revision sooner rather than later'. Collier, S., 'Assisted Reproduction – Statutory Overhaul Overdue' 154 New Law Journal 1201, (2004) Mahendra, B. 'A Design for Life' 153 New Law Journal 153 (2003). See also Morgan, R., 'Ethics, Economics and the Exotic: The Early Career of the HFEA' 12 Health Care Analysis 7 (2004).*
326 *See 'The IVF Meddlers Must Go', The Guardian, Thursday 1 September 2005. Lord Robert Winston argues that there is a strong case for abolishing the HFEA. 'Some authority members boast that the British system is a model of regulation that other countries envy. This boast seems flatly untrue. Over 15 years, many countries peered hesitantly at the British system and then rejected it. There is not a single member country of the European Union with a precisely similar body. There is no evidence that practice in France, Singapore or Australia is more flawed without an equivalent body. As far as I am aware, only Canada has recently established a body along the lines of the HFEA'.*
327 *See Human Reproductive Technologies and the Law, HC 7-II, 200, evidence from Anne McLaren.*
328 *Liddell and Hall, loc cit, at p. 215.*
329 *Id.*
330 *See the Independent review of the circumstances surrounding four adverse events that occurred in the Reproductive Medicine Units at The Leeds Teaching Hospitals NHS Trust, West Yorkshire, June 2004.(The Toft Report). The report concludes that the events were caused through a mixture of inadvertent human error and systems failure. One incident involved fertilisation of a woman's ova with the wrong sperm. See Leeds Teaching Hospitals NHS Trust v A and others [2003] EWHC 259 (QB) which had to resolve the issue of paternity where the genetic father was not the husband of the genetic mother. Weaknesses in the inspection system included problems with the inspection process, particularly in regard to the role of the HFEA executive and training of inspectors. In response to the Toft report, the HFEA announced an Incident Alert System in 2003. Under this system licensed centres are required to report any adverse incidents or near misses to the HFEA. The information is then anonymised and sent to other licensed centres to enable them to take any necessary measures.*
331 *See Lee, R. and Morgan, D., Human Fertilisation and Embryology, London, Blackstone, 2001, at p.14.*
332 *See Human Reproductive Technologies and the Law, HC 7-II, Q 1235, supra cit.*
333 *See Human Reproductive Technologies and the Law, HC 7-1, 3, supra cit.*

334 *The Partial Regulatory Impact Assessment stated that the purpose and intended effect of the Government review is to ensure that the law remains effective and fit for purpose in the 21st century. The review considers factors such as; the development of new technologies and procedures; international developments in standards; the need to ensure the effectiveness of regulation. 'In reviewing the law the Government has regard to the principles of good regulation – proportionality, accountability, consistency, transparency, and targeting'.*

335 *See Government Response to the Report from the House of Commons Science and Technology Committee, August 2005, Cm6641.*

336 *The oral and written evidence is contained in Volume II of the Fifth Report of Session 2004 – 2005.*

337 *See Human Reproductive Technologies and the Law, HC 7 -1, para 7, p 5.*

338 *The strongly libertarian approach is reflected in the following conclusions of the Science and Technology Committee. They found that there is no adequate justification for a prohibition of germline engineering, reproductive cloning or the creation of hybrids and chimeras for research purposes. It was also proposed that the welfare of the child provision be abolished. For a discussion of the place of the welfare provision in relation to the UK context, see Sheila McLean, 'Assisted Reproduction and the Welfare of the Child' available at: www.ccels.cf.ac.uk/literature/publications/2005/mcleanpaper.pdf*

339 *See Human Reproductive Technologies and the Law, HC 7-1, 171 para 391.*

340 *See Inquiry into Human Reproductive Technologies and the Law, Eighth Special Report of the 2004-2005 Session, 23 March 2005, HC-491.*

341 *Inquiry into Human Reproductive Technologies and the Law, Eighth Special Report of the 2004-2005 Session, 23 March 2005, HC-491, 4.*

342 *Human Reproductive Technologies and the Law, HC 7-1, para 28, p 16, supra cit.*

343 *Ibid, paras 46, 47, p 22. The Committee felt that this was consistent with the precautionary principle currently prevalent in scientific research and clinical practice. They were critical of prohibitively restrictive applications of the precautionary principle.*

345 *See Schulman, J.D., 'Further Comment on the House of Commons Report Human Reproductive Technologies and the Law' 11 Reprod Biomed Online 158 (2005).*

346 *Human Reproductive Technologies and the Law, HC 7-1, para 208, p 93, supra cit.*

347 *Human Reproductive Technologies and the Law, HC 7-1, Para 355, supra cit.*

348 *Human Reproductive Technologies and the Law, HC 7-1, para 109 p 52, supra cit.*

349 *See Nuffield Council on Bioethics 2002, Genetics and Human Behaviour: the Ethical Context, supra cit, para 111, p 53.*

350 *See Human Reproductive Technologies and the Law, HC 7-1 Para 124, p58, supra cit.*

351 *Ibid, para 129, p 60.*

352 *See Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, August 2005, Cm 6641, para 120.*

353 *Human Genetics Commission, Making Babies: Reproductive Decisions and Genetic Technologies, January 2006, 17.*

354 *See Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, August 2005, Cm 6641.*

355 *Ibid. para 44.*

356 *Review of the Human Fertilisation and Embryology Act – A Public Consultation, Department of Health 2005.*

357 *See definition of 'relevant material', Human Tissue Act 2004.*

358 *Reconfiguring the DoH Arms Length Bodies (DoH, 2004)).*

359 *Directive 2004/23.EC of the European Parliament of the Council of 31 March 2004 sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The Directive provides a framework for inspection and accreditation, incorporating amongst other things the establishment of a register of accredited establishments, guidelines for inspectors, and the requirement of a notification system for adverse incidents.*

360 *It is intended that the new Regulatory Authority will also become the competent authority for the EU Blood Directive and take on certain regulatory functions from NHS Blood and Transplant.*

361 *See Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, August 2005, Cm 6641, para 113, 114.*

362 *See Department of Health, Review of the Human Fertilisation and Embryology Act: A Public Consultation, 2005, section 10.*

363 *See Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, August 2005, Cm 6641, para 118.*

364 *See Department of Health, Review of the Human Fertilisation and Embryology Act: A Public Consultation, 2005.*

365 *Morgan, R., 'Ethics, Economics and the Exotic: The Early Career of the HFEA' 12 Health Care Analysis 7, at p. 20 (2004).*

366 *Analysis of the regulatory system in the US is provided by Assoc Prof Mildred Cho and Ms Ana Kralovec, Stanford Center for Biomedical Ethics Center for Integration of Research on Genetics and Ethics, the US collaborators for the New Zealand Law Foundation-sponsored Human Genome Research Project.*

