

PREIMPLANTATION GENETIC DIAGNOSIS AND PARENTAL PREFERENCES: BEYOND DEADLY DISEASE

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I. INTRODUCTION

Preimplantation genetic diagnosis (PGD) is the genetic testing of embryos created through in vitro fertilization (IVF) before selection of embryos for transfer to a woman's uterus.¹ PGD developed initially as an alternative to prenatal genetic diagnosis and termination—a way to have a child free of fatal or severe genetic

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¹ Santiago Munné & Dagan Wells, *Preimplantation Genetic Diagnosis*, 14 CURRENT OPINION IN OBSTETRICS AND GYNECOLOGY 239 (2002); A.H. Handyside et al., *Pregnancies From Biopsied Human Preimplantation Embryos Sexed by Y-Specific DNA Amplification*, 334 NATURE 768 (1990).

disease.² However, it is possible for PGD to be used by prospective parents to select characteristics of their children beyond those linked with serious immediate health concerns. Numerous ethical questions exist about whether it is appropriate for parents to use PGD for this purpose. The ability to test for genetic sequences associated with diseases and other inherited characteristics is increasing, and currently, genetic tests for more than a thousand genetic diseases are either available or under development.³ PGD makes it possible to use virtually any of these tests on a small amount of genetic material from an egg or embryo outside the womb.⁴ However, since PGD was first reported in 1990, little information has been reported or available concerning the reasons for which it is used in the United States.⁵

The specter of “designer babies” and parents selecting children based on characteristics such as appearance or intelligence has long haunted scientists, bioethicists, and policymakers alike.⁶ Will parents and providers employ PGD for such reasons if and when it is possible to do so? If yes, are there appropriate and effective forms of oversight to prevent such uses?

New data from a recent survey conducted by the Genetics and Public Policy Center at Johns Hopkins University (hereafter the Center) suggest that some parents currently use PGD to select genetic characteristics beyond those linked to severe or deadly disease.⁷

² Yury Verlinsky et al., *Over a Decade of Experience with Preimplantation Genetic Diagnosis: A Multicenter Report*, 82 FERTILITY & STERILITY 292 (2004).

³ GENETESTS, <http://www.genetests.org> (last visited on Sept. 22, 2005).

⁴ Munné & Wells, *supra* note 1, at 239.

⁵ Susannah Baruch et al., *Genetic Testing of Embryos: A Critical Need for Data*, 11 REPROD. BIOMED. ONLINE 667 (2005).

⁶ See, e.g., R.G. Edwards, *A Burgeoning Science of Embryological Genetics Demands a Modern Ethics*, 15 REPROD. BIOMED. ONLINE 34 (2007); Sonia M. Suter, *Brave New World of Designer Babies*, 22 BERKELEY TECH. L.J. 897 (2007); Bartha M. Knoppers et al., *Preimplantation Genetic Diagnosis: An Overview of Socio-ethical and Legal Considerations*, 7 ANN. REV. OF GENOMICS & HUM. GENETICS 201 (2006); John A. Robertson, *Extending Preimplantation Genetic Diagnosis: The Ethical Debate – Ethical Issues in New Uses of Preimplantation Genetic Diagnosis*, 18 HUM. REPROD. 465 (2003); Jason C. Roberts, *Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas*, DUKE L. & TECH. REV. 12 (2002); THE PRESIDENT’S COUNCIL OF BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES (2004), <http://www.bioethics.gov/reports/reproductionandresponsibility/index.html>.

⁷ Susannah Baruch et al., *Genetic Testing of Embryos: Practices and Perspectives of U.S. IVF Clinics*, 89 FERTILITY & STERILITY 1053-58 (2008).

Although some options for government oversight exist, this article argues that, at present, government oversight is better suited to issues of the safety and efficacy of PGD rather than the personal and complicated ethical dimensions. At a minimum, more comprehensive data and significant follow-up research are necessary to understand fully the ethical dimensions of current use of PGD by parents and to determine whether there are appropriate policy approaches to these ethical concerns.

Section II of the paper provides a short introduction to the science of PGD. Section III describes the Center's new data, which illuminate details of the use of PGD for four indications beyond avoidance of serious genetic conditions. Section IV presents the ethical debates about these uses of PGD and approaches to oversight of ethical issues. Section V describes current legal oversight of PGD in the United States and Section VI concludes that issues of data collection and the safety and efficacy of PGD are ripe for oversight in the United States.

