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CONSTRUCTING 'HEALTH', DEFINING 'CHOICE': LEGAL AND POLICY PERSPECTIVES ON THE POST- PGD EMBRYO IN FOUR JURISDICTIONS

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ABSTRACT

Through Preimplantation Genetic Diagnosis, embryos created by IVF are selected for transfer to a woman based on particular characterisations, including the presence of genetic markers or a tissue match for a sibling. In this paper we examine the precise language used in the recent policy and regulatory documents of four jurisdictions (the United Kingdom, Australia, Canada and New Zealand) that in any way characterises the post-PGD embryo. We then explore the mutually constructed relationship between how that embryo is characterised and the purposes for which PGD is applied, as well as the types of uses to which the post-PGD embryo is ultimately relegated. As our analysis indicates, based on the information provided through PGD, a number of possible categorisations of the post-PGD embryo emerge depending both on the outcome of PGD, and the initial intention behind the procedure.

I. INTRODUCTION

New technical possibilities, clinical considerations and research purposes are influencing both how we look at the embryo and what we look for.² By convention, the term 'embryo' refers to the product of fertilisation of a human oocyte by a human sperm usually up to the first eight weeks of development.³ Attempts have been made to characterise the human embryo from scientific,⁴ medical,⁵ ethical,⁶ religious⁷ and social⁸ perspectives, and have frequently been influenced by views, interests and objectives of particular communities.⁹ As observed in Australia, the legislative definition of 'human embryo' is 'a compromise between different views and resulted from the legal

imperative to have a defined point against which legal judgements could be made'.¹⁰ Heightened interest in defining and characterising the human embryo has resulted from the creation and manipulation of embryos outside of women's bodies for assisted reproduction¹¹ and, more recently, genetic testing.¹² Sub-definitions of the word 'embryo', such as 'pre-embryo' emerged in relation to *in vitro* fertilisation (IVF) and related genetic research.¹³ Research purposes, involving embryos created for the above clinical purposes, may also define characteristics of the human embryo.¹⁴

The characterisation of human embryos is influenced by and plays an important role in determining the possible uses and non-uses of an embryo by women undergoing IVF, clinicians and scientists.¹⁵ For example, there has been recent emphasis on selection of the 'best' or 'most suitable' embryo for implantation in order to have the highest pregnancy rate without the risk of high order multiple pregnancy¹⁶ including professional practice guidelines recommending single embryo transfer.¹⁷ As assisted reproductive technology (ART) extends to genetic testing through preimplantation genetic diagnosis (PGD), new characterisations of the embryo emerge based on the genetic information available.¹⁸ Through PGD, embryos created by IVF are selected for transfer to the woman¹⁹ based on the presence of genetic markers.²⁰ In addition, as new research opportunities arise, such as stem cell research, human embryos may be characterised in particular ways in order to promote research.²¹

In IVF laboratories prior to the advent of embryo cryopreservation,²²

microscopic determinations of embryo 'health' based on morphologic criteria, including evidence of cell division, lack of fragmentation, and blastomere symmetry and clarity, were undertaken in an attempt to determine the 'best' three (or more) embryos to transfer to the woman's uterus with the remaining embryos being discarded to avoid high-order multiple pregnancy.²³ For the past 15 years, embryos not transferred in the IVF 'treatment cycle' have been cryopreserved for later transfer to the woman so that she may avoid the harms of menotropin drugs²⁴ and oocyte retrieval surgeries²⁵ inherent in additional IVF cycles.²⁶ Some IVF clinicians and scientists continue to use microscopic criteria to determine which are the 'healthiest-looking' embryos in order to transfer the 'best' embryos while 'fresh' as they believe this practice achieves the highest pregnancy rate. However, no evidence exists that an embryo's potential to become a child can be ruled out on morphologic characteristics as viewed through a microscope, indeed there is evidence to the contrary.²⁷

The development and application of PGD provides another context in which determinations of the 'best' or 'healthy' embryo are made by providing access to a rapidly increasing number of gene markers.²⁸ These biomedical determinations may be used to prevent perceived 'health' problems in prospective children, or to select characteristics of a potential child.²⁹ PGD was developed in the late 1980s³⁰ as a technology that would allow women/couples to be able to assess particular markers of inherited conditions in embryos created through IVF rather than in fetuses. By assessing IVF embryos for inherited

conditions, and transferring to the women only the embryos that do not have the genetic marker, women/couples who are considering preventing having a child who could develop a particular genetic condition, would not have to consider the physically and emotionally stressful alternatives of amniocentesis or chorionic villous sampling³¹ followed by genetic abortion almost half way through the pregnancy (frequently after fetal movement has been felt).³²

Embryos undergo PGD when they have divided to the 8-cell stage (day 3 post-IVF) or the following day at the blastocyst stage.³³ It is also possible to perform PGD on 'polar bodies'³⁴ that are extruded from the eggs following the metaphase II division. When an 8-cell embryo undergoes biopsy for genetic assessment, all cells (blastomeres) are identical. One or two of these blastomeres can be removed from the embryo, usually without decreasing the embryo's ability to implant in the uterus.³⁵ To remove a blastomere, a tiny hole is made in the covering of the embryo (zona pellucida). This hole was originally made with a dissolving solution,³⁶ but now is usually made through a laser incision.³⁷ The blastomere is then removed from the embryo through gentle suction.³⁸ Chromosome number and structure are assessed through fluorescent *in situ* hybridisation.³⁹ The DNA in the blastomeres is multiplied using polymerase chain reaction.⁴⁰ When looking for a genetic marker embryos from which the blastomeres were removed may be transferred to the woman's uterus, or cryopreserved to be transferred in later cycles.⁴¹

The focus of our exploration is on what we refer to as the 'post-

PGD embryo' – those embryos that have undergone testing through PGD. We examine the precise language used in the recent policy and regulatory documents of four jurisdictions (the United Kingdom, Australia, Canada and New Zealand) that in any way characterises the post-PGD embryo. We then explore the mutually constructed relationship between how that embryo is characterised and the purposes for which PGD is applied, as well as the types of uses to which the post-PGD embryo is ultimately relegated. As our analysis indicates, based on the information provided through PGD, a number of possible categorisations of the post-PGD embryo emerge depending both on the outcome of PGD, and the initial intention behind the procedure.⁴² In the context of this examination we reveal how understandings of 'health' are being produced through the clinical practice and scientific application of PGD.

II.METHODS

Our research is based on the examination of documents from relevant government departments and agencies, research bodies and the policies and guidelines of various professional bodies, which relate to the practice of PGD in the United Kingdom,⁴³ Australia,⁴⁴ Canada⁴⁵ and New Zealand.⁴⁶

The documents examined contemplate the regulation and control of PGD as part of the governance of ART and the use of *in vitro* human embryos. In the relevant legislation of the jurisdictions

examined here, PGD is generally referred to only in limited terms,⁴⁷ or not specifically referred to.⁴⁸ We contend that the documents from regulatory and professional bodies examined here play an important, but under-examined, role in informing and shaping the clinical practice and scientific applications of PGD in such legislative regimes. Our examination of these documents will analyse the precise language through which characterisations of the post-PGD embryo occur. Further, we will explore how the resulting uses or non-use of post-PGD embryos are intertwined with understandings of 'health' emerging from the practice of PGD.

III. CATEGORISATION & ISSUES

Five overarching categories of characterisation of post-PGD embryos emerge from the analysis of the documents we examined:⁴⁹

1) the affected embryo; 2) the unaffected embryo; 3) the sex-selected embryo; 4) the HLA tissue-typed embryo; and 5) the carrier embryo.

Within each category issues related to assumptions behind the various categorisations of the post-PGD embryo, who makes decisions about categorisation, and what the implications of these processes and decisions are for women, people living with disabilities, practitioners, scientists and society-at-large, are discussed.

There are important differences in the way that each characterisation is constructed and determined in different jurisdictions as will be noted in our discussion. As well, these characterisations

are not mutually exclusive, rather the post-PGD embryo may fall into multiple categories at the same time, or shift from one to another depending on its possible use or non-use.

1. The Unaffected Embryo

An embryo that has been tested using PGD for genetic markers of a 'disease' or 'condition' and is free of these markers can be characterised as an *unaffected* embryo. This theme emerged from the documents in terms used to describe such an embryo, as 'healthy',⁵⁰ 'normal',⁵¹ 'disease-free',⁵² 'not known to have such an abnormality',⁵³ 'suitable',⁵⁴ as well as 'unaffected'.⁵⁵

The unaffected embryo is deemed to be 'suitable' for transfer or implantation based on its status as being 'disease-free',⁵⁶ 'without the genetic disorder',⁵⁷ 'free of the genetic disorder',⁵⁸ 'without a specific serious genetic disorder or chromosomal abnormality',⁵⁹ not having 'a copy of the faulty gene',⁶⁰ or that they 'do not carry markers for the condition in question',⁶¹ are 'not known to have such an abnormality',⁶² or 'do not have a particular gene mutation'.⁶³

Only post-PGD 'embryos that are predicted to be unaffected'⁶⁴ are implanted in the woman, providing 'an opportunity to begin a pregnancy knowing that only unaffected embryos have been transferred'.⁶⁵ As recent policies in New Zealand,⁶⁶ Australia,⁶⁷ and the UK⁶⁸ proscribe 'the number of embryos transferred is kept to a minimum'⁶⁹ including the possibility of a single-embryo transfer⁷⁰

to avoid the problems associated with multiple pregnancy and the 'health' problems of the children born prematurely thereof.⁷¹ As with all IVF embryos, post-PGD embryos that are 'no longer required'⁷² for the reproductive purposes for which they were created, may be described as 'remaining',⁷³ 'supernumerary',⁷⁴ 'spare',⁷⁵ 'surplus'⁷⁶ or 'excess'.⁷⁷

The way embryos are classified under one of these terms differs across jurisdictions as do the ways in which they can be used for either reproductive or research purposes beyond the reproductive needs of the woman or couple for whom they were created.⁷⁸ The unaffected embryos that are 'remaining',⁷⁹ could be 'destroyed',⁸⁰ 'stored for later use',⁸¹ 'placed in storage',⁸² or 'used for research purposes',⁸³ as well as donated to 'another individual'⁸⁴ for 'reproductive purposes'.⁸⁵

It is in this context that unaffected embryos are characterised, in some documents, as 'healthy'⁸⁶ or 'normal'.⁸⁷ While 'healthy' is not used as a general descriptor of the unaffected embryo, it has been used to refer to 'unaffected' embryos in discussions about the disposition of embryos that will not be used for reproductive purposes, either because there are more unaffected embryos than are needed for implantation, or because PGD is being used to select for a tissue-match or against a carrier embryo. In these situations the ethical dilemma is framed in regards to the disposal or use of unaffected embryos deemed 'healthy' as a result of PGD. By implication the disposal or use of affected post-PGD embryos is not seen to pose the

same ethical issues.

We contend that a characterisation of 'health' based on the outcome of PGD is problematic as only specific and limited genetic markers are identified, and therefore 'health' is understood as the absence of these markers and the conditions they are associated with in living persons. As the HGRP cautions, 'PGD is not a guarantee of a healthy baby'.⁸⁸

PGD is not a guarantee that any resulting pregnancy and child will be perfect, or even healthy. The genetic testing can only find what is looked for so, whilst a fetus may be free of the Tay-Sachs disease it was screened for, it may be born with cystic fibrosis.⁸⁹

The HFEA has pointed out, through the use of PGD '...the woman makes a decision about suitability based on information about the genetic status of the embryo',⁹⁰ and it is clear that genetics is only one of many factors in the overall health of a child. In our view, the characterisation of the post-PGD embryo based on 'health' is further problematised by the implication of such statements that while limited in its scope, PGD could ultimately determine the health of an embryo. Moreover, no critical comment about what the word 'health' implies in relation to disabled persons is included in these statements.⁹¹

2. The Affected Embryo

'The Affected Embryo' emerged as a characterisation of post-PGD embryos which have been determined to have markers for a genetic condition and are described by terms such as: 'known to have a gene, chromosome or mitochondrion abnormality',⁹² 'affected'⁹³ or those that have been found to have a genetic 'anomaly',⁹⁴ 'mutation',⁹⁵ an 'abnormality',⁹⁶ 'a genetic disease',⁹⁷ a 'serious genetic disorder',⁹⁸ 'serious genetic defects',⁹⁹ 'genetic abnormality or disease',¹⁰⁰ 'serious genetic abnormality or a disease',¹⁰¹ or 'genetic conditions incompatible with life, or with a life of quality'.¹⁰²

These post-PGD embryos are generally also characterised as 'unsuitable for implantation',¹⁰³ 'not suitable for implantation',¹⁰⁴ 'unsuitable for transfer',¹⁰⁵ 'not suitable for reproductive use',¹⁰⁶ 'unfit',¹⁰⁷ 'unfit for transfer',¹⁰⁸ and 'not fit for implantation'.¹⁰⁹ Generally post-PGD embryos characterised in these ways have been 'rejected',¹¹⁰ 'allowed to perish',¹¹¹ 'stored',¹¹² 'destroyed',¹¹³ or 'discarded'.¹¹⁴ The HFE Bill requires that these embryos 'must not be preferred'.¹¹⁵ However, there is an emerging demand for such embryos as a supply of 'fresh' embryos for 'research, training and improvements in clinical practice'.¹¹⁶ In the jurisdictions we examined PGD is currently applied in cases of X-linked conditions, 'numerical chromosomal abnormalities',¹¹⁷ specific gene mutations or 'single-gene defects'.¹¹⁸

a. The Seriously Affected Post-PGD Embryo

The term 'serious' is invoked in a number of jurisdictions as a threshold from which to distinguish between current and acceptable applications of PGD and those characterised as 'trivial or [for] social reasons'.¹¹⁹ Despite widespread reliance on the term, there is no agreed upon definition of what 'serious' means in any of the jurisdictions we examined.¹²⁰ The HGC has stated that, '[i]t has proved impossible to define what 'serious' should mean in this context'.¹²¹

The HFEA's *Code of Practice* specifies that PGD will be available 'only where there is a significant risk of a serious genetic condition being present in the embryo',¹²² while the HGC recommends that PGD should be limited to 'specific and serious conditions'.¹²³ The *HFE Bill* introduced in the House of Lords in November 2007 would amend the HFE Act to limit 'embryo testing' for 'gene chromosome or mitochondrial abnormality' to cases where 'there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other medical condition'.¹²⁴ Or in the case of identifying the sex of an embryo, to 'serious' cases of 'gender-related physical or mental disability', 'illness', or 'medical condition'.¹²⁵ In their 2005 report on the use of PGD for 'lower penetrance susceptibility conditions', the HFEA suggested, '[h]ow serious a condition is depends on how having the condition affects, threatens or limits the life of the individual'.¹²⁶ In their view, a condition that will not 'cause someone to suffer or detrimentally affect their life' would be 'unlikely to be regarded as

serious', whereas a condition that requires 'regular invasive treatment, or was life-limiting or life threatening' would be.¹²⁷ Following this report the HFEA announced a policy approving the use of PGD for BRCA 1 and 2, genes linked to breast cancer, and HNPCC genes linked with colorectal cancer,¹²⁸ arguably opening PGD wider than their previous practice of limiting the application to high penetrance¹²⁹ and early onset conditions.¹³⁰

The HFEA does not provide a definition of 'serious', leaving it to 'discussion between the people seeking treatment and the clinical team'¹³¹ to determine. The *Code of Practice* outlines factors to be considered in determining when PGD is appropriate, including consideration of the perspective of the woman, or couple, and the family situation, available support, as well as the nature of the specific condition in question.¹³² Interestingly the original *Draft Bill* would have amended the HFE Act to require the consideration of five factors in determining whether embryo testing is 'necessary or desirable', including the extent of impairment, the age of potential onset, rate of degeneration, the proportion of those with the 'abnormality' who are 'affected', and the reliability of the test,¹³³ but excluding the perspectives of the woman and her partner or the family circumstances.¹³⁴ However, this provision was not included in the HFE Bill under consideration by the House of Lords in 2007.

