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PREIMPLANTATION GENETIC DIAGNOSIS: DISEASE CONTROL OR CHILD OBJECTIFICATION?

I. INTRODUCTION

With the advances in assisted reproduction technology (ART), parents now have more choices regarding how and when they start a family. In vitro fertilization (IVF) has been available for some time now as a way to help infertile individuals conceive. However, difficulty conceiving is not the only problem parents may encounter. Some may also face the probability of having a child afflicted with genetic disease. In the past, amniocentesis¹ and chorionic villous sampling (CVS)² were performed on fetuses to detect genetic disease or defects. A new ART technique may make such prenatal diagnostic procedures unnecessary. This new technique is called preimplantation genetic diagnosis (PGD) and is one of the latest tools parents may use to prevent genetic defects in their offspring. Although PGD may help ensure the health of children, there are concerns that it could be used for purposes other than solely for their benefit. While discussing the positive aspects of PGD, it is necessary to consider guarding against the possible exploitation and objectification of children. This paper will begin by outlining the specifics of the PGD procedure. The therapeutic uses of PGD will be distinguished from the non-therapeutic uses. The social, ethical and legal questions regarding their implementation will also be explored. This paper will conclude with a review of existing international regulation of PGD and recommendations for legislation in the United States.

II. DESCRIPTION OF PGD

PGD is a diagnostic procedure that is performed before the embryo is implanted into the woman's uterus.³ A simplified explanation of PGD may be

1. See STEDMAN'S MEDICAL DICTIONARY 62 (26th ed. 1995) (Amniocentesis is the transabdominal aspiration of fluid from the amniotic sac.).

2. See LIFE SCIENCES ONLINE DICTIONARY, at <http://biotech.icmb.utexas.edu/search/dict-search.mhtml>, (last visited June 8, 2003) (CVS is the process of taking a biopsy of the placenta, usually at the end of the second month of pregnancy, to test the fetus for genetic abnormalities (mutations)).

3. M.A.F. El-Hazmi, *Potential Usefulness of Preimplantation Genetic Diagnosis in the Control and Prevention of Genetic Diseases*, 5 E. MEDITERRANEAN HEALTH J. 1134, 1134 (1999).

outlined in three steps: first, several embryos are created using IVF; second, after reaching a certain stage in development, each embryo DNA is tested for genetic disease; third, embryos determined to be unaffected by genetic disease are implanted in the woman's uterus in hopes of a successful pregnancy.⁴ Although each step described above is important, the second step (testing for disease) is crucial to the PGD process. Detecting genetic disease in an embryo can be very complicated and should be explained more fully.⁵ First, oocytes⁶ are recovered by ultrasound-guided aspiration and grown in culture.⁷ Oocytes are then subjected to micromanipulation⁸ and the first polar body⁹ is removed.¹⁰ The polar body is then biopsied and undergoes genetic diagnosis.¹¹ The oocyte is then injected with sperm for zygote¹² formation.¹³ Next, the second polar body is removed for genetic diagnosis.¹⁴ The zygote is allowed to grow to a six-to-eight cell stage one or two cells are then removed for

4. This indeed is a simplified explanation of the PGD process. PGD is a very complicated process requiring expertise in both reproductive and genetic medicine. See Richard J. Tasca & Michael E. McClure, *The Emerging Technology and Application of Preimplantation Diagnosis*, 26 J.L. MED. & ETHICS 7, 12-14 (Spring 1998) (The six technologies involved in PGD include hormonal stimulation, IVF to produce embryos, culture of embryos, biopsy of cells from embryo or polar body biopsy of unfertilized egg, subjecting cells to genetic analysis and transferring the unaffected embryos to uterus.); see also W. Lissens et al., *Review: Preimplantation Diagnosis of Inherited Disease*, 19 J. INHERITED & METABOLIC DISEASE, 709, 719 (1996) ("Preimplantation diagnosis is . . . a procedure requiring the multidisciplinary collaboration of a clinical IVF unit, a laboratory IVF unit with micromanipulation facilities, a molecular biology and cytogenetics laboratory, and clinical genetics unit. Most centers still consider [PGD] an experimental method and request and advise follow-up prenatal diagnosis in cases of pregnancy.").

5. For a detailed discussion of PGD, see generally *A Practice Committee Report: Preimplantation Genetic Diagnosis*, AM SOC'Y OF REPROD. MED. 1 (June 2001) [hereinafter ASRM], available at <http://www.asrm.org/Media/Practice/Preimplantation.pdf>; see also E. Kanavakis & J. Traeger-Synodinos, *Preimplantation Genetic Diagnosis in Clinical Practice*, 39 J. MED. GENETICS 7 (Jan. 2002); El-Hazmi, *supra* note 3, at 1134, 1134-39 (1999).

6. STEDMAN'S MEDICAL DICTIONARY, *supra* note 1, at 1248 (An oocyte is an "immature ovum").

7. El-Hazmi, *supra* note 3, at 1134.

8. STEDMAN'S MEDICAL DICTIONARY, *supra* note 1, at 1113 (Micromanipulation is the "dissection, teasing, stimulation, etc., under the microscope, of minute structures.").

9. LIFE SCIENCE ONLINE DICTIONARY, *supra* note 2 (A polar body is a "small cell which is the product of an uneven division of the cytoplasm during meiosis; the smaller of the two cells produced during a meiotic division of oogenesis (the larger one becomes an oocyte or ovum). It eventually degenerates.").

10. El-Hazmi, *supra* note 3, at 1134.

11. *Id.*

12. STEDMAN'S MEDICAL DICTIONARY, *supra* note 1, at 1976 (A zygote is the "diploid cell resulting from a union of sperm and ovum.").

13. El-Hazmi, *supra* note 3, at 1134.

14. *Id.*

genetic analysis.¹⁵ Analysis is performed by extracting DNA from the cells and subjecting it to polymerase chain reaction¹⁶ (PCR) or fluorescence in situ hybridization¹⁷ (FISH).¹⁸ Although PGD was first performed nearly 13 years ago¹⁹ and has successfully eliminated genetic disease in a number of children,²⁰ clinical application of PGD has remained limited.²¹ Several reasons exist for its slow implementation. First, PGD is a multi-step procedure that requires combined expertise in reproductive medicine and molecular genetics.²² Second, genetic diagnosis of cells is challenging at all stages.²³ Accuracy problems have become apparent,²⁴ including allelic drop out.²⁵ In addition to the practical and technical problems with PGD, there are many social, ethical and legal issues that require further attention and debate. As will be discussed later, some countries have taken steps to address these concerns, while others are just beginning.

