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5 Update: Preimplantation Genetic Haplotyping (PGH) 120
I INTRODUCTION

Preimplantation genetic diagnosis (PGD) constitutes one of the most significant medical innovations of the last two decades in the area of assisted reproductive technology. The information derived from the genetic analysis of cells aspirated from an embryo created by \textit{in vitro} fertilisation (IVF) may be used for diverse purposes, all of which may influence the decision as to which embryos should be implanted, and which discarded. With the introduction of the Human Assisted Reproductive Technology (HART) Act 2004, the performance of PGD is now subject to legislative and regulatory restraint. The purpose of this report is to consider extensions to the current scope of permissible PGD in New Zealand, and to determine the effect of the HART Act 2004 provisions on decision-making in this area.

PGD was first performed to determine the sex of embryos at risk of inheriting an X-linked condition. As the technology has become more sophisticated, it has become possible to determine the precise location of many genetic mutations and to develop genetic tests capable of diagnosing the presence of such mutations. At its simplest, PGD provides an opportunity for parents and clinicians to avoid the birth of a child who may be seriously impaired as a result of a familial single gene or familial chromosomal disorder. This category of PGD has been declared an ‘established procedure’ under the HART Act 2004 and may be carried out as a routine clinical procedure.\(^1\) PGD may also be used to screen embryos for numerical chromosomal abnormalities in the case of women who are of advanced reproductive age or who have had recurrent implantation failures or miscarriages. This category of PGD, which has also been declared to be an established procedure, permits the negative selection of embryos with chromosomal abnormalities which may threaten successful implantation and gestation. This type of PGD, commonly referred to as aneuploidy screening, constitutes the greatest demand for PGD and has largely escaped controversy.\(^2\) Prospective parents undergoing aneuploidy screening are simply trying to achieve a successful pregnancy and birth, rather than selecting against, or in favour of, a particular trait.

Beyond PGD simpliciter, PGD may be utilised for a multiplicity of purposes. For example, it may be performed to determine whether an embryo possesses the same tissue type as an existing sibling in need of a stem cell transplant. This latter application of PGD has stimulated vigorous international debate, particularly where the prospective embryos are not at risk of inheriting a genetic disorder. Testing for disorders which confer susceptibility, rather than a certainty, of developing a genetically-based condition is another example of an extended application of PGD. It too has engendered significant discussion because an individual may never develop the particular disorder or, even if they do, may live many years before the disorder becomes apparent. PGD can also reveal not only whether an embryo has a particular
genetic mutation which will manifest in disease, but also whether the embryo is a healthy carrier of the mutation. Healthy carriers of a familial mutation do not, with some exceptions, have any physical manifestation of the disorder, but may transmit the genetic disorder to the next generation. Hence, selection against healthy carrier embryos is controversial because it eliminates healthy embryos rather than embryos which would result in an affected child.

The advent of preimplantation genetic haplotyping (PGH) signals a further scientific advance in the area of preimplantation genetic testing. The procedure is reportedly more accurate than PGD. Significantly, PGH does not require that the precise details of a genetic mutation are known in advance. All that is required is knowledge of the region on a particular chromosome associated with a specific genetic mutation which results in a genetic disorder. With the introduction of PGH the number of single gene disorders that may be detected at the preimplantation stage has multiplied. In some instances, it is possible to distinguish embryos which are healthy carriers of a defective gene where it was previously not possible. In the case of a disorder such as Duchenne muscular dystrophy, an X-linked recessive disorder, PGD currently requires selection against all male embryos. With PGH, it is possible to determine which of the male embryos are affected and which are not. This in turn increases the number of embryos suitable for transfer and the success rate of a PGH cycle. PGH can also distinguish which female embryos are healthy carrier embryos of the mutation and which are healthy non-carriers. In the future whole genome screening, which could provide a complete genetic profile with the use of microarray technology, may be possible if current technical problems can be overcome. Progress in this area will provide significantly more scope for choosing embryos based on genetic characteristics.

The provision of PGD in New Zealand is still in its infancy, the first cycle only being performed towards the end of 2005. The HART Act 2004, the Human Assisted Reproductive Technology (HART) Order 2005 and the Guidelines on Preimplantation Genetic Diagnosis (2005) have established the lawful parameters of this relatively new medical technology. An in-depth analysis of these regulatory initiatives was undertaken in a prior report. The current regulatory framework is, in some respects, conservative in comparison to some other common law jurisdictions. The only applications of PGD permitted in New Zealand are strictly therapeutic, as understood in the narrow sense of the term, and they may only be undertaken to prevent the transmission of serious genetic disorders. The regulatory regime reflects an approach that permits PGD in the least controversial circumstances when it is generally perceived to be a medical imperative. However the current regulatory framework for PGD is not static. Regulatory mechanisms exist which enable the statutory Advisory Committee on Assisted Reproductive Technology (ACART) to restrict, or extend, the boundaries of PGD in New Zealand.
In view of developments in science and in other jurisdictions, it is likely that there will be a demand to extend the current ambit of the regulatory framework. Extending, or refusing to extend the current parameters for PGD will require a clear articulation of how the principles declared in the HART Act 2004 which govern decision-making in this area are to be applied.\(^9\)

This report examines the conducting of PGD in areas which would broaden the existing regulatory scheme. In the following section an analysis of the HART Act 2004, and in particular the purposes and principles of the Act, will be undertaken to provide a foundation for the substantive examination of expansions to PGD in the following sections. The expansions discussed in sections 3 and 4 involve human leukocyte antigen (HLA) tissue typing and negative selection of healthy carrier embryos, respectively. In a field of rapid scientific progress, the last section in this report provides an update regarding the most recent development in the field of PGD: preimplantation genetic haplotyping (PGH).

2 HUMAN ASSISTED REPRODUCTIVE TECHNOLOGY ACT 2004

2.1 Introduction

It has been observed that the extent to which the use of genetic technology is determined by Parliament reflects the underlying public health and social policy agenda of a particular government.\(^{10}\) The introduction of the HART Act 2004 has signalled that human assisted reproduction is no longer an area of medicine regulated simply by professional self-regulation and the applicable general medical law; instead, it is now subject to a specific legislative scheme.

This report will argue that, with the establishment of the HART Act 2004, the New Zealand Government has established a mid-ground philosophy which on the one hand eschews radical reproductive liberty but on the other seeks to secure the benefits of assisted reproductive technology for ‘individuals and for society in general’ within a protective framework. Arguably, Parliament has opted for a flexible regime which may keep pace with progress and which requires dialogue with the public, whilst prohibiting what are deemed to be ‘unacceptable’ procedures or research. However, it is argued in this report that the objectives and purposes of the Act still support a presumption of reproductive liberty as the starting point when determining the appropriate parameters of assisted reproductive procedures such as PGD.

A brief outline of the current regulatory framework will be provided. However, the focus of this section is an analysis of the relevant purposes, principles and corresponding duties contained in the HART Act 2004, before the report moves on to consider expansions to the current regulatory framework for PGD in sections 3 and 4.
2.2 Current Regulatory Framework – The Act, the Order and the Guidelines

The HART Act 2004 establishes certain prohibitions such as the ban on reproductive cloning and germline genetic modification. In all other respects, the role of determining and advising what restrictions should be imposed on the use of reproductive genetic technology, in particular PGD, has been delegated to the statutory advisory body created under the Act, ACART.

The Act creates three categories of assisted reproductive procedures. The first encompasses procedures which are statutorily prohibited, such as PGD for social sex selection.11 The second category comprises procedures which are regulated and require the approval of the Ethics Committee on Assisted Reproductive Technology (ECART) in accordance with guidelines formulated by ACART before they may be performed.12 The third category constitutes activities which have been declared by Order in Council to be established procedures.13 Established procedures are routine clinical procedures that may be carried out without external scrutiny.

The Act provides no express guidance in relation to PGD with one exception. The conducting of PGD to diagnose and select on the grounds of sex in the absence of an X-linked condition is prohibited.14 This is a clear indication from Parliament that PGD should not extend to the selection of nondisease-related traits.

HLA tissue typing is currently a regulated procedure under the Act and applications may only be approved by ECART in accordance with the Guidelines on Preimplantation Genetic Diagnosis.15 HLA tissue typing to enable the selection of an embryo which has a compatible tissue type with an existing sick sibling in need of a stem cell transplant is permitted on a case-by-case basis according to specified criteria. However performing tissue typing is prohibited unless the embryos are at risk of inheriting a genetic disorder for which there is a test available.

PGD for familial single gene disorders, familial sex-linked disorders and familial chromosomal and non-familial chromosomal disorders in restricted circumstances are currently established procedures under the provisions of the HART Order 2005.16 Selection against healthy carrier embryos was not considered in the public consultation on PGD prior to the drafting of the PGD Guidelines, and is not expressly referred to in the HART Order 2005.17 Consequently it is unclear whether selection against healthy carrier embryos is permitted as a routine procedure under the Order.

It has been argued elsewhere that performing PGD for late-onset susceptibility disorders is permitted under the current established procedures category, although this does not appear to have been intentional on the part of the policy-makers.18 Whilst the merits of permitting PGD for susceptibility disorders has not been debated in New Zealand, the wording of the established procedures order appears
to be sufficiently broad to encompass PGD for lower-penetrance disorders as an established procedure.

As already indicated, this analysis is concerned with extensions to the regulatory framework in the areas of HLA tissue typing and selection against unaffected carrier embryos. However, a substantive analysis of these issues cannot be undertaken without first addressing the implications of the HART Act 2004. Consequently, the report now examines the objectives and purposes of the Act, and the duties imposed by the principles declared in the Act.

2.3 The purposes and the principles

Section 3 of the HART Act 2004 articulates six distinct purposes. Additionally, a set of principles is provided which must guide persons exercising powers or performing functions under the Act if relevant to the particular power or function being exercised. Taken together, these objectives and principles do not overtly reveal an underlying principle or approach which is to be applied to human assisted reproductive technology. To distil an overriding principle necessitates careful dissection of the relevant purposes and principles of the Act.

Section 5(1) of the Interpretation Act 1999 states that ‘the meaning of an enactment must be ascertained from its text and in the light of its purpose’. The objectives of the HART Act 2004 may be condensed down to four main themes.19 The first is to secure the benefits of assisted reproductive technology and research within a framework which protects and promotes the ‘health, safety, dignity and rights of all individuals’, particularly those of women and children, in the use of such technologies (s 3(a)).20 The second is to prohibit ‘unacceptable’ assisted reproductive procedures and research including certain commercial transactions relating to human reproduction such as the sale of human embryos or gametes (ss 3(b) and 3(c)). The third is to establish a flexible regulatory framework which delegates policy-making and regulatory authority to the two statutory bodies, ACART and ECART (ss 3(d), 3(e), 32, and 35). The fourth objective is to establish an information-keeping regime to ensure that people born from donated embryos or cells can find out about their genetic origins (s 3(f)). It is the first objective with which this analysis is concerned.

As already observed, the New Zealand Parliament has conferred on ACART the authority to determine and provide advice as to what constitutes permissible assisted reproductive procedures in New Zealand. When regulating contentious issues it is helpful, and often necessary, to adopt an overarching principle or set of principles that informs and supports the conclusions reached. Section 4 of the HART Act 2004 provides seven principles which must guide all persons (which implicitly includes ACART and ECART) who are exercising relevant powers or performing relevant
functions under the Act. (Emphasis added.) The principles relevant to this discussion are as follows:

(a) the health and well-being of children born as a result of the performance of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure:

(b) the human health, safety, and dignity of present and future generations should be preserved and promoted:

(c) 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:

(d) 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

…

(e) the needs, values, and beliefs of Maori should be considered and treated with respect:

(f) the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect.

(Emphasis added.)

The principles apply to the full range of human assisted reproductive procedures and human reproductive research. The legislation encompasses activities such as human embryonic research, human cloning, the supply of embryos and gametes, and other related activities, so the principles are necessarily generic. Whilst these principles are intended to provide guidance for policy-makers, their generic nature means that their application to a particular issue may support a variety of outcomes. When considering the legitimacy of the current regulatory restraints on PGD, and extensions to the framework, an in-depth analysis of the first purpose and the principles contained in the Act is necessary.

2.3.1 The first purpose – Whose dignity and what rights?

The first purpose of the Act refers to securing the benefits of assisted reproduction for individuals and for society in general by taking appropriate measures to protect and promote the health, safety, dignity and rights of all individuals. The full text of section 3(a) provides:
3 Purposes
This Act has the following purposes:
(a) 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.

Whilst the concept of health and safety are self-explanatory, the concepts of ‘dignity’ and ‘rights’ beg closer analysis. Both of these are explored in greater detail before attention is turned to the principles provided in the Act.

2.3.1.1 Dignity
The promotion and protection of human dignity is a stalwart principle in international instruments as a criterion for guiding policy-making in the area of human rights as well as that of controversial scientific advances. This trend to incorporate the principle of human dignity into legislative instruments is evident in the HART Act 2004; but it is not defined, nor is it clear how it is to be applied.

The traditional human rights informed view of human dignity ascribes to the inherent worth of an individual, recognising a right to individual autonomy and the right to self-determination. Whilst autonomy is taken by many to be a core component of the concept of dignity, a broader concept of human dignity has been articulated by Justice Iacobucci of the Supreme Court of Canada:

*Human dignity means that an individual or group feels self-respect and self-worth. It is concerned with physical and psychological integrity and empowerment.*

The problem with the concept of human dignity is the inherent difficulty in determining what it is and how respect for human dignity is best achieved. Human dignity is an amorphous concept, which changes according to the diverse perspectives held by various groups in society. It is difficult to attribute a precise meaning to the concept even in the particular context of the HART Act 2004. Dignity may be invoked to justify alternative sides of the same argument. For example, some would argue that to select an embryo on the basis of defined genetic characteristics is an inappropriate instrumentalisation and an affront to the prospective child’s dignity. Others may counter that to arbitrarily restrict parents from making decisions which they perceive would enhance the quality of life of their child and family is an affront to their personal dignity and autonomy.
It has been claimed that, in the light of new genetic technologies, human dignity is increasingly used ‘as a form of general condemnation and as blanket justification for regulatory restraint’\(^2\)\(^5\). The use of human dignity as a criterion for policy-making has been described by at least one commentator as a ‘useless concept’\(^2\)\(^6\) and its relevance in bioethical discourse has been questioned.\(^2\)\(^7\) It has been argued that often

\[
\text{the use of human dignity seems to amount to little more than an articulation of a general social unease with a given technology.}^2\)\(^8\]
\]

Whilst human dignity may support the right of an individual to make autonomous choices, dignity may also be used as a means of restraint. In this latter context, the use of dignity as a criterion is ‘meant to reflect a broad social or moral position that a particular type of activity is contrary to public morality or the collective good’.\(^2\)\(^9\) The result is that an undefined notion of human dignity may determine whether a particular scientific activity is acceptable depending on whether it offends human dignity, rather than on the basis of tangible harms that may result from it.\(^3\)\(^0\) It is generally conceded that although the concept of human dignity is of great importance, it is not helpful as a sole guiding principle when determining the appropriate scope of reprogenetic technology. As one commentator observed:

\[
\text{… it is something of a loose cannon, open to abuse and misinterpretation; it can oversimplify complex questions; and it can encourage a paternalism that is incompatible with the spirit of self-determination that informs the mainstream of human rights thinking.}^3\)\(^1\]
\]

Although the concept of respect for human dignity has been described as ‘comprehensively vague’,\(^3\)\(^2\) most consider that it has a place in discussions involving new genetic technologies.\(^3\)\(^3\) It has been observed that the idea of human dignity may be of greatest assistance when it is used as a vehicle for exploring differing philosophical approaches in a pluralistic society.\(^3\)\(^4\) Such an approach considers the different values held and deemed important by different individuals or groups, and essentially involves having respect for others. It is argued here that, when considering the performance of assisted reproductive procedures under the HART Act 2004, competing claims based on dignity must be fully articulated and weighed against the relevant interests at stake or by reference to an overriding principle.

2.3.1.2 Reproductive rights

As already indicated, the first purpose declared in the HART Act 2004 is to secure the benefits of assisted reproductive technology for individuals and society by taking measures to protect and promote the ‘rights of all individuals’ in the use of assisted reproduction. The Act does not elaborate on the nature of applicable rights. Arguably a highly relevant right in this context is the claimed right to reproductive liberty.
However, it is not sufficient to simply assert that reproductive liberty is preserved under the Act without an analysis of the basis of the right and whether it is applicable to assisted reproduction.

One of the political characteristics of a liberal democracy is the philosophy that citizens should be free to conduct their lives without interference by the State unless such interference is necessary to avoid harm to others. This principle effectively means that individuals ‘should be free to make their own choices in the light of their own values whether or not these are acceptable to the majority’, unless there is an adequate justification for the State to intervene.

The liberal democratic presumption encompasses two central elements, autonomy and liberty. Respect for autonomy is premised on the idea that an individual’s best interests are generally best served by allowing a person to make autonomous decisions; and individuals are assumed to be able to judge, better than anyone else, what constitutes their own interests. Autonomy requires not only ‘independence from controlling influences’, but also the ‘capacity for intentional action’.

It stands to reason that when an individual’s liberty is curbed, so too is that person’s autonomy and, potentially, the capacity to further their relevant interests. This is generally perceived to constitute a ‘harm’, and is the basis for the harm principle articulated by the American philosopher Joel Feinberg. The harm principle provides that

\[
\text{state interference with a citizen’s behaviour tends to be morally justified when it is reasonably necessary … to prevent harm or the unreasonable risk of harm to parties other than the person interfered with.}\]

Given the liberal presumption, it has been argued that the burden of justifying restrictions on liberty is placed on ‘those who would deny liberty, not on those who would exercise it’. The concept of reproductive liberty is subsumed within the liberal democratic presumption.

The basis of reproductive liberty, which had its genesis in the reproductive rights movement of the twentieth century, is the right claimed by women to control their reproductive capacities and to make reproductive choices. The right to reproductive liberty was asserted as the moral justification for permitting access to lawful termination of pregnancy in the abortion debates of the mid 1900s. The right to reproductive liberty was established as a legal right with the acknowledgment by the legislature of a woman’s right to a lawful abortion. In the context of abortion, reproductive liberty in a liberal, rights-based society has been acknowledged as a basic freedom.
Reproductive liberty is a facet of both the liberal democratic presumption and liberty in general. The overlap between reproductive liberty, human dignity and democracy is illustrated in the following words of Dworkin:

*The right of procreative autonomy has an important place … in Western political culture … The most important feature of that culture is a belief in individual human dignity: that people have the moral right – and the moral responsibility – to confront the most fundamental questions about the meaning and value of their own lives for themselves, answering to their own consciences and convictions … The principle of procreative autonomy, in a broad sense, is embedded in any genuinely democratic culture.*

Although the principle of reproductive liberty has been established in the context of abortion and the right to choose, closer analysis is required to determine whether it is automatically applicable to assisted reproductive technology. Reproductive liberty is generally accepted as a negative right against interference by the state or others with regard to reproductive decisions. In the modern context, reproductive liberty has been used as a moral argument in favour of permitting the use of reprogenetic technologies to assist parents to have ‘healthy, biologically related offspring.’ It is argued that the right in a liberal democratic society to reproductive liberty is applicable to the performance of assisted reproductive procedures such as PGD, and is implicitly adopted in the purpose declared in section 3(a) of the Act. Before addressing this latter issue, the nature of the right to reproductive liberty established in relation to abortion is first considered.

Although reproductive liberty has been recognised as an important freedom, which provides a strong argument in favour of a woman’s right to choose whether or not to continue a pregnancy, it is not absolute. In the context of abortion, it is relatively common to hear a person refer to ‘abortion on demand’. Yet this is based on a widely held misapprehension. In New Zealand, abortion is lawful up until the twentieth week of pregnancy, but only where continuing the pregnancy would pose a serious risk to the life, or to the physical or mental health, of the woman, or where there is a substantial risk of serious handicap in the child. The law reflects a view that the further developed a foetus has become, the more protection it is owed. Late abortions carried out in the second trimester for perceived trivial grounds have attracted scrutiny both internationally and domestically.

Clearly there is evidence of a widely held view that the more advanced a pregnancy is, the more compelling a reason must be to justify termination. Although the intrinsic value of reproductive liberty has been a powerful argument in favour of permitting abortion, it is a concept which is limited by the dictates of what is perceived to be broadly acceptable by society and the law.
It is plausible to argue that the principle of choice and reproductive liberty provides a strong moral basis for claims in relation to the desire to conceive a child, just as it deserves respect in relation to the desire not to have a child. However, it must be acknowledged that, although it may exist, a right is not necessarily unqualified. The Report of the United Kingdom’s House of Commons Science and Technology Committee endorsed the view that achieving a pregnancy with the assistance of reproductive technology is an exercise of reproductive freedom. However, the Committee also agreed with the view that reproductive freedom was not absolute. Reproductive freedom does not necessarily confer positive rights of access to assisted reproductive procedures. But it does mean that ‘the principles of choice and autonomy are principles or values that, among others, must be seriously considered’. John Robertson has cogently argued that:

… recognizing procreative liberty as a moral or legal right or important freedom does not mean that it is absolute, but rather that there is a strong presumption in its favor, with the burden on opponents to show that there is a good case for limiting it. Many critics, however, assume that claims of procreative liberty are claims of an inalienable or absolute right. But a right can be inalienable – not transferable to others – without being absolute. And no serious proponents of procreative liberty argue that it is absolute and can never be limited. Rather, the debate is (or should be) about whether particular exercises or classes of exercise of the right pose risks of such harm to others that they might justly be limited.

The approach adopted in this analysis is that the moral arguments which support reproductive liberty are as valid in respect of conceiving a child using assisted reproductive technology as they are in respect of supporting a woman’s right to choose to terminate an unwanted pregnancy. However, the concept of reproductive liberty does not confer unfettered choice. Rather, it signals the importance of the interests at hand. A presumption of reproductive liberty is arguably consistent with the objectives provided in the HART Act 2004. These expressly focus on protecting and promoting the interests of the individuals involved, particularly women and the putative children. The question is, to what extent should reproductive liberty be restrained and why? By virtue of the harm principle, legitimate restrictions on PGD require not only that a risk of harm must be demonstrated, but that it is of ‘sufficient magnitude to justify the harm caused to those whose liberty interest is curtailed’.

2.3.1.3 Disability rights

Other rights which may be relevant to section 3(a) of the HART Act 2004 include disability rights. Some disability rights proponents have voiced concern that PGD devalues people with disabilities. The New Zealand Bill of Rights Act (NZBORA) 1990 provides that everyone has the right to freedom from discrimination on the
grounds of discrimination in the Human Rights Act 1993, which include the right not to be discriminated against on the grounds of disability. The NZBORA 1990 applies to every person or body in the performance of any public function, power or duty conferred or imposed on that body by or pursuant to law. Consequently, the right to freedom from discrimination is an established legal right and persons exercising powers under the HART Act 2004 are subject to the provisions of the NZBORA 1990.

Although there are several strands to the concerns held by a subsection of disability rights advocates in regard to PGD and prenatal testing, the relevant concern for this section of the Act relates to discrimination. It is frequently observed that a ‘major problem with having a disability is not the disability per se, but the discrimination the disabled face for themselves and their families’. It follows that disability that results principally from impairment should be distinguished from disability that results from ‘a socially inadequate or discriminatory response to impairment’. Consequently, the experience of disability extends beyond physical limitations to the way that society responds to the needs of people with particular disabilities.

This is highly relevant. It has been said that the ‘choices’ provided by new genetic technologies may be illusory, given that

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\text{society does not truly accept children with disabilities or provide assistance for their nurturance. Thus, a woman may see no realistic alternative to diagnosing and aborting a fetus likely to be affected,} \]

or, by analogy, engaging in PGD. In this context, it is important to consider that choices may be made on grounds that ‘reflect a particularly inflexible social structure rather than the particular severity of a medical condition’. There is also a resistance to PGD by those who perceive that permitting embryo diagnosis devalues and expresses discriminatory attitudes towards those already born with impairments. Yet the fact remains that not all the difficulties associated with disability are socially constructed; and parents may legitimately seek to avoid having their children experience significant functional limitations. Nor is it incompatible to wish on the one hand to avoid transmitting a genetic mutation, but on the other to support attempts to minimise discrimination towards the disabled and to support policies which assist the disabled to achieve their potential. As one commentator has noted:

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\text{for parents to wish to avoid the harms of impairment that are accentuated by lack of social support is not necessarily to collude in discriminatory practices, where society cannot be expected absolutely, rather than reasonably, to provide social support, given the diverse and conflicting interests that it is required to accommodate.} \]
The current policy in New Zealand permits prospective parents to undertake PGD if they are at risk of transmitting a serious genetic disorder. That decision is in keeping with the grounds for lawful abortion on the grounds of foetal abnormality. What is apparent is that there should not be an assumption on the part of providers or counsellors that parents must act to avoid disability, or make certain choices. Rather, families should be supported in decision-making with non-directive counselling and sufficient understanding of the relevant disorder.

2.3.2 The principles

Under section 4 of the HART Act 2004 all persons exercising powers or performing functions pursuant to the Act must be guided by the principles declared in the Act. The first of these seven principles provides that the health and well-being of children born as a result of an assisted reproductive procedure or an established procedure should be an important consideration in all decisions about that procedure.

2.3.2.1 Health and well-being of the child

Clinicians, as well as policy-makers, have a specific responsibility concerning the interests of the future child. The primary aim of assisted reproductive technology, including PGD, is the achievement of a healthy live birth, yet the relative importance of the interests of the prospective child is not clearly established. The wording of the health and well-being principle in the Act deliberately eschews the usual paramount importance attributed to a child’s welfare in family law. Although the HART Bill (as amended by Supplementary Order Paper, No. 80, 2003) initially required that the health and well-being of children born as a result of assisted reproduction should be ‘paramount’ in all decisions about procedures, this provision was altered by the Health Select Committee during the legislative process.

The paramount welfare principle was rejected because it would narrowly circumscribe the performance of any procedure which may pose a physical or psychological risk to the prospective child. It could even be interpreted as implying that ‘one should not knowingly and intentionally bring a child into the world in less than ideal circumstances.’ Because assisted reproductive technology necessarily entails greater risks than those associated with natural conception, the paramount provision could prevent the approval of assisted reproductive procedures because of those heightened risks. Similarly, it has been observed that, if the paramount welfare principle were consistently applied to all instances of reproduction, it would ‘exclude the overwhelming majority of the population from procreation’.

The polar opposite of the maximum risk principle is the minimum risk principle. The application of this principle would preclude the performance of an assisted reproductive procedure only when there is a serious risk that the life of the prospective child would be so miserable that it would not be a life worth living. Such a standard
would mean that the range of permissible procedures would be extremely broad regardless of risk. It attributes enormous importance to reproductive autonomy and parental autonomy.

The welfare principle declared in the HART Act 2004 suggests that Parliament intends an intermediate position between these two extremes: it does not ascribe paramountcy to the future child’s welfare, but still requires that the future child’s health and well-being should be an important consideration. This avoids outcomes that would be counter-intuitive to many, such as preventing procedures from being undertaken on the basis of a risk so small as to be negligible on the one hand, or permitting procedures to be performed impervious to the risks posed to the future child on the other.

Significantly, ‘health and well-being’ would appear to encompass not only physical well-being, but also the social, emotional, psychological and cognitive aspects of a child’s welfare. This potentially provides greater scope for expanding the ambit of PGD, by permitting a range of factors to be considered – not just physical considerations. What constitutes sufficient health and well-being is an open question. It may simply constitute ‘the abilities that are required for an individual to enjoy a normal range of opportunity in society’, as opposed to a life that is ‘significantly deficient in one or more major respects that generally make human lives valuable and worth living’.

2.3.2.2 Intergenerational justice

The second principle of the HART Act 2004 provides that ‘the human health, safety, and dignity of present and future generations should be preserved and promoted’. (Emphasis added.) It appears expressly to incorporate the principle of intergenerational justice into the principles of the HART Act 2004.

The application of the principle of intergenerational justice to reproductive decision-making has emerged over the last decade and a half. Adherence to this principle requires a consideration of the interests of future generations when making current decisions and is, essentially, the duty to prevent intergenerational harm.

The principle of intergenerational justice is open to wide interpretation. If given a radical interpretation, this requirement may be interpreted as precluding persons from knowingly passing on deleterious genes to their offspring and could justify the prevention, either by legal means or by overt pressure on prospective parents, of the births of children with severe genetic disease. Applying this interpretation, failure to avoid an affected pregnancy by undertaking PGD, or knowingly carrying an affected pregnancy, may contravene the concept of intergenerational justice. Such an outcome was foreseen by the commentator who made the following statement:
the completion of the human genome project will provide a basis for acting on a moral obligation for future generations, a claim that has appeared weak in the past. A generation with such knowledge who neglected to use it to minimize the risks in reproduction could hardly be said to respect the requirements of intergenerational justice.\textsuperscript{77}

Applying the concept of intergenerational justice in this way is to assert that parents who have a disabled child are harming not only that child, but also the community and potentially successive generations. It has been argued that the advances in reproductive genetics

\textit{both reflect and reinforce the negative attitudes of our society towards those with disabilities. Indeed, medical genetics may add a new dimension if genetic disorder came to be seen as a matter of choice rather than of fate.}\textsuperscript{78}

Such a position would represent the imposition of a coercive eugenic philosophy under the Act. Government imposed eugenics, a practice perceived as being both abhorrent and a breach of civil liberties, is arguably inconsistent with the intention of the Act which preserves individual rights. The purpose of the Act, which is to secure the benefits of assisted reproductive technology for individuals and society by providing for the protection and promotion of the health, safety, dignity and rights of all individuals, particularly women and children, in the use of these procedures, does not support such an extreme interpretation of this provision. It is clear from this purpose and the principles of the Act that the legislation is most concerned with protecting the interests and rights of those directly involved in assisted reproduction, that is the future child and the prospective parents, rather than imposing a genetic blueprint for society.\textsuperscript{79} Consequently, a less extreme application of the concept of intergenerational justice would ascribe more emphasis on individual rights and is more sympathetic to the overall philosophy of the HART Act 2004.