II. WHAT IS PREIMPLANTATION GENETIC DIAGNOSIS?

PGD requires egg extraction, in vitro fertilization, cell biopsy, genetic analysis, and embryo transfer.⁸ The prospective mother takes drugs to stimulate egg production. Her eggs then are removed and fertilized with sperm in a Petri dish in the laboratory.⁹ Most commonly genetic tests are performed on one or two cells taken from an embryo two to four days after fertilization.¹⁰ The test may involve chromosomal analysis to assess the number or structure of chromosomes present in the cells or DNA analysis to detect specific gene mutations.¹¹ Test results are used by parents and providers to

⁸ Anver Kuliev & Yury Verlinsky, *Place of Preimplantation Diagnosis in Genetic Practice*, 134 AM. J. MED. GENETICS 105 (2005); Munné & Wells, *supra* note 1, at 239; *see also* Alan H. Handside & Joy D. A. Delhanty, *Preimplantation Genetic Diagnosis: Strategies and Surprises*, 13 TRENDS IN GENETICS 270, 271 (1997) (reporting of PGD).

⁹ *See generally* Kuliev & Verlinsky, *supra* note 8, at 105 (describing two approaches in performing PGD).

¹⁰ Alternatively, genetic tests can be performed on polar body cells that are cast off by the egg as it matures and is fertilized. *See* Yury Verlinsky & Anver Kuliev, *Preimplantation Polar Body Diagnosis*, 58 BIOCHEMICAL & MOLECULAR MED. 13 (1996).

¹¹ *See* Kuliev & Verlinsky, *supra* note 8, at 105; *see also* Munne & Wells, *supra* note 1, at 239.

select which embryos are transferred back to the woman's uterus.¹²

PGD originally was developed for families affected by serious inherited genetic illnesses¹³ and has been used by families to avoid having children afflicted with such diseases as cystic fibrosis, Tay Sachs disease, Fanconi Anemia, and sickle cell anemia.¹⁴ It also has been used to detect mutations linked with adult-onset disorders.¹⁵ Although PGD was initially developed to detect serious disorders, more recently PGD has been used in an effort to improve success rates in infertility treatment.¹⁶ Chromosome analysis is used as an adjunct to standard IVF to detect abnormalities in chromosome number, called aneuploidy, that arise during egg or embryo development and often lead to Down syndrome, birth defects, and the failure of embryos to implant or develop normally.¹⁷ This use of PGD often is referred to as preimplantation genetic screening (PGS), and some IVF providers recommend PGS for patients who have had repeated miscarriages, are over 35, or have had repeated IVF failure.¹⁸ More than 1% of all U.S. newborns are IVF babies, and well more than half of IVF patients are over 35.¹⁹ Given the large number

¹² *Id.*

¹³ The first PGD cases were performed to determine embryo sex, in order to avoid X-linked disease. Munné & Wells, *supra* note 1, at 239. Other early uses included detection of genes causing cystic fibrosis, Tay-Sachs disease, and Lesch-Nyhan syndrome. Joy A. Delhanty, *Preimplantation Diagnosis*, 14 *PRENATAL DIAGNOSIS* 1217 (1994); *see also* Yury Verlinsky et al., *Preconception and Preimplantation Diagnosis for Cystic Fibrosis*, 12 *PRENATAL DIAGNOSIS* 103 (1992).

¹⁴ Verlinsky et al., *supra* note 2; Joyce C. Harper et al., *Preimplantation Genetic Diagnosis for Single Gene Disorders: Experience with Five Single Gene Disorders*, 22 *PRENATAL DIAGNOSIS* 525, 526 (2002); *see also* Verlinsky et al., *supra* note 13, at 103-10.

¹⁵ Karen Sermon et al., *Preimplantation Genetic Diagnosis for Huntington's Disease with Exclusion Testing*, 10 *EUR. J. HUM. GENETICS* 591-98 (2002); Svetlana Rechitsky et al., *Preimplantation Genetic Diagnosis for Cancer Predisposition*, 5 *REPRO. BIOMED. ONLINE* 148 (2002); Yury Verlinsky et al., *Preimplantation Genetic Diagnosis for Early Onset Alzheimer Disease Caused by V717L Mutation*, 287 *JAMA* 1018 (2002).

¹⁶ Verlinsky et al., *supra* note 14, at 292.

¹⁷ Yury Verlinsky et al., *Preimplantation Testing for Chromosomal Disorders Improves Reproductive Outcome of Poor-Prognosis Patients*, 11 *REPROD. BIOMED. ONLINE* 219 (2005).

