Creating a Child to Save a Child: New Zealand's Regulation of Preimplantation Genetic Diagnosis and Human Leukocyte Antigen Tissue Typing to Create "Saviour Siblings"

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INTRODUCTION

Assisted reproductive technology has made enormous strides in recent times, creating possibilities that were barely comprehensible in the not so distant past. Principle amongst these technological innovations has been the development of Preimplantation Genetic Diagnosis (PGD). Through the negative testing and selection of embryos, PGD provides a means of avoiding the birth of children destined to suffer from genetic disease. The use of PGD is not without controversy but when combined with Human Leukocyte Antigen Tissue Typing to create a "saviour sibling", the controversy is taken to a whole new level.

A number of diseases can be treated or cured through stem cell transplantation. These transplants have a far higher chance of success if the stem cell donor's Human Leukocyte Antigen (HLA) tissue type matches that of the recipient. For families in which a matched donor does not exist for a sick child, much hope is generated by the use of PGD in conjunction with HLA tissue typing to select embryos for implantation that have this required tissue type. Upon birth, stem cells are harvested from the baby's umbilical cord blood and transplanted to the sick child.

The potential for this technology to cure serious disease is just one side of the story. As well as attracting the inevitable moral and ethical scrutiny generated by the need to create and destroy excess embryos, this technology gives rise to numerous additional ethical concerns. At the root of these concerns is the fact that tissue typing PGD is the first instance of the positive selection of a genetic feature that is of no importance to the health of the child that the embryo will become.

The regulatory structure currently governing tissue typing PGD in New Zealand involves a set of guidelines[1] to be followed by an ethics committee who will assess each application for use of the technology on a case-by-case basis. There have been no applications for approval of tissue

[1] Guidelines on Preimplantation Genetic Diagnosis: Prepared by the National Ethics Committee on Assisted Human Reproduction, March 2005

typing PGD in New Zealand to date, leaving the adequacy of this regulatory structure and the requirements it imposes uncertain.

A system of regulation enabling technological innovation whilst displaying respect and concern for legitimate moral and ethical views is the ideal in this area yet it is notoriously difficult to achieve. New Zealand's regulatory system needs to be assessed against this ideal to determine whether an appropriate and realistic approach has been adopted in terms of the substance and structure of the current regulatory regime.

Consideration must first be given to the major ethical concerns that arise from the use of tissue typing PGD and to the weight that each concern should be accorded. With this ethical basis in mind, an analysis of the requirements imposed by the New Zealand regulatory regime will be undertaken and suggestions given for the improvement of the current Guidelines. Focus will then shift from the substance of New Zealand's regulatory regime to its structure. An overview will be given of two foreign jurisdictions that have taken markedly different approaches to the regulation of tissue typing PGD. This comparison will aid in determining whether New Zealand has adopted the regulatory structure best suited to our social and political environment.

Before this assessment can be undertaken, a basic understanding of the technology and the science upon which it is based is necessary.

CHAPTER I: THE TECHNOLOGY

The technology required to create a tissue matched or "saviour" sibling involves the combination of three techniques; in vitro fertilisation (IVF), pre-implantation genetic diagnosis (PGD), and human leukocyte antigen tissue typing (HLA).

IVF is the first step in the process, bringing together egg and sperm for fertilisation outside the body. The IVF process thus creates embryos outside the body and it is at this stage that PGD is utilised. PGD involves the genetic screening and characterisation of embryos, enabling transfer to the uterus of those embryos carrying, or not carrying, specific genetic traits[2].

The embryo is usually allowed to grow in an incubator until it consists of eight cells. This will be at approximately three days after fertilisation. At this point one or two of these cells are removed to undergo an embryo biopsy in which they are tested for specific genetic markers. At this early stage every cell of the embryo is genetically identical to every other cell. The genetic complement shown from the results of the tested cells is therefore indicative of the genetic complement of the child that will eventually be born.

The final process necessary to create a tissue matched child is HLA tissue typing. This involves screening of the embryos to select those that can provide transplantable tissue compatible with that of an existing sick sibling. In any transplant, the risk is run of the recipient's immune system rejecting the transplanted tissue if it recognises the material as foreign. Knowledge of a matching HLA tissue type removes that risk. The success of any transplant will therefore depend upon how well the HLA tissue

[2] The first successful utilisation of PGD was reported in humans in 1990 when it was undertaken as an alternative to the pre-natal testing and subsequent termination of pregnancies with male foetuses. By only allowing implantation of female foetuses, a sex-linked disease that occurred only in males was successfully avoided (Handyside et al "Pregnancies from biopsied human preimplantation embryos sexed by Y-specific DNA amplification" (1990) 344 Nature 768)

types of the donor and recipient match. Hence the desire to produce a tissue matched sibling to provide a transplant[3].

Should an embryo be found that is a tissue match for the sick child, that embryo is implanted in the mother's uterus and brought to term. Upon birth, the haematopoietic stem cells in the umbilical cord of the baby are collected and transplanted to the sick sibling in the hope of providing a cure.

The science behind this technology is only half the story and a true assessment of the situation can only be achieved with an understanding of the ethical issues that the use of tissue typing PGD creates.

[3] All humans inherit half of their HLA type from their mother and the other half from their father, leaving each embryo with a one in four chance of having an HLA tissue type identical to one of its siblings.

CHAPTER II: THE ETHICAL CONTROVERSY

The potential for tissue typing PGD to save the lives of the seriously ill and avoid the birth of children destined to a life of suffering will not be sufficient justification to permit the use of the technology should the moral and ethical grounds raised in opposition to it prove to carry greater weight. As was cautioned by one writer,

> some of the worst medical atrocities to date have been rationalized with the notion that there is something wonderful to achieve and no other way to achieve it…We need to be careful lest misguided compassion moves us to pursue a quick fix that will foster a way of thinking that will harm a much larger number in the long run.[4]

The New Zealand Guidelines on tissue typing PGD are directed towards addressing three of these ethical concerns and it is these that will be primarily focussed upon. They are that the embryo biopsy is detrimental to the future child's physical health and development; that resultant children will be victims of unacceptable instrumentalisation; and that the technology will set society on a slippery slope towards designer babies and eugenics. These issues will be raised in conjunction with specific points to be discussed further but a general overview of the major arguments is necessary to gain an understanding of the perceived risks and dangers of creating 'saviour siblings'.

2.1 The Moral Status of the Embryo

Before discussing these three major ethical concerns consideration must be given to what is perhaps the most fundamental moral and ethical issue confronting any reproductive technology. The status that should be accorded to the embryo is an issue that will shape an individual's view on the use of tissue typing PGD. However, the issue will be quickly dismissed. This is not aimed at belittling the matter, but, beliefs concerning the moral status that should be accorded to a preimplantation

[4] Kilner, J.F. Commentary: *"Poor Prognosis for Preimplantation Genetic Diagnosis (PGD)?"* The Center for Bioethics and Human Dignity, August 6 2004

embryo are based upon an individual's religious beliefs or even solely upon intuition. Such views can not be easily changed, making reasoned argument of little or no utility. One's opinion on the moral and ethical acceptability of tissue typing PGD hinges entirely on one's view of the moral status of the preimplantation embryo. A belief that the embryo deserves equal moral status to post-natal life leads to the conclusion that PGD is wrong; the necessary embryo destruction would be the equivalent of murder.

A belief that the preimplantation embryo lacks any inherent moral status would mean embryo rejection and destruction would not be a major issue and consideration of the acceptability of the technology could proceed to further ethical arguments.

Another frequently adopted approach is that the moral status of the embryo increases gradually throughout development[5]. When an embryo is tissue typed it will be no more than three days old and will consist of just six to ten cells. Upon a graduating view of the embryo's moral status, an embryo at this stage would be deserving of a very minimal degree of respect and tissue typing would likely be seen as acceptable. Indeed, it would be far less objectionable to pre-natal screening and selective abortion of a much older foetus. While the existence of a law can not be said to demonstrate a "correct" moral approach, this graduating view of an embryo's moral status is consistent with New Zealand's current abortion laws which allow a foetus to be aborted until 20 weeks of gestation. There are situations in which terminations will be allowed later than 20 weeks but these are very limited and demonstrate an increased moral status being accorded to the foetus throughout development[6].

To enable this discussion to proceed, it shall be assumed that when tissue typing occurs the embryos do not have sufficient moral status to preclude them from being destroyed upon non-selection.

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[5] See for example, Scott, R. "Choosing between Possible Lives: Legal and Ethical Issues In Preimplantation Genetic Diagnosis" (2006) 26 Oxford Journal of Legal Studies 153 at 156.

[6] Contraception, Sterilisation, and Abortion Act 1977 and Crimes Act 1961, ss182-187

2.2 Physical Harm From Embryo Biopsy

The fear that tissue typing PGD may be detrimental to the physical wellbeing of the resultant child concerns the possible detrimental effects of embryo biopsy on the future health and development of the child[7]. These concerns and their effect on the regulation of the technology will be discussed more fully, further on[8], and it is sufficient to say here that, at this stage, the embryo biopsy has not been proven to cause any harm to the resultant child[9]. However, owing to the technology's relative novelty, there has not yet been opportunity for any long term follow-up studies of children born as a result of its use. What can be said is that a child born following tissue typing PGD will not suffer any greater detriment than a child born through any other form of PGD[10].

2.3 Instrumentalisation

The most frequently raised ethical concern is that tissue typing PGD involves the unacceptable instrumentalisation or commodification of children. It is feared that prospective offspring will be considered a commodity and be viewed as a means rather than an end in themselves.

If the parents have no intention of bringing up the child and intend to abandon it following the harvesting of stem cells it could be said that the child was being instrumentalised and was created purely as a means to an end. One author has suggested that such actions should not be too strongly criticised as they are somewhat analogous to surrogacy arrangements which, although deprecated, are not banned[11]. That author is not a lone voice. Sheila McLean[12] has commented that even if the

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[7] With the general intention being that the cells used for transplant to the sick sibling will be harvested from the new born's umbilical cord blood, there is no bodily intrusion on the child in terms of the stem cell transplantation and consequently no physical harm in that regard.

[8] See discussion of clause 7.5 of the New Zealand Guidelines, para. 3.6

[9] Animal trials suggest the safety of embryo biopsy, see for example, Cui K.H. et al. "Histopathological analysis of mice born following single cell embryo biopsy" (1994) 9 Human Reproduction 1146, and Cui K.H. et. Al. "Hatching rate – an optimal discriminator for the assessment of single blastomere biopsy" (1993) 10 Journal of Assisted Reproductive Genetics 157.

[10] Freeman, M. *"Saviour Siblings"* in McLean, S.A. *First Do No Harm* (Ashgate, 2006)

[11] Freeman, M. Above n10 at 399

[12] McLean, S "Saviour Siblings" in *Modern Dilemmas Choosing Children* (Capercaillie Books Limited, 2006) 90

parents never intended to raise the child, the mere fact of its existence means it has been benefited, not harmed,

> the life, which they would not have had in the in the absence of the desire to save an existing child is, therefore, *ex hypothesi* a benefit, even if it is not perfect.[13]

McLean concludes that if there is an instrumentalisation problem, it is best dealt with by taking care of the born child rather than not permitting these choices to be made. This is dependent on the view one takes on life and whether any life is always better than no life at all. McLean's position assumes that any life would be desirable over never having been born but such a view will not be shared by all. Even if a child is "taken care of" following birth, the environment it has been born in to, and the knowledge it has of the instrumental reason behind its birth, may be enough to make that child feel that having never been born would have been preferable to the life they live. A conclusion on this issue is entirely dependent upon one's fundamental views on the value of life. Therefore, while these arguments may seem entirely logical to some, it is doubtful that they would be enough to satisfy those that look upon the creation of a child solely to serve another's purpose as ethically and morally wrong.

