

Submission to the National Ethics Committee on Assisted Human Reproduction - 'Guidelines for Preimplantation Genetic Diagnosis in New Zealand'

December 2004

Law Foundation Project

This submission is based on work undertaken by Dana Wensley, Research Fellow in Bioethics, University of Otago, and funded by the Law Foundation of New Zealand in relation to the project that is looking into legal implications of human genome-based technologies for New Zealand. A substantial report has arisen from this body of research entitled '**Acceptable Limits of Reproductive Genetics' (July 2004)**. The report considers the question of how we should regulate preimplantation genetic diagnosis, and in particular what our response should be if new advances in genetics make it possible to test for conditions and traits that have nothing to do with the health status of the future child.

Summary of Submissions

The submission is generally supportive of the approach adopted by NECAHR and congratulates NECAHR on framing such comprehensive and thoughtful guidelines. The purpose of this submission is to raise a number of areas where clarification and (in a few cases) modification of the guidelines may be desirable. The areas where in my view further attention is necessary are summarised below. Details of reasons why these amendments are desirable are provided in the substance of the submissions at pp 8 – 19.

Familial single-gene disorders

1. The reference in clause 1.1 to 'the family mutation has been identified' should be clarified by changing it to read: (See p 8 of these submissions).

'the abnormality responsible for such a disorder has previously been identified in one of the parents'

2. The requirement in clause 1.2 that 'there is a 25 – 50 % risk of an affected pregnancy' is potentially too restrictive and should be changed to: (See p 8 of these submissions).

'there is a greater than 25% risk of an affected pregnancy.'

Serious abnormality

3. Guideline 5 relating to how decisions are made as to what is considered to be a 'serious abnormality' would benefit from more detailed guidance. I submit that an alternative approach which details factors that should guide the decision-making process should be provided. To achieve this result guideline 5 should be replaced with the following: (See pp 8 – 11 of these submissions).

'In reaching a decision about whether a condition constitutes a 'serious abnormality' for the purposes of these guidelines the following factors should be considered:

- ***the view of those seeking treatment of the condition;***
- ***their previous reproductive experience;***
- ***the likely degree of suffering associated with the condition;***
- ***the availability of effective therapy or management now and in the future;***
- ***the speed of degeneration in progressive disorders;***
- ***the extent of any intellectual impairment;***
- ***the extent of social support available; and***
- ***the family circumstances of the people seeking treatment.'***

Familial Sex-linked disorders

4. NECAHR's current guidance specifically excludes sex selection for medical reasons in some cases, namely where a specific test for the disorder is already available. I submit that this prohibition on the use of sex selection is neither ethically necessary, nor medically justifiable, and guideline 2 should be replaced with the following: (See pp 11 - 13 of these submissions).

'Sex determination for familial sex-disorders may only be carried out in cases where its object is to prevent a serious hereditary sex-linked disorder affecting the future child, and the basis for the disorder has been previously identified in one of the parents'

5. *If* the current approach adopted in the guidelines is to be retained, then the wording in clause 2.1 should be changed from 'no specific test for the disorder' to: (see p 13 of these submissions).

'no specific test for the particular mutation associated with the disorder is available'.

Human leukocyte antigen (HLA) tissue typing

6. The approach adopted by NECAHR that applications for HLA tissue typing be approved on a case-by-case basis is an ethically acceptable one. In considering these future applications NECAHR will need to take a number of factors into account. Subsequent submissions will be made on the question of HLA tissue typing, outlining how the proposed framework based on the welfare of the child (discussed at p 13 – 14 of these submissions) may be utilised by NECAHR in its decision-making in this area.

Equity and Access

7. Cost and accessibility are two of the most significant non-clinical ethical concerns arising from preimplantation genetic diagnosis. NECAHR's guidance states that the issue of funding is to be left up to the Government. I submit that questions of equity and rights of access are so *fundamentally important* and *inextricably linked* to the larger question of the ethical acceptability of the techniques themselves, that **before NECAHR allows any applications it should ensure that measures are in place to ensure that all New Zealanders have equal ability to access these services.** It is not ethically acceptable for PGD services to be available only to those who can afford the huge cost in accessing them privately (see p 14 of these submissions).

Prohibited Applications and the Question of Selecting for Disability

7. NECAHR's prohibition against couples selecting embryos with a genetic abnormality seen in a parent is too restrictive for two reasons.