367 *Genetics and Public Policy Center, 'Preimplantation Genetic Diagnosis: A Discussion of Challenges, Concerns, and Preliminary Policy Options Related to the Genetic Testing of Human Embryos.' Washington, D.C. (2004)*
368 *Genetics and Public Policy Center, op cit*
369 *ibid*
370 *ibid*
371 *ibid*
372 *Centers for Medicare and Medicaid Services. (2005). Available at http://www.cms.hhs.gov/clia*
373 *Genetics and Public Policy Center, op cit*
374 *ibid*
375 *ibid*
376 *Department of Health and Human Services, Centers for Disease Control and Prevention., Implementation of the Fertility Clinic Success Rate and Certification Act of 1992- A Model Program for the Certification of Embryo Laboratories; Notice. Federal Register, Vol. 64, No. 139. (1999).*
377 *Note 1, supra*
378 *American Society for Reproductive Medicine, Practice Committee Report. (2004).'Preimplantation Genetic Diagnosis', Fertility and Sterility, 82 Supp. 1, 120-122.*
379 *American Society for Reproductive Medicine, Ethics Committee Report. (2004). 'Sex Selection and Preimplantation Genetic Diagnosis', Fertility and Sterility, 82 Supp. 1, 245-248.*
380 *Caughey, AB., Shahine, L.K., 'Preimplantation Genetic Diagnosis: The Earliest Form of Prenatal Diagnosis' 60 Gynaecologic and Obstetric Investigation 39-46, (2005).*
381 *PGD Consortium, European Society of Human Reproduction and Embryology. "List of World Clinics." (2005) http://www.eshre.com/emc.asp?pageId=390.*
382 *Genetics and Public Policy Center, op cit*
383 *DeNavas-Walt, Carmen, Bernadette D. Proctor, and Robert J. Mills, US Census Bureau, Current Population Reports, Income, Poverty, and Health Insurance Coverage in the United States: 2003, US Government Printing Office, Washington, D.C., 2004*
384 *Cohen, Robin A., Michael E. Martinez, Division of Health Interview Statistics, National Center for Health Statistics. (2005). Health Insurance Coverage: Estimates from the National Health Interview Survey, January- June 2005. http://www.cdc.gov/nchs/data/nhis/earlyrelease/insur200512.pdf*
385 *The InterNational Council on Infertility Information Dissemination, Inc. "States Mandating Infertility Insurance Coverage." 2005. http://www.inciid.org/article.php?cat=statemandates&id=275*
386 *ibid*
387 *Substitute Senate Bill No. 508, Public Act No. 05-196. An Act Concerning Health Insurance Coverage for Infertility Treatment and Procedures. http://www.cga.ct.gov/2005/act/Pa/2005PA-00196-R00SB-00508-PA.htm*
388 *ibid*
389 *Genetics and Public Policy Center, op cit*
390 *Reproduction and Responsibility: The Regulation of New Biotechnologies, The President's Council on Bioethics, op cit, p.103*
391 *ibid, p.15*
392 *ibid, p.102*
393 *Regulating Preimplantation Genetic Diagnosis: The Pathologization Problem' 118 Harvard Law Review 2770-2779, (2005)*
394 *See Gotkin, J., 'Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis', 26 J.L. Med & Ethics, 17, at p. 22 (1998) where the concerns commonly taken into account are listed: the moral status of the embryo and foetus, the limits of professional authority, the limits, if any, of our respect for parental autonomy, and the impact of individuals with disabilities on the family and society. Also to be considered is the impact of PGD on those who live with disabilities and the impact of broad choice on the parent-child relationship.*
395 *For example, USA, India, NSW. Even where there are no specific laws in place, it must be remembered that the law applying to all doctor-patient consultations still applies, such as the duty to take reasonable care.*
396 *See Wensley, D., Acceptable Limits or Reproductive Genetics; A Report Prepared for the New Zealand Law Foundation, July 2004 for a discussion of the French legislation.*
397 *Prohibitive legislation may forbid PGD expressly, or implicitly. For example, in Italy, preimplantation testing is permitted, but selecting the embryos for implantation is forbidden. All embryos must be implanted. However, abortion on the basis of a genetic abnormality is permitted. See Boggio, A., 'Italy Enacts New Law on Medically Assisted Reproduction' 20 Hum Rep 1153, (2005) In Germany, PGD is expressly prohibited.*
398 *See Liddell, K., "Biolaw and Deliberative Democracy: Regulating Human Genetic Technology in a Morally Pluralist Society' (D Phil Thesis, Faculty of Law, University of Oxford 2000-2003).*
399 *Liddell, K. and Hall, A., 'Beyond Bristol and Alder Hey: The Future Regulation of Human Tissue' 13 Med L Rev 170, 173, 216, (2005). In this article the authors assessed the extent to which the Human Tissue Act 2004 (UK) fairly and pragmatically accommodated the competing moral outlooks of citizens on human tissue. They concluded that the government tended in parts to 'proselytise a strict view that to use tissue without consent fundamentally disrespects a person … The policy-makers were carried along by a discourse that puts an exceedingly high value on consent'.*

400 *Brownsword, R., 'Regulating Human Genetics: New Dilemmas For A New Millennium' 12 Med L Rev. at p 31 (2004); Halliday, S., 'The Regulated Gene: New Legal Dilemmas' 12 Med L Rev. at p 13 (2004)*

401 *A somewhat cynical view of legislative decision-making in the American context is evident in the following quote. 'Academics who argue against the view that life begins at conception sometimes go to great lengths to demonstrate their recognition of the special character of the embryo … Like it or not, the question has become essentially a political one, and in politics there are no correct answers, only polling data. If sixty percent of likely voters thought that 'embryos' (or ova) had the same moral status as an inflamed appendix, then the elected champions of the religious right might change their tune', Noah, L., 'A Postmodernist Take on the Human Embryo Research Debate, 36 Conn L Rev 1133, at p. 1138, (2004) cited in Kiessling, A., 'What Is an Embryo?: A Rejoinder' 37 Conn L Rev 1, (2004)*

402 *Handyside, A. et al, 'Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-specifiec DNA Amplification' 344 Nature 766-760, (1990); Handyside, A., et al, 'Pregnancies from Biopsied Human Preimplantation Embryos Sexed by Y-Specific DNA Amplification' Lancet 347-349, (1989).*

403 *See Infertility (Medical Procedures) Act 1984 (Viv).*

404 *John Stuart Mill, Utilitarianism & On Liberty (Fontana Press; 1962). See Human Reproductive Technologies and the Law, HC 7–I, para 31, supra cit. The Nuffield Council on Bioethics describes the libertarian view of embryo selection in a similar vein. 'The main argument in favour of the permissibility of selection is that it is a legitimate exercise of individual liberty. There is, quite generally, a strong presumption in favour of the exercise of individual liberty wherever its exercise does not conflict, directly or indirectly, with the legitimate interests of others'. Nuffield Council on Bioethics, Genetics and Human Behaviour; the Ethical Context, 2002.*

405 *This is the position taken by the German legislature, which has prohibited PGD.*

406 *Towns, C.R. and Jones, D.G., 'Stem Cells, Embryos, and the Environment; a Context for Both Science and Ethics' (2004) 30 J Med Ethics 410. In this paper it is argued that ethical debate cannot be reduced to 'potential for life' claims. In their view, a blastocyst or even a later embryo in the laboratory lacks the capacity to develop into a human individual as successful implantation and development within the uterus of a woman is required to achieve a viable foetus. On this approach, the context of blastocysts and later embryos is crucial, ethically, as well as scientifically and clinically and should not be viewed in isolation from their physical context.*

407 *Knoppers, B. and Isasi, R., 'Regulatory Approaches to Reproductive Genetic Testing' 19 Human Reproduction 2695-2701, at p. 2697, (2004).*

408 *See The Report of the Cervical Cancer Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and Into other Related Matters, 1988.*

409 *See Beecher, H.K., 'Ethics and Clinical Research' (1966) 274 N Engl J Med 1354. See also McNeill,P., The Ethics and Politics of Human Experimentation, Cambridge, Cambridge University Press, 1993 p. 57 and p. 61.*

410 *Parens, E. and Knowles, L., 'Reflections and Recommendations' 33 Hastings Centre Report S3, (2003)*

411 *Barrit et al, 'Mitochondria in Human Offspring Derived from Ooplasmic Transplantation' 16 Human Reproduction 513-516 (2001), cited in Parens and Knowles, loc cit.*

412 *The American FDA assumed jurisdiction over nuclear transfer, and required researchers to submit an Investigational New Drug Application. The application process – normally followed by drug companies – would be too time consuming and expensive for most infertility researchers working in clinics and universities. It effectively put an end to nuclear transfer work in the United States. The Grifo team assisted a Chinese team in 2003 to perform the procedure for a woman in China. Five embryos were implanted, resulting in a triplet pregnancy, which was medically reduced to twins. One foetus died at 24 weeks, and the other at 29 weeks. See Grady, D., 'Pregnancy Created with Egg Nucleus of Infertile Woman,' New York Times, October 14, 2003, available at http://www.nytimes.com/2003/10/14/science/14CELL.html?ex=1067180662&ei=1&en=13034bc691d2844d (accessed on 26 August 2005).*

413 *The FDA signalled to clinics that any clinicians providing ooplasm transfer would need to submit an application to the FDA and satisfy the Innovative New Drug requirements. After the initial imposition of the FDA's regulatory requirements it was reported that persons seeking the procedure sought treatment outside the USA. See Spar, D., 'Reproductive Tourism and the Regulatory Map' 352 N Engl J Med 531 (2005)*