Arguments concerning instrumentalisation tend to be based on the Kantian dictum that one should never treat a person simply as a means, but always at the same time as an end.[14]

A number of convincing points have been made to rebut this argument. Ram[15] raises the point that in defining personhood Kant makes reference to rationality. This is a characteristic not possessed by embryos or abstract future children so the application of the imperative to this situation may not be appropriate. More importantly, Kant counselled against *solely* using a person as a means to an end. If a donor child is also

[13] McLean, S. above n12
[14] Kant, I. *The Groundwork of the Metaphysics of Morals,* (Harper and Row, 1964)
[15] Ram, N.R. "Britain's new preimplantation tissue typing policy: an ethical defence" (2006) 32 Journal of Medical Ethics 278

wanted as a loved and cared for addition to the family, Kant's dictum can not be taken to speak against tissue typing PGD. As has been said,

> the birth of a child creates a powerful bond regardless of the circumstances of conception. Indeed, the fact that the parents are willing to conceive another child to protect the first suggests that they are highly committed to the wellbeing of their children, and that they will value the second child for its own sake as well.[16]

Sheldon and Wilkinson are quick to dismiss any argument based upon Kantian principles. They state that we all treat people as a means at some point and that most of the time it is completely innocuous. Every person who receives a blood transfusion has treated that donor as a means to an end and that action is never questioned.[17] This certainly shows that instrumentalisation does frequently occur and usually without controversy. However, the situation of a blood donor is not a sound analogy to 'saviour siblings'. Blood donations entail an important element that umbilical cord blood stem cell donations lack, the element of choice. A baby born following tissue typing PGD does not volunteer their tissue. This may weaken the blood donation analogy but it can not be denied that children are created every day for any number of 'instrumental' purposes for which they have no element of choice,

> Though we might aspire to a world where parents always dote on their children as unconditional ends, in reality many children are born for a purpose: to care for their parents, as a companion to a sibling, or to run the family business…Provided that parents love their child, there is little problem with that child benefiting others.[18]

These 'instrumental' purposes are different to the creation of a 'saviour sibling' as they involve no obvious, physical instrumentality but, given the lack of bodily intrusion or harm caused, it would be difficult to say that

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[16] Robertson, J., Kahn, J., & Wagner, J. "Conception to Obtain Hematopoietic Stem Cells" (2002) 32 The Hastings Center Report 3 34 at 35

[17] Sheldon, S. &Wilkinson, S. "Should selecting saviour siblings be banned?" (2004) 30 J Med Ethics 34 at 35

[18] Boyle, R. & Savulescu, J. "Ethics of using Preimplantation Genetic Diagnosis to select a stem cell donor for an existing person" (2001) 323 British Medical Journal 1240

they are any worse. In fact, it is hard to see a better use of instrumentalisation than to save the life of another.

Harris and Alghrani have commented that the fact that

> …the law insists that only those individuals who require assistance in founding a family are screened for their potential as prospective parents is…inconsistent and unjustifiable.[19]

When children are conceived naturally, parental motivations for their conception are seldom, if ever, questioned and the same should apply to parents reproducing through assisted reproductive technology. Parents of "saviour siblings" should be judged on the way they raise their child, not on their reason for creating that child.

2.4 Slippery Slopes and Eugenics

The final major ethical concern associated with tissue typing PGD is that it will set society on the slippery slope towards the selection of offspring based on desirable non-medical characteristics.

In the case of 'saviour siblings' there are two quite distinct situations to be considered. There are those cases where the embryo is at risk of a heritable disease so is screened for that disease as well as for its tissue compatibility with an existing sibling. Embryos are negatively selected based on the absence of a genetic disease and from these negatively selected embryos, those that have the necessary HLA type will be implanted. The second situation is where the affected sibling suffers from a sporadic disorder, meaning the embryo is at no greater risk of being born with the disease than the general population. In this situation the embryos chosen for implantation will be positively selected based upon tissue type. This second situation holds the greatest weight in any ethical argument concerning slippery slopes. It enables the positive selection of a genetic feature and may lead to acceptance of embryo selection based on non-

[19] Alghrani, A. & Harris, J. "Reproductive Liberty: should the foundation of families be regulated?" (2006) 18 Child and Family Law Quarterly 2 (191)

medical features such as height, eye colour, intelligence or even behavioural features[20].

There are typically two arguments raised under this "slippery slope" concern[21]. The first is that allowing embryos to be selected based on their HLA type will lead to acceptance of embryo selection based on any genetic feature. While it can not be said with any certainty that this will not occur, such an assumption is based on no more than speculation and speculation is not sufficient to outweigh the demonstrable benefits of tissue typing PGD. To give these fears too much weight would be to "overvalue anxiety at the expense of logic."[22] Furthermore, there is no reason why, through regulation, the purposes for which the technology can be used could not be restricted, allowing the creation of "saviour siblings" and prohibiting the selection of trivial or frivolous genetic features[23].

Fears that this technology may be seen as a eugenic attempt to eliminate the disabled from society can not be so easily dismissed. It is hard to avoid the conclusion that the genetic screening of potential offspring implies that people with the conditions being avoided do not lead valuable lives or perhaps even should not have been born at all. From this, it is a short step to a desire for a society in which there is no disability. Tissue typing PGD does seek to avoid the birth of disabled children and for someone suffering from such a disability the conclusion that their life is being deprecated would be hard to avoid. Robertson believes that,

> Society can demonstrate respect and concern for persons with congenital disabilities, for example, by protecting them against discrimination…without also depriving

[20] This concern will be covered in more depth in a later section when the New Zealand requirement that the embryo tested must be at risk of inheriting a genetic disease, is considered. See analysis of New Zealand Guidelines, clause 7.5, para. 3.6
[21] Sheldon, S. & Wilkinson, S. Above n17
[22] McLean, S. above n12 at 92
[23] Sheldon, S. & Wilkinson, S. "Hashmi and Whitaker: An Unjustifiable and Misguided Distinction?" (2004) 12 Medical Law Review 137

> other persons of the means to avoid having children with those conditions[24]

This envisages an ideal and rational world in which there are no existing prejudices against the disabled when it can not sensibly be claimed that this is the case. Prejudices do exist and the use of tissue typing PGD will only serve to reinforce them. However, this should not be used as a reason to prevent the use of tissue typing PGD. Tissue typing PGD may provide a means to further these prejudices but it is not their cause and a prohibition on the technology would not eliminate the issue from society. Every effort should be made to prevent prejudice and discrimination against the disabled but these efforts should be made alongside the use of the technology through refinement of current laws, procedures and organisations dealing with discrimination.[25]

The second argument is that the selection of 'saviour siblings' and the selection of embryos based on non-medical features are not morally distinguishable so if 'designer babies' should be banned, so should 'saviour siblings'. The problem with this argument is that the creation of 'saviour siblings' is well removed from the genetic selection of offspring, with the most obvious distinction being the ultimate goal of each. As Freeman has noted,

> in comparison to the goal of creating a 'saviour sibling', which is to save life, the reasons for seeking to design a baby pale into insignificance.[26]

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[24] Robertson, J "Procreative liberty in the era of genomics" (Winter, 2003) 29.4 American Journal of Law and Medicine 439 at 49.

[25] Laws are currently in place in New Zealand to deal with disability and discrimintation issues, with the two major pieces of legislation being the New Zealand Bill of Rights Act 1990 and the Human Rights Act 1990. New Zealand also has an Office for Disability Issues that is responsible for ensuring government observes the New Zealand Disability Strategy which provides a framework for removing barriers to the full participation of disabled people in society. These strategies focus upon integration and inclusion of the disabled in society which is very necessary but strategies to address underlying prejudices against the disabled may also be necessary to lessen any negative effect the use of tissue typing PGD may have on the disabled.

[26] Freeman, M. Above n10 at 400

There is clearly a difference between the selection of a 'designer baby' based on non-medical, trivial or frivolous genetic traits and the selection of embryos that will be a tissue match for a sick child. The fear of tissue typing PGD heralding the beginning of a slippery slope to the use of the technology in a manner detrimental to society is therefore flawed and is not sufficient to prevent the use of this technology to save the lives of sick children.

These ethical concerns are of much importance, they should not be forgotten or underestimated and need to be considered in the formulation of any regulation of this technology. However, these fears are not sufficiently substantiated to warrant a prohibition on tissue typing PGD. "Slippery slope" and physical safety arguments rest on what is at best speculation while fears of instrumentalisation can not be confined to this technology, and to allow such arguments would be unduly discriminatory towards parents reproducing through assisted reproductive technologies. These ethical concerns should therefore not be allowed to take precedence over the fact that tissue typing PGD can and will save lives. The current New Zealand Guidelines do recognise this utility by permitting certain uses of the technology. The three major ethical concerns outlined have clearly provided a basis for a number of the requirements and it must now be determined whether the weight they have been given is appropriate.

CHAPTER III: THE NEW ZEALAND GUIDELINES

Assisted reproductive technology in New Zealand is primarily regulated by the Human Assisted Reproductive Technology Act 2004 (the HART Act). The Act divides assisted reproductive technology in to three categories; "Prohibited procedures"[27]; "Assisted Reproductive Procedures"[28], which may not be performed without prior ethical approval[29]; and "Established Procedures"[30] that may be carried out without any need for approval.

The Human Assisted Reproductive Technology Order 2005, made under section 6 of the Act, declares which medical procedures are to be established procedures and therefore able to be undertaken without the need to first gain ethical approval. Importantly, preimplantation genetic diagnosis is one such procedure. However, when used in conjunction with HLA tissue typing, PGD loses its status as an established procedure and ethical approval is required before it may be undertaken. The body vested with the power to grant such approval is the Ethics Committee on Assisted Reproductive Technology (ECART). This committee is designated by the Minister of Health under section 27 of the HART Act.

The basis upon which approval is granted or denied is the 'Guidelines on Pre Implantation Genetic Diagnosis' (the Guidelines). These were prepared by ECART's predecessor, the National Ethics Committee on Assisted Human Reproduction, and were published in March 2005.
These guidelines are less than satisfactory. They lack clarity and are plagued by ambiguity. One is left with little or no certainty as to the definitions to be given to the terms and concepts contained within the guidelines and their intended method of application is also very unclear.

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[27] HART Act 2004, 1st schedule
[28] HART Act 2004, s5.
[29] HART Act 2004, s16
[30] s5 of the HART Act 2004 defines an established procedure as any procedure, treatment or application declared to be an established procedure under s6 of the Act. s6 allows these to be declared by the Governor General by Order-in-Council on recommendation by the Minister following advice from the Advisory Committee

Some form of guidance in this area is desirable. Without such regulation the commonly noted fears that this is just the "thin end of the wedge" leading to a society in which eugenic breeding prevails, may well gain some ground. If there is no limitation on the use of such procedures the moral values which are inextricably intertwined with such technology could well be lost sight of.