¹⁸ A.P. Ferraretti et al., *Prognostic Role of Preimplantation Genetic Diagnosis for Aneuploidy in Assisted Reproductive Technology Outcome*, 19 *HUM. REPROD.* 694, 695-96 (2004); Santiago Munne, *Preimplantation Genetic Diagnosis and Human Implantation – A Review*, 24 *PLACENTA* 570, 571-72 (2003).

¹⁹ CENTERS FOR DISEASE CONTROL AND PREVENTION, 2005 ASSISTED REPRODUCTIVE TECHNOLOGY (ART) REPORT (2007), <http://www.cdc.gov/ART/ART2005/section1.htm>.

of couples using IVF who therefore fall into the groups for which PGS may be recommended, the potential growth of PGS is enormous.²⁰ However, the effectiveness of PGS is in question among reproductive medicine providers.²¹ One recent study of PGS found that it does not increase the chances of having a healthy baby for women of advanced maternal age—in fact, birth rates were lower among women who used PGS as compared to those who did not.²²

PGD does involve some risk to the embryo. Concerns about the safety of PGD focuses on how often embryo biopsies may damage or destroy embryos. In the biopsy, only one cell is removed, and the rest of the embryo must remain unharmed. Genetic analysis must be performed on that single cell. Those performing both the biopsy and the analysis must be highly technically skilled. In addition to the risks of PGD, it is difficult to assess the baseline risk of IVF.²³ Data are incomplete and conflicting on the long-term health effects of IVF for women and children.²⁴

There is evidence suggesting that removal of a cell may reduce implantation rates—a risk that would need to be overcome by the

²⁰ Anver Kuliev & Yury Verlinsky, *The Role of Preimplantation Genetic Diagnosis in Women of Advanced Reproductive Age*, 15 CURRENT OPINION IN OBSTETRICS & GYNECOLOGY 233, 235-38 (2003).

²¹ Compare Sebastiaan Mastenbroek et al., *In Vitro Fertilization with Preimplantation Genetic Screening*, 357 N. ENG. J. MED. 9 (2007) with Santiago Munné et al., *Substandard Application of Preimplantation Genetic Screening May Interfere with Its Clinical Success*, 88 FERTILITY & STERILITY 781 (2007); see also The Practice Comm. of the Soc’y for Assisted Reprod. Tech. & the Practice Comm. of the Am. Soc’y for Reprod. Med., *Preimplantation Genetic Testing: A Practice Committee Opinion Corrected Proof*, 88 FERTILITY & STERILITY 1497-504 (2007) (outlining a recent practice opinion on this issue).

²² Mastenbroek et al., *supra* note 21, at 9.

²³ In all IVF processes there are risks associated with the hormones used to stimulate ovulation, and there is the risk that the procedure could result in an ectopic pregnancy (in which the fetus develops in the fallopian tubes of the mother, and not in the uterus). Because more than one embryo is usually transferred to the uterus simultaneously, there is a heightened risk that the mother will carry multiple fetuses, which can create a higher risk pregnancy for both the mother and fetuses. See Ruth Farrell et al., *IVF, EGG DONATION, AND WOMEN’S HEALTH* (2006), http://www.dnapolicy.org/resources/IVF_Egg_Donation_Womens_Health_final.pdf; Liza Mundy, *EVERYTHING CONCEIVABLE: HOW ASSISTED REPRODUCTION IS CHANGING MEN, WOMEN, AND THE WORLD* (2007); David Meldrum, *Reducing the Incidence of Multiple Gestation*, in *THE TEXTBOOK OF ASSISTED REPRODUCTIVE TECHNIQUES* 675-80 (David Gardner ed., 2001).

²⁴ Daniel Navot, *Severe Ovarian Hyperstimulation Syndrome*, in *THE TEXTBOOK OF ASSISTED REPRODUCTIVE TECHNIQUES*, *supra* note 23, at 645-54; Raoul Orvieto & Zion Ben-Rafael, *Bleeding, Severe Pelvic Infection, and Ectopic Pregnancy*, in *THE TEXTBOOK OF ASSISTED REPRODUCTIVE TECHNIQUES*, *supra* note 23, at 655-62.

benefit of an unaffected pregnancy or by the increased rate of pregnancy that PGS promises. In all cases of PGD, it is critical to know whether the positive effect of selecting "normal" embryos or those with the desired trait is worth the risks and potentially detrimental effect of removing a cell for analysis. The risks are more troubling when the benefit becomes less clear, as with PGS for infertility patients, or less compelling, as with some of the indications described in Section III. Finally, it is notable that there have been no systematic studies on the health and developmental outcomes for children born following PGD.²⁵