It is argued that section 4(b) acknowledges that assisted reproductive procedures can have intergenerational effects, and requires that the health, safety and dignity of both current and future generations be deemed relevant in the exercise of a power or performance of a function under the Act. Whilst the current regulatory framework signals that the prevention of the birth of children suffering from serious disorders is an acceptable reproductive choice for some prospective parents, it is not a government-imposed public health requirement.

Although the concept of intergenerational justice may not be used as a basis for requiring parents to make certain choices, it may and has been used to justify permitting certain choices, such as sex selection.\textsuperscript{80} Although sex selection is prohibited under the Act, an argument in favour of sex selection on the grounds of intergenerational justice has been made.
This claim is predicated on the grounds that if it is accepted that one of the goals of assisted reproductive technology is to improve the objective well-being in a future child (by avoiding the birth of a disabled child), then the prevention of physical illness should not be the sole goal in the use of assisted reproductive technology. Rather, it is also justifiable to use such procedures when a future child could suffer poor levels of objective well-being not only as a result of medical factors, but also as a result of cognitive, emotional and social factors. This could occur when a child is exposed to harm ‘created because of the gender hostility of a specific social environment’. If the objective well-being of children and parents is reduced, the existing and new children will be objectively harmed. This will apply to their children, and thus to a diminution of the objective well-being of future generations. In this way, the concept of intergenerational justice in section 4(b) of the Act may be used to justify an expansion of the range of reproductive choices, when they are construed as enhancing or protecting the well-being of future children.

2.3.2.3 Health and well-being of women

The third principle of the HART Act 2004 provides 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’.

This provision was drawn from one of the core principles provided by the Canadian Assisted Human Reproduction Act 2004. However, in contrast to the HART Act 2004, the Canadian legislation expressly prioritises the interests of the child to be born by providing that ‘the health and well-being of children born through the application of assisted human reproductive technologies must be given priority in all decisions respecting their use’.

Arguably, section 4(c) of the HART Act 2004 does not seek to prioritise the interests of the women involved. It merely seeks to signal the fact that women, regardless of the circumstances which have required them to seek assisted reproduction, are necessarily required to undertake the greatest burden of assisted reproduction. Consequently their health and well-being must be safeguarded in the performance of assisted reproductive procedures. The justification for the principle in the Canadian framework was as follows:

Equality should be promoted among women and men; however, reproductive policy development should not proceed as though reproduction affects women and men in the same way. The physical and social burdens and risks of reproduction are borne primarily by women. These realities should be acknowledged and reflected in reproductive policy.
Although it is unavoidable that women carry the greatest physical burden of IVF, in the context of PGD there may be additional considerations. PGD may be necessary because the man is a carrier of an autosomal dominant disorder. Because of this, he may feel significant guilt that his partner has to go through an invasive and difficult procedure. There is also mounting evidence that men’s reproductive health needs are insufficiently provided for in health policies in general. Whilst section 4(c) expressly provides that the health and well-being of women must be protected, it should not be seen to diminish the effects that assisted reproduction may have on men.

It is argued that these principles flag the competing interests which must be taken into account under the Act, but do not elevate the interests of one party.

2.3.2.4 Informed choice and informed consent

Additional principles in the Act include the principle that no procedure should be performed unless an individual has provided informed consent. This principle merely restates the general law with regard to medical treatment and, at first glance, appears unremarkable. However, in the context of assisted reproduction, decision-making involving in vitro embryos is seldom a solitary endeavour.

It is an open question whether PGD, for example, requires the consent of only one or both prospective parents, or whether implantation of an embryo may occur if the prospective father withdraws consent. Although these issues beg further analysis, they are beyond the scope of this report, which focuses on PGD in conjunction with HLA tissue typing, and negative selection of carrier embryos.

The Act also provides a principle regarding donor offspring. However this principle is not relevant in the context of the current discussion. A further principle requires that the ‘needs, values, and beliefs of Māori should be considered and treated with respect’. A comprehensive analysis of PGD from a Māori perspective was undertaken in a prior report, and so will not be repeated here. Another relevant principle for this discussion is the final principle provided in the Act. It requires that the different perspectives in society are considered and treated with respect.

2.3.2.5 Ethical, spiritual and cultural perspectives in society

Section 4(g) of the Act declares the principle that ‘the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect’. This last principle is significant as it derogates from what has, for the most part, dealt with the interests of those directly involved in assisted reproduction, and moves to collective interests in society.

The principle contained in section 4(g) acknowledges the extreme diversity of opinion which exists in relation to assisted reproduction. Whilst differing perspectives may not be reconcilable, the Act requires the exploration of these perspectives
in a conscientious and meaningful way. However, in no way does it diminish the underlying purpose of the Act, which is to secure the benefits of advances in assisted reproduction within a protective framework.

Several perspectives are relevant when considering PGD and expansions to the regulatory framework. These include the differing perspectives on the moral status of the embryo. As this issue was canvassed in detail in a prior report, it will not be analysed further here. Another perspective equates the use of new reprogenetic technologies with the conducting of eugenics. It is alleged that the avoidance of genetic disorders through the use of reprogenetic technology may have a negative impact on society. These perspectives have been central in debates regarding the introduction of PGD simpliciter, and are relevant when contemplating expansions beyond.

2.3.2.5.1 Eugenics

When PGD was first introduced it was accompanied by an outpouring of eugenic concerns. This was, in part, a reaction rooted in the legacy left by the systematic government-imposed discrimination towards individuals on the basis of genetic characteristics in the late nineteenth and early twentieth centuries. The eugenics movement subscribed to the idea that certain characteristics such as intelligence were hereditary. Consequently, those considered to have suitably good heritable characteristics were encouraged to have more children, and others were discouraged or actively prevented from parenting.

New Zealand was not immune to eugenic influences when the Mental Defectives Amendment Bill was introduced into Parliament in 1928. The Bill contained provisions which, if enacted, would have permitted the compulsory sterilisation of people judged to be mentally defective. It also restricted the right of persons deemed mentally defective to marry. These provisions were met with vehement parliamentary opposition. Although the Bill was eventually passed, these clauses were not included. It has been claimed that ‘New Zealand was alone in the economically developing world in rejecting a formal proposition for the sterilization if not castration of people designated socially as “unfit”’. Some commentators have argued that as a result of ‘social pressures and eugenic attitudes held by clinical geneticists in most countries, it [PGD] results in eugenic outcomes even though no state coercion is involved’. Because PGD concerns embryos rather than established pregnancies, it is distinguishable from prenatal testing in ‘ethical, legal, social and psychological terms’. Consequently, the scope for selection is arguably greater as is the possibility of coercion and reduced choice.

Other commentators have cautioned that we should take care not to misuse eugenic events, such as the Nazi experience, which may in fact have very little to do with
an individual’s or couple’s decision not to have a child with a severe disease. The World Health Organisation (WHO) has provided the following definition of eugenics:

A coercive policy intended to further a reproductive goal, against the rights, freedoms, and choices of the individual … Cultures or medical settings may be implicitly coercive and are aware of the need for vigilance against tacit coercion, but considered such problems as part of the general social context rather than as eugenic programs.

It goes on to observe:

Under the above definition, knowledge-based, goal-oriented individual or family choices to have a healthy baby do not constitute eugenics. Such choices are unlikely to affect the gene pool or to reduce the numbers of persons with disabilities. Most disabilities are not the results of chromosomal or single-gene disorders, and most babies born with a genetic disorder are born to families with no known risk for having a child with that condition.

Eugenics is directed against whole populations, whereas the work of today’s clinical geneticists is directed towards individuals and families. However, it is important to be aware that collective results of individual decisions could lead to social policies that discriminate against the minority who make different decisions and especially against persons with disabilities.

Arguments based on eugenics ignore the fact that, for some parents at risk of transmitting what they consider are serious heritable diseases, PGD is a medical imperative and should be a matter of individual choice. PGD is not a State-imposed requirement. However, the provision of services and perceived coercion by professionals is very much a live issue. Eugenic concerns do not displace the presumption of reproductive liberty when considering expansions to PGD for disease-related genotypes. However, as is evident in the WHO report, eugenic concerns are relevant to the way in which PGD services are provided.

2.4 Conclusion

Crafting public policy on contentious issues, such as those raised by assisted reproductive technology and PGD where there is not only an absence of public consensus but also extremely polarised and strongly held views, requires more than an intuitive, personal response to complex issues. Mary Warnock’s characterisation of the difference between policy-making and intuitive private moral responses is compelling in this context:
The pub bore speaks intuitively ... Even if he has good reasons for his judgement that something is ‘disgusting’, he may not be able to articulate them ... His conclusion, that the thing is wrong, may be perfectly sound. But he makes the false assumption that his judgement should, or could, be instantly translated into a law which should govern everyone, and turn that which he is objecting to into a criminal offence. When people become legislators or politicians, they assume new responsibilities. They have specifically to exercise reason and caution in attempting to foresee the consequences for everyone, including minority groups, of the measures they are proposing ... Moreover, they owe a duty to be able to explain why they have come to the conclusion they have. They must be seen to have thought rationally; and in public circumstances this means that they be seen to have thought about the long-term consequences of what it is they propose. They must be seen to be steady and consistent in the stance they take, not only because they will probably advance their own careers if so perceived, but because steady and principled government is what is actually needed by society. So the overlap, or interplay, between the public and private comes at the place where principles are to be articulated, and the consequences for society as a whole openly taken into account.

Clearly, the formulation of good social policy requires close examination of the issues involved, a rejection of rhetoric and dogma and a search for a shared value. Principles must be articulated and the consequences for society as a whole openly taken into account. This is what is required by the HART Act 2004.

Although the provision of PGD in New Zealand has become part of mainstream medicine, and may be carried out as an established procedure in some instances, it is still subject to regulatory restraint under the HART Act 2004. When considering the legitimacy of those restraints, and possible extensions to the framework, it is necessary to determine the effect of the objectives and principles contained in the Act.

The HART Act 2004 declares certain objectives and provides a list of principles which must guide both policy-makers and providers of fertility services. However, there is no clear articulation of the underlying principle or principles which should be applied in this context, nor of how the stated objectives and principles are to be balanced. With the introduction of the HART Act 2004, Parliament arguably has established a middle ground which on the one hand rejects radical reproductive liberty (which would render all reproductive decision-making a matter of personal conscience), but on the other hand seeks to secure the benefits of assisted reproduction within a protective framework.

Although the principle of reproductive liberty is not expressly stated or incorporated in the Act, the objectives and principles taken together do not preclude a presumption of reproductive liberty as a starting point. Rather, the first objective of the Act is to
protect and promote the health, safety, dignity and rights of all individuals, and of women and children in particular, in the use of assisted reproductive procedures. The purpose of the Act expressly refers to the promotion of the dignity and rights of individuals in the use of assisted reproductive technology, and clearly expresses a commitment to the preservation of individual rights. Reproductive liberty may be reconciled within the principles which expressly focus on the interests of the individuals involved, particularly women and the prospective children, and the perspectives of the community.

Reproductive liberty is an established principle in relation to natural conception. It is argued that it is equally applicable to assisted reproduction and is preserved by virtue of the first purpose declared in the Act. The moral arguments which support reproductive autonomy with regard to a woman’s right to abortion are equally valid with regard to the use of assisted reproductive technology to conceive a healthy, genetically related child. Reproductive autonomy is intimately associated with a woman’s right to make reproductive choices. In the context of PGD, decisions are generally those of the prospective parents, made on the basis of their combined genetic codes; it is seldom a solitary endeavour. In both contexts there are strong moral arguments in favour of respecting autonomy and values such as freedom of choice which underlie reproductive endeavours. Individual choices may not be universally endorsed, but this does not mean that certain activities should necessarily be prohibited. The principle of reproductive liberty does not confer a right to unfettered choice or access, but it signals the importance of the interests involved and the respect owed. The question is why and to what extent reproductive liberty should be limited.

It can be argued that when contemplating the current regulatory framework for PGD, and the expansion of the scope of permissible PGD, a presumption of reproductive liberty is the appropriate starting point. This position should then be scrutinised with reference to the principles set out in the Act.

Whilst it has been argued that human dignity is an elusive concept which has, in relation to scientific progress, been used to support various outcomes, dignity has traditionally been associated with an individual’s inherent right to autonomy and respect. The notions of human dignity and human rights are easily invoked to support various outcomes in relation to repregenetic technology. Whilst they may be used as a justification for restraint, they may also be used in support of autonomous action. The reference to both ‘dignity’ and ‘rights’ in the Act supports the argument that the right to reproductive liberty, a freedom which is accepted as a fundamental human right to varying degrees in all liberal democracies, is not abrogated by the Act. However, claims based on dignity must be fully articulated and weighed against the relevant interests and principles at stake, including the right to reproductive liberty.
The principle regarding the welfare of the future child is notable in that it does not ascribe paramountcy to the health and well-being of a future child, a protection accorded a child in family law proceedings once born. Significantly, ‘health and well-being’ arguably encompasses not only physical well-being, but also the social, emotional, psychological and cognitive aspects of welfare. The well-being of a child is significantly affected by the family into which it is born. Consequently, the well-being of the family is integral to the well-being of the child. This may provide greater scope for expanding the ambit of PGD in certain circumstances.

The concept of intergenerational justice may support arguments for expanding the regulatory framework; indeed, a radical interpretation of the concept may require parents to use PGD and prenatal diagnosis where there is a known risk of harm to a future generation. However, this is inconsistent with the current public health and social policy agenda of New Zealand if it is accepted that the objective in the provision of reprogenetic technology is to enable access to treatment and to help at-risk people make fully informed, autonomous decisions. The principle of intergenerational justice should not be used to exert pressure on prospective parents to make certain choices as part of a public health or social policy agenda, as this is not consistent with the purposes of the Act.

The requirement that the health and well-being of women must be protected in the use of assisted reproductive technology acknowledges the central role played by women in assisted reproduction, but is arguably limited to the safe provision and use of assisted reproductive technology. Neither disability rights arguments nor eugenic concerns displace the presumption of reproductive liberty when considering expansions to PGD for disease-related genotypes. However these concerns are potently relevant to the way in which PGD services are provided. Whilst expanded reproductive choice in relation to heritable disease-related genotypes is to be welcomed, the obligation to engage in PGD, or to make certain choices, is another thing altogether.

The issue, for the purposes of this report, is whether the current limits on reproductive liberty in relation to HLA tissue typing and negative selection of carrier embryos may be justified, or whether the scope should be extended. The report is mindful that, on the basis of the harm principle, legitimate restrictions to PGD require not only that a reasonable risk of harm must be demonstrated, but also that it is of sufficient magnitude to justify curtailing the autonomy of those seeking PGD services.101
3 PGD AND HUMAN LEUKOCYTE ANTIGEN (HLA) TISSUE TYPING

3.1 Introduction

PGD in conjunction with human leukocyte antigen (HLA) tissue typing involves testing embryos to determine their compatibility as hematopoietic stem cell (HSC) donors for siblings suffering from life-threatening diseases. When a child is suffering from a congenital disease or neoplastic disorder which affects the formation of blood cells and/or the immune system, transplantation of HSCs such as those contained in umbilical cord blood or bone marrow is currently the best course of treatment for the affected child. HSC transplantation may also be indicated for a number of metabolic diseases such as adreno-leukodystrophy. When there is no HLA-identical donor available in the family, PGD can be used to select an embryo with the same HLA tissue type as the sick sibling.

The first applications of PGD in conjunction with HLA tissue typing in both the United States and the United Kingdom involved performing PGD to diagnose the presence of a deleterious genetic mutation (in the former case Fanconi anaemia and in the latter thalassaemia) in addition to carrying out HLA tissue typing on in vitro embryos. Performing PGD to create a child to save another has attracted considerable debate in itself as evidenced by the interest generated by these two cases. However, the distinction between performing preimplantation tissue typing as an adjunct to the diagnosis of a serious genetic condition and performing it solely to determine tissue compatibility with a seriously ill sibling has added another dimension to the controversy.

New Zealand has only recently begun to address these issues with the introduction of the Guidelines on Preimplantation Genetic Diagnosis in 2005. Although drafted by the ethical body which preceded the introduction of the HART Act 2004, the Guidelines now constitute ACART guidelines for the purposes of the Act.

PGD in conjunction with HLA tissue typing is currently the only application of PGD that comes within the remit of ECART as a regulated activity. Pursuant to the Act, PGD with HLA tissue typing may only be performed with the prior written approval of ECART. Applications are assessed on a case-by-case basis. Ethical approval may only be given when the applicants meet the requirements prescribed in the Guidelines. Currently, the Guidelines restrict the performance of HLA tissue typing in conjunction with PGD to circumstances in which the live sibling is suffering from a familial single gene or sex-linked disorder, as well as providing significant other restraints. It is the substantive provisions of these Guidelines which are the focus of this section.
Before undertaking an analysis of the Guidelines, a brief background will be provided regarding the history of the donation of HSCs by a minor child to a sibling suffering from a severe, life-threatening disorder. General clinical considerations raised by embryonic HLA tissue typing and HSC transplantation will then be outlined. Following this, the provisions and implications of the current Guidelines will be examined. Because of the nature of the subject matter, this analysis necessarily requires a review of the legal position regarding the donation of tissue and organs by an incompetent minor to a sick sibling. The question addressed in this section is whether, given the presumption of reproductive liberty established in the previous section of this report, the restraints on HLA tissue typing provided in the Guidelines are justified. It will be argued that the Guidelines are ethically and legally problematic.

3.2 Background

The complexity of the saviour sibling issue exists because of the breadth of interests implicated by the use of this new technology. These interests have been described by one commentator as including:

*the rights of parents to be able to make reproductive decisions, the rights of the sick child to medical treatment and to hope, the rights of the donor child to be loved for themselves and to be free from exploitation, the ethics of tissue donations from incompetent individuals, the degree to which family autonomy will be upheld, and the rights of the broader community to have a say in the directions new science takes us.*

Sibling donation of HSCs is not a new medical technology. Nor is the intentional conception of HLA-matched sibling donors. Rather, it is the performance of these activities in the context of PGD that is new.

Prior to the advent of PGD, parents of children with severe, life-threatening diseases that could be cured by a HSC transplant attempted to conceive a healthy HLA-matched child naturally. The precursor to transplantation of HSCs from cord blood was transplantation of HSCs from bone marrow. The attempted conception of children to save siblings was practiced as early as 1987, and was achieved in some instances. The first successful allogeneic bone marrow transplant (i.e. bone marrow from another person) was carried out in 1968 when a five-month-old infant received HSCs from a sibling. When it became possible to diagnose Fanconi anaemia and HLA-type prenatally in the 1980s, it was reported that between 1985 and 1993 thirty-two pregnancies were conceived in the hopes of providing a donor child for a sibling with the disease. Some of these attempts failed whilst other couples were faced with aborting affected foetuses. In two cases healthy foetuses that were not HLA compatible with the sick sibling were terminated.
Allogeneic bone marrow transplantation is now an established therapy in the treatment of haematological malignancies, bone marrow failure syndromes, immunodeficiency states, and metabolic disorders.112 Because of the limitations associated with bone marrow transplantation, namely the lack of suitable donors, the risk of graft-versus-host disease and opportunistic infection, transplants using umbilical cord blood stem cells were first postulated as an alternative source of HSCs in the early 1980s.113

In 1988 the first successful umbilical cord blood transplant was undertaken for a child suffering from Fanconi anaemia.114 Twelve years later the first child conceived after successful PGD and HLA tissue typing was born in the United States. The parents wished to avoid the birth of a child affected by Fanconi anaemia, and to have a child who was a tissue match for their affected daughter. The six-year-old sibling underwent a successful cord blood transplant three weeks later.115 Since then the range of diseases and indications for which PGD for HLA matching could theoretically be used has grown considerably, as illustrated by the list provided at the end of this section. Although the conception of sibling donors has a long history, the use of PGD to diagnose tissue type is an innovation of the twentieth century and is strictly regulated in New Zealand. Before considering the nature of those restrictions, the following section provides a brief précis of the clinical context.

3.3 Clinical considerations

Any analysis of the Guidelines requires some appreciation of the clinical context. Whilst there are strong clinical reasons in favour of umbilical cord transplant from an HLA-matched sibling, other considerations must also be taken into account.

3.3.1 Rationale for using umbilical cord blood haematopoietic stem cells (HSCs)

Transplantation of HSCs from umbilical cord blood is generally considered to be superior to bone marrow transplant, and transplantation of cord blood from an HLA-matched sibling even more so. The benefits of cord blood HSC transplantation (HSCT) include the diminished risk for the donor. The physical collection of stem cells from the umbilicus is a relatively safe and straightforward procedure, without the risks of general anaesthesia, bleeding or infection associated with bone marrow harvesting.

Most importantly, there is a lower incidence of acute and chronic graft-versus-host disease in the recipient in the case of sibling cord blood transplants compared with bone marrow transplants.116 Umbilical cord blood donors and recipients may not need to be HLA matched with the same rigour as for bone marrow transplants.117 In addition, there is a lower risk of viral contamination with cord blood than with bone marrow transplants.118 Whilst transplantation of HSCs from the umbilical cord blood of an HLA-matched sibling may present the best chance of recovery for
children suffering from some serious, life-threatening conditions, it is not without clinical limitations.

### 3.3.2 Limitations

The statistical chance that a cycle of PGD will provide an HLA-matched embryo is relatively low, at only 25 per cent. This percentage falls to around 18 per cent if PGD is performed to diagnose an embryo that is both free of an autosomal recessive condition, such as Fanconi anaemia or thalassaemia, and is a suitable match.\(^{119}\)

Transplantation of umbilical stem cells is currently limited by the age and weight of the affected child. Whilst cord blood may be adequate for small children below 25kg, bone marrow transplantation is usually indicated in the case of older children.\(^{120}\) In some instances this may preclude the performance of an umbilical transplant even after an HLA-identical sibling is born. Because of this, parents may seek subsequent bone marrow donation.\(^{121}\)

Although an umbilical cord blood transplant lowers the risk of morbidity and mortality in the recipient, there is always a possibility that HSCT of umbilical cord blood will not be successful for several reasons. The transplant may be unsuccessful as a result of graft failure or because of a recurrence of disease in the sibling post transplant. Additionally, the success of the treatment may differ depending on the disease from which the sick child suffers.

### 3.3.3 Disease-free survival (DFS) of sibling

It is established that disease-free survival (DFS) after HSCT with an HLA-identical donor is variable depending upon the disease suffered by the sick child.\(^{122}\) HSCT from a compatible donor does not guarantee the donee a disease-free existence; but, for certain diseases, it comes close. Whilst DFS is only 30 to 50 per cent for some acquired illnesses, such as acute leukaemia and non-Hodgkin lymphoma, it may be as high as 80 to 90 per cent in the case of acquired severe aplastic anaemia.\(^{123}\) DFS also appears to be relatively high in the case of genetic diseases such as thalassaemia major (70 to 90 per cent cure), sickle cell anaemia (80 to 90 per cent cure) and Fanconi anaemia (80 to 90 per cent cure), and in the case of immunodeficiencies (70 to 90 per cent cure).\(^{124}\)

### 3.3.4 Risks to the newborn saviour sibling

Possible risks to the future child have also been a limiting factor. Potential harms to a child born as a result of PGD with HLA tissue typing may arise not only as a result of the retrieval of cord blood stem cells, but as a result of the IVF cycle, or at the point of embryo biopsy. Currently, evidence indicates that the physical risk to a child born after embryo biopsy carried out in the course of PGD is not significantly greater than that incurred with IVF in general.\(^{125}\) The incidence, and nature, of
obstetric and neonatal complications after PGD is comparable to those reported after IVF alone.\textsuperscript{126}

Although the risks involved with PGD are not significantly greater than those linked to IVF, there are established risks associated with IVF. 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.\textsuperscript{127} 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.\textsuperscript{128} Although these risks exist, they are not generally considered sufficiently high to deter infertile people from attempting to achieve a pregnancy, or legally to preclude them from doing so.

Generally, obtaining cord blood HSCs poses negligible physical risk to the neonate as the cells are aspirated from the umbilical cord and placenta after the umbilical cord has been clamped. However, it is possible that aggressive early cord clamping may have adverse effects on a premature newborn or a newborn of very low birth weight.\textsuperscript{129} Because the likelihood of successful transplantation of cord blood HSCs is related to the volume and cell dose collected, there is pressure to ensure a sufficiently large volume of cord blood at the time of collection.\textsuperscript{130} Early cord clamping as close to the neonate as possible ensures that the largest possible volume of neonatal blood is retained in the placenta and umbilical cord. However preterm babies are at risk of anaemia and haemodynamic instability. There is some evidence that a 30 to 120-second delay in umbilical cord clamping is associated with fewer transfusions for anaemia and fewer intra-ventricular haemorrhages in preterm infants.\textsuperscript{131}

A little-mentioned fact is that certain diseases, such as insulin-dependent diabetes mellitus, multiple sclerosis and rheumatoid arthritis, have shown associations with certain HLA antigens.\textsuperscript{132} For example, ankylosing spondylitis is associated with the HLA B27. A person with B27 has a ‘markedly increased risk’ of developing the condition.\textsuperscript{133} When an embryo is HLA tissue typed, the procedure is carried out without determining if it is associated with a certain disease. However, it has been stated that the increased risk will be relatively small in most cases.\textsuperscript{134}

3.3.5 Summary

It may be thought difficult to justify HLA tissue typing given the low prospects that an HLA-matched embryo will be created, and the even lower chance that an embryo at risk of inheriting a genetic disease will be both an HLA match and mutation-free. However, it may also be argued that the statistics are not so low as to make it unreasonable to attempt PGD with HLA tissue typing in the case of some severe or life-threatening diseases where cord blood HSC transplant confers a reasonable chance of success.
Because using PGD to conceive an HLA-matched child involves intensive technical intervention, it is inaccurate to describe the entire process as a minimal-risk procedure. The clinical risks involved are the generic risks associated with IVF, with additional potential risks in the case of a preterm or low birth weight neonate in relation to early cord clamping. What may be said is that the risks are those known risks associated with IVF, and the as yet unknown long-term effects of embryo biopsy. However, these clinical risks must be balanced against the disease-free survival rates of children after umbilical cord HSC transplant from HLA compatible siblings. These statistics are extremely compelling for certain disorders, and include disorders which are both genetic and non-genetic in origin.

However, it is clearly possible that a child conceived to be an HLA match for a sick sibling could face the prospect of donating bone marrow instead of umbilical cord blood; or could face subsequent bone marrow donation after an initial umbilical cord cell transplant fails. It is possible that chemotherapy and irradiation or immunosuppressive drugs, which must be undertaken by the donee prior to HSCT, may cause organ damage and subsequent organ failure in the recipient’s kidneys, liver or other organs. Hence there is potential for the recipient, at some point in the recipient’s life, to require tissue or even solid organs beyond that provided by the initial cord blood transplant, and the HLA-matched sibling will be a likely candidate as a donor.

Consequently, concerns are not limited to potential physical risks, but extend to possible psychological sequelae for a child that is conceived to be a donor. Justifications provided for restraint include the potential instrumentalisation of the future child, the possible physical exploitation of the donor child for ongoing donation and the concern that parents may feel morally obliged to engage in this technology if it becomes more prevalent. There are concerns that extending the ambit of PGD to selection on the basis of tissue type could lead to the use of foetal tissue to provide HSC, and the use of PGD for selection of non-medical traits.

Starting from a presumption of reproductive freedom, the critical issue is whether the concerns raised are sufficient to displace the interests of parents, who wish to undergo the procedure when there is a reasonable chance of success, and of the sick child, who may have an opportunity for survival. The principle of reproductive freedom and the primary purpose of the HART Act 2004, which is to ‘secure the benefits of assisted reproductive procedures …’, must be borne in mind. Also relevant is section 4(a) which provides that the ‘health and well-being of children born’ should be an ‘important consideration’ in all decisions about that procedure. The Act also requires that the ‘health, safety and dignity of present and future generations should be preserved and promoted’. This clearly focuses attention not only on the child to be born, but also on the children already born to a family and the parents.
It will be argued that it is far more difficult to justify the restriction of this procedure than it is to defend its provision. Whilst it is accepted that there is a role for regulatory oversight by the State to protect the welfare of the donor child, the degree to which the State circumscribes access to this technology must be justified by reference to significantly relevant harms. Although there may be concerns that mandate caution, there are principles such as reproductive liberty and parental autonomy which point in a different direction.

3.4 Guidelines on Preimplantation Genetic Diagnosis

3.4.1 Introduction

Although there is an established legal regime which permits parents to provide proxy consent to sibling bone marrow donation on behalf of their incompetent minor children, most jurisdictions which permit PGD with HLA tissue typing require prior approval from the relevant body. New Zealand is no different. The reason for caution lies in the distinction between permitting an existing child to donate tissue, and creating a child for that purpose. However, the current guidelines narrowly restrict those who may access PGD with HLA tissue typing.