However, it seems highly unlikely that these particular Guidelines will be adequate to deal with a difficult application for approval for the use of the technology at the present time. It seems even more unlikely that they will be sufficient to cope with applications in the future following further progression of the technology.

Section Two of the Guidelines regulates uses of PGD requiring ethical approval and PGD with HLA tissue typing is the only procedure falling within this category.

3.1 Clause 7

Section two begins with Clause 7. This states that HLA tissue typing in conjunction with PGD must be submitted to the committee for ethics approval on a case-by-case basis and may only be carried out if the requirements in clauses 7.1 to 7.6 are met.

3.2 Clause 7.1

Clause 7.1 requires that

> the affected child[31] suffers from a familial single gene disorder or a familial sex linked disorder…

Of most uncertainty in this requirement is the phrase "suffers from". This is defined in the Oxford English Dictionary as "to be affected by"[32]. "Suffers from" is therefore clearly capable of describing the fact that a

[31] The affected child is the child intended to be treated by way of stem cell transplantation.

[32] *Oxford English Dictionary,* (Oxford University Press, 2001)

person has a disorder no matter what the extent or seriousness of that disorder may be. There is a whole spectrum of effects which a person can "suffer" when they are afflicted with a disorder. These can range from very minimal effects such as learning difficulties to those which are very severe and quite possibly life threatening.

The Guidelines do not contain an interpretation section, leaving one with no indication as to the extent of 'suffering' which must occur before approval will be given for an HLA matched embryo to be selected and implanted.

Reference to earlier sections of the Guidelines may provide assistance. Section One[33] requires that the embryo may be "seriously impaired" as a result of the disorder, thus implying a higher threshold than merely to 'suffer from'. While this could be the result of a drafting oversight, the higher standard set in Section One does suggest that "suffers from" was chosen to indicate that the level of suffering endured by the affected child needn't be so great as to seriously impair them.

A broad, literal and liberal interpretation such as this would have far reaching consequences when considered alongside the strong moral and ethical viewpoints on the issue. Saving the life of a sick child is often raised as a counter to the "slippery slope" argument - because another life is being saved, the selection of embryos based on their tissue type should be the one exception to a general ban on any form of positive genetic selection. This reasoning has also been employed to justify the creation and subsequent disposal of unwanted embryos because the intention to heal disease in another provides a non-trivial, and therefore acceptable, motive for the discarding of embryos[34].

These justifications would be largely nullified if "suffers from" was interpreted so as to include a child experiencing the effects of a disorder falling at a low level on the spectrum of impairment. Approval could be given where the affected child only suffered mildly from the disorder. A

[33] Section One of the Guidelines outlines uses of PGD that do not require ethical approval in order to proceed.

[34] Bellamy, Stephen, "Born to Save?: The Ethics of Tissue Typing" Paper prepared for "Science and Religion: Global Perspectives" June 2005, Philadelphia, USA.

child's life would not be saved or drastically improved in such a situation so fears of slippery slopes or disrespect for human life would not be quelled.

The statutory guidelines in Western Australia[35] require that the medical condition of the sibling to be treated be "life-threatening"[36]. In the United Kingdom, the Human Fertilisation and Embryology Authority (HFEA)[37] require that the condition of the affected child should be "severe or life-threatening".

These standards are more precise and certain than the New Zealand approach. They too will suffer from definitional difficulties but an element of seriousness is very apparent, particularly from the term 'life-threatening'. Those doubtful as to the ethical virtues of tissue typing PGD are more likely to find the procedure acceptable if it is undertaken to save the life of a child rather than to merely improve an already tolerable life.

An alternative approach to this problem was taken by The European Society for Human Reproduction and Embryology PGD Consortium (ESHRE).[3839]

The equivalent to the clause 7.1 requirement under the ESHRE guidelines avoids the issue of defining the required seriousness of the affected child's

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[35] Assisted reproductive procedures are governed by the Human Reproductive Technology Act 1991 (WA). The National Health and Medical Research Council has also issued guidelines on the Use of Assisted Reproductive Technology (NHMRC Guidelines 2004)

[36] NHMRC Guidelines 2004, para. 12.3.1

[37] A central, non-governmental licensing body set up in August 1991 as part of the Human Fertilisation and Embryology Act 1990. See n80 below.

[38] ESHRE has published "Best Practice Guidelines for Clinical PGD/PGS Testing" The guidelines state that they are not intended as rules and are not enforceable given differences in local and national regulations but that they are hoped to provide a minimum standard for PGD across all centres providing such services.

[39] The viability of taking in to account the approach of this group is highlighted by the fact that in the Introduction to the New Zealand Guidelines it is stated that the ethics committee "encourages New Zealand PGD providers to use the [ESHRE PGD Consortium] as an avenue for worldwide collaboration and *a way to promote best practice for PGD providers*". This indicates approval of the standard set in the European guidelines and may suggest that the ethics committee would have recourse to those guidelines should the ambiguities of the New Zealand guidelines cause difficulty in any decision being made as to approval.

disorder by setting the requirement in terms of the expected result of cord blood transplantation. It is required that the disorder

> is likely to be cured or life expectancy is seriously prolonged by stem cell transplantation…[40]

This is a preferable approach as it enables an objective, medically based assessment of the likelihood of a certain outcome and avoids the inevitable emotive factors involved in determining a child's current condition and categorising their degree of suffering. Uncertain terms such as "likely to be cured" mean this too can not be seen as a flawless approach but a goal of absolute certainty is unrealistic in the area of human health where broad variables are inevitable. The use of a term such as "likely" could actually be helpful in this respect as it is well recognised and its definition has been the subject of much legal scrutiny[41] which can only aid in achieving a higher level of certainty.

Clause 7.1 is insufficient in expressing the extent to which the existing child should be suffering. This problem must be addressed and the most effective means of doing so is to include a term more along the lines of the approach taken by ESHRE. Clause 7.1 should require that there is a likelihood the affected child will be cured or their life expectancy seriously prolonged by a stem cell transplantation.

3.3 Clause 7.2

Clause 7.2 requires that there be

> no other possibilities for treatment or sources of tissue available for the affected child.

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[40] Inclusion criteria specific to PGD: ESHRE PGD Consortium Guidelines

[41] In *Commissioner of Police v Ombudsman* [1988] 1 NZLR 385,404 McMullin J observed that "likely" may mean "something less in the scale of possibilities than something which is more probable than not". In *Re H(Minors)* [1996] AC 563, a case directed to the risk of harm to a child, Lord Nicholls of Birkenhead determined that the primary meaning of 'likely' is "probable, in the sense of more likely than not."

Some suggest that in setting such a requirement a statement is being made about the inherent wrongness of the procedure[42]. If there was nothing wrong with the use of the technology why would this stringent precondition be necessary? However, this clause could equally be seen as an attempt to reach a 'middle ground' between enabling utilisation of a beneficial technology and respecting the moral and ethical belief that embryos should not be destroyed[43]. It recognises the technology's utility by allowing tissue typing to occur whilst according some degree of respect to the embryo through ensuring the procedure is only undertaken when there are no other means available to treat the sick child.

This balancing of values is desirable but it loses much of its effect through a lack of precision and clarity.

Uncertainty exists in the term "no other possibilities for treatment". With every disorder there are multiple possibilities for treatment, each carrying its own probability of success. The simple requirement that there be "no other possibilities for treatment" leaves the door open for a literal interpretation that, should an alternative treatment exist, albeit one with a much lesser probability of success, PGD tissue typing could be declined on the basis that another possibility for treatment did exist.

The scope of the term "treatment" is also unclear. It could be taken to refer not only to conventional medical treatment but also to, for example, natural medicines[44]. Such a wide definition would raise the bar for ethical approval to an insurmountable level as for any disorder there is likely to be at least some form of treatment, obscure as it may be, available.
Common sense should dictate that such an interpretation is not adopted, however, the very broad and vague terms used in the Guidelines would not rule it out.

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[42] Gavaghan, C. "Designer Donors?:Tissue typing and the regulation of pre-implantation genetic diagnosis" [2004] 3 Web Journal of Current Legal Issues.
[43] See discussion of the various moral and ethical views on this issue, para. 2.1
[44] Treatment is defined in the Shorter *Oxford English Dictionary* (Oxford University Press, 2002) as "the application of medical care or attention to a patient…"

The requirement that there be no other sources of tissue available also lacks clarity and if interpreted literally, is never likely to be fulfilled. The opportunity for a transplant from a mismatched related donor or a matched unrelated donor will almost always exist. But such a transplant does not have the same likelihood of acceptance by the recipient's immune system as would a transplant from an HLA matched sibling[45]. In its report on preimplantation tissue typing[46] the HFEA, on the basis of expert opinion and literature review, concluded that related donors were preferable to unrelated matched donors and advised against the use of unrelated matched donors because of lower success rates and a higher risk of significant complications.

A source of tissue could also become available through natural conception followed by the selective abortion of non-HLA matched foetuses until a tissue matched child was conceived. This is surely less acceptable than tissue typing PGD yet a literal interpretation of the current guidelines would require it to be used before tissue typing PGD was approved.

A literal reading of clause 7.2 will lead to absurd results. In almost every case "other sources of tissue" will be available. The requirement may be an attempt to appease those with ethical concerns at the use of tissue typing PGD when it is not the only option, but its lack of clarity and precision defeats that purpose. Not only could it lead to an interpretation that is detrimental to the life of the affected child but it could also lead to the use of alternative procedures which raise moral and ethical concerns above and beyond those created by tissue typing PGD.

To have any sensible and meaningful effect clause 7.2 must be interpreted by the committee in a very practical and non-literal manner. As it is

[45] For example, it has been stated that the mortality rates in Fanconi's Anaemia (FA) when using an HLA-identical sibling donor, as compared to a non-related donor, are substantially lower. There is reported to be long-term survival in 75 to 100 percent of patients with FA after sibling donation compared to 18 to 33 percent survival following donation from an unrelated donor. (Wagner, Davies & Auerbach "Haematopoietic Cell Transplantation in the treatment of Fanconi Anemia" in Thomas, Blume and Forman, eds, *Haematopoietic Cell Transplantation* (Blackwell Science, 1999) 1204)

[46] Human Fertilisation and Embryology Authority Report: Preimplantation Tissue Typing, 2004

currently worded, they alone must determine the threshold as to the viability of other treatment possibilities as well as the extent to which other available tissue should be used. The wording is in need of change so as to avoid the absurdities capable of arising from such a broad clause.

In Victoria, Australia[47] the condition corresponding to New Zealand's clause 7.2 requires that

> in relation to the clinical management of the affected child, all reasonable possibilities of treatment and sources of tissue for the affected child should have been explored.

This formulation of the requirement is more workable and realistic. By incorporating an element of reasonableness, the Victorian condition removes the possibility of an overly literal interpretation and any consequently absurd results such as an obscure natural medicine being deemed a treatment possibility. More importantly, the Victorian condition refines the focus of the inquiry to the clinical management of the child. It avoids the uncertainty and possible ambiguity arising from the term "treatment" by enabling the extent to which other treatments are a viable alternative to be investigated and determined in accordance with the reasonable view of the affected child's clinical team.