- (i) It is not necessarily the case that a couple will seek *at the outset* of treatment to bring about the birth of a child with the same condition as themselves. A recent HFEA consultation into the matter raised the situation where a couple testing for one disorder found that they were at risk of another.¹ In this (hopefully rare) case a couple may feel that implanting the embryo affected by the

second disorder is their only opportunity for pregnancy, and may, in these *specific circumstances* choose to have the affected embryo implanted, for fear of losing the chance of having children at all.

- (ii) Even in the rare case that a couple does seek, from the outset, to bring about the birth of a child with the same condition as themselves, it is not necessarily the case that this decision is ethically unacceptable, or represents an 'abuse' or misuse of the process of PGD. (Reasons for this statement are provided at pp 15 – 18 of this submission).

8. What is important in the discussion on the ethical acceptability of 'chosen disability' is the welfare of the child resulting from the process, not whether he or she does (or does not) have a particular genetically inherited condition or trait. For some genetically inherited conditions it may be entirely appropriate for parents to select for children who share the same condition as themselves, for others it will not be appropriate and should not be allowed. Rather than imposing a blanket prohibition on using PGD to select a child with the same condition as his or her parents, a preferable approach would be for NECAHR to consider these applications on a case-by-case basis. For these reasons I submit that the prohibition in guideline 13.3 be deleted and a new guideline be inserted which reads: (See discussion pp 15 – 18 of these submissions).

'Chosen disability'

- 1. The use of PGD to select embryos with a genetic abnormality or with the same genetic condition seen in a parent is prima facie considered to be an unacceptable use of the technology.***
- 2. Applications to use PGD for these purposes must be submitted to NECAHR for ethical approval on a case-by-case basis, and will only be approved in the exceptional circumstances that the granting of such an application is consistent with the principle of the welfare of the child.***

The Principle of the Welfare of the Child: - A Proposed Framework for NECAHR's Future Decision-making

The guidelines provide for NECAHR to consent to PGD being used in a number of additional circumstances if approval is given on a 'case-by-case' basis. In reaching decisions on a case-by-case basis I submit that the framework developed in the report '**Acceptable Limits of Reproductive Genetics**' should be adopted by NECAHR. The framework is based on the principle of the welfare of the future child, and suggests a number of layers of considerations that should be taken into account before consent is given. The framework is an attempt to draw together various ethical concerns around the use of preimplantation genetic diagnosis, and has two main merits not yet seen in other frameworks. First, it emphasises the importance of the principle of the welfare of the child, and second, it contains an original mechanism by which the onus shifts from those who want to use technology, to those who want to prohibit its use, in certain circumstances.

The framework has been developed after a lengthy period of research into alternative approaches. It is both workable and comprehensive, which are almost mutually exclusive terms when dealing with any issues in reproductive genetics. Although the details of this framework fall outside the scope of this submission, a subsequent submission will be forthcoming, explaining the framework and detailing its use in a specific case study, namely the case of HLA tissue typing.

Introduction to Submissions

The question of how far we should go to regulate new genetic technologies such as preimplantation genetic diagnosis is not an easy one to address. NECAHR should be congratulated for its handling of such a thorny issue, and the scope of matters covered in its proposed guidelines. No position is, however, going to satisfy everyone's demands. The question of how much information about the genetic makeup of a fetus or embryo should be made available to parents, and what use they should be able to make of this information, is one of the most difficult questions in bioethics. It touches on questions of reproductive autonomy, rights of (and duties to) prenatal life, obligations to future generations, and wider social issues around the changing nature of parenthood and the position of the disabled in our society.

Some of the most troubling questions arising out of new genetic technologies emerge when we consider the question of how genetic knowledge can be applied in the context of reproduction. The fear is often expressed that as more advanced analysis of the human genome is undertaken, we will find more evidence of genetic links to conditions that have nothing to do with health and disease. It has recently been suggested that advancements in biotechnology may enable us to identify 'desirable genetic markers for intelligence, musicality, and so on, as well as undesirable markers for obesity, nearsightedness, color-blindness, etc'.² This raises questions such as those identified by NECAHR in its consultation document, around whether (and when) it is acceptable to use this information about our potential offspring to select one embryo over another.