As previously indicated, HLA tissue typing is a regulated procedure under the HART Act 2004. PGD in conjunction with HLA tissue typing may only be carried out with prior ethical approval from ECART, the ethics committee established under the Act. ECART may only approve applications which are consistent with guidelines issued by ACART. The Guidelines are effective until 21 November 2007, unless revoked sooner.

Section 2 of the Guidelines provides that HLA tissue typing in conjunction with PGD must be submitted for ethics committee approval on a case-by-case basis. The discretionary power of the ethics committee is significantly limited. The Guidelines provide specific criteria, which must be met in relation to both the affected child and the prospective embryo, before approval may be given. The final criterion requires that HLA tissue typing in conjunction with PGD may only be carried out where the health and well-being of the family/whānau has been fully considered. In relation to the existing sick child it is required that:

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
as regards the embryo, it is required that:

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.

The restrictive nature of the Guidelines indicates an overriding concern to protect the perceived interests of the future child. Section 4(a) of the HART Act 2004 provides that ‘the health and well-being of children born as a result of the performance of an assisted reproductive procedure should be an important consideration in all decisions about that procedure’. However, it is not the only relevant principle in this context. A critique follows of arguments based on the health and well-being of the future child which have been put forward to justify the restricting of HLA tissue typing.

Those who are fundamentally opposed to HLA tissue typing in principle perceive that conceiving a child for the purposes of providing a donor sibling is an aberration of responsible parenthood. The concept of responsible parenthood in this context presumes two beliefs in particular: first, that ‘good parents conceive a child for itself’; and, secondly, that ‘good parents accept the child as it comes’. This latter view which demands nothing less than unconditional acceptance of a prospective child is problematic under existing law. It would preclude the conception of a saviour sibling when the sick sibling suffers from a genetic disorder – a process already permitted under the current Guidelines. If carried to its logical conclusion, it would also preclude prenatal testing and abortion as well as selection on the basis of any disability whatsoever, and this would be incongruent with the law. Consequently, this is not a tenable argument to justify legal restriction.

It has been argued that intentionally conceiving an HLA-matched child to act as a donor instrumentalises and treats the prospective child as a means to an end, rather than as an end in its own right. This constitutes a prima facie breach of that future child’s inherent dignity and breaches the Kantian dictum to “Act so that you treat humanity, whether in your own person or in that of another, always as an end and never as a means only.” However, it is trite to counter this perceived ethical breach by distinguishing between using a person as a means to an end and solely using a person as a means to an end. Whilst the former is a part of every day life, the latter is objectionable.

The idea that parental motives for having a child must not be superimposed with any collateral parental goals is an idealistic concept. The reasons why parents choose to conceive children are numerous and varied, and some undoubtedly nobler than others. Conception may occur as a result of a couple’s combined desire to raise and love a child, or to appease a partner who wants a child, or to provide a playmate for an existing child, or to attempt to have a child of a particular sex. Concerns of
instrumentalisation are not persuasive when it is considered that conceiving a child to be a donor ‘is not any worse or less altruistic than the myriad of other reasons for which children are sought’. The morally relevant point is that the parents want the child in the child’s own right.

It has been observed that concerns that a saviour sibling were regarded solely as a means to an end would be borne out if the parents abused or neglected the donor child, or surrendered the child for adoption after cord donation. Some ethics committees have considered that the absence of a prior wish to conceive a child before the need to create a donor arose may be prima facie evidence of instrumentalisation of the prospective child. This could constitute criteria for denying parents the opportunity to conceive a saviour sibling. Yet this ‘prior wish’ concern is not persuasive. It is not uncommon for people to change their reproductive plans given a change in parental attitudes or personal circumstances. What is important is that the prospective child is wanted as well as being able to be a compatible tissue donor. The motives parents have for conceiving a child are not decisive of the relationship they will have with that child. Rather:

*The morally relevant point is not that parents have the right motive for conceiving the child, but that they love and care for the donating child and protect its best interests once it is born. The few instances in which parents have asked for medical assistance to obtain a compatible sibling strongly indicate that they intend to do so. The use or instrumentalization of the donating child does not demonstrate disrespect for his or her autonomy and intrinsic value.*

The basis for concerns regarding instrumentalisation is that the procedure is not carried out for the benefit or best interests of the child born, but to benefit a third party. However, it has been cogently argued that psychosocial benefits may accrue to a donor child as a result of being a donor. These benefits are that the child is born into a family which has a chance of remaining intact. The child has the benefit of growing up with the sibling if the HSCT is successful. Essentially, the benefit is that which accrues to the entire family in the event that the sick child is cured.

Although embryo biopsy does not appear significantly to increase the risks associated with IVF, the long-term effect of PGD will not be known until sufficient empirical studies establish good scientific data. This uncertainty must be balanced against the potential benefit to the sick sibling and the family.

It will be argued that the limitations imposed both in relation to the sick child and the prospective embryo, except for the requirement that the embryo be a sibling of the affected child, are clinically, ethically and legally problematic. Taken together, these difficulties mandate wholesale revision of the HLA guidelines.
3.4.2 Clause 7.1

*The affected child suffers from a familial single gene disorder or a familial sex-linked disorder*

The objective of clause 7.1 is to restrict the performance of HLA tissue typing to circumstances in which the sick child is suffering from a disorder which is genetic in origin.\(^{151}\) However, the effect of drawing a distinction between genetic and non-genetic conditions can have capricious results. The restriction means that the parents of a child who is suffering from a serious, life-threatening condition cannot attempt to access this procedure if their child’s illness is not heritable. Some conditions such as diamond black fan anaemia (DBA) may be the result of either a sporadic or an inherited mutation. DBA is a rare form of anaemia which results in bone marrow failure. Although DBA may initially be treated with steroids, the only cure is HSC transplantation. Under the current guidelines, parents whose child is suffering from inherited DBA may apply to undergo PGD with HLA tissue typing, whilst those whose child has a sporadic mutation may not.

The restriction in clause 7.1 is based on concerns for the putative donor child. Whilst the consequences of being conceived to be a donor child must be addressed under the Act, the balance of argument weighs against restricting HLA tissue typing to instances where there is a genetic risk. This very issue was played out in the United Kingdom when the interim HLA tissue typing policy of the Human Fertilisation and Embryology Authority (HFEA) was released in 2001.\(^{152}\) It was the first attempt to delineate parameters permitting the creation of saviour siblings utilising PGD technology.\(^{153}\) The current New Zealand policy on HLA tissue typing bears a striking resemblance to this initial HFEA policy.

Under the Human Fertilisation and Embryology Act 1990 (UK), the HFEA, when drafting policy, is similarly required to take account of the welfare of any child born as a result of treatment.\(^{154}\) Significantly, the HFEA received advice provided by the HFEA Ethics Committee that, when considering the welfare of the unborn child, the inquiry should not be restricted to a narrow, legal perspective regarding the future child’s welfare or best interests.\(^{155}\) Rather, it should include the ‘wider question of the putative child’s moral, psychological, social and physical welfare’.\(^{156}\) The Ethics Committee favoured a principle of ‘constrained parental decision-making’ with regard to performing PGD with HLA tissue typing.\(^{157}\) It was recommended that the technique should be available where an existing sibling suffered from a life-threatening but non-genetic condition.

These recommendations were not followed by the HFEA. The interim HFEA policy authorised the performance of HLA tissue typing in conjunction with PGD, but
restricted the procedure, as under the current New Zealand guidelines, to instances where the condition suffered by the sick sibling was genetic in origin. The rationale for this distinction was the purported lack of evidence regarding future health risks to the resulting child from the embryo biopsy. Consequently, embryo biopsy could only be considered to be in the interests of the future child if it conferred the primary benefit of being born free of a genetic disorder. Where the putative risks of biopsy could not be justified on the basis of this perceived benefit to the future child, then carrying out the procedure could not be justified, as it would not be in the interests of the future child.

The distinction made by the HFEA has been the subject of sustained academic criticism. One criticism made is that it is inaccurate to describe embryo biopsy as conferring the benefit of a disease-free existence on the resulting child where there is a risk of inheriting a genetic disorder. Biopsy merely detects the presence or absence of a genetic mutation; it does not change disease status. Ultimately, biopsy confers the benefit of provision of information on which the decision to select the embryo for transfer is made. The benefit comes down to selection for implantation. Consequently, the distinction between performing biopsy in the presence or absence of genetic risk on the basis that it confers a benefit on the resulting child in the former case but not in the latter is erroneous.

The restrictive interim HFEA policy was put to the test when the first family with a child suffering from a disorder which was not genetic in origin applied, unsuccessfully, for approval to undertake PGD in conjunction with HLA tissue typing. The case received widespread media and academic attention. Ultimately the HFEA’s restrictive policy could not be retained in the face of the compelling arguments raised.

In 2004 the HFEA released a new policy on preimplantation tissue typing, which dispensed with the distinction between performing HLA tissue typing in the presence or absence of genetic disease. Effectively, the original recommendations made by the Ethics Committee in 2001 were adopted in the revised policy. It was stated that:

*Balancing the likely benefit of preimplantation tissue typing – to the sick sibling, the new baby and the family as a whole – against a better understanding of the possible physical and psychological risks to the child to be born, the Authority concluded that preimplantation tissue typing should be available, subject to appropriate safeguards, in cases in which there is a genuine need for potentially life-saving tissue and a likelihood of therapeutic benefit for an affected child.*

For similar reasons, the current restrictive policy in New Zealand should be rejected.
The restriction contained in clause 7.1, that the sick child must be suffering from a familial single gene or sex-linked disorder, is not only unjustified, it is *reductio ad absurdum* when clause 7.5 is taken into consideration. The criteria set out in the *Guidelines* are cumulative; hence, all of the criteria specified must be present before approval may be given by ECART. Clause 7.5 permits HLA tissue typing when, in *addition* to the other requirements, 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. Consequently, if a prospective child is at risk of inheriting a disorder such as cystic fibrosis, and an existing sibling is suffering from a non-heritable condition which could be cured by HSCT, HLA tissue typing may not be performed because the life-threatening condition of the sick sibling is not genetic in origin as required by clause 7.1. This is the case even though PGD to diagnose cystic fibrosis may be performed as an established procedure.

There is a remote possibility that parents with a healthy child may want to undergo PGD with HLA tissue typing to conceive an HLA-compatible sibling, in the absence of any disorder, to create a family in which the children could serve as mutual donors if ever necessary. In this context there is ‘reciprocity of opportunity and obligation, unlike the situation in which the first-born was already ill’.

What if such couples are sufficiently wealthy to pay for treatment and are willing to accept the risks involved with the procedure?

At least one commentator is of the view that, based on considerations regarding the risks of PGD and the welfare of the donor, we have no good reason to object as ‘we already accept the risks of PGD in order to benefit people with the desire for a child, and the child will certainly be created for its own sake, since its use as a donor is only conditional’. Yet there seems to be a relevant distinction to be made in the case where there is no threat to the life of a sibling. Relevant factors include the risks associated with IVF babies which may utilise additional public resources. Aggressive ovarian hyperstimulation regimes will potentially be required, so that there are sufficient ova to be fertilised from which to obtain a match, which confers health risks for the woman involved. It would also be harder to maintain arguments relating to ‘designer babies’ and ‘slippery slopes’ in this context.

Conversely, selection on the basis of HLA compatibility could be construed as falling within the domain of preventative medicine and, on these grounds, could be argued to be acceptable. Yet the chances of children needing an HSC or solid organ transplant in their lifetime are not high unless they have a particular genetic history. Additionally, there is no positive right to treatment. A fertility services provider is at liberty to decline to provide a procedure. Because of this, performing the procedure in these circumstances has a low value, apart from gratifying parental preferences, and less justification is required for restricting such an endeavour.
3.4.2.1 Summary

The current prohibition of HLA tissue typing in the absence of a heritable disorder is not morally or legally justifiable on the grounds of lack of benefit to the future child. The benefits which derive from HLA tissue typing are selection itself, which is the same whether there is the risk of transmitting a genetic disorder or not, and the potential benefits which may accrue to the family as a whole. In the absence of empirical evidence indicating that embryo biopsy is harmful to the prospective child, public policy which precludes a therapy by which a sibling’s life may be preserved is exceedingly difficult to justify and appears to make an arbitrary distinction.

PGD with HLA tissue typing and HSC transplant should only be considered when the sick sibling has a disorder which is serious or life-threatening and there is a reasonable chance that HSC transplant will be successful. This acknowledges the concerns in relation to the donor child. In this context, ‘serious’ should be interpreted as sufficiently serious to justify the clinical risks to the recipient in undergoing the transplant. These risks include the treatment regime prior to transplant, which may involve ablative chemotherapy and total body irradiation ‘to destroy disease and prevent the rejection of donor cells’, and the post-operative risks such as graft-versus-host disease, infection and relapse.\(^\text{168}\)

3.4.3 Clause 7.2

**No other possibilities for treatment or sources of tissue are available**

Clause 7.2 restricts HLA tissue typing to circumstances where there are no other possibilities for treatment or sources of tissue available. It suggests that all other avenues for treatment must be exhausted before considering the conception of an HLA-matched sibling with the aid of PGD, effectively making it a last-resort therapy. The high threshold is not problematic in instances where there is no alternative effective clinical course available, such as in the case of Fanconi anaemia.\(^\text{169}\) However, other diseases may not be as straightforward.

The provision which requires that HSCT should not be performed where there is an alternative treatment available is *prima facie* defensible. Many children with serious stem cell defects can be successfully treated without HSC transplantation.\(^\text{170}\) For example, bone marrow transplantation for childhood acute leukaemias, such as acute lymphoid leukaemia (ALL) and acute myeloid leukaemia (AML), may not necessarily be required because treatment with chemotherapy alone has an 80 per cent five-year cure rate in children with ALL and 60 per cent in children with AML.\(^\text{171}\) Stem cell transplant for children with a first remission is ‘generally considered only for those at high risk’, as results for transplantation are claimed to be less successful than those for chemotherapy alone.\(^\text{172}\)
However, some sick children who are not in immediate need of a transplant may require transplant in the future if their current therapy fails.\textsuperscript{173} Waiting until a child relapses before initiating PGD may mean that the mother has lost valuable reproductive time, or that the child may deteriorate in the time taken to conceive an HLA-matched sibling. Performing PGD solely to obtain a backup or possible donor may seem disproportionate in terms of the technical expertise, personnel and cost involved.\textsuperscript{174} Conversely, a pathological condition exists which, although in remission, has a statistical chance of recurring. On balance, it seems difficult to justify prohibiting this option when parents desire another child.

The HFEA considered this issue when it undertook the review of preimplantation tissue typing policy in 2004. It found that there was ‘no objection in principle’ to applications for HLA tissue typing being considered in the same way both in cases when the existing child is not symptomatic but is in remission and when the affected child is symptomatic at the time of the application.\textsuperscript{175} This is a flexible approach, which is still guided by the underlying medical condition of the sick child and the clinical context.

### 3.4.3.1 Summary

The current provision that PGD with HLA tissue typing may only be performed when no other possible treatments or sources of tissue are available is unduly onerous. Tissue typing should be permitted when HSC transplant from an HLA-matched sibling constitutes the best clinical option after all other possibilities for treatment for the affected child have been explored. However if the parents wish to have a subsequent child, their application to perform HLA tissue typing should also be considered because of the risk of relapse, even if the affected child has undergone successful alternative treatment.

### 3.4.4 Clause 7.3

*The planned treatment for the affected child will utilise only the cord blood of the donor child*

Clause 7.3 imposes a limit on the extent to which a donor child may provide tissue for a sibling. The intuitive fear that an HLA-matched child may be used as spare parts is not easily dismissed. Ethicists and experts alike have voiced concerns regarding the potential exploitation of the vulnerable neonates and the children they develop into.\textsuperscript{176} Such concerns are articulated in the following:

*The donor child is at lifelong risk of exploitation, of being told that he or she exists as an insurance policy and tissue source for the sibling, of being repeatedly subjected to testing and harvesting procedures, of being used this way no matter how severe the psychological and physical burden, and of being pressured,
manipulated, or even forced over protest. The parents must intend to rear the donor child lovingly with that child’s individual best interests governing all medical decisions for the child.¹⁷⁷

However, clause 7.3 is problematic both procedurally and substantively. Guidelines promulgated pursuant to the HART Act 2004 may legitimately regulate assisted reproductive procedures. Conversely, procedures which do not constitute an assisted reproductive procedure, such as sibling bone marrow transplant undertaken after the birth of a child or, for that matter, the donation of cord blood postnatally, are not within the scope of the policy-making authority conferred under the Act. However, the purpose of HLA tissue typing is relevant to procedures performed under the HART Act 2004. The relevant purpose of HLA tissue typing is to determine whether a prospective child is a tissue match for a seriously ill sibling and could act as a tissue donor. But restricting procedures performed after birth is outside the scope of the authority conferred on ACART or ECART by the Act. Clause 7.3 seems to be ultra vires the Act.¹⁷⁸ Setting aside the vires issue, the question is whether it is appropriate to limit to cord blood only the future donation by the HLA-matched child. It is argued that such a restriction is not justified and is not consistent with existing law and practice in relation to naturally conceived children.

Because of these legitimate concerns regarding exploitation, it is impossible to address in isolation the issue of the creation of children who are compatible tissue matches and cord blood donors for seriously ill siblings. The enduring concern that a saviour sibling may be an ongoing source of tissue for a sick child means that this analysis necessarily requires a review of the ethics and law in respect of the donation of tissue and organs by an incompetent minor to a sick sibling. It is necessary to consider the donation of both regenerative and non-regenerative tissue by incompetent children to siblings. This analysis focuses on whether, as a matter of law, babies born as saviour siblings may provide bone marrow or non-regenerative organs to sick siblings.

3.4.4.1 Altruistic sibling donation of bone marrow by incompetent minors on the basis of parental (proxy) consent

3.4.4.1.1 Introduction

It is worth noting at the outset of this section a submission NECAHR (the body responsible for drafting the Guidelines on Preimplantation Genetic Diagnosis) received from the Health and Disability Commission when it undertook the public consultation on the Guidelines. The Health and Disability Commission is required under the Health and Disability Commissioner (HDC) Act 1994 to make public statements in relation to any matter affecting the rights of health and disability services consumers, and consequently provided a submission on the Guidelines.¹⁷⁹
Whilst it appeared to accept that creating an HLA-compatible child was justifiable in some circumstances, based on the medical health of the family, strong support was given in the submission for restraining the future donation of tissue from the donor child. The submission opined that the regulatory body should

\[ \textit{predicate its approval [for PGD in conjunction with HLA tissue typing] upon assurance from the family and the clinic that only cord blood (and not other tissues or organs) of the new child will be used to treat the ill sibling.} \]

It was stated in the submission, uncontroversially, that the HDC Act 1994 and the Code of Health and Disability Services Consumers’ Rights apply to children resulting from PGD.\(^{181}\) Although not a person for the purposes of the Act or the Code at the time PGD is performed, the child born as a result of PGD is a health consumer as defined in the HDC Act 1994. Right 2 of the Code confers on health consumers the right to be free from discrimination, coercion, harassment and exploitation, and right 3 confers the right to dignity and independence. It was claimed that, taken together, rights 2 and 3 would prohibit the subjection of a patient below the age of consent to surgery for the benefit of another. This aspect of the submission is open to the challenge that the legal basis for the recommended restraint is questionable.

There are no specific legislative provisions governing children acting as tissue or organ donors for siblings in New Zealand, nor has this issue come before the Courts.\(^{182}\) However, section 16(1) of the Care of Children (CoC) Act 2004 provides that ‘the duties, powers, rights, and responsibilities of a guardian of a child include (without limitation) the guardian’s – (a) having the role of providing day-to-day care for the child … ; and (b) contributing to the child’s intellectual, emotional, physical, social, cultural, and other personal development; and (c) determining for or with the child, or helping the child to determine, questions about important matters affecting the child’. ‘Important matters affecting the child’ include medical treatment for the child (if that medical treatment is not routine in nature).\(^{183}\) Consequently, guardians have the power to determine important matters affecting the child; and, specifically, they have the right and responsibility to determine questions regarding non-routine medical treatment.

Section 36(3)(a) of the CoC Act 2004 provides that, where consent to any medical, surgical, or dental treatment or procedure is necessary or sufficient, consent may be given by a guardian. The parental right to make decisions regarding medical treatment or procedures has long been part of the common law, but it is not absolute.\(^{184}\) However, the scope of parental power, and the point at which a Court will find that a decision is beyond the ambit of parental authority, differs between jurisdictions.\(^{185}\)
It seems that the provision of proxy consent for bone marrow donation by an incompetent minor to a sibling has been viewed as coming within the scope of ordinary parental decision-making authority since sibling bone marrow transplants were first performed in New Zealand. The same has been true in some other jurisdictions, such as the United Kingdom; however this has changed to a certain extent with the introduction of the English Human Tissue (HT) Act 2004.

The HT Act 2004 came into force in September 2006. Under the Act, the Human Tissue Authority (HTA) is responsible for approving the transplantation of solid organs, bone marrow and peripheral blood stem cells from living donors. The HTA has statutory authority to issue Codes of Practice to provide guidance and standards for persons performing functions within its remit. Such a Code has been released with regard to the donation of allogeneic bone marrow and peripheral blood stem cells (PBSC) for transplantation. It has introduced new safeguards for incompetent minors. Whilst a guardian may provide consent for an incompetent minor, bone marrow donation may only be performed if the HTA and an accredited assessor are satisfied that the best interests of the child have been properly considered and the HTA's code of practice has been properly implemented. The assessor is responsible for interviewing the child and guardian, and acts as an advocate for the child. Following this a report must be submitted to the HTA stating that the assessor is satisfied that:

- the senior clinician has taken all reasonable steps to ensure that a suitable adult donor is not available;
- the best interests of the donor have been properly considered;
- where appropriate, the child has received all the necessary information in a way they are most able to understand;
- the senior clinician has explained to the person who has parental responsibility for the child the nature of the medical procedure in question, the risks involved and any other wider implications. This report should include the information given as to the nature of the procedure and the risks involved, the full name of the registered medical practitioner and their qualification to give this information;
- the person with parental responsibility understands the nature of the medical procedure in question, including the risks and the possible after-effects, has the capacity to consent, and consents to the removal of the bone marrow or PBSC;
- the consent has been obtained from the person who has parental responsibility for the child;
• the consent was not obtained by duress or coercion or the offer of any other inducement;
• there is no evidence of an offer of reward;
• the person with parental responsibility understands that they are entitled to withdraw consent at any time and understands the consequences of withdrawal for the recipient;
• there were no difficulties in communicating with the person with parental responsibility.\textsuperscript{190}

The report is valid for six months. Whilst there is no criminal sanction for breaching the Code of Practice, any breach may be taken into account in decisions regarding licensing. If the transplant does not occur within the six months, another report must be undertaken.

In Australia, the donation of regenerative tissue such as bone marrow by a minor to an immediate family member is generally covered by statutory provisions, and the requirements vary amongst the different States and Territories.\textsuperscript{191}

In New Zealand, bone marrow donation by an incompetent minor is not specifically regulated, but is governed by the general law regarding consent for medical procedures on incompetent minors, i.e. the CoC Act 2004, the common law and the Code of Consumers’ Rights. Right 7(1) of the Code of Consumers’ Rights provides that ‘services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise. Clause 4 of the Code provides that, for the purposes of right 7(1), ‘consumer’ includes a person entitled to give consent on behalf of that consumer, which encompasses parents who are legally entitled to provide proxy consent for health care procedures performed on their minor children.

Clearly, the Code does not alter the position at law, and guardians may provide proxy consent for incompetent minors. The Health and Disability Commission submission appears to have been based on an assumption that the donation of bone marrow by an incompetent minor to a sick sibling was exploitative, a breach of the dignity of the donor child and not capable of being consented to by a guardian. It is significant that the Council of Europe’s Convention on Human Rights and Biomedicine countenances the donation of regenerative tissue by a minor to a sibling suffering a life-threatening condition where there is no other competent available donor.\textsuperscript{192}

It is argued that the Health and Disability Commission submission was flawed and does not represent the legal position in New Zealand. There is, as yet, no judicial or
legislative statement that providing proxy consent to sibling bone marrow donation is beyond the scope of parental authority. However, parental consent to a medical procedure on a minor can be challenged by any eligible person under the CoC Act 2004.\textsuperscript{193} If donation is not in the best interests of the child, the Court has powers under the CoC Act 2004 to place the child under the guardianship of the Court and to appoint an agent of the Court.\textsuperscript{194} Alternatively, an application may be made to the Family or District Courts under the Children, Young Persons, and Their Families Act 1989 for a declaration that a child is in need of care and protection.\textsuperscript{195} The Court may then make a guardianship order.\textsuperscript{196}

This report now examines the common law basis for provision of proxy consent by parents for the donation of tissue by an incompetent minor to a sibling in relation to both regenerative and non-regenerative tissue. It considers at the outset the risks of bone marrow donation to the donor child. Finally, the question of whether a distinction should be made between donation of tissue by neonates and donation by older children will be addressed.

\subsection*{3.4.4.1.2 Physical and psychological risks associated with sibling bone marrow donation by incompetent minors}

Prior to bone marrow donation, pre-harvest screening tests must be undertaken to determine whether a child is HLA compatible with the sick sibling. In the case of HLA compatibility, bone marrow aspiration is performed under general anaesthesia. Because anaesthesia is required, bone marrow donation poses more than a minimal physical risk to a donor child. This risk is heightened to an extent if a blood transfusion is required as part of the procedure.

Pain and fatigue are the most common symptoms described by donors after donation of bone marrow. However, bone marrow regenerates in approximately three weeks. It is reported that minor complications occur in between 6 per cent to 20 per cent of bone marrow donations, with serious complications in 0.1 per cent to 0.3 per cent.\textsuperscript{197} In the case of paediatric donation serious complications are rare, but children are more likely than adults to receive a blood transfusion.\textsuperscript{198}

One small study which looked at the psychosocial impact of bone marrow donation by siblings cautiously indicated that the psychological effect on a bone marrow donor is significantly affected by whether the HSCT is successful or not.\textsuperscript{199} Whilst almost all sibling donors who participated in a successful HSCT believed that the donation had had a mostly positive impact on their lives, this theme emerged to a much smaller extent with those siblings who participated in an unsuccessful transplant. Siblings often felt responsible for the death of their sibling when the transplant was unsuccessful. All donors reported that the psychological burden of being a donor was greater than the physical aspect of undergoing the procedure. The study highlighted
the importance of providing children with developmentally appropriate, accurate information and psychological support. Another study, which looked at the psychosocial impact on siblings of children who underwent successful bone marrow transplant, found symptoms of post-traumatic stress in both donor and nondonor siblings. The study emphasised the need for ongoing research and support for both donor and nondonor siblings.

It has been argued that, when balancing the harms and benefits involved in sibling bone marrow donation, if the ‘minimal risks affecting the donor are compensated, according to a reasonable prediction, by significant potential benefits for the recipient-patient’ … then compliance with the ethical principle of nonmaleficence is achieved. Consequently, paediatric bone marrow transplantation ‘has been confirmed as an ethical practice, because its benefits abundantly prevail over its costs and risks’.

However, if the physical risk to the donor of bone marrow is substantially greater than minimal, harvesting should not be permitted unless that risk may be ameliorated.

3.4.4.1.3 Justification for parental (proxy) consent to altruistic sibling bone marrow donation by incompetent minors

It has traditionally been argued that parental consent to sibling bone marrow donation may be justified on the grounds that it is in the best interests of the child to donate. (However, it should be noted that section 36 of the CoC Act 2004, which authorises proxy consent by a guardian when such consent is necessary and sufficient, does not specify best interests.)

There is increasing criticism of the use of the best interests standard in the context of sibling donation. It seems to be widely perceived as inaccurate to view a procedure which poses some risks and confers no physical therapeutic benefit to be in the best interests of the donor child. However, a broad approach to the best interests test may be applied. Such an approach has been adopted by the High Court in the United Kingdom, authorising the performance of blood tests and bone marrow harvesting on a mentally incapacitated adult for the benefit of her sister. It was held that the best interests standard included both physical and psychosocial interests. Similarly, a wider construction of the best interests standard arguably includes the ‘benefits the child receives when he or she makes a contribution to the welfare of another person to whom he or she stands in an intimate relationship’. In an Australian case it was held that consent to bone marrow donation by a nine-year-old boy for the benefit of his aunt would be beyond the ordinary scope of parental decision-making. In this particular case it was held to be in his best interests because the boy firmly wished to be a donor and had a close relationship with his extended family, and the risks were small. An alternative means of justifying proxy parental consent for sibling bone marrow donation is where a procedure is ‘not against the interests’ of the child.
Some commentators have argued that bone marrow donation by minors to siblings should be regulated and parents should be required to apply to a specialised national or regional ethics committee to ensure that donation is not against the interests of the donor. Others believe strongly that legislating is not the appropriate response in order to protect the interests of children in this context. Rather, parents should be made fully cognisant of what is entailed in bone marrow donation for both donor and donee, and be motivated to consider the interests of both children.

As already indicated, bone marrow donation is not specifically regulated at present, and parents may provide proxy consent under the general law governing incompetent minors. However, it should be acknowledged that it is not only the donor child’s interests which must be considered in this context. A highly relevant clinical question is whether the parents are acting in the best interests of the sick child, as well as in the best interests of the donor child. This is apparent in the following statement by a clinical paediatric oncologist:

… I think a far more compelling issue [than that of putting more constraints on bone marrow donations by siblings] is whether a parent is acting in the best interest of the ill child who is the potential recipient. Often parents believe a bone marrow transplant is the only hope and are compelled to try it even when the evidence for success is slim.