The same is true in the United Kingdom where the HFEA requires[48] that any application to carry out the procedure is fully supported by the affected child's clinical team. They are expected to have given consideration to every other appropriate treatment before making an

[47] the Infertility Treatment Authority, under s106 of the Infertility Treatment Act 1995 (Vic) [47] has issued a policy on "Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis"

[48] Human Fertilisation and Embryology Authority Report: Preimplantation Tissue Typing (2004). This requires that applications be accompanied by a statement from the consultant responsible for the care of the affected child demonstrating that all possible alternative treatments have been investigated, including searches of bone marrow registries and cord blood banks, and to explain the reasons why preimplantation tissue typing is the preferred option. The Authority may require the application to be supported by an additional expert report on the suitability of using cord blood or bone marrow for the particular disease in question.

application and it has been made clear that tissue typing should be a last resort[49].

This is a more sensible and practical approach to a determination of treatment alternatives. The clinical team will have greater knowledge and insight in to the viability of alternative treatment possibilities and tissue sources than an external decision making body. A condition that, to their satisfaction, tissue typing PGD is the only reasonable or appropriate treatment option is far superior to a vague requirement that there are no other possibilities for treatment or tissue sources available.

3.4 Clause 7.3

Clause 7.3 requires that

> The planned treatment for the affected child will utilise only the cord blood of the future sibling

This clause succinctly addresses one of the major ethical concerns raised in relation to tissue typing PGD: that the "saviour sibling" will be the subject of unacceptable instrumentalisation, and be treated as a commodity rather than a person[50]. This is a very real and commonly held fear with one article going so far as to suggest that

> 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[51]

Clause 7.3 is attempting to overcome the fear that should the cord blood transplant fail, the donor child will be called upon to provide a bone marrow transplant or even to donate a "hard" organ.

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[49] HFEA Press Release *HFEA agrees to extend policy on tissue typing* 21 July 2004
[50] Sheldon, S., and Wilkinson, J. Above n17 at 137
[51] Wolf, S., Kahn, J. & Wagner, J. "Using Preimplantation Genetic Diagnosis to Create a Stem Cell donor: Issues, Guidelines & Limits" (2003) 31 The Journal of Law, Medicine and Ethics 3, 327

Tissue typing PGD is largely used to generate umbilical cord blood stem cells for transplantation but there is no medical reason preventing the selection of a 'saviour sibling' to provide an organ such as a kidney, liver or lung[52]. It is one thing to collect and utilise the cord blood of a new born baby as it is widely accepted that the harvesting of umbilical cord blood does not physically intrude on the newborn child or on the mother. It is quite another to harvest non-regenerative organs from that child as not only is there little certainty as to the safety of such procedures[53] but the removal of an organ involves a large degree of bodily intrusion.

HLA-matched siblings will be the best and most obvious source for any future tissue or organ transplant, so the intentions behind clause 7.3 are well grounded but the clause is ineffective in removing these concerns.
To expect the ethics committee to ascertain the parents' true intentions is unrealistic. It is not beyond belief that a couple, desperate to save the life of an existing child, will claim they 'plan' to utilise only the umbilical cord blood of the child, knowing full well that should that transplant fail they will desire the harvesting of further tissue. Furthermore, even the most well meaning and sincere plans are susceptible to failure as a result of unforeseen circumstances. While a couple may genuinely plan to use only the child's cord blood, that plan is unlikely to bear much weight if further down the track the affected child's life is at risk should it not receive a further HLA matched transplant.
This problem is compounded by the fact that once the application for tissue typing has been approved, the process has been undertaken and the embryo implanted, the committee will no longer have jurisdiction over decisions regarding the 'saviour sibling'. The fact that the ethics committee approved the application because the couple only planned to

[52] In VG Norton, "Unnatural selection: non therapeutic preimplantation genetic screening and proposed regulation" (1994) 41 UCLA Law Rev. 41 1581 it was reported that a family had conceived a child to provide a kidney for a sibling with chronic kidney failure
[53] "…whilst the practice of living organ donation has been shown to be safe both in the short and long term in large series of adult patients, such surgery is rarely performed in children and statements about safety of donation cannot therefore be made with the same degree of certainty." Webb, N. & Fortune, P. "Should children ever be living kidney donors?" Pediatric Transplantation 2006

use the cord blood of the child will be of no consequence to any future decision to use the bone marrow or other organs of the child.

This concern is not unique to tissue typing PGD, an on-going demand for tissue would be equally applicable to a naturally conceived, fortuitously HLA matched sibling. Once a 'saviour sibling' has been born and the umbilical cord blood harvested, he or she will have no different legal status to any naturally conceived child. The question is whether New Zealand's current laws are sufficient to prevent tissue matched siblings, however conceived, from being used as "spare part" siblings. This is somewhat removed from the current inquiry but must be briefly considered given the strong concern to avoid the instrumentalisation of 'saviour siblings'.

There is no legislation or case law in New Zealand directly relating to tissue donation from minors but if the donor child is under 16 years of age[54] they will be presumed incompetent and the right to give or refuse consent to any medical procedure[55] will generally fall to the child's guardian[56].

Bone marrow transplants from children are not overly invasive, harvesting is safe for the donor and discomfort following the procedure is usually mild. The overall risk of the procedure is low and for all ages of donors is comparable to that seen with other minor operative procedures[57]. In New Zealand these transplants are generally undertaken without recourse to a

[54] An exception to this may arise from *Gillick v West Norfolk and Wisbech A.H.A* [1986] AC 112 where the House of Lords held that some children are legally competent to consent to some medical treatment when they have reached sufficient age and understanding to weigh the risks and benefits of the proposed treatment.

[55] This right arises under s11 of the New Zealand Bill of Rights Act 1990 which gives everyone the right to refuse to undergo any medical treatment. In *Re S* [1992] NZLR 363, 374 Barker J noted that "everyone" is taken to mean "every person who is competent to consent". The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, Right 7(1) also gives the right to make an informed choice and to give informed consent.

[56] s36 Care of Children Act 2004

[57] Bortin MM, Bucker CD. "Major complications of marrow harvesting for transplantation." (1993) 11 British Journal of Haematology 916.

court for approval[58] and there is very little preventing tissue matched children from being used as a source of bone marrow[59].

This is emphasised in the case of 'saviour siblings' by the principles of the HART Act 2004[60]. The first principle[61] requires that

> The health and wellbeing 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.

If a bone marrow transplant would be detrimental to the health and wellbeing of the donor child then approval should not be given. However, there is no suggestion that the health and wellbeing of the 'saviour sibling' should be the only, or even the paramount consideration. It need only be *an* important consideration. This suggests that the legislature intended other considerations to be of equal importance and the health of the donee could be one of those equally important considerations. Medical opinion is that bone marrow transplantation is not detrimental to the health and wellbeing of the donor, the possibility of such a procedure should therefore not be enough for the ethics committee to deny approval for tissue typing PGD on the basis of clause 7.3.

'Hard' tissue donations would be more controversial as the loss of a non-regenerative organ could hardly be claimed to be in a child's best interests. World wide there is increasing reluctance to use children as solid organ donors and they are never used for donation of organs other than kidneys. This is emphasised by the World Health Organisation

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[58] Thomas, C. *Pre-Implantation Testing and the Protection of the "Saviour Sibling"* [2004] 5 Deakin Law Review 5

[59] A similar situation exists in the United Kingdom, the HFEA concluded that "a medical procedure may be carried out with the consent of a holder of parental responsibility if it is considered to be in the best interests of the child, a test which is often interpreted broadly, to include the child's psychological wellbeing. If…a bone marrow transplant would save the life of a sibling, it is likely to be in the best interests of the child, since to lose a sibling is psychologically damaging". (HFEA Report – Preimplantation Tissue typing, 2004)

[60] the HART Act 2004, s4 requires that "all persons exercising powers or performing functions under this Act must be guided by each of the…principles that is relevant to the particular power or function".

[61] HART Act 2004, s4(a)

principle that "no organ should be removed from the body of a living minor for the purposes of transplantation."[62] A parental request for the transplantation of non-regenerative tissue from one child to another is therefore highly likely to be refused by doctors or legally challenged[63]. Applying a "best interests"[64] test to any challenge, a court is unlikely to permit such a procedure to be undertaken.

The parents of a naturally conceived child could not legally use that child as a source of spare parts for a sick sibling and this position would not be altered merely as a result of the method of conception of the child. This conclusion is based on an assumption that the law would protect tissue matched children from exploitation by parents desperate to save another child but it can not be said conclusively that this will always be the case. However, any inadequacies in the current law protecting the rights of children should not be allowed to act as a barrier to the use of this technology. Clarification or reform of the law in this area would be a superior option to outlawing PGD upon a fear that tissue matched children will not be adequately protected.

The approach taken in the United Kingdom lends support to this view. The HFEA imposes no equivalent requirement to clause 7.3 of the New Zealand Guidelines and has stated that although

> it could not place conditions on a treatment license that would allow them to stop any future bone marrow

[62] World Health Organisation Guiding Principles on Organ Transplantation (1991) 337 Lancet 1470-1471, Principle 4.

[63] Under s31 of the Care of Children Act 2004, an eligible person can apply to the court (Family Court or High Court, see s30) for the child to be placed under the guardianship of the court or a court appointed agent. s31(2) defines an "eligible person" and would enable medical personnel (with leave of the court) or various members of the child's immediate family to make such an application should they object to a parental decision of organ donation. The High Court also has the inherent power of *parens patriae,* an ancient jurisdiction preserved by s16 Judicature Act 1908 that enables the court to protect subjects of the Crown that are unable to take care of themselves. This jurisdiction extends to minors and has been used by the courts to override parental refusal of consent so could conceivably be used to override a parental request for treatment. (Manning, J. "Parental Refusal of Life-Prolonging Medical Treatment for Children: A Report from New Zealand" (2002) 8 Journal of Law and Medicine 263 at 269)

[64] s4(1)(a) of the Care of Children Act 2004 would require the welfare and best interests of the donor child to be the first and paramount consideration in any proceedings under the Act.

> transplant from taking place…there are procedures designed to protect child bone marrow donors in place already and such a child would enjoy the same protection as any other child…[65]

As is the case in New Zealand, United Kingdom law does not explicitly acknowledge tissue and organ donation by minors but the HFEA took the view that a court would be extremely unlikely to approve the harvesting of hard organs from a minor[66]. A similar approach should be adopted in New Zealand. Medical practice in this country and around the world is such that a parental request for a hard organ transplant from a child is unlikely to be met with acceptance by medical personnel and there are avenues for requests to be legally challenged. This, along with the aforementioned difficulties in ascertaining the true intentions of parents with regard to future 'use' of the child, means clause 7.3 is essentially redundant and should be completely removed from the Guidelines.

3.5 Clause 7.4

It is required by clause 7.4 that

> the embryo will be a sibling of the affected child.

To enable a sensible reading of this clause, "sibling" must be given a wide interpretation. Rather than merely referring to a biological brother or sister, it must also mean that the two children will be brought up alongside one another in the same family[67]. Should it be read narrowly, ethically questionable possibilities could arise.