III. DEMAND FOR PREIMPLANTATION GENETIC DIAGNOSIS

Despite the many questions that surround the use of PGD, demand for the procedure is increasing.²⁶ Potential uses for PGD can be divided into two

15. *Id.*

16. LIFE SCIENCE ONLINE DICTIONARY, *supra* note 2 (PCR is a method used for amplifying a DNA base sequence using a heat-stable polymerase and two 20-base primers, one complementary to the (+)-strand at one end of the sequence to be amplified and the other complementary to the (-)-strand at the other end. Because the newly synthesized DNA strands can subsequently serve as additional templates for the same primer sequences, successive rounds of primer annealing, strand elongation, and dissociation produce rapid and highly specific amplification of the desired sequence. PCR also can be used to detect the existence of the defined sequence in a DNA sample.)

17. *See* NATIONAL HUMAN GENOME INSTITUTE GLOSSARY, at <http://www.genome.gov/glossary.cfm> (last visited June 8, 2003) (FISH is “a process which vividly paints chromosomes or portions of chromosomes with fluorescent molecules. This technique is useful for identifying chromosomal abnormalities and gene mapping.”).

18. *See* Kanavakis & Traeger-Synodinos, *supra* note 5, at 6; *see also* El-Hazmi, *supra* note 3, at 1134.

19. *See* El-Hazmi *supra* note 3, at 1134-35.

20. *See e.g.*, Denise Grady, *Baby Spared Mother's Fate by Genetic Tests as Embryo*, N.Y. TIMES, Feb. 27, 2002, at 16A (PGD used to ensure the absence of gene that causes early onset of Alzheimer's in resulting child); *see also* Lisa M. Krieger, *Ferretting Out Flawed Embryos*, MERCURY NEWS, March 12, 2002 (offers several examples of successful uses of PGD).

21. Kanavakis & Traeger-Synodinos, *supra* note 5, at 6.

22. *Id.*

23. *Id.*

24. *Id.*

25. ASRM, *supra* note 5, at 1. (Allelic drop out occurs when one of the two alleles selectively amplifies, thus contributing to diagnostic errors.)

26. *See* Aaron Zitner, *A Girl or Boy, You Pick*, L.A. TIMES, July 23, 2002, at 1, at <http://www.latimes.com/la-na-gender23jul23012035>.

groups: therapeutic and nontherapeutic. Therapeutic uses involve utilizing the procedure to prevent and treat disease in children. Nontherapeutic applications involve using PGD for superficial or non-medical reasons like selection of embryos based on gender and physical appearance.

A. *Therapeutic Uses of PGD*

There are two types of therapeutic uses for PGD: one, to prevent genetic disease in *future* children; and two, to treat disease in *existing* children. Parents who are carriers of diseases are often aware of their genetic make-up and the potential of passing those diseases on to the next generation. PGD can be used for those who do not wish their children to suffer from genetic disease. A recent case involved a woman who carried the gene for early onset Alzheimer's disease.²⁷ She used PGD to produce a daughter free of the affected gene.

Other diseases which can be eliminated by using PGD include cystic fibrosis, Tay Sachs, Marfan's Syndrome, Duchenne's muscular dystrophy, Fragile X syndrome, sickle cell and Fanconi's anemia, thalassaemia and Down's syndrome.²⁸ Normally amniocentesis and chorionic villous sampling (CVS) are used to detect such diseases and malformation in fetuses. With those procedures, the woman may consider terminating the pregnancy if the fetus is found to have a disease or defect. PGD is considered more advantageous than these prenatal diagnostic methods because diagnosis is performed before the embryo is implanted in the woman. This way the woman does not have to face the potential emotional and physical effects of abortion.

The second and more controversial therapeutic use of PGD involves using the procedure to select a donor match for an existing ill child. It is possible to choose an embryo that may produce a child who will provide stem cells or bone marrow for a sibling or other relative. PGD has been used for such reasons in the United States and England. In 1999, a couple in the United States used PGD to screen their embryos for one that was a tissue match for their daughter who had Fanconi's anemia.²⁹ Five suitable embryos were implanted in the woman and one resulted in a successful pregnancy. When the new child was born, birth blood from the umbilical cord was harvested and used in a successful stem cell transplant for the daughter. In Britain, where the Human Fertilisation and Embryology Authority must authorize such uses of

27. See Grady, *supra* note 20, at 16A.

28. See ASRM, *supra* note 5, at 2; see also Tasca & McClure, *supra* note 4, at 7.

29. See Lisa Belkin, *The Made-to-Order Savior*, N.Y. TIMES MAG., July 1, 2001, at 38-39 (describing the experiences of parents using PGD to conceive donor matches for their existing children).

PGD, the parents of a 2-year-old boy with beta thalassaemia were given permission to use PGD to produce a matching donor.³⁰

Although these two therapeutic uses of PGD are employed to ensure the health of future and existing children, many questions surround their use. Such concerns include the success rate and reliability of the procedure, discrimination against the disabled, new eugenics worries, creating a social divide between those who have access to the procedure and those who do not, and the ethics of creating a child for donor purposes. All of these concerns will be addressed in turn.

1. Reliability of PGD

As mentioned above, because it is a technically complicated procedure, there may be problems with the accuracy of PGD. The overall diagnostic error rate for PGD is 1.8%.³¹ In fact, one couple tried to sue the institution where they underwent PGD because the procedure failed.³² Despite the fact that the couple had their embryos screened for cystic fibrosis, their daughter was born with the disease.³³ For this reason, the American Society of Reproductive Medicine (ASRM) recommends that for quality control purposes the diagnosis of the affected, non-transferred, abnormal embryos be confirmed on additional blastomeres to ensure the accuracy of the techniques and diagnosis.³⁴ ASRM further suggests that the normality of implanted embryos be reconfirmed by subsequent CVS or amniocentesis.³⁵ Potential parents using PGD should be counseled during the informed consent process that there is a slight chance the procedure may not work. They should be informed further that if the fetus is found later to have a disease or defect, the woman may choose to terminate the pregnancy.