Sometimes paediatric bone marrow recipients suffer immensely because of the side effects and complications of a transplant that has almost no chance of success. There could usefully be far more scrutiny of the process by which parents make the decision for their child to undergo bone marrow transplantation.

One factor, identified as an important consideration affecting the decision-making of parents of seriously ill children, has been described as ‘anticipated decision regret’. Parents need to know that they have done everything possible to save a child, so as not to blame themselves later. Some parents may consider that conceiving a saviour sibling to provide cord blood or bone marrow is both a parental and medical imperative. Parents may be driven to pursue this. Depending on the clinical circumstances, however, bone marrow transplant may not be the best course of action. Ultimately, a provider may not be compelled by parents to provide treatment which is clinically inappropriate and contrary to good medical practice. When the situation is not as clear-cut as this, the matter may need to be resolved in Court.

The law currently confers significant latitude on parents to provide proxy consent for a child to donate regenerative tissue for a sick sibling. A major factor in this is the assumption that parents will sometimes be justified in making decisions which affect individuals in a family differently, but which are required to further the interests of the entire family. However, such latitude is only permissible when the harm is
considered to be *de minimis* and there are contingent benefits to the donor.\textsuperscript{218} Clearly clinicians as well as parents are justified in refusing donation when it is perceived that the harms of the procedure are not mitigated by any putative benefits.\textsuperscript{219} The Code of Consumers’ Rights should not be interpreted as precluding parents from providing proxy consent for bone marrow donation by an incompetent minor to a sibling with a life-threatening illness. However, each case should be judged on its own facts and the clinical circumstances.

3.4.4.1.4 Neonates as donors of bone marrow – Is there a distinction?

In a survey reported in 1996, seven out of fifty-six North American paediatric transplantation centres reported that they would not collect bone marrow from infant donors under six months old.\textsuperscript{220} However, most would be prepared to harvest marrow from infant donors over the age of six months. Although serious complications are rare in the case of paediatric donors, a 1987 study revealed that donor children under the age of two are likely to receive blood transfusion.\textsuperscript{221}

It has been argued that neonatal donation of umbilical cord blood (which imposes virtually no physical risk) should be distinguished from neonates acting as bone marrow donors for a sick sibling. This argument is predicated on both psychological and physical grounds. It is claimed that the lack of a close relationship with a sibling precludes a presumption of psychological benefit to the neonate donor. Because of this, a neonate should not serve as bone marrow donor for a sick sibling.\textsuperscript{222} Donation would have to wait until a sufficiently close relationship developed between the siblings, regardless of whether this was too late.

This claim seems hard to sustain. Generally, it is perceived to be a benefit to have a healthy sibling to grow up with. At the very least, an ordinary sibling relationship may be assumed if the sick sibling survives. Additionally, it is likely that the saviour child will have a happier family life living in an intact family rather than one marred by the effects of a sibling’s premature and potentially avoidable death. In addition, in the event that the transplant were not successful it would be extremely unlikely that the neonate or infant would have any recollection of the events which had taken place.

Bone marrow donation by an HLA-matched child conceived with the aid of PGD is governed by the CoC Act 2004, the common law and the Code of Consumers’ Rights. Donation of bone marrow places significantly greater physical burdens on a neonate or child than is the case with donation of umbilical cord blood.

Clinical considerations will be highly relevant in determining whether the procedure is in the best interests of the child when the donor child is a neonate. However, the procedure may be in the best interests of the child as understood in the wider sense of the term or at least may not be contrary to the child’s interests. In that case parents
may provide proxy consent to bone marrow donation by a child regardless of the child’s age. If, on the other hand, the procedure is contrary to the child’s interests, the parents’ consent is open to legal challenge.

3.4.4.1.5 Altruistic donation of non-regenerative organs by incompetent minors

A much more difficult issue in the context of children conceived to be donors is the donation and transplant of non-regenerative organs, such as kidneys. Whilst there have been no reported cases of incompetent minors acting as kidney donors in New Zealand and Australia, this appears to be a result of clinical practice, rather than formal policy.\textsuperscript{223}

The British Medical Association considers that it is inappropriate for incompetent minors to donate non-regenerative tissue or organs.\textsuperscript{224} In contrast, professional guidelines in the United States endorse living kidney donation by minors but provide strict criteria.\textsuperscript{225} In Hart v Brown\textsuperscript{226} a United States Court allowed a seven-year-old girl to donate a kidney for her identical twin sister.\textsuperscript{227} In Australia, the only jurisdiction that expressly permits donation of non-regenerative tissue from minors is the Australian Capital Territory.\textsuperscript{228} The removal of non-regenerative tissue from minors is expressly prohibited in Victoria, South Australia and Western Australia and is arguably prohibited by implication in the three remaining Australian States.\textsuperscript{229}

Although it has been argued that it is not within the mandate of ACART to determine parameters regarding donation of tissue by a child conceived by PGD with HLA tissue typing after birth, it is impossible to consider the merits of allowing PGD with HLA tissue typing in isolation from the possible long-term sequelae. This was expressly acknowledged by the HFEA when revising the guidance on preimplantation tissue typing:

\textit{The HFEA does not have the power to impose a condition on a license that would prohibit any future attempt to obtain bone marrow, should a cord blood donation fail. However, the Authority noted that obtaining bone marrow for the treatment of siblings from children from the age of one year was a relatively routine treatment strategy where no other matched donor was available. The Authority also noted that, under common law, the best interests test applied by the courts when considering the type of medical procedures that may be performed on a child, is very much higher when such treatment gives no health benefit to the child concerned. As such, solid organ donation is extremely unlikely to be held to be in a child’s best interest. Having considered typical arrangements for decision making with respect to child bone marrow donors, the Authority found that existing arrangements were sufficient to protect the welfare of the child in these circumstances.}\textsuperscript{230}
3.4.4.2 Summary

Because there is ethical scrutiny, by virtue of the Guidelines, of parents wishing to conceive an HLA-matched child in New Zealand, external ethical oversight is imposed which does not occur with sibling bone marrow donation. Whilst some may advocate similar ethical approval of bone marrow donation, these decisions have been made by parents and clinicians for many years without incident. Whilst there may seem little reason to introduce such regulatory oversight, in the light of scientific advances, which mean that children may be born because of their HLA tissue type, it may be timely to consider additional safeguards.

Concerns regarding exploitation are valid but may be accommodated by standards of clinical practice, and are not sufficient on their own to justify restricting the performance of HLA tissue typing. Good medical practice should dictate that, if a cord blood HSCT fails, then HSC transplant using bone marrow is an acceptable clinical course, depending on the clinical circumstances of the affected sibling and the HLA-matched infant. It would seem inhumane to permit a couple to conceive an HLA-matched child, only to draw an arbitrary line regarding donation once the child is born. It is also inconsistent with current practice regarding sibling bone marrow donation.

If such a transplant fails, subsequent donation should be a matter of clinical and parental judgment. Ideally an appropriately qualified independent advocate should be appointed on the donor child’s behalf, as well as a physician who is not responsible for the treatment of the affected sibling.

3.4.5 Clause 7.4

The embryo will be a sibling of the affected child

Clause 7.4 limits the potential recipients of umbilical cord blood in the case of an intentional HLA tissue match to a sibling. However, the question of whether PGD in conjunction could or should be performed for the benefit of others, in particular a parent, has been raised.

3.4.5.1 HLA tissue typing for the benefit of a parent

The possibility of conceiving a tissue-matched child to benefit a parent in need of an HSC transplant has been raised following reports from the Netherlands that a man suffering from leukaemia was a recipient of a successful HSC transplant using the cord blood of his infant daughter. (A woman who is suffering from a disorder which necessitates HSC transplant is unlikely to be sufficiently robust to undergo PGD to create an HLA-matched child. Consequently it is assumed that the majority of these cases, of which there would not be many, would involve an illness suffered by the prospective father.) In addition to ethical concerns regarding the creation of
an HLA-matched child for the benefit of a parent, there is doubt whether such a procedure is clinically advantageous.

3.4.5.1.1 Clinical considerations

The small cell dose of HSCs derived from umbilical cord blood has been a major limitation in the use of cord blood for allogeneic transplantation in adults.\textsuperscript{233} The transplanted cell dose procured from umbilical cord blood is approximately 10 per cent of that obtained from bone marrow transplant, so has usually been limited to the treatment of small children.\textsuperscript{234} Regardless of this, transplantation of umbilical cord blood from unrelated donors into adults has been performed worldwide.\textsuperscript{235} Currently research is being undertaken into \textit{ex vivo} expansion of umbilical cord blood stem cells to increase the cell dose.\textsuperscript{236}

Although cord blood transplant into unrelated adults is occurring internationally, the chances of creating a child who is an HLA match for a parent are extremely low. The HLA genes are located in three clusters on chromosome six; each child has two copies of chromosome six, one inherited from the father and one from the mother.\textsuperscript{237} The three HLA gene clusters on each parental chromosome contain multiple HLA genes with many individual variants. The HLA markers present on a child’s leukocytes are a complex mix of HLA antigens inherited equally from each parent. Since the child inherits half of the HLA antigens (haplotype) from one parent and half from the other parent, a child will only match half of each parent’s tissue type exactly (a haplotype mismatch, or a half match). However, in some very rare instances a child can be matched with a parent.

Because a parent–child match would only be a partial as opposed to a complete match, it has been observed that a partial tissue match for the benefit of a parent would be ‘more practically achieved by searching existing donor registers than by selecting a tissue-matched embryo’.\textsuperscript{238} However, a complicating factor is that New Zealand does not have a public umbilical cord blood bank and adult patients with relatively unique mixed ancestry are sometimes impossible to match on the NZ Bone Marrow Donor Register, or on Bone Marrow Donors Worldwide.\textsuperscript{239} There is increasing evidence that ‘well collected and stored cord blood units’ can provide sufficient HSCs for transplanting adult patients in some instances.\textsuperscript{240} Because of this, it has been observed that it may be appropriate to revisit the arguments in favour of establishing a non-profit, public cord blood bank for the altruistic gifting of cord blood ‘specifically to meet New Zealand’s unique ethnic needs’.\textsuperscript{241} Significantly, a greater HLA mismatch is tolerated by the recipient when umbilical cord blood is used than is tolerated with bone marrow.\textsuperscript{242} Because of this tolerance for HLA incompatibility, it has been recommended that a ‘matched’ cord unit constitute a ‘4-of-6’ match.\textsuperscript{243} It is likely that the example from the Netherlands involved a partial match in the absence of an unrelated matched donor.
3.4.5.1.2 Ethical considerations

Ethical concerns regarding the creation of a donor child for the benefit of a parent have been based on the conflict of interest which may arise when a parent, who is also the proxy decision-maker for the putative child, is a potential recipient of the child’s umbilical cord blood. Welfare concerns include the possibility that the child may be born into a family which suffers the bereavement of a parent if the transplant is unsuccessful, or that the parent–child relationship will be distorted. Yet it is not generally suggested that parents with severe chronic illness, or potentially terminal illness, should not conceive children naturally. Rather, it is a matter of personal conscience. Some parents have gone to considerable lengths to conceive a child even after the death of a spouse.\textsuperscript{244} It could also be argued that the putative child’s interests may be affected more by the health status of a parent than is the case with a sibling. However, it has been observed that:

\begin{quote}
A parent who intends to have a child to save his or her own life cannot expect much goodwill from the social environment. Our moral intuitions condemn these applications, because of the considerable self-interest of the decision maker. The parent should declare him or herself incompetent due to a conflict of interest. Nevertheless, the same justification can be offered as for the donation to a sibling. The HLA-matched child will be better off, since it will have two healthy parents, while its incompatible possible sibling will experience parental death or will grow up in a family with a chronically ill parent. The conception of a child as a donor for a parent would also be acceptable according to the postnatal test: if an existing child in the family would be a suitable donor, it would be judged acceptable to use it as a donor of haematopoietic stem cells for a parent. However, we should take our moral intuitions into account by appointing an independent guardian who should, even more than in other cases, carefully scrutinise parental decision making.\textsuperscript{245}
\end{quote}

Six years ago Dr Paul Serhal of University College Hospital, London announced his intention to perform PGD with HLA typing for thalassemia, where the umbilical cord HSCs of the child could help cure the father.\textsuperscript{246} However, this procedure is not yet permitted in the United Kingdom. The HFEA originally precluded tissue typing for the benefit of a parent on the advice of its Ethics Committee.\textsuperscript{247} The Ethics Committee stated that, in this situation, a parent’s right to consent to donation on behalf of an incompetent child donor would be vitiated. However, the suggestion that the prospective child would not necessarily be loved or cared for any less was acknowledged. When reconsidering the issue three years later, the HFEA simply stated that the use of the PGD and HLA tissue typing to produce a donor for a parent ‘raises distinct and significant issues and recommended that this matter needed further consideration’.\textsuperscript{248}
In support of allowing parents to undertake the procedure where it may help a loved one, whether or not it is a sibling, it has been argued that:

_In liberal countries, the decision to have children is an area of private life in which the state may only intervene to prevent serious harms. Consequently in such countries if there is no reason to think the future child will be harmed, couples requesting PGD for HLA typing in order to have a donor child should be allowed to seek the necessary treatment._

The Victorian Infertility Treatment Authority provides that PGD in conjunction with HLA tissue typing will only be available where the primary intended tissue recipient is a sibling; but should a relative have a similar genetic condition, a decision about further donation of cord blood or bone marrow resides with the parents of the child.

### 3.4.5.1.3 Summary

The chances of achieving an exact tissue match between a child and a parent are extremely low. Further, it is unlikely such an umbilical cord blood transplant would offer greater chance of success than that which occurs with the transplantation of HSCs from an unrelated donor. Consequently, the scientific limitations present a considerable barrier to performing this procedure. However, the ethical concerns do not appear to be sufficient on their own to justify prohibition.

In the case of a partial match, cord blood could be used because of the greater tolerance of graft-versus-host disease; but subsequent donation of bone marrow or tissue would not be possible because of the haplotype mismatch. Significantly, no further demands could be placed on the donor child, which eliminates the potential for ‘exploitation’.

Provided that the welfare of the child is promoted and protected by professional standards and external oversight of parental decisions, there seems to be little justification for denying parents access to this technology if the procedure confers a clinically significant chance of recovery. It should be noted that there is no legal impediment to a parent being the recipient of cord blood from a naturally conceived child.

### 3.4.6 Clause 7.6

_The health and well-being of the family/whānau has been fully considered_

Section 4(a) of the Act requires that the ‘health, safety and dignity of present and future generations should be preserved and promoted.’ The final criterion provided in the Guidelines requires a consideration of the health and well-being of the family. Taken together, the principle in the Act and the clause in the Guidelines place emphasis on the welfare of the family. This arguably augurs towards respecting
parental autonomy in decision-making, which in turn promotes the well-being of the parents and subsequently of the family as a whole.

It is well established that transplantation of HSCs from the umbilical cord blood of an HLA-matched sibling is currently the best course of treatment for children suffering from certain disorders affecting blood cell formation or the immune system. Permitting PGD with HLA tissue typing, when the established risks to a donor child are no greater than those associated with IVF and there is a reasonable chance of success, clearly promotes the health interests of the existing sick child and family and consequently the present generation.

Consideration of the health and well-being of the family requires an acknowledgement of the fact that the ordinary give and take of family life necessarily entails that, at times, the interests of one child may prevail over another. Parents must balance the sometimes-competing interests of their children, and their wider family. The interest involved for one child in the current context is the chance to live an ordinary life span. Conversely there are understandable but potentially speculative psychological risks to the donor child, which must be balanced. However, considerations regarding the health and well-being of families/whānau seem to mandate a more liberal approach to HLA tissue typing than is currently permitted by the Guidelines.

3.5 Additional justifications for restraint?

Section 4(g) of the Act provides that the different ethical, spiritual and cultural perspectives in society should be considered and treated with respect. Although ethical perspectives have been encompassed in the preceding analysis, when considering the current framework for HLA tissue typing it is also necessary to consider any additional arguments for restraint.

3.5.1 Positive (moral) duty on parents

In an era where reference is increasingly made to the ‘rights’ of individuals, it has been suggested that it may eventually become accepted that a sick sibling has ‘a positive right against its parents that they take proportionate steps’ to provide a saviour sibling, and the resulting child has a positive obligation to assist the sick sibling.252 It is suggested that this web of ‘rights and responsibilities’, which initially appears to be an extreme proposal, might not be out of place in a future context if it became ‘commonplace’ for parents to engage in this technology.253

It is significant that the language of rights and obligations is associated with moral arguments both for prohibiting and permitting use of this technology. However, it is increasingly being used in support of permitting creation of saviour siblings. This is apparent in the following:
Another commentator has observed that the decision to have another child in order to save an existing child must be a matter of choice; although he "would not find it difficult to justify imposing a moral obligation in these circumstances." Yet imposing such a moral obligation to undergo PGD with HLA tissue typing fails to take into account the physical, psychological and economic burden of performing PGD and HLA typing. The comparatively small chances of success and the fact that it necessarily involves introducing a new family member into a potentially stressed family situation are deterrents with regard to conception of a saviour sibling. Even if the creation of saviour siblings were to become more commonplace, it would constitute an extreme view that parents who were unwilling to engage in the procedure were neglectful, or abdicating their parental responsibility. In addition, the fact that parental pressure or coercion may eventuate in a future context is speculative, and does not justify the restriction of the procedure in the present.

3.5.2 Non-medical selection and the slippery slope

It has been claimed that permitting HLA tissue typing will open the floodgates for the use of PGD for non-medical purposes. However, the slippery slope claim is flawed on at least two grounds. The first is that selecting for HLA type is not a frivolous choice but one which is directly associated with a serious, life-threatening disease process. It may be justified by the direct medical benefit accruing to another individual. As Mance LJ observed in the United Kingdom Court of Appeal, there is a distinction between performing embryo biopsy for trivial preferences, and performing it in the face of compelling medical situations. Tests for HLA compatibility lie conceptually between the two poles of ‘good medical reasons’ for tests and testing for ‘purely social reasons’, and 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 … 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.

Secondly, it is difficult to see why HLA tissue typing might be permitted, whilst selection based on other non-medical characteristics which do not confer a health benefit is circumscribed. The permitting of HLA tissue typing where a sick sibling is in need of HSCT, as opposed to the permitting of PGD for non-medical purposes, offers a vivid moral demarcation. Additionally, any concerns regarding eugenics
do not gain traction in this context, as the purpose of the procedure is to cure a particular condition, not to eradicate a disease from the human gene pool. Slippery slope arguments verge on the irrational, and do not warrant limiting this technology given the purpose of the procedure.

3.5.3 Saviour foetuses

A possible ethical concern in this context is the hypothetical use of an aborted foetus as a source of HSCs for transplantation. The same HSCs that are present in an umbilical cord at birth are present in the liver of a sixteen-week foetus, and could theoretically be used to provide a HSCT for a sick sibling. In the United States couples have enquired about conceiving an HLA-matched child and then undergoing an induced abortion to harvest the HSCs. Harvesting stem cells from an aborted foetus is illegal under federal law in the United States. At present there is no applicable law in New Zealand regarding the use of tissue or organs from an aborted foetus, and it is thus not directly prohibited.

Although conception for termination and donation might generally run counter to moral intuitions, it may be a rational course of action for parents of a seriously ill child. It is potentially stressful to introduce a new baby into a family already coping with a seriously ill child. A family may wish to save their existing child, but not wish to extend their family at that particular time. Arguably, conception for termination may avoid problems if the transplant fails, as the child is not born into a grieving family, and will not feel guilt for the HSCT failure. Additionally, there is no child to ‘exploit’ for further tissue. One commentator has stated that this approach, which effectively avoids the birth of a child, may be ‘one way to remove all doubts about respect for future persons’. If HSCs can be harvested before viability, ‘problems of commodification and instrumentalisation of persons’ do not apply.

There has been very little discussion about conception for donation after termination. It seems that clinicians and ethicists consider it to be, at the very least, ethically unacceptable, or even morally repugnant. This moral perturbation stems from the fact that terminations occur in the main because pregnancy is an unintended and unwanted occurrence of ordinary social life. In contrast, PGD and HLA tissue typing require considerable effort, resources and time. If this process were proposed, not for the purpose of implanting and developing a healthy foetus, but in order to terminate the foetus and harvest tissue, the nature and quality of the activity would change.

In the absence of foetal abnormality, an abortion during the first twenty weeks of gestation is rendered lawful if continuing the pregnancy would result in serious danger to the life, or the physical or mental health of the woman. In circumstances where a healthy foetus is intentionally conceived it is difficult then to claim that
termination is required for the mental well-being of the woman, particularly in the case of a late, second trimester abortion.

Performing HLA tissue typing on embryos necessarily requires the creation and destruction of embryos which are not a suitable match, or which are affected by a serious genetic disorder. Whilst destroying embryos is not a morally neutral act, it has been generally accepted as justifiable in the face of preventing or treating serious disease. However, a foetus is attributed a greater moral status which progressively increases the more developed it becomes, and it is a greater leap to justify a late termination.

3.6 Other jurisdictions

New Zealand is not alone in addressing the saviour sibling issue. Consequently, it is worth considering the approach taken to the issue of saviour siblings in other jurisdictions.

3.6.1 Norway

PGD and HLA tissue typing became topical in Norway when the story of six-year-old Turkish boy, Mehmet Yildiz, was reported in the media. Mehmet suffers from the genetic disorder, beta thalassaemia major. The only curative treatment for the disease is HSCT from a related HLA-compatible donor which has a success rate reported to be above 90 per cent.

According to legislation which came into force in January 2004, PGD is restricted in Norway to serious, X-linked diseases where there are no other possibilities for treatment. As thalassaemia is an autosomal recessive condition, it did not come within the indications for PGD; nor was HLA tissue typing permitted under the Act. Mehmet’s case was televised a month after the Act came into force. The underlying message of the broadcast was that, without HSCT, Mehmet’s condition was terminal. After the programme screened, the Progressive Party called for a law change that would permit children with serious diseases in need of HSCT to have access to treatment, regardless of the origin of the disorder. The Progressive Party subsequently proposed a Bill which would have amended the Biotechnology Act of 5 December 2003, but which was strongly opposed by the Minister of Health.

The Socialist Leftist Party, which had supported the Government coalition in the parliamentary debates on the legislation, came under heavy pressure to change its stance on PGD. It subsequently proposed an exemption to the ban on PGD if and when ‘particular considerations speak in favour of a case’. The reference to ‘particular considerations’ meant the ‘presence, or the risk, of serious genetic disease without treatment possibilities’. An independent medical Ethics Committee was empowered
to grant the exemption and to evaluate individual applications for the performance of PGD to conceive a child unaffected by a serious genetic disorder, as well as to evaluate the use of HLA typing to conceive a compatible donor for a sibling suffering from a genetic disorder. A Bill was passed to incorporate these amendments in May of 2004. (It would have been interesting to see if the outcome had been the same if Mehmet’s illness were not genetic in origin.)

It was claimed that the Socialist Leftist Party changed its position for several reasons. These included not only the pressure exerted by the media campaign but also the fact that the restrictive policy was not able to be defended in the face of its ‘first reality test’ and the better arguments made in the ensuing debate.268 It is important that the New Zealand policy regarding HLA tissue typing is sufficiently robust to withstand its first ‘reality test’.269

3.6.2 Netherlands

The Health Council of the Netherlands (an independent scientific advisory body whose task it is to advise Ministers and Parliament in the field of public health) recently advised that the life-threatening nature of a disease can justify HLA tissue typing in cases where parents are able to love and nurture the child. The Council also observed that whether or not the condition of the affected child is hereditary is not of critical importance. Selection has an indirect medical motive: the curing of the sibling.270 The Secretary of State, however, did not endorse this advice, and PGD carried out in the absence of a genetic risk to the embryo remains prohibited in the Netherlands.271

3.6.3 Denmark

In Denmark, PGD is permitted if there is a risk of transmission of a serious genetic disorder.272 In 2004, an amendment was passed which permits PGD and selection on the basis of HLA tissue type.273 Under this provision the Minister of Health may authorise PGD with HLA tissue typing where a compatible donor is required for a sibling suffering from a serious disease.274 It is not a requirement that the disease suffered by the affected child is hereditary.

3.6.4 Sweden

In Sweden PGD is regulated by guidelines promulgated by the Government and Parliament and is restricted to diagnosing severe, progressively developing hereditary disorders which could lead to early death and for which there is no available treatment.275 The Committee on Genetic Integrity has not yet come to a decision regarding tissue typing.
3.6.5 Victoria, Australia

The Victorian Infertility Treatment Authority (ITA) restricts the performance of HLA tissue typing to circumstances in which the existing child has a severe or life-threatening genetic disease. However the Victorian Infertility Treatment Act 1995 only permits access to assisted reproductive services in the case of infertility, or where there is a risk of transmission of a genetic disorder. This restricts the discretion of the ITA to permit HLA tissue typing in the absence of a genetic risk to the prospective child. The New Zealand policy body is not restricted in the same way. The ITA Guidance provides that the resulting child, born as a result of the procedure, should only provide cord blood or bone marrow, and stipulates that the harvesting of ‘hard’ or non-regenerative organs is not acceptable.

3.6.6 United Kingdom

HLA tissue typing is approved by the HFEA on a case-by-case basis. Applications are expected to demonstrate that all possible alternative treatments have been investigated, and to show why preimplantation tissue typing is the preferred option. It is expected that tissue typing will only be undertaken for an existing child with a serious or life-threatening condition, and this condition is not limited to diseases that are genetic in origin.

3.6.7 European Society for Human Reproduction and Embryology (ESHRE)

The ESHRE Ethics Task Force has stated that HLA tissue typing is morally justified if the potential child’s use as a donor is not the only motive for the parents to have the child. Performing PGD for the creation of an HLA-matched sibling to cure a sick child with a serious non-genetic disease is also deemed acceptable. However, it has stated that, given the low chance of success, it may be inappropriate to recommend the course of treatment ‘in cases of advanced maternal age and/or poor ovarian reserve’. ESHRE has also recommended that follow-up should be performed as reliable empirical research is required to determine the psychological and social consequences for the donor sibling. For this reason, a register should be set up to record donations.

3.6.8 Summary

The majority of the jurisdictions covered in this brief overview permit the use of HLA tissue typing with PGD to conceive an HLA-matched child. Whether the disease suffered by the sick sibling is genetic in origin is immaterial in both the United Kingdom and Denmark. Proposals to extend HLA tissue typing where there is no genetic risk have occurred in two jurisdictions, but have been unsuccessful. Both the United Kingdom and Victorian jurisdictions countenance the transplantation of bone marrow tissue from a child conceived by PGD and HLA tissue typing.
3.7 Public perceptions

The best justification for State intervention in this context is the concern that children may be exploited as donors in violation of their dignity. Yet it is also possible that the creation of saviour siblings may be perceived from within a human rights framework.\textsuperscript{281} Within such a rights framework, individuals have ‘positive obligations to assist one another’ in some circumstances when they can do so at little or negligible cost to themselves.\textsuperscript{282} There seems to be support for this sentiment in surveys undertaken to assess the views of the public.

In a large survey of Americans, undertaken by the Genetics and Public Policy Centre, John Hopkins University, the majority of respondents approved the use of PGD to select an embryo that was a match for a sick sibling. Strong support was reported for such a technology when it provides a health benefit, even when that benefit accrues to another person.\textsuperscript{283}

When reviewing its \textit{Guidance on Preimplantation Tissue Typing}, the HFEA commissioned research into public opinion on issues related to embryo selection for tissue typing and sibling cord blood and bone marrow donation.\textsuperscript{284} A series of workshops consisting of six groups comprising six to eight members of the public was conducted. Two of these groups had ‘direct interest in either genetic disease or assisted conception’. To investigate how public opinion on these issues was formed and influenced, these groups met to discuss the issues and to develop their opinions on the use of assisted reproductive technologies. The same individuals were then brought together, for a half-day workshop with experts, to explore their views further.

It was reported after the initial discussion that participants’ views were ‘broadly in favour of the use of any technique which could save the life of a child, as long as the risks were well managed’. The majority of participants did not consider it important whether the condition suffered by the sick sibling was hereditary. What was important was the seriousness of the condition affecting the sick sibling. However, many of the participants expressed greater reservations about the use of the procedure to produce a bone marrow donor. Reportedly, these views changed after discussion with an expert.

3.8 Conclusion

Parents have been attempting to conceive potential donors for seriously ill siblings ever since it was possible to diagnose certain medical conditions and HLA tissue type prenatally. The fact that this can be achieved more easily and with greater accuracy with the use of PGD does not mean that it should necessarily be integrated into mainstream medicine without careful analysis. Whilst the HART Act 2004 seeks to secure the benefits of assisted reproductive technology, it is also concerned to protect the health, safety, dignity and rights of all individuals in the use of such technologies.
The ability to create saviour siblings utilising PGD technology has called into question what constitutes responsible parenthood and the legitimate scope of parental decision-making authority. It has resulted in the formulation of guidelines, which now have legal status under the HART Act 2004.\textsuperscript{285} This section has analysed the risks and benefits of HLA tissue typing, as well as the arguments in favour of and against liberalising the current guidelines. It concludes that the current restrictive HLA policy is both ethically and legally problematic.

Significant benefits accrue from HLA tissue typing in conjunction with PGD. It is widely accepted that transplantation of umbilical cord blood HSCs from an HLA-matched sibling provides the best chance, or possibly the only chance, of successful treatment for children suffering from certain disorders. The physical risks to a donor child conceived for this purpose are not high. They comprise the ordinary risks associated with IVF and embryo biopsy as well as a relatively small additional risk in the case of low birth weight or preterm babies. The psychological sequelae for children conceived to be cord blood donors are not yet established. They will only be deduced after sufficient time has elapsed for qualitative research to be undertaken. In the interim, the issue is whether the concerns outweigh the potential or, in some cases, inevitable death of a child.