414 *See Marjoribanks, J. et al, Systematic Review of the Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis (PGD) Advice for the National Ethics Committee on Assisted Human Reproduction and the Ministry of Health, prepared by the Cochrane Menstrual Disorders and Subfertility Group (CMDSG) for the New Zealand Guidelines Group, September 2004. Pregnancy rates after PGD are comparable to pregnancy rates following IVF alone, which are around 25-30% per cycle. The incidence and nature of obstetric and neonatal complications after PGD are also comparable to those reported after IVF alone.*

415 *It is reported that there is a 2.6%-4.2% risk of major birth defects associated with ART, compared with the risk of 2-3% in the general population. See Report to the Director-General of Health on the Risks and Benefits Associated with Assisted Reproductive Technologies, The Advisory Group on Assisted Reproductive Technologies (Ministry of Health, 2005), vi.*

416 *Epigenetics is the study of modifications to DNA that control gene expression without changing DNA sequence. However, technologies for detecting epigenetic changes in embryos are currently very limited. See Abstracts – 6th International Symposium on Preimplantation Genetics 2005, Oral Presentation O-67.*

417 *See Report to the Director-General of Health on the Risks and Benefits Associated with Assisted Reproductive Technologies, The Advisory Group on Assisted Reproductive Technologies (Ministry of Health, 2005).*

418 *See Ibid, vi.*

419 *Kirby, M., 'The Human Genome Project – Promise and Problems' 11 Journal of Contemporary Health Law and Policy 1, at p. 19 (1994).*

420 *In the extensive review of Human Reproductive Technologies and the Law carried out recently in the UK it was said '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 problem 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'. See Human Reproductive Technologies and the Law, HC 7–I, para 116, supra cit. See also Parker, M., Forbes, K. and Findlay, I., 'Eugenics or Empowered Choice? Community Issues Arising from Prenatal Testing' 42 Aust NZ J Obstet Gynaecol 10 (2002).*

421 *Alternatives to PGD for people who wish to avoid transmitting serious heritable genetic disorders include; remaining childless, undergoing prenatal diagnosis with the option of terminating an affected pregnancy, achieving a pregnancy through gamete donation, or adoption.*

422 *See Robertson, J., 'Ethics and the Future of Preimplantation Genetic Diagnosis' 1 Reprod Biomed Online 97 (2005). Savalescu, J., 'Procreative Beneficence: Why We Should Select the Best Children' 15 Bioethics 413 (2001). For a critique of this last article see Birch, K., 'Beneficence, Determinism and Justice: An Engagement with the Argument for the Genetic Selection of Intelligence' 19 Bioethics 12 (2005).*

423 *The fact that tests for characteristics such as intelligence, athleticism or beauty are not available at the moment should not stifle debate on these issues. It is better to debate these questions before the technology becomes available. See Human Reproductive Technologies and the Law, HC 7–I, para 143, supra cit.*

424 *In addition, the approach of using public opinion as a guide may be limited where views are held on false premises or misinformation regarding harms and benefits, or where scientific progress has altered the risk-benefit ratio.*

425 *An example of this is the outcry over IVF when it was reported that the first test tube baby had been born, which eventually subsided into social acceptance. See Peterson, M., 'Assisted Reproductive Technologies and Equity of Access Issues' 31 J Med Ethics 281 (2005). See also Caulfield, T., Knowles, L. and Meslin, E., 'Law and Policy in the Era of Reproductive Genetics' 30 J Med Ethics 414, at p. 415 (2004).*

426 *Brownsword, R., 'Reproductive Opportunities and Regulatory Challenges' Mod L Rev 304, at p. 321 (2004).*

427 *These five principles (proportionality, accountability, consistency, transparency and targeting) have been set out by the United Kingdom's Better Regulation Task Force, which is to become the Better Regulation Commission in January 2006, available at http:/www.brtf.gov.uk. These principles may be expressed in different ways, but the effect is similar. For example, the Code of Good Regulatory Practice formulated by the New Zealand Quality of Regulation Team, Competition and Enterprise Branch of the Ministry of Economic Development, November 1997 cited the following principles; Efficiency, Effectiveness, Transparency, Clarity and Equity. Available at http://www.med.govt.nz/buslt/compliance/regprac.html (accessed on 16 November 2005).*

428 *For Māori views on assisted reproductive technology in general, see Manatu Māori Guidelines on Assisted Reproductive Technology, Wellington, 1994. Manatu Māori has since become Te Puni Kokiri, the Ministry of Māori Development, and was established under the Ministry of Māori Development Act 1991.*

429 *Non-legislative measures may still provide constraints on activities in countries that do not have overriding legislation. For example, when it was reported that the experimental technique of mitochondrial transplant had been carried out in the United States, the Food and Drug Administration (FDA) intervened to collect information and conduct hearings on the technique's safety and efficacy. The FDA assumed jurisdiction over nuclear transfer, and required researchers to submit an Investigational New Drug Application. The application process – normally followed by drug companies – would be too time consuming and expensive for most infertility researchers working in clinics and universities which effectively put an end to nuclear transfer work in the United States. After the initial imposition of the FDA's regulatory requirements it was reported that persons seeking the procedure sought treatment outside the USA. See D Spar, 'Reproductive Tourism and the Regulatory Map' 352 N Engl J Med 531 (2005).*

430 *See Wensley, D., Acceptable Limits or Reproductive Genetics; A Report Prepared for the New Zealand Law Foundation, July 2004 for a discussion of the French legislation.*

431 *Prohibitive legislation may forbid PGD expressly, or implicitly. For example, in Italy, preimplantation testing is permitted, but selecting the embryos for implantation is forbidden. All embryos must be implanted. However, abortion on the basis of a genetic abnormality is permitted. See Boggio, loc cit. In Germany, PGD is expressly prohibited.*

432 *The first attempt to introduce legislation regulating reproductive technology and research was made in 1996 via a Private Members Bill introduced into Parliament by Labour MP, Dianne Yates. The Human Assisted Reproductive Technology Bill provided for a licensing authority that would grant licences for fertility treatment services, the storage of embryos, and research. In 1998 a government bill was introduced to Parliament, in the form of the Assisted Human Reproduction Bill. The Government Bill in the name of National MP Doug Graham contained substantively similar subject matter as the initial Bill, but recommended a different structure for decision-making, delegating ethical oversight to the National Ethics Committee for Assisted Human Reproduction. Five years later, the HART Bill became*

the subject of Supplementary Order Paper No. 80 in April 2003, which contained substantial amendments to the Bill introduced by Dianne Yates, in particular, removing the licensing requirements of the HART Bill. This process culminated with the passing of the Human Assisted Reproductive Technology Act 2004.

433 *At Commonwealth level there is the National Health and Medical Research Council Ethical Guidelines on Assisted Reproductive Technology in Clinical Practice and Research (2004). See Petersen, K., Baker, H., Pitts, M. and Thorpe, R., 'Assisted Reproductive Technologies: Professional and Legal Restrictions in Australian Clinics' 15 JLM 373 (2005).*

434 *The Assisted Reproductive Technology Bill 2003 (NSW) was tabled and circulated for public discussion in December 2003. The closing date for comment was 9 April 2004.*

435 *The Victorian legislation created a number of new criminal offences, the commission of which could lead to a term of imprisonment of up to four years. (This was dubbed 'white coat crime'). Access to infertility services was statutorily limited to legally married couples. A doctor who admitted an unmarried woman to an IVF programme committed an offence under the Act, although no one was ever prosecuted. See Skene, loc cit, at p. 269*

436 *See Szoke, H., 'Regulation of Assisted Reproductive Technology: The State of Play' in Australia' in Freckleton and Petersen, op cit.*

437 *It should be noted that although the UK system is essentially a civil system whereby licences can be revoked or varied by the HFEA, it is backed up by criminal sanctions for operating without a licence, or acting in breach of licence conditions. See HFE Act 1990, s41(1)(a), (b), s41(2).*

438 *The adoption of a split regulatory framework instead of a central regulatory body has been criticised on the basis that it goes against an international trend which perceives that the creation of a single body creates greater consistency, provides greater accountability, and therefore increases the ability to foster public confidence. See H Davidson, Embryonic Stem Cell Research, Dissertation Submitted in partial fulfilment of the requirements of the degree of Master of Bioethics and Health Law, University of Otago, October 2003, 128.*