Some of the most significant calls for caution in relation to the potential uses of PGD come from ethics committees that have devoted enormous time and resources to considering the ethical implications of emerging technologies. The report '**Acceptable Limits of Reproductive Genetics**' provides an in depth analysis and review of emerging principles relating to genetics, detailing position statements and policy from a wide range of organisations, including the Council of Europe's Steering Committee on Bioethics, the International Bioethics Committee of UNESCO, the World Health Organisation, the European Group on Ethics in Science and New Technologies, the World Medical Association, and of course the vast body of material coming from both sides of the Atlantic from the Human Genetics Commission, the HFEA, and the President's Council on Bioethics.³

These emerging ethical principles from overseas create an important 'operational framework' for New Zealand to reflect on when it considers approaches to regulation and policy in this area. There are two ways we can impose limits on technology. The first, is to prohibit the practice of that technology altogether, and this has been widely used in the case of reproductive cloning, sex-selection, and genetic modification. The second, is to allow those technologies which seem to operate at the 'borders of acceptability' to be used, but only under strictly controlled circumstances. The second type of control is the more difficult of the two to establish, and it is in this area that NECAHR functions. Enormous uncertainty and debate

surrounds how we limit potential applications of technologies such as PGD, while not prohibiting the technologies themselves.

The general approach that has been adopted in relation to PGD is to allow genetic analysis in the context of reproduction insofar as it enables parents to avoid the birth of a child with a serious health related condition. This use is widely considered to be ethically acceptable, although the manner in which this technology is used is still opposed by some groups. ***This submission supports the general approach adopted by NECAHR, but suggests that NECAHR gives further thought to how it will approach applications made to it for consideration on a case-by-case basis.***

Finally, NECAHR has identified the real need for some form of regulation to be introduced in New Zealand, to ensure that new reproductive technologies such as preimplantation genetic diagnosis are introduced in an ethically acceptable manner. While this submission raises a number of areas where it may be desirable to clarify the guidelines, it does not take issue with the general approach suggested by NECAHR. The aim of these submissions is to seek clarification on a number of matters, and to flag some areas where further guidance/ consideration would be desirable.

Detailed Submissions

1. Familial single-gene disorders

The guidance provides that:

'PGD for familial single-gene disorders may be carried out where:

1.1 the family mutation has been identified and

1.2 there is a 25–50% risk of an affected pregnancy and

1.3 there is a high risk of serious abnormality and

1.4 the option of prenatal testing alone is unacceptable to the couple.'

- 1.0 While it is consistent with overseas practice to limit PGD to serious genetic conditions, the limitations provided in the guidelines need clarification in the following matters.
- 1.1 The reference in 1.1 to 'family mutation' having been identified, is vague. A better approach may be to adopt an alternative terminology (such as along the lines that is used in France) and require that diagnosis may only be carried out where 'the abnormality responsible for such a disorder has previously been identified in one of the parents'.⁴
- 1.2 The requirement that the risk of an affected pregnancy be between 25 – 50 % could be seen as being too restrictive to those who have a *greater than 50%* risk of passing on a genetic condition to their offspring. I am sure that this was not the aim of the section. Although there are at present thought to be no conditions which confer a 50-99% risk, to allow testing for these couples (should this risk be identified) a better wording of clause 1.2 would be 'a greater than 25% risk of an affected pregnancy'. Some homozygous dominant couples may carry a 100% risk of passing the condition on to their offspring, but for these couples PGD confers no advantage, since all embryos will be affected anyway, and therefore there is no point to selection.⁵

2. Serious Abnormality

- 2.0 Clauses 1.3, 2.2, 3.1, all require that testing can only be carried out where (among other things) there is a 'high risk of serious abnormality'. The requirement that the condition tested for constitute a 'serious abnormality' is an understandable limitation on the availability of PGD, and is entirely consistent with practice overseas. The report

'Acceptable Limits of Reproductive Genetics' provides a comparative analysis of approaches taken in other jurisdictions to the question of 'serious abnormality'.