It is also important to note that only diseases selected for screening will be successfully eliminated by PGD. For instance, if a couple uses PGD to screen embryos for cystic fibrosis only, the child may still be born with Down's syndrome or Fanconi's anemia, for which the embryos were not screened. Similarly, the child may still be born with congenital malformations and non-

30. *Health, Go-ahead for 'Designer' Baby*, BBC NEWS, Feb. 22, 2003, at <http://news.bbc.co.uk/1/low/health/1836827.stm>.

31. See Editorial, *Preimplantation Donor Selection*, 358 LANCET 1195 (Oct. 13, 2001).

32. *Doe v. Illinois Masonic Med. Ctr.*, 696 N.E. 2d 707 (Ill. App. Ct. 1998) (resulting child was born with Cystic Fibrosis even after PGD was used to screen for the disease).

33. *Id.*

34. ASRM, *supra* note 5, at 2.

35. *Id.*

genetic diseases that PGD cannot detect.³⁶ Parents should be made aware of these possibilities and counseled before and after undergoing the procedure.

2. Discrimination Against the Disabled

Considered to be a therapeutic procedure, PGD has been called an “effective and compassionate” way to prevent suffering of future children.³⁷ However, there is opposition to PGD being used to identify and discard embryos affected by genetic disease.³⁸ Some advocates for the disabled argue that using PGD will increase intolerance and discrimination against those with disabilities and those afflicted with genetic diseases.³⁹ “As society focuses on improving the human race, compassion for the disabled may decrease to traumatic levels affording less appreciation for differences between individuals.”⁴⁰ This statement assumes that improving the human race means eliminating individuals instead of disease.

Others disagree that choosing to discard diseased embryos will result in “intolerance, aversion or disdain for disabled life” and find a difference between genetic selection and discrimination against the disabled.⁴¹ They point out that many disabled people lead active productive lives and thrive in society. It is argued that these individuals should not be denied any right or aspect of life. However, it should not be assumed that all disabled or ill people share the same positive outlook or are able to appreciate life in the same way.⁴² There are also disabled people who have no cognitive ability or are unable to understand their situation. “Reality proves that, in the worst circumstances, life brings some disabled children only pain, hopelessness, and bodily

36. See Jeffrey Botkin, *Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis*, 26 J.L. MED. & ETHICS 17, 18 (1998) (“PGD is not useful for predicting congenital malformations or diseases that do not have an identified genetic basis.”).

37. Megan Anne Jellinek, Note, *Disease Prevention and the Genetic Revolution: Defining a Parental Right to Protect the Bodily Integrity of Future Children*, 27 HASTINGS CONST. L.Q. 369, 371 (2000).

38. See David S. King, *Preimplantation Genetic Diagnosis and the “New” Eugenics*, 25 J. MED. ETHICS 176 (1999).

39. See Renee C. Esfandiary, Note, *The Changing World of Genetics and Abortion: Why the Women’s Movement Should Advocate for Limitation on the Right to Choose in the Area of Genetic Technology*, 4 WM. & MARY J. WOMEN & L. 499, 499 (1998); see Martha A. Field, *Killing “the Handicapped”—Before and After Birth*, 16 HARV. WOMEN’S L.J. 79 (1993) (discussing the woman’s right to terminate a pregnancy upon discovering a defect in the fetus and the parental right to refuse medical treatment of a new born affected by disease).

40. Esfandiary, *supra* note 39, at 499.

41. See Jellinek, *supra* note 37, at 390; see also Botkin, *supra* note 36, at 23 (“Current experience indicates that society can simultaneously promote respect and opportunity for the disabled while enabling couples to prevent the birth of a disabled child through prenatal diagnosis.”).

42. This is supported by the on going debate over right-to-die issues.

degradation".⁴³ PGD may offer parents a way to prevent "needless suffering" in their future children.⁴⁴

In addition, since parents have been afforded discretion in health matters at all stages of a child's development, they may also have the right to intervene at the embryonic level. For example, parents may use amniocentesis and chorionic villous sampling to determine the health of a fetus. If problems are found, women may choose to terminate pregnancy before viability of the fetus.⁴⁵ Furthermore, when a newborn is found to have a debilitating disease, parents may sometimes choose to cease nourishment or forego life-saving treatment allowing the child to die.⁴⁶ In some instances parents may also choose to forego life support for minor children.⁴⁷ The ability of parents to make end-of-life decisions for their children has been considered by Florida courts:

[D]ecisions of this character have traditionally been made within the privacy of the family relationship based on competent medical advice and consultation by the family with their religious advisors, if that be their persuasion.⁴⁸

Since parents have the right to protect the bodily integrity of future and existing children at the fetal and post birth stages, it would seem parents should also have the power to do so at the embryonic level.⁴⁹

However, should parents have total control at the embryonic level? What if they want to use PGD to purposely create a child *with* a genetic defect? Although there have been no such reported cases, one hypothetical is a deaf

43. Jellinek, *supra* note 37, at 391.

44. *Id.* at 394.

45. See June Coleman, Note, *Playing God or Playing Scientist: A Constitutional Analysis of State Laws Banning Embryological Procedures*, 27 PAC. L.J. 1331, 1346 (1996).

46. See James Bopp, Jr. & Mary Nimz, *A Legal Analysis of the Child Abuse Amendments of 1984*, in *COMPELLING COMPASSION: GOVERNMENT INTERVENTION IN THE TREATMENT OF CRITICALLY ILL NEWBORNS* 73-103 (Arthur L. Caplan, et al., eds., 1992); *but see* 45 C.F.R. § 1340.15(2)(i-iii) (Treatment may only be withheld if the infant is chronically and irreversibly comatose, treatment would merely prolong dying, or the treatment would be futile.); *see also* HCA, Inc. v. Miller, 36 S.W.3d 187, 194 (Tex. App. 2000) (Parents did not have a common law right to withhold treatment from a child who was not terminally ill.).

47. See Ann MacLean Masssie, *Withdraw of Treatment for Minors in a Persistent Vegetative State: Parents Should Decide*, 35 ARIZ. L. REV. 173, 176 (1993).