There are some limits to the ways PGD may be used. Not all diseases or non-health-related traits (such as intelligence or strength) have a clearly diagnosable genetic component; many result from the interaction of multiple genetic and environmental factors and cannot be detected by genetic testing.²⁶ PGD does not give parents the power to select every characteristic of their future children. In any given cycle of PGD, parents can select among the genetic combinations present in the embryos they have produced. PGD does not create new genetic characteristics in those embryos that neither parent possesses, nor does it allow parents to pick and choose among characteristics present in different embryos.²⁷ Although PGD involves a diagnostic test and embryo selection, it is not genetic manipulation or "engineering" of the embryo itself.²⁸

PGD requires IVF, and thus a woman who wishes to pursue PGD must be willing to endure the risks, discomfort and expense of

²⁵ PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 94-95 (2004), available at <http://www.bioethics.gov/reports/reproductionandresponsibility/chapter3.html>.

²⁶ Alan E. Guttmacher & Francis S. Collins, *Realizing the Promise of Genomics in Biomedical Research*, 294 JAMA 1399, 1400 (2005).

²⁷ Kathy Hudson et al., *Genetic Testing of Human Embryos: Ethical Challenges and Policy Choices*, in EXPANDING HORIZONS IN BIOETHICS 103, 105 (Arthur Galston & Christiana Peppard eds., 2005).

²⁸ PGD can reveal a considerable amount of information about an embryo's genetic makeup, but it cannot correct or alter an embryo's genes. Human germline genetic modification aims to create permanent heritable genetic changes by changing the genetic makeup of human eggs or sperm, or human embryos at the earliest stages. For a complete discussion of the scientific, ethical, and policy issues related to human germline genetic modifications, see Susannah Baruch et al., *Human Germline Genetic Modification: Issues and Options for Policymakers*, GENETICS & PUBLIC POLICY CENTER (2005), <http://www.dnapolicy.org/images/reportpdfs/HumanGermlineGeneticMod.pdf>.

IVF. According to the American Society for Reproductive Medicine, the average cost of an IVF cycle in the United States is \$12,400. PGD adds significant cost—up to \$10,000-12,000 per cycle.²⁹ PGD adds significant cost to IVF – approximately \$3,000-\$5,000 per cycle.³⁰

III. BEYOND DEADLY DISEASE: FOUR ADDITIONAL WAYS PROSPECTIVE PARENTS USE PGD.

Lee Silver, Francis Fukuyama, and others have argued that genetic technologies such as PGD could result in increased societal inequality between the genetic “haves” and “have nots.”³¹ However, the expense, discomfort, and risks of PGD and IVF described in Section II suggest that few parents would pursue PGD casually, for the sole purpose of having children with preferred genetic characteristics.

Nevertheless, it is likely to become increasingly possible for prospective parents using IVF because of infertility, or fertile couples seeking PGD for a serious genetic concern, to add additional genetic analysis for less serious genetic attributes.³² Powerful genetic testing tools known as microarrays permit multiple genetic tests to be performed at one time.³³ Although microarrays are not yet in widespread use in PGD, they could vastly expand the number of traits for which each embryo is tested. Parents might seek out as much additional genetic data on the embryos as possible in order to choose the embryos most aligned with their preferred characteristics (which could some day include intellectual, physical, or behavioral

²⁹ Am. Soc. for Reprod. Med., Frequently Asked Questions About Infertility, <http://www.asrm.org/Patients/faqs.html> (last visited Aug. 6, 2008).

³⁰ Resolve: The National Infertility Association, The Costs of Infertility Treatment, http://www.resolve.org/site/PageServer?pagename=lrn_mta_cost (last visited Aug. 6, 2008).

³¹ Francis Fukuyama, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION 83 (2002); Lee M. Silver, REMAKING EDEN: CLONING AND BEYOND IN A BRAVE NEW WORLD 221 (1997); REPRODUCTION & RESPONSIBILITY, *supra* note 25, at 97-98.

³² C.S. Salvado et al., *Towards Preimplantation Diagnosis of Cystic Fibrosis Using Microarrays*, 8 REPROD. BIOMED. ONLINE 107-14 (2004); Caroline Ryan, *Gene Test 'Improves Embryo Checks'*, BBC NEWS, June 29, 2004, available at <http://news.bbc.co.uk/1/hi/health/3847815.stm> (last visited Aug. 6, 2008); see also MED. NEWS TODAY, *New Technology Predicted To Revolutionize Genetic Analysis Of Preimplantation Embryos*, Oct. 22, 2006, <http://www.medicalnewstoday.com/articles/54745.php>.