- 2.1 The report examines the position in countries that have placed tight restrictions upon the use of preimplantation genetic diagnosis, requiring that it is only used by couples with *serious and progressive hereditary diseases* which could lead to *premature death and for which no treatment is available*. This approach is compared with countries which do not require that the disease be progressive or lead to premature death, merely that there be a high probability that the child, if born, would have a *serious incurable disease*. More flexible approaches still are discussed, such as where preimplantation genetic diagnosis is allowed insofar as it can be used to detect a serious genetic condition, and there is no requirement that the condition be progressive, or incurable, or lead to premature death.
- 2.2 Different approaches have been used to determine what falls within the category of serious disease. NECAHR's guidelines do not propose a fixed list of conditions. This is consistent with approaches overseas. A fixed list is generally seen to be too inflexible, and one that threatens to categorise the births of those with conditions contained on the list as being 'undesirable'.⁶
- 2.3 I note that the guidelines specifically refer to approaches adopted in the UK and in Australia. It should be recognised that these approaches *do not provide a full view* of the varied responses to the question of regulation in the area of PGD. Many countries adopt a more restrictive approach than these two countries which NECAHR examines.
- 2.4 In **Sweden**, preimplantation genetic diagnosis can only be performed to diagnose severe and progressive hereditary disease leading to premature death for which no treatment or cure is possible.⁷ In **Norway**, Law N^o 56, August 5, 1994 provides that testing for preimplantation genetic diagnosis should be done only in cases involving a serious untreatable hereditary disease. In **Denmark**, the *Act on Assisted Reproduction in Connection with Medical Treatment, Diagnosis and Research* (N^o 460, dated June 10, 1997) allows preimplantation genetic diagnosis but its use is limited to cases where the future child is at significant risk of being affected by a serious genetic disorder or significant chromosomal abnormality.⁸
- 2.5 Some countries adopt an even more restrictive approach and prohibit preimplantation genetic diagnosis for *any* purposes although this position is increasingly being reconsidered. In **Austria**, the law on reproductive medicine (N^o 275 of 1992) is understood to implicitly prohibit preimplantation genetic diagnosis by providing that the use of cells capable of continued development for any purpose other than for medically assisted reproduction is prohibited, although there are a number of uncertainties

related to the application and scope of this law.⁹ In **Switzerland**, the Reproductive Medicine Act (*Fortpflanzungsmedizingesetz*) of 18 December 1998 (which came into force on 1 January 2001) prohibits the genetic testing of embryos by embryo biopsy, which effectively prohibits preimplantation genetic diagnosis except insofar as it may be possible to test without biopsy by light-microscopic investigation before transfer (*Article 5, s3*).

2.6 These approaches are all detailed in the report '**Acceptable Limits of Reproductive Genetics**' (pp 132 – 135) and provide an important reminder that the position adopted in the UK is one that establishes one of the most liberal regulatory mechanisms in the world in relation to uses of PGD. It is my view that we can learn from each of these different approaches, since they remind us that the question of ethical acceptability in the area of PGD has much to do with cultural values and beliefs about how we show respect to life, particularly prenatal life. How we tailor our approach to regulation in this area in New Zealand must be based on our commonly held ethical beliefs and a clear understanding of approaches that work well, and those that are already in need of refinement.

2.4 How NECAHR will view specific applications in relation to testing for **late onset conditions, susceptibility genes, carrier status and a combination of conditions** will need to be addressed by NECAHR as a priority. It is submitted that a further consultation process specifically addressing these matters be undertaken. The report '**Acceptable Limits of Reproductive Genetics**' provides a detailed analysis of the ethical concerns around using PGD to test in these circumstances, and describes the results and method by which public opinion has been specifically sought on these issues in the UK and United States.¹⁰ Further submissions will be forthcoming on these specific issues.

2.5 The guidelines use the term 'serious abnormality' as a means to limit the uses of PGD. Guideline 5 provides that:

'It is the responsibility of PGD providers, in collaboration with a genetic counsellor, to ascertain whether a familial disorder is likely to be serious in offspring of a particular couple considering PGD.'

2.7 This leaves the matter of serious to be determined by service providers and genetic counsellors, presumably after consultation with the particular situation and views of the family concerned. While this allows for the perception of risk of the couple concerned to be considered, it is not clearly stated how much weight needs to be given to this factor, or what other considerations are relevant. I submit

that an alternative approach which details factors that should guide the decision-making process should be provided. To achieve this result guideline 5 should be replaced with the following:

'In reaching a decision about whether a condition constitutes a 'serious abnormality' for the purposes of these guidelines the following factors should be considered:

- the view of those seeking treatment of the condition;***
- their previous reproductive experience;***
- the likely degree of suffering associated with the condition;***
- the availability of effective therapy or management now and in the future;***
- the speed of degeneration in progressive disorders;***
- the extent of any intellectual impairment;***
- the extent of social support available; and***
- the family circumstances of the people seeking treatment.'***