48. *In re Barry*, 445 So. 2d. 365, 371 (Fla. Dist. Ct. App. 1984).

49. See Jellinek, *supra* note 37, at 387 ("Unlike the limits on reproductive rights, the right to protect children's bodily dignity is more thoroughly grounded in fundamental rights doctrine and, therefore, provides a more trustworthy means of protecting parental discretion in making difficult procreative choices.").

couple using PGD to select an embryo that will develop into a deaf child.⁵⁰ A gene for deafness has been identified,⁵¹ making it possible to use PGD for this purpose. Couples have used other ART methods to purposely increase their chances of having deaf children. A deaf couple in the United States, used a sperm donor who was totally deaf and had five generations of deafness in his family.⁵² Ms. Duscheneau, the expecting mother, explained her position on creating a deaf child as follows, “A hearing baby would be a blessing. A deaf baby would be a special blessing.”⁵³ In 2001, Ms. Duscheneau’s child, Gauvin McCullough, was born with only a slight amount of hearing in one ear.⁵⁴

PGD may be used to accomplish the same goal of having a deaf child. To some critics, intentionally selecting an embryo that will develop into a deaf child may seem unnecessary and of more benefit to the parent than the child. Some may see it as worse than unnecessary - as affirmatively harmful.

But how should harm be defined? What if a parent or physician does not consider deafness to be harmful or to be a disability? This question cannot be asked in terms of other diseases such as cystic fibrosis, Fanconi anemia or Tay-Sachs. Pain and death are associated with these diseases, whereas deaf people are capable of living long and happy lives. This issue relates back to the discussion regarding diversity and tolerance of others. Parents often discover birth defects using CVS or amniocentesis prior to delivery, then decide to carry the pregnancy to term anyway, and raise the child. Is this any different from selecting a diseased embryo for implantation, carrying the pregnancy to term, and raising the child?

However, it seems that if the law allows individuals to sue physicians or institutions that have caused their deafness,⁵⁵ deafness may be viewed as a disability most of society would choose to avoid. There also may be disadvantages to being deaf in terms of education, with the need of translators

50. See Stephanie Adamson, *Genetics and Assisted Reproduction Survey* (1998) available at <http://www.dartmouth.edu/~cbbc/courses/bio4/bio4-1998/StephanieSurvey.html> (last visited June 8, 2003).

51. See *Nonsyndromic Deafness DFNA1 Associated with Homolog of the Drosophila Gene diaphanous*, GENETIC SCIENCE LEARNING CENTER (on file with the author).

52. See *Couple “Choose” to Have a Deaf Baby*, BBC NEWS, Apr. 8, 2002, at <http://news.bbc.co.uk/1/hi/health/1916462.stm> (last visited June 8, 2003).

53. Liza Mundy, *A World of Their Own; In the Eyes of His Parents, If Gauvin Hughes McCullough Turns Out to be Deaf, That Will Be Just Perfect*, WASH. POST, Mar. 31, 2002, at W22.

54. *Couple ‘Choose’ to Have a Deaf Baby*, *supra* note 52 (The couple says they will allow the child to decide if he wants to wear hearing aids when he is older).

55. See *United States v. Kubrick*, 444 U.S. 111 (1979) (A veteran who received treatment at VA hospital that resulted in his deafness would have had a claim had he met the statute of limitations requirements.).

and possibly special schools.⁵⁶ To some it may seem unethical to allow parents to choose a trait in a child that is treated by society as a disability or disadvantage.⁵⁷

3. The Social Divide

Besides discrimination against the disabled, there exists another social concern surrounding the therapeutic use of PGD for future children. The cost of PGD may prevent less financially secure families from access to the procedure. It has been reported that the PGD procedure can cost \$15,000 to \$20,000.⁵⁸ At that cost, only wealthy families may be able to use PGD to prevent disease in future children.⁵⁹ This may create a greater social divide where the rich suffer from fewer diseases and the poor are identified by a higher incidence of genetic defect.

There are also concerns that those who do not use PGD will face higher health insurance costs for their children. A time may come when insurance companies offer a discounted price for those who underwent PGD screening. More troubling is the possibility that instead of merely offering a benefit to those who underwent PGD, insurance companies will start penalizing those who procreate without submitting to PGD. Of course these concerns are all speculative for the moment. However, it is never too early to consider legislation preventing insurance companies from creating a greater divide between those who are able afford coverage and those who are not.

A divide may also develop between countries. When a change in a country causes a shift from poverty to a stronger economy, the health needs of its citizens also shift.⁶⁰ Countries in which starvation was once the main health concern may suddenly face a pattern of diseases that occur later in a person's life. Blood diseases such as sickle cell anemia and thalassaemias have become

56. See Mundy, *supra* note 53.

57. However, some in society may also consider being female or a racial minority a disadvantage. This does not mean that parents should be able to discard embryos merely for these reasons.

58. See Krieger, *supra* note 20; cf. Botkin, *supra* note 36, at 18 ("In a 1997 publication, Bradley Van Voorhis, et. al., calculate the cost per delivery of IVF in 71 couples to be \$43,000 per delivery of an infant.").

59. See Vicki G. Norton, Comment, *Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Legislation*, 41 UCLA L. REV. 1581, 1598 (1994) ("It appears that current costs are prohibitive even for therapeutic preimplantation screening According to Director Joseph D. Schuman [of the Genetics and IVF Institute in Fairfax, Virginia] couples who have inquired about the procedure have been deterred by the cost and lack of insurance coverage for the procedure.").

60. See WORLD HEALTH ORGANIZATION, GENOMICS AND WORLD HEALTH: REPORT ON THE ADVISORY COMMITTEE ON HEALTH RESEARCH §3.2 (2002).

more prevalent in countries going through such demographic transition.⁶¹ Although a country's medical needs may change, its ability to meet those needs may not.⁶² A rapid increase in disease may outpace a country's access to new technology required to counter health problems. If disease prevention methods, such as PGD, are not readily available in these countries, the incidence of genetic disease will be higher than that of more developed nations with better access to advanced medical technologies.