In Health Canada's consultation document on the regulation of PGD the use of PGD for 'medical/health reasons' is distinguished from its use for 'non-health related traits such as hair or eye

colour'.¹³⁵ Health Canada cites the 'serious condition' standard as a limitation on the use of PGD around which there is some agreement, but acknowledges that it would be 'difficult to define' and that 'there are many complex factors that need to be accounted for in this definition'.¹³⁶

In New Zealand's PGD guidelines, one of the conditions for the use of PGD in the case of 'familial single gene disorders', 'familial sex-linked disorders' and 'familial chromosomal disorders' is 'evidence that the future individual may be seriously impaired as a result of the disorder'.¹³⁷ The determination of seriousness is not defined, but subsection six of the guidelines provides that '[i]t is the responsibility of PGD providers, in collaboration with a clinical geneticist, to determine whether a disorder is likely to be serious in the offspring'.¹³⁸ In this scenario the woman and her partner or family are absent from the determination of 'seriousness'. The New Zealand guidelines initially included the wording 'high risk of a serious abnormality' rather than 'evidence that the future individual may be seriously impaired' which appears in the final approved guidelines.¹³⁹ The HGRP report argues that this shift opens up the range of disorders that might be considered to be included by providers, particularly disorders of late onset in which there is only a risk that the condition will present at some point in the future.¹⁴⁰

The 'seriousness' standard can be critiqued from a number of perspectives. In the case of some conditions, '[a]lthough PGD can confirm the presence of a genetic anomaly, it cannot predict

the extent to which the *in vitro* embryo, if transferred into the womb and born alive, would be affected as a child or adult'.¹⁴¹ This becomes particularly problematic in the use of PGD for 'later onset' disorders such as Alzheimer's or 'low penetrant' conditions.¹⁴² Further, understandings of what constitutes 'suffering', what might be considered 'detrimental effects', and when a condition is 'life limiting' or 'threatening' are subjective and depend on a number of factors in relation to both the individuals and family involved, as well as the particular condition in question.¹⁴³ As the HFEA itself suggests 'these factors may be difficult to predict before the affected person is born'.¹⁴⁴

Evidence shows that 'people with genetic disorders, their families and professionals have different views about which conditions give rise to a poor quality of life. In general, those who have a direct experience of living with a genetic disorder are likely to rate the quality of their lives more highly than would medically qualified professionals'.¹⁴⁵ As discussed below, the approach of the HFEA and Western Australia to consider the perceptions of people seeking IVF and PGD in determining 'seriousness' highlights the subjectivity of such a determination. While the UK legislative review dismissed the critics use of the word eugenics 'as an emotive term of abuse to obscure rational debate',¹⁴⁶ concerns about who is defining what a 'serious' condition is, and on what basis, have not adequately been addressed by policy or professional guidelines for PGD, particularly in light of the shifting nature of 'seriousness'. Rather than confronting

the complexity of such determinations and their consequences, our analysis reveals that the legal and policy approaches tend to privilege 'medical' or 'scientific' objective criteria, rather than more subjective considerations, implying that 'seriousness' can somehow be defined outside the context of people's lives and experiences.

b. Licensing, Power, and Reproductive Autonomy in the Detection and Handling of the Affected Post-PGD Embryo

In 2005 the HFEA altered the approval process for PGD licences such that once approval for a particular condition in one clinic has been granted, other clinics with 'proven expertise in performing embryo biopsies' will not have to go through the full licensing process to be approved for the same condition, using the same technique.¹⁴⁷ Thus while there is no formal 'list' of approved conditions, in practice particular applications of PGD will form an 'accepted list of conditions'.¹⁴⁸

In Australia, while research on human embryos is governed nationally, the regulation of PGD falls under state jurisdiction. Many states rely on the Commonwealth regulatory regime governed by the NHMRC's Ethical Guidelines, which restrict PGD to conditions that 'seriously harm' .¹⁴⁹ However, some States do have specific legislation governing ART and PGD. In Western Australia the RTC advises that the 'seriousness of a genetic disease should be

considered in the broad context of the environmental and personal factors of the participants'.¹⁵⁰ Licence applications for PGD should include the report of a 'clinical geneticist' in relation to a number of factors including: the family's 'experience with, and attitude to' the condition; the 'level of impairment to body functions and structures that is usually associated' with a condition; the difficulties expected in 'participating in activities such as learning and applying knowledge, communication, mobility, self care, employment, community, social and civic life; the 'level of support' required and the 'capacity of the family' to provide it; and the 'prospects for new and longer term treatments and interventions for the condition'.¹⁵¹

In Victoria the ITA's PGD policy uses the criteria outlined in s.8(3) of the *Infertility Treatment Act* 1995 that a 'genetic abnormality or disease might be transmitted to a person born', but they do not provide a definition of a genetic disease or abnormality.¹⁵² The policy 'entrusts' such a determination to 'the specialist with qualifications in human genetics ', explicitly putting the physician in the role of 'gatekeeper' in relation to PGD.¹⁵³ The Authority's 3-tiered approach to the regulation of PGD includes a schedule of 'Approved Genetic Testing' published in June 2006 which outlines the 'routine' uses of PGD that do not require notification of application.¹⁵⁴ The ITA also includes uses of PGD that 'require approval on a case by case basis' such as sex-linked conditions where there is 'inconclusive evidence about the transmission of that condition' including Autism and Asperger's Syndrome.¹⁵⁵ Conditions not covered by the schedule

would require 'prospective notification' to the authority.¹⁵⁶ Approval in these situations requires fulfilment of the s. 8(3) criteria of a 'genetic abnormality or disease', based on the advice of a 'doctor with specialist qualifications in genetics'.¹⁵⁷

Access to PGD in Canada 'is currently controlled by the medical profession',¹⁵⁸ however, 'there are no Canadian standards or professional guidelines relating to the use of PGD in Canada'.¹⁵⁹ Falling outside of formal regulation, decisions relating to PGD are privately made by the women, or couple, with her doctor.¹⁶⁰

The HGRP points out that in New Zealand the professionals involved with PGD have been given 'a broad mandate to determine what constitutes a disorder that could cause serious impairment in a future child, and the likelihood of it happening'.¹⁶¹ They distinguish between the role of clinicians in the determination of the 'likelihood of a disorder manifesting in prospective offspring' (which they see as 'generally unproblematic'), and their role in determining 'what constitutes a serious disorder'.¹⁶² In their view, this determination involves both 'objective considerations' such as the age at which a disease would emerge or the potential of prevention and/or therapy, and 'subjective considerations' such as the 'experience of the prospective parents in relation to the condition'.¹⁶³ The report considers the possibility that 'by leaving such decisions in the hands of treating clinicians, rather than in those seeking the procedure, PGD cannot be represented as providing greater autonomy and reproductive freedom'.¹⁶⁴

Respect for reproductive autonomy is invoked as a justification for placing determinations of 'seriousness' in the private realm.¹⁶⁵ Leaving decisions about PGD to a 'discussion between the people seeking treatment and the clinical team' is presented as a way to balance 'respecting the views of those seeking PGD whilst preventing the use of technology for purposes that are widely considered to be unacceptable'.¹⁶⁶ While we support the primacy of women's role in determining what reproductive choices are best for herself and her family, we caution that respect for reproductive autonomy should not be invoked to allow policy makers and clinicians to avoid complex and difficult questions about the potential impact of reproductive and genetic technologies on understandings of 'health' and 'normalcy'. Questions about how the use of technologies like PGD will affect broad social norms about family and being human¹⁶⁷ or how '... reproductive choices are being made against a background of inadequate social support for, and widespread discrimination against, disabled people and people with genetic disorders'¹⁶⁸ should not be sidestepped or kept behind the closed doors of the clinic.

c. Relationship of PGD and Traditional Prenatal Diagnosis

Until the new *Code of Practice* was released in 2007¹⁶⁹ the HFEA maintained that the 'indications for the use of PGD should be consistent with (though not necessarily the same as) current practice

in the use of prenatal diagnosis',¹⁷⁰ while the Royal College of Obstetricians and Gynaecologists, in their response to the review of the HFE Act,¹⁷¹ stated that the conditions for which PND is allowed should be the 'minimum' for which PGD can be applied. Such a regulatory approach would have mirrored that in place for PND with a similar approach of 'general guidance' rather than 'a list of specific conditions'.¹⁷² While the current *Code of Practice* no longer considers the relationship between PGD and PND, it is nonetheless revealing to examine how it has been presented in the development of PGD policy.

It is often argued that PGD is a preferable practice to PND for at least two reasons: it is less traumatic for the woman because of the avoidance of termination of a pregnancy¹⁷³ and it facilitates a moral distinction that is made between 'an unimplanted embryo and a fetus in an established pregnancy', which serves to justify the application of PGD in situations where termination would rarely be considered.¹⁷⁴ However, a number of concerns follow from this hierarchical ordering of the *in vitro* embryo in relation to the fetus and of PGD versus PND. For example, what effect might the imputed moral distinction between the *in vitro* embryo and the *in utero* fetus have on attitudes to abortion and women's reproductive autonomy? Arguably, it could become less socially acceptable for women to seek abortions following PND in light of an ethical preference for the use of PGD – a practice that is both expensive and invasive.

An additional consequence of regarding PGD as more ethically

acceptable than PND entails a shift away from characterising the purpose of screening and diagnosis as the provision of information for potential parents through which they can decide to terminate a pregnancy, *or* prepare for the birth of a child with a particular condition.¹⁷⁵ The HGC contends, in relation to PND, that '[c]urrent clinical best practice rejects the notion that women will necessarily end a pregnancy after the identification of a fetal abnormality'. In the case of PGD there is no pretence that given a positive diagnosis the woman could or would choose to have a child with a genetic condition, in fact in some jurisdictions such as Victoria and New Zealand, this would be prohibited.¹⁷⁶ In Australia, embryos identified as affected by PGD are now defined under s.7(1) of the RIHE Act as 'unsuitable for implantation' by law as a result of the recent amendments in the Patterson Act.¹⁷⁷ It is important to consider what effect this subtle shift towards a presumption of selecting out genetic conditions may have on our attitudes to people living with them, and also towards parents who choose not to use PGD or PND to select out genetic conditions.¹⁷⁸ Already people with disabilities and their families experience high levels of discrimination and a lack of social support.¹⁷⁹ Will the expansion of PGD, in which de-selection of such conditions is presumed and normalised, exacerbate the exclusion and inequality faced by people with disabilities?

d. Disposition of the Affected Post-PGD Embryo to Research Purposes

As illustrated above, the 'affected' post-PGD embryo is generally considered to be incompatible with reproduction. Characterised as 'unsuitable'¹⁸⁰ or 'unfit',¹⁸¹ the affected embryo is assumed to be 'discarded',¹⁸² 'allowed to perish',¹⁸³ or undergo other steps that will result in their 'disposal',¹⁸⁴ or 'destruction'.¹⁸⁵ The 2005 legislative review in Australia found that due to the cryopreservation requirements for the donation of 'excess' embryos, 'embryos that are not suitable for implantation for any reason, including embryos that are found to have a genetic disease using preimplantation genetic diagnosis, are allowed to die and are not available for research'.¹⁸⁶ Our analysis reveals that the characterisation and disposition of the post-PGD affected embryo are shifting, and we suggest that this driven, at least in part, by the demand for embryos for research and training purposes.¹⁸⁷

Following the 2005 legislative review, debates in Australia suggest that designation as an affected embryo may signal a shift in an embryo's potential purpose and/or value. On the one hand, the value of the affected embryo for reproductive purposes is diminished, since it is assumed that the intention of undergoing the diagnostic procedure is to avoid transfer of an embryo affected by the genetic condition for which it is being tested.¹⁸⁸ However, on the other hand, the affected embryo becomes potentially valuable for research and

training purposes.¹⁸⁹ Indeed, in a recent consultation on embryo research in New Zealand, the ACART singled out post-PGD embryos as a specific source of surplus embryos for research purposes.¹⁹⁰

ACART proposes the use of post-PGD embryos for research purposes since 'they may never be transferred to a woman's uterus'.¹⁹¹ Likewise the question of whether the post-PGD affected embryo should be considered to be available for research and training based on the presumption that it would otherwise be 'discarded'¹⁹² was prominently discussed in the 2005 Australian legislative review and has since been the subject of major amendments to the RIHE Act through the Patterson Act which came into force in 2007. A number of submissions made during the review pointed to the lack of clarity in the RIHE Act regarding the status of post-PGD affected embryos deemed to be 'unsuitable for implantation'.¹⁹³ It was argued by a number of parties¹⁹⁴ that post-PGD affected embryos should not be characterised as 'excess' embryos and thereby subject to the same consent and donation process outlined in the 'ART Guidelines' that applies to those embryos created by IVF, but no longer required for reproduction.¹⁹⁵ Avoiding their characterisation as 'excess', would free up post-PGD affected embryos to be used as a source of 'fresh' embryos for research and training purposes.¹⁹⁶

Researchers and professional bodies who made submissions to the Australian Legislative Review Committee consistently suggested that 'fresh embryos' were 'required',¹⁹⁷ would be 'useful'¹⁹⁸ and that 'abnormally fertilised' and 'unsuitable' embryos 'should

be made available for research and training' .¹⁹⁹ The Review Committee recommended that post-PGD embryos 'diagnosed ...as being unsuitable for implantation should be permitted to be used under licence for research, training and improvements in clinical practice' .²⁰⁰ The recommendation was expressly aimed at addressing the problems with availability of 'fresh'²⁰¹ embryos due to the 14-day 'cooling-off' ²⁰² period that applies to donations of 'excess' embryos resulting from IVF to research,²⁰³ effectively requiring that donated embryos be frozen and stored before they are available for research. The Committee specifically relied on the assumption that affected embryos would 'normally be discarded',²⁰⁴ as they are unsuitable for reproductive purposes, and therefore should not be subject to the "proper consent" procedures:

It appeared to the Committee that the RIHE Act is not clear on whether such embryos could ever be considered to be 'excess ART embryos' (because they are not suitable for reproductive use in the first place), and therefore whether they could ever lawfully be used for research purposes (even if they are first frozen) ...In the view of these ambiguities in the Act, as well as the potential use of embryos that are not suitable for implantation in research, training, and quality assurance activities, the Committee considers that there should be clear and unambiguous provisions within the legislation and licensing arrangements for declaring embryos that are unsuitable for implantation as 'surplus embryos', and that such embryos should be permitted to be used for research, training, and improvements in clinical practice.²⁰⁵

It is significant that this debate emerged in Australia where the creation of human embryos for research purposes was prohibited under the *Prohibition of Human Cloning Act*²⁰⁶ until the recent amendments lifting the ban on cloning by allowing for the creation of a human embryo clone but not the 'placing of a human embryo clone in the human body or the body of an animal'.²⁰⁷

As the case of Australia reveals, the demand for embryos for research, particularly fresh embryos, may put a strain on regulatory measures restricting access to embryos created through IVF that are not used for reproductive purposes. Recent developments in Canada and New Zealand reveal similar debates about access to 'fresh' embryos, and post-PGD embryos in particular. Interestingly a similar debate has not emerged in the United Kingdom where the creation of *in vitro* embryos for research has been legal under licence pursuant to s.3(1) of the *Human Fertilisation and Embryology Act*,²⁰⁸ although the 'question of what can or should be done with those considered spare or unsuitable for implantation' was acknowledged in the most recent legislative review in 2005 as a 'major stumbling block for some individuals and groups'.²⁰⁹

In Canada, with the exception of the creation of a small number of *in vitro* embryos for improving or providing instructions in assisted human reproduction procedures, only embryos no longer required for reproduction, will become available for research purposes, through non-commercial donation with written consent to their use.²¹⁰ Until recently donation of fresh embryos to research was not generally offered to

women undergoing IVF, and although not technically illegal, had not been approved by the Canadian Institutes for Health Research (CIHR).²¹¹ However, recent changes to the CIHR *Guidelines for Human Pluripotent Stem Cell Research*,²¹² which govern embryo donation to research under s.40(3.1) of the AHR Act, explicitly allow for fresh embryo donation, approving both embryonic stem cell lines and other pluripotent cell lines from human embryos where:

1. The embryos used, whether fresh or frozen, were originally created for reproductive purposes and are no longer required for such purposes ;
and
2. There was free and informed consent from the persons for whom the embryos were originally created for reproductive purposes ...;
and
3. Neither the ova nor sperm from which the embryos were created, nor the embryos themselves were obtained through commercial transactions ...²¹³

We suggest that there has been a recent shift to allow for the use of 'fresh' embryos in stem cell research, in response to the demands of stem cell researchers.