This submission is based on recommendations from an HFEA report which are reflected in the latest version of the HFEA's *Code of Practice* (2003).¹¹

3. Familial Sex-linked disorders

NECAHR's guidance currently provides that:

2. Sex determination for familial sex-linked disorders may be carried out where:

- 2.1 no specific test for the disorder is available and***
- 2.2 there is a high risk of serious abnormality and***
- 2.3 the option of prenatal testing alone is unacceptable to the couple.***

- 3.1 The area of sex-selection is one area of enquiry where much legal and ethical attention has been focused to date. From this high level of enquiry there has emerged an almost universal consensus that sex-selection should not be undertaken for non-medical reasons. NECAHR's approach is therefore entirely consistent with overseas guidelines / policy in this matter and, of course, the prohibition contained in the newly passed *Human Assisted Reproductive Technology Act*.
- 3.2 As NECAHR correctly identifies, sex-selection can be used for medical and non-medical (social) reasons. The report, '**Acceptable Limits of Reproductive Genetics**' (pp 163 – 172) describes three main reasons why parents may want to choose the sex of their offspring, (i) for medical reasons (i.e. to avoid the birth of a child who will have a sex-linked disorder such as haemophilia); (ii) for societal reasons (i.e. in some societies children of a particular sex may be valued above others) and (iii) for reasons of 'family balancing' (i.e. when the parents already have one or more children of one sex and seek to use preimplantation genetic diagnosis to ensure that they have a child of the other sex).
- 3.3 While NECAHR's consultation paper identifies these three reasons, the guidance *specifically excludes sex selection for medical reasons in some cases*, namely where a specific test for the disorder is already available. I submit that this prohibition on the use of sex selection is neither ethically necessary, nor medically justifiable. Personal communication with one leading geneticist also indicates support for the contention that the 'way should remain open' for sex selection for medical reasons, notwithstanding the presence of a specific test.¹²
- 3.4 It has been suggested that when a genetic disease is directly associated with a gender (as is the case in sex-linked conditions) it is sometimes easier to test for gender and choose the gender that will not have the disorder than to analyse the embryo for the condition itself.¹³ This practice is generally considered both a desirable *and* justifiable use of sex selection, despite the fact that a specific test could be used to examine all embryos. The parents are not choosing the sex of a child for non-medical reasons, they are merely choosing a child unaffected by a genetic condition, and using the most effective means to do so.
- 3.5 Further supporting the submission that the present restriction in NECAHR's guidelines be reconsidered is the fact that to date, sex-selection has been seen to be a problem because of the presumption that it will be used to select male embryos and discard female embryos. Sex selection for medical reasons, even in cases where there is a specific test for the condition, will be highly unlikely to result in a 'backdoor' selection of males over females. This

is because of the two hundred or so known sex-linked diseases (which range in severity from colour blindness to haemophilia and Duchenne's muscular dystrophy) most only affect males.¹⁴

- 3.6 I submit that for these reasons the present wording of the guidance is unduly restrictive and unnecessarily so. Universal moral principles exist that *support* sex-selection for medical purposes, even in the presence of a specific test for the condition in question. I submit that the current wording of clause 2 be changed to the following:

Familial sex-linked disorders

'Sex determination for familial sex-disorders may only be carried out in cases where its object is to prevent a serious hereditary sex-linked disorder affecting the future child, and the basis for the disorder has been previously identified in one of the parents'

- 3.6 Finally, the current wording of clause 2.1 is problematic in its reference to a 'specific test for the disorder'. For some conditions (such as muscular dystrophy) there are specific tests for *some* mutations but not for others.¹⁵ If the present approach is to be retained by NECAHR, then the wording should be changed from 'no specific test for the disorder' to 'no specific test for the particular mutation associated with the disorder' is available.

4. Human leukocyte antigen (HLA) tissue typing

- 4.0 The approach adopted by NECAHR in the guidance is an acceptable means to address the myriad of ethical problems associated with HLA tissue typing. The requirement that PGD for the purposes of HLA tissue typing be approved on a case-by-case basis is an important one to ensure that the process is not abused, or that fears associated with the procedure (i.e. that it signals the start of a 'slippery slope' in which children are created as a means to another's end, rather than valued as an 'end' in themselves) are addressed.
- 4.1 In considering applications for HLA tissue typing NECAHR will need to take a number of factors into account. Subsequent submissions will be made on the question of HLA tissue typing, outlining how the proposed framework based on the welfare of the child (discussed at p 5 of these

submissions) may be utilised by NECAHR in its decision-making in this area.