4. Using PGD to Create a Child-Donor for an Existing Sibling

As mentioned above, parents may use PGD not only to prevent disease in future children, but also to benefit existing ill children. In a 2000 meeting, ASRM considered such uses of PGD and concluded that the procedure was justified.⁶³ Since parents have an affirmative right to procreate and may consent to a child being used as a tissue donor, they may conceive a second child in hopes of creating a match for the sick sibling. Parents have used a wide range of conception methods, from PGD to natural coitus, to create children who will provide matching stem cells or bone marrow.⁶⁴

In the Ayala case, the parents of a young girl suffering from chronic myelogenous leukemia conceived another child through natural coitus in the hopes that it would be a compatible bone marrow donor.⁶⁵ When selecting to produce a donor through natural coitus, parents are not certain if the new child will be a tissue-type match. In the Ayala case, the new child was a match and the procedure was a success,⁶⁶ but some parents may wish to eliminate some of the uncertainty when trying to produce a suitable donor match. With PGD, the embryos can be screened before implanting them into the woman's uterus, thus eliminating most uncertainty.

61. *See id.* §5.2.1.

62. *See id.* at §3.2

The evolution of thalassaemia in Cyprus is a good example. This condition was not identified in the island until 1944, when, after a major malaria eradication programme and accompanying improvements in public health, it became clear that among the children there was a common form of anaemia which was later identified as thalassaemia. By the early 1970s it was estimated that, if no steps were taken to control the disease, in about 40 years time the blood required to treat all the severely ill affected children would amount to 78,000 units per annum, 40% of the population would have to be blood donors, and the total cost of managing the disease would equal or exceed the Island's health budget.

63. Robert J. Boyle & Julian Savulescu, *Ethics of Using Preimplantation Genetic Diagnosis to Select a Stem Cell Donor for an Existing Person*, 323 BRIT. MED. J. 1240, 1241 (2001).

64. *See* Belkin, *supra* note 29.

65. *See* Sally Ann Stewart, *Toddler May Be Sister's Lifesaver*, USA TODAY, June 4, 1991, at 3A; *see also* Boyle & Savulescu, *supra* note 63, at 1240 (The Ayala case: parents conceived a child in order to provide stem cells for sibling.).

66. *See* Boyle & Savulescu, *supra* note 63, at 1240.

Commentators have criticized the creation of a child for donor purposes as an unethical reason for having children and as an immoral objectification of the child.⁶⁷ There are worries that the child will not be valued beyond its role as a donor. The child is essentially being brought into the world to benefit the existing members of the family, not necessarily because he or she is a desired addition to the family. Some critics have described creating children to provide stem cells as “using an unborn child as a commodity.”⁶⁸

Supporters of PGD counter this argument by stating that many children are born for a particular purpose, whether it is to care for their parents, as a companion to a sibling or to run a family business.⁶⁹ Advocates of PGD also argue that it is more unethical not to use the procedure when a life of another child can be saved.⁷⁰ Another criticism of creating a donor through PGD stems from the psychological effects it may have on the donor child. This differs from the post-traumatic stress syndrome⁷¹ that some child or adult donors may go through. In contrast, PGD created children will not remember the procedure. Rather, PGD children could be harmed by the later knowledge that they were conceived primarily for their tissue harvested at birth. Such theories of psychological harm have been dismissed as “unpredictable, unlikely to occur, and even if [occurring], unlikely to be so severe that it would be better for that particular child never to have existed.”⁷² It has also been argued that it is difficult to claim that being born for a particular reason is against a child’s best interest, or inflicts harm on that child.⁷³ It cannot be said that a child whose conception was motivated by the need to produce a donor is harmed, because the alternative for that child is to never have been born.⁷⁴ Others even

67. See Stephanie J. Hong, *And “Cloning” Makes Three: A Constitutional Comparison Between Cloning and Other Assisted Reproductive Technologies*, 26 HASTINGS CONST. L.Q. 741, 780 (1999) (“There are, however, some commodification-objectification concerns in creating a child simply to produce an organ or tissue donor.”).

68. See Boyle & Savulescu, *supra* note 63, at 1241.

69. *Id.*

70. See Belkin, *supra* note 29, at 40 (Dr. John Wagner argues that it is “indefensible” not try to save a dying child when you have the capability).

71. See Cara Cheyett, Note, *Organ Harvests from the Legally Incompetent: An Argument Against Compelled Altruism*, 41 B.C. L. REV. 465, 477 (2000) (“Fully one-third of children whose siblings were bone marrow recipients suffered from signs of post traumatic stress syndrome.”).

72. Boyle & Savulescu, *supra* note 63, at 1240.

73. Michael T. Morley, Note, *Proxy Consent to Organ Donation by Incompetents*, 111 YALE L.J. 1215, 1223 (2002).

74. Boyle & Savulescu, *supra* note 63, at 1240.

argue that due to the intense bonding that can occur between siblings there are psychological benefits, not harm, to tissue donation.⁷⁵

While these are intriguing points from supporters of PGD, using the procedure to produce a donor should not be advocated lightly. Physicians should develop protocols to ensure that children created by using PGD are valued as individuals and not mere tissue donors. First, doctors should ensure that there are no other treatments available for the existing child. This includes ensuring that there are no available adult donors. Second, doctors should only perform the procedure for families indicating they desire more children.⁷⁶ Third, the family should be counseled on the success rate of the procedure. They should be reminded that PGD is a complicated procedure involving six separate technologies, each complex and subject to technical errors.⁷⁷ The parents should be prepared not only for the possibility that the child may still be born with the disease for which it was screened,⁷⁸ but that it could be born with other diseases for which it was not screened.⁷⁹ Fourth, the parents should be counseled on the possible psychological effects on the donor child. Finally, the family should agree to periodic follow up counseling sessions to monitor the family's adjustment after the procedure.

The medical community has also considered the possibility that parents will use PGD and then decide to abort the fetus once it reaches the stage at which the desired tissue or "cord blood can be retrieved."⁸⁰ Although labeled an "extreme speculation,"⁸¹ the possibility of aborting a fetus after harvesting donor tissue remains a constant issue in the discussion of using PGD to help an existing child.⁸²

75. Peter Browett & Stephen Palmer, *Altruism by Proxy: Volunteering Children for Bone Marrow Donation: Legal Barriers Might Have Catastrophic Effects*, 312 BRIT. MED. J. 242 (1996).