One such possibility is that the donor child could be adopted out following collection of the umbilical cord blood. Many, possibly most, people

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[65] Summary of the 113th meeting of the Human Fertilisation and Embryology Authority, 29 November 2001, www.hfea.gov.uk/aboutHFEA/Authority Minutes/2001/November2001

[66] Human Fertilisation and Embryology Authority. *Minutes of the seventh meeting of the HFEA ethics and law committee* 17th June 2004

[67] "Sibling" is not defined in the Guidelines. A broad definition of "sibling" can be found in s11F of the Education Act 1989: the children will be siblings if they share a common parent, a parent of one is married or in a de facto relationship with a parent of the other or "both children live in the same household and, in recognition of family obligations, are treated by the adults of that household as if they were siblings".

would regard this as unacceptable instrumentalisation of the child as the sole reason for its birth would be to harvest the umbilical cord blood. There are some with more liberal views in this regard. Robertson et al[68] question if such action would actually harm the child and whether parents should be legally stopped from doing so. The main justification used is that had the parents not decided to conceive the child it would never have existed and that the life of an adopted child is just as meaningful and fulfilling as that of any other child[69].

Irrespective of the manner in which the term "sibling" is interpreted clause 7.4 would prohibit tissue typing PGD being carried out in order to select an embryo that could provide a tissue match for a sick parent or some other family member. It is, arguably, less morally acceptable to select an embryo with the intention of saving a parent than it is when the intention is to collect tissue for a sibling as concern for another is being replaced by concern for oneself. Without the justification that the procedure is being used in a valiant parental effort to save a sick sibling, the moral basis of the technology becomes a lot less stable.

This view is not shared by all. It has been argued[70] that to think this, is to conflate morally acceptable actions with morally commendable actions. Gavaghan states that

> undertaking a physically, emotionally and perhaps financially demanding process such as IVF and pregnancy in order to save the life of another may perhaps scale heights of altruism and selflessness greater than undertaking these burdens to save one's own life. But that is not to say that the latter course of action is unacceptable.[71]

[68] Robertson et al. above n16 at 35
[69] Robertson et al. above n16 at 36
[70] Gavaghan, C. above n42
[71] Gavaghan, C. above n42

The author goes on to state that neither the Act governing assisted reproductive technology in the United Kingdom[72] nor the Common Law require parental motives to be purely non-selfish when they act on their child's behalf. He therefore questions why there is a higher standard set for parents who wish to utilise tissue typing PGD. The same could be said of the New Zealand legal situation.

The absence of an explicit prohibition on tissue typing to save a parent (or some other relative) in the Guidelines, could suggest that the idea was not entirely unfathomable to the drafters and has purposefully been left open for the future. There is support for such a proposition. Boyle and Savulescu ask:

> Who is harmed by allowing PGD to be performed solely for the benefit of a relative? Not the couple who wish to produce an embryo. Nor the child who would not otherwise have existed. Nor the person who receives the stem cell transplant that might save his or her life. We must avoid the trap of interfering with individual liberty by preventing such procedures for no good reason, simply out of the 'genophobia' that grips much of society today.[73]

The current situation in the United Kingdom also indicates increasing acceptance of this idea. The HFEA originally explicitly stated that tissue typing PGD was not to be used when the intended recipient was a parent[74]. However, it does not consider the prohibition to be final and has noted that further discussion is required on the issue[75]. Furthermore, in a report[76] released in January of 2006 the United Kingdom's Human Genetics Commission commented that

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[72] Human Fertilisation and Embryology Act 1990
[73] Boyle, R.J. & Savulescu, J. above n18
[74] 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* (HFEA Press Release Office): 1 August 2002
[75] HFEA, Minutes of meeting, 21 July 2004 "The committee takes the view that the situation in a case of this kind is ethically more problematic than that in a "saviour sibling" case and recommends that the matter be set aside for further discussion."
[76] Human Genetics Commission – *Making Babies: Reproductive Decisions and Genetic Technologies* 2006; pp1-99

> Although the HFEA has currently only permitted preimplantation tissue typing to save a sibling, and not a parent or other family member, this distinction could be difficult to maintain. If all lives are equally valuable, and it is generally good to save a life, whichever life it may be, it is arguably wrong to place limits on which lives can be saved by embryo selection.[77]

The chance of an embryo being an HLA match for a parent is very slim[78] and the number of stem cells that can be collected from umbilical cord blood is not presently sufficient to treat an adult but research aimed at overcoming this difficulty is currently underway.

Should this research prove successful, clause 7.4 should be deleted altogether. The arguments in support of extending the use of tissue typing PGD to save a parent can not be ignored. With growing acceptance of this technology distinction between lives to be saved through tissue typing will be increasingly difficult to maintain. Genetic limitations mean that the chances of an embryo being available for selection that is a tissue match for an unrelated person are practically nil. This will ensure that broadening the scope of recipients will not open the floodgates to such challenging concepts as the commercialisation of umbilical cord stem cell transplantation and so there seems little reason to restrict the use of tissue typing PGD to siblings of the donor child.

3.6 Clause 7.5

Clause 7.5 requires that

> 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.

Tissue typing PGD is prohibited when the sole aim is to ensure implantation of an embryo with an HLA tissue type identical to that of an existing child. If the embryo is not at risk of suffering from a heritable

[77] Human Genetics Commission. Above n76 at p51
[78] The chance is 1/200

disorder, tissue typing will not be approved. An identical requirement in the United Kingdom was removed in 2004[79], raising doubts as to the continuing justification for such a condition in New Zealand.

In the United Kingdom, the HFEA first produced a policy on preimplantation tissue typing in 2001[80]. That policy, by the authority's own admission, took a "cautious view of the science involved"[81] in PGD owing to a lack of knowledge of the consequences of the embryo biopsy on the child's development and future health. The policy was along very similar lines to the current New Zealand Guidelines, albeit with superior clarity and certainty.

In a major change to this policy, the HFEA announced in 2004 that the requirement that the embryos be at risk from the condition by which the existing child is affected would be abolished. A major impetus for this decision was the large amount of public attention generated by two highly publicised applications for use of the technology.

The first case was that of the Hashmi family. Three year old Zain Hashmi, suffered from the blood disorder Beta-thalassaemia (BT). BT is a hereditary disease and because both parents were carriers any child they produced had a one-in-four chance of being born with the disease. In an effort to provide Zain with a potentially life-saving transplant an

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[79] HFEA Press Release, *HFEA agrees to extend policy on tissue typing,* 21 July 2004

[80] HFEA Interim policy on preimplantation tissue typing, November 2001
(a) the condition of the affected child should be severe or life threatening, of a sufficient seriousness to justify the use of PGD;
(b)the embryos conceived in the course of this treatment should themselves be at risk form the condition by which the existing child is affected;
(c)All other possibilities of treatment and sources of tissue for the affected child should have been explored.
(d)the technique should not be available where the intended tissue recipient is a parent;
(e)the intention should be to take only the cord blood for the purposes of the treatment, and not other tissues or organs;
(f)appropriate implications counseling should be a requirement for couples undergoing this type of treatment;
(g)families should be encouraged to participate in follow-up studies and, as with PGD, clinics should provide detailed information about treatment cycles and their outcomes;
(h)embryos should not be genetically modified to provide a tissue match.

[81] HFEA Report: Preimplantation Tissue Typing, 2004

application was made to the HFEA for approval to use PGD in conjunction with HLA tissue typing. The intended result was the birth of a child who was not only free of BT but who was also able to provide Zain with the transplant of which he was in need. The HFEA granted this approval stating,

> Where PGD is already being undertaken we can see how the use of tissue typing PGD to save the life of a sibling could be justified. We would see this happening only in very rare circumstances and under strict controls.[82]

This prompted the HFEA to produce the 2001 Guidelines[83]. The decision to include the condition that the embryos conceived in the course of treatment should be at risk of the condition by which the existing child is affected went against advice given by the HFEA's ethics committee[84] and the importance of the distinction soon became apparent.

Michelle and Jayson Whitaker sought approval for tissue typing PGD in an attempt to treat their son Charlie who suffered from Diamond Blackfan Anaemia (DBA). There is no cure for this distressing disorder but a stem cell donation from an HLA matched sibling would give him a 90 percent chance of recovery. Despite the apparent similarities between this and the Hashmi case there was one crucial difference, DBA is not hereditary. The chances of Charlie's parents having another baby with DBA were no higher than that of the general population. To allow the procedure would be a clear violation of the condition that the embryos conceived in the course of the treatment should be at risk from the condition by which the existing child is affected. The Whitaker's application was rejected by the HFEA.

The HFEA's main justification for this decision was that the embryo biopsy may cause health risks for the resultant child and so should only be

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[82] HFEA press release, *'HFEA to Allow Tissue Typing in Conjunction with Pre-implantation Genetic Diagnosis'* 13 December 2001
[83] Above n80
[84] Ethics Committee of the HFEA, *Ethical Issues in the Creation and Selection of Pre-implantation Embryos to produce Tissue Donors,* 22 November 2001 at para. 3.14

undertaken when benefit would accrue to the embryo[85]. If the embryo is being tested solely for its tissue type all benefit arguably flows to the affected sibling.

Should a similar situation arise in New Zealand, this is the approach that would be taken under the Guidelines. ECART would deny approval for tissue typing if it was not needed in conjunction with screening for a heritable disorder.

In July 2004 the HFEA, having "carefully reviewed the medical, psychological and emotional implications" of tissue typing PGD, undertook a major policy reversal and made PGD licensable where tissue typing was the sole purpose of the testing[86].

Whether New Zealand should follow in the footsteps of the United Kingdom and abolish this distinction is a highly contentious issue. As was seen by the HFEA's original stance, the distinction is primarily based upon concern for the physical wellbeing of the resultant child following the embryo biopsy. Concern for the physical well being of the child is a very valid reason for such a distinction to be drawn but the grounds upon which this concern rests are now questionable. In 2001 when the distinction was first implemented in the United Kingdom there was little or no evidence available with regard to the health risks of embryo biopsy to the future child. It was felt that this lack of knowledge necessitated a cautious approach. A cautious approach as such is not criticised. However, the justification for such an approach is doubtful given that eight months prior to the release of the New Zealand Guidelines, the United Kingdom decided that a cautious and restrictive approach was no longer warranted.

To determine whether it was acceptable to overlook the United Kingdom policy change it will be helpful to consider the HFEA's reasons for its reversal.

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[85] Sally Sheldon & Stephen Wilkinson above n23. From a personal interview with Ann Furedi, then HFEA Director of Communications.

[86] HFEA Press Release, *HFEA agrees to extend policy on tissue typing,* 21 July 2004

The HFEA was solely concerned with the health of the future child, embryo death was not at issue[87] despite the knowledge that tissue typing PGD carried a risk of around five percent of damage to the embryo and that that damage was most likely to render the embryo unviable[88]. A major reason for ignoring this risk of embryo death was that the Warnock Report[89], the precursor to the Human Fertilisation and Embryology Act (UK), stated that,

> though the human embryo is entitled to some added measure of respect beyond that accorded to other animal subjects, that respect cannot be absolute…

This meant the focus of the HFEA was solely on possible non-fatal negative effects of the embryo biopsy.