5. Equity and Access

- 5.0 Cost and accessibility are two of the most significant non-clinical ethical concerns arising from preimplantation genetic diagnosis. While a significant number of couples may undergo prenatal testing to determine whether their future offspring may have a genetic condition, only a few hundred babies have been born as a result of preimplantation genetic diagnosis world-wide. While prenatal genetic testing costs vary, most would be less than several thousand dollars, so that even if these are not met by the health budget, couples may be able to afford to purchase these services privately from a private service provider. In most countries, however, costs associated with prenatal testing are covered in the health care budget.
- 5.1 Costs for preimplantation genetic diagnosis, on the other hand, can be anywhere between \$10,000- \$100,000, depending on the centre involved in the testing and the number of cycles of IVF required. These costs are in most cases not met by the health care budget, causing preimplantation genetic diagnosis to be largely privately funded.¹⁶ This raises serious issues of equity of access.
- 5.2 NECAHR's consultation document highlights the question of how PGD services, if allowed by NECAHR, will be accessed by the general public. NECAHR states that the issue of funding is to be left up to the Government. I submit that questions of equity and rights of access are, however, so *fundamentally important* and *inextricably linked* to the larger question of the ethical acceptability of the techniques themselves, that **before NECAHR allows any applications it should ensure that measures are in place to ensure that all New Zealanders have equal ability to access these services.** It is not ethically acceptable to allow these services to be available only to those who can afford the huge cost in accessing them privately.

6. Prohibited Applications and the Question of Selecting for Disability

- 6.0 In 2003 the International Bioethics Committee published a report specifically examining the question of preimplantation genetic diagnosis and germ-line intervention.¹⁷ The report considered which constraints may be appropriate in relation to the use of genetic technologies, especially preimplantation genetic diagnosis. The Committee did not consider it had the moral authority

to make a general statement on the ethical acceptability of preimplantation genetic diagnosis, due to differing views held by its members in relation to the value of human prenatal life. It did, however, make specific recommendations in relation to the following:¹⁸

- **Sex selection:** Sex selection for non-medical reasons is considered to be unethical.
- **Donor siblings:** Embryonic HLA typing for fitness as a donor of blood stem cells after birth to save the life of a sibling is considered ethically acceptable *only* if it is carried out simultaneously with PGD for the disease concerned and if mismatching of the HLA type is not considered in itself as a basis for selecting against the embryo unaffected by the disease concerned.
- **'Chosen disability':** PGD to select and implant embryos with a similar genetic disease or condition as (one of) the parents is considered unethical.

- 6.1 In line with this, NECAHR's guidelines specifically prohibit the use of PGD for the purposes of selecting embryos with a genetic abnormality seen in a parent. Despite the position proposed by the International Bioethics Committee, the prohibition against 'chosen disability' contained in NECAHR's proposed guidelines is not one that is expressly contained in current regulatory mechanisms elsewhere, although the general tone of the *Human Fertilisation and Embryology Act* is that assisted reproduction techniques will be used for the purposes of *avoiding* serious genetic conditions and neither the Act (nor the *Code of Practice* arising from it) directly considers the possibility of using these techniques to *enable* a child affected by a genetic condition to be born.
- 6.2 The prohibition in the guidelines proposed by NECAHR is likely to receive significant challenge from disability rights groups. It is not necessarily the case that couple's will seek at the outset of treatment to bring about the birth of a child with the same condition as themselves. A recent HFEA consultation into the matter raised the situation of a couple testing for one disorder but tests revealing the presence of another.¹⁹ A couple may, in these circumstances, feel that implanting the embryo affected by this 'second' disorder is their only opportunity for pregnancy, and may choose to have the affected embryo implanted for fear of losing the chance of having children at all.
- 6.3 It may, of course, be that some couples will seek to use PGD to bring about the birth of affected child from the outset. It is understandable that NECHAR has sought to prohibit this activity since it *prima facie* seems to harm the child created from the process, and therefore be morally wrong.