76. See Belkin, *supra* note 29, at 40 (Dr. Mark Hughes proposed such a requirement on parents wishing to use PGD to save an existing child.).

77. See Tasca & McClure, *supra* note 4, at 12; see text accompanying note 4.

78. *Doe v. Illinois Masonic Med. Ctr.*, 696 N.E.2d 707 (Ill. App. Ct. 1998) (resulting child was born with Cystic Fibrosis even after PGD was used to screen for the disease).

79. See Botkin, *supra* note 36, at 19.

80. LANCET, *supra* note 31, at 1195.

81. *Id.*

82. See Belkin, *supra* note 29, at 40

The author asks, "If society gives its blessing to the use of one child to save another, then what would prevent couples from someday going through with the process but aborting when the pregnancy was far enough along that the cord blood could be retrieved? Or what would prevent couples whose child needed a new kidney from waiting until the fetal kidney was large enough, then terminating pregnancy and salvaging the organs?"

While a woman may terminate a pregnancy for any reason up to the point of viability,⁸³ state laws prohibiting experimentation on fetuses may prevent women from aborting fetuses to retrieve tissue needed to save an existing child.⁸⁴ Within Florida's abortion statute is a provision that bans experimentation on fetuses:

No person shall use any live fetus or live, premature infant for any type of scientific, research, laboratory, or other kind of experimentation either prior to or subsequent to any termination of pregnancy procedure except as necessary to protect or preserve the life and health of such fetus or premature infant.⁸⁵

Since PGD involves human subjects and the technology is considered "new" or "experimental," it may be classified as research.⁸⁶ If the step of collecting tissue samples or cord blood from the fetus, subsequent to termination were considered a part of the experimental PGD process, Florida law would then prohibit the practice. However, it is unclear what is meant by the phrase "live fetus." If the harvesting of the needed blood cells or tissue is conducted on a fetus that is no longer "live" immediately after termination, the procedure may be permissible. It is also interesting to consider what the outcome would be if the fetus is determined to be dead within the womb. Arguably, it could be permissible to collect the needed blood cells or tissue in that situation since the fetus is no longer "live."

B. *Nontherapeutic Uses of PGD*

PGD can also be used for nontherapeutic reasons, some of which may be superficial. It is not always clear what reasons should be defined as nontherapeutic and superficial. Do they go beyond hair and eye color? Should I.Q. be included? For the purposes of this paper nontherapeutic uses of PGD

83. See *Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

84. See FLA. STAT. ANN. § 390.0111(6) (2001).

85. *Id.*

86. See NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, Part A (1979) ("Experimental" does not always make a procedure "research," but new procedures should be the object of formal research at an early stage to determine if it is safe.); see also ASRM, *supra* note 4, at 5 ("Procedure for the treatment of infertility is considered experimental until there is scientific evidence indicating safety and efficacy."); see also THE NEW YORK TASK FORCE ON LIFE AND THE LAW, ASSISTED REPRODUCTIVE TECHNOLOGIES: ANALYSIS AND RECOMMENDATION FOR PUBLIC POLICY, 223 (1998) (Standards are generally stricter in cases involving experimental treatments, both because the risks to the patient may not be known and because the physician, as researcher, may not be motivated solely by the patient's best interests.); see also Karin Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 167 (1998) (Innovative therapies should be conducted as research.).

will be divided into three categories.⁸⁷ The first category consists of selection based on cosmetic traits, associated with the physical appearance of an individual (hair and eye color). The second includes selection based on performance traits, concerning a person's skills and aptitudes (I.Q. and musical ability). The third category involves selection based on gender/sex traits, relating to an individual's sexual identification and possibly sexual orientation⁸⁸ (male or female, heterosexual or homosexual).⁸⁹

1. Cosmetic Selection

The first category, cosmetic selection, may be compared to racial discrimination. Racial discrimination is prejudice against a person based on outward appearance, including skin color, hair color, eye color and physical build.⁹⁰ If it is both morally and legally objectionable to discriminate against someone due to skin color, it may be just as unacceptable to discriminate against someone based on superficial traits like hair and eye color. However, whether it should be unacceptable depends on the reasoning for outlawing racial discrimination.⁹¹ If the purpose of the law prohibiting discrimination is to protect a "discrete and insular" minority,⁹² then discrimination based on nonracial cosmetic traits may be permitted. Certain groups of people may not be considered discrete and insular just for having specific cosmetic traits. On the other hand, if the reason for preventing racial discrimination is grounded in the idea that a person should not be judged by traits that have nothing to do with ability, then it follows that a person should not be discriminated against based on cosmetic traits.⁹³

87. Norton, *supra* note 59, at 1604-06 (The first two of the categories used here are based on those mentioned by Norton.)

88. Although a "gay gene" has not been discovered, scientists have been unable to invalidate the idea that genetics influence sexual orientation. See Erica Goode, *Study Questions Gene Influences on Male Homosexuality*, N.Y. TIMES, Apr. 23, 1999, at A18; see also Rick Weiss, *Research Casts Doubt on "Gay Gene" Theory; Study Finds Nothing Within X Chromosome That Predicts Male Homosexuality*, WASH. POST, Apr. 23, 1999, at A12 (Both articles report that a team of researchers were unable to confirm a study linking male homosexuality to "gay gene.").

89. Gender traits fall outside the category of cosmetic traits because sex identification cannot always be based on physical appearance. In addition, there are issues of gender equality and homophobia that are more easily addressed if gender and sexual orientation selection occupy a separate category.

90. Norton, *supra* note 59, at 1607.

91. *Id.* at 1607-08.

92. See *United States v. Carolene Prod.*, 304 U.S. 144, 152 n.4 (1938).

93. Here discrimination against people is being analogized with discrimination against embryos. It should be noted that in most cases embryos are not given the same constitutional status as people, making this analogy invalid.

Parents who use PGD to select for specific physical traits should be reminded that the procedure sometimes fails. They may feel disappointed if they do not get the blond hair, blue-eyed bundle of joy they ordered. Furthermore, even if the procedure is a success, the child may later choose to change his or her appearance. PGD may enable parents to select traits at the genetic level, but it cannot control the environment into which the child is born. Parents should be counseled on possible unrealistic behavior expectations placed on children selected for certain physical traits. Since environment also has an impact on a child's development and personality, selecting a child based on physicality may not always result in the family parents envisioned.