This risk of rendering the embryo unviable could be sufficient justification for New Zealand's continued restriction on tissue typing alone if respect for the embryo dictates that it should not be put at risk when it will not receive any quantifiable benefit from the biopsy. Debate as to the moral status to be accorded to the embryo can clearly not be ignored[90] but in this context it is of little utility. In the area of assisted reproductive technology it has already been accepted that surplus embryos will be destroyed. The most basic idea of PGD is that excess embryos will be created and those that are not selected are more than likely to be destroyed. That this process can, by the Guidelines, be carried out without the need for ethical approval[91] is testament to the fact that embryo death has been accepted in such a situation. Further support for this approach can be found in the 'purposes' and 'principles' of the HART Act 2004[92] where no explicit

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[87] Ram, NR. Above n15
[88] HFEA Report: Preimplantation Tissue typing, 2004 at para. 13
[89] The Warnock Committee, Report of the Committee of inquiry in to Human Fertilisation and Embryology, Department of Health and Social Security, command paper 9314 (1984). London UK: Her Majesty's Stationery Office.
[90] See earlier discussion of the embryo's moral status, para. 2.1
[91] Guidelines on Preimplantation Genetic Diagnosis, 2005, Section One: Uses of PGD Not Requiring NECAHR Approval.
[92] Human Assisted Reproductive Technology Act 2004, ss 3 and 4

reference is made to the embryo or the degree of respect which it requires. The first purpose given includes the taking of

> …appropriate measures for the promotion of the health, safety, dignity and rights of individuals, but particularly those of women and children, in the use of procedures and research[93].

Women and children have been named here and there is no reason why particular reference could not have been made to embryos if their protection was to be a high priority in reproductive procedures.

Even if this 'purpose' requires measures to be taken to promote the dignity and rights of an embryo as an "individual" it is only "appropriate" measures that are required. The Act aims to "secure the benefit of reproductive procedures…for individuals and for society in general…"[94] and those benefits will hardly be gained if measures are taken to give the embryo a status that precludes destruction. Defining the embryo as an "individual" so as to gain this protection would also lead to absurd results when other principles are considered. For example, principle (d) holds that

> No assisted reproductive procedure should be performed on an individual…unless the individual has made an informed choice and given informed consent.[95]

An embryo is not capable of making an informed choice or giving informed consent so the term "individual" can not have been intended to encompass embryonic life.

The first principle[96] given in the Act also suggests that preserving the life of the embryo should not be a major factor in assisted reproductive procedures. That principle requires that

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[93] Human Assisted Reproductive Technology Act 2004, s3(a)
[94] Human Assisted Reproductive Technology Act 2004, s3(a)
[95] Human Assisted Reproductive Technology Act 2004, s4(d)
[96] s4 requires that all persons exercising powers or performing functions under the Act be guided by any of the principles that are relevant to that power or function.

> The health and wellbeing 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.[97]

The legislature has been explicit in requiring that resultant children are protected and has made no mention of a need to protect embryonic life.
The final principle does require that "the different ethical, spiritual, and cultural perspectives in society should be considered and treated with respect"[98]. A belief that an embryo has a moral status deserving of protection would be one of these perspectives. The fact that this is the last principle listed could indicate that it is of the least importance but that can not be said with any certainty. What can be said is that the principle merely requires such perspectives be considered and treated with respect. It doesn't give them precedence over any other factors or allow them to dictate decision making under the Act.

These purposes and principles make it clear that the legislature did not intend for a degree of protection to be given to the embryo that would justify the prohibition of reproductive technologies. The need for respect for the embryo should not be forgotten but without returning to debate the very foundations of reproductive technology, an argument that a risk of embryo death should negate a policy change to allow tissue typing alone is of little benefit.

The decision to include clause 7.5 must have been based largely on a concern for the physical wellbeing of the child. This is not easy to sustain when the findings of the HFEA are considered:

> in the majority of cases where the embryo continues to develop following the biopsy, the development of the

[97] Human Assisted Reproductive Technology Act 2004, s4(a)
[98] Human Assisted Reproductive Technology Act 2004, s4(g)

> embryo and subsequent development of the foetus and child is thought to follow a normal path.[99]

This followed a review of existing published studies, evidence collected by the European Society of Human Reproduction and Embryology and evidence from a paediatric follow up study at one UK centre and led to the conclusion that

> …the risk to the resulting child associated with embryo biopsy is not enough to warrant a policy which distinguishes between cases in which preimplantation tissue typing is used in combination with PGD for serious disease and where discovering tissue type is the sole treatment objective.[100]

Terms such as "…in the *majority* of cases…" and "…is *thought* to follow a normal path…" make it clear that the available evidence was not conclusive. The position was accordingly qualified by a statement that "there are as yet no long-term follow up studies of PGD offspring available…further follow up work is required"[101].

Lack of opportunity for long term follow up studies is not an adequate reason to deny families the chance to create a tissue match for a sick child. Families should be made aware of the fact that long term risks for the physical wellbeing of the future child have not been fully ascertained but given that all current data points to the safety of the procedure, to prevent the use of this technology until such time as a conclusive follow-up study is carried out[102] is to unnecessarily delay the opportunity for children to be born that could provide potentially lifesaving transplants for their sick siblings.

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[99] Human Fertilisation and Embryology Authority Report: Preimplantation Tissue Typing, 2004 para.13

[100] Human Fertilisation and Embryology Authority Report: Preimplantation Tissue Typing (2004) at para.14

[101] Human Fertilisation and Embryology Authority Report: Preimplantation Tissue Typing (2004) at para.14

[102] An effective follow-up study could take in the vicinity of another 15years as it will require waiting until a substantial amount of children born through PGD have stopped developing.

Sheldon and Wilkinson[103] have raised a very insightful and persuasive argument in this context. In discussing the aforementioned "net beneficiary principle", they have suggested that when there is a genetic disorder to be tested for, the embryo is not actually the recipient of any significant benefit above that received by an embryo not at risk of inheriting a disorder. PGD does not alter the embryo's genetic composition so if an embryo is found to be disease free following PGD it still would have been disease free in the absence of the PGD test. There is no benefit to the embryo other than an increased probability of being implanted and this implantation will only occur if the embryo is of the desired tissue type. The exact same criteria as that used for tissue typing alone. The harms and benefits of selection for an embryo are consequently equal in tissue typing PGD and disease testing PGD. This means that fears for the safety of the future child's physical health should speak equally strongly against disease testing PGD as against tissue typing PGD and to allow one and not the other defies common sense.

Having regard to this argument and to the approach of the HFEA in the United Kingdom it is clear that speculation as to potential risks to the physical health and development of the future child is not sufficient justification for New Zealand's retention of the requirement that the embryo must itself be at risk of inheriting a disorder for tissue typing PGD to be approved. This is not to say that clause 7.5 should be removed, the ethical arguments raised in favour of such a requirement may have sufficient strength to outweigh this conclusion and justify retention of the clause.

The main ethical argument in this context is that tissue typing PGD represents the first example of the positive selection of desirable genetic traits and that this heralds the beginning of the slippery slope towards eugenics and designer babies. When the procedure is undertaken solely to screen for tissue type the primary goal of the screening is to select an

[103] Sheldon, S. & Wilkinson, S. above n17

embryo with a particular genetic trait – HLA tissue type. For many, this opens the door to the use of PGD to select for desirable, non-medical traits such as intelligence, appearance, behaviour or sexual orientation. Alexander Hecht has warned of the technology evolving "unchecked into a new age eugenics movement where only the strongest and smartest babies are brought in to the world."[104]

The English Court of Appeal has wisely cautioned against the use of such terms as 'eugenics' and 'designer babies', stating that they suggest "personal indulgence or predilection and the luxury of real choice"[105] when this is clearly not the case. The use of such terms does invite conclusions to be drawn that are far out of proportion to the issues being faced. It is hard to find any moral or ethical equivalence between 'designer babies' and 'saviour siblings'. The two concepts involve vastly different goals with one aimed at saving life while the other merely fulfils trivial parental desires.

The use of the term eugenics is also inappropriate and unnecessarily emotive. David King has written that;

> In the conventional definition, the key aspect of eugenics is coercion of people's reproductive choices, for social ends, which may include improving the quality of the population, preventing suffering of future generations, or reducing financial costs to the state.[106]

Definitions such as this could encompass tissue typing PGD but they are unhelpful in this context, not least for the connotations of Nazi policies and state-imposed sterilisation automatically brought to mind. Tissue typing PGD is well removed from such practices. It is not imposed by the state[107] and is undertaken on an entirely voluntary basis. Furthermore, the

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[104] Hecht, A.N. "The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology" (2001) 1 Hous. J. Health L. & Pol'y 235 at 227

[105] *R(Quintaville) v HFEA* [2002] E.W.C.A Civ. 667 per Mance L.J. at para. 134

[106] King, D.S. "Preimplantation genetic diagnosis and the 'new' eugenics" (1999) 25 Journal of Medical Ethics 182 at 177

[107] Although, not all believe this to be a necessary component, King has written that "While it is true that in some countries eugenics movements succeeded in persuading the

primary goal of tissue typing PGD is the wellbeing of an individual or family, a genetically superior or perfect society is not the desired outcome. In practical terms, PGD can not, at this point, be used to screen for insignificant features such as eye colour let alone for complex features such as intelligence or behaviour. It is far from certain that testing for complex features will ever be possible as large numbers of genes are involved with complex interactions between them, the screening for which may never become a possibility. To add to this, environmental factors, for which a genetic test can not account, play a significant role in complex traits.

The creation of a 'saviour siblings' is well removed from eugenics and, even if similar in a practical sense, is morally and ethically distinct from the creation of 'designer babies'. The prospect of tissue typing PGD heralding the start of a slippery slope towards a society of designer babies and eugenics is fanciful and unrealistic. It is more a product of unsubstantiated fears than a true understanding of the scope and potential of the technology.

To see tissue typing PGD as setting us on a slippery slope to undesirable uses of this technology is an ill-informed view to take. There should be a recognised difference between choosing a trait that benefits another and choosing a non-medical trait that is of benefit to one's self. Furthermore, HLA type is not of the parent's choosing. The type selected for is the specific and only one which must be chosen if the sick child's life is to be saved.

To allow the selection of *any* genetic trait of the parent's choosing would be a morally challenging approach to take but this need not be the case. As was sensibly submitted by Sheldon and Wilkinson[108] it would not be difficult to avert a slide down the feared slippery slope through a

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state to support their aims, coercion was never an essential feature of eugenic theory. From its very beginnings, many eugenicists…were opposed to coercion, believing that if people were properly informed they would naturally make the "right" reproductive decisions." See King, above, n106.

[108] Sheldon, S & Wilkinson, S. Above n23 at 143

regulatory regime that allows the selection of genetic features in some situations but not others. In fact this already exists, the Guidelines allow tissue typing in some situations and prohibit it in others.