³³ Ryan, *supra* note 32.

genetic markers).³⁴

A recent survey of IVF clinics reveals that prospective parents already use PGD to make choices about their future children beyond avoidance of the most severe or fatal genetic diseases. No entity collects comprehensive data about the practice of PGD in the United States; thus, we do not know how often PGD is performed, for what indications, and by which clinics or laboratories. Even data such as how many babies are born following PGD in the United States each year are not available.³⁵ Many observers have speculated about the potential use of PGD in selecting genetic characteristics of future offspring. Some of these uses have been reported in medical literature,³⁶ but outside of annual data reported from primarily European PGD providers,³⁷ little is known about how frequently these uses occur.

To address this gap in data, in 2006 the Center conducted a survey of all IVF clinics in the United States to get a comprehensive snapshot of the current practice of PGD in the United States.³⁸ The Center's survey, which asked IVF clinics to report data for their PGD cycles in 2005, found that PGD is used for both serious and less serious health reasons, as well as for genetic traits such as sex selection.³⁹ Overall, 74% of IVF clinics provided some type of PGD services to patients in their clinics.⁴⁰ Two-thirds of all PGD cycles were for PGD for infertility (PGS).⁴¹

This section describes four examples of parental use of PGD to choose embryos based on criteria other than avoiding immediate, fatal or severe genetic diseases, and presents the Center's findings as

³⁴ On the other hand, some parents who seek PGD to avoid a particular disease will want only that information, and will not want the responsibility or burden of choosing an embryo based on the whole genomic package.

³⁵ Susannah Baruch et al., *supra* note 5, at 667-70. For data related primarily to PGD in Europe, see Joyce C. Harper et al., *ESHRE PGD Consortium Data Collection V: Cycles from January to December 2002 with Pregnancy Follow-Up to October 2003*, 21 *HUM. REPROD.* 3-21 (2006).

³⁶ See, e.g., Verlinsky et al., *supra* note 15, at 1018.

³⁷ Karen D. Sermon et al., *ESHRE PGD Consortium Data Collection VI: Cycles from January to December 2003 with Pregnancy Follow-Up to October 2004*, 22 *HUM. REPROD.* 323-36 (2007).

³⁸ Baruch et al., *supra* note 7, at 1053-58.

³⁹ *Id.* at 1053.

⁴⁰ *Id.* at 1054.

⁴¹ *Id.* at 1055.

to the frequency of use.

A. HLA Matching to Save an Older Child

Some prospective parents have used PGD to attempt to have a baby who is an immunological match for an existing seriously ill child—the baby’s cord blood is used for stem cell transplantation. This use of PGD is known as Human Leukocyte Antigen (HLA) typing. The Center’s survey shows that 23% of IVF clinics have performed PGD for HLA typing in conjunction with genetic analysis to ensure the baby will also be free of the genetic disease affecting the older sibling.⁴² Some families have sought HLA typing to have a baby who is a match for an older child when the disease is not inherited and for which the future baby is *not* at risk. Six percent of IVF clinics have provided PGD in such cases.⁴³

B. Adult Onset Diseases

Prospective parents have used PGD to screen embryos for genetic mutations indicating risk for an adult-onset disease. According to the Center’s survey, 28% of IVF clinics have provided PGD in this manner to avoid diseases such as Huntington disease, hereditary breast cancer, or Alzheimer disease.⁴⁴

C. Non-Medical Sex Selection

PGD can be used to select the sex of an embryo, either to avoid a genetic disease caused by a mutation on the X chromosome (X-linked disease) or simply to satisfy the preferences of the future parents. When PGD for sex selection is done in the absence of other medical indications it is often referred to as “non-medical sex selection.”

According to the Center’s survey, 42% of IVF clinics have provided PGD for non-medical sex selection.⁴⁵ Of all PGD cycles clinics reported providing in 2005, non-medical sex selection was

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.* at 1056.

performed in 9% of cases.⁴⁶ According to the survey, clinics' specific policies on non-medical sex selection vary. Nearly half (47%) are willing to defer to parental preferences and provide PGD for non-medical sex selection under all circumstances.⁴⁷ Forty-one percent will only provide the service for a second or subsequent child.⁴⁸ Seven percent will only provide PGD for sex selection and permit the parents to choose the sex of the embryo if there is another medical reason to undergo PGD and there are enough unaffected embryos to choose from.⁴⁹