439 *HART Act 2004, s3(a). This provision is very similar to the Canadian legislative equivalent. Section 2(b) of the Canadian Assisted Human Reproduction Act 2004 provides the following principle, 'the benefits of assisted human reproductive technologies and related research for individuals, for families and for society in general can be most effectively secured by taking appropriate measures for the protection and promotion of human health, safety, dignity and rights in the use of these technologies and in related research'.*

440 *'Reproductive autonomy' has been interpreted as including both the right to make reproductive decisions and the right to make decisions that impact upon reproduction. See Foster, J. and Slater, B., 'Privacy and Assisted Human Reproduction: A Discussion Paper,' 11 Health Law Report, 56, at p. 58 (2002). Reproductive autonomy has been described as a negative right, or a right to non-interference in reproductive choices, unless there are compelling reasons for state intervention.*

441 *See HART Act, s13, 14. In this way it may be said that the Act adopts a 'social justice perspective'. In the United Kingdom the HFEA permits the import and export of gametes, and the sale and purchase of gametes. Surrogacy is not prohibited by law in the UK, but it is illegal for an individual or agency to act on a commercial basis to organise or facilitate a surrogacy arrangement for another person. Agencies or individuals may perform this function on a non-commercial basis and individual surrogate mothers may be paid expenses by the intended parents.*

442 *This interpretation is reinforced by comments in a Cabinet Paper from the Associate Minister of Justice to the Cabinet Policy Committee that a prohibition on genetic screening for social reasons would be consistent with the purpose and principles of the HART SOP, but prohibiting the beneficial uses of genetic screening without public consultation and expert advice would not. See Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee' POL (04) 147, 21 June 2004, p4.*

443 *See Human Assisted Reproductive Technology Act 2004, s3(d).*

444 *Human Assisted Reproductive Technology Act 2004, s4(a).*

445 *Human Assisted Reproductive Technology Act 2004, s4(b). The question of what constitutes an affront to 'dignity' in the context of emerging scientific advances is rarely explained. Whilst it is an important value to maintain, 'human dignity is a poorly conceptualised and vague concept'. See Caulfield, T. and Chapman, A, 'Human Dignity as a Criterion for Science Policy' 2 PLoS Medicine 0736, [public library of science] (2005)*

446 *Human Assisted Reproductive Technology Act 2004, s 4(c). The latter criterion signals that provisions must be made to protect the health and well-being of women who undertake assisted reproductive procedures or established procedures. It should not be taken to indicate that concern for the health and well-being of women is of greater importance than other interests when making decisions about procedures. This principle was drawn from the Canadian legislation. See Assisted Human Reproduction Act 2004, s2(c). See Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee' POL (04) 147, 21 June 2004, p6.*

447 *Human Assisted Reproductive Technology Act 2004, s3(g).*

448 *For a discussion of the application of the Ethic of Care to assisted reproductive technologies, see Lee and Morgan, op cit., at p. 37.*

449 *Sections 3(a) and 4(c) of the HART Act 2004 are almost identical to sections 2(b) and (c) of the Assisted Human Reproduction Act 2004 (Can). These sections were inserted into the HART Bill by the Health Select Committee in 2004. The ethic of care principle was first adopted in relation to assisted reproductive technology in New*

Zealand by the Ministerial Committee on Assisted Reproductive Technologies, appointed by the Minister of Justice, in their report Navigating the Future in 1994. The authors of the Ministerial Committee Report outlined a set of principles that they believed should dictate the development of policy and practices concerning assisted reproduction in New Zealand. They adopted the Ethic of Care principle following the recommendations in the Report of the Canadian Royal Commission on New Reproductive Technologies which was published in 1993.

450 *Infertility Treatment Act 1995, s1.*

451 *Infertility Treatment Act 1995, s5(1), (2).*

452 *See McBain v The State of Victoria & Ors (2000) 99 FCR 116, see also Commonwealth of Australia Constitution Act 1900 (Cth) s 109. The IT Act has not been amended to take account of the McBain decision.*

453 *See ITA, Conditions for Licence: Applications for Licences by Hospitals and Day Procedure Centres, (5th Ed.), January 2004, 22.*

454 *See Petersen, Baker, Pitts and Thorpe, loc cit, at p. 377.*

455 *See Victorian Law Reform Commission, Human Reproductive Technology – Law and Legislation – Victoria, April 2005, 7. The paper makes interim recommendations for law reform which are based on consideration of the issues raised in the Victorian Law Reform Commission, Assisted Reproductive Technology and Adoption: Consultation Paper,(2003), research carried out by the Commission, on the basis of three occasional papers published by the Commission and on public consultation and submissions received in response to the consultation paper. It was recommended that a new principles section include the clause, 'people seeking to undergo assisted reproductive procedures must not be discriminated against on the basis of their sexual orientation, marital status, race or religion'.*

456 *Szoke, H., 'The Nanny State or Responsible Government?' 9 JLM 470, at p. 480 (2002).*

457 *Ibid, at p. 481, although the author of this article disputes this claim.*

458 *Szoke, loc cit, at p. 481.*

459 *Restrictive legislation embeds a definition in the legislation that attempts to exhaustively specify the conditions that meet the requirement of a 'genetic abnormality or disease' for the purposes of treatment. See Neame, L., 'Regulating Preimplantation Genetic Diagnosis in the Victorian Context' Poster Presentation, ITA Victoria.*

460 *Although there is no principles section in the Act, the HFEA has a list of guiding principles in the HFEA Code of Practice. 'In framing the Code of Practice, the HFEA has been guided both by the requirements of the HFE Act and by: the respect which is due to human life at all stages of its development; The right of people seeking assisted reproductive treatment to proper consideration of their request; A concern for the welfare of children, which cannot always be adequately protected by concern for the interests of the adults involved; and A recognition of the benefits, both to individuals and to society, which can flow from the responsible pursuit of medical and scientific knowledge. See HFEA, Code of Practice, 6th Ed, 2003.*

461 *See Department of Health and Social Security, Report of the Committee of Inquiry into Human Fertilisation and Embryology (The Warnock Report), Cm 9314/1984.*

462 *The HFE Act sets out several purposes. The first is to regulate certain infertility treatments which involve keeping or using human gametes and to regulate the keeping of human embryos outside the human body, HFE Act, s3. Other purposes declared under the Act are to regulate embryo research, and to prohibit certain practices.*

463 *The House of Commons Science and Technology Committee carried out a review of the Act in 2004. They concluded that the regulation of ART should proceed under the precautionary principle prevalent in scientific research and clinical practice. This required that 'alleged harms to society or to patients need to be demonstrated before forward progress is unduly impeded'. The Government disagreed with the Committee's interpretation of the precautionary principle in their response to the Committees' report. 'The potential harms that should be taken into account may not necessarily be susceptible to demonstration and evidence in advance. For example, in our view the application of a precautionary approach requires that consideration of harms to society or to patients must include the consideration of potential harms to future offspring'. See Government Response to the Report from the House of Commons Science and Technology Committee: Human Reproductive Technologies and the Law, August 2005. Cm 6641,6.*

464 *HFE Act 1990, s13(5).*

465 *Johnson, M., 'The Art of Regulation and the Regulation of ART: The Impact of Regulation on Research and Clinical Practice' 9 JLM 399, at p. 412 (2002). The absence of an overarching purpose created difficulty when the Courts were required to adjudicate on the case of R(On the application of Quintavalle) v the Human Fertilisation and Embryology Authority [2005] UKHL 28, 2 All ER 555. In determining the purpose and intent of the legislature in relation to the scope of the Authority's power to permit tissue typing to be carried out via PGD, the House of Lords sought guidance from the Warnock Report. (See the Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cmnd 9314/1984, (Warnock Report) and the subsequent Government White Paper. (White Paper, Human Fertilisation and Embryology: A Framework for Legislation (Cm 259), 1987 para 13.) It was noted that the basic principle underlying the Warnock recommendations in regard to the authority's power was adopted in the White Paper, which was namely 'to regulate and monitor practice in relation to those sensitive areas which raise fundamental ethical questions'. These areas included 'any treatment involving human embryos created in vitro'. The intention was therefore to define the functions of the authority in very broad terms, with an emphasis on flexibility and safety.*

466 *Brazier, loc cit, at p.172. 'Britain opted for a limited and pragmatic regulation of research and treatment focusing on ensuring public accountability on the part of both researchers and clinicians, facilitating medical and scientific progress and largely skating over fundamental questions of reproductive choice'.*