The HART Act 2004 requires that the health and well-being of a child born as the result of an assisted reproductive procedure is an important consideration in all decisions about that procedure; but it is not a paramount consideration, nor is it the only consideration. Equally, the Act requires that the human health, safety and dignity of present and future generations should be preserved and promoted. Permitting parents to conceive an HLA-compatible sibling provides a seriously ill child with a chance of disease-free survival. This clearly promotes the health of the existing child and the well-being of the family and, potentially, the next generation. These principles and the first purpose of the Act support reproductive liberty and provide strong support for a less restrictive policy.

The Act also requires that the different ethical perspectives in society should be considered and treated with respect. Concerns regarding responsible parenthood and instrumentalisation of the donor child are insufficient to displace the interests of parents who wish to undertake this clinical course when there is a reasonable chance of success, and the interests of the sick child who will have an opportunity for survival. Conception of a child to be a donor is no worse or less altruistic than the multitude of other reasons for conception of a child. Indeed, the decision to conceive a child who may provide HSCs for a sick sibling perhaps constitutes one of the more rational reasons for conceiving a child.
Concerns that a donor child may face ongoing requests for donation are valid, but may be managed by standards of clinical practice. They are not sufficient on their own to justify restricting the performance of HLA tissue typing. Slippery slope arguments are weak and fail to provide sufficient justification for limiting HLA tissue typing given the purpose of the procedure. Whilst there may be ethical concerns for the welfare of donor children, which mandate caution, what can be said is that:

\[ \text{it is far from obvious that considerations of child welfare should count against, rather than for, the practice of saviour sibling selection.}^{286} \]

It has been argued on a clause-by-clause basis that the Guidelines are problematic, and require revision. There is no good reason to restrict HLA tissue typing to circumstances where the sick child is suffering from a single gene or sex-linked disorder, as there is no valid moral distinction between performing PGD and HLA tissue typing in the presence or absence of a genetic risk. The Guidelines should simply require that the sick sibling is suffering from, or has suffered from, a condition which is serious or life threatening.

The restriction, which limits performance of PGD with HLA tissue typing to situations where there are no other possibilities for treatment or sources of tissue available, is unduly onerous. Cord blood registries may contain a reasonable match for the sick child in some cases, but a sibling HLA match may constitute the best chance of a successful outcome. In addition, parents may wish to conceive a donor child in the event that the therapy currently being undertaken by the sick child is unsuccessful. It would be preferable to require that ‘all other possibilities of treatment and sources of tissue for the affected child have been explored’.

Finally, whilst the purpose of conceiving an HLA-matched child is relevant to decision-making under the Act, it is not within the jurisdiction of ACART to impose limits on tissue donation after a child is born. Sibling bone marrow donation has occurred with naturally conceived children who are an HLA match with a sick sibling in accordance with the general law regarding incompetent minors. It is argued here that there is no relevant moral objection to permitting bone marrow donation if a cord blood HSC transplant fails, or is unable to be performed. This should be a matter for parental and clinical decision-making, taking into account the clinical circumstances of the infant or child and the sick sibling, and based on the usual legal standard for the provision of proxy consent. There does not appear to be any evidence that deference to parental autonomy in relation to providing proxy consent to bone marrow transplantation has led to an inappropriate exercise of parental authority in the past. However, good medical practice should dictate that the donor child has an independent physician and an appropriately qualified independent advocate who may act on the child’s behalf. Whenever there is doubt regarding the appropriateness of the procedure, the jurisdiction of the Family Court should be invoked.
It is manifestly reasonable to state that good medical practice would dictate a limit to the number and type of procedures which may be performed on an incompetent saviour sibling for the benefit of a sick child. However, imposing a precise limit may be an arbitrary restriction. It may be of greater value to appoint a professional advocate for a child, such as a child psychologist, who is able to communicate with the child and is independent of the parents and the physicians. Such an appointment may best achieve the protection and promotion of the donor child’s interests. In the case of disagreement, any eligible persons involved should apply to the Court for determination.

Introducing a register to record all those children born as a result of preimplantation HLA tissue typing, and to record subsequent tissue donations, is imperative so that empirical studies may be undertaken on the effects on donor children which may inform subsequent policy-making.

3.9 Summary of conclusions

3.9.1 Policy
Conception of a child who may provide cord blood or bone marrow for a sick sibling should be permitted where as well as wanting a donor child the child is wanted in its own right and:

1. The sick sibling is suffering from, or has suffered from, a condition which is serious or life threatening, and
2. All other possibilities of treatment and sources of tissue for the affected child have been explored, and
3. HSC transplant confers a reasonable chance of disease-free survival for the recipient sibling.
4. Cord or bone marrow donation may be performed on the basis of proxy parental consent when it is consistent with the current law. However, in the event that ongoing demands for donation are made, good medical practice requires the appointment of an appropriately qualified independent advocate for the child, and an independent physician.

3.9.2 Governance
A register should be set up by the Ministry of Health to record the birth of all children born from PGD with HLA tissue typing, and to record subsequent tissue donation. Parents must agree to participate in follow-up studies if and when they are undertaken.
**Figure 1:** Conditions for which HSCT may be indicated

**Source:** K. Moise, ‘Umbilical Cord Stem Cells’ (2005) 106 Obstetrics & Gynecology 1393, 1394

<table>
<thead>
<tr>
<th>Indications for Cord Blood Transplant</th>
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<tr>
<td><strong>Thalassemias</strong></td>
<td>Red cell aplasia</td>
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<td>• a-thalassemia intermedia (hemoglobin H disease)</td>
<td>• Refractory anemia</td>
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<td>• a-thalassemia major (hydrops fetalis)</td>
<td>• Schwachman Syndrome</td>
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<td>• β-thalassemia major (Cooley’s anemia)</td>
<td>• Severe aplastic anemia</td>
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<td>• β-thalassemia intermedia</td>
<td>• Systemic mastocytosis</td>
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<td>• E-β° thalassemia</td>
<td>• Severe neonatal thrombocytopenia</td>
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<td>• E-β+ thalassemia</td>
<td>• Congenital sideroblastic anemia</td>
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<td>• Thrombocytopenia with absent radius (TAR syndrome)</td>
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<td><strong>Sickle Cell disorders</strong></td>
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<td>• Sickle cell anemia (hemoglobin SS)</td>
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<td>• HbSC disease</td>
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<td>• Sickle β° thalassemia</td>
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<td><strong>Oncologic Disorders</strong></td>
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<td>• Autoimmune lymphoproliferative syndrome</td>
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<td>• Burkitt lymphoma</td>
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<td>• Cytopenia related to monosomy 7</td>
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<td>• Familial histiocytosis</td>
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<td>• Hemophagocytic lymphohistiocytosis</td>
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<td>• Non-Hodgkin’s lymphoma</td>
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<td>• Langerhans cell histiocytosis</td>
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<td>• Lymphomatoid granulomatosis</td>
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<td><strong>Hematologic Disorders</strong></td>
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<td>• Amegakaryocytic thrombocytopenia</td>
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<td>• Autoimmune neutropenia (severe)</td>
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<td>• Congenital dyserythropoietic anemia</td>
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<td>• Cyclic neutropenia</td>
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<td>• Kostmanns syndrome</td>
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<td>• Hypogammaglobulinemia</td>
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<td>• Immune dysregulation polyendocrinopathy</td>
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<td>• Myelokathesism</td>
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<td>• X-linked immunodeficiency</td>
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<td>• Severe combined immunodeficiency</td>
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<td>• Adenosine desaminase deficiency</td>
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<td>• Wiscott-Aldrich syndrome</td>
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<td>• X-linked agammaglobulinemia</td>
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<td>• X-linked lymphoproliferative syndrome</td>
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<td><strong>Metabolic Disorders</strong></td>
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<td>• Gaucher’s disease (infantile)</td>
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<td>• Metachromatic leukodystrophy</td>
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<td>• Globoid cell leukodystrophy (Krabbe disease)</td>
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<td>• Gunther disease</td>
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<td>• Hermansky-Pudlak syndrome</td>
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<td>• Hurler-Scheie syndrome</td>
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<td>• Sanfilippo syndrome</td>
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<td>• Mucolipidosis Types II, III</td>
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<td>• Alpha mannosidosis</td>
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<td>• Neimann Pick Syndrome, types A and B</td>
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<td>• Sandhoff Syndrome</td>
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<td>• Tay Sachs Disease</td>
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* Personal communications: Mark Walters, MD, of Children’s Hospital Oakland Research Institute and Joanne Kurtzberg, MD, Director Carolinas Cord Blood Bank at Duke
4 PGD AND NEGATIVE SELECTION OF UNAFFECTED CARRIER EMBRYOS

4.1 Introduction

The use of PGD to diagnose and select against embryos which are affected by serious single gene or chromosomal disorders is permitted as a routine clinical procedure by virtue of the HART Order 2005. However, as was observed in the first report of the Human Genome Research Project, the position regarding negative selection of unaffected carrier embryos is equivocal. Embryos which are ‘unaffected’ or ‘healthy’ carriers of a genetic mutation have an allele which is associated with a particular genetic disorder, but have also inherited a normal allele which is dominant. These heterozygote carrier embryos, if implanted and carried successfully to term, will not be born with any clinical manifestations of the relevant genetic disorder, but will be an unaffected ‘carrier’ of the familial mutation. Individuals who are healthy carriers of a heritable mutation do not, with some exceptions, have any phenotypic characteristics of the genetic disorder, but are capable of passing on the genetic condition to their future offspring.

The current regulatory scheme restricts the performance of PGD on a strictly therapeutic normative basis. PGD may only be performed to prevent the transmission of disorders capable of causing serious impairment in a future individual. As yet, the established procedures policy does not expressly provide for the negative selection of carrier embryos.

Two developments in particular signal that the issue of preimplantation selection of embryos and the status of unaffected carrier embryos will become a significant topic in the context of PGD. First, as science provides more choices for genetic selection, it also provides better treatment and improved quality of life for people with inherited genetic conditions such as haemophilia or cystic fibrosis. More people affected by serious genetic disorders may now live to reproductive age and beyond. They may consider parenthood, and reprogenetic technology, when they might not have done so if they had been born even a decade before. Secondly, as PGD technology becomes more sophisticated and accurate and is performed more regularly, more embryos will be identified as carriers of recessive disorders and prospective parents may want a choice as to which are implanted.

This section explores whether the arguments that have been raised against PGD simpliciter are enhanced in the case of PGD, which may result in selection against healthy carrier embryos. It clarifies at the outset the different implications of being a carrier of an X-linked recessive disorder as opposed to being an unaffected carrier of an autosomal recessive disorder. The effect of the current New Zealand law in relation to the negative selection of carrier embryos is considered, and an overview
is provided of other jurisdictions that have considered this issue. Ultimately, this section considers who should decide whether carrier embryos may be negatively selected, and according to what criteria.

4.2 Implications of unaffected carrier status

4.2.1 Genetic implications – Transmission

When selecting against carrier embryos, the genetic condition for which a prospective carrier is at risk impacts greatly on the implications of carrier status. Although a female carrier of an X-linked recessive disorder such as Duchenne muscular dystrophy is unaffected, the risk of passing the disorder on to a future son is 50 per cent.

In contrast, for a carrier of an autosomal recessive gene (whose reproductive partner is not a carrier) the risk of passing on the disorder may only be 1 per cent, or even less. Clearly, the reproductive risk for a carrier of an autosomal recessive condition is much lower. Consequently, there is a significant distinction between healthy carriers of X-linked recessive conditions and heterozygote carriers of autosomal recessive conditions. This factor necessarily affects the nature and quality of negative selection in these circumstances.

4.2.2 Physical implications

Although the issue of carrier status is often referred to in terms of the ‘reproductive risk’ for the carrier, it is not merely reproductive interests that are of concern in the case of some recessive conditions. It is possible that carriers of certain recessive disorders may manifest phenotypic symptoms. An example of this is X-linked adrenoleukodystrophy. Although this disorder is inherited in an X-linked pattern, carrier females can exhibit symptoms of the condition. Such a clinical scenario arguably fits within a therapeutic PGD framework, rendering negative selection in these circumstances permissible; or at least enhancing the arguments in favour of selecting against carrier embryos in this context.

4.2.3 Psychosocial implications

Construing the interests at stake simply as ‘reproductive interests’, as opposed to health interests, may not be a true reflection of the implications of carrier status on future individuals, particularly in the case of carriers of X-linked conditions. In addition to potentially imposing a physical burden on the prospective carrier, an individual’s carrier status may also impose a significant psychological burden. This burden rewrites the rules of engagement not only for pregnancy, but also potentially the relationships that carrier offspring may develop.
4.2.4 Implications of selection when it is a contingent activity versus a primary purpose

There are two possible situations when the issue of selecting against carrier embryos using PGD may arise. The first and most likely situation is when PGD is indicated because of the risk of passing on a serious hereditary disorder, and selecting against carrier embryos becomes a contingent or additional possibility. For the purposes of this discussion it will be described as ‘contingent selection’ (i.e. secondary or additional selection).

The second possible situation occurs when an individual who is not at risk of having an affected child wishes to avoid having a child who will be an unaffected carrier child; this will be referred to as ‘primary purpose PGD’. Requests to perform PGD to negatively select an unaffected carrier are more likely to occur in the case of X-linked recessive conditions where an affected male wishes to avoid passing the mutation on to a daughter, who would be at risk of transmitting the disorder to her sons. The distinction between selecting against carrier embryos on a contingent basis versus a primary basis is made in the following example using the case of haemophilia.

4.2.4.1 PGD and contingent selection against unaffected carriers

A female carrier of haemophilia has a 25 per cent chance of conceiving a son affected by haemophilia, and a 25 per cent chance of having a healthy daughter who is a carrier of the haemophilia mutation. In this example the possibility of selecting against a carrier daughter is a secondary possibility as a result of PGD, which is principally performed to avoid the transmission of haemophilia to a son. The possible reproductive outcomes for a female carrier of the X-linked disorder haemophilia are represented in Table 1:

<table>
<thead>
<tr>
<th>Pregnancy outcome</th>
<th>Probability</th>
<th>Clinical problems</th>
<th>Implications for next generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Male with haemophilia</td>
<td>25 per cent</td>
<td>Bleeding tendency, lifelong therapy</td>
<td>Daughters 50 per cent risk of being carriers</td>
</tr>
<tr>
<td>B Healthy Male</td>
<td>25 per cent</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>C Carrier Female</td>
<td>25 per cent</td>
<td>90 per cent healthy, 10 per cent mild bleeding</td>
<td>Daughters 50 per cent risk of being carriers, sons 50 per cent risk for haemophilia</td>
</tr>
<tr>
<td>D Healthy Female</td>
<td>25 per cent</td>
<td>Nil</td>
<td>Nil</td>
</tr>
</tbody>
</table>

*Table 1: Reproductive outcome for a female carrier of X-linked haemophilia*
4.2.4.2 Negative selection of healthy carriers as a primary purpose

The other category entails the utilisation of PGD to avoid the creation of healthy carrier offspring as a primary goal. PGD is engaged in solely to deselect a carrier embryo. This could occur in the case of a haemophiliac male. He cannot pass the mutation on to any prospective sons because it is an X-linked condition. However, any prospective daughters will be carriers. In these circumstances PGD is performed where there is no risk of transmitting the genetic disorder, but there is a risk of transmitting carrier status to female offspring. The possible reproductive outcomes in this situation are represented in Table 2:

<table>
<thead>
<tr>
<th>Pregnancy outcome</th>
<th>Probability</th>
<th>Clinical problems</th>
<th>Implications for next generation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A Healthy male</td>
<td>50 per cent</td>
<td>Nil</td>
<td>Nil</td>
</tr>
<tr>
<td>B Carrier female</td>
<td>50 per cent</td>
<td>90 per cent healthy, 10 per cent mild bleeding</td>
<td>Daughters 50 per cent risk of being carriers, sons 50 per cent risk of haemophilia</td>
</tr>
</tbody>
</table>

*Table 2: Reproductive outcome for a male affected by haemophilia*

There are no reports, as yet, of a demand for PGD where no risk exists of having a child affected by a serious genetic disorder, but where there is a risk of transmitting carrier status to offspring, i.e. primary purpose PGD. However, the same is not true in the case of prenatal diagnosis and X-linked genetic disorders. Requests have been made for prenatal diagnosis of carrier status in relation to haemophilia A and fragile X syndrome, both X-linked recessive disorders. The parents requesting prenatal diagnosis were prepared to terminate not only an affected male foetus, but also a female foetus if it were diagnosed as a carrier of the particular X-linked recessive disorder.

As has already been observed, female carriers of X-linked disorders do not generally manifest any phenotypic symptoms; only males who inherit the abnormal gene are affected. However there are exceptions to this. In some cases females will exhibit effects of the X-linked recessive mutation that they are carrying. Approximately 10 per cent of female carriers of the haemophilia A gene, for example, may display a mild bleeding tendency. In the case of fragile X, the most common inherited form of mental retardation apart from Down syndrome, carrying a premutation has no observable phenotypic impact on female offspring; but female carriers of full mutations can be affected. Whilst there may be evidence that a female carrier foetus of fragile X syndrome will be affected, there is only a small risk that a female carrier of haemophilia will be mildly affected.
It was reported that the motivation of the parents who presented for prenatal diagnosis of carrier status was to expunge the haemophilia and fragile X disorders from their families. Clearly, there is evidence that some prospective parents have a strong desire to avoid the transmission of carrier status to their offspring. If being a carrier of an X-linked recessive disorder poses a reasonable risk of phenotypic manifestations, negative selection of ‘healthy’ carrier embryos may be justified on health grounds. However, when carrier status may only pose a risk of a ‘minor’ genetic abnormality or no abnormality at all, selection against broadly ‘unaffected’ carrier embryos can represent a considerable moral dilemma.

4.2.5 Summary
There is evidence that some parents would consider termination if a foetus were a female carrier of a serious X-linked disorder. With the introduction of PGD, avoiding carrier offspring is now possible at the preimplantation stage. When PGD has been performed to diagnose serious heritable disorders, and carrier status has been determined in the process, it is a matter of debate whether selection on the basis of unaffected carrier status should be permitted, and who should decide. A more problematic issue is whether PGD should be accessible to parents who are not at risk of having offspring affected by a particular serious genetic disorder, but who may transmit the recessive allele to the following generation. This analysis considers whether negative selection of carrier embryos is permitted under the current legal framework and, if not, whether it should be. It concludes that the law is unclear, but that there is no principled basis to prevent parents from choosing to avoid implantation of carrier embryos.

4.3 Current legal position
In the course of ordinary IVF the embryologist is responsible for selecting the best-quality embryo or embryos for implantation. This involves selecting the embryo with those characteristics conferring the greatest chance of implantation and of being successfully carried to term. However, performing PGD for single gene disorders brings an additional dimension to embryo selection. This is because some embryos will be affected by a single gene disorder, some will be unaffected and some will be unaffected carriers of the relevant mutation. Although carrier status is not always diagnosed in the course of preimplantation diagnosis, some tests will indicate unaffected carriers as an unavoidable by-product of preimplantation testing.

There are two related issues. The first is whether parents have a right to know the carrier status of their embryos and second is whether they should be permitted to select against carrier embryos.
The following passage seeks to determine what information parents are entitled to receive in the course of PGD. The related issue, whether parents ought to be able to select against carrier embryos, will then be considered.

4.3.1 Right to know

4.3.1.1 Code of Consumers’Rights

The Code of Health and Disability Services Consumers’ Rights establishes the civil standard for the provision of health services by health care providers to health care consumers in New Zealand.296 The Code, promulgated pursuant to the HDC Act 1994, declares that consumers have rights and providers have duties.297 The Code encompasses both providers and consumers of fertility services, and imposes extensive information requirements on providers. To determine the relevance of the Code to the performance of PGD, it is necessary to unpack not only the rights, but also the relevant definitions provided in both the Code and the HDC Act 1994.

Right 6(1) of the Code provides that ‘every consumer has the right to the information that a reasonable consumer, in that consumer’s circumstances, would expect to receive’, including the results of tests (6(f)) and the results of procedures (6(g)). (Emphasis added.) Clause 4 of the Code provides that a ‘consumer’ is a health consumer. The definition of a ‘health consumer’ is provided in section 2 of the HDC Act 1994, which declares that a health consumer ‘includes any person on or in respect of whom any health care procedure is carried out’. A ‘health care procedure’ is further defined as 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. The definition of ‘health services’ in section 2 of the Act includes diagnostic services and fertility services.

Embryo biopsy is clearly a diagnostic procedure, which comes within the meaning of a ‘health service’. The question is whether embryo biopsy comes within the definition of a ‘health care procedure’. Diagnosing embryos for genetic abnormalities constitutes a health examination. The issue is whether it is carried out ‘on or in respect of any person by any health care provider’. The embryologist comes within the definition of a ‘health care provider’ contained in section 3 of the Act. However, as the embryo is not a person, the procedure is not carried out ‘on any person’.298 To come within the definition of a health care procedure, the biopsy must be carried out ‘in respect of any person’. The biopsy is not carried out on a body part or tissue provided by the mother, but on a separate entity created by in vitro fertilisation. In this context, it is possible that the embryo biopsy, whilst it is a health service, is not a health care procedure carried out on or in respect of any person. Therefore, the right to be fully informed of the results of the testing is potentially not triggered under the Code.
However, it would be difficult to sustain this line of argument when an embryo is selected for transfer. The process of implantation clearly comes within the definition of a health care procedure carried out on a health care consumer, with the corresponding right under 6(1) of the Code to be fully informed with regards to the implantation procedure. On this analysis, the right to be fully informed under the Code arises in the context of implantation, but does not necessarily arise as a matter of course when the results of embryo biopsy are known. Whether it should arise at the point of diagnosis is a moot point.  

If selection against unaffected carrier embryos is permissible under the established procedures order, there may be no reason to refuse disclosure of the information. However, if selection against carrier embryos is not permitted under the HART Order 2005, it could create significant difficulties for a provider if parents wished to know in advance and consequently attempted to influence embryo selection. If negative selection of unaffected carriers is not permitted, then it is arguable that a reasonable consumer in that consumer’s circumstances would not expect to be privy to that information at the point of biopsy; but it could be reasonable to expect to be informed of carrier status of any embryos selected for implantation. Information regarding carrier status of an embryo is health information and is information that a reasonable consumer, in that consumer’s circumstances, may expect to receive in the course of embryo transfer.

The caution exercised by clinicians worldwide in relation to the performance of carrier testing on minors, and the disclosure of carrier information, may be relevant to the disclosure to parents of carrier status determined as a result of PGD. A recent systematic review, which examined fourteen guidelines from various jurisdictions, revealed that all of the guidelines were unanimous in recommending that carrier testing in minors should not be performed, but should be deferred until the child could give informed consent to testing. It was stated that:

*Despite the lack of conclusive evidence that carrier testing performed during childhood harms children psychologically, the great majority of genetic testing guidelines espouse the premise that carrier testing might be detrimental to the mental well being of tested children, and as such, should be disallowed in children.*

However two bodies, the British Medical Association and the United Kingdom Genetic Interest Group, have a more flexible stance regarding the testing of minors. In their view, providing information to a minor regarding carrier status could help a child to cope with this knowledge from an early age and could ‘reduce the anxiety and uncertainty experienced by parents about their child’s carrier status.’
When carrier status is discovered incidentally (which may occur in the course of PGD or in newborn screening) the British Medical Association guidelines and the American Academy of Pediatrics recommend that carrier status results should be conveyed to parents. However, the American Medical Association and the German Society of Human Genetics recommend that the child’s carrier status should not be disclosed to parents or to other third parties. They suggest that the information regarding carrier status should be ‘discussed with the child when he reaches reproductive age’. The American Medical Association guidelines also provide instructions for maintaining confidentiality, and state that this ‘privileged information’ should be kept separately from a patient’s medical record to avoid inadvertent disclosure. Yet it seems that there is a paucity of evidence regarding the beneficial or detrimental effects of carrier testing and disclosure to minors.

4.3.1.2 Summary

As discussed, it is likely that parents may wish to know the carrier status of embryos created and implanted in the course of PGD. It seems counter-intuitive to withhold information regarding carrier status given the seriousness of the genetic disorders involved, and the lack of evidence regarding harm in disclosure of such information. However, there is evidence that some organisations recommend not disclosing carrier status when it is discovered incidentally. Two organisations, the British Medical Association and the American Academy of Pediatrics, provide that disclosure of carrier status to parents is acceptable. Given the lack of evidence regarding harm, the balance seems to be in favour of informing parents of the carrier status of embryos created and embryos transferred for implantation.

4.3.2 Right to choose

4.3.2.1 Code of Consumers’ Rights

Right 7(1) of the Code provides that ‘services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise’. Right 7 does not confer on consumers a choice regarding the implantation of a non-carrier or carrier embryo if it has been legally precluded by the HART Order 2005. Right 7 simply maintains a consumers’ right to informed consent as is generally required in the health context. It is consequently necessary to determine whether negative selection against carrier embryos is permitted under the Order.

4.3.2.2 Human Assisted Reproductive Technology (HART) Order 2005

The current legal position under the HART Order 2005 is as follows. PGD may be performed as an established procedure for familial single gene disorders where the disorder has been identified in the family, there is a 25 per cent or greater risk of an affected pregnancy and the future individual may be seriously impaired as a result of
the disorder. Sex selection is also permitted in the case of familial X-linked disorders where there is no specific test for the particular disease-causing mutation available, there is a 25 per cent or greater risk of an affected pregnancy and the future individual may be seriously impaired as a result of the disorder. PGD which falls within these categories may be carried out as a routine clinical procedure.

4.3.2.2.1 Contingent selection

A rigid interpretation of the established procedures order may suggest that intentional selection against healthy carriers in the course of PGD is not permitted because positive carrier status is not a serious impairment. However, it could be argued that transmission of carrier status is capable of causing serious impairment in a future individual in some instances.

Being a carrier of an X-linked or autosomal recessive disorder undeniably associates an unaffected carrier embryo with a particular genetic disorder. However, carriers of X-linked conditions are burdened more directly. Female carriers of X-linked recessive mutations have a one in two risk that prospective sons will inherit and develop the disorder, and a one in two chance that female offspring will also be carriers. In the case of carrier daughters, there is a 25 per cent chance that a future grandson will be affected. Because of the statistical risk of transmission, selection against unaffected (female) carriers of X-linked disorders meets the criteria provided in the Order, and may arguably be carried out as an established procedure.

However, carriers of autosomal recessive disorders will only be burdened by the mutation if they reproduce with a partner carrying the same recessive disorder, so the risk of an affected pregnancy is much lower. It is unlikely that being a carrier of an autosomal recessive disorder would generally be characterised as a serious impairment, unless it were open to a subjective assessment. Serious impairment is not defined in the HART Order 2005.

Regardless of whether the transmission of healthy carrier status is categorised as causing serious impairment, it is possible that selection against carrier embryos may be a legitimate activity in the course of PGD performed to prevent the direct transmission of the disorder. It is reasonable to interpret the Order as merely providing threshold criteria for accessing PGD, with subsequent selection decisions being left to the clinicians and parents involved.

There is a precedent for this type of approach in other similar jurisdictions. In the United Kingdom the HFEA’s Code of Practice declares that PGD should only be considered where there is a ‘significant risk of a serious genetic condition being present in the embryo’. However, it is clear that some clinics in the United Kingdom have a policy of preferentially transferring unaffected embryos first; and, if there
aren’t any, they will then discuss with parents the possibility of implanting carrier embryos.\textsuperscript{308} The HFEA has acknowledged that selection against carrier embryos may occur as a result of the PGD process, although it seems there are no formal guidelines for practice.

The effect of the current regulatory framework is that if selection against carriers is not permitted under the established procedures category, and it is not an expressly prohibited activity under the Act, then it is by default a regulated activity. The only application of PGD which is expressly prohibited by the HART Act and the Guidelines is PGD performed for social reasons.\textsuperscript{309} As selection against carrier embryos is based on a disease-related genotype, it would be inaccurate to consider it to be social selection. It is therefore not prohibited, and falls into the regulated category if it is not covered by the established procedure Order. A regulated activity may not be carried out unless it is carried out in accordance with Guidelines promulgated by ACART.\textsuperscript{310} In the absence of Guidelines, the procedure may not be lawfully performed.

4.3.2.2.2 Primary purpose selection

There is a major distinction between performing PGD to negatively select carrier embryos as a primary goal and performing it as a contingent or additional procedure to avoid conception of a child who will manifest symptoms of the disease. In the latter case the PGD cycle and embryo biopsy is, arguably, a medical imperative because the future individual may be directly affected. Embryo biopsy is justified in the case of contingent PGD because of the risk of disease transmission; testing for carrier status is merely a contingent activity. However with primary purpose carrier selection, the only reason for performing PGD is to determine the carrier status of otherwise healthy embryos.