While there has not yet been an explicit distinction drawn between the use of affected versus unaffected embryos in Canadian law or policy regarding embryo donation, the changes to the CIHR guidelines have inspired some debate about the need to distinguish

between 'healthy' and 'unsuitable' embryos for the purposes of donation to research. Notably in a recent presentation to the Senate Standing Committee on Social Affairs, Science and Technology, Dr. Francois Baylis advocated for revisions to proposed consent regulations pursuant to the AHR Act to permit embryo research only on frozen embryos and 'fresh embryos 'unsuitable for transfer' (for morphological, biological, or genetic reasons)' .²¹⁴ While the Standing Committee did not adopt Baylis's recommendations, they did recommend a 'more in-depth review' of 'the research use of fresh, viable, embryos' and included her submissions in their report.²¹⁵

ACART's consultation document regarding embryo research in New Zealand reports that '[w]hereas formerly all the surplus embryos were frozen, they are now allowed to develop further and only the viable embryos are now frozen' .²¹⁶ It is unclear whether this would exclude post-PGD affected embryos from being frozen, as 'non-viable' embryos are defined by ACART as those without 'the potential to develop into a foetus because of arrested growth, defects within the blastomeres, or poor morphology' and in which 'analysis of the genetic component ...reveals abnormalities in the chromosomes' .²¹⁷ However, given that post-PGD affected embryos 'may never be transferred to a woman's uterus' ²¹⁸ it is not clear that they would be frozen along with unaffected surplus embryos for future use. ACART's document suggests that the results of PGD will increasingly determine the types of use deemed appropriate for post-PGD embryos in New Zealand in light of their explicit consideration as a source for research embryos.

According to the consultation document, embryos that would otherwise be considered 'viable', given their potential to develop into a foetus, might be excluded from consideration for reproductive use in New Zealand based on their genetic characteristics.

While there are clearly important reasons to be concerned about the donation of fresh embryos to research in relation to the future reproductive interests of the women undergoing IVF treatment,²¹⁹ our analysis reveals that there are equally important concerns about how and by whom determinations of 'suitability' are made in the context of embryo donations to research. Without a public and transparent debate about how, and by whom, concepts like 'unsuitable' will be defined – one which accounts for the perspectives of people living with genetic conditions and their families – we must be careful not to uncritically adopt genetic technologies such as PGD as sources of objective determinations of health or normalcy and reproductive use.

The use of post-PGD embryos as a source of 'fresh' embryos raises concern about the potential for the need for research embryos to influence the type of determinations made by those practicing PGD. Increased comfort with this production of embryos through IVF for non-reproductive purposes may help to justify the expansion of PGD's application and raises the possibility that standards regarding what is considered a 'suitable' or 'unaffected' embryo may become narrower in the interests of ensuring a supply of fresh embryos for research. In turn, this could further shift our understanding of what kinds of conditions are compatible, or incompatible, with reproduction and

health.

Despite ongoing debate about the implications of using PGD to select against embryos with inherited genetic conditions, and the lack of transparency in decision-making about the conditions for which PGD should be available, the presumption in favour of selection against genetic conditions is found throughout the literature we examined:

...there are some situations in which it is known that embryos will never be used for reproductive purposes; for example, embryos identified by preimplantation genetic diagnosis (PGD) to be carrying genetic diseases, and embryos where other abnormalities are identified.

These embryos would normally be discarded.²²⁰

Distinctions are being made between embryos to be used for reproduction and affected embryos based on problematic assumptions about the use and purposes of reproductive technologies. The submissions of Professor Agnes Bankier of Genetic Health Services Victoria clearly demonstrate how clinicians and researchers presuppose that 'couples would not go through PGD unless they wanted to avoid having a child with the genetic disease'.²²¹ The assumption that 'reproductive use' inherently means the use of an embryo free of a particular genetic condition or abnormality subtly shifts the meaning of reproductive use, such that it necessarily excludes the conditions for which PGD is licensed and utilised. However, it is the process of

PGD itself, and the subsequent characterisations and determinations of clinicians about the presence of particular genetic markers or abnormalities in the post-PGD embryo which produce this lack of suitability or fitness in the embryo; and, in doing so it redefines reproduction to exclude the affected embryo.

e. Legislating Suitability: The Unsuitable Post-PGD Embryo in Law

Australia's Patterson Act²²² amends the RIHE Act to authorise modifications of 'proper consent' for licenses for the use of 'unsuitable' embryos. The Act now defines 'unsuitable for implantation, in relation to a human embryo' in the following way:

- (a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004)*, issued by the CEO of the NHMRC; or
- (b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* and prescribed by the regulations for the purposes of this paragraph.²²³

The amendment responds directly to the Lockhart REVIEW'S recommendations that the unsuitability of ART embryos be determined according to 'objective criteria', and through the use of PGD to detect 'serious genetic defects'.²²⁴ The REVIEW contrasted the objective determinations of PGD to the subjectivity of determining 'when the embryo appears less healthy',²²⁵ and the amended RIHE Act now legally sanctions PGD as one objective means of determining the suitable from the unsuitable, based on genetic information.

Implicit in the Lockhart recommendations, and now in the amended law, is an understanding of 'health' as the absence of the particular genetic mutations identified by PGD. This implicit assumption about the relationship between 'health' and the absence of particular genetic mutations allows the Review to avoid debates about the limitations of genetic determinations of health,²²⁶ as well as concerns about the implications of PGD for people living with disabilities.²²⁷ By positioning PGD as an 'objective' means of determining 'suitability' the Review failed to acknowledge the subjective factors involved in clinical decisions about when PGD should be applied, and for what purposes. The Review relied on the fact that these embryos would 'never'²²⁸ have been used for reproductive purposes to justify this kind of use. We suggest that given the problematic nature of determinations about 'seriousness', 'health' or 'quality of life' in relation to genetic conditions, it is the application of PGD itself which produces the inevitability that embryos with particular genetic conditions will not be transferred

to the woman, not the inherent or biomedical incompatibility of particular genetic mutations with reproduction. Under Australia's new law the practice of ART professionals in administering PGD becomes the source of an 'objective' ²²⁹ determination of suitability, and their determinations become the means through which 'fresh' embryos are made available for 'research, training and improvements in clinical practice'. ²³⁰

Section 24 of the RIHE Act, which sets out the licensing conditions for the use of excess ART embryos, now specifies that:

- (a) a licence may provide that that guidelines referred to in the definition of *proper consent* apply in a modified form in relation to the use, under the licence, of excess ART embryos that are unsuitable for implantation; and
- (b) if a licence so provides, the guidelines as modified by the licence have effect in relation to the giving of consent for such creation or use.²³¹

While the amendment does not specifically implement the removal of the cooling-off period for post-PGD affected embryos as recommended by Lockhart and accepted by the Senate Committee,²³² it includes the following note: '[f]or example, the guidelines could apply to a particular licence in a modified form, to alter the cooling-off period required in relation to the use of excess ART embryos that

are unsuitable for implantation'.²³³

The Lockhart Review gave considerable weight to the arguments that undesirable constraints have been put on ART research and training under the current legislative scheme: 'It is clear that areas of ART research have been impeded or stopped altogether' and that '... the licensing requirements place a significant barrier on training and quality assurance activities, further limiting the progress and quality of developments in ART'.²³⁴ The Committee expressed 'concern'²³⁵ about this 'apparently unintended consequence of impeding valuable research and clinical practice in ART clinics'²³⁶ and their recommendations about the use of post-PGD affected embryos are a direct response.²³⁷ In their statement of support for the Lockhart recommendations, the Senate Committee cited Australia's 'leading role in biotechnology'²³⁸ implying that any legislative changes should ensure this leadership continues. Attention to these kinds of concerns are also indicated by amendments to s.47(4) of the RIHE Act, which require that review of the Act will now 'take into account' a number of additional factors including 'an analysis of any research or clinical practice which has been prevented as a result of legislative restrictions'.²³⁹

f. The Positively Affected Post-PGD Embryo

Women may choose to undergo PGD in order to have a child with particular characteristics that others might view as a disability

and thus not in the best interest of the future child's well-being.²⁴⁰ This is frequently termed 'positive selection'.²⁴¹ The most often cited potential example is selection of a gene for deafness, based on a US case in which a deaf lesbian couple intentionally chose a deaf sperm donor with an extensive family history of deafness in order to produce a child who was also deaf.²⁴² The couple maintained that they considered deafness to be a culture, not a disability, challenging those who would characterise the decision as harmful or not in the child's best interests,²⁴³ as well as supporting arguments against accepting concepts of 'health', 'disease' and 'normalcy' without critical appraisal.²⁴⁴

This reasoning complicates dichotomous categories assumed to be natural and mutually exclusive such as 'medical' and 'social', and in the case of PGD, acceptable and unacceptable.²⁴⁵ Disability rights perspectives contend that disability is a socially and politically constructed concept, not a self-evident medical category.²⁴⁶ While the STC in the UK contends that '[w]e should use the current impracticality of screening for desirable social characteristics to engage in a rational debate on the subject',²⁴⁷ a disability rights perspective would suggest that current PGD practices of selecting-out genetic conditions is doing precisely this kind of screening.²⁴⁸ The STC's report also refers to the example of selection in favour of fertile achondroplastic dwarfism,²⁴⁹ finding that support for such uses of PGD are justified by the need to respect reproductive autonomy and popular discomfort would not justify state intervention:

We can imagine that many clinicians would balk at the idea of selecting, for example, a deaf child using PGD but we do not feel that the creation of a child with reduced life opportunities is sufficient grounds for regulatory intervention, else we might logically deny poor people IVF.²⁵⁰

However, the STC's position is premised on a characterisation of deafness and dwarfism offered by Dr Professor Tom Shakespeare in his submissions to the committee as 'minor or trivial conditions', where the child would suffer 'disadvantage' rather than 'discomfort'.²⁵¹ They maintain such decisions would be 'more challenging' in the case of 'obvious discomfort',²⁵² but fail to explore this further and engage with critical perspectives on disability which point out that there is no clear line between what is trivial or serious.²⁵³

In the UK and Canada, the legal status of this kind of genetic selection is not certain;²⁵⁴ however, other jurisdictions have expressly prohibited selection for 'a genetic impairment seen in a parent'²⁵⁵ in the case of New Zealand, or 'in favour of genetic disease or abnormality'²⁵⁶ in Victoria. Australia's NHMRC *Ethical Guidelines* restrict this use of PGD '[p]ending further community discussions'.²⁵⁷ If passed, the UK's HFE Bill will amend the HFE Act to ban positive selection of an embryo 'known to have a gene, chromosome or mitochondrion abnormality involving a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical

condition' where there are embryos without the abnormality available for transfer.²⁵⁸ Interestingly the Bill will also prohibit selection of an embryo or gamete donor with a specific condition, effectively outlawing positive selection through the use of ART even outside of the application of PGD.²⁵⁹ The explanatory notes of the original Draft Bill, from which the HFE Bill was developed, specifically reference the 'positive selection of deaf donors in order deliberately to result in a deaf child' as being prevented by the proposed law.²⁶⁰

As Canada's *Brave New World* report considers there may be significant human rights issues raised by these kinds of provisions in regards to both the individual liberty and equality aspects of reproductive choices.²⁶¹ Such a prohibition is also inconsistent with the fact that we would not stop someone with a genetic condition from having children without ART procedures in order to prevent the condition from being inherited. Further, as the HGRP PGD report considers, the New Zealand prohibition 'may in fact limit some reproductive choices', using the example of a couple who undergo PGD for one condition with a limited number of eggs, and find that all the embryos are 'affected with the disorder being screened for'.²⁶² They suggest that the Guidelines would preclude the couple from choosing an 'affected' embryo 'in the hope that the expressivity of the disorder in the resulting child will be only mild'.²⁶³

4. The Sex-Selected Embryo

When PGD is used to test for sex-linked 'disorders', the

determination as to suitability will be based on the sex of the embryo,²⁶⁴ and only post-PGD embryos 'not of the affected sex' are transferred to the woman.²⁶⁵ However, selecting for sex where there is no serious medical reason for doing so is prohibited in several jurisdictions.²⁶⁶

PGD can be used to identify the sex of an embryo.²⁶⁷ As noted in documents from all countries,²⁶⁸ in the case of sex-linked 'disorders', sex selection through PGD is used to avoid the implantation of embryos of the sex that is likely to exhibit a particular genetic condition in a child.²⁶⁹ While this type of sex selection, referred to as sex selection for medical purposes, 'has become widely accepted as a legitimate route'²⁷⁰ many of the issues discussed above regarding selecting against particular genetic conditions²⁷¹ or 'undesirable characteristics'²⁷² are also applicable to the sex-selected embryo. However, additional considerations arise when PGD is used to determine the sex of an embryo for 'social'²⁷³ or 'non-medical'²⁷⁴ reasons, which include 'family balancing', 'rebuilding a family after the death of a child with another of the same sex', or 'to fulfil a general preference for children of one sex over another'.²⁷⁵ Indeed, sex-selection for 'social' reasons is one of the most contentious aspects of the debate surrounding PGD, as the 'simple genetic basis' of sex makes it currently available unlike other forms of 'social' selection and 'designer babies', which are commonly dismissed as 'unrealistic'.²⁷⁶

In the majority of jurisdictions examined, non-medical sex

selection is expressly prohibited in either legislation, or through professional guidelines referring to PGD. New Zealand's PGD Guidelines expressly prohibit the use of PGD for 'social reasons – including sex selection'.²⁷⁷ Canada's AHR Act makes it an offence to 'identify' the sex of an embryo except to avoid a sex-linked disorder.²⁷⁸ In the *Brave New World* report it was suggested that challenges to this prohibition on the basis of the 'legal doctrine of informed consent with respect to medical treatment' may not be successful as '[t]he state could likely establish that such a prohibition or regulation is rationally connected to a legitimate government purpose'.²⁷⁹ As well, the report suggested that while in Canada information related to genetic disease in an *in vitro* embryo may be 'categorised as central to a person's decision regarding reproduction', knowledge related to the sex of the embryo may be seen as more of a 'lifestyle choice'.²⁸⁰ In Australia, the NHMRC Guidelines prohibit 'selection of the sex of an embryo except to reduce the risk of transmission of a serious genetic condition' pending further discussions.²⁸¹ The Victoria ITA's policy lists 'the use of sex-selection except to reduce the risk that the child will be affected by a genetic abnormality or a disease'²⁸² as prohibited under the IT Act.²⁸³ The Western Australian RTC also states the 'use of an embryo diagnostic procedure for sex selection alone is not permitted'.²⁸⁴

The UK's HFE Act does not expressly prohibit sex selection for non-medical reasons, however, the HFEA's restriction of PGD to 'serious genetic conditions' has, in the past, effectively ruled this

out.²⁸⁵ Recently, the STC Committee's Report reveals that there is pressure to open up the use of PGD for social sex selection. While the report notes objections based on demographic, international and psychosocial implications, as well as ethical considerations and sex discrimination, they conclude that '[t]he onus should be on those who oppose sex selection for social reasons using PGD to show harm from its use ...On balance we find no adequate justification for prohibiting the use of sex selection for family balancing'.²⁸⁶ The report states that evidence of 'harms to individuals of society' does not counterbalance a restriction on 'reproductive freedom' in the case of sex-selection for family balancing.²⁸⁷ In contrast the Ethics Committee of the Royal College of Obstetricians and Gynaecologists (RCOG) suggested that 'the evidential burden' should be 'the responsibility of those advocating the introduction of PGD to show that it does not lead to unfair discrimination'.²⁸⁸ In their response to the STC's report, the UK Government declined to adopt the Committee's recommendation stating that '[t]he Government has no plans to alter this position to allow sex selection other than for compelling medical reasons'.²⁸⁹ Indeed, the HFE Bill would continue to prohibit non-medical sex-selection, and amendments to the embryo testing provisions could not authorise such a practice.²⁹⁰

While the STC's position is consistent with their own definition of the 'precautionary principle' – 'that alleged harms to society or to patients need to be demonstrated before forward progress is unduly impeded',²⁹¹ the Government's response to the STC contests '...the

Committee's interpretation of the precautionary principle', arguing that '[t]he potential harms that should be taken into account may not necessarily be susceptible to demonstration and evidence in advance'.²⁹² The weight given to public concerns and critiques about the use of PGD for non-medical/social sex selection²⁹³ may offer valuable lessons for those seeking to critique genetic diagnosis in relation to disability. Fears about eugenics and 'designer babies' are characterised in many of the documents we examined as irrational or emotive:

If ensuring that your child is less likely to face a debilitating disease in the course of their life can be termed eugenics, we have no problem with its use. State programs that impose a genetic blueprint are another matter. They should be outlawed as part of any regulation of assisted reproduction. Use of the word eugenics must not be used as an emotive term of abuse to obscure rational debate.²⁹⁴

The HGRP states that, '[i]t may be the case that most fears of eugenics are unfounded, based as they are on unrealistic expectations of what can be achieved through genetic technology'.²⁹⁵ And the Human Genetics Commission in the UK cites 'practical limitations' to show that '[t]he anxiety that PGD lies at the top of a slippery slope leading to the possibility of a wide range of potential enhancements, such as intelligence or beauty is misplaced'.²⁹⁶

However, disability rights critiques make it clear that selection on the basis of genetic markers or conditions is not necessarily any less 'social' than selection for athletic ability or hair colour.²⁹⁷ Socially

constructed norms about intelligence and beauty are as much a part of our acceptance of selection out of genetic conditions as are those rooted in medical realities. As the RCOG points out in their position on sex selection: 'If sex is allowed as a sole criterion, then selection for other characteristics (e.g. intelligence, beauty, sporting prowess etc) would be permissible should the techniques for doing so become available'.²⁹⁸ Their position acknowledges the inconsistency between the position that 'it is ethical to use PGD to discriminate against one sort of condition (disability)' but not 'against another condition (i.e. sex)'.²⁹⁹ This inconsistency clearly demonstrates the need to examine assumptions about the inherent objectivity of 'medical' selection, particularly as the uses of PGD extend beyond concerns about the embryo itself.