The sex of embryos is revealed during PGD examination of chromosomes, for example, when looking for chromosomal abnormalities that contribute to infertility. Once the information is revealed, parents can learn the sex of those embryos unaffected by an abnormality and select those to be transferred based on sex. Clinical practices for handling this situation vary. More than one-third of IVF clinics that provide PGD will inform parents of the sex of the embryos and comply with parental preferences in selecting embryos for transfer.⁵⁰ Fifteen percent of clinics providing PGD will inform parents and comply with their preferences in transferring embryos only for a second or subsequent child.⁵¹ Thirty percent of IVF clinics that provide PGD report that they do not volunteer the information but will provide it if asked and will comply with parental wishes for which embryos to transfer, while 10% never inform the parents about sex in the absence of an X-linked disorder.⁵² Eight percent of IVF clinics providing PGD said they may reveal the sex, but transfer the best embryo with no regard for gender.⁵³

D. Selection for a Disability

There has been speculation that PGD could be used to select an

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.* at 1057.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

embryo for the presence of a particular disease or disability, such as deafness or dwarfism, in order that a child would be certain to share that characteristic with his or her parents.⁵⁴ According to the Center's survey, four U.S. IVF clinics (3% of IVF clinics) report that they have provided PGD to parents for this reason.⁵⁵ In addition, in response to an open-ended question, one clinic reported that they had been asked to provide PGD to select for hereditary deafness, but they did not indicate whether they actually provided PGD in this case.⁵⁶

In response to this finding from the Center's survey, several U.S. PGD providers—the laboratories providing the genetic analysis ordered by clinic doctors—have stated they would not provide PGD to families who seek PGD simply to select for a disability.⁵⁷ The Center believes that the four clinics which have provided PGD for this purpose are likely to have done so for families in particular situations involving dwarfism. Dwarfism is a dominant genetic condition, which means that if the child inherits the mutation for dwarfism from one parent, the child will also be a dwarf. When both prospective parents are dwarves, the children have a 25% chance of inheriting a “double dominant” mutation, a condition which is usually fatal soon after birth. Dwarf couples may use PGD to select embryos free from the double dominant mutation, and PGD laboratories are willing to perform this genetic analysis.

However, given a choice between some embryos free of the double mutation which would develop into children with dwarfism and embryos that would become children of normal stature, many dwarf parents might choose to have dwarf children. Whether or not this choice is permitted is left up to the IVF clinics.⁵⁸

⁵⁴ See, e.g., Robertson, *supra* note 6, at 470; see also Darshak M. Sanghavi, *Wanting Babies Like Themselves, Some Parents Choose Genetic Defects*, N.Y. TIMES (Dec. 5, 2006), available at <http://www.nytimes.com/2006/12/05/health/05essa.html?ex=1322974800&en=9fbb1b0e738b55d1&ei=5088&partner=rssnyt&emc=rss>.

⁵⁵ Baruch et al., *supra* note 7, at 1056.

⁵⁶ Sanghavi, *supra* note 54.

⁵⁷ *Id.*

⁵⁸ Personal communication to Genetics and Public Policy Center from Marcus Hughes, Laboratory Director, Genesis Genetics, January 22, 2007.

IV. PGD AND ETHICS

The use of PGD for reasons other than the avoidance of severe genetic disease has given rise to numerous ethical concerns. For example, consider the use of PGD for HLA matching. Conceiving a child for the purpose of curing an older sibling gives many people pause, as strained family relationships seem likely when one child has been selected to serve as an immunological match for another.⁵⁹ In cases where the disease affecting the older sibling has no hereditary basis, risks from IVF or embryo biopsy would be imposed upon the younger child without any countervailing benefit to that child—a prospect that is, as Susan Wolf and colleagues have argued, particularly troubling.⁶⁰

Similarly, using PGD to screen embryos for diseases that will not develop until adulthood, or for mutations that confer a heightened risk (as opposed to a certainty) for developing a particular disease, raises issues of how to weigh the possible benefits of PGD to the future child and adult against the known and unknown risks of PGD and IVF.⁶¹ Having a genetic mutation associated with a particular disease, such as hereditary breast cancer, does not mean there is a certainty that the disease would develop.⁶² Children with those mutations could expect to remain healthy for decades before symptoms, if any, would begin, and a prevention strategy, treatment, or cure could be discovered in the interim.⁶³

The use of PGD for sex selection has triggered ethical concerns

⁵⁹ For a popular fictionalized account of such a family, see Jodi Picoult, *MY SISTER'S KEEPER* (2004), in which the younger sister undergoes numerous surgeries throughout childhood in an effort to save the life of her older sister who is struggling with leukemia.

⁶⁰ See Susan Wolf, Jeffrey Kahn & John Wagner, *Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines & Limits*, 31 J. L. MED. & ETHICS 327-39 (2003).

⁶¹ For more analysis of ethical issues related to the use of PGD for adult onset disease and additional indications, see Robertson, *supra* note 6, at 465.