2. Performance Traits Selection

It may be more difficult to argue against using PGD for the second category, performance traits. We allow discrimination against naturally born persons who do not fulfill certain ability or aptitude requirements.⁹⁴ This is an accepted form of discrimination because many in the United States subscribe to the theory that those who occupy the low end of nature's bell curve are necessary to the functions of society. This is the classic capitalist view of society. So, for example, if parents have the economic means they may use PGD to produce the musical prodigy they always wanted.

As previously mentioned, however, PGD cannot control the environment in which a child is born. The child could have other influences besides the parents, leading to a passion for something besides music. With this possibility, it is important that children not be exploited to attain the goals and interests of their parents. There needs to be a balance between the interest in preventing the exploitation of children and the harm in not allowing parents to select an "ideal" child.⁹⁵ While preventing parents from using PGD to select a child based on performance traits may inhibit their procreative freedom, caring for a normal child would cause no greater cost than caring for a gifted child. However, the expectations placed on an "ideal" child may cause psychological or self esteem issues. Therefore, the interest in protecting the child outweighs the parents' desire to select a child based on performance traits. For this reason, using PGD to select children based on performance traits should not be permitted.

Furthermore, allowing parents to select children based on performance traits again raises questions regarding the social divide. If only the wealthy are

94. Examples include employers who hire based on speed typing skills, schools that reject students based on SAT or LSAT scores, and art institutions that pass over individuals considered to lack talent.

95. Norton, *supra* note 59, at 1608.

able to use PGD to select children with the best performance traits, those who are less financially secure are placed at yet another disadvantage. Although speculative at this point, it is foreseeable that only offspring of the wealthy would be able to attain high scores, preferred college acceptance and laudable employment.⁹⁶ The status quo may become harder to overcome for those who do not have access to the procedure.

3. Gender/Sex Selection

Of the three categories of nontherapeutic PGD uses to benefit future children, selection based on gender/sex traits has received the most debate.⁹⁷ Using PGD for sex selection originated out of the desire to create children who lacked an X chromosome linked disease.⁹⁸ Once it was determined that the procedure could be used to select embryos on the basis of sex, potential parents began inquiring into its use for non-medical purposes.⁹⁹ In 2002, a California woman, who already had three sons, used PGD to select a girl.¹⁰⁰ The mother said that she loved her sons, but longed to recreate the intimacy that she enjoyed with her own mother.¹⁰¹ This is a valid wish, but it may be that the daughter is unable to fulfill the mother's desire for a healthy mother-daughter relationship. Not all mothers and daughters enjoy each other's company.

This has raised the dilemma of balancing a parent's procreative freedom to choose a male or female child against the larger societal concern regarding gender stereotypes and equality. "Sex selection is sex discrimination, and I don't think that is ethical," said Dr. James Grifo of the Society for Assisted Reproductive Technology.¹⁰² In contrast, at a lecture, Dr. Joe Leigh Simpson, Chairman of the Department of Obstetrics and Gynecology at Baylor University said, "I would submit that gender selection is really not an issue

96. How is this prediction any different from the social divide that exists now? The wealthy already have an advantage in being able to afford the best schools and academic prep course for their children. The thousand dollar fee to enroll a child in an ACT, SAT, MCAT or LSAT prep course may be out of reach for many families, leading to lower scores in students who could not afford to take the classes. Furthermore, the cost of tuition for higher education also makes it harder for the less financially secure to overcome the status quo.

97. Since a gene has not been found that relates to homosexuality, the focus has mainly been on the consequences of using PGD to select the gender of future children.

98. See Rachel E. Remaley, "The Original Sexist Sin: Regulating Preconception Selection Technology," 10 HEALTH MATRIX 249, 253 (2000) ("To summarize, certain diseases cannot be genetically detected, but are linked to a sex chromosome in such a way that only boys of the prospective parents in question can be affected.").

99. *Id.* ("PGD for non-therapeutic purposes is quickly becoming a reality.").

100. See Zitner, *supra* note 26.

101. *Id.*

102. Gina Kolata, *Fertility Ethics Authority Approves Sex Selection*, N.Y. TIMES, Sept. 28, 2001, at A16.

... Basically, common sense will reign. I think the public is too sophisticated to succumb to any slippery-slope uses of this technology.”¹⁰³

While it is true that PGD has not been proven to be used in the United States to overwhelmingly select one gender over another, Dr. Simpson must be unaware of, or ignoring the popular use of, ARTs for sex selection in other countries.¹⁰⁴ In India and China, other methods of sex selection (ultrasounds, abortion and infanticide) are used to attain a preferred male child.¹⁰⁵ If nothing is to stop parents in other countries from slippery-slope use of ART technology, is it not possible that it will happen in the United States? Both India and China have banned prenatal tests used to determine the sex of a fetus, and India’s law may also apply to preconception methods.¹⁰⁶ However, illegal use of ARTs for sex selection still occurs in those countries.

Without any regulation of PGD for nontherapeutic purposes in the United States, many turn to the American Society for Reproductive Medicine (ASRM) for guidance on such issues.¹⁰⁷ ASRM has fluctuated in its views. In 1999, ASRM said that selecting embryos on the basis of sex should be discouraged.¹⁰⁸ “The initiation of IVF with PGD solely for sex selection holds even greater risk of unwarranted gender bias, social harm, and the diversion of medical resources from genuine medical need.”¹⁰⁹ However, in 2001 the acting head of ASRM’s ethics committee, John Robertson, said it would be acceptable to use PGD for selection under the same conditions as those outlined for sperm sorting.¹¹⁰ Those conditions are: (1) the couple is fully informed of the risk of failure; (2) they affirm that they will accept children of the opposite sex if the selection method does not work; (3) they are counseled about having unrealistic expectations about the behavior of children of a particular gender; and (4) they are offered the opportunity to participate in

103. Am. Soc. Of Reprod. Med., *57th Annual Meeting of the American Society of Reproductive Medicine*, DAILY NEWS (2000), available at <http://asrm.online-daily.com/day3/Day3story1.htm> (It is interesting to note that the majority of the speakers at the meeting were male.).