To prohibit tissue typing PGD when there is no disease to be tested for based on a fear of embarking on a 'slippery slope' not only wrongly equates the procedure with the screening in of desirable non-medical traits, it also underestimates the ethics and morals of the majority of society. History has shown that eugenic policies can have hideous consequences but a great majority of people have the moral strength to separate such ideas from a technology which can save the life of a seriously ill child. Ethical arguments concerning "slippery slopes" do not bear sufficient weight to overcome the mounting evidence that the embryo biopsy does not pose any significant risk to the future health and development of the child. New Zealand should follow the example of the United Kingdom and remove the requirement that an embryo be at risk of inheriting a genetic disorder before tissue typing PGD will be approved.

3.7 Clause 7.6

Clause 7.6 requires that the health and wellbeing of the family/whanau has been fully considered. The clause seems to be a 'catch-all' provision enabling approval to be denied even if all of the preceding requirements are satisfied. It enables the ethics committee to go beyond the strict confines of written rules and assess the true nature of the situation. There will be families who fulfil all the requirements for tissue typing PGD according to the letter of the rules but who, through their physical or mental health, are clearly not suited to such an intense and intrusive procedure. The stress and anxiety involved in assisted reproductive technologies can not be underestimated and a successful outcome is far from certain[109]. This, together with the huge financial burden[110] involved,

[109] The success rate for IVF alone is just 30% per embryo transferred (Wells, D. & Levy, B. "Cytogenetics in reproductive medicine: the contribution of comparative genomic hybridization (CGH)" (2003) 25 Bioessays 289) and PGD has a success rate of between 10-30% per cycle.

[110] The New Zealand government has recently announced public funding for 40 cycles of PGD per annum nationally but this is only available for couples at high risk of passing on

may be more than some families are equipped to cope with. In these situations, clause 7.6 could provide a means for approval to be denied.

Thus clause 7.6 is a legitimate and worthwhile tool in the Guidelines. However, just who should carry out such a consideration is uncertain. Families desperate to save a sick child can not be expected to be cooperative in any inquiry and some would understandably make every effort to conceal a family situation that could lead to approval being denied. Having the ethics committee make such an inquiry would be ineffective, they can not be expected to know and understand the family situation. It would be more appropriate for the clinical team to undertake the consideration. They will have spent much time with the family and will possess more intimate knowledge of the situation than an ethics committee could hope to gain from what could be no more than a brief and superficial investigation. This type of knowledge, knowledge of how the family really functions and its true capacity to cope with stressful and trying situations, could be more realistically relied upon as a true assessment of the health and wellbeing of the family.

Guidelines from other jurisdictions[111] do leave certain decisions, such as the viability of alternative treatments, to the discretion of the clinicians. New Zealand did not elect to go down this path. The entire assessment, including, it is assumed, consideration of the health and well being of the family, has been left to the ethics committee.

Such an approach is not without benefit. The Ethics Committee may be more capable of giving an objective and impartial assessment of the family situation. It would remove the inherent danger that the treating clinicians could form an emotional attachment to the family, clouding honest assessment, or that they would only account for medical matters and have no regard for the emotional wellbeing of the family. This, however, is a risk which should be taken. The necessary assessment of patients to whom a clinician has formed an emotional bond is a frequent

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a serious, single gene genetic condition. (Press Release *Funding to screen for serious genetic conditions* 205 at http://wwwbeehive.govt.nz/ViewDocument.aspx?DocumentID=24576)

[111] Western Australia and the United Kingdom. See clause 7.2 analysis, para. 3.3

aspect of medical work and it should be assumed that any professional is capable of maintaining unimpaired judgment in such a situation.

Clause 7.6 should be reformulated so as to make it explicit that consideration as to the health and wellbeing of the family/whanau be undertaken by the clinical team.

CHAPTER IV: THE STRUCTURE OF NEW ZEALAND'S REGULATION

There is an entire spectrum of regulatory possibilities for tissue typing PGD, ranging from the most liberal and permissive of policies to the most restrictive. At the present time, New Zealand has assumed the middle ground, with a possible inclination toward the restrictive. Certain uses of the technology are allowed but others, such as tissue typing when there is no genetic disorder to be tested for, remain prohibited. The approach taken in New Zealand is to require an application to be made for every use of the technology. Applications are assessed by an independent statutory body (ECART) on a case-by-case basis in accordance with the prescribed guidelines.

Consideration of the regulatory approach taken in two foreign jurisdictions, each assuming its regulatory position at opposite ends of the spectrum, may be of assistance in analysing the utility and appropriateness of the New Zealand approach.

4.1 Alternate Regulatory Methods in Foreign Jurisdictions

Germany, with its laws giving strong formal protection to embryos, occupies the conservative end of the spectrum. Embryos are constitutionally protected[112] and entitled to the same right to life and dignity as all living persons. It is not certain whether this constitutional protection extends to preimplantation embryos[113].

A strong German Catholic movement has had much influence in this conservative approach but of greater importance is the deeply held fear of a return to the atrocities and embarrassment of the Nazi regime and

[112] Article 1 of the German Constitution ("Basic Law") recognises that all persons have the right to life and Article 2 gives every person the right to "free development of his personality"

[113] Neuman, GL. "Casey in the Mirror: Abortion, Abuse and the Right to Protection in the United States and Germany" (1995) 43Am. J. Comp. 273. In 1993 a majority of the Federal Constitutional Court, in deciding that the unborn belongs to human life and so should receive the protection of the state, left open the question of the legal status of a fertilised egg prior to implantation. (BVerfGE 88,203) See Robertson, J, (2004) 3 "Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics" (2004) 43 Columbia Journal of Transnational Law 189 at 198

Holocaust. Upon assumption of power in 1933 the Nazis adopted a eugenic policy which required the killing of the mentally ill and deformed. This spawned the "final solution" whereby Jews, Gypsies and others not conforming to the "Aryan" biological model were exterminated. The effect of this on many German people has been an intense repugnance of genetic science and any reproductive technology capable of determining genetic composition.

The German legal framework severely limits any possibility of the utilisation of tissue typing PGD. The Embryo Protection Act 1990[114] is extremely protective of embryos, declaring them to be inviolable from the moment of conjugation (ie. the two cell stage). This, along with a prohibition on the creation of embryos that will not be transferred to the uterus, makes PGD a practical impossibility in Germany.

When assessed alongside other German laws concerning life before birth, this strict policy seems largely contradictory. It is suggestive more of a fear of new technology and misunderstanding of its potential than any realistic belief that it could return the country to the horrors of its past.
The relatively liberal abortion rules in Germany are a prime example of this with women able to obtain abortions as late as the 22nd week of pregnancy should that pregnancy be likely to produce a child with severe birth defects[115]. Some have labelled this a "glaring inconsistency"[116] and rightfully so. It is a bizarre policy that forbids embryos to be selected and discarded prior to implantation should they be at risk of genetic disease or defect and yet allows the termination of an established pregnancy on the same grounds. One commentator has perceptively noted that

> in Germany, the embryo is never better protected than when it is outside the woman's body during the first

[114] Gesetz zum Schutz von Embryonen (Embryonenschutzgesetz – EschG) [Embryo Protection Act], v. 13.12.1990 (BGB1. I S.2746) (F.R.G.)
[115] Robertson, J.A. above n110
[116] Robertson, J.A. above n113 at 223 at 198

> days of development – it has to be transferred before it is allowed to be aborted.[117]

To allow genetic selection in one situation and forbid it in another demonstrates a considerable lack of consistency. It makes a conclusion that the main driving force behind German policy is a fear and lack of understanding of new technology, not a repulsion of genetic selection, difficult to avoid.

This restrictive approach is in stark contrast to that taken in the United States of America where there is virtually no federal regulation of PGD. There is no central body regulating reproductive technologies and consequently no guidelines in existence on the proper use of PGD to create a stem cell donor. The same is true across the entire area of assisted reproductive technology. Citizens are free to practise abortion, contraception, assisted reproduction, and embryo research with the only federally imposed hindrance being that no state funding is made available to do so.

This lack of regulation has not gone without consideration and in March 2004 the President's Council on Bioethics issued a report noting that there is

> no authority, public or private, that monitors how or to what extent these new technologies are being or will be used, or that is responsible for attending to the ways they affect the health and wellbeing of the participants or the character of human reproduction more generally. [118]

Despite this, the Council refrained from proposing any form of regulation, stating that gaps in current information would make doing so premature

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[117] Ludwig, M. "Preimplantation Genetic Diagnosis: The German Situation" (2001) 17 Trends in Genetics 473

[118] The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies* (Mar 2004) at http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf

and that deep differences over the moral status of embryos would make any regulation problematic[119].

This strongly suggests an abdication of responsibility on the part of the Federal Government. Assisted Reproductive Technology is an area fuelled by strong ethical, moral and emotional viewpoints and on first analysis it would seem that to regulate, while keeping at least a majority of the people happy, is seen as a virtual impossibility by the government and so, by default, no regulation has been imposed. Such an analysis may be lacking in substance.

Reluctance to regulate on these issues must be considered alongside the fact that the country prides itself on fostering the ideals of individual liberty and grants of broad autonomy[120]. These ideals co-exist with strong religious views and expectations of religious freedom. The likelihood of conflict between these ideals and expected freedoms has led to a government solution that makes a sharp distinction between public and private spheres.

Procreative liberty is frequently voiced as a justification for maintaining the status quo and resisting state regulation of reproductive technology. The US Supreme Court has never explicitly recognised a constitutional right to procreate but statements it has made could be interpreted so as to suggest the existence of such a right. In *Skinner v Oklahoma*[121] the court held a state statute that required the sterilisation of individuals convicted of three offences to be unconstitutional, largely because it was an unwarranted intrusion on marriage and procreation. It was stated in obiter dicta that marriage and procreation were among the "basic civil rights of man" and "are fundamental to the very existence and survival of the race"[122]. This may imply a fundamental right to procreate but the statement was made over 60 years ago and it is by no means clear that it

[119] The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies* (March 2004) at http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf

[120] Robertson, J.A. above n113 at 194

[121] 316 U.S. 535 (1942)

[122] 316 U.S. 535 (1942) at 541

can be extrapolated so as to include a right to select the product of that procreation.

These contrasting methods of regulation are not based upon the same considerations. The practical statutory ban in Germany is founded on strong moral concerns about the status of the embryo and a deep fear of potential future uses of the technology. The prevailing concern in the US is the liberty and autonomy of its citizens[123] and the practical difficulties of imposing limits and restrictions in a country with such widely divergent viewpoints on the issue.

4.2 The New Zealand Approach

The most persuasive argument for a loosening of New Zealand's current regulatory regime would be one of reproductive autonomy. Oakley[124] has commented that reproductive autonomy concerns more than just the freedom to reproduce and the avoidance of involuntary reproduction but that it includes access to means of overcoming involuntary childlessness and infertility. This may be so but there is a difference between a right to assisted reproductive technology to overcome childlessness and a right to assisted reproductive technology to determine what kind of child will be born, or more accurately what genetic characteristics that child will bear.

In New Zealand, citizens have a statutory right to consent to and refuse medical treatment but these do not extend to a right to treatment aimed at predetermining the genetic characteristics of one's offspring.
Section 11 of the New Zealand Bill of Rights Act 1990[125] provides a right to refuse to undergo any medical treatment. While this would provide a right to resist reproduction by artificial means it can not be said to provide a statutory right to general reproductive autonomy.