467 *Prohibited actions which carry liability to imprisonment for up to five years, or a fine of up to $200 000 are set out in section 8(2)(3) and Schedule 1 of the Act. These activities include: artificially forming, for reproductive purposes a cloned embryo or a hybrid embryo; implanting into a human being a cloned embryo, an animal gamete or embryo, or a hybrid embryo; implanting into an animal a human gamete or human embryo, or a hybrid embryo; implanting into a human being a genetically modified gamete, human embryo, or hybrid embryo; and implanting into a human being gametes derived from a foetus, or an embryo that has been formed from a gamete or gametes derived from a foetus.*

468 *Although assisted reproductive procedures which are declared to be established are not within the regime of the HART Act 2004, any provider who is performing an established procedure is still required under the Act to comply with the Health and Disability Services (Safety) Act 2001. See section 80(1)(2).*

469 *HART Act 2004, s6.*

470 *Human Assisted Reproductive Technology Act 2004, s35(1)(a).*

471 *Human Assisted Reproductive Technology Act 2004, s35(1).*

472 *Human Assisted Reproductive Technology Act 2004, s36(1)(a).*

473 *Human Assisted Reproductive Technology Act 2004, s36(1)(b).*

474 *Human Assisted Reproductive Technology Act 2004, s36(3).*

475 *Human Assisted Reproductive Technology Act 2004, s 39.*

476 *There is some cynicism as to how much the duty take into account public submissions will affect policy-making. This is reflected in the following comment of Sue Kedgley, a Green MP Deputy Chair of the Select Committee responsible for the HART Bill as amended by Supplementary Order Paper No. 81. 'This unelected and unaccountable body must go through a process of consultation. Although that is some comfort, it is, based on our recent experience, only a little comfort because all of us have written thousands of submissions to various bodies and they have completely ignored those submissions. We hope that the ministerial advisory committee will not behave like so many expert committees and ignore public submissions, but we cannot be certain of that'. See Hansard, Human Assisted Reproductive Technology Bill, 16841, 10 Nov 2004.*

477 *Human Assisted Reproductive Technology Act 2004, s41. See Wellington Airport International Airport v Air New Zealand [1993] 1 NZLR 671 (CA) for a statement of what is legally required by a duty to consult.*

478 *Human Assisted Reproductive Technology Act 2004, s16. Breach of this section carries liability for a fine of up to $50 000, s16(2).*

479 *Human Assisted Reproductive Technology Act 2004, s19(2).*

480 *It is stated in the Terms of Reference of the Advisory Committee on Assisted Reproductive Procedures and Human Reproductive Research that the ACART should monitor the decisions of the ethics committees to ensure they fall within the guidelines as intended by ACART. If, after consideration of one of ECART's decisions, ACART considers that the decision falls outside of its guidelines, ACART should inform ECART of this.*

481 *Section 11(2) of the Human Assisted Reproductive Technology Act 2004 sets out the procedure that must be followed before a procedure may be declared to be established. PGD in circumstances which come within the ambit of an 'established procedure' does not escape regulation completely, but falls within guidelines promulgated on the request of the Minister of Health by the National Ethics Committee on Assisted Human Reproduction. These Guidelines have been designated interim ACART Guidelines under the HART Act.*

482 *See Human Assisted Reproductive Technology Order 2005, 181, Part 2.*

483 *Human Assisted Reproductive Technology Act 2004, s 11(2).*

484 *Human Assisted Reproductive Technology Act 2004, s 11(3). It should be noted that there could be a lawful excuse under this section, but there may still be a breach of the Human Assisted Reproductive Technology Order, 181 which sets out further criteria regarding sex selection in the presence of a genetic disorder.*

485 *Sperm sorting allows a parent to choose which sperm is to be used to fertilise an oocyte, and thus the sex of the resulting embryo. Each single spermatozoa carries either an X or Y chromosome, which will determine the sex of an embryo should fertilisation occur. As the oocyte carries only X chromosomes, if the successful spermatozoa carries a Y chromosome a male individual will result (XY), whereas if the spermatozoa carries an X chromosome, a female will result (XX).*

486 *Other methods based on the positioning and timing of intercourse, or special diets have been claimed as influencing sex of offspring. See Liao, loc cit, at p. 116.*

487 *It had been intended to prohibit the selection of embryos on the basis of genetic characteristics unless it was to prevent a serious genetic disorder in order to avoid the use of PGD to select for social reasons, such as selecting for desirable traits. However, advice given to Cabinet warned that such a prohibition could prevent the use of assisted reproductive procedures to select an embryo on the basis that is the most likely to be successfully implanted. It could also prevent HLA tissue typing. It was noted in a Cabinet Paper from the Minister of Justice to the Cabinet Policy Committee that a prohibition on genetic screening for social reasons would be consistent with the purpose and principles of the HART*

SOP but prohibiting the beneficial uses of genetic screening without public consultation and expert advice would not. See Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee' POL (04) 147, 21 Jun 2004, p4.

488 *See Cabinet Paper in the name of Associate Minister of Justice, Hon David Benson Pope to the Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee', POL (04) 147, 21 June 2004, 3.*

489 *The prohibition in relation to genetic modification of gametes and embryos for reproductive purposes, and the use of gametes from a foetus for reproductive purposes were also added at the same time by the Select Committee in response to concerns that New Zealand was being more permissive than other jurisdictions. See Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee' POL (04) 147, 21 June 2004.*

490 *Many medical procedures are not met with widespread acceptance by society when they are first introduced. For example, IVF was met with suspicion and concern by the general public when the first 'test tube' embryos were created in laboratories.*

491 *See Human Assisted Reproductive Technology Order 2005, 181.*

492 *See Report to the Director-General of Health on the Risks and Benefits Associated with Assisted Reproductive Technologies, The Advisory Group on Assisted Reproductive Technologies (Ministry of Health, 2005) and Marjoribanks et al, Systematic Review of the quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis (PGD) Advice for the National Ethics Committee on Assisted Human Reproduction and the Ministry of Health, prepared by the Cochrane Menstrual Disorders and Subfertility Group (CMDSG) for the New Zealand Guidelines Group, September 2004.*

493 *See Ministry of Health, Health Report, Ref No 20057668, paras 85, 88.*

494 *It has been reported in the United States that PGD is most commonly used to detect anueploidies. See Reproduction and Responsibility: The Regulation of New Biotechnologies, The President's Council on Bioethics, Washington, DC, March 2004, Chapter 3 available at http://www.bioethics.gov (accessed on 15/8/2005).*

495 *For example in the case of haemophilia A and B, it is possible to reliably assess the mutation in the FVIII or FIX genes. If there was no restriction in the Guidelines, sex selection could occur which would systematically discard male embryos, although 50% of the embryos are unaffected. See Abstracts, 6th International Symposium on Preimplantation Genetics 2005, Oral Presentation, 33. Neither the Infertility Treatment Act 1995 (Vic) or the Infertility Treatment Authority restrict sex selection to avoid a sex-linked genetic disorder in this way.*

496 *See NECAHR, 'Guidelines for Preimplantation Genetic Diagnosis in New Zealand: Consultation Document', Wellington, September 2004.*

497 *See NECAHR Guidelines on Preimplantation Genetic Diagnosis, Wellington, March 2005. These Guidelines have been approved by gazette notice under section 83 of the Act as Interim Guidelines of the Advisory Committee on Assisted Reproductive Technology, ACART.*

498 *Note that there are two ways of interpreting this provision in the Guidelines. The first is that it relates to the degree of likelihood of the disorder manifesting itself in the offspring being determined by clinicians. The other is that it leaves the question of whether a disorder is a serious disorder up to clinicians.*

499 *Leschot, Cobben and Brocker-Vriends, op cit, at p. 21.*

500 *Draper and Chadwick, loc cit., at p. 351.*

501 *Leschot, Cobben, and Brocker-Vriends, op cit, at p. 21.*

502 *FAP is a genetically inherited form of colon cancer which usually manifests in early adolescence or early adulthood. It is an autosomal dominant mutation. Individuals who have this condition have an almost 100% chance of developing colorectal cancer in the absence of treatment for polyposis.*