104. Bonnie Stienbock, *Sex Selection: Not Obviously Wrong*, 32 no.1 HASTINGS CTR. REP., 23, 26 (2002).

105. *Id.*

106. *Id.*

107. See generally John Robertson, *Sex Selection: Final Word from the ASRM Ethics Committee on the Use of PGD*, 32 no.2 HASTINGS CTR. REP. 6 (2002).

108. Ethics Committee of the Am. Soc. of Reprod. Med., *Sex Selection and Preimplantation Genetic Diagnosis*, 72 ETHICS COMMITTEE REP., FERTILITY AND STERILITY, 861, 863-64 (May 2001) available at http://www.asrm.org/Media/Ethics/Sex_Selection.pdf.

109. *Id.*

110. See Stienbock, *supra* note 104, at 25.

research tracking the safety and efficacy of the selection process.¹¹¹ Reversing the reversal, in 2002 Mr. Robertson said that upon additional review such uses of PGD “should be discouraged” even when parents only want to use the procedure to add gender variety to the existing family.¹¹² Ultimately, in January of 2002, the ASRM committee found that there is a difference between preconception sex selection, like sperm sorting, and PGD embryo sex selection.¹¹³ Embryos created through IVF, unlike sperm, are accorded “special respect.”¹¹⁴ Since embryos are given a special respect above that of sperm or eggs, ASRM has asserted that using PGD for sex selection alone cannot be justified because embryos would be discarded merely because they were the “wrong” sex. “[T]he committee concluded that the interest in choosing the gender of offspring had not yet been shown to be strong enough to justify the creation and destruction of embryos solely for gender variety in a family.”¹¹⁵

111. Ethics Committee of the Am. Soc. for Reprod. Med., *Preconception Gender Selection for Nonmedical Reasons*, 75 ETHICS COMMITTEE REP., FERTILITY AND STERILITY, 861, 863-64 (May 2001) available at <http://www.asrm.org/Media/Ethics/preconceptiongender.pdf>.

112. See Gina Kolata, *Fertility Society Opposes Choosing Embryos Just for Selection*, N.Y. TIMES, Feb. 16, 2002, at A16.

113. See Robertson, *supra* note 107.

114. AFS Publication, Vol. 46, No. 3, at 29S

Embryos deserve respect greater than accorded to human tissue, but not the respect accorded to actual persons. The [embryo] is due greater respect than any other human tissue because of its potential to become a person and because of its symbolic meaning for many people. Yet, it should not be treated as a person, because it has not yet developed the features of personhood, is not yet established as developmentally individual, and may never realize its biological potential.

115. Robertson, *supra* note 107.

IV. PROPOSED REGULATION OF PGD

In England, PGD is authorized on a case-by-case basis as prescribed by the Human Fertilisation and Embryology Act of 1990 (HEFA).¹¹⁶ In Germany, PGD and embryo screening has been outlawed by the federal government.¹¹⁷ The United States has not passed any federal laws specifically regulating the technology, but some state statutes may prohibit the use of PGD.¹¹⁸

If any legislation in the United States is proposed, a balance must be struck between advancing disease prevention and guarding against the objectification of children. Although HEFA seeks to control any misuse of PGD on a case-by-case basis, it may actually inhibit disease prevention.¹¹⁹ In Germany, use of PGD is barred completely.¹²⁰ There, the Embryo Protection Law protects embryos from “improper use” and guards against improper use of reproduction technologies.¹²¹ Also, the Federal Physicians Chamber provides guidelines for the conditions of IVF use in Germany, preventing the procedure for any use other than infertility.¹²² Since PGD is used to benefit children and not infertile couples, the guidelines prohibit the procedure.

The United States should not follow Germany’s lead, but instead enact federal regulations similar to England’s – with a few modifications. While physicians should exercise caution in implementing PGD, the procedure should remain available to families for certain reasons. Parents should be able to use PGD to prevent serious disease in future children, but not to select embryos on the basis of superficial traits such as physical characteristics, performance ability, or gender. Further debate and dialogue is needed to

116. See generally Human Fertilisation and Embryology Act, 1990, c. 37, §§ 11-13, sched. 2 (Eng.) available at http://www.legislation.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm (last visited June 8, 2003).

117. See Stephan Mueller, *Ethics and the Regulation of Preimplantation Diagnosis in Germany*, 7 EUBIOS J. OF ASIAN AND INT’L BIOETHICS, 5, 5-6 (1997) available at <http://www.biol.tsukuba.ac.jp/~macer/EJ71/EJ71D.html>; Dorothy Wertz, *Germany Reconsiders Preimplantation Diagnosis Ban*, GENELETTER, (Apr. 1, 2001), at <http://www.geneletter.org/04-01-01/features/germany.html>; see Zitner, *supra* note 26 (“In Germany, the federal government has barred embryo screening for any purpose.”).

118. See LA. REV. STAT. ANN. § 9:124 (West 1991) (This statute declares embryos to be “judicial person which shall not be intentionally destroyed.”). In the PGD process, most embryos found to be affected by disease are discarded and destroyed. The statute makes it impossible to discard any embryo, even those known to be affected by disease. Therefore, parents in Louisiana may have to forgo PGD or pay for the continuous storage of embryos affected by disease.

119. See *Couple’s “Designer Baby” Plea Denied*, UK NEWSQUEST REGIONAL PRESS, Aug. 2, 2002 (A couple whose son suffered from Diamond Blackfan anaemia was denied the use of PGD to provide him with a bone marrow donor.); see also *Six Couples “Want Designer Babies,”* BBC NEWS, Feb. 24, 2002 at <http://news.bbc.co.uk/1/hi/health/1839071.stm>.

120. See Wertz, *supra* note 117.

121. See Mueller, *supra* note 117, at 5.

122. *Id.*

determine if legislation is required to prevent parents from using PGD to create a genetic condition or disability in a future child. While parents have the right to carry a pregnancy to term when a defect is detected in the fetus through CVS or amniocentesis, it is questionable whether they should be able to intentionally create disease in a future child using PGD. Strict protocols should also be instituted for situations in which PGD is used to create a donor match for an existing ill child. In this case, parents should be screened for a desire to have more children, informed of the success rates and counseled on the problems that they may encounter in raising a donor child. These precautions will ensure that PGD remains available to help prevent and treat disease while guarding against the objectification of children.

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