⁶² U.S. Preventive Services Task Force, *Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Recommendation Statement*, 143 ANNALS OF INTERNAL MED. 355, 357 (2005).

⁶³ Merle Spriggs, *Genetically Selected Baby Free of Inherited Predisposition to Early Onset Alzheimer's Disease*, 28 J. MED. ETHICS 290 (2002).

that sex selection amounts to sex discrimination.⁶⁴ In practice, although some providers believe that selecting an embryo of a particular sex for non-health-related reasons is unethical, others provide these services and advertise their availability.⁶⁵

In the United States, providers report that preferences appear to be equally divided between the sexes. However, whether the preferred sex is male or female, critics of sex selection say the preference amounts to an expectation of what a boy or a girl will be like. For example, parents might choose a male embryo expecting their son to love sports and toy trucks, but he may well prefer traditionally “female” games and activities. Sex selection may result in disappointment and strained parent-child relationships if the child does not meet the expectations imposed by gender stereotypes. On the other hand, as Judith Daar has argued, in cases where parents deeply prefer a child of one gender, both the child and parents may be better off if the parents are able to pursue their wish.⁶⁶ In cultures that openly prefer male children to female children, such as China and India, sex preferences are almost always for boys and the concern is that PGD for sex selection devalues women further.⁶⁷

Of all the controversial uses of PGD, the one that appears to occur least often but nevertheless attracts significant public attention has been the use of PGD to select embryos with a disability such as deafness or dwarfism.⁶⁸ Because PGD for dwarfism is initially employed to avoid the fatal “double dominant” dwarfism mutation,

⁶⁴ Marcy Darnovsky, *High-Tech Sex Selection: A New Chapter in the Debate*, 17 *GENEWATCH* 1 (Dec. 31, 2003), available at http://www.genetics-and-society.org/resources/cgs/200401_genewatch_darnovsky.html.

⁶⁵ See, e.g., Genetics & IVF Institute, *Preimplantation Genetic Diagnosis for Family Balancing*, http://www.givf.com/gender_selection.cfm (last visited Oct. 6, 2005); The Ethics Committee of the American Society of Reproductive Medicine, *Sex Selection and Preimplantation Genetic Diagnosis*, 72 *FERTILITY & STERILITY* 595, 598 (1999).

⁶⁶ Judith F. Daar, *ART and the Search for Perfectionism: On Selecting Gender, Genes, and Gametes*, 9 *J. GENDER RACE & JUST.* 241, 244 (2005).

⁶⁷ The belief is that allowing sex selection purely on the basis of parental preference is inherently based in sexism. The fear is that sex selection will reinforce existing gender roles, encouraging stereotypical expectations of children born following its use. Nahar Alam, *Open Letter on Sex Selection to Fertility Industry Trade Group*, *CTR. FOR GENETICS AND SOCIETY* (2002), http://www.genetics-and-society.org/resources/cgs/2002_asrm_sex_selection.html (writing to Dr. J. Benjamin Younger, Executive Director of the American Society for Reproductive Medicine).

⁶⁸ See, e.g., Sanghavi, *supra* note 54.

there is a clear distinction between cases where parents ultimately select among embryos that include some with dwarfism (although dwarfism may include other health conditions and risks) and those where parents use PGD solely to select for a disability such as deafness. For many medical providers, a parent's "choice" to initiate the use of PGD simply to have a deaf child—rather than an effort to avoid a serious or lethal illness—would be tantamount to inflicting harm and would unacceptably cause the future child to suffer with a serious medical condition.⁶⁹ Yet many in the deaf community argue that deafness is not a disability but a culture and a community united by sign language.⁷⁰ The Center's survey found only a small percentage of parents have sought to use PGD to have a deaf child.⁷¹ The more difficult questions are first whether such a use is ethically acceptable, and second who would create and enforce appropriate guidelines in this complex area.

In each of these situations—HLA matching, selecting against mutations for risk of adult-onset disease, sex selection, and selecting for a disability such as dwarfism or deafness—parents decide to undergo the risks and costs of PGD in order to select genetic attributes of future children. The chosen embryos are not simply those that will survive early childhood without suffering and death, but rather the ones that will have genetic attributes the parents strongly desire. Thus, the parents will have used PGD to control aspects of the health and medical futures of their children.