The legality of performing PGD with the primary purpose of negatively selecting embryos which are healthy carriers of recessive disorders differs according to whether the disorder is X-linked or autosomal recessive. PGD carried out for the primary purpose of preventing the transmission of carrier status in the case of X-linked disorders arguably comes within the established procedures order. In the case of a male with haemophilia, his offspring will not be affected, but his daughters will all be carriers. Hence, the risk that a future grandson will have the disorder is 25 per cent.\textsuperscript{311}

This situation meets the criteria in the HART Order 2005, as there is a 25 per cent or greater risk of an affected pregnancy and evidence that the future individual may be seriously impaired as a result of the disorder. Consequently PGD may arguably be performed in the case of X-linked disorders, when the primary purpose is selecting against a healthy carrier embryo, as an established procedure.
The risk of transmission for autosomal recessive disorders arguably does not meet the threshold. Although there is a 50 per cent chance that an individual who is a carrier of an autosomal recessive condition will pass on carrier status to offspring, the reproductive risk to the future offspring (i.e. the grandchildren) may be less than 1 per cent. Consequently, the legality of performing PGD as an established procedure to detect carrier status of an autosomal disorder as a primary purpose depends upon whether carrier status alone is construed as causing serious impairment.

4.3.3 Summary

Ultimately the current legal position regarding selection against healthy carrier embryos in the course of PGD is unclear. A literal interpretation of the established procedures Order would suggest that selection against healthy carriers is not permissible in the case of autosomal recessive conditions, but is possibly permissible for X-linked conditions. However, it is arguable that selection against carrier embryos of both autosomal and X-linked conditions may occur at the very least as a contingent procedure to ordinary PGD covered by the established procedures Order. According to this view, once the threshold for PGD is met selection against carrier embryos may be permitted in the case of contingent PGD as an exercise of clinical and parental decision-making.

It is also plausible that selection against X-linked carriers may be legally performed as a primary procedure under the established procedures category. Selection against healthy carriers of autosomal recessive disorders as a primary procedure is not arguable on a literal interpretation of the established procedures Order, because of the required 25 per cent or greater risk of an affected pregnancy; unless being a carrier of an autosomal recessive disorder constitutes serious impairment in itself. This is almost impossible to argue, because the entire population would be seriously impaired.

Ultimately there are two distinct questions: first, whether selection against carrier embryos is permitted under the current law; and, secondly, if it is not permitted, whether it should be. As explained earlier, the answer to the former is not clear-cut. The following is concerned with the second question and considers whether the purpose and principles of the HART Act 2004 support permitting carrier testing either as a contingent procedure to ordinary PGD or as a primary purpose.
4.4 Should carrier testing be permitted?

This section examines whether selection against carrier embryos should be permitted either as a contingent or primary procedure. The framework proposed in the second section of this report will be used to consider this question. It starts from a presumption of reproductive autonomy and then takes into account the relevant principles of the Act. The relevant principles include the provision that the health and well-being of children born should be an important consideration in all decisions regarding a procedure; the health, safety and dignity of present and future generations should be preserved and promoted; and the different ethical, spiritual and cultural perspectives in society should be considered and treated with respect. The arguments in favour of negative selection of carrier embryos are considered first, followed by the arguments against carrier testing. While the arguments against carrier testing must be accorded respect, it is argued that they should not displace the arguments in favour of reproductive liberty and parental choice.

4.4.1 Arguments in favour of permitting negative selection of healthy carrier embryos

Arguments in favour of permitting selection against carrier embryos may be made on the grounds of reproductive liberty or the reproductive interests of the future child. They may also be predicated on the grounds of intergenerational benefit. Conversely, moral barriers to permitting selection against carrier embryos may be made on the grounds that it involves the destruction of healthy embryos, that it is an exercise based on genetic essentialism, that it harms society by reducing genetic diversity or that it stigmatises healthy carriers.

The standard justification for permitting selection against embryos carrying recessive disorders is to prevent carrier offspring from facing the same reproductive issues as their parents. The relevant issue is whether there are sufficient reasons or harms to restrict prospective parents from selecting against unaffected carrier embryos, either contingently to PGD, when it is performed to diagnose a serious disorder, or as a stand-alone primary purpose procedure.

As already discussed, the justification for selecting against unaffected carriers is generally based on the reproductive implications for the carriers, not the prospective health of the grandchildren or the intergenerational effects. For the vast majority of carriers of autosomal recessive conditions, who reproduce with non-carriers, carrier status will not be an issue. In addition, carriers will have the same reproductive options available to them as currently exist, such as prenatal genetic diagnosis or PGD. Hence the means to prevent the transmission of deleterious mutations will be available.

Yet it is easy to over-simplify the implications of carrier status as simply impacting upon reproductive freedom. Not all carrier offspring will engage in reprogenetic
technology. They may conceive, carry and deliver affected offspring, whether intentionally or not. Not all pregnancies are planned, nor do all those at risk of having affected children wish to engage in preventive technology. It is undeniable that raising a child with a severe X-linked recessive disorder causes a parent or parents significant mental anguish. Hence, selecting against carrier embryos may not be viewed simply from the perspective that harm is avoided for the next generation; potential harm to subsequent generations is also prevented. A wish to avoid carrier offspring may stem from the parents’ desire to prevent a putative child experiencing the guilt of passing on a deleterious gene, and consequently suffering significant psychological or emotional distress through witnessing the suffering of a child affected by a disorder for which they feel responsible. This mental anguish has been vividly described by a carrier mother of a son affected by haemophilia in the following statement:

*How often do we hear or make the statement, ‘Hemophilia affects males and is passed on by females.’ Here lies the seed that grows into that canker called guilt which lies heavily on the hearts of many carrier mothers.*

As argued above, the potential reasons for selecting against carrier embryos may extend beyond the reproductive interests of future offspring to intergenerational considerations. Nevertheless, it should not be assumed that exclusion of carrier embryos will be a priority for those undertaking PGD to avoid passing on a serious single gene disorder. It is unclear whether there will be great demand by prospective parents undergoing PGD for the exclusion of healthy carrier embryos.

A relatively recent Australian study evaluated the social and moral concerns of patients presenting for PGD prior to initiating the treatment cycle. The study group consisted of three patient groups, one group presenting for PGD for single gene disorders, another group for aneuploidy screening and a control group who were about to commence their first IVF cycle. A questionnaire was administered individually and anonymously to each person. One part of the questionnaire dealt with issues surrounding selection and transfer of embryos as well as concerns in relation to knowledge of the carrier status of the embryo. The following question was posed:

*If given the choice, would you accept the transfer of an embryo identified as being a healthy carrier?*

In the group of couples presenting for PGD for single gene disorders, 63 per cent answered Yes, compared with only 8 per cent in the group presenting for aneuploidy screening and 22 per cent in the control group. The fact that those affected by the disorder in question were more willing to have a carrier embryo implanted in the hypothetical situation is significant. This may indicate a better understanding of carrier status on the part of the group presenting for PGD for single gene disorders.
Alternatively, it could mean that those not presenting for PGD for single gene disorders either did not understand carrier status or were more concerned not to pass on deleterious genes to subsequent generations. The authors of the study observed that:

*Since half the subjects in this group are either asymptotic [sic] carriers themselves or have the indicated genetic condition, it is not surprising that they value their own genetic status.*

The majority of subjects (78 per cent) considered that the couple (after consultation with the doctor) should decide which embryos should be available for transfer.

The study was carried out in the Australian state of Victoria. At the time, performing PGD for single gene disorders was restricted to selection against affected embryos only. This was subject to the exception of female carrier embryos of an X-linked disorder in which some disease symptoms could manifest.

Earlier studies have questioned whether there will be a wholesale uptake of PGD in general. One such study published in 1997 researched the attitudes to PGD of 245 people who were carriers of recessive disorders and at risk of having affected children (as opposed to carrier children). It found that despite support for PGD, natural conception followed by prenatal diagnosis remained the treatment of choice. Whilst the significant advantages of PGD were acknowledged, they were not sufficient to displace the reproductive option of prenatal diagnosis despite the difficulties associated with termination.

A study of approximately half the New Zealand haemophiliac population carried out in the mid 1990s found very little enthusiasm even for prenatal testing. (PGD does not appear to have been discussed in the research, which focused on the options of amniocentesis or chorionic villus sampling.) This was because of the perceived link between a test revealing haemophilia and termination. This reluctance was partly based on the idea that ‘you took what you got’, but was also to avoid the expectation that termination should follow a positive result. Those who underwent prenatal testing did so mainly to prepare themselves for what lay ahead.

These studies may only be relevant for the particular period of time during which they were conducted. As PGD becomes more established and accessible, and people are reassured of the safety of the procedure, it may become a more realistic option for those who are at risk of transmitting serious heritable disorders. It has recently been reported that between 4 to 6 per cent of IVF carried out in the United States includes PGD. However, two-thirds of all cycles in 2005 were for aneuploidy screening. Some points may be extrapolated from the studies discussed.
The first is that not all people at risk of transmitting serious disorders will find PGD an acceptable option and engage in this technology. The second is that many people who are undergoing PGD for single gene disorders will be prepared to have an unaffected carrier embryo implanted if given a choice. Sometimes technologies such as prenatal diagnosis, which are presented as providing greater options to prospective parents, may not be experienced by those people as providing a real choice. In the context of prenatal diagnosis and developments in the ability to screen foetuses it has been observed that:

As ‘choices’ become available, they all too rapidly become compulsions to ‘choose’ the socially endorsed alternative. In this realm, it is amazing how quickly so-called options are transformed into obligations that, in fact, deprive us of choice.\(^{320}\)

Accordingly, when considering the issue of unaffected carrier embryos, what is regarded as legally permissible must be distinguished from what is morally required. A related issue is that carrier status may not always be well understood. A prime example of this is a pilot genetic screening project which was carried out in Greece. The aim was to identify carriers of the gene that causes sickle cell disease. However, as a result of poor understanding, carriers were ‘stigmatised by their community and considered ineligible for marriage, except to other carriers’.\(^{321}\) As one commentator noted:

Few, if any of us, would choose to have a child who suffers from a genetic condition, but the impact of carrier status, as has already been seen, is poorly understood and may lead to the destruction of embryos based on the false belief that in some way they are ‘unhealthy’ or ‘defective’.\(^{322}\)

In Sweden, information is not provided to parents regarding the carrier status of embryos, regardless of the seriousness of the condition involved, on the grounds that carrier status will not adversely affect the prospective child. This stance seems to be predicated on the belief that society should not start selecting against unaffected carriers since everyone carries genetic mutations which do not necessarily affect them. Therefore ‘there is an unknown risk for everyone that the combination of one’s own genes with the genes of another carrier will result in a child with a recessive disorder’.\(^{323}\) It has been estimated that each individual person carries between 4 and 8 recessive deleterious genes.\(^{324}\)

Yet, it has been argued that whilst all people are carriers and mostly unaware of the array of mutations in their genetic blueprint, this is vastly different from the situation where information is available regarding a specific genetic risk which, if it occurs, is serious. It is true that a couple who go through PGD will be aware of the possible risk that the child may be a carrier, and that the child is free to access that information when they wish to do so. However, it has been claimed that ‘in all other areas of life it is assumed that one should try to minimise risks and exposure to risk’.\(^{325}\)
4.4.2 Summary

Attitudes to carrier status amongst the group of individuals affected by autosomal disorders or X-linked disorders are not uniform. Not all of those individuals who are at risk of transmitting a single gene disorder will access PGD. There is evidence that, for some who do, the prime objective is to conceive a healthy child, and carrier status does not represent as big an issue as it does for individuals who are not affected by a genetic disorder.

Patients who are accessing PGD will generally be well informed regarding the implications of the relevant genetic disease, and are well placed to make fully informed decisions. Choices regarding negative selection may be construed as being motivated by parental concerns regarding the health status of their offspring, or their offspring’s future children. Whilst it has been accepted that embryos deserve respect, there is no right to implantation or right to life conferred on embryos.

The vast majority of carriers of recessive disorders do not manifest any disease symptoms. Whilst X-linked disorders clearly manifest in affected individuals down through generations of a family, parents often ‘don’t see the train coming’ in the case of an autosomal recessive disorder unless they are affected by the disorder themselves, or have been put on notice that they are carriers. Consequently, X-linked disorders have extensive intergenerational effects, whilst autosomal disorders have more sporadic effects on the population, but an effect nevertheless.

There are therefore compelling arguments to respect the fully informed and autonomous decision of couples wishing to select against their carrier embryos. These arguments are based on reproductive liberty which, as argued in section 2, is compatible with the first purpose and the principles of the HART Act 2004. The principles relating to the health and well-being of the future child and intergenerational justice reinforce this view. However, there are also arguments against negative selection of carrier embryos, which are addressed in the following section.

4.5 Arguments against negative selection of healthy carrier embryos

Although the HART Act 2004 aims to secure the benefits of assisted reproductive procedures, another purpose is to prohibit unacceptable reproductive procedures. There are arguments which may be based on the principles of the Act that militate against negative selection of healthy carrier embryos. Concerns have been raised about the health and well-being of the future child and intergenerational justice. There are also ethical and spiritual arguments against carrier testing which, in terms of section 4(g) of the Act, must be considered and treated with respect.
4.5.1 Health and well-being of the future child and intergenerational justice

Concerns have been raised that reproductive decisions may have unpredictable effects on future generations and genetic diversity. For example, it is possible that carrying a recessively inherited genetic mutation may convey some kind of biological advantage that is not yet fully understood. An example of this is the link between sickle cell disease and increased malaria protection. Both those affected and unaffected carriers of sickle cell disease have a resistance to malaria. It has been established that both sufferers and heterozygote carriers of cystic fibrosis may have a resistance to tuberculosis and/or secretory diarrhoea. Conversely, evidence also suggests that heterozygote carriers of cystic fibrosis may be prone to other disorders associated with cystic fibrosis, such as disseminated bronchiectasis. The United Kingdom Human Genetic Commission concluded in its recent report, Making Babies, that:

… these remote possible effects seem impoverished reasons not to make carrier screening for certain conditions available for those that want it.

The fact that being a heterozygote carrier of some diseases may confer some kind of selective benefit may provide some truth to the old idiom ‘better the devil you know than the devil you don't’. Conversely, it may not be sufficient to preclude screening for those who wish to use it.

4.5.2 Moral status of the embryo

The fact that more embryos will be wasted if unaffected carrier embryos are deselected triggers concerns in relation to the moral status of the embryos. Parents may embark on additional PGD cycles when previously biopsied, unaffected carrier embryos could have been utilised or cryopreserved. Negatively selecting carriers of autosomal recessive conditions is arguably more morally weighty than selecting against carriers of X-linked recessive disorders because of the comparative risks involved. However, the gradualist position, which accords an embryo special, but limited, status, may not be sufficient on its own to preclude parents from having a choice in the case of carriers of recessive conditions.

4.5.3 Genetic essentialism

The term ‘geneticisation’ describes the potential for genetics to ‘fundamentally alter how we view ourselves and others’. The downstream effect of such a view is the adoption by society of an essentialist view, which reduces a person to their genes, awakening a new ‘eugenic ethos’.

Because the success of PGD depends on producing surplus embryos it may seem intuitive or obvious to choose to implant the carrier-free ones and destroy the others, rather than the reverse. Alternatively, to destroy an embryo on the grounds that it is a carrier – rather than a sufferer – of an hereditary condition may ‘smack more of
social experimentation than good medicine’. It is plausible that permitting negative selection against carriers may start a form of ‘selection creep’ – that is, negative selection of carriers may become an expectation rather than a choice. As previously observed, what is legally permissible in this context should not be morally required, but should be a matter of personal conscience.

The rationale for permitting negative selection and subsequent destruction of embryos which are unaffected by a serious disorder but are carriers of a serious genetic disorder must be based on the philosophy underpinning the HART Act 2004. Whilst one of the purposes of the Act is to secure the benefits of assisted reproductive procedures, another is to prohibit unacceptable assisted reproductive procedures. The ultimate question is whether the harm associated with permitting parental choice is sufficient to prohibit the reproductive liberty of parents to choose in these circumstances.

4.5.4 Embryo morphology and resource implications

In the course of ordinary IVF, an embryologist selects the embryo(s) for transfer with characteristics indicating the greatest chance of successful implantation and pregnancy. In the case of IVF with PGD, additional criteria apply because of the affected embryos. A preference for selection against both affected and healthy carrier embryos will reduce the number of embryos available for transfer.

When an embryo is at risk of inheriting an autosomal recessive condition there is only a one in four chance of having an implantable embryo if unaffected carrier embryos are excluded as suitable for transfer. The chances are one in two in the case of a female carrier of an X-linked disorder. The reduction in available embryos has significant resource implications, as more PGD cycles may be required.

A recent study was undertaken in Australia to determine the average and age-specific cost per live birth for all IVF treatment cycles carried out in Australia in the year 2002. The average health care cost per live birth event was AUD$32,903.

For publicly funded treatment, choosing a less optimal embryo for transfer (i.e. an unaffected embryo which appears to have a lower chance of successful implantation than an unaffected carrier embryo) increases the potential costs and reduces the chance of successful pregnancy and birth. This must be balanced against competing national health care demands. If couples are accessing public funds, this may be a very real factor in decision making for both parents and clinicians. Permitting selection against carrier embryos of rare recessive conditions, with negligible risk to a carrier’s children, is not easily justified when resources are limited. In private contexts, this may be less of an issue where parents are able, and willing, to pay for extra cycles.
4.5.5 Summary

Under the HART Act 2004, the different perspectives held by society must be considered and treated with respect when contemplating issues regarding PGD. The arguments raised against the negative selection of carrier embryos are not sufficient to displace the arguments in favour of parental choice and clinical judgment. Eugenic concerns could be borne out if it became a requirement that carrier embryos were to be discarded. However, giving couples a choice in the context of their own circumstances does not constitute eugenics. Arguments based on genetic diversity are, in some instances, speculative, and do not constitute a sufficient risk to the population as a whole to limit individual choices. Embryo morphology and resource implications are factors. They may impose some limits as a matter of practice, but they do not discount negative selection as a matter of principle. It would seem to be a matter best judged by the clinician and the individual couple involved according to the circumstances.

4.6 Other jurisdictions

Whilst policy must be determined in New Zealand in the light of the HART Act 2004, it is useful to look to other jurisdictions which have considered this issue.

4.6.1 United Kingdom

When PGD was first carried out in the United Kingdom, the decisions regarding carrier embryos resided with the patient in consultation with the clinical team. In 1999 the HFEA and what was then the Advisory Committee on Genetic Testing undertook a public consultation on PGD. The public was invited to make comments on the general issue of replacing carrier embryos. The joint working party, which after the reconstitution of the Advisory Committee on Genetic Testing as the Human Genetics Commission (HGC) became a HFEA and HGC collaboration, endorsed the following view in their recommendations:

… in the case of chromosomal re-arrangements or autosomal recessive conditions, if it is possible to exclude affected embryos without discovering the carrier status of others and without compromising the accuracy of the test, then this is to be preferred.

X-linked recessive disorders were not included in this recommendation, which presumably suggests that selection against carriers of X-linked conditions is acceptable. The recommendation is arguably an unhelpful prevarication. The development of the capacity to test for more disorders and to determine carrier status means that tests will often reveal whether an embryo is an unaffected carrier. The HGC addressed the issue of selecting against carrier embryos three years later in its public consultation, Choosing the Future. It set out the following views but did not commit to a position on the issue:
Some would argue that people should generally be given a choice to use artificial reproductive technologies as they feel appropriate as long as it does not harm that child. Others argue that using these technologies undervalues the life of the child born. For example, if a couple is using PGD for a condition like cystic fibrosis and there may be a choice between embryos with cystic fibrosis, healthy carriers, and embryos which neither have the genetic disorder nor are carriers, then parents should have the option to implant the embryo without the condition or carrier status. On the other hand, some argue that in some situations, carriers of cystic fibrosis may have a genetic advantage because of resistance to certain diseases. It could certainly be suggested that we should not exclude such genetic variation from human populations. It does mean that there is a risk for the next generation that if the person who is a carrier has a child with another carrier, they will run the risk of having a child with cystic fibrosis. 

The HGC observed in its report, Making Babies, that some couples undergoing PGD would prefer to avoid having a child who is a carrier, even if that child could be expected to be healthy, because they wished to protect their child from the risk of having affected children when they reproduce. Others felt, however, that the exclusion of a healthy embryo purely on the basis of its carrier status was unreasonable, and it may also significantly reduce the chances of achieving a successful pregnancy. The HGC concluded with the following:

if there are several embryos from which a selection can be made to maximise the chance of achieving a healthy pregnancy and minimise the risk of misdiagnosis, there may be a hierarchy of preference in which unaffected embryos that look healthy are scored higher than embryos that are carriers or look less likely to implant successfully. We suggest that in situations where PGD is being used, and where there are both carrier and unaffected embryos of equal quality, parents should be able to request which they prefer to be implanted.

The HGC recommendation is slightly ambiguous. On the one hand it appears to be indicating that unaffected embryos may be scored more highly than unaffected carrier embryos of equivalent morphology and seems to equate carrier embryos with embryos of poor quality. What is apparent is that a non-directive approach is being utilised, which permits flexibility at the coal-face. It is of course possible that the embryo which has the best morphological features overall (the best chance of implanting) will be an unaffected carrier. The decision as to which to implant becomes more complicated when choosing against a carrier embryo may also reduce the chances of successful implantation and pregnancy.
4.6.2 Australia

Victoria, Western Australia and South Australia have introduced legislation which regulates assisted reproductive technology services, but only Victoria and Western Australia specifically address the issue of carrier embryos.

4.6.2.1 Victoria

The Infertility Treatment Authority (ITA) of Victoria has adopted the view that applications of PGD for genetic testing must be guided by the current practice of prenatal diagnosis and the Policies of the Human Genetics Society of Australia. However, an important qualification has been made to this statement. The ITA has specifically stated that there might be a greater range of indications where PGD may be considered, such as selection against carrier embryos.342

The ITA has expressly acknowledged that, in terms of selecting against carrier embryos, there is a significant difference between carrier status for X-linked conditions and autosomal recessive conditions.343 The most recent ITA policy provides that selection against carrier embryos of X-linked disorders, which have already been tested for and which appear on list B of the schedule of approved genetic testing, is permitted as a matter of course – no application to the Authority is required.344 However, where it is proposed to identify and select against carrier embryos of autosomal recessive conditions, in addition to testing for the condition in question, an application must be made to the Authority.345 The Authority determines each application on a case-by-case basis and decides whether or not the application should progress to the relevant Ethics Committee for approval.

4.6.2.2 Western Australia

As a result of amendments to the Human Reproductive Technology Act 1991 (WA) PGD is permitted in Western Australia, but all diagnostic procedures carried out on an embryo must have the prior approval of the Reproductive Technology Council. The Act provides that approval may only be given if there is ‘a significant risk of a serious genetic abnormality or disease being present in the embryo’.346 When deciding whether to approve an embryo diagnostic procedure, the Council is required to consider the risk and severity of the condition that is to be tested for and the safety and reliability of the procedure.

Couples undergoing PGD may indicate their preferred clinical course of action: the implantation of healthy carrier embryos; preferential implantation of healthy non-carrier embryos; or negative selection of healthy carrier embryos prior to the performance of PGD. In the case of autosomal recessive conditions, if they are considering implanting only non-carriers, or preferentially implanting non-carriers, parents should be informed of the low risk of inheritance to the second and future
generation. Consequently, they may either request that unaffected carriers are not transferred, or that they would accept the transfer of healthy carriers in certain circumstances.

However, if they elect to permit the transfer of healthy carriers, along with unaffected embryos, they are not informed of the carrier status of the embryo subsequently transferred. The purpose of this restriction is to comply with the policy on predictive genetic testing of children formulated by the Human Genetics Society of Australia. This policy does not expressly refer to testing for carrier status, but the principles in regard to predictive testing seem to have been extrapolated to carrier testing in minors. The Human Genetics Society of Australia recommendation is made on the grounds that there are no proven health benefits for a child in knowing their genetic status, and that it is preferable that individuals are given the opportunity to make autonomous decisions regarding genetic testing. Importantly, whilst parents are given a choice in relation to the transfer of unaffected carrier embryos, they are not permitted to access that information.

There are exceptions to this policy. In advice given to clinics the Council has observed that there may be circumstances where it would be appropriate to provide information to participants about the carrier status of tested embryos, with the approval of the Council, particularly where a carrier may be symptomatic for the disease state. In these circumstances, a request for approval to disclose information about the carrier status to participants is required when applying for approval to perform PGD.

In the case of primary purpose PGD, where a person wishes to access PGD but there is no chance of having affected offspring, such as the case of a male with an X-linked recessive condition, approval is predicated upon whether the condition would have a serious effect on a carrier embryo.

The Australian Health Ethics Committee, a principal committee of the Australian National Health and Medical Research Council, has promulgated the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research. These guidelines provide generic advice, and do not expressly address the issue of healthy carrier embryos. The guidelines state that, pending further community discussion, PGD must not be used for the ‘prevention of conditions that do not seriously harm the person to be born’.

4.6.3 Netherlands

A recent report released by the Health Council of the Netherlands (an independent advisory body charged with providing Ministers and Parliament with scientific advice on public health matters) addressed the acceptability of the negative selection of unaffected carrier embryos. PGD is permitted in the Netherlands where there
is an elevated individual risk that the child will have a severe abnormality. The Health Council advised that, where parents who are undertaking PGD to prevent the transmission of a serious genetic disorder request selection against carrier embryos, there is little reason not to comply with their request. However, it also advised that selection against carriers is only acceptable if being a carrier presents serious problems, such as in the case of X-linked Duchenne muscular dystrophy. The Secretary of State endorsed the position of the Health Council, stating that selection against carrier embryos could only occur when PGD was indicated to prevent the transmission of a severe genetic disorder.  

4.6.4 European Society of Human Reproduction and Embryology

In 2003, the ESHRE Taskforce opined that the fundamental argument for not replacing carrier embryos is not based on eugenic considerations, but rather on the wish to spare offspring from the burden of similar reproductive decisions. It asserted that, if there are both carriers and non-carriers available, the non-carriers should be replaced first and the carriers cryopreserved. The Taskforce recommended that the transfer of carrier embryos be discussed with patients prior to the initiation of the PGD cycle, particularly in the case of X-linked diseases. According to the ESHRE Taskforce, the ultimate decision as to whether or not carrier embryos are replaced resides with the parents.

ESHRE subsequently released its ‘Best Practice Guideline for PGD and PGS’ in 2005. It recommended that embryo selection criteria for PGD procedures be based primarily on unaffected diagnosis and secondarily favourable embryo morphology. The guidelines declare that transfer of carrier embryos (of an autosomal recessive disorder), or possibly carrier female embryos (of an X-linked disorder), is acceptable since adverse health consequences to the resulting child are unlikely. However, occasionally carriers of genetic conditions, in particular X-linked disorders, may manifest milder forms of the disease. Each case requires careful evaluation and informed discussion with the couple.

4.7 Possible Regulatory Responses

As discussed, the magnitude of reproductive risks for carrier embryos in the case of autosomal recessive disorders differs greatly from those for X-linked recessive disorders. Because of this, at least one commentator has advocated that guidelines should differentiate between these different types of heritable disorders.

Guido de Wert has identified three possible policies in relation to the issue of healthy carrier embryos diagnosed in the course of carrying out PGD for a serious genetic disorder. He cogently argues that a differentiated policy for carriers of X-linked conditions compared to carriers of autosomal recessive conditions is required because
of the very low risk that a future carrier of an autosomal recessive condition will face similar reproductive problems. This consequently makes it disproportionate to categorically discard healthy embryos in the case of unaffected carriers of autosomal recessive disease. The three possible policies are summarised in Table 3.361

<table>
<thead>
<tr>
<th>ACTION</th>
<th>PROS</th>
<th>CONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Ignore carrier status: Non-selectively transfer all healthy embryos including carriers according to best morphology</td>
<td>Embryo with best chance of implantation transferred</td>
<td>Some offspring will face similar reproductive challenges as parents</td>
</tr>
<tr>
<td></td>
<td>Carriers grow into healthy children, adults</td>
<td>Some offspring may have affected children</td>
</tr>
<tr>
<td></td>
<td>We are all carriers of recessive disorders</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Avoids stigmatising carriers</td>
<td></td>
</tr>
<tr>
<td>2 Refrain from transferring carrier embryos</td>
<td>Prevents future reproductive dilemmas</td>
<td>Healthy carrier embryos wasted</td>
</tr>
<tr>
<td></td>
<td>Prevents intergenerational transmission</td>
<td>May be disproportionate to categorically discard carriers of autosomal recessive conditions in view of low risk to next generation; more relevant for X-linked recessive disorders</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Potentially stigmatises other healthy carriers</td>
</tr>
<tr>
<td>3 Preferential selection: Transfer healthy non-carrier embryos first, then carrier embryos in subsequent cycles</td>
<td>Avoids wastage of healthy embryos in subsequent IVF cycles just because embryos are carriers</td>
<td>Still ascribes to idea that non-carrier embryos are ‘preferable’ to carriers</td>
</tr>
</tbody>
</table>

Table 3: Possible regulatory responses
The third option prioritises the transfer of non-carrier embryos over carrier embryos. This may appear to be a reasonable strategy in relation to carriers of autosomal recessive disorders, but it is also problematic. At best, it avoids the destruction of embryos and possibly avoids further IVF cycles; but it still has as its central premise the notion that transfer of healthy carriers is a second-tier option. In addition, it does not accord weight to the fact that morphology is the most significant predictor of successful implantation and pregnancy. At least one PGD centre has adopted a policy that prioritises good morphology over carrier status.  

4.7.1 Contingent selection

If there is a risk of transmitting an X-linked condition, and prospective parents do not wish to implant unaffected carrier offspring, then the second category has merit.

4.7.2 Primary purpose selection

As discussed, it is possible that there may be a demand for PGD to select against unaffected carrier offspring as the sole purpose. Reportedly some male haemophiliac patients prefer to conceive only boys, as the sons will not be affected by the condition, whilst all daughters will be unaffected (usually) carriers of haemophilia and have a 50 per cent risk of passing the disorder on to their sons.