503 *HFEA, Choices and Boundaries, November 2005.*

504 *Prior to the enactment of the HART Act, the Minister of Heath approved in principle the provision of preimplantation genetic diagnosis services in New Zealand, provided that the National Ethics Committee for Assisted Human Reproduction (NECAHR) developed guidelines for the safe and ethical use of the procedure. NECAHR commissioned a Systematic Review of the Quantifiable Harms and Benefits of Preimplantation Genetic Diagnosis by the Cochrane Menstrual Disorders and Subfertility Group for the New Zealand Guidelines Group to provide an evidence base for the draft guidelines. The proposed Guidelines for Preimplantation Genetic Diagnosis in New Zealand formulated by NECAHR were disseminated in October 2004 to fertility clinics, District Health Boards, professional organisations, consumer groups, government agencies and interested individuals for public consultation. Public meetings throughout the country were also held in order to hear oral submissions. The revised guidelines were approved by the Minister of Health and released in March 2005. At any time within three years after the enactment of the HART Act 2004, the Minister may require an ethics committee to treat specified provisions of any document as interim guidelines issued by the advisory committee for the purposes of the Act. The Minister has approved the NECAHR Guidelines as interim Guidelines under the Human Assisted Reproductive Technology Act 2004. They are effective until 21 November 2007, unless revoked sooner.*

505 *Neoplasms are new and abnormal growth of tissue, which may be benign or cancerous.*

506 *See Shenfield, F., et al 'Taskforce 9: the Application of Preimplantation Genetic Diagnosis for Human Leukocyte Antigen Typing of Embryos' 20 Human Reproduction 845 (2005).*

507 *Transplantation of umbilical stem cells is limited by the age and weight of the affected child. Cord blood may be adequate for small children below 25 kg, whilst in the case of older children, a bone marrow transplantation is indicated. See ibid, at p. 845.*

508 *Three main arguments are frequently raised against allowing PGD with tissue typing in these circumstances are: (i) the saviour sibling is used as a commodity, (ii) the slippery slope argument whereby allowing such a practice may lead to the creation of 'designer babies', (iii) child welfare arguments according to which saviour siblings may be physically and/or psychologically harmed. See Sheldon and Wilkinson, loc cit; see also Brownsword, R., 'Happy Families, Consenting Couples, and Children with Dignity; Sex Selection and Saviour Siblings' 17 Child and Family Law Quarterly 435 (2005).*

509 *For ease of reference, a copy of the Guidelines are provided in Appendix 2 of this section of the report.*

510 *This would exclude disorders such as childhood leukaemias and cancers that are not genetically inherited. Children suffering from disorders such as Diamond Blackfan Anaemia, where the parents are not carriers of the disorder and the child is suffering from the symptoms of a sporadic mutation rather than a genetically inherited mutation, will not be eligible.*

511 *See the Guidelines for Preimplantation Genetic Diagnosis in New Zealand Consultation Document formulated by NECAHR and disseminated in October 2004 for public consultation.*

512 *Personal communication, Kathy Spencer, Deputy Director General, Sector Policy Directorate, Ministry of Health.*

513 *Devolder, K., 'Preimplantation HLA Typing: Having Children to Save Our Loved Ones' 31 J Med Ethics 582 (2005).*

514 *However, the HFEA initially restricted HLA tissue typing to clinical circumstances where prospective embryos were at risk of inheriting a genetic disorder, against the advice of the HFEA ethics committee.*

515 *See Petersen, K., 'The Regulation of Assisted Reproductive Technology: A Comparative Study of Permissive and Prescriptive Laws and Policies' 9 JLM 483, at p. 485 (2002).*

516 *See Szoke, loc cit, at p. 481.*

517 *See H Szoke, 'Regulation of Assisted Reproductive Technology: The State of Play in Australia' in Freckleton and Petersen, op cit.*

518 *See IT Act 1995, s97(3).*

519 *ITA, Genetic Testing and the Requirements of the Infertility Treatment Act 1995: Policy in Relation to the Use of Preimplantation Genetic Diagnosis for Genetic Testing, January 2004; ITA, Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis, January 2004.*

520 *Infertility Treatment Act 1990 (Vic), s 50.*

521 *See ITA, Genetic Testing and the Requirements of the Infertility Treatment Act 1995: Policy in Relation to the Use of Preimplantation Genetic Diagnosis for Genetic Testing, January 2004.*

522 *See ITA, Genetic Testing and the Requirements of the Infertility Treatment Act 1995 January 2004, 3.*

523 *See ITA, Approved Genetic Testing, October 2005.*

524 *For example, the list includes AZF-c deletion of the Y chromosome and RhD factor incompatibility.*

525 *Human Genetics Commission, Making Babies: Reproductive Decisions and Genetic Technologies, January 2006, para 29.*

526 *The Infertility Treatment Act 1995 is consumer focused, with the emphasis on informed decision-making apparent in the statutory provision which stipulates that consent must be obtained in writing and be lodged with the designated officer at the relevant clinic. (s9). The Act also provides that sufficient information must be provided to consumers about the procedure and the relevant alternatives to enable the woman and her husband to make an informed decision about whether or not to undergo the procedure. (s 10(1)(b)). Counselling is also a mandatory requirement under the Act. (s11(1)). It is also required of the doctor in charge of a woman's case that he or she must take all reasonable steps to ensure that an approved counsellor is available to give further counselling to the woman and her husband after the procedure is carried out. (s 11(2). In New Zealand, section 4(d) of the HART Act 2004 provides that no assisted reproductive procedure should be performed on an individual unless the individual has made an informed choice and given informed consent. Information and counselling requirements are set out in the Guidelines.*

527 *See Victorian Law Reform Commission, Human Reproductive Technology – Law and Legislation – Victoria, April 2005, 8. H Szoke, 'The Nanny State or Responsible Government?' 9 Journal of Law and Medicine 470, at p. 481 (2002).*

528 *ITA, Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis, January 2004.*

529 *See Infertility Treatment Act 1995, s8(3)(b).*

530 *The lack of flexibility provided by the Infertility Treatment Act 1995 (Vic) has been a major source of criticism of the regulatory regime. 'The governing body is restricted in its ability to monitor and review community attitudes and responses to the development of the technology, and to propose modifications to the regulatory framework accordingly. The Authority has the ability to advise the Minister, and has regard to the advice provided by the Minister. However, any modifications to the Act are not easily made, and without the ability to respond to changes in community understanding, or the impact of the legislation, it is difficult to undertake regular community responses and interaction.' H Szoke, 'The Nanny State or Responsible Government?' 9 Journal of Law and Medicine 470, (2002).*