- 6.4 The ethical question here, however, is whether it is morally wrong to deliberately seek to bring about the birth of a child with a 'disability'. Members of the deaf community, for example, may argue that being deaf is not a disability and that deafness, is not a disabling condition.²⁰ In support of an application to use PGD to select *for* a child who is non-hearing, they may additionally argue that non-hearing children *do better* with deaf parents than hearing children do.²¹ Similar arguments may be made by other members of the disability community, particularly those who do not consider their condition to be inherently disabling.
- 6.3 The question of what is, and what is not, a disabling condition is one of the most problematic (and controversial) in bioethics. This is extremely well highlighted by some valuable research conducted by Dorothy Wertz, who has demonstrated through her survey of attitudes of geneticists that the concept of disease and severity are relative terms.²²
- 6.4 Furthermore, there is no consensus even *within* the disability community as to what conditions are considered to cause a significant impairment in a future child, rather than just leave them 'differently abled'. Even some of those who strongly argue against the categorisation of disease and disability based on the 'medical model', are willing to accept that some conditions are so bad and affect the future quality of life of the sufferer so much, that it is appropriate to use genetic technologies to avoid the birth of those who would suffer from these conditions.
- 6.5 Rather than imposing a blanket prohibition on using PGD to select a child with the same condition as his or her parents, a preferable approach would be for NECAHR to consider these applications on a case-by-case basis. What is important is the welfare of the child resulting from the process, not whether he or she does (or does not) have a particular genetically inherited condition or trait. For some genetically inherited conditions it may be entirely appropriate for parents to select for children who share the same condition as themselves, for others it will not be appropriate and should not be allowed.
- 6.6 If NECAHR is committed to ensuring that its guidelines prohibit using PGD in ways that are detrimental to the welfare of the future child, it may consider more appropriate ways to achieve this result. It is my submission that the present prohibition on using PGD to select for a 'genetic abnormality' does not reflect the complexity of ethical concerns around using, and *not* using, PGD for these purposes. Alternative approaches should be sought, and awareness should be given to the fact that emerging research is now challenging our views of disability and enriching our understanding of how what many would consider to be a 'disability', may be regarded by the 'sufferer' as a normal state of being, contributing to their identity

and sense of belonging within a community through a shared common identity, customs, and experiences.

- 6.7 A fuller discussion of the complexity of issues around testing for, and selecting against, disability is contained in the report '**Acceptable Limits of Reproductive Genetics**'.²³ In addition to this, I have personally undertaken a large body of research on the disability rights critique of genetic technologies for the purposes of my Ph.D., and I would be happy to discuss with NECAHR alternative approaches to the question of 'chosen disability'. Of paramount importance to my mind is the belief that we must do everything we can to ensure that the welfare of any child resulting from the process of PGD is protected and promoted. I believe that there are alternative (and preferable) approaches to attain this result, rather than the blanket prohibition proposed by NECAHR in its current guidance. I have developed detailed guidelines for ethical bodies such as NECHAR to consider in considering these applications on a case-by-case basis, but for now I submit that the simplest solution for the purposes of the guidance is to delete 13.3 and replace it with a new guideline which reads:

'Chosen disability'

1. The use of PGD to select embryos with a genetic abnormality or with the same genetic condition seen in a parent is prima facie considered to be an unacceptable use of the technology.

2. Applications to use PGD for these purposes must be submitted to NECAHR for ethical approval on a case-by-case basis, and will only be approved in the exceptional circumstances that the granting of such an application is consistent with the principle of the welfare of the child.

Conclusion

The aim of these submissions has been to flag areas where I think further investigation of the issues and / or clarification of the proposed guidelines is desirable. Once again, I would like to reiterate my support of the general approach taken by NECAHR and congratulate them on their handling of some of the most difficult issues to arise out of advances in genetics to date. Should NECAHR be interested in discussing any of the matters raised in these

submissions further, or obtaining more detailed information on the research undertaken already for the Law Foundation project (specifically that contained in the report '**Acceptable Limits of Reproductive Genetics**') I would be more than happy to be contacted at some stage in the future.

¹ Human Fertilisation and Embryology Authority and Advisory Committee in Genetic Testing, *Consultation Document on Preimplantation Genetic Diagnosis* (November 1999).

² The President's Council on Bioethics, *Beyond Therapy: Biotechnology and the Pursuit of Happiness*, (Washington, D.C: October, 2003) p 39.