It has been argued that it is difficult to maintain a distinction between permitting parents to select against carrier embryos, when it is contingent upon PGD to prevent the transmission of a serious X-linked genetic disorder, and PGD in which the primary purpose is to select against a carrier embryo of an X-linked condition. Yet, arguably, embryo biopsy is justified in the case of contingent PGD as all the embryos are already biopsied. Testing for carrier status is a contingent activity.

In contrast when selection against female carriers of the haemophilia gene is proposed as the primary purpose, it is not performed to prevent the direct transmission of a serious genetic disorder. It is to eliminate a future adult's potential psychological distress and reproductive dilemma regarding transmission of the disease.

Section 4(b) of the Act provides the guiding principle that the human health, safety and dignity of present and future generations should be preserved and promoted. It could be argued that a health benefit accrues in permitting PGD to be performed for the sole purpose of deselecting heterozygote carriers: a benefit that is intergenerational. Arguably, parents who are sufficiently concerned to prevent the transmission of the particular gene to undertake PGD in the first place will benefit psychologically from having lawful access to it. Whether this is perceived to be an acceptable use of PGD or to warrant prohibition depends on whether parental reasons for engaging in PGD (effectively because of the reproductive and psychological risk to the future child) are perceived to be proportionate to the wastage of healthy female carrier embryos, and the perpetuation of the idea that heterozygote carriers are undesirable. It may
be perceived by many as advancing towards selection which is not based on direct medical benefit.

Yet, as observed in the first section, it is possible to wish to avoid transmission of a genetic mutation, without seeking to discriminate against others with the mutation. Indeed, those seeking primary PGD will either be males affected by an X-linked disorder, or individuals who are autosomal recessive carriers themselves.

Although current data suggest that the risk of harm to the prospective child born as a result of PGD is no greater than that of routine IVF or intracytoplasmic sperm injection (a fertilisation procedure), there may (or may not) be longer-term effects that manifest in the future. It should also be acknowledged that IVF and PGD carry small attendant risks to both the mother and prospective child. The strength of the argument for the procedure to be permitted is diminished in the case of IVF and PGD carried out in circumstances where there is no infertility, and no risk of the immediate offspring inheriting the disease. This creates a distinction between selection against unaffected carriers contingent to PGD, and when it is the primary purpose for performing PGD. However, the ultimate issue is whether these are sufficient reasons to prohibit primary purpose PGD; or whether these reasons merely indicate that it would be extremely rare for an individual to undertake the procedure, and that many providers may be reluctant to perform it. Arguably, there appears to be little justification for prohibiting a fully informed couple from undergoing the procedure, apart from the risks involved in IVF and PGD.

4.8 Conclusion

As reprogenetic technology develops it offers new possibilities. Among these developments is the expansion in the number of genetic disorders which may be detected by PGD, and an increased ability to determine the carrier status of embryos. As a result of the IVF and PGD process, it is likely that several embryos will be diagnosed as unaffected or unaffected carriers. It is a valid concern that the threshold for selection of embryos will be significantly lowered as a result of these factors.

Methods that would avoid the dilemmas in relation to carrier embryos include employing tests that do not identify carrier status if available. This is simply not possible for many tests, such as sickle cell disease. Refusing to disclose carrier status is another option; but this is contrary to the ethos of fully informed health consumers. The reality is that, in the course of PGD procedures, carrier status may be determined and parents may want to know.

Selecting against heterozygote carrier embryos is problematic because negative selection is not based on a genetic trait that has deleterious effects on the physical health of a child that will be born. Rather, it is based on a genetic trait that imposes,
or may impose, a psychological and reproductive burden on the future individual, and may pose a risk to subsequent generations. The desire to select against a carrier embryo may seem to be a disproportionate response where there is no physical risk to the future individual; and, in particular, where the embryo is an unaffected carrier of an autosomal recessive mutation. Everyone carries within their own genetic blueprint numerous recessive mutations, which will not manifest in affected offspring unless a child is conceived with a person with the same autosomal recessive mutation. The issue is whether these concerns are sufficient to displace the presumption of reproductive liberty and the interests of those who wish to select against carrier embryos.

It has been argued that permitting selection against carrier embryos may be justified on the grounds of reproductive liberty and the reproductive and psychological interests of the future child. It may also be predicated on the grounds of intergenerational benefit. Arguments against allowing negative selection of carrier embryos have been made on the grounds that it involves the destruction of healthy embryos; it is an exercise based on genetic essentialism; it harms society, by reducing genetic diversity; and it potentially stigmatises healthy carriers. Selection against carrier embryos also potentially reduces the success of a PGD cycle, and has resulting resource implications.

It is unclear whether permitting parents a choice in relation to the negative selection of unaffected carrier embryos of single gene disorders will open the floodgates for this particular type of selection. One small study has indicated that, of all groups presenting for IVF, couples presenting for IVF with PGD for single gene disorders were least concerned with the possible transfer of an embryo which was an unaffected carrier of a recessive disorder. In addition, the person undergoing PGD who requests selection against carrier embryos may be in the best position to determine the personal impact of being a carrier of the particular genetic mutation at hand. It is difficult to maintain rigid restrictions in this context in the face of current abortion law.

Prenatal diagnosis is often used as a benchmark for determining the permissible limits of PGD. An abortion during the first twenty weeks of gestation is rendered lawful where there is a substantial risk that a child, if born, will be severely physically or mentally handicapped. It is extremely unlikely that an abortion on the grounds that the foetus is a carrier of an X-linked or autosomal recessive disorder would meet this requirement. However, an abortion is also lawful if continuing the pregnancy would result in serious danger to the life, or the physical or mental health, of the woman. Terminations on the basis of mental health accounted for approximately 98.7 per cent of abortions in New Zealand in the year 2003. Clearly access to termination on mental health grounds, at least in the first trimester, is permitted relatively liberally in New Zealand. In addition, given the significant difference in moral status between a three to five-day-old embryo and a foetus, a wider range of selection is morally acceptable.
With the introduction of the regulatory framework for PGD in New Zealand, it has been accepted that parents have the right to avoid the birth of a child with a serious genetic disorder. The question is whether that extends to unaffected carriers of serious genetic disorders. On a literal interpretation of the HART Order 2005, it is at least arguable that negative selection against carrier embryos of X-linked disorders is permitted both as a contingent or primary purpose procedure; but it is much more difficult to argue for this approach in the case of autosomal recessive disorders. It is possible that negative selection against carrier embryos, in the course of PGD covered under the HART Order 2005, will be deemed permissible by ACART. This leaves open the question of whether selection against carrier embryos as a primary purpose should be permitted. It has been argued that the purposes and principles of the HART Act 2004 are broad enough to permit carrier testing and negative selection both as a contingent procedure to PGD and as the primary purpose of testing in the case of X-linked disorders. However, negative selection of carrier embryos of autosomal recessive conditions as a primary purpose is very difficult to justify.

It has been argued that the decision as to which embryos are selected for transplantation should be a matter for the couple and clinicians to decide. This is consistent with the first purpose and principles of the HART Act 2004. However, it should not become a matter of routine clinical practice that carrier embryos are systematically discarded. Rather, it should be a combined decision made with full information provided.

Negative selection of carrier embryos has been recently considered by various jurisdictions. Carriers of certain X-linked conditions may be selected against contingent to PGD in the State of Victoria, Australia, and approval for selection against carriers of autosomal recessive conditions is made on a case-by-case basis. Western Australia permits prospective parents to indicate how they wish to deal with the issue of carrier embryos prior to undergoing a treatment cycle; but they are not informed of the carrier status of embryos that are implanted. The Western Australia Reproductive Technology Council will consider applications for primary purpose PGD, but is required to consider whether the condition will have a serious effect on the carrier embryo. In the Netherlands carriers of serious genetic conditions may be selected against in the course of PGD where being a carrier presents serious problems. In contrast, Sweden does not permit selection on the basis of carrier status, nor are parents informed of carrier status. The United Kingdom generally leaves the decision to the parents and clinicians involved.

Arguments against negative selection of carriers based on genetic diversity are not strong. This is particularly so, given that, although PGD will become more utilised in the future, only 3 per cent of serious disorders are single gene disorders, and not all of those at risk of transmitting a serious single gene disorder will access the technology. Considering reproductive risks, and applying a gradualist approach to the moral
status of the embryo, it is much harder to justify the negative selection of unaffected carriers of autosomal recessive conditions than X-linked conditions. Whilst there might be hesitation in the case of negative selection of healthy carriers of autosomal conditions, it is difficult to see on what basis parents should be prohibited from making this choice.

Taken together, the harms raised are not sufficient to displace the presumption of reproductive liberty in this context. Although the implications of transferring a carrier embryo may seem, to some people at least, to be benign, this is not sufficient reason to justify a State-imposed prohibition. It is possible that the greatest societal harm may be seen in prospective parents who are insufficiently informed, or who feel that they do not have a ‘real’ choice but to reject a carrier embryo. Whilst it is inevitable that consideration of resources must be taken into account, this consideration should be a matter for clinical and parental judgment, rather than a reason for outright prohibition.

4.9 Summary of conclusions

4.9.1 Carrier selection contingent to PGD for serious genetic impairment

1 Parents should be informed that embryo quality/morphology is the best predictor of successful implantation and pregnancy.

2 Carrier embryos of X-linked disorders (which may or may not cause phenotypic manifestations) come within the scope of the HART Order 2005 and may be lawfully selected against as an established procedure.

3 Permitting selection against unaffected female carrier embryos of serious X-linked disorders is arguably permitted under the HART Order 2005 and is morally justified because female carrier offspring will have a high risk of having affected children (i.e. there is a 25 per cent risk that a couple undergoing PGD will have an affected grandchild).

4 Negative selection of unaffected carriers of autosomal recessive conditions should be distinguished because of the low reproductive risk. Ultimately, selection against carriers of autosomal recessive conditions should be a matter for the parents and provider.

Decisions must be made subject to the following information:

a. prospective parents must be sufficiently informed regarding the reproductive risk for autosomal recessive carriers;

b. prospective parents must be sufficiently informed that the number of available transferable embryos will be reduced;
c. prospective parents must be appraised of the fact that everyone carries recessive mutations;
d. the particular significance of carrying an autosomal recessive condition if the individual is in a high-risk ethnic group should be taken into account (e.g. cystic fibrosis in persons of European descent, sickle cell disease in persons of African descent).

4.9.2 Carrier selection as primary purpose

1 This is justified where males affected by X-linked conditions wish to avoid producing carrier daughters (i.e. there is a 25 per cent risk that a haemophiliac male will have an affected grandson).

2 It is more difficult to justify for autosomal recessive conditions, given the invasiveness of the procedure, the risks of the procedure and the low reproductive risk to offspring and, consequently, low value of screening.

5 UPDATE: PREIMPLANTATION GENETIC HAPLOTYPING (PGH)

Recent technological advances in PGD have considerable implications for the future use of PGD. The application of PGH has signalled a major transition in the performance of PGD. The first birth (twins) resulting from PGH was recently reported in the United Kingdom. The parents underwent PGH as they were both carriers of a cystic fibrosis mutation. The couple already had twins, one of whom had cystic fibrosis.

To understand the procedure of haplotyping, it is necessary to review some basic concepts of genetics. Genes consist of defined sequences of DNA which provide instructions for making protein. While each chromosome pair contains the same genes, the gene sequences may not be identical. Individual gene copies exist as variant in a population and often differ from each other by small changes in the DNA base sequence. These variants are termed ‘alleles’, and arise as a result of mutation. Whilst some mutations are harmful, others simply provide variation such as freckled skin. Hence DNA sequences vary among individuals, yet do not necessarily change the phenotype or health of a person. It is possible to distinguish sequence variants that are inherited from a person's mother or father; these are the maternal and paternal alleles.

‘Polymorphism’ is a generic term, which includes disease causing and non-disease causing variants, and variants that have no appreciable effect at all. A polymorphism is a variation in DNA sequence that occurs in 1 per cent or more of the population. The single-nucleotide polymorphism (SNP) is the most common polymorphism in the human genome. More than three million SNPs have been identified by researchers. SNPs occur when a single nucleotide in the DNA (A, G, C or T) differs
from the most common nucleotide at that position. Because human cells are diploid, that is they contain two sets of chromosomes, a person can have one of several genotypes. At any chosen SNP an individual may either be homozygous for the major allele, heterozygous, or homozygous for a minor allele.\textsuperscript{374}

Ova or sperm are produced in the reproductive cells, termed ‘germ cells’. In a process during meiosis called recombination, maternal and paternal chromosomes contained in germ cells pair up and exchange segments of DNA.\textsuperscript{375} The result of recombination is that the chromosomes in the ova or sperm contain a mixture of alleles from each parent of an individual. Groups of alleles are known as haplotypes and are rarely separated by recombination. Haplotypes are defined as ‘a combination of alleles at different markers along the same chromosome that are inherited as a unit’.\textsuperscript{376} In the human genome, haplotypes may contain up to sixty SNPs that travel as a group.\textsuperscript{377} Essentially, at any given section of a chromosome each individual has two haplotypes. One represents the maternal and the other the paternal chromosomes.\textsuperscript{378} Consequently:

\textit{A new mutation responsible for a genetic disease always enters the population within an existing haplotype, which is termed the ancestral haplotype.}

\textit{Over several generations, recombination events may occur within the haplotype but the disease allele and the closest SNPs still tend to be inherited as a group. If this haplotype can be identified in a group of patients with the disease, typing the alleles within the haplotype allows a conserved region to be identified, which pinpoints the mutation responsible for the disease.}\textsuperscript{379}

When family members are tested for ‘multiple polymorphic markers that lie within a disease gene and/or which closely flank it’, the high-risk, potentially mutation-carrying haplotype(s) (inherited by the affected person) and the low-risk haplotypes may be identified.\textsuperscript{380} This enables the molecular geneticist to determine the genetic status of embryos for that family. Figure 2 illustrates this process.
A new mutation (X) arises in the proximity of six single nucleotide polymorphisms, with the ancestral haplotype signature TATCAT. Over several generations, the haplotype signature may be eroded by recombination. For example, contemporary haplotype 1 was produced by recombination between the first and second SNPs. The new alleles are shown in pink. However, the smallest conserved haplotype signature in all patients carrying the disease allele places the disease between SNPs 3 and 4. This technique provides a candidate region of about 10,000 bp, which is smaller than most human genes.

PGH has been described as a ‘paradigm shift’ for embryo diagnosis.\textsuperscript{381} Traditional PGD for single gene defects requires the development of family-specific single cell polymerase chain reaction (PCR) mutation tests.\textsuperscript{382} In addition to the potentially lengthy time required to design and optimise single cell PCR multiplex reactions, to minimise allele drop out, reportedly PCR testing may not be performed in proximity to other DNA diagnostic work because of the risk of contamination.\textsuperscript{383} The effect of these limitations is that few laboratories provide PGD services. Where testing is carried out, usually only a small number of disease tests are offered by any one centre.\textsuperscript{384}

PGH requires analysis of pedigree. There must be at least one affected individual in a family or enough unaffected members to permit conclusive identification of the high and low risk haplotypes.\textsuperscript{385} One of the main advantages of PGH over direct mutation analysis is that ‘the same test can be used for all families even when there is heterogeneity in the pathogenic mutations’.\textsuperscript{386} Significantly, testing is not only limited to common mutations, but can even be applied when the causative mutation has not
been identified. Hence, any family with a mapped single gene disorder may access preimplantation testing.

In the case of X-linked diseases where there is no specific test available for the particular mutation, PGD is employed to sex select against male embryos. In contrast, PGH enables the identification of normal males by identifying high and low risk haplotypes in embryos, which increases the number of embryos available for biopsy and possible transfer. PGH provides information as to whether a female embryo is a carrier of the high-risk haplotype, and therefore whether or not it is an unaffected carrier embryo.

Consequently, PGH has the potential significantly to increase the number of single gene disorders that may be tested for and, in the case of some X-linked disorders, to increase the number of embryos available for transfer by identifying unaffected male embryos. It is anticipated that the uptake of PGH will reduce waiting times for the creation of new tests for specific disorders.

This analysis is current up to March 2007.

ENDNOTES


4 Marker panels have been set up for cystic fibrosis (which will allow PGD for all CF mutations), junctional epidermolysis bullosa, myotonic dystrophy and Prader-Willi syndrome. See P. Renwick et al., ‘Extending the Possibilities in Preimplantation Genetic Diagnosis – The First Clinical Case Using Whole Genome Amplification with Haplotype Analysis’ (2006) 21 Human Reproduction Supp. 1, P-521, i200.


6 See http://www.nzherald.co.nz/section/story.cfm?c_id=1&objectid=10359350 viewed 22 May 2006. PGD was performed in this particular instance for the purpose of aneuploidy screening as the woman had suffered recurrent miscarriages over a period of five years.


10 See A. Nordgren, ‘Reprogenetics Policy: Three Kinds of Models’ (1998) 1 Community Genetics 61. The author argues that there are three different models for governmental policy on genetics and reproduction: (1) governmental steering of procreation; (2) radical reproductive autonomy; and (3) reproductive autonomy with certain restrictions. Arguably, New Zealand falls under the third model.
11 See ss 8–15 and schedule 1 of the HART Act 2004 for a list of statutory prohibitions.
12 HART Act 2004, s 16(1), s 19(2).
13 HART Act 2004, s 6(1).
14 HART Act 2004, ss 11(1) and (3).
15 See NECAHR, Guidelines on Preimplantation Genetic Diagnosis, March 2005, 6. NECAHR, the National Ethics Committee on Assisted Human Reproduction, was the ethical body which existed prior to the introduction of the HART Act 2004 and was responsible for drafting the Guidelines. These Guidelines have been designated ACART guidelines under the interim provisions of the HART Act 2004. See HART Act 2004, s 83(2). (NECAHR has been disestablished with the introduction of the HART Act 2004 and the establishment of ACART and ECART.)
16 See cl 6 of part 2 of the schedule to the HART Order 2005.
20 Section 3(a) was not in the HART SOP originally, but was included in the HART Bill on the recommendation of the Health Select Committee. In a Cabinet paper which sought agreement to the changes from Cabinet it was stated that ‘the new purpose statement reflects the positive intentions of the legislation, and complements the statements about prohibited activities’. See Cabinet Policy Committee, ‘HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee’ POL (04) 147, 21 June 2004, 5. Released under the Official Information Act 1982.
21 Article 2(a) of the UNESCO Universal Declaration on the Human Genome and Human Rights, 11 November 1997, proclaims the following right: ‘Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics’.
23 Law v Canada (Minister of Employment and Immigration) [1999] 1 S.C.R 497. This definition is comprehensive in terms of what it may encompass, and incorporates the principle of self-determination in the concept of dignity. See J. Downie, ‘Unilateral Withholding and Withdrawal of Potentially Life-Sustaining Treatment: A Violation of Dignity Under the Law in Canada’ (2004) 20 J Palliative Care 143. Downie states at 147 that the concept of dignity as articulated by the Supreme Court may at times relate to privacy, reputation, self-worth, self-image, intrinsic worth and self-determination.


See C. Gavaghan, ‘Deregulating the Genetic Supermarket: Preimplantation Screening, Future People, and the Harm Principle’ (2000) 9 Cambridge Quarterly of Healthcare Ethics 242, 244, citing T. Beauchamp and J.S. Childress, Principles of Biomedical Ethics, fourth edn (New York: Oxford University Press, 1994) 121. Gavaghan states that the ‘degree to which a choice may be said to be autonomous will depend on the extent to which it fulfills both of these criteria. It is the former element of autonomy to which they [Beauchamp and Childress] attach the name “liberty”’.


For an overview of global reproductive rights activity and abortion law reforms in the twentieth century, see J. Ernst, L. Katzive and E. Smock, ‘The Legacy of Roe: The Constitution, Reproductive Rights, and Feminism: The Global Pattern of U.S. Initiative Curtailing Women’s Reproductive Rights: A Perspective on the Increasingly Anti-choice Mosaic’ (2004) 6 U Pa J Const L 752. Securing access to lawful abortion was not the only goal of the reproductive rights movement. It was also concerned with attempting to free women from societal constraints, or social self-constraints adopted by women, which recognise fertility and motherhood as the only possible or accepted identity of women. See H. Haker, ‘Harm as the Price of Liberty? Preimplantation Diagnosis and Reproductive Freedom’ (2003) 10 Ethical Perspectives 215. See also M. Berer, ‘Whatever Happened to a “Woman’s Right to Choose”? ’ (1988) 29 Feminist Review 24.

It should be noted that there is no right to an abortion enshrined in legislation as such. Rather, the Act renders an abortion lawful if the circumstances fit within the specified criteria. See Crimes Act 1961, s 187A(1) and s 187(A)(3).
In Roe v Wade 410 U.S. 113 (1973) the Supreme Court of the United States acknowledged that a woman’s right to decide whether to terminate her pregnancy was protected under the constitutional principles of individual autonomy and privacy. For the first time, reproductive choice was recognized as a fundamental right, entitled to the same protection as guarantees of religious freedom and free speech, and afforded the highest standard of constitutional protection under the doctrine of strict scrutiny. The decision not only secured the legality of abortion in the United States, but also gave strength to an emerging reproductive rights movement that transcended national borders. See J. Ernst, L. Katzive and E. Smock, ‘The Global Pattern of US Initiatives Curtailing Women’s Reproductive Rights: A Perspective on the Increasingly Anti-choice Mosaic’ (2004) 6 U Pa J Const L 752, 753. See also R v Morgentaler [1988] 1 S.C.R. 30. In this case a majority of the Supreme Court of Canada found that the provisions in the Criminal Code which limited access to abortion violated a pregnant woman’s rights under s 7 of the Canadian Charter of Rights and Freedoms by interfering with bodily integrity and subjecting her to serious psychological stress.


See Crimes Act 1961, s 187A. The group ‘Right to Life New Zealand Inc’ has recently commenced judicial review proceedings, claiming that the Abortion Supervisory Committee is not discharging its putative functions under the Contraception Sterilisation and Abortion (CSA) Act 1977 by failing to ensure that terminations are occurring in accordance with the provisions of ss 32 and 33 of the CSA Act 1977, and s 187A of the Crimes Act 1961. See Right to Life New Zealand Inc v Rothwell [2006] 1 NZLR 531.


Emily Jackson has argued that ‘the assumption that a woman’s reasons for wanting to terminate her pregnancy are a matter of legitimate public interest’, and consequently that ‘access to abortion should depend on whether or not those reasons are acceptable’, is inconsistent with the priority granted to the common law principle of self-determination. Jackson argues that demands for further restriction of the acceptable grounds for abortion is anomalous when compared with the common law’s vigorous protection of an individual’s freedom to make irrational or morally objectionable choices about medical treatment. ‘An essential feature of this respect for a patient’s right of self-determination is that it extends to decisions of dubious moral quality.’ See E. Jackson, ‘Abortion, Autonomy and Prenatal Diagnosis’ (2000) 9 Social & Legal Studies 467.

See A. Alghrani and J. Harris, ‘Reproductive Liberty: Should the Foundation of Families be Regulated?’ (2006) 18 Child and Family Law Quarterly 191. See at 191: ‘… Certainly there is no widespread agreement as to the nature and scope of this right, however it is clear that it [reproductive liberty] must apply to more than conventional sexual reproduction and that it includes a range of the values and liberties which normal reproduction embodies or subserves’.

For an analysis which argues that reproductive autonomy is an insufficient principle to guide decisions in the context of assisted reproduction, see T. Murray, ‘What Are Families For? Getting to an Ethics of Reproductive Technology’ (2002) Hastings Center Report 41. Murray argues that an ethical framework should begin with the moral significance of the relationship between parents and children, the values at the heart of that relationship, and the ways in which people flourish or shrivel.


See the New Zealand Bill of Rights Act (NZBORA) 1990, s 19(1) and the Human Rights Act 1993, s 21(h).

See NZBORA 1990, s 3(b).

See E. Parens and A. Asch (eds), Prenatal Testing and Disability Rights (Washington DC: Georgetown University Press, 2000) 12. A second concern of the Disability Rights Critique is that, by rejecting an otherwise wanted child because it is feared that ‘the child’s disability will diminish their parental experience’, parents indicate an unwillingness to accept any significant departure from parental aspirations. This, it is argued, could harm parental attitudes towards children generally. Another concern is that selecting on the basis of disability reflects an ‘unfortunate, often misinformed decision that a disabled child will not fulfil what most people seek in child rearing’.


This type of claim has been described as the ‘expressivist argument’. See E. Parens and A. Asch (eds), Prenatal Testing and Disability Rights (Washington DC: Georgetown University Press, 2000) 13.


Section 4 of the Care of Children (CoC) Act 2004 provides that, in any proceedings under the Act, the ‘welfare and best interests of the child must be the first and paramount consideration’.


Crown Law advised the Health Committee considering the Bill that the word ‘paramount’ in the principle concerning the health and well-being of children: created structural difficulties for the operation of the Act; gave rise to an increased risk of Crown liability; and created a conflict between this principle and the new purpose of securing the benefits of assisted reproductive procedures. See Cabinet Policy Committee, ‘HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee’ POL (04) 147, 21 June 2004, 4. Released under the Official Information Act 1982.

G. Pennings, ‘Measuring the Welfare of the Child: In Search of the Appropriate Evaluation Principle’ (1999) 14 Human Reproduction 1146, 1147. In some instances, the interests of the child have assumed importance not only when evaluating specific applications of assisted reproductive technology, but also when considering individuals wishing to access technologies. See discussion in Human Genome Research Project, Choosing Genes for Future Children: Regulating Preimplantation Genetic Diagnosis (Dunedin, New Zealand: Human Genome Research Project, 2006) 246.


HART Act 2004, s 4(b).


See s 2(c) of the Assisted Human Reproduction Act 2004 (Can). The Canadian Act received Royal Assent on 29 March 2004. Section 4(c) was not in the original HART Bill as amended by Supplementary Order Paper, No. 80, 2003 (HART SOP) but was recommended by the Health Select Committee. See Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee' POL (04) 147, 21 June 2004, 6. Released under the Official Information Act 1982.

See Assisted Human Reproduction Act 2004 (Can), s 2(a).

In relation to the amendments to the HART SOP proposed by the Health Committee, which resulted in ss 4(c) and 3(a), it was stated that: 'The proposals seek to provide protections and benefits to all individuals and society, while recognising the women (and children) are more directly affected by AR procedures. Overall the provisions are consistent with the goal and philosophy of gender equity.' See Cabinet Policy Committee, 'HART SOP: Confirmation of Framework and Proposed Changes Arising from Select Committee' POL (04) 147, 21 June 2004, 9. Released under the Official Information Act 1982.

See New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health, Minister of Health, Canada, June 1996, 16. The proposed regulatory regime and the guiding ethical principles underpinning the Canadian legislative framework are described in this document.

See S. Sheldon, 'Reproductive Choice: Men’s Freedom and Women’s Responsibility?' in J. Spencer and A. Du Bois-Pedain (eds), *Freedom and Responsibility in Reproductive Choice* (Oregon: Hart Publishing, 2006) 189. Sheldon argues that there is ‘growing medical and lay recognition both of the importance of reproduction to men and of the vulnerability of male reproductive bodies. The result is that men, like women, are likely to find themselves increasingly asserting their need
for information and, where available, treatment to enable them to act as responsible reproductive agents'. Sheldon also refers to an international study which suggested that men are the sole cause, or are at least a contributing factor, in over half of couples experiencing infertility. See ibid., 191.

88 HART Act 2004, s 4(d).
92 The Bill proposed amendments to the Mental Defectives Act 1911. The *Committee of Inquiry into Mental Defectives and Sexual Offenders of 1924–1925* which preceded the proposed amendments expressed concern at ‘feeble-minded’ children. It was stated by the Committee that unless action was undertaken promptly, ‘the multiplication of these degenerates will increase and the race will steadily deteriorate’. The goal should be to prevent an ‘inferior strain’ in the population and to ‘increase the elements of the mental, moral, and physical strength of the nation’. See M. Tennant, ‘Disability in New Zealand: An Historical Survey’ (1996) 2 *New Zealand Journal of Disability Studies* 14. Of the Christian churches which appeared before the Committee of Inquiry, the Catholic Church was the only denomination that ‘presented the moral argument against sterilization’. See T. Taylor, ‘Thomas Hunter and the Campaign Against Eugenics’ (2005) 39 *New Zealand Journal of History* 195, 202.
93 The Deputy Leader of the Labour Party, the Honourable Peter Fraser, Tommy Hunter (Professor of Mental and Moral Philosophy at Victoria University College) and half a dozen other academics, including a Professor of Education and a Professor of Moral Philosophy, supported the campaign against sterilisation. See T. Taylor, ‘Thomas Hunter and the Campaign Against Eugenics’ (2005) 39 *New Zealand Journal of History* 195, 206. However, a Eugenics Board was set up to keep a register of ‘mentally defective persons’; it was short-lived.
95 D. King, ‘Preimplantation Genetic Diagnosis and the “New” Eugenics’ (1999) 25 *Journal of Medical Ethics* 176.
96 D. King, ‘Preimplantation Genetic Diagnosis and the “New” Eugenics’ (1999) 25 *Journal of Medical Ethics* 176, 179.
102 See F. Shenfield et al., ‘Taskforce 9: The Application of Preimplantation Genetic Diagnosis for Human Leukocyte Antigen Typing of Embryos’ (2005) 20 *Human Reproduction* 845. Congenital disorders include diseases such as β thalassaemia or sickle cell anaemia. Neoplastic disorders are disorders such as leukaemia.
105 See HART Act 2004, s 83(2) and s 83(6). See also the New Zealand Gazette, No. 123, 11 August 2005, 3010.
106 See HART Act 2004, s 16(1).
107 See HART Act 2004, s 19(2).
121 This was the case recently when a Swiss couple undertook PGD with HLA tissue typing in Belgium. Their six-year-old child suffered from chronic granulomatous disease, a genetic disease which affects
the immune system. Because of the age of the sibling and the small birth weight of the baby there were insufficient stem cells in the umbilical cord blood to provide a transplant of cord blood cells. Consequently, a bone marrow transplant was performed. See K. Duke, ‘Belgian Loophole Allows Swiss Parents a “Saviour” Baby’ (2006) 368 Lancet 355. It was stated by the Brussels Centre for Medical Genetics where the PGD was performed that generally PGD is refused to couples where the ill child is too old to be treated with cord blood cells. See also B. Pancevski, ‘Swiss Child has Successful Bone Marrow Transplant from “Saviour Sibling”’ (2006) 332 BMJ 1352.