4. The HLA Tissue-Typed Embryo

Through PGD, human leukocyte antigen (HLA) tissue typing strategies can characterise the post-PGD embryo according to whether the tissue-type of the child the embryo might become, will be an appropriate match for stem cell donation to a living sick sibling.³⁰⁰ HLA tissue typing or preimplantation tissue typing (PTT)³⁰¹ uses PGD for 'third party benefit'³⁰² by allowing the woman undergoing IVF and her family to 'ensure that their next child will have identical HLA proteins'³⁰³ so that its stem cells can be 'transplanted into the

affected sibling'.³⁰⁴

The use of HLA tissue typing has been confined to siblings in all jurisdictions that have produced relevant regulations or guidelines.³⁰⁵

In Canada where no guidelines or regulations yet exist, the recent policy document on PGD refers to the 'existing child', the 'affected child' and the 'saviour sibling phenomenon',³⁰⁶ and the *Brave New World* report refers to 'a seriously ill sibling'.³⁰⁷ The HFEA's 2004 policy on tissue typing, which expanded the application of tissue typing, did not conclusively rule out its use for a genetic parent's benefit, suggesting it needed 'further consideration'.³⁰⁸ The policy approved tissue typing 'subject to appropriate safeguards', where 'a genuine need for potentially life-saving tissue' exists for an 'affected child'.³⁰⁹ The 2005 review of the HFE Act in the UK rejected this position and concluded that, 'there are no compelling reasons for a statutory authority to make judgements on whether or not a family can seek preimplantation tissue typing, provided they fall within the parameters set out by Parliament', and explicitly contemplates the possibility of 'saviour sons and daughters, or even nephews and nieces'.³¹⁰ However, the HFE Bill currently under consideration would amend the HFE Act to limit PTT to a sibling suffering from a 'serious medical condition'.³¹¹

In the case of PTT, embryos found to be a 'match' for a sick sibling would be deemed suitable for transfer to the woman. Embryos found not to be a match would therefore be deemed 'unsuitable' for implantation to the woman undergoing IVF. As the notion of 'third-

party benefit'³¹² makes clear, suitability in this case would be determined not by the well-being of a potential future child, but by their potential to produce stem cells to treat an existing sibling with a disease or condition. Canada's *Brave New World Report* describes the benefit of tissue typing as 'making it possible to select for and transfer *only* those in vitro embryos that have certain traits needed' for donation to the living sibling.³¹³ The report uses the term 'donor child' to characterise the future child produced through this process of selection.³¹⁴

This description challenges the often-invoked 'seriousness' justifications for the use of PGD and this inconsistency is dealt with differently in the jurisdictions we examined. In New Zealand the embryo to be tested must itself be at risk for an inherited genetic condition for which PGD is already applied, thus making PGD for PTT an 'add-on' procedure.³¹⁵ In contrast PGD can be applied with 'the sole treatment objective' for the purpose of finding a tissue match in the UK.³¹⁶ The HFEA tissue typing policy has moved from a 'restrictive' application of PGD for the purpose of finding a tissue match only where the use of PGD was justified by the embryo 'at risk from the condition by which the existing child is affected',³¹⁷ to a new 'extended' policy in which there is no distinction made between 'inherited and sporadic diseases'.³¹⁸

Two cases from the UK illustrate the complexity of regulating PGD for PTT.³¹⁹ The situation of the Hashmi family became the basis for *R (on the application of Quintavalle) v. Human Fertilisation and Embryology Authority*³²⁰ a case which sought judicial review of the

HFEA's approval of a licence for PTT.³²¹ The Hashmi's fell under the accepted applications of the tissue typing 2001 UK policy however, the case was based on a third-party challenge to the authority of the HFEA to licence for the use of PGD for the purposes of PTT.³²² Zain Hashmi, the fourth child in a family of five, had a blood condition called beta thalassaemia major which could be cured with a stem cell transplant from someone with matching tissue, likely a sibling. None of the existing children were a match; and while Mrs. Hashmi got pregnant twice in hopes of producing a match she chose to terminate one pregnancy after the prenatal testing showed the child would have the same blood condition, and the next child was not a tissue match for Zain. The Hashmis, through a physician, applied to the HFEA to undergo IVF treatment and use PGD to find a tissue match. The license was granted, however one attempt produced only one tissue match which was also 'affected' by the same condition, and while a second produced two 'unaffected' tissue matches, neither of these successfully implanted in Mrs. Hashmi.³²³

The court challenge was appealed to the House of Lords which held that PTT was an activity within the provision of IVF for which the HFEA was authorised to grant a licence, under paragraph 1(1)(d) of Schedule 2 of the Act: 'practices designed to secure that embryos are in a suitable condition to be placed in a woman or to determine whether embryos are suitable for that purpose' .³²⁴ By interpreting 'suitable' in a purposive manner, the court granted the HFEA broad powers to judge what was ethically acceptable, which included

an acceptance of 'the purposes of the mother' as included under 'suitability'.³²⁵ This logically opens the door to the HFEA authorising the use of PGD for social selection, however the court determined that it would be the responsibility of Parliament to step in if this were to occur.³²⁶

Charlie Whitaker was born with Diamond Blackfan syndrome, which is a rare form of anaemia that can be cured by stem cells from a tissue match. Neither of his parents are carriers, and his sister was not a tissue match. The family went to an ART centre, which applied for a licence to the HFEA to perform PGD for the purposes of finding a tissue match for Charlie. In this case the HFEA rejected the application under the 2001 policy because the condition of the existing child was not an inherited condition; therefore, it is highly unlikely that the embryos the Whitakers would produce through IVF would be 'affected', and directly 'benefit' ³²⁷ from undergoing PGD. The Whitakers chose to travel to the US to undergo the procedure and a successful tissue match was produced.³²⁸ While the story of the Whitaker family provides important context for understanding the UK's shift to a more expansive policy, the House of Lords' conclusions in *Quintavalle* help to explain the recent push to have more legally defined parameters about the use of PGD in the UK.

In her submissions to the SCT, the Chair of the HFEA suggested that 'she would like to see permitted purposes of PGD set out in legislation in a similar way to research',³²⁹ to avoid the dilemmas involved in dealing with PGD. Clearly the HFEA's reliance on 'a

significant risk of a serious genetic condition being present in the embryo'³³⁰ as the basis for limiting the application of PGD is complicated by both the broad authority they were found to have by the House of Lords and the court's purposive interpretation of suitability. The SCT did recommend reducing the 'freedom' of the HFEA granted by the current HFE Act in order to ensure that 'Parliament is able to revisit contentious issues relating to the creation of new life and the permissible uses of human embryos'.³³¹ The Government's response to the review agreed 'that it would be preferable if the parameters for PGD were more clearly set out in law'.³³² The HFE Bill would provide explicit parameters, codifying acceptable purposes for the HFEA's approval of licenses for embryo testing, including PTI.³³³

The New Zealand policy on HLA tissue typing restricts PGD for PTT to situations where there are 'therapeutic indications for the embryo to justify embryo biopsy'.³³⁴ It permits tissue typing where both the 'affected child' and the embryo are at risk of being affected by a 'familial single gene disorder or a familial sex-linked disorder' and restricts the 'planned treatment' to the use of 'only the cord blood of the future sibling'.³³⁵ The HGRP has pointed out that the potentially unintended consequence of New Zealand's approach is that even where PGD would be 'clinically indicated' for the embryo, if the sibling is not suffering from a 'genetic' condition, but requires stem cell transplantation for another condition, PGD would not be authorised. Further, if the sibling did have a genetic disorder but the

embryo was not at risk of inheriting that particular condition, PGD could still be performed³³⁶ as long as the embryo could be affected by a 'familial single gene disorder or a familial sex-linked disorder for which a PGD test is available'.³³⁷ In this case the HLA tissue typing is seen as an 'add on' justified by 'medical indication' for embryo biopsy.³³⁸

The concept of restricting PGD for PTT so that the 'embryo may benefit' (as described in the Whitaker case) or to situations where a 'therapeutic indication' for the embryo exists,³³⁹ or to which the embryo may receive a 'clinical benefit'³⁴⁰ raises a series of problems.

First, it presupposes that an embryo can have a 'therapeutic indication' to, or 'clinical benefit' from its being biopsied, or from a therapeutic intervention that could occur to the embryo based on the results of the biopsy (or even to the fetus through, for example, fetal surgery). Embryo therapy currently does not exist, although it may in the future, as fetal surgery is now being performed for anomalies such as those related to the cardiovascular³⁴¹ and neuro/skeletal systems.³⁴² Rather, the 'therapeutic indication' or 'clinical benefit' that is implied in cases where PGD has been approved for the embryos at risk of having a genetic condition is the destruction of the embryo: the antithesis of both a 'therapeutic indication' and a 'clinical benefit'. In our opinion the therapeutic indication is for the child that is already born and who will die without stem cell transplantation. It is for this child that a woman is willing to go through the risks of IVF medication and surgery. We believe that it is compassionate as well as logical 'to

justify embryo biopsy' on the basis of its 'benefit' to a child rather than to the destruction of an embryo.

One of the most common concerns raised in relation to tissue typing is that 'children are being 'designed' to meet the needs of an existing person' .³⁴³ 'Objectification' or 'commodification' arguments³⁴⁴ pointed out in some commentaries ³⁴⁵ can be problematised by arguments about the diversity and complexity of motivations behind the choice to have children in all situations.³⁴⁶ As the STC in the UK pointed out, some people may object to PGD for PTT 'in principle', but others differentiate where 'the child born as a result of the test was at risk of developing the condition'.³⁴⁷ Such differentiations rest on the notion that the embryo should 'benefit from the process'³⁴⁸ to balance out concerns about the 'safety of the biopsy process'³⁴⁹ and the dilemma of children being born 'solely as a means to an end' .³⁵⁰

In their most recent policy the HFEA revisited the issue of safety and

took the view 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. However, the latest evidence should be considered in relation to each application.³⁵¹

Health Canada's issues paper on PGD cites undue exposure of an embryo to the 'potential health risks of PGD' as a concern where 'there is no risk to inherit a genetic condition'.³⁵² The paper points out that 'whatever the potential benefits of PGD-HLA, they must also counterbalance the fact that in vitro embryos that would otherwise be fit for transfer may not be used for reproductive purposes'.³⁵³

Another related set of concerns has emerged about the 'welfare' of a child born as a 'saviour sibling', particularly in relation to the impact on family relationships³⁵⁴ and 'psychological' effects.³⁵⁵ The submissions of the British Medical Association to the STC Review cited concerns about 'psychological harm'³⁵⁶ and the Royal College of Obstetricians and Gynaecologists noted that '[t]his area is too new for the full effects to be known on the child conceived'.³⁵⁷ The HFEA policy notes that there are also concerns as to the 'welfare of the mother undergoing IVF at an already stressful time'.³⁵⁸ However, while the HFEA cautioned that 'these issues be carefully and sensitively addressed',³⁵⁹ they concluded that there was 'no evidence ...that adverse psychological effects would result from the procedure'.³⁶⁰ The STC's response to the concerns about tissue typing, in line with their general preference for minimal regulatory intervention discussed above, characterises these issues as 'matters for doctors to explain clearly in advance and not for regulation or legislation'.³⁶¹ The ITA in Victoria leaves the decision of the application of PGD for PTT to 'Ethics Committee at the institution where the procedure is being undertaken' on a 'case by case basis',³⁶² however they do direct them

to consider impacts on the future child such as the potential failure of treatment for the living sibling.³⁶³

5. The Post-PGD Carrier Embryo

Beyond identifying embryos that are themselves 'affected' by a genetic condition, PGD can also identify embryos which are 'carriers'³⁶⁴ of genes for autosomal 'recessive disorders'.³⁶⁵ The person into which a carrier embryo may develop does not develop the genetic 'condition', as it possesses only one of the two genes³⁶⁶ required to express the phenotype (characteristics) of the condition. Although the person the embryo can become will not exhibit the condition, if this person becomes a biological parent with a person who 'carries' a gene for the same 'recessive' condition, their child has a 25% chance of expressing this condition and a 50% chance of being a carrier, based on Mendelian genetics.³⁶⁷ The post-PGD embryo, thus could become a person who could pass on the condition to their children,³⁶⁸ but who is *unaffected* by the gene themselves.

The status of the carrier embryo is unclear in most jurisdictions as there is considerable controversy about the ethics of not implanting such 'healthy' embryos where the reason to not implant them is based on the very small possibility that, if the embryo becomes an adult who has a child with another individual who carries the recessive gene, the child could have the condition.³⁶⁹ In support of not implanting

carrier embryos, it has been suggested that women 'may wish to ensure that their future children will not have to experience the same difficulties'³⁷⁰ in making reproductive choices about genetic disorders, and should therefore be able to 'choose not to replace carrier embryos as part of their treatment'.³⁷¹ In the UK, such a decision 'rests with the patient in consultation with the clinical team'.³⁷²

In the case of a carrier embryo, 'health' or 'suitability' for reproductive use is defined in relation to the potential children of the potential future person that would result from an embryo's implantation in the woman. In Australia, this kind of multigenerational selection against genetic conditions appears to be incompatible with the national guidelines on PGD.³⁷³ Although there is no national regulation in Australia specifically addressing the post-PGD carrier embryo, the NHMRC's guidelines specifically state that '[p]ending further community discussion ... PGD must not be used for prevention of conditions that do not seriously harm *the person to be born*'.³⁷⁴ Therefore in the case of an embryo carrying a gene that does not in itself express a 'serious' condition, as is the case for autosomal recessive genes, the NHMRC guidelines indicate that post-PGD carrier embryos should be implanted.³⁷⁵ Victoria's ITA guidelines specify that testing and selection for carrier status would be approved on a case-by-case basis;³⁷⁶ however, interestingly the guidelines differentiate between carriers for sex-linked disorders for which there is no approval from the Authority required, and carriers of autosomal recessive disorder where 'the future child's risk of transmitting a

genetic abnormality is much lower than with x-linked conditions' for which approval of the Authority is required.³⁷⁷

The decision to transfer carrier embryos to the woman will likely be affected by the number of embryos that are deemed 'suitable for transfer' through PGD.³⁷⁸ In the UK, the HGC's response to the HFEA consultation on PGD in 2000 suggested '...if it was possible to exclude affected embryos without discovering the carrier status of others without compromising the accuracy of the test, then this is to be preferred'.³⁷⁹ They cited both the 'increased chance of an unaffected pregnancy' and protection of 'the unborn child's subsequent right to decide for themselves whether or not to be tested for their carrier status'³⁸⁰ as the basis for this recommendation. The latter is consistent with the overall respect for individual reproductive autonomy in the UK, however autonomy could also be the basis for arguments that '...people should generally be given a choice to use artificial reproductive technologies as they feel appropriate as long as it does not harm that child'.³⁸¹

Another justification for selecting against carriers is the 'obligation . . .to have the best possible child' both in terms of that individual child's 'health' and the concern 'that the child should not burden future generations in terms of health and social care'.³⁸² The subjective assessment of what is to be considered 'best', what 'health' means, and what should be considered a 'burden' on society are avoided by a reliance on assumptions of health and normalcy as the absence of disability and/or a genetic condition which, in our

view, should not be the case.³⁸³ This kind of argument ultimately undermines justifications for the use of PGD based on its limitation to 'serious' conditions, and 'objective' criteria.³⁸⁴

Interestingly, the HGC reversed its cautious position on carrier embryos in the 2006 *Making Babies* report. They state that '...in situations where PGD is being used, and where there are both carrier and unaffected embryos of equal quality, parents should be able to request which they prefer to be implanted' .³⁸⁵ Their report cites the position of the British Medical Association .³⁸⁶ While noting concerns about the unreasonableness of rejecting an embryo 'predicted to be healthy', they accept that '[i]n practice ...there may be a hierarchy of preference in which unaffected embryos that look healthy are scored higher than embryos that are carriers or look less likely to implant successfully' .³⁸⁷ As the pregnancy rate following PGD is already lower than the thirteen percent pregnancy rate generally accepted for IVF,³⁸⁸ it would be clinically appropriate to cryopreserve (and transfer to the woman at a later time) post-PGD carrier embryos, if there are more embryos than the one or two that can be safely implanted following an IVF treatment cycle,³⁸⁹ in order that the woman need not risk harms of additional IVF cycles.³⁹⁰ Carrier embryos may be seen currently as occupying an uncertain position between 'suitable' and 'unsuitable' depending on the supply of in *vitro* embryos for research. This uncertain position excludes 'healthy' embryos with particular genetic characteristics that have no consequences for the potential child itself from reproductive use.