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[123] Whether or not this is actually achieved is arguable given that there is no public funding of reproductive technology, leaving it out of reach for many people.
[124] Oakley, A. *Subject Woman.* (Fontana, 1985)
[125] New Zealand Bill of Rights Act 1990

The Code of Health and Disability Services Consumers' Rights[126] recognises a right to make an informed choice and give informed consent[127] but of most relevance in this context is the 'Right to Dignity and Independence'[128]. Every consumer is entitled to "have services provided in a manner that respects the dignity and independence of the individual". Respect for the dignity and independence of the individual could include respect for that person's moral and ethical values. Given that the restrictions on the creation of "saviour siblings" in New Zealand are primarily based on moral and ethical concerns about the technology, the Guidelines could be violating this right. An individual's dignity and independence is surely not being respected when the moral and ethical aspects of their reproductive decisions are being dictated to them.

Rights prescribed by the Code do not take precedence over the restrictions imposed by the Guidelines[129] but the existence of this right indicates that the New Zealand legislature is not oblivious to the desirability of a right to independent choice. This provides support for the proposition that, despite lacking an explicit statutory footing, individuals should have the freedom to make their own reproductive choices. Ronald Dworkin has defined this concept of reproductive autonomy as "a [couple's] right to control their own role in procreation unless the state has a compelling reason for denying them that control"[130] and it is based on one of the fundamental presumptions of liberal democracies, that the freedom of citizens should not be interfered with unless good and sufficient justification can be provided for doing so.[131] The restrictive nature of the Guidelines means the state does currently deny couples complete control

[126]. This Code was prescribed by the Health and Disability Commissioner Act 1994 and is contained in the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996
[127] Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, Reg2(2) Right 7
[128] Above n127, Reg2(2) Right 3
[129] The Code does not require a provider to act in breach of any duty or obligation imposed by any enactment. Above n127, Reg2(5))
[130] Dworkin, R. *Life's Dominion* (Harper Collins, 1993) 166
[131] Alghrani, A. & Harris, J. above n19

over reproductive decisions and it must be determined whether this restriction is justified.

That rights and freedoms may be limited by the state if there is a "compelling reason" to do so[132] is a broad test and one that is not capable of simple interpretation. Therefore, while accepting the general idea of this proviso, others have set a higher threshold for state interference, holding that a presumption in favour of liberty should only be rebutted in situations that would cause

> real and present dangers of significant harm either to individuals or society. It is not enough that others are made uncomfortable by its exercise, nor that they do not like it, nor that they find it repugnant.[133]

Could it therefore be possible that a presumption in favour of reproductive autonomy can be rebutted because to allow the positive selection of embryos based on the genetic characteristic of HLA tissue type could set society on the slippery slope towards eugenics and designer babies? A trip down that slippery slope would surely cause significant harm to society. While this argument was earlier dismissed as being either unrealistic or able to be dealt with through appropriate regulation, it may not be possible to be so dismissive should a complete right to reproductive autonomy exist. A belief that such a right exists and has precedence over any state attempts at regulation of reproduction would make it particularly difficult to draw a line between the acceptable and necessary medical selection of a genetic trait and the unacceptable selection of desirable or trivial genetic characteristics.

Speaking of PGD generally, one author has written that

> If we insist on absolute reproductive autonomy we must accept the use of genetic technologies to prevent the birth of those who are unwanted for any reason: that they will be the "wrong" gender, or sexual orientation or

[132] See for example, Dworkin, R. above n130
[133] Alghrani, A. & Harris, J. above n 19

> of short stature, or prone to obesity…Used this way, medical genetics will surely reinforce a host of social prejudices.[134]

There is little doubt that the complete non-regulation of means of genetic selection could pose a danger to society. History has shown that the pursuit of desirable genetic characteristics in a society can have dire consequences, consequences that should provide sufficient justification for state restriction on a right to reproductive autonomy. The quest for an HLA matched child can not be compared with the pursuit of desirable genetic characteristics and the consequences flowing from that. HLA type is a genetic characteristic but if it is to save an existing child it is not a genetic feature of the parent's choosing, it is the one and only type that can be chosen.

For this reason, the current regulatory regime in New Zealand can be commended. The Guidelines do impose restrictions on absolute reproductive freedom as citizens are prevented from using PGD in any way and for any purpose they desire. But these restrictions are necessary to enable the use of the technology for legitimate medical purposes, such as preventing disease or saving a child, while preventing it from being abused or utilised in a manner that could be detrimental to society.

This by no means permits a conclusion that the restrictions that have been placed on tissue typing PGD in New Zealand are appropriate. However, it can be said that the method of regulation being used, allowing restricted use of the technology following assessment on a case-by-case basis, is preferable to non-regulation based upon the recognition of a complete right to reproductive autonomy. It helps to quell the fear, and avoid the risk, that use of this technology would enable the creation of 'designer babies' or foster a 'eugenic' society.

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[134] Paul, D.B. *Controlling Human Heredity: 1865 to the Present* (Humanities Press,1995) 135

A complete ban on the use of the technology is a viable regulatory option. It avoids the need to take a stance on the ethically difficult concepts involved. It removes any fears generated from the fact that the physical and psychological effects on resultant children have not yet been fully ascertained. However, the technology provides a significant and important means by which sickness and disease can not only be treated but also completely avoided. To impose a complete ban on the use of tissue-typing PGD is to remove the possibility of saving the lives of sick children. It would deny couples the ability to bear offspring free from the fear of bringing a child in to the world inflicted with disease and destined to an early death or a life of suffering. Quite simply, a ban would lead to the death of children who could have been saved. Any justification for a statutory ban on tissue-typing PGD in New Zealand must be capable of overcoming these practical realities as "you have got to have a very powerful reason to resist the means by which a child's life can be saved."[135] In New Zealand, sufficient justifications do not exist.

To impose a complete ban would be to conclusively determine that the use of the technology is ethically unacceptable or that its potential future uses pose too great a danger for society. Taking such a view accords a great deal of weight to those carrying such ethical and moral convictions and fails to sufficiently acknowledge those who truly support the technology and are committed to its advancement.

Furthermore, the fact that New Zealand does not currently impose any restrictions on prenatal testing nor on the reasons chosen for abortion[136] means a complete statutory ban would be entirely inconsistent with current policy in this area.

New Zealand's current method of regulation, while far from perfect in its substance, is superior in structure to one of non-regulation or a complete

[135] Glover, J. Quoted in: BBC News. *Doctor plans "designer baby" clinic* 11 December 2001, http://news.bbc.co.uk/1/hi/health/1702854.stm

[136] There are no restrictions placed on the reasons for an abortion up to 20 weeks gestation. The law relating to abortion is governed by the Contraception, Sterilisation, and Abortion Act 1977 and the Crimes Act 1961 ss182-187A.

statutory ban. Ethical concerns as to instrumentalisation, slippery slopes and harms to the health of the resultant child are able to be addressed without allowing them to stifle medical advancement and technological development.

CONCLUSION

Tissue typing PGD is a technology capable of changing, improving and saving lives yet if not respected it could be detrimental to society as a whole. Moral, religious, ethical and political beliefs play a major role in shaping an individual's response to this technology and ensure that community consensus to regulation is a practical impossibility. A carefully crafted and flexible regulatory approach is necessary to accommodate these divergent views and to deal with the inevitable technological advancement in this area.

The Guidelines do attempt to strike a workable balance between ethical concerns and the desirability of saving lives. Embryo destruction is a necessary aspect of the technology but requiring that the existing child is suffering from a genetic disorder[137] and that there be no other possibilities for treatment or other sources of tissue available[138] seeks to ensure that embryos will not be frivolously created and destroyed when other options are available. The requirement that the planned treatment for the affected child will utilise only the cord blood of the future sibling[139] aims to protect the 'saviour sibling' from instrumentalisation through ongoing requests for tissue donation. Prohibition on the use of tissue typing PGD when the embryo is not at risk of the disorder from which the existing child is affected[140] is aimed at preventing the embryo from being put at risk when it will not receive any demonstrable benefits from the procedure and at ensuring society is not set on a slippery slope towards eugenics and designer babies.

Unfortunately, the intended effect of these requirements has been lost through a lack of clarity and certainty and the wording of the Guidelines is in need of revision. Clause 7.3, requiring that the planned treatment for the affected child will only utilise the cord blood of the future sibling, should be removed as it is impossible to foresee or enforce and adequate protection should be provided under present laws protecting children. The

[137] Clause 7.1
[138] Clause 7.2
[139] Clause 7.3
[140] Clause 7.5

requirements that the embryo be at risk of the disorder from which the existing child is suffering[141] and be a sibling of the existing child[142] are based on an outdated, overly cautious approach and should also be removed from the Guidelines.

In light of this, section two of the Guidelines should be revised[143]. In applying these revised Guidelines to each application, ECART must be guided by the principles of the HART Act[144]. Thus, while no explicit mention of the embryo is made in the revised guidelines, the Act requires that "the health and wellbeing of children born as a result of assisted reproductive procedures…be an important consideration"[145] so approval should not be given to any use of the technology that will be detrimental to the health and wellbeing of the resultant child. The principles also require that "the different ethical, spiritual, and cultural perspectives in society should be treated with respect"[146]. This should constantly be borne in mind by ECART and no decision should be made without all ethical, spiritual and cultural issues at least being considered. Finally, the first purpose of the Act[147] aims to secure the benefits of assisted reproductive procedures for individuals and for society in general. While the Committee will work under the constant pressure of conflicting ethical, cultural and spiritual beliefs the benefit and utility of tissue typing PGD should always be remembered and should not be denied to individuals and society without good reason.

The structure of New Zealand's regulatory regime should not be changed. A permissive regime with an independent body taking a case by case approach to each application is far superior to non-regulation or a complete prohibition on the technology.

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[141] Clause 7.5
[142] Clause 7.4
[143] See Appendix II
[144] HART Act 2004, s4. These "must" guide anyone exercising powers or performing functions under the Act and therefore apply to ECART as they are designated under s27 of the Act.
[145] HART Act 2004, s4(a)
[146] HART Act 2004 s4(g)
[147] HART Act 2004, s3(a)

The advent of this technology has introduced society to a whole new world of reproductive opportunities and New Zealand has acted sensibly in regulating and ensuring that these possibilities are kept in check. Revision and improvement will ensure the continued protection of society while at the same time according the necessary degree of consideration and compassion to those whose lives will be deeply affected by the regulation of tissue typing PGD.

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Section Two – Uses of PGD Requiring NECAHR Approval

PGD with Human Leukocyte Antigen (HLA) Tissue Typing

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

Affected Child

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

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

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

Embryo

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

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

Family/Whānau

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

Recommended Guidelines:

Section Two – Uses of PGD Requiring ECART Approval:

PGD with Human Leukocyte Antigen (HLA) Tissue Typing

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

Affected Child

7.1 the affected child is likely to be cured or his or her life expectancy seriously prolonged by stem cell transplantation.

7.2 all reasonable possibilities of treatment and sources of tissue for the affected child should have been explored by the child's clinical team.

Family/Whānau

7.3 the health and wellbeing of the family/ Whānau has been fully considered by the clinical team treating the existing child.