³ Wensley, D; *Acceptable Limits of Reproductive Genetics: A Discussion of Ethical Principles and Regulatory Mechanism of Control*, a report prepared for the New Zealand Law Foundation.

⁴ For an examination of the wording of relevant regulation in France, see Wensley, D; *Acceptable Limits of Reproductive Genetics: A Discussion of Ethical Principles and Regulatory Mechanism of Control*, a report prepared for the New Zealand Law Foundation.

⁵ Personal communication with Professor Stephen Robertson, Professor of Paediatric Genetics, Department of Paediatrics and Child Health, Dunedin School of Medicine, University of Otago.

⁶ For a discussion of problems around the question of 'line drawing' in relation to uses of PGD see Wensley, D; *Acceptable Limits of Reproductive Genetics: A Discussion of Ethical Principles and Regulatory Mechanism of Control*, a report prepared for the New Zealand Law Foundation, especially pp 201 – 211.

⁷ See Law N° 115 of March 14, 1991 and Instructions by the Ministry of Health and for Social Affairs on Prenatal and PGD (described in Comité Consultatif National d'Ethique pour les sciences de la vie et de la santé (CCNE), *Reflections Concerning an Extension of Preimplantation Genetic Diagnosis*, Opinion N° 72 (July 4, 2002).

⁸ See Law N° 460, dated June 10, 1997 (concerning artificial fertilisation) and Order N° 758, dated September 30, 1997 (concerning PGD).

⁹ Feichtinger, W; 'Preimplantation Diagnosis (PGD)-A European Clinician's Point of View' *Journal of Assisted Reproduction and Genetics* (2004) Vol 21. No. 1.

¹⁰ Wensley, D; *Acceptable Limits of Reproductive Genetics: A Discussion of Ethical Principles and Regulatory Mechanism of Control*, a report prepared for the New Zealand Law Foundation, especially pp 48 – 58, pp 138 – 145, pp 155 – 157.

¹¹ See discussion at pp 143- 145 of the report Wensley, D; *Acceptable Limits of Reproductive Genetics: A Discussion of Ethical Principles and Regulatory Mechanism of Control*, a report prepared for the New Zealand Law Foundation.

¹² Personal communication with Professor Stephen Robertson, Professor of Paediatric Genetics, Department of Paediatrics and Child Health, Dunedin School of Medicine, University of Otago.

¹³ See discussion in the report by the Working party on the Protection of the Human Embryo and Fetus (CDBI-CO-GT3) prepared for the Steering Committee on Bioethics, *The Protection of the Human Embryo In Vitro* (June 2003), p 35.

¹⁴ HFEA, 'Sex Selection: Choice and Responsibility in Human Reproduction' (2002), p9. X-linked disorders may be either *X-linked dominant* or *X-linked recessive inheritance*. Since a female has two X chromosomes, whereas a male has only one, X-linked recessive inheritance affects males almost exclusively. X-linked dominant condition can affect either male or females, although females are more mildly affected.

¹⁵ Personal communication with Professor Stephen Robertson, Professor of Paediatric Genetics, Department of Paediatrics and Child Health, Dunedin School of Medicine, University of Otago.

¹⁶ International Bioethics Committee of UNESCO, *Report of the IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention* (2003).

¹⁷ International Bioethics Committee, *Report of the IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention* (2003).

¹⁸ Ibid.

¹⁹ Human Fertilisation and Embryology Authority and Advisory Committee in Genetic Testing, *Consultation Document on Preimplantation Genetic Diagnosis* (November 1999).

²⁰ See discussion in Stern1, S; Arnos, K S; Murrelle, L; *et al*; 'Attitudes of deaf and hard of hearing subjects towards genetic testing and prenatal diagnosis of hearing loss' *Journal of Medical Genetics* (2002)39 pp 449-453.

²¹ Ibid.

²² Wertz, D; 'Drawing Lines: Notes for Policy Makers' in Parens E, and Asch A, (eds) *Prenatal Testing and Disability Rights* (Washington D.C. : Georgetown University Press, 2000) pp 261-287.

²³ Wensley, D; *Acceptable Limits of Reproductive Genetics: A Discussion of Ethical Principles and Regulatory Mechanism of Control*, a report prepared for the New Zealand Law Foundation, especially pp 31 – 38 and pp 201 – 211.