The HGRP report states that while, '[t]esting for carrier status' is not covered by the current guidelines in New Zealand,³⁹¹ 'some families are using PGD to select against carrier embryos'.³⁹² In the absence of regulatory direction, selection against carrier embryos appears to be increasingly accepted in New Zealand without public debate or discussion.

Canada's AHR Act does not specify what the status of carrier embryos identified by PGD would be. Although it was not clear in any of the Canadian documents examined, arguably it is likely that carrier embryos deemed unsuitable for transfer on the basis of genetic characteristics would be characterised the same way as an 'affected' embryo, and would therefore be subject to the applicable consent and donation process for use in research or training.

In the appendix to Australia's NHMRC 2004 Guidelines, which are currently under review, one of the listed 'reasons for opposing or limiting the use of genetic technologies associated with ART' is that '[o]therwise normal (so-called 'carrier') embryos that would be expected to have a normal life will be discarded'.³⁹³ In addition, our study suggests that selection against carrier embryos is problematic because of the potential for genetic carriers to be deemed incompatible with reproductive use, once again raising questions noted above about how this may change social and medical attitudes and practices, and what kind of implications this would have for people living with disabilities, and their families.³⁹⁴

IV. CONCLUSION

Our analysis suggests a mutually constructive relationship between characterisations of the post-PGD embryo and the expanding purposes for which PGD is applied, as well as the uses to which embryos are ultimately relegated. The language of characterisation exposed above, through which post-PGD embryos are deemed to be 'unaffected' or 'affected', to be 'carriers', or are selected on the basis of sex or an HLA tissue match, all raise important social and ethical questions that must be examined as the regulation of ART develops internationally. Driven by imperatives such as reproductive autonomy, the desire for children of particular characteristics, 'disease' prevention, and sources of embryos, particularly 'fresh' embryos, for research purposes, clinicians, patients, researchers and policy makers are circumventing debates about the social dimensions of using PGD for a growing number of genetic indications. The consequences of this lack of social concern could be profound for people living with genetic conditions, other disabilities, their families and broader society. Subtle shifts in language and terminology about what it means for an embryo to be 'healthy', or compatible with reproductive use, can have long-term consequences on broad social norms and values; and, as discussed above, far from being neutral, such determinations point to the ongoing medicalisation of disability and women's reproductive choices. Assumptions about the meaning of health, normalcy and

reproductive choice must be exposed and examined to ensure that new technologies and practices benefit all members of society, and that reproductive health policy is developed with a broad spectrum of perspectives and experiences in mind.

APPENDIX I: ACRONYMS

UNITED KINGDOM

| | |
|----------------------------------|---|
| HFE Bill | <i>Human Fertilisation and Embryology Bill</i> |
| Draft Bill | Department of Health, <i>Human Tissues and Embryo (Draft) Bill 2007</i> |
| HFE Act | <i>Human Fertilisation and Embryology Act (U.K.) 1990</i> |
| Science and Technology Committee | House of Commons Science & Technology Committee |
| HFEA | Human Fertilisation and Embryology Authority |
| HGC | Human Genetics Commission |

AUSTRALIA

| | |
|-----------------|---|
| Patterson Act | <i>Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006 (Cth)</i> |
| RIHE Act | <i>Research Involving Human Embryos Act 2002 (Cth.)</i> |
| Lockhart Review | Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002 |
| NHMRC | National Health and Medical Research Council |
| IT Act | <i>Victoria Infertility Treatment Act 1995</i> |
| ITA | Infertility Treatment Authority |
| HRT Act | <i>Western Australia Human Reproductive Technology Act 1991</i> |
| RTC | Reproductive Technology Council |

CANADA

| | |
|------|--|
| AHRO | Health Canada Assisted Reproduction Office |
| CBS | Canadian Biotechnology Secretariat |
| CIHR | Canadian Institute of Health Research |

NEW ZEALAND

| | |
|----------|--|
| HART Act | <i>Human Assisted Reproductive Technology Act 2004</i> |
| NECAHR | National Ethics Committee on Assisted Human Reproduction |
| HGRP | Human Genome Research Project |
| ACART | Advisory Committee on Assisted Reproductive Technology |

NOTES

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- 2 R. Mykitiuk, & J. Niskier, 'Embryo Health': Biomedical and Social Determinants' [forthcoming in 2008] [Mykitiuk & Niskier, 'Embryo Health'].
- 3 UK, *Report of the Committee of Enquiry into Human Fertilisation and Embryology*, by M. Warnock (London: HMSO, 1984) [Warnock].
- 4 K. L. L. Moore & T.V.N. Persaud, *The Developing Human: Clinically Oriented Embryology*, 7th edition. (Philadelphia: Saunders, 2003).
- 5 A. Huxley, 'Research and the embryo' (1985) 106 *New Sci.* 2; H. E. Reiss, ed. *Reproductive Medicine from A-Z* (Oxford: Oxford Medical Publications, 1998).
- 6 D. Evans & N. Pickering, eds., *Conceiving the Embryo: Ethics, Law, and Practice in Human Embryology* (Hingham, MA: Kluwer, 1996).
- 7 J. J. Davis, (2006) 'The Moral Status of the Embryonic Human: Religious Perspectives' 22 *Ethics and Medicine*: 9; C. Foster, (2005) 'Embryo Research: Some Anglican Perspectives' 16 *Islam and Christian Muslim Relations*: 285.
- 8 Warnock, *supra* note 3.
- 9 Mykitiuk & Niskier, 'Embryo Health', *supra* note 2.
- 10 Lockhart Review, *infra* note 44. This statement was made in relation to the definition of human embryo in s.7(1) of the *Research Involving Human Embryos Act 2002* (Cth.): 'a live embryo that has a human genome or an altered human genome and that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means'. The definition has since been amended by the *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth.), Sch.2 'II 2 (Patterson Act) to be:
'a human embryo means a discrete entity that has arisen from either:
(a) the first mitotic division when fertilization of a human oocyte by a human sperm is complete; or
(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the state at which the primitive streak appears; and has not reached 8 weeks of development since the first mitotic division.
However, the general point about the contingency of the legal definition of the human embryo remains equally relevant, and perhaps even reinforced by the context in which these changes were made (see the discussion in Australia's Legislative Review, *infra* note 44).
- 11 P. C. Steptoe & R. G. Edwards 'Birth after the reimplantation of a human embryo' (1978) 2 *Lancet* 366; A. Yuzpe et al., 'Transvaginal ultrasound-guided oocyte retrieval for in vitro fertilisation' (1989) 34 *J. Reproductive Med.* 937.
- 12 A. H. Handyside et al., 'Pregnancies from biopsied human preimplantation embryos sexed by Y-specific DNA amplification' (1990) 344 *Nature* 768 [Handyside. 'Pregnancies']; G. N. Verlinsky et al., 'Analysis of the first polar body: preconception genetic diagnosis'(1990) 5 *Human Reproduction* 826 [Verlinsky et al 'Preconception genetic diagnosis']; Y. Verlinsky et al., 'Current progress in preimplantation genetic diagnosis' (1993) 10 *J. Assisted Reproductive Genetics* 353 [Verlinsky et al. 'Current Progress']; Y. Verlinsky et al. 'Preimplantation Diagnosis for Fanconi Anemia Combined with HLA Matching' (2001) 285 *J. Am. Med. Assoc.* 3130 [Verlinsky et al 'Preimplantation Diagnosis']; J. Niskier & R Gore-Langton 'Pre-implantation genetic diagnosis: a model of progress and concern' (1995) 17 *J. Ob. Gyn. Can.* 247 [Niskier & Gore-Langton]; Mykitiuk & Niskier 'Embryo Health', *supra* note 2.
- 13 D. Davies 'Embryo Research' (1986) 319 *Nature*: 208; A. McLaren 'Embryo Research' (1986) 320 *Nature* 570; Voluntary Licensing Authority for Human In Vitro Fertilisation and Embryology *Guidelines for Both Clinical and Research Application of Human In Vitro Fertilisation*, 1985 cited in: p. Spallone, 'The

- Salutary Tale of the Pre-Embryo' in N. Lykke & R. Braidotti, eds., *Between Monsters, Goddesses and Cyborgs* (London: Zed, 1996) 207.
- 14 Mykitiuk & Nisker 'Embryo Health', *supra* note 2.
 - 15 *Ibid.*
 - 16 R. Mykitiuk & J. Nisker 'Assisted Reproduction' in P. A. Singer & A. M. Viens, eds., *Cambridge Textbook of Bioethics* (Cambridge: Cambridge University Press) [forthcoming 2008] [Mykitiuk & Nisker 'Assisted Reproduction'].
 - 17 J. Min, P. Claman & E. Hughes, 'Guidelines for the number of embryos to transfer following in vitro fertilization' (2006) 182 J. Ob. Gyn. Can. 803 [Min, Claman & Hughes 'Guidelines']; The Practice Committee of the Society for Assisted Reproductive Technology and the American Society for Reproductive Medicine, 'Guidelines on the Number of Embryos Transferred' (2004) 82 Fertility & Sterility; European Society for Human Reproduction and Embryology, 'Guidelines: Prevention of twin pregnancies after IVF/ICSI by single embryo transfer: ESHRE Campus Course Report' (2001) 16 Hum Reprod. 790.
 - 18 Mykitiuk & Nisker 'Embryo Health', *supra* note 2.
 - 19 In the documents we examined there is little reference to the woman who is undergoing IVF and PGD, the focus being almost exclusively on the embryo outside of the woman's body. Where the woman is referred to we found no consistent terminology. As ART, and PGD in particular, involve intensive and invasive procedures on women's bodies, it is important to consider the gendered and embodied nature of these practices and their effects on women's lives and experiences. To this end we will refer to 'the woman' or the 'woman undergoing PGD' in this paper to ensure that she is visible in the process and practice of PGD.
 - 20 Handyside. 'Pregnancies', *supra* note 13; Nisker & Gore-Langton *supra* note 12.
 - 21 J. Nisker & A. White, 'The CMA Code of Ethics and the Donation of Fresh Embryos from Stem Cell Research' (2005) 173 Can. Med. Assoc. J: 621; Mykitiuk & Nisker 'Embryo Health', *supra* note 2.
 - 22 A. Trounson & L. Mohr 'Human pregnancy following cryopreservation, thawing and transfer of an eight-cell embryo' (1985) 305 Nature 707.
 - 23 Mykitiuk & Nisker 'Embryo Health', *supra* note 2.
 - 24 Y. Abramov, U. Elchalal & JG Schenker 'Severe OHSS: An 'epidemic' of severe OHSS: a price we have to pay?' (1999) 14 Human Reproduction 2181-3 [Abramov, Elchala & Schernker].
 - 25 M. Alsalili et al., 'Cumulative pregnancy rates and pregnancy outcome after in-vitro fertilization:5000 cycles at one centre' (1995) 10 Human Reproduction 470-4.
 - 26 Mykitiuk & Nisker 'Embryo Health', *supra* note 2.
 - 27 F. Tekpetey et al., 'Blastocyst formation and pregnancy potential of delayed day 3 human embryos' (Abstract presented to the Canadian Fertility and Andrology Society Annual Meeting, 2003) [unpublished]; T. Ebner et al. 'Selection based on morphological assessment of oocytes and embryos at different stages of preimplantation development: a review' (2003) 9 Hum. Reprod. 251; Z.P. Nagy et al., 'Pronuclear morphology evaluation with subsequent evaluation of embryo morphology significantly increases implantation rates' (2003) 80 Fertil Steril 67; S. Ziebe et al., 'FISH analysis for chromosomes 13, 16, 18, 21, 22, X and Y in all blastomeres of IVF pre-embryos from 144 randomly selected donated human oocytes and impact on pre-embryo morphology' (2003) 18 Hum Reprod 2575; P. Sjoblom et al., 'Prediction of embryo developmental potential and pregnancy based on early stage morphological characteristics' (2006) 86 Fertility & Sterility 848.
 - 28 T.K. Lau, T.N. Leung 'Genetic screening and diagnosis: Prenatal diagnosis' (2005) 17 Current Opinion in Obstetrics & Gynecology 163.
 - 29 N. Levy 'Deafness, culture, and choice' (2002) 28 J Med Ethics 284.
 - 30 A. Handyside et al., 'Biopsy of Human Preimplantation Embryos and Sexing by DNA Amplification' (1989) 1 Lancet 347 [Handyside, 'Biopsy'].