126 Ibid., 25. However 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. This could apply to infants born as a result of PGD.


128 See ibid., vi.


136 HART Act 2004, s 4(b).

137 HART Act 2004, s 16(1).

138 HART Act 2004, s 19(2). The Guidelines on Preimplantation Genetic Diagnosis were approved by the Minister of Health in March 2005. Although these guidelines were created by the National Ethics Committee on Assisted Human Reproduction, they have been designated ACART Guidelines under the interim provisions provided by the Act. See HART Act 2004, s 83(2).

139 See New Zealand Gazette, No. 123, 11 August 2005, 3010.

140 NECAHR, Guidelines for Preimplantation Genetic Diagnosis, March 2005.

142 Ibid., 56.
146 G. Pennings and G. de Wert, ‘Evolving Ethics in Medically Assisted Reproduction’ (2003) 9 *Human Reproduction Update* 397, 402. The authors claim that although some would argue that a child is not ‘harmed’ by this decision, it ‘would certainly be wronged’.
150 Others view justifications for the procedure which are based on the best interests of the future child as artificial, claiming that it is inaccurate to construe HLA tissue typing and subsequent cord blood donation as being in the best interests of the donor. Rather, the justification for the procedure is the promotion of the interests of the recipient. Consequently, an alternative justification which permits parents to undertake this course of treatment on behalf of a sick child is required. G. Pennings, R. Schots and I. Liebaers, ‘Ethical Considerations on Preimplantation Genetic Diagnosis for HLA Typing to Match a Future Child as a Donor of Haematopoietic Stem Cells to a Sibling’ (2002) 17 *Human Reproduction* 534, 536. See analysis under cl 7.6.
151 In contrast to the limitations placed on performing PGD for familial single gene or familial sex-linked disorders under the established procedures Order, there are no similar qualifications placed on what constitutes a single gene or sex-linked disorder suffered by the sick child in the context of HLA tissue typing. See cl 6 of part 2 of the schedule to the HART Order 2005.
152 The performance of PGD is not an activity that the United Kingdom’s HFEA is expressly, or even obviously implicitly, authorised to licence under the Human Fertilisation and Embryology Act 1990 (UK). However, the HFEA has approved applications from clinics to perform PGD to diagnose serious genetic disorders from 1999. It was only when approval was given in 2001 to perform HLA tissue typing in conjunction with PGD that judicial review of the legitimacy of the Authority’s decision-making was sought by the group CORE. Curiously CORE did not object to performing PGD for serious disorders, but took issue with the use of HLA tissue type as a criterion to select between healthy embryos. The litigation which ensued did not concern the merits of performing HLA tissue typing in order to conceive a child who could be a prospective tissue donor for a sick sibling. Rather, it simply addressed the question of whether the licensing of HLA tissue typing in conjunction with PGD was within the scope of the authority conferred on the HFEA by the Human Fertilisation and Embryology Act 1990 (UK).
153 See Human Fertilisation and Embryology Authority, ‘HFEA to Allow Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis’, press release, 13 December 2001. See also, Human Fertilisation and Embryology Authority, ‘HFEA Confirms that HLA Tissue Typing May Only Take Place When Preimplantation Genetic Diagnosis is Required to Avoid a Serious Genetic Disorder’, press release, 1 August 2002.
154 See Human Fertilisation and Embryology Act 1990 (UK), s 13(5).

156 Ibid. This broad approach is analogous with that taken by the English Courts when considering what was in the best interests of an incompetent adult asked to donate bone marrow to a sister suffering from leukaemia. See *Re Y (Mental Patient: Bone Marrow Donation)* [1997] Fam 110.


167 Section 174 of the Health Practitioners Competence Assurance Act 2003 provides that whenever a person requests a health practitioner to provide a service (including, without limitation, advice) with respect to contraception, sterilisation or other reproductive health services, and the health practitioner objects on the grounds of conscience to providing the service, the health practitioner must inform the person who requests the service that he or she can obtain the service from another health practitioner or from a family planning clinic.


169 For children suffering from Fanconi anaemia, an autosomal recessive disease which leads to progressive bone marrow failure and which carries an increased predisposition for acute leukaemia as well as other cancers, the only proven long-term cure of the bone marrow manifestations is successful allogeneic haematopoietic stem cell (HSC) transplantation. HSC transplant with donors other than HLA-identical siblings is associated with high morbidity and poor survival. See S. Grewel et al., ‘Successful Hematopoietic Stem Cell Transplantation for Fanconi Anemia From an Unaffected HLA-Genotype-Identical Sibling Selected Using Preimplantation Genetic Diagnosis’ 103 (2004) *Blood* 1147.


173 Verlinsky and colleagues recently reported that they have performed HLA testing in nine families wanting an HLA-matched child who could provide cord blood for siblings with non-genetic hematological disorders. At the time the article was published, no transplants had been performed as the children were all in remission. See Y. Verlinsky, S. Rechitsky, T. Sharapova, R. Morris, M. Taranissi and A. Kuliev, ‘Preimplantation HLA Testing’ (2004) 291 JAMA 2079. Verlinsky’s team stated that ‘given the sizeable proportion of treatment failures’ after treatment with chemotherapy alone, the option of HSCT ‘should still be available for patients for whom chemotherapy is not effective, particularly if the parents plan to have another child anyway’. See A. Kuliev, S. Retchitsky and Y. Verlinsky, ‘In Reply’ (2004) 292 JAMA 804.


176 Lord Winston, Britain’s foremost fertility expert, has been quoted as saying, of a child in the position of Jamie Whitaker, the sibling of Charlie Whitaker, ‘This child has the spectre of being born for somebody else’s benefit throughout his whole life’. See M. Spriggs, ‘Is Conceiving a Child to Benefit Another Against the Interests of the New Child?’ (2005) 31 J Med Ethics 341.


178 Ultra vires means beyond the legal capacity of a person or other legal entity.

179 See Health and Disability Commissioner (HDC) Act 1994, s 14(d).


181 See the Schedule to the Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996 which sets out the Code of Rights.


183 Care of Children (CoC) Act 2004, s 16(2)(c).

184 See J. Caldwell, ‘Parents, Courts, and the Sick Child’ (2000) 3 BFLJ 129 citing MJB v D-GSW [1996] 2 NZFLR 337. The Court of Appeal held that parental rights (in this case to refuse a blood transfusion for their three-year-old child) were to be overridden where there was a real or substantial risk that the child’s condition would require a blood transfusion.

185 The High Court of New Zealand has held that s 25(3) of the Guardianship 1968 conferred on the parents of an intellectually handicapped child with a mental age of about three months the right to consent to sterilisation to prevent menstruation. (The Guardianship Act 1968 was reformed and replaced by the CoC Act 2004. Section 25(3) of the Guardianship Act 1968 is the equivalent of s 36(3) of the CoC Act 2004.) It was observed that an application to the Court for consent was not necessary but could be made if there were any doubt on the part of the parties involved as to the
appropriate procedure. The court also provided guidelines for the consideration of the medical profession in cases concerning sterilisation of intellectually handicapped minors. See Re X [1991] 2 NZLR 365. In contrast the High Court of Australia has held that Court authorisation would be required before a non-therapeutic sterilisation could be carried out on an intellectually disabled minor. See Secretary, Department of Health and Community Services v JWB and SMB (Marion’s case) (1992) 175 CLR 218.

The HT Act 2004 provides a new legal framework which encompasses not only the removal, storage and use of tissues and organs from the dead but also tissue from the living.

For a list of activities within the HTA remit, see s 14.

An independent assessor is a trained and accredited representative of the HTA, who will conduct interviews and prepare reports in certain circumstances.

See HTA, Code of Practice – Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation (July 2006).

An eligible person includes a parent or guardian; grandparent, aunt or uncle; sibling; spouse or partner of a parent; the child; the chief executive; or any other person granted leave to apply by the Court. See CoC Act 2004, s 31(2).

An application under s 31(1) of the Act may be made by any eligible person for an order placing the child under the guardianship of the Court and appointing a named person as an agent of the Court for any particular purpose, such as making decisions with regard to medical procedures. In any proceedings brought under the Act, the welfare and best interests of the child must be the first and paramount consideration (s 4(1)), and the welfare and best interests of the particular child must be considered in that particular child’s circumstances (s 4(2)).

The definition of a child in need of care and protection is contained in s 14(1) of the Act. It includes a child who is being, or is likely to be, harmed (whether physically, emotionally or sexually), ill-treated, abused or seriously deprived (s 14(1)(a)); or if the child or young person’s development or physical, mental or emotional well-being is being, or is likely to be, impaired or neglected, and the impairment or neglect is, or is likely to be, serious and avoidable (s 14(1)(b)). Under the CYPF Act 1989, the welfare and interests of the child must be the first and paramount consideration, having regard to the principles set out in ss 5 and 13 of the Act.
The study involved interviewing fifteen sibling HSCT donors, eight of whom had participated in successful transplants, and seven whose recipient sibling had died. The mean age at the time of the interviews was 19.6 years, and 13.3 years at the time of the sibling’s HSCT. It was reported that the sibling donors felt that at the time they had had ‘no choice’ but to donate. Two-thirds based the ‘no choice’ aspect on the fact that due to the severity of their sibling’s illness there was no option but to be a donor i.e. internally imposed lack of choice. A third of those surveyed reported that they felt that their parents or medics did not give them an opportunity to refuse, i.e. externally imposed lack of choice. See K. Macleod et al., ‘Pediatric Sibling Donors of Successful and Unsuccessful Hematopoietic Stem Cell Transplants (HSCT): A Qualitative Study of Their Psychosocial Experience’ (2003) 28 Journal of Pediatric Psychology 223. See also G. Parmar, J. Wu and K. Chan, ‘Bone Marrow Donation in Childhood: One Donor’s Perspective’ (2003) 12 Psycho-Oncology 91, in which the experiences of a medical student who was a donor for his brother at the age of ten are described.

W. Packman, ‘Psychosocial Impact of Pediatric BMT on Siblings’ (1999) 24 Bone Marrow Transplantation 701.


Re W [1997] 136 FLR 421. The Family Law Act, s 67ZC(2) requires that the Family Court of Australia must regard the best interest of the child as the paramount consideration when making an order relating to the welfare of the child.

In the case of S v S; W v Official Solicitor [1970] AC 24 the House of Lords considered the question of performing blood tests on children for paternity purposes. Lord Reid suggested that a ‘reasonable parent’ test was more appropriate than applying a strictly best interests approach to the parents’ decision to allow testing, as the reasonable parent may consider wider motives than the child’s physical protection, such as the public interest. An alternative test, that procedures could be allowed as long as they were not ‘clearly against the interests’ of the child, was also suggested. It has been argued that this latter approach is relevant to any non-therapeutic medical intervention carried out on children, which ‘do not involve pain, discomfort or risk to health’. See P.D.G. Skegg, ‘Consent to Medical Procedures on Minors’ (1973) 36 Mod L Rev 370, 381. See also M. Spriggs, ‘Is Conceiving a Child to Benefit Another Against the Interests of the New Child?’ (2005) 31 Journal of Medical Ethics
341, 342, where it is argued that parental consent when it is ‘not against the interests of the child’ test constitutes a valid consent. See also S. Mumford, ‘Bone Marrow Donation – The Law in Context’ (1998) Child and Family Law Quarterly 135, where it is stated that departing from the traditional welfare test (i.e. best interests) may be more realistic in ‘allowing the sort of balancing that happens within a family where decisions cannot always protect the welfare of each child equally’.


211 Ibid.

212 S. Month, ‘Preventing Children from Donating May Not be in Their Interests’ (1996) 312 BMJ 240.


214 In contrast, physicians and medical institutions in the United States have been sued by families who may have benefited from PGD with HLA tissue typing for failing to inform the family that such technology exists. In Ferrell v Rosenbaum 691 A.2d 641 (D.C. App 1997) it was argued that the failure of a geneticist to review and follow up on a child’s blood test which would have revealed that she was suffering from Fanconi anaemia was a breach of the applicable standard of care required. Additionally, it was argued that the failure to provide an early diagnosis deprived the parents of the opportunity to be informed, prior to their separation and estrangement, that the child’s best opportunity of survival was a bone marrow transplant from an HLA-matched sibling. This precluded the chance of the child ever obtaining a matched sibling donor. It was held by the District of Columbia Court of Appeals that it was arguable that the negligence was a proximate cause of the child’s loss of the opportunity for the best possible treatment.

215 Thomas J provided definitive criteria for the assessment of ‘good medical practice’ in Auckland Area Health Board v Attorney-General [1993] 1 NZLR 235, 250. This was revised by the Court of Appeal in Shortland v Northland Health Limited (Unreported, CA 230/97, 10 November 1997, Richardson P, Keith J, Tipping J). To meet the requirement of good medical practice, a decision must be made in good faith to be in the best interests of the patient; must conform with prevailing medical standards and with practices, procedures and traditions commanding general approval within the medical profession; and in some, but not all, cases consultation with appropriate medical specialists and the appropriate ethical body may be required depending on the circumstances.


219 See Curran v Bosze (1990) 566 N.E. 2d 1319, in which a mother, who was estranged from her former partner and had custody of the twins resulting from the relationship, refused to consent to HLA testing of her minor children. The father of the twins had a son from a previous relationship who was suffering from leukaemia. The father petitioned the Court to authorise the testing and, if compatible, bone marrow harvest of the children for the benefit of his son. The twins had only met their half-brother once. The American Court denied relief on the grounds that, in the absence of a close relationship between the children, donation was not in the twins’ best interests.


222 S. Wolf et al., 327, 334.


226 (1972) 289 A.2d 386.

227 A United States study has shown that most United States transplant centres are opposed to using children as living kidney donors. See A. Spital, ‘Should Children Ever Donate Kidneys? Views of US transplant centres’ (1997) 64 Transplantation 232.


231 ‘Sibling’ is not defined in either the HART Act 2004, or the Guidelines. However, the HART Order 2005 defines a sister/brother as a sister/brother of full blood or half blood, a step sister/brother, or a sister/brother by adoption. In this context, it is likely that only a full-blood sibling would be an identical HLA match and therefore a potential donor.


235 W. Tse and M. Laughlin, ‘Umbilical Cord Blood Transplantation: A New Alternative Option’ (2005) Hematology (Am Soc Hematol Educ Program) 377. ‘Banked unrelated umbilical cord blood (UCB) has emerged as an alternative allogeneic stem cell source, providing available and suitably HLA-matched donors for patients requiring allogeneic transplantation. Early clinical reports of UCB transplantation, in pediatric and adult recipients, show slower rates of hematopoietic engraftment, higher rates of infection, yet importantly, a low incidence of severe (grade III/IV) acute GVHD, even when HLA-disparate grafts are infused’ (at 382).


237 The authors would like to gratefully acknowledge Dr Michael Sullivan, Paediatric Oncologist and Director of Research, Children’s Cancer Research Group, Christchurch School of Medicine and Health Sciences, University of Otago for providing help with the following explanation.


243 Ibid., 1397.

244 See R v Human Fertilisation and Embryology Authority, ex p Blood [1997] 2 All ER 687 (CA).


247 HFEA Ethics Committee, Ethical Issues in the Creation and Selection of Preimplantation Embryos to Produce Tissue Donors, 22 November 2001, paras 2.21 and 3.15.


251 HART Act 2004, s 4(b).


253 Ibid., 468.

254 G. Pennings and I. Liebaers, ‘Creating a Child to Save Another: HLA Matching of Siblings by Means of Preimplantation Genetic Diagnosis’, in F. Shenfield and C. Sureau (eds), Ethical Dilemmas in Reproduction (London: Parthenon Publishing, 2002) 63. Notably, it is a crime, punishable by imprisonment, for parents to neglect to provide the necessaries of life for a child under the age of sixteen. See s 152, Crimes Act 1961. The parents of a boy suffering from osteosarcoma who failed to ensure that he obtained medical treatment were convicted under s 152 of omitting to provide the necessaries of life. See R v Laufau (HC, Auckland, T 000759, 2 October 2000, Potter J). For a child suffering from a condition such as Fanconi anaemia, providing HLA-matched cord blood or bone marrow from a sibling is effectively providing the necessaries of life for that child in the form of a functioning bone marrow. But see also Re T (a minor) (wardship: medical treatment) [1997] 1 All ER 906 (CA).


256 S. Sheldon and S. Wilkinson, ‘Should Selecting Saviour Siblings Be Banned?’ (2004) 30 J Med Ethics 533. The fear is that by permitting selection for non-medical genetic traits, such as athleticism or intelligence, the nature of society will change.

258 See Opinion of the Ethics Committee of the Human Fertilisation and Embryology Authority, Ethical Issues in the Creation and Selection of Preimplantation Embryos to Produce Tissue Donors, 22 November 2001, 11.


261 Pub L No. 105-277, 112 Stat 2681, cited in S. Grewel et al., supra cit.

262 The Human Tissue Act 1964, which governs the removal of human tissue from a dead body for therapeutic purposes, does not apply to foetuses, or stillborn children. In the review of the Human Tissue Act 1964, undertaken by the Ministry of Health between 2003-2004, the Minister of Health (then Hon. Annette King) proposed that the definition of human tissue will include whole bodies and body parts through to blood, cell lines derived from tissue, stillborn children and foetal material. It is proposed that the therapeutic uses of human tissue will be regulated by the Australia New Zealand Therapeutic Products Authority (ANZTPA). See Review of the Regulation of Human Tissue and Tissue-based Therapies: Paper One: Overview and Principles for Human Tissue Legislation (Wellington: Office of Minister of Health, Hon. Annette King, Chair, Cabinet Social Development Committee, March 2006.) Available at: http://www.moh.govt.nz/moh.nsf/0/40A21654C99717CACC2571230076A57A/$File/human-tissue-cab-paper-1.doc viewed on 6 December 2006. The Human Tissue Bill was introduced into Parliament on 7 November, 2006. In vitro human embryos, and in vitro human gametes are not human tissue for the purposes of the Human Tissue Bill.


267 See the Biotechnology Act of 5 December 2003, No. 100, § 2.14.


269 It is significant that the Minister of Health took the opportunity not to re-nominate the members of the National Advisory Board on Biotechnology, who had publicly criticised him for his fierce stance on PGD, after the Government lost the vote on the Mehmet case.


273 Act No. 240, 5 April 2004, amending the Act on Artificial Fertilisation.
274 See Act No. 460, 10 July 1997, Concerning Artificial Fertilisation in Connection with Medical
Treatment, Diagnostic Procedure and Research, etc., s 73.
275 M. Hartlev, 'Legislation and Regulation in the Nordic Countries: Is There a Nordic Dimension?';
in I. Jonsdottir (ed), PGD and Embryo Selection: Report from an International Conference on
Preimplantation Genetic Diagnosis and Embryo Selection (TemaNord 2005: 591) 119.
277 Infertility Treatment Act 1995 (Vic), s 8(3)(a) and (b).
278 ITA, Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis, January 2004, 3.
Preimplantation Genetic Diagnosis for Human Leukocyte Antigen Typing of Embryos' (2005) 20
Human Reproduction 845, 846.
Preimplantation Genetic Diagnosis for Human Leukocyte Antigen Typing of Embryos' (2005) 20
Human Reproduction 845, 846.
281 R. Brownsword, 'Happy Families, Consenting Couples, and Children with Dignity: Sex Selection and
282 R. Brownsword, ‘Happy Families, Consenting Couples, and Children with Dignity: Sex Selection and
involved 4834 Americans; 66 per cent of those surveyed supported the use of PGD to determine
tissue type for a sick sibling in need of a transplant.
284 HFEA, New Guidance on Preimplantation Tissue Typing, CH(04)05, 4 August 2004. HFEA, Human
285 It is an offence under the HART Act 2004 to perform an assisted reproductive procedure without
the prior written approval of ECART (s 16(1)). Conviction may incur a fine not exceeding $50,000
(s 16(2)). ECART may only approve applications which are consistent with relevant guidelines
issued by ACART (s 19(2)). The Guidelines have been designated as ACART guidelines under the
provisions of the Act (s 83(2)).
Ethics 533, 536.
287 S. Wolf et al., Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues,
288 Human Genome Research Project, Choosing Genes for Future Children: Regulating Preimplantation
289 See J Ross, ‘Perspectives of Haemophilia Carriers’, in Treatment of Hemophilia (Canada: World
author gives the following example of cystic fibrosis: there is a 50 per cent chance that an individual
who is a carrier will transmit the recessive allele; a 1 in 25 chance that the partner of the carrier
offspring is a carrier (in the case of Caucasians); and again a 25 per cent chance of transmission.
This means there is a 1 in 100, or 1 per cent, chance of transmission from an unaffected carrier of an
autosomal recessive condition.
291 The figure of 1 per cent is relevant to a condition such as cystic fibrosis because 1 in 25 Caucasians
carry the autosomal recessive mutation. However, there will be a much lower risk for less common
recessive mutations.
292 C.J. Shaw-Smith, S.J. Lewis and E. Reid, ‘X-linked Adrenoleukodystrophy Presenting as Autosomal
Dominant Pure Hereditary Spastic Paraparesis’ (2004) 75 Journal of Neurology Neurosurgery and
Psychiatry 686.

294 Most males with fragile X syndrome have mental retardation or serious learning disabilities. Approximately one-third to one-half of female carriers of a full mutation will exhibit signs of fragile X syndrome, but they are usually less severely affected than males with full mutations.


296 See the Schedule to the Health and Disability Commissioner (Code of Health and Disability Services Consumers’ Rights) Regulations 1996 which sets out the Code of Rights.

297 Code of Health and Disability Services Consumers’ Rights, cl 1.

298 For a discussion regarding the legal status of the embryo, see N. Peart, ‘The Legal Status of Life Before Birth’, in P.D.G. Skegg and R. Paterson (eds), Medical Law in New Zealand (Wellington: Brookers, 2006) 467.

299 The position in relation to disclosing the sex of embryos may be distinguished from disclosing carrier status. Under our current law, parents are prohibited from selecting on the basis of non-disease traits, such as sex, unless it is performed to prevent or treat a genetic disorder. Such traits, if they have nothing to do with the health of the foetus, do not constitute health information. It seems cogent to argue therefore that health care providers have no obligation under the Code to provide information about non-disease traits such as the sex of an embryo.

300 This may also arise where parents, who have a strong preference for a child of a particular sex, wish to know the gender of the embryos created.


303 P. Borry et al., supra cit., 137.

304 P. Borry et al., supra cit., 136.

305 P. Borry et al., supra cit., 136.

306 The position may be distinguished where the sex of an embryo is discovered and sex selection is not required to prevent or treat a genetic disorder. As sex selection on the basis of gender is an offence punishable by imprisonment under the HART Act 2004, and is not health information, it is arguable that there is no obligation to disclose this information under the Code. This is a relevant factor which may provide a defence for a provider who does not disclose the sex of embryos created or selected for transfer. Clause 3 of the Code provides a defence to any alleged breach of the Code where a provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in the Code. For the purposes of this clause, ‘the circumstances’ means all the relevant circumstances. This particular clause may be relevant to disclosing the results of embryo biopsy.


308 Leeds Reproductive Medicine Unit, NHS provides the following information for patients: ‘For single-gene defects, embryos will be tested and unaffected embryos will be transferred into the uterus. In some cases there may not be any unaffected embryos, and we may discuss with you the possibility of putting unaffected but carrier embryos into the uterus. These carrier embryos do not have the disease but may pass it on to their children’. Available at: http://www.leedsreproductivemedicine. co.uk/referral_and_treatments/diagnosis.php viewed 28 September 2006.

309 See HART Act 2004, ss 11(1) and (3), which prohibits sex selection unless it is to prevent or treat a genetic disorder or disease. See also cl 8.1 of the Guidelines on Preimplantation Genetic Diagnosis which prohibits the conducting of PGD for social reasons.

310 See HART Act 2004, s16 (1), s 19(2).
See Table 2 for an illustration of this.


M. Katz et al., supra cit., 1121.

C. Snowdon and J.M. Green, ‘Preimplantation Diagnosis and Other Reproductive Options: Attitudes of Male and Female Carriers of Recessive Disorders’ (1997) 12 Human Reproduction 341, 349. The sample (which included men and women) represented carriers of forty-three different disorders, the most frequent being cystic fibrosis (34 per cent), infantile spinal muscular atrophy (18 per cent), and intermediate SMA (8 per cent). The reproductive history of the sample revealed that 93 per cent of the sample had an affected child, 34 per cent had had a child die from the disorder, 58 per cent had used PND and 19 per cent had terminated an affected pregnancy.


M. Hansson, supra cit., 89.

See HART Act 2004, s 3(b).


331 There are differing views on the moral status of the embryo. At one end of the spectrum it is held that an embryo has the moral status of a fully live person, and should be protected accordingly. An intermediate or gradualist position holds that the embryo has a special status, which means it is entitled to some protection and acquires greater moral status as it develops. The most liberal position taken is that the embryo is no more than a collection of cells, albeit with the potential to develop into a human being. 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, para 28, 16.

332 Geneticisation has been defined in the following way: ‘Geneticization refers to the increasing tendencies to make distinctions between people on the basis of what one believes are genetic differences, to view most disorders, behaviors and physiological variations as determined (wholly or in part) by genes, and as I have defined and use the term, comprises ways both of thinking and of doing, applying genetic technologies to diagnose, treat and categorize conditions previously identified in other ways’. See A. Lippman, ‘Geneticization and the Canadian Biotechnology Strategy’, in Geneticization, Geneticization: The Canadian Biotechnology Strategy, 2. Available at www.cwhn.ca/groups/biotech/availdocs/5-lippman.pdf viewed 1 November 2006.


338 The Scottish Executive and Advisory Committee on Genetic Testing, Consultation Document on Preimplantation Genetic Diagnosis, November 1999, para 36.

339 See HGC and the HFEA, The Scottish Executive and Advisory Committee on Genetic Testing, Consultation Document on Preimplantation Genetic Diagnosis, November 2001, para 39. This was taken verbatim from a submission made by the HGC, which also stated that ‘this will result in an increased chance of the couple achieving an unaffected pregnancy. It will also protect the unborn child’s subsequent right to decide for themselves whether or not to be tested for their carrier status’. See HGC, Response to the HFEA on the Consultation on Preimplantation Genetic Diagnosis, March 2001, 3.


346 Human Reproductive Technology Act 1991, s 14(2b)(a)(i) and (ii) as amended by the Human Reproductive Technology Amendment Act 2004.

347 Personal communication, Antonia Clissa, Executive Officer, Reproductive Technology Council, 1 December 2006.
348 See, for example, L. Curnow, R. Savarirayan and J. Massie, ‘Genetic Counselling After Carrier Detection by Newborn Screening When One Parent Carriers F508 and the Other R117H’ (2003) 88 Arch Dis Child 886, 887.


352 Personal communication, Antonia Clissa, Executive Officer, Reproductive Technology Council, 1 December 2006.

353 National Health and Medical Research Council, Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, September 2004, 40.


356 ESHRE is the European Society for Human Reproduction and Embryology. ESHRE develops guidelines to promote best quality practices in reproductive medicine.


359 ESHRE recommends the following post-biopsy criteria to facilitate embryo selection: diagnosis of unaffected status; cell number pre-and post-biopsy; evidence of active cell division post-biopsy; and evidence of embryo morphology pre and post-biopsy. A.R. Thornhill et al., ‘ESHRE Consortium “Best Practice Guidelines for Clinical Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS)”’ (2005) 20 Human Reproduction 35, 45.


362 See G. de Wert, supra cit., 3264, referring to Maastricht academic hospital.

363 G. de Wert, supra cit., 3265.

364 Ibid.


375 See the website of the Wellcome Trust, ‘The Human Genome: Haplotype Mapping’. Available at http://genome.wellcome.ac.uk/doc%5Fwtd020781.html viewed 3 August 2006.
377 See the website of the Wellcome Trust, ‘The Human Genome: Haplotype Mapping’, supra cit.
379 See the website of the Wellcome Trust, ‘The Human Genome: Haplotype Mapping’, supra n. 376.
381 P. Renwick et al., supra cit., 110.
382 P. Renwick et al., supra cit., 111.
383 P. Renwick et al., supra cit., 111.
384 P. Renwick et al., supra cit., 111.
385 P. Renwick et al., supra cit., 117.
386 P. Renwick et al., supra cit., 117. Genetic heterogeneity occurs when a similar phenotype (ie the physical expression of a particular trait or disorder) is caused by different mutations. Allelic heterogeneity refers to different mutations in the same gene.
387 P. Renwick et al., supra cit., 117.