531 *ITA, Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis, January 2004.*

532 *Section 106(2)(d) permits the Authority to impose conditions on licences.*
533 *The only exception to this could be the scenario where the putative organ donor had been declared to be clinically brain dead.*
534 *Human Fertilisation and Embryology Act 1990, s5.*
535 *Human Fertilisation and Embryology Act 1990, 25.*
536 *HFE Act 1990, s3(1). Placing a live embryo or gametes other than human gametes in a woman is also prohibited. A licence cannot authorise keeping or using an embryo after the appearance of the primitive streak, placing an embryo in any animal, keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo.*
537 *Human Fertilisation and Embryology Act 1990, s11(1)(a).*
538 *Human Fertilisation and Embryology Act 1990, s2.*
539 *Human Fertilisation and Embryology Act 1990, schedule 2, paragraph 1.-(2).*
540 *Human Fertilisation and Embryology Act 1990, s13.*
541 *Human Fertilisation and Embryology Act 1990, s13(5). For a recent review of how clinics should deal with this legal obligation, see HFEA, Tomorrow's Children Report of the Policy Review of Welfare of the Child Assessments in Licensed Assisted Conception Clinics, November 2005.*
542 *See the HFEA and ACGT Consultation Document on Preimplantation Genetic Diagnosis (November 1999) para 10. The HFEA was of the opinion that the Act implicitly supported the licensing of PGD for severe or life-threatening disorders, and it was consequently within their mandate to create policy in the area for the following reasons. The possibility of developing methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation was recognised at the time the HFE Act was enacted. The provision was enacted against the background of a clinical trial which had just been undertaken to establish the technique of preimplantation genetic diagnosis in the case of a life threatening sex-linked disorder.*
543 *Human Fertilisation and Embryology Act 1990, schedule 2, para 1-(1)(g). Such a regulation passed by the Secretary for State must be subject to an affirmative resolution of the House of Parliament, and does not take effect until Parliament approves it. See Human Fertilisation and Embryology Act 1990, s45,45(3). Human Fertilisation and Embryology Act 1990. s 45(3).*
544 *R. (on the application of Quintavalle) v Human Fertilisation and Embryology Authority [2003] 2 All E.R. 105 (Maurice Kay J) HC. Josephine Quintavalle represented the group Comment on Reproductive Ethics (CORE) whose purpose is to 'focus and facilitate debate on ethical issues arising from human reproduction and, in particular, assisted reproduction'. Absolute respect for the human embryo is a principal tenet of CORE.*
545 *See R (Quintavalle) v Secretary of State for Health [2003] EWCA Civ 667, [2004] QB 168 paras 38-41. Lord Phillips of Worth Matravers MR, obiter dicta.*
546 *R (on the application of Quintavalle) v Human Fertilisation and Embryology Authority [2005] 2 All ER 555 UKHL, [2005] UKHL 28, [2005] 2 WLR 1061.*
547 *HFEA Press Release, HFEA to allow tissue typing in conjunction with preimplantation genetic diagnosis, 1 August 2002. The decision was made at the 113th meeting of the Authority, 29 November 2001.*
548 *House of Commons Science and Technology Committee Report, Developments in Human Genetics and Embryology, 2002, para 25.*
549 *FAP is an autosomal dominant genetic condition. Individuals who have this condition have an almost 100% chance of developing colorectal cancer in the absence of treatment for polyposis.*
550 *See Leading Edge, 'Screening for Disease: How Far is Too Far?' 4 Lancet Neurology 1 (2005).*
551 *See ibid, 1, 'In defence of the HFEA's decision, each licence application is peer reviewed by experts in PGD and the disease in question and several important factors are taken into consideration. For example, is there a treatment available for the disease, or is one likely to be developed in the near future? Does the disease strike early in life or is onset in adulthood? Does the disease cause substantial suffering? Although answers to these questions are not clear-cut, they provide an ethical framework for HFEA's decision-making.'*
552 *See Morgan, R., 'Ethics, Economics and the Exotic: The Early Career of the HFEA' 12 Health Care Analysis 7, at p. 20 (2004). 'There may be a lack of realisation that in terms of regulatory regimes the HFEA still operates within one of the most liberal laissez-faire schemes in Europe'. See also Henaghan and Wensley, loc cit, at p. 48. 'Only the United States provides a more 'liberal' approach to PGD than that seen in the UK'.*
553 *When the Human Tissue Act 2004 (UK) was passed, the HFEA provided a model for the Human Tissue Authority which was established under the Act. Although the HT Act regulates gametes and embryos, (see definition of 'relevant material' HT Act) it excludes gametes and embryos outside the human body. Hence prenatal genetic diagnosis comes within the jurisdiction of the Human Tissue Authority, whilst PGD is regulated under the HFEA. Although the HTA has a separate legislative mandate, the two authorities are to be merged to create a single body.*

554 *Directive 2004/23.EC of the European Parliament of the Council of 31 March 2004 sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The Directive provides a framework for inspection and accreditation, incorporating amongst other things the establishment of a register of accredited establishments, guidelines for inspectors, and the requirement of a notification system for adverse incidents.*

555 *Human Fertilisation and Embryology Authority, Code of Practice, 6th Edition, 2003.*

556 *Ibid, para 14.22.*

557 *It is expected that PGS for aneuploidy will only be used in the following categories of patients; women who are over the age of 35; women with a history of miscarriage not caused by translocations or other chromosomal rearrangements; women with several previous failed IVF attempts where embryos have been transferred; women with a history of aneuploidy not caused by translocations or other chromosomal rearrangements.*

558 *HFEA Code of Practice, (6th ed, 2003) paras 3.28-3.29.*

559 *See Human Reproductive Technologies and the Law, HC 7-1, para 117, supra cit.*

560 *HFEA Report, Preimplantation Tissue Typing, July 2004.*

561 *'When we first suggested PGD to our consultant, we were told, 'You can't do that here but what you can do is get pregnant, you can have amniocentesis, you can have a test and then you can terminate.' I am not anti-abortion, I am not pro-life, people can do what they want to do, but the human and emotional and ethical cost for my wife of being pregnant, carrying a child and then terminating was the unethical question. That was actually suggested to us as an alternative, a legal NHS approved alternative that could be done here. That, to me, was disgusting'. Jayson Whitaker, Human Reproductive Technologies and the Law, HC 7-1, para 119, supra cit.*

562 *The Royal Society of Edinburgh (RSE) is an educational charity, registered in Scotland. It is an independent and non-partisan group. The RSE has a peer-elected, multidisciplinary Fellowship of 1400 men and women who are experts within their fields.*

563 *See Human Reproductive Technologies and the Law, HC 7 –I, para 119, supra cit. See also the Report by the Council of Europe's Working Party on the Protection of the Human Embryo and Fetus, The Protection of the Human Embryo In Vitro, Strasbourg, 19 June 2003, (CDBI-CO-GT3), at p. 34.*

564 *See the Guidelines on Preimplantation Genetic Diagnosis, Prepared by the National Ethics Committee on Assisted Human Reproduction, March 2005, p 2 since designated as ACART Guidelines under section 83 of the HART Act 2004. In the earlier proposed guidelines disseminated for public consultation, testing in the categories of familial single gene disorders, familial chromosomal disorders and sex-linked disorders was to be limited to circumstances when 'the option of prenatal testing alone is unacceptable to the couple'. The implication of the proposed provision was that prenatal testing was to be considered as a first option, and only when it was an unacceptable primary clinical course of action for the proposed parent(s) should PGD be considered. There is no such limitation in the revised Guidelines.*

565 *PGD for BRCA 1 and 2 has reportedly been carried out in the United States and in Belgium.*

566 *See HFEA, Choices and Boundaries, November 2005.*

567 *Tilstone, C., 'UK Clinicians to Screen for BRCA Mutations' 6 Lancet Oncol 358 (2005).*

568 *See Henderson, M., IVF Screening Looms for Breast Cancer Gene, 11 August, 2005. Available at http://www.timesonline.co.uk/article/0,,2-1731325,00.html See Press Release, 11 August 2005, 'Should Embryo Screening Help Parents Prevent Passing on a Wider Range of Inheritable Diseases?' available at http://www.hfea.gov.uk/PressOffice/Archive/1123751318 accessed 6/09/2005*

569 *Each application for a treatment licence requires the payment of a £200 fee. Currently research license fees are set at £200, with the intention to increase them to up to £6000. The reason for the leap is justified by the expensive nature of administering research licenses. If they are to be administered more efficiently, with less delays for the researchers, more staff are required creating more expense. See Human Reproductive Technologies and the Law, HC 7-II, 200, supra cit. evidence of Anne McLaren.*

570 *See HFEA Press Release, 19 January 2005.*

571 *These include licensing for new conditions; PGD with tissue typing; tissue typing on its own; and testing for late onset conditions or susceptibility genes.*

572 *Brazier, loc cit.*

573 *See Lee, R and Morgan, D., 'Regulating Risk Society: Stigmata Cases, Scientific Citizenship & Biomedical Diplomacy' 23 Sydney Law Review 297, at p. 310 (2001).*

574 *Kalfoglou, A., 'PGD Patients' and Providers' Attitudes to the Use and Regulation of Preimplantation Genetic Diagnosis' 11 Reprod Biomed Online 486 (2005). Concerns about the safety and quality of PGD have been uppermost in both consumers and providers minds.*

575 *Human Assisted Reproductive Technology Act 2004, s 80(1).*

576 *Standards New Zealand is contracted by the Ministry of Health to develop this standard. It is likely to be completed in early January 2007. The standard will be referred to as NZS 8181:2007 Fertility Standards and Audit Workbook. The standard will cover ethical and cultural safety, and consumer rights amongst other things.*