- 31 J. Spencer & D. Cox 'Emotional responses of pregnant women to chorionic villi sampling or amniocentesis' (1987) 157 *Am J Ob Gyn* 1155; I. Kowalcek et al., 'Depressive reactions and stress related to prenatal medicine procedures' (2002) 19 *Ultrasound in Ob Gyn* 18.
- 32 Nisker & Gore-Langton, *supra* note 12.
- 33 Verlinsky et al. 'Current Progress', *supra* note 12.
- 34 Verlinsky et al 'Preconception genetic diagnosis', *supra* note 12.
- 35 Verlinsky et al. 'Current Progress', *supra* note 12.
- 36 Handyside, 'Biopsy' *supra* note 30.
- 37 H. Strohmer & W. Feichtinger, 'Successful clinical application of laser for micromanipulation in an in vitro fertilization program' (1992) 58 *Fertility Sterility* 1274; M. Boada et al., 'Successful Use of a Laser for Human Embryo Biopsy in Preimplantation Genetic Diagnosis: Report of 2 Cases' (1989) 15 *J. Assisted Reproduction and Genetics* 302.
- 38 Handyside, 'Biopsy' *supra* note 30.
- 39 J. Delhanty et al., 'Detection of Aneuploidy and Chromosomal mosaicism in human embryos during Preimplantation sex determination by fluorescent *in situ* hybridisation, (FISH)' (1993) 2 *Human Molecular Genetics* 1183.
- 40 K.B. Mullis & F.A. Faloona, 'Specific synthesis of DNA in vitro a polymerase-catalyzed chain reaction' (1987) 155 *Methods in Enzymology* 335.
- 41 Examples of conditions for which PGD is used differ among jurisdictions and the range of specific conditions that can be detected by PGD is continually expanding. Examples include x-linked disorders such as haemophilia or Duchenne muscular dystrophy, 'numerical chromosomal abnormalities' such as Turner's syndrome or Down's syndrome. It is also increasingly undertaken for the detection of specific gene mutations, or 'single-gene defects' associated with a particular genetic disease or disorder by which the embryo, and future child may be affected. The Human Fertilisation and Embryology Authority provides a sample list of conditions for which PGD is applied: <http://www.hfea.gov.uk/docs/Public_PGD_list_up_to_December_2004.pdf>, and the Infertility Treatment Authority in Victoria has a Schedule of conditions for which PGD is either 'routinely' applied or for which approval must be sought on a case by case basis: <<http://www.ita.org.au/www/257/1001127/displayarticle/1001217.html>> In Canada, New Zealand and outside of Victoria in Australia no list is provided however policy documents cite examples of specific conditions (see NECAHR, *Guidelines*, *infra* note 46; Canadian Biotechnology Secretariat, *infra* note 45; HGRP, *infra* note 46).
- 42 Mykitiuk & Nisker 'Embryo Health', *supra* note 2.
- 43 See *Appendix* for glossary of acronyms used below to refer to specific documents and organisations. Bill 6, *Human Fertilisation and Embryology Bill [HL]*, 2007-2008 Sess, 2007 [HFE Bill]; Department of Health, *Human Tissues and Embryo (Draft) Bill*, Cm 7087 (London: TSO, 2007) [Department of Health, *Draft Bill*]; *Human Fertilisation and Embryology Act* (UK), 1990, c. 37 [HFE Act]; Department of Health, *Human Reproductive Technologies and the Law: Government Response to the Report from the House of Commons Science and Technology Committee*, Cm 6641 (London: TSO, 2006) [Department of Health, *Government Response*]; Department of Health, *Report on the Consultation on the Review of the Human Fertilisation & Embryology Act 1990* by People Science & Policy Ltd. (Hamilton House, London, 2006) [Department of Health, *Report on Consultation*]; Department of Health, *Preimplantation Genetic Diagnosis: Guiding Principles for Commissioners of NHS Services* (London: TSO, 2002); House of Commons Science & Technology Committee, *Human Reproduction and the Law 5th Report of Session 2004-05 Vol.J*, (London: TSO, 2005) [Science and Technology Committee]; Human Fertilisation and Embryology Authority [HFEA], *Code of Practice 7th Edition*, (London: HFEA, 2007) [HFEA, *Code of Practice 7*]; HFEA *Choices and Boundaries: Should People be Able to Select Embryos Free from an Inherited Susceptibility to Cancer?* (London: HFEA, 2005) [HFEA, *Choices and Boundaries*]; HFEA, *Code of Practice 6th Edition*, (London: HFEA, 2004) [HFEA, *Code of Practice 6*]; HFEA, *Human Fertilisation and Embryology Authority Report: Preimplantation Tissue Typing*, (2004) online: HFEA <www.hfea.gov.uk/en/494.html> [HFEA, PTT Report]; HFEA, Press Release 'HFEA agrees to

- extend policy on tissue typing' (21 Jul 2004). www.hfea.gov.uk/en/1046.html; [HFEA, 'tissue typing']; HFEA & Advisory Committee on Genetic Testing, *Consultation Document on Preimplantation Genetic Diagnosis*, (London: HFEA, 2000) [HFEA, *Consultation*]; Human Genetics Commission [HGC], *Making Babies: Reproductive Decisions and Genetic Technologies* (London: HGC, 2006) [HGC, *Making Babies*]; HGC, *Choosing the Future: Genetics and Reproductive Decision Making* (London: HGC, 2004) [HGC, *Choosing the Future*]; HGC, *Response to the Human Fertilisation and Embryology Authority on the Consultation on Preimplantation Genetic Diagnosis*, (London: HGC, 2000) [HGC, *Response*].
- 44 *Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006* (Cth) [Patterson Act]; *Research Involving Human Embryos Act 2002* (Cth.) [RIHE Act]; Austl., Commonwealth, Senate Committee on Community Affairs, *Legislative responses to recommendations of the Lockhart Review* (Canberra: Senate Printing Unit, 2006) [Austl, *Senate Response*]; Austl., Commonwealth, *Legislation Review: Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002* (Canberra: Australian Government Publishing Service, 2005) (Chair: J. S. Lockhart AO QC) [Austl., *Lockhart Review*]; Austl., Commonwealth, National Health and Medical Research Council [NHMRC] '*Human Embryo*': *A Biological Definition: Discussion Paper* (Canberra Australian Government Publishing Service, 2006) [NHMRC, *Human Embryo*]; Austl., Commonwealth, NHMRC, *Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research* (Canberra: Australian Government Publishing Service, 2004) [NHMRC, *Ethical Guidelines*]; Austl., Commonwealth, National Health and Medical Research Council [NHMRC] *Consultation Draft 2007: Ethical Guidelines on the use of Assisted Reproductive Technology in Clinical Practice and Research 2004 (as updated in 2007)* (Canberra: Australian Government Publishing Service, 2007) [NHMRC, *Consultation Draft 2007*]; Austl., Commonwealth, NHMRC *Ethical Aspects of Human Genetic Testing: An Information Paper*. (Canberra: Australian Government Publishing Service, 2000) [NHMRC, *Ethical Aspects*]; *Infertility Treatment Act 1995* (Vic.) [Victoria, IT Act]; Austl., Vic., Infertility Treatment Authority [ITA], *Genetic Testing and the Requirements of the Infertility Treatment Act 1995: Policy in Relation to the Use of Preimplantation Genetic Diagnosis (PGD)* (Victoria: ITA, 2006) [ITA, *PGD Policy*]; Austl., Vic., ITA, *Approved Genetic Testing* (Victoria: ITA, 2006) [ITA, *Approved Genetic Testing*]; Austl., Vic., ITA *Tissue Typing in Conjunction with Preimplantation Genetic Diagnosis* (Victoria: ITA, 2004) [ITA, *Tissue Typing*]; *Human Reproductive Technology Act 1991* (W.A.) [W. A. HRT Act]; Austl., W.A., Reproductive Technology Council [RTC], *Approval for Diagnostic Testing of Embryos: Advice to Clinics* (Perth: RTC, 2004) [RTC].
- 45 *Assisted Human Reproduction Act*, R.S.C. 2004, c.2 [AHR Act]; Health Canada Assisted Reproduction Office, *issues Related to the Regulation of Pre-Implantation Genetic Diagnosis under the Assisted Human Reproduction Act*, (Ottawa: Government of Canada, 2005) [AHRO]. Canada, Canadian Biotechnology Secretariat, *Brave New World: Where Biotechnology and Human Rights Intersect* (Ottawa: Government of Canada, 2005) [Canadian Biotechnology Secretariat]; Canadian Institute of Health Research [CIHR], *Updated Guidelines for Human Pluripotent Stem Cell Research* (Ottawa: CIHR, 2006) [CIHR]; Senate Standing Committee on Social Affairs Science and Technology, *Ninth Report* (2007) online: <http://www.parl.gc.ca/39/1/parlbus/commbus/senate/com-e/soci-e/15rp-e.htm?Language=E&Parl=39&Ses=1&comm_id=47> [Senate].
- 46 *Human Assisted Reproductive Technology Act* (N.Z.), 2004 092 [HART Act]; National Ethics Committee on Assisted Human Reproduction [NECAHR] *Guidelines for Preimplantation Genetic Diagnosis in New Zealand: Consultation Document* (Wellington: Ministry of Health, 2004) [NECAHR, *Consultation*]; NECAHR, *Guidelines on Preimplantation Genetic Diagnosis*, (Wellington : Ministry of Health, 2005) [NECAHR, *Guidelines*]; Human Genome Research Project [HGRP] *Choosing Genes for Future Children: Regulating Preimplantation Genetic Diagnosis* (Dunedin, N.Z, 2006.) [HRGP]; Advisory Committee on Assisted Reproductive Technology [ACART] *Use of Gametes and Embryos in Human Reproductive Research: Determining Policy for New*

- Zealand*, (Wellington: ACART, 2006) [ACART].
- 47 See HART Act, *supra* note 46; RIHE Act, *supra* note 44.
- 48 See HFE Act, *supra* note 43, AHR Act, *supra* note 45, Victoria IT Act, *supra* note 44, and WA. HRT Act, *supra* note 44. But see HFE Bill, *supra* note 43, under review by the House of Lords at the time of writing. The current HFE Act in the UK does not refer to PGD or embryo testing, but the Draft Bill does specifically contemplate embryo testing and sets out criteria for licensing. In the 2006 legislative review of the current Act, HFEA called for more specific legislative parameters in the case of PGD following the legal challenge in *Quintavalle v. Human Fertilisation and Embryology Authority* [2005] UKHL 28. The decision granted the HFEA broad authority over the application of PGD.
- 49 While we recognise that characterisations of the human embryo occur in a variety of contexts, here we focus specifically on characterisations in relation to post-PGD embryos and not those made in other clinical or related contexts. Therefore, while some of the language we have identified may also be used in other contexts such as microscopic assessments of the embryo, here we have identified instances where the language is used to refer specifically to the post-PGD embryo.
- 50 HGC, *Making Babies*, *supra* note 43 at 14, 51; HGRP, *supra* note 46 at 35, 43, 47, 278; NHMRC, *Consultation Draft 2007*, *supra* note 44 at 42.
- 51 HFEA, *Consultation*, *supra* note 43 at 29; HGRP, *supra* note 46 at 43, 47; NMHRC, *Ethical Guidelines*, *supra* note 44 at 61.
- 52 Canadian Biotechnology Secretariat, *supra* note 45 at 2, 22, 23.
- 53 Department of Health, *Draft Bill*, *supra* note 43, s.21(4); *HFE Bill*, *supra* note 43, s.14(4)(9).
- 54 ACART, *supra* note 46 at 12; Science and Technology Committee, *supra* note 43 at 65; HGRP, *supra* note 46 at 50.
- 55 Science and Technology Committee, *supra* note 43 at 56; HFEA, *Choices and Boundaries*, *supra* note 43 at 7; HGC, *Choosing the Future*, *supra* note 43 at 5; HGC, *Making Babies*, *supra* note 43 at 14, 29, 44; HGRP, *supra* note 46 at 4, 235, 321; NECAHR, *Guidelines*, *supra* note 46 at 2.
- 56 Canadian Biotechnology Secretariat, *supra* note 45 at 3-2.
- 57 HGC, *Choosing the Future*, *supra* note 43 at 10.
- 58 NECAHR, *Consultation*, *supra* note 46 at 3.
- 59 HGC, *Choosing the Future*, *supra* note 43 at 18.
- 60 HFEA, *Choices and Boundaries*, *supra* note 43 at 7.
- 61 AHRO, *supra* note 45 at 1.
- 62 *HFE Bill*, *supra* note 43, s.14(4)(9); Department of Health, *Draft Bill*, *supra* note 43, s.21(4).
- 63 Canadian Biotechnology Secretariat, *supra* note 45 at 3-5.
- 64 HGC, *Making Babies*, *supra* note 43 at 44.
- 65 HFEA, *Consultation*, *supra* note 43 at 8.
- 66 ACART, *supra* note 46 at 12; HGRP, *supra* note 46 at 46.
- 67 Lockhart Review, *supra* note 44 at 26.
- 68 HFEA, *Code of Practice 7*, *supra* note 43 at G.8.5.
- 69 HGRP, *supra* note 46 at 46.
- 70 Lockhart Review, *supra* note 44 at 26; HFEA, *Code of Practice 7*, *supra* note 43 at G.8.5.
- 71 J. Barrett, & A. Bocking, 'The SOGC Consensus Statement: Management of Twin Pregnancies Part 2' (2000) 22 SOGC 607-610.
- 72 Lockhart Review, *supra* note 44 at 7.
- 73 Canadian Biotechnology Secretariat, *supra* note 45 at 3-5.
- 74 *Ibid.* at 4-2, 4-3, 4-6, 4-12,
- 75 Science and Technology Committee, *supra* note 43 at 23; HGRP, *supra* note 46 at 47;
- 76 ACART, *supra* note 46 at 13; HGRP, *supra* note 46 at 47.
- 77 RIHE Act, *supra* note 44 at s. 7.(1).
- 78 The HFEA's Code of Practice 7th Ed. specifies that '[o]nly those fresh or frozen gametes and embryos that are surplus to treatment will be used for research' (*supra* note 43 'G.5.13 .l(b)'). Consent for the donation of embryos is required

under the HFE Act 1990 (*supra* note 43 Sch. 3 '1!6(3)) and the purpose must be specified (*supra* note 43 at Sch.3 '1!2(1)). Under Australian law an 'excess ART embryo' is one that was created for ART treatment *and* is 'excess to the needs of' both the woman and the individual who was her spouse at the time of creation (RIHE Act, *supra* note 44). An embryo is defined as 'excess to the needs' of the parties if written authority is given both that it is excess *and* that it can be used for purposes other than treatment of the woman concerned (*ibid* at s.9(1)). In Australia, the recent legislative review committee emphasised the ambiguity in relation to whether 'embryos that are not suitable for implantation for any reason, including embryos that are found to have a disease using ' PGD 'could ever be considered to be 'excess ART embryos' (Lockhart Review, *supra* note 44 at 169). As is discussed in more detail below the recent amendment to the RIHE Act does not change the definition of an 'excess' embryo itself, but rather attempts to distinguish between affected and unaffected embryos for the purposes of the consent procedures. For the purposes of the 'unaffected' this distinction means that it would necessarily be considered an 'excess' embryo by virtue of its suitability for transfer to the woman; and, in the case of Australia this is significant because this characterisation imposes constraints on its use and necessitates the consent procedures in place for the 'use of an excess

ART embryo'. See Lockhart Review, *supra* note 44 at 8; RIHE Act, *supra* note 44 at s.10(2). In New Zealand the use of 'surplus' embryos is governed by the HART Act and reproductive donation is regulated by the NECAHR *Guidelines on Embryo Donation for Reproductive Purposes* (2005), policy in relation to donation for research is currently under development pursuant to the requirement under s.37 of the Act for ACART to provide advice on human reproductive research to the Minister of Health. See ACART, *supra* note 46. In Canada embryo donation is governed by the AHR Act s.8 and proposed regulations for consent are currently under review http://www.hc-sc.gc.ca/ahc-asc/media/nr-cp/2005/2005_IOO_e.html.

- 79 Canadian Biotechnology Secretariat, *supra* note 45 at 4-33.
- 80 HGRP, *supra* note 46 at 163.
- 81 Science and Technology Committee, *supra* note 43 at 23; HFEA, *Choices and Boundaries*, *supra* note 43 at 7.
- 82 HFE Bill, *supra* note 43 at s.15(2)(b)(ab); Department of Health, *Draft Bill*, *supra* note 43 at s. 22 (2)(aa). This section does not pertain only to the storage of 'unaffected' embryos, but to the storage of all embryos.
- 83 HGRP, *supra* note 46 at 163.
- 84 Science and Technology Committee, *supra* note 43 at 23.
- 85 Canadian Biotechnology Secretariat, *supra* note 45 at 4-33.
- 86 HGC, *Making Babies*, *supra* note 43 at 14, 51, 52; HGRP, *supra* note 46 at 21, 43; NHMRC, *Consultation Draft 2007*, *supra* note 44 at 42.
- 87 HGRP, *supra* note 46 at 43.
- 88 HGRP, *supra* note 46 at 17.
- 89 *Ibid* at 52.
- 90 HFEA, *Choices and Boundaries*, *supra* note 43 at 9.
- 91 Mykitiuk & Nisker 'Embryo Health', *supra* note 2.
- 92 HFE Bill, *supra* note 43 at s.14(4)(10); Department of Health, *Draft Bill*, *supra* note 43 at s.21(4).
- 93 AHRO, *supra* note 45 at I, 3; HFEA, *Choices and Boundaries*, *supra* note 43 at 8, 11; HGRP, *supra* note 46 at 7, 44, 47, 50, 134, 240, 262.
- 94 Canadian Biotechnology Secretariat, *supra* note 45 at 3-1, 3-2, 3-5, 3-7.
- 95 HGRP, *supra* note 46 at 1.
- 96 Lockhart Review, *supra* note 44 at 120; HFE Bill, *supra* note 43 at s.14(4)(10); Department of Health, *Draft Bill*, *supra* note 43 at s.21(4).
- 97 ACART, *supra* note 46 at 13.
- 98 HGC, *Choosing the Future*, *supra* note 43 at 12.
- 99 Lockhart Review, *supra* note 44 at xvi.
- 100 ITA, *PGD Policy*, *supra* note 44 at 1.
- 101 W.A. HRT Act, *supra* note 44 s.14 (2b)(a)(ii).
- 102 Science and Technology Committee, *supra* note 43 at 28.
- 103 Patterson Act, *supra* note 44 at s.4; RIHE Act, *supra* note 44 at s.7(1); Lockhart Review, *supra* note 44 at xvi, xxiii, 168, 169; Austl., *Senate Response*, *supra*

note 44 at 37; NHMRC, *Consultation Draft 2007*, *supra* note 44 at 44; Science and Technology Committee, *supra* note 43 at 23. We note that 'suitability' is not used exclusively in relation to PGD, it is a characterisation also used in relation to the clinical assessment of the embryo through the microscope. For example the amendment to the Australian RIHE Act deems an embryo to be unsuitable as determined through PGD *or* through 'objective criteria' set by the NHMRC which relate to what can be observed about the embryo through the microscope (a draft of the objective criteria is available on the NHMRC website: <http://www.nhmrc.gov.au/consult/art.htm>). What is important for our purposes is that PGD is emerging as *one* of the means through which human embryos are deemed 'unsuitable for implantation' and that in the context of PGD 'suitability' is constructed to have particular meanings depending on the purposes for which PGD is being applied.

- 104 HGRP, *supra* note 46 at 304.
- 105 Lockhart Review, *supra* note 44 at 78.
- 106 *Ibid* at 169.
- 107 *Ibid* at 169, 175.
- 108 NHMRC, *Ethical Guidelines*, *supra* note 44 at 49.
- 109 Lockhart Review, *supra* note 44 at 38.
- 110 HGRP, *supra* note 46 at 163.
- 111 HFEA, *Choices and Boundaries*, *supra* note 43 at 7; Canadian Biotechnology Secretariat, *supra* note 45 at 4-3, 4-24).
- 112 HGRP, *supra* note 46 at 163.
- 113 *Ibid*.
- 114 Lockhart Review, *supra* note 44 at xvi; Canadian Biotechnology Secretariat, *supra* note 45 at 3-5; HGRP, *supra* note 46 at 7, 55, 320.
- 115 *Supra* note 43 at s.14(4).
- 116 Lockhart Review, *supra* note 44 at 169.
- 117 HGRP, *supra* note 46 at 3, 37; NECAHR, *Consultation*, *supra* note 46 at 4.
- 118 NECAHR, *Consultation*, *supra* note 46 at 4.
- 119 HGC, *Choosing the Future*, *supra* note 43 at 19; HGRP, *supra* note 46 at 46.
- 120 AHRO, *supra* note 45 at 11; HGC, *Choosing the Future*, *supra* note 43 at 22; HGRP, *supra* note 46 at 236; NECAHR, *Consultation*, *supra* note 46 at 9; NHMRC, *Consultation Draft 2007*, *supra* note 44 at 42.
- 121 HGC, *Response*, *supra* note 43 at 2.
- 122 HFEA, *Code of Practice 7*, *supra* note 43 at G.12.3.2.
- 123 HGC, *Response*, *supra* note 43 at 2.
- 124 *Ibid* at Sch.2 s.3. IZA(1)(a), (2).
- 125 *HFE Bill*, *supra* note 43 at Sch.2 s.3. IZA(1)(c).
- 126 HFEA, *Choices and Boundaries*, *supra* note 43 at 11.
- 127 *Ibid*.
- 128 See: HFEA, Authority decision on PGD policy. <http://www.hfea.gov.uk/cps/rde/xchg/SID-3F57D79B-FDBD411B/hfea/hs.xsl/1_124.html>.
- 129 We note that the penetrance of BRCA gene mutations in the Ashkenazi Jewish community is very high – approaching 80%, see J. P. Struewing et al., 'The carrier frequency of the BRCA 1 183delAG mutation is approximately 1 percent in Ashkenazi Jewish individuals' (1995) 11 *Genetics Nature* 198; P.N. Tonin et al., 'Founder BRCA 1 mutations in Ashkenazi Jewish women' (1995) 57 *Am. J. Hum. Genet* 189.
- 130 T. Krahn 'Where are we going with preimplantation genetic diagnosis?' 2007 176 *Canadian Medical Association Journal* 1455.
- 131 HFEA, *Code of Practice 7*, *supra* note 43 at G.12.3.2.
- 132 *Ibid*, at 12.3.3.
- 133 *Ibid*, at 1ZA(3)(a)-(e).
- 134 Department of Health, *Draft Bill*, *supra* note 43 at 1ZA(3).
- 135 AHRO, *supra* note 45 at 11.
- 136 *Ibid*.
- 137 NECAHR, *Guidelines*, *supra* note 46 at 5.
- 138 *Ibid*.
- 139 HGRP, *supra* note 46 at 236, 316.
- 140 *Ibid*.

- 141 Canadian Biotechnology Secretariat, *supra* note 45 at 3-2.
- 142 AHRO, *supra* note 45 at 11; HGRP, *supra* note 46 at 50.
- 143 HGRP, *supra* note 46 at 37.
- 144 HFEA, *Choices and Boundaries*, *supra* note 43 at 11.
- 145 HGRP, *supra* note 46 at 37.
- 146 Science and Technology Committee, *supra* note 43 at 55.
- 147 *Ibid*, at 67.
- 148 *Ibid*.
- 149 NHMRC, *Consultation Draft 2007*, *supra* note 44 at r.12.2.
- 150 RTC, *supra* note 44 at 3.
- 151 *Ibid* at 4-5.
- 152 ITA, *PGD Policy*, *supra* note 44.
- 153 *Ibid*. at para. 4.2.
- 154 ITA, *Approved Genetic Testing*, *supra* note 44. List A of the schedule covers the '[U]se of PGD where women have already been admitted for treatment and where the purpose of PGD is to detect chromosomal imbalances' in the cases: recurrent implantation failure; recurrent miscarriage; advanced maternal age; previous history of fetal aneuploidy; known carriers of chromosomal rearrangements'. List B covers '[C]urrent use of PGD in Victoria where further notification to the Infertility Treatment Authority is not required': known carriers of chromosomal rearrangements; determination of embryonic sex in specific conditions; and specific heritable single gene disorders.
- 155 *Ibid*. See List C in the schedule.
- 156 *Ibid*. at 5.
- 157 ITA, *PGD Policy*, *supra* note 44 at para 6a), c).
- 158 Canadian Biotechnology Secretariat, *supra* note 45 at 3-2.
- 159 AHRO, *supra* note 45 at 6.
- 160 Canadian Biotechnology Secretariat, *supra* note 45 at 3-2.
- 161 HGRP, *supra* note 46 at 236.
- 162 *Ibid*.
- 163 *Ibid*.
- 164 *Ibid*.
- 165 HGC, *Making Babies*, *supra* note 43 at 45.
- 166 HFEA, *Choices and Boundaries*, *supra* note 43 at 12.
- 167 HGC, *Choosing the Future*, *supra* note 43 at 20.
- 168 *Ibid* at 22; *Code of Practice 6*, *supra* note 43 at '1!14.21.
- 169 *Code of Practice 7*, *supra* note 43.
- 170 HFEA, *Choices and Boundaries*, *supra* note 43 at 14.
- 171 Available online at: www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=17899&Rendition=Web.
- 172 FEA, *Consultation*, *supra* note 43 at 10.
- 173 *Ibid*. at 8.
- 174 GC, *Making Babies*, *supra* note 43 at 49.
- 175 GC, *Choosing the Future*, *supra* note 43 at 8.
- 176 GRP, *supra* note 46 at 240, 320.
- 177 *Supra* note 44.
- 178 HGRP, *supra* note 46 at 26.
- 179 *Ibid*. at 23.
- 180 Lockhart Review, *supra* note 44 at 169; Science and Technology Committee, *supra* note 43 at 23.
- 181 Lockhart Review, *supra* note 44 at 175.
- 182 *Ibid* at xvi; Canadian Biotechnology Secretariat, *supra* note 45 at 5, 7, 22; HFEA, *Consultation*, *supra* note 43 at 8; HGRP, *supra* note 46 at 7, 55, 320; NECAHR, *PGD Policy*, *supra* note 46 at 7.
- 183 HFEA, *Choices and Boundaries*, *supra* note 43 at 7.
- 184 HFEA, *Consultation*, *supra* note 43 at 8.
- 185 HGC, *Choosing the Future*, *supra* note 43 at 45; HGRP, *supra* note 46 at 163.
- 186 Lockhart Review, *supra* note 44 at 168.
- 187 Nisker & White, *supra* note 21; Mykitiuk & Nisker 'Embryo Health', *supra* note 2.

- 188 Lockhart Review, *supra* note 44 at 120; ITA, *PGD Policy*, *supra* note 44 at para. 3.
- 189 Lockhart Review, *supra* note 44 at xvi.
- 190 ACART, *supra* note 46 at 13.
- 191 *Ibid.* at 13.
- 192 Lockhart Review, *supra* note 44 at xvi.
- 193 *Ibid* at xvi, 31, 38, 76, 169. As noted in the Review, the lack of clarity does not necessarily apply to the states which have independent legislation in place governing ART and PGD (2005, 169). The possibility of research under Victoria's *Infertility Act 1995* is much more clear because s.24(a) prohibits research on an in vitro embryo 'if the embryo is unfit for transfer to a woman'. In Western Australia under the HRT Act performing a diagnostic test on an embryo 'unsuitable for transfer' requires consent, and 'any consent given for subsequent use of nonviable embryos is done so freely and is well informed. The use of nonviable embryos for preimplantation genetic diagnosis training has now been approved in three clinics'. See WA HRT Act 1991 at s.22, 26. In the WA Human Reproductive Technology Council's 2004 'Approval for Diagnostic Testing of Embryos: Advice to Clinics', the application process for diagnostic procedures 'carried out as part of a Quality Assurance program' specifies that approval from the NHMRC is required, and that the embryo 'is unfit for implantation on the basis of its biological fitness for implantation'. See s.53W(2)(d)(1) of the WA HRT Act 1991.
- 194 Those most heavily referenced by the committee on this point are confidential submissions and are unavailable to the public. Those available include: The Plunkett Centre for Ethics, Submission LRC550; M. Pera et al, Monash University, Submission LRC509 and Sydney IVF, Submission LRC 819. All available online: <http://www.lockhartreview.com.au/submissions.html>.
- 195 See NHMRC, *Ethical Guidelines*, *supra* note 44 at para 17.17.
- 196 Lockhart Review, *supra* note 44 at 120.
- 197 *Ibid.* at 37.
- 198 *Ibid* at 37, 168.
- 199 *Ibid.* at 37.
- 200 *Ibid* at xvii.
- 201 *Ibid* at 38.
- 202 *Ibid* at 37.
- 203 NHMRC, *Ethical Guidelines*, *supra* note 44 at para 17.17.
- 204 Lockhart Review, *supra* note 44 at 120.
- 205 *Ibid.* at 196.
- 206 *Ibid.* at 43.
- 207 Patterson Act, *supra* note 44 at s.9.
- 208 *Supra* note 43.
- 209 Science and Technology Committee, *supra* note 43 at 23.
- 210 AHR Act, *supra* note 45 at s.5(1)(b), s.7(2)(a)(b), s.8(3).
- 211 Nisker & White, *supra* note 21 at 173. While the provisions of the *AHR Act* apply to all activity regarding assisted human reproduction and related research in Canada, the TCPS and the CIHR Guidelines apply only to research funded by any of the three federal granting agencies, or conducted 'under the auspices' of an institution that receives agency-funding.
- 212 CIHR, *supra* note 45.
- 213 *Ibid* s.8.1.1.1. The inclusion of 'fresh' embryos under s.8.1.1.1 occurred in the June 2005 changes to the Guidelines, however the *Updated Guidelines for Human Pluripotent Stem Cell Research* released in June 2006 supersedes the 2005 version.
- 214 Senate, *supra* note 45.
- 215 *Ibid.*
- 216 ACART, *supra* note 46 at 13.
- 217 *Ibid.* at 12.
- 218 *Ibid* at 13.
- 219 Nisker & White, *supra* note 21.
- 220 Lockhart Review, *supra* note 44 at 120.
- 221 *Ibid.*

- 222 The Act came into operation June 12th, 2007.
- 223 Patterson Act, *supra* note 44 at s.7(1).
- 224 Lockhart Review, *supra* note 44 at xvi. The 'objective criteria' which are to inform decisions based on the observation of a scientist looking at the embryo through a microscope, are currently under review by the NHMRC. A draft of the criteria can be found online at: http://www.nhrnc.gov.au/consult/_files/objective_criteria.pdf. A draft of the 'Contextual Information for the objective criteria issued by the National Medical Research Council (NHMRC) for determining embryos that are unsuitable for implantation' is available online at: http://www.nhrnc.gov.au/consult/_files/contextual_info.pdf.
- 225 *supra* note 44 at 17.
- 226 NECAHR, *Consultation*, *supra* note 46 at 14.
- 227 *Ibid.* at 40, 61.
- 228 Lockhart Review, *supra* note 44 at 120.
- 229 *Ibid.* at 169.
- 230 *Ibid.*
- 231 *Supra* note 44 at s.8. See draft Objective Criteria, *supra* note 224.
- 232 Austl, *Senate Response*, *supra* note 44 at 48.
- 233 Patterson Act, *supra* note 44 at para. 24.
- 234 Lockhart Review, *supra* note 44 at 38.
- 235 *Ibid.* at xv.
- 236 *Ibid.*
- 237 *Ibid xvi.*
- 238 Austl, *Senate Response*, *supra* note 44 at 49.
- 239 Patterson Act, *supra* note 44 at s.35(g).
- 240 Canadian Biotechnology Secretariat, *supra* note 45 at 3-23; Science and Technology Committee, *supra* note 43 at 65.
- 241 L. Mundy 'A world of their own' *Washington Post* (31 March 2002) W22 [Mundy]; M. Spriggs, 'Lesbian couple create a child who is deaf like them' (2002) 28 J. Med. Ethics 283 [Spriggs]; D. W. Brock, 'Shaping Future Children: Parental Rights and Societal Interests' 2005 13 J. Pol. Phil. 377; E. Van Wagner, 'Equal Choice, Equal Benefit: Gendered Disability & the Regulation of Assisted Human Reproduction in Canada' [forthcoming in 2008].
- 242 Mundy, *supra* note 241; 'Couple "choose" to have deaf baby' BBC News (April 8 2002) <<http://news.bbc.co.uk/2/hi/health/1916462.stm>>; J. Savulescu, 'Deaf lesbians, 'designer disability' and the future of medicine' (2002) 325 Br. Med. J. 771; Spriggs, *supra* note 241.
- 243 Canadian Biotechnology Secretariat, *supra* note 45 at 3-23; Science and Technology Committee, *supra* note 43 at 65; HGRP, *supra* note 46 at 240.
- 244 Mykitiuk & Niskier 'Embryo Health', *supra* note 2.
- 245 Science and Technology Committee, *supra* note 43 at 60; HGRP, *supra* note 46 at 240. For a critical perspective on these assumptions in relation to disability see, A. Asch 'Disability, Equality and Prenatal Testing: Contradictory or Compatible?' (2003) 30 Fla. St. U.L. Rev. 315 [Asch, 'Disability']; Adrienne Asch 'Why I haven't changed my mind about prenatal diagnosis: Reflections and refinements' in E. Parens & A. Asch eds. *Prenatal Testing and Disability Rights* (Washington, DC: Georgetown University Press, 2000) 234 [Asch 'Why I haven't changed'].
- 246 J. Mosoff 'Reproductive technology and disability: searching for the 'rights and 'wrongs' in explanation' (1993) 16 Dal. L.J. 98 [Mosoff]; Asch 'Disability', *supra* note 245; Asch 'Why I haven't changed', *supra* note 245. While this perspective is not substantively dealt with it, is sometimes acknowledged in the documents we examined, see, Science and Technology Committee, *supra* note 43 at 58; HGRP, *supra* note 46 at 169.
- 247 *supra* note 43 at 65.
- 248 Asch 'disability', *supra* note 245; Asch 'Why I haven't changed', *supra* note 245; HGRP, *supra* note 46 at 169.
- 249 *supra* note 43 at 65.
- 250 *Ibid.*
- 251 *Ibid.* at 66.
- 252 *Ibid.*