577 *Human Assisted Reproductive Technology Act 2004, s81(6).*

578 *Health and Disability Services (Safety) Act 2001, s9.*
579 *Human Assisted Reproductive Technology Act 2004, s 81(1)(a-d).*
580 *Notice of this approval appeared in the New Zealand Gazette, No 158, Wellington, , Thurs 2 December 2004, p 3925 pursuant to section 81(4) of the Human Assisted Reproductive Technology Act 2004. (Note an error in the notice, which refers to the relevant clauses as they appeared in the HART Bill, rather than as they appear in the HART Act 2004). A provider who is accredited by RTAC in the interim period is deemed to be certified for the purposes off section 26 of the HDS(S) Act 2001.*
581 *See Human Assisted Reproductive Technology Act 2004, s82. The RTAC Code of Practice provides guidelines relating to staff and resources, patient information, consent, laboratory services, treatment methods, record keeping, ethics and research, quality control and accreditation. In relation to laboratories, the Code of Practice provides that biochemistry/endocrinology and andrology laboratories must both be accredited by the National Association of Testing Authorities or the New Zealand equivalent to ISO 17025 guidelines. See The Fertility Society of Australia Reproductive Technology Accreditation Committee, Code of Practice for Assisted Reproductive Technology Units, Revised February 2005.*
582 *Human Assisted Reproductive Technology Act 2004, S35(2).*
583 *AGART recommended that fertility clinics should collect and report an ART infants NHI number to the Ministry of Health so that it may be anonymously linked with the New Zealand Birth Defects Register and other databases held by the Ministry of Health. See Ministry of Health, Health Report, Ref No 20057668, (21 April 2005). The recommendations were made by the Director General of Health. Under section 79 of the Act the Director-General of Health is deemed to be the advisory committee until the relevant section of the HART Act comes into force on 22 August 2005. However, not all health outcomes will be picked up as birth defects, such as some epigenetic disorders. Nor are medium or long term data collected. It is intended that the NHI number of ART babies will be periodically matched with the Birth Defects Monitoring Programme. No other matching is intended, although theoretically the data could be matched to any database which also has the National Health Index number. Personal communication via letter, Kathy Spencer, Deputy Director General, Sector Policy Directorate, Ministry of Health, 23 Feb 2006.*
584 *This is described as 'transport PGD'.*
585 *These activities include the carrying out of treatment procedures or treatment procedures of a particular kind; the forming of an embryo outside the body of a woman; the storage of gametes, zygotes or embryos; the undertaking of approved research.*
586 *See IT Act 1995, s97(3).*
587 *ITA, Conditions for Licence: Applications for Licences by Hospitals and Day Procedure Centres (5th Ed) January 2004). In drafting the document, the ITA drew upon the NHMRC Ethical Guidelines on Assisted Reproductive Technology (20004) and the RTAC Code of Practice for Centres Using Assisted Reproductive Technology.*
588 *IT Act, s13. Before suspending a licence the Authority must allow the licensee to make written submissions, s113(2). However, under section 114 of the Act an immediate suspension may be put into effect by the Authority if in the Authority's view there is an overriding public interest in doing so, and the Authority has obtained the approval of the Minister for Health. Where a person has been found guilty of an offence against the Act, the Authority may, upon having given written notice, cancel a licence. However, such a cancellation must be preceded by the opportunity for a written submission by the licence holder. Further, the decision to cancel the licence must have the approval of the Minister for Health. See s 115.*
589 *See IT Act 1995, s110(b).*
590 *Human Fertilisation and Embryology Act 1990 s17(1)(b),(d).*
591 *Code of Practice, (6th Ed.), 2003 para 14.11.*
592 *Human Reproductive Technologies and the Law, HC 7-1, para 366, supra cit. The CPA does include andrology laboratories.*
593 *HFE Act 1990, s13-17.*
594 *See Human Reproductive Technologies and the Law, HC 7-1, p. 103 para 233, supra cit.*
595 *These include the Association of Clinical Embryologists, the British Andrological Society, the Royal College of Nursing and the British Infertility Counselling Association.*
596 *The Whitakers travelled to Chicago, and successfully conceived a child who was a tissue match.*
597 *'We are in the process, for instance, of streamlining how we license PGD, to make it simpler and to involve patients more directly. So I believe that patients will feel more involved in our processes and they will have the opportunity to give evidence to us face to face, if that is what they want to do'. Suzi Leather, in evidence to HC Select Committee. Human Reproductive Technologies and the Law, HC 7-II, Q1235, supra cit.*
598 *The primary purpose of Ombudsmen, who are appointed by the New Zealand Parliament is to inquire into complaints raised against New Zealand central, regional and local government organisations or agencies. They are independent review authorities and are accountable to Parliament, not the Government. An ombudsman may undertake a review of any decision or recommendation made or act done or omitted by a central or local government department or organisation which affects any person or body of persons in their personal capacity.*

As a statutory body under the auspices of the Ministry of Health, ACART would be within the jurisdiction of the Office of the Ombudsman. These complaints fall under the Ombudsmen Act 1975. After an investigation into the complaint the Ombudsman forms an opinion whether the act, omission, decision complained of: appears to have been contrary to law, was unreasonable, unjust, oppressive or improperly discriminatory; was in accordance with a rule of law or a practice that is or may be unreasonable, unjust, oppressive of improperly discriminatory; was based on a mistake of law or fact; or was wrong. An Ombudsman can also consider whether a discretionary power has been exercised for an improper purpose or on irrelevant grounds or after taking account of irrelevant considerations, or whether reasons should have been given for the decision or recommendation. Where an Ombudsman forms the opinion that a complaint has merit, it may be recommended that the department or organisation concerned take action to remedy the complaint. Although an Ombudsman has no power to force a department or organisation to accept a recommendation, most recommendations are accepted.

599 *See ITA 1995, s149.*

600 *ITA 1995, s149(2).*

601 *HFE Act 1990, s9(1).*

602 *1991 No. 1889.*

603 *Human Fertilisation and Embryology Authority (Licence Committees and Appeals) Regulations 1991, 1889, reg 4, 5. Three members constitutes a quorum.*

604 *HFE Act 1990, s20(6).*

605 *HFE Act 1990, s20(3).*

606 *HFE Act 1990, s20(4)(a)(b).*

607 *See Lee and Morgan, op cit, at p. 126.*

608 *Hansard, Human Assisted Reproductive Technology Bill, third reading, 10 Nov 2004, 16839.*

609 *The prohibitions in relation to human reproductive research fall short of a complete ban. The prohibited actions set out in Schedule 1 of the Act exclude artificially forming for reproductive purpose a cloned embryo, but do not preclude artificially forming a cloned embryo for research purposes. The other provisions only preclude implanting the specified organisms.*

610 *See HART Act 2004, s35(1)(b)(iii).*

611 *Not least by Sue Kedgeley, the Deputy Chair of the Health Select Committee considering the Human Assisted Reproductive Technology Bill as amended by Supplementary Order Paper, no 81. See Hansard, Dianne Yates.*

612 *Two major high profile legal challenges have been taken in particular. The first involved cloning, see R (On the application of Bruno Quintavalle) v Secretary of State for Health [2003] UKHL 13, and tissue typing R (On the application of Josephine Quintavalle) v Secretary of State for Health [2005] 2 All ER 555 UKHL, [2005] UKHL 28, [2005] 2 WLR 1061.*

613 *Id. See also Lord Winston.*

614 *Prior to the Act all fertility services in New Zealand sought accreditation by the Reproductive Technology Accreditation Committee (RTAC) of the Fertility Society of Australia on a voluntary basis.*

615 *Liddell and Hall, loc cit, at p. 215.*

616 *The concept of regulatory legitimacy is discussed in detail by Dr Kathy Liddell in her unpublished PHD thesis, Biolaw and Deliberative Democracy: Regulating Human Genetic Technology in a Morally Pluralist Society, (D Phil Thesis, Faculty of Law, University of Oxford 2000-2003).*

617 *McCarthy, D., 'Why sex selection should be legal', J. Med Ethics 2001;27:302-307 at p. 302*

618 *See Ministry of Health, Terms of Reference, Advisory Committee on Assisted Reproductive Technology, 2005.*

619 *Liddell, K., Biolaw and Deliberative Democracy: Regulating Human Genetic Technology in a Morally Pluralist Society (Unpublished D Phil Thesis, Faculty of Law, University of Oxford 2000-2003).*

620 *Prepared by the National Ethics Committee on Assisted Human Reproduction, March 2005, and since designated as interim ACART Guidelines under section 83 of the HART Act 2004.*