- 253 See Mosoff, *supra* note 246; Asch 'Disability', *supra* note 245; Asch 'Why I haven't changed', *supra* note 245; R. Devlin & D. Pothier, *Critical Disability Theory: Essays in Philosophy, Politics, and Law*, (Vancouver: University of British Columbia Press, 2006) [Devlin & Pothier].
- 254 Canadian Biotechnology Secretariat, *supra* note 45 at 3-23; Science and Technology Committee, *supra* note 43 at 66; Van Wagner, *supra* note 241.
- 255 NECAHR, *Guidelines*, *supra* note 46 at 6.
- 256 ITA, *PGD Policy*, *supra* note 44 at s. 4.3(c).
- 257 NHMRC, *Ethical Guidelines*, *supra* note 44 at 40.
- 258 *HFE Bill*, *supra* note 43 at s.14(4)(10).
- 259 *Ibid.*
- 260 *Ibid* at 100.
- 261 Canadian Biotechnology Secretariat, *supra* note 45 at 3-24; See Van Wagner, *supra* note 241.
- 262 *supra* note 46 at 240.
- 263 *Ibid.*
- 264 Science and Technology Committee, *supra* note 43 at 61; HGC, *Making Babies*, *supra* note 43 at 41.
- 265 HFEA, *Consultation*, *supra* note 43 at 2.
- 266 NECAHR, *Guidelines*, *supra* note 46 at 6; NHMRC, *Consultation Draft 2007*, *supra* note at 44 at r.11.1, 12.2; ITA, *PGD Policy*, *supra* note 44 at s.50; AHR Act, *supra* note 45 at s.5(1)(c); HFEA, *Code of Practice 7*, *supra* note 43 at G.8.7; *HFE Bill* *supra* note 43 at Sch.2 IZA, IZB, IZC.
- 267 Handyside, 'Biopsy', *supra* at note 30; Nisker & Gore-Langton *supra* note 12.
- 268 AHRO, *supra* note 45 at 4; HGRP, *supra* note 46 at 5; NECAHR, *Guidelines* *supra* note 46 at 5; Science and Technology Committee, *supra* note 43 at 64.
- 269 Science and Technology Committee, *supra* note 43 at 61. For examples of specific conditions see above under 'Affected Embryo' or NECAHR, *Guidelines*, *supra* note 46 at 5.
- 270 *Ibid.*
- 271 *Ibid* at 58.
- 272 *Ibid* at 65.
- 273 *Ibid* at 64.
- 274 *Ibid* at 61.
- 275 *Ibid.*
- 276 *Ibid* at 65; HGRP, *supra* note 46 at 55.
- 277 NECAHR, *Guidelines*, *supra* note 46 at 6.
- 278 *Supra* note 45 at s.5(1)(c).
- 279 *Supra* note 45 at 25.
- 280 *Ibid* at 26.
- 281 *Supra* note 44 at 11.1, 12.2.
- 282 ITA, *PGD Policy*, *supra* note 44 at 4.
- 283 *Supra* note 44 at s.50.
- 284 RTC, *supra* note 44 at 5.
- 285 Science and Technology Committee, *supra* note 43 at 61.
- 286 *Ibid* at 61, 64.
- 287 *Ibid.*
- 288 Royal College of Obstetricians and Gynaecologists Ethics Committee, *Advice to President on Preconception Gender Selection for Non-medical Reasons*, (17 April 2002), < <http://www.rcog.org.uk/index.asp?PageID=845#sex> > [RCOG].
- 289 Department of Health, *Government Response*, *supra* note 43 at 12.
- 290 *HFE Bill*, *supra* note 43 at Sch.2 s.31ZA (1)(c), (3), 1ZB-1ZC.
- 291 Science and Technology Committee, *supra* note 43 at 22.
- 292 Department of Health, *Government Response*, *supra* note 43 at 6. This is a fascinating inversion of the precautionary principle which is generally understood to be based on two general criteria: '(a) appropriate public action should be taken in response to limited, but plausible and credible, evidence of likely and substantial harm; (b) the burden of proof is shifted from demonstrating presence of risk to demonstrating absence of risk'. P. Vineis, 'Scientific basis for the Precautionary Principle' (2005) 207 (Supp. 1) *Toxicology & Applied*

- Pharmacology 658; P. Grandjean et al., 'Implications of the Precautionary Principle in research and policy-making' (2004) 45 Am. J. Ind. Med. 382. For a brief discussion of the genealogy of the precautionary principle see M-C, Boissier, 'Pondering the Precautionary Principle' (2003) 70 Joint Bone Spine 318.
- 293 Department of Health, *Government Response*, *supra* note 43 at 12.
- 294 Science and Technology Committee, *supra* note 43 at 55.
- 295 HGRP, *supra* note 46 at 168.
- 296 HGC, *Making Babies*, *supra* note 43 at 15.
- 297 Asch 'Why I haven't changed', *supra* note 245; Devlin & Pothier, *supra* note 253.
- 298 *Supra* note 288.
- 299 *Ibid.*
- 300 K. Devolder, 'Preimplantation HLA typing: having children to save our loved ones' (2005) 31 J. Med. Ethics 582; Y. Verlinsky et al. 'Preimplantation HLA testing' (2004) 291 J. Am. Med. Assoc. 2079; H. Van de Velde et al., 'Novel universal approach for preimplantation genetic diagnosis of B-thalassaemia in combination with HLA matching of embryos' (2004) 19 Hum Reprod 700.
- 301 Science and Technology Committee, *supra* note 43 at 58.
- 302 HGRP, *supra* note 46 at 238.
- 303 *Ibid* at 50.
- 304 *Ibid.*
- 305 NHMRC, *Ethical Guidelines*, *supra* note 44 at 40; NECAHR, *Guidelines*, *supra* note 46 at s.2.7.4; */TA Tissue Typing*, *supra* note 46 at s.1.
- 306 AHRO, *supra* note 45 at 3.
- 307 Canadian Biotechnology Secretariat, *supra* note 45 at 3-26.
- 308 HFEA, PTT Report, *supra* note 43 at 10.
- 309 Science and Technology Committee, *supra* note 43 at 10.
- 310 *Ibid.*
- 311 *Supra* note 43 at Sch.2 s.3 IZA(d).
- 312 HGRP, *supra* note 46 at 238.
- 313 Canadian Biotechnology Secretariat, *supra* note 45 at 26.
- 314 *Ibid.*
- 315 HGRP, *supra* note 46 at 11.
- 316 HFEA, PTT Report, *supra* note 43 at 5.
- 317 *Ibid.* at 2; Science and Technology Committee, *supra* note 43 at 110, table 13.
- 318 Science and Technology Committee, *supra* note 43 at 110, table 12. This approach would be codified if the HFE Bill becomes law, see *supra* note 43 at Sch.2 s.3 IZA(d).
- 319 *Ibid.* at 58.
- 320 [2005] 2 All ER 555 UKHL, [2005] UKHL 28, [2005] 2 WLR 1061 [*Quintavalle*].
- 321 HGRP, *supra* note 46 at 278.
- 322 HGRP, *supra* note 46 at 278.
- 323 *Quintavalle*, *supra* note 320; Science and Technology Committee, *supra* note 43 at 59, Box 4.
- 324 *Quintavalle*, *supra* note 320 at para. 25, 62.
- 325 *Ibid* at para 24, 25, 26; HGRP, *supra* note 46 at 280.
- 326 *Ibid.* at para 26, 62.
- 327 Science and Technology Committee, *supra* note 43 at 111.
- 328 *Ibid.* at 59, box 5.
- 329 *Ibid.* at 141.
- 330 HFEA, *Code of Practice 6*, *supra* note 43 at para.14.2; HFEA, *Code of Practice 7*, *supra* note 43 at para. G.12.3.2.
- 331 Science and Technology Committee, *supra* note 43 at 141.
- 332 Department of Health, *Government Response*, *supra* note 43 at 18.
- 333 *HFE Bill*, *supra* note 43 at Sch.2 s.3 IZA-IZC.
- 334 HGRP, *supra* note 46 at 238.
- 335 NECAHR, *Guidelines*, *supra* note 46 at s.2(7).
- 336 HGRP, *supra* note 46 at 238.
- 337 NECAHR, *Guidelines*, *supra* note 46 at s.2(7).

- 338 HGRP, *supra* note 46 at 238.
- 339 *Ibid.*
- 340 *Ibid.*
- 341 R. Quintero et al., 'In utero cardiac fetal surgery: Laser atrial septotomy in the treatment of hypoplastic left heart syndrome with intact atrial septum' (2005) 193 Am. J. Ob. Gyn. 1424; N.S. Adzick et al., 'Fetal lung lesions: management and outcome' 1998 179 Am. J. Ob. Gyn. 884-889; K. D. Wenstrom, 'Fetal Surgery for Congenital Diaphragmatic Hernia' (2003) 349 New Eng. J. Med. 1887; 'Fetal surgery: Several conditions are proving amenable to treatment in this nascent field' (2003) 326 BMJ 461.
- 342 D. D. Cochrane, B. Irwin, K. Chambers 'Clinical outcomes that fetal surgery for myelomeningocele needs to achieve' (2001) 11(suppl 1) Eur. J. Pediatr. Surg. 2001 S18-S20; L. N. Sutton et al., 'Improvement in hindbrain herniation demonstrated by serial fetal magnetic resonance imaging following fetal surgery for myelomeningocele' (1999) 282 J. Am. Med. Assoc. 1826.
- 343 Science and Technology Committee, *supra* note 43 at 58, 125.
- 344 Canadian Biotechnology Secretariat, *supra* note 45 at 3-26.
- 345 See R. Knox 'Preimplantation Genetic Diagnosis: Disease Control of Child Objectification?' (2003) St. Louis U. Pub. L. Rev. 435 at 6-7 (Lexis Nexis).
- 346 Canadian Biotechnology Secretariat, *supra* note 45 at 3-27.
- 347 Science and Technology Committee, *supra* note 43 at 58, 59.
- 348 *Ibid.* at 60.
- 349 HFEA, *Code of Practice 6*, *supra* note 43 at 3.
- 350 Science and Technology Committee, *supra* note 43 at 60.
- 351 HFEA, *PTT Report* *supra* note 43 at 5.
- 352 Canadian Biotechnology Secretariat, *supra* note 45 at 3-12.
- 353 *Ibid.*
- 354 Science and Technology Committee, *supra* note 43 at 60.
- 355 HFEA, *PTT Report*, *supra* note 43 at 5.
- 356 Department of Health, *Report on Consultation*, *supra* note 43 at 36.
- 357 *Ibid* at 37.
- 358 HFEA, *PTT Report* *supra* note 43 at 5.
- 359 *Ibid.*
- 360 *Ibid.*
- 361 Science and Technology Committee, *supra* note 43 at 60.
- 362 ITA, *Tissue Typing*, *supra* note 44 at 3.
- 363 *Ibid.*
- 364 HFEA, *Consultation*, *supra* note 43 at 11; HGC, *Response*, *supra* note 43 at 4; HGC, *Choosing the Future*, *supra* note 43 at 21, 24, 25; NHMRC, *Ethical Guidelines*, *supra* note 44 at 61; Science and Technology Committee, *supra* note 43 at 58, 61; HGC, *Making Babies*, *supra* note 43 at 14, 23; HGRP, *supra* note 46 at 47, 50, 236, 320, 321.
- 365 HFEA, *Consultation*, *supra* note 43 at 11.
- 366 In autosomal conditions two genes (alleles) occupy a locus, both of which must be the specific gene for the genetic condition under consideration in order for the person to develop the genetic condition. If one gene for the genetic condition occupies the locus, and the second gene is 'normal' the genetic condition is not expressed. This is different from X-linked recessive conditions where the gene for the genetic condition is carried on the X chromosome. Females carrying the gene for the condition on one chromosome, but carrying a 'normal' gene on the other chromosome will not express that condition but are carriers of the gene for the genetic condition whereas males, having only one X chromosome (the other being a Y at this locus) if the X chromosome carries the gene for the genetic condition, the genetic condition will be expressed eg. Haemophilia and Duchennes Muscular Dystrophy.
- 367 A.J. F. Griffiths et al., *An Introduction to Genetic Analysis*, (New York: W.H. Freeman and Company, 2000).
- 368 HFEA, *Consultation*, *supra* note 43 at 11; HGC, *Making Babies*, *supra* note 43 at 14; HGRP, *supra* note 46 at 47, 50.
- 369 Science and Technology Committee, *supra* note 43 at 58, 61; HGRP, *supra* note 46 at 50.

- 370 HFEA, *Consultation*, *supra* note 43 at 11.
- 371 *Ibid.*
- 372 *Ibid.*
- 373 NHMRC, *Ethical Guidelines*, *supra* note 44 at 40.
- 374 *Ibid.*; NHMRC, *Consultation Draft 2007* *supra* note 44 at 42 [emphasis added].
- 375 Implantation of carrier embryos (or temporarily cryopreserving them for later transfer) would also increase the woman's chance of becoming pregnant without the harms associated with additional IVF (and PGD) cycles. See Mykitiuk & Nisker 'Embryo Health', *supra* note 2; Mykitiuk & Nisker 'Assisted Reproduction' *supra* note 16.
- 376 ITA, *PGD Policy*, *supra* note 44 at 2
- 377 ITA, *PGD Policy*, *supra* note 44 at 5.
- 378 HFEA, *Consultation*, *supra* note 43 at 11; Lockhart Review, *supra* note 44 at 11.
- 379 HGC, *Response*, *supra* note 43 at 3.
- 380 *Ibid.* at 3-4.
- 381 HGC, *Choosing the Future*, *supra* note 43 at 24.
- 382 *Ibid.* at 25.
- 383 Mykitiuk & Nisker 'Embryo Health', *supra* note 2.
- 384 *Ibid.*
- 385 HGC, *Making Babies*, *supra* note 43 at 14, 42.
- 386 *Ibid.* at 61.
- 387 *Ibid.* at 14, 42. See S. Mastenbroek et al., 'In Vitro Fertilization with Preimplantation Genetic Screening' (2007) 357 *New Eng. J. Med.* 9: 'Results: Four hundred eight women (206 assigned to preimplantation genetic screening and 202 assigned to the control group) underwent 836 cycles of IVF (434 cycles with and 402 cycles without preimplantation genetic screening). The ongoing-pregnancy rate was significantly lower in the women assigned to preimplantation genetic screening (52 of 206 women [25%]) than in those not assigned to preimplantation genetic screening (74 of 202 women [37%]; rate ratio, 0.69; 95% confidence interval [CI], 0.51 to 0.93). The women assigned to preimplantation genetic screening also had a significantly lower live-birth rate (49 of 206 women [24%] vs. 71 of 202 women [35%]; rate ratio, 0.68; 95% CI, 0.50 to 0.92).
- Conclusions: Preimplantation genetic screening did not increase but instead significantly reduced the rates of ongoing pregnancies and live births after IVF in women of advanced maternal age. (Current Controlled Trials number, ISRCTN76355836 [controlled-trials.com]'
- 388 *Ibid.*
- 389 Min, Claman & Hughes 'Guidelines', *supra* note 17.
- 390 J.S. Younis, et al., 'Late manifestation of pelvic abscess following oocyte retrieval, for in vitro fertilization, in patients with severe endometriosis and ovarian endometriomata' (1997) 14 *J. Assist. Reprod. Genet.* 343; P.B. Miller et al., 'Acute ureteral obstruction following transvaginal oocyte retrieval for IVF: Case report' (2002) 17 *Hum. Reprod.* 137; H. Mertes & G. Pennings, 'Oocyte donation for stem cell research' (2007) 22 *Hum. Reprod.* 629; Abramov, Elchalal & Schenker, *supra* note 25; C.R. Newton, M.T. Heam & A.A. Yuzpe, 'Psychological assessment and follow-up after in vitro fertilization: assessing the impact of failure' (1990) 54 *Fertil Steril.* 879; J. Boivin, L.C. Scanlan & S.M. Walker, 'Why are infertile patients not using psychosocial counselling?' (1999) 14 *Hum. Reprod.* 1384.
- 391 HGRP, *supra* note 46 at 321.
- 392 *Ibid.* at 50.
- 393 NHMRC, *Ethical Guidelines*, *supra* note 44 at C2.
- 394 Mykitiuk & Nisker 'Embryo Health', *supra* note 2.