In considering these uses of PGD, as well as possible future uses to select traits and abilities of "designer" children, observers such as Eric Cohen and Michael Sandel argue that such reasons for PGD are unacceptable because parents ought to love and accept their children regardless of their child's abilities, disabilities, gender, or characteristics.⁷² The concern is that PGD will result in parents utterly

⁶⁹ Rena Ellen Palk & Nathan Fischel-Ghodsian, *Hereditary Hearing Loss*, THE GENETIC BASIS OF COMMON DISEASES (Richard A. King et al. eds., 2d ed. Oxford 2002).

⁷⁰ Anna Middleton et al., *Attitudes of Deaf Adults Toward Genetic Testing for Hereditary Deafness*, 63 AM. J. HUM. GENETICS 1175, 1175 (1998).

⁷¹ Baruch et al., *supra* note 7.

⁷² See Michael J. Sandel, *The Case Against Perfection: What's Wrong with Designer Children, Bionic Athletes, and Genetic Engineering*, ATLANTIC MONTHLY (2004), available at <http://www.theatlantic.com/doc/200404/sandel>; see Eric Cohen, *The Real Meaning of Genetics*, 9 THE NEW ATLANTIS 29, 29-41 (2005).

disappointed in the reality of their children if that reality—be it health, the ability to save a sibling’s life, or gender role—does not live up to whatever was promised by the technology.⁷³ PGD in these cases seems to tweak the nature and the unconditional premise of pregnancy, parenting, and human reproduction.⁷⁴

In some ways, PGD is not so different from older technologies available to prospective parents such as prenatal genetic testing and screening. For decades prospective parents have learned about their developing future children’s genetic characteristics through prenatal genetic testing. Amniocentesis and Chorionic Villus Sampling (CVS) are used to look for serious genetic diseases and conditions, many of the same ones that PGD now can detect.⁷⁵ These tests, like PGD, provide parents with information and, in cases where a genetic problem is found, leave parents to face the often extremely difficult decision of whether to terminate a pregnancy.

To some, the decision to discard embryos tested using PGD may be less troubling than prenatal testing because pregnancy under the traditional medical definition has not begun and the prospective mother is not yet carrying the future baby.⁷⁶ For others, of course, life or potential life begins at conception, and the sheer number of embryos that may be discarded using PGD could present as untenable a choice as the decision to terminate.

In fact, in both prenatal testing and PGD, parents make assumptions and choices—sometimes difficult and controversial choices—about who their children will be, and whether they will be born at all.⁷⁷ Some parents, upon learning that a fetus is affected with a genetic disease, choose to terminate the pregnancy to avoid having

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Francoise Shenfield, *Times of Transition: Modern Ethical Dilemmas*, in *THE TEXTBOOK OF ASSISTED REPRODUCTIVE TECHNIQUES*, *supra* note 23, at 753-60.

⁷⁶ Moniek Twisk et al., *Preimplantation Genetic Screening as an Alternative to Prenatal Testing for Down Syndrome: Preferences of Women Undergoing In Vitro Fertilization/Intracytoplasmic Sperm Injection Treatment*, 88 *FERTILITY & STERILITY* 804, 804-10 (2006).

⁷⁷ Parents constantly make decisions affecting whom their child will become. For example, parents decide whether their children will have a sibling, take swimming lessons, have speech therapy or braces, or play sports.

a child with a disability. Others decline the testing altogether.⁷⁸ Still others undergo testing and choose to welcome and raise the child, in spite of the challenges involved.

To demonstrate many of the parallels, it is worth considering recent public debate about prenatal testing and termination for Down syndrome, one of the most common prenatal tests, a debate which echoes some of the ethical concerns about the use of PGD for diseases other than for the most serious and deadly. A new law originally introduced by Senators Edward Kennedy and Sam Brownback highlights a number of questions about how amniocentesis and CVS are used and how often terminations take place.⁷⁹ The primary criticism has been that the information prospective parents are given about what it is like to have and raise a child with Down syndrome often presents the worst case scenario in the most clinical fashion. Individuals with Down syndrome often have mild or manageable mental and physical impairments. The new law addresses these concerns by funding better data collection on the life expectancy of people with Down syndrome and programs to connect prospective parents with families that include children with the disease. During consideration, supporters of the bill were concerned that the pressures put on parents and the resulting high rate of termination of Down syndrome pregnancies reduces the number of individuals living with Down syndrome—and, in turn, increase the stigma of those who are born with the disease.⁸⁰ Similarly, Adrienne Asch and Erik Parens have described how the use of prenatal testing and abortion could negatively affect the way society treats individuals who have or may develop genetic diseases detectable through

⁷⁸ No reliable data has been collected on the number of prenatal diagnostic tests performed and the degree to which it declines each year, but as an example of the number of children living with genetic diseases, approximately 5,000 babies are born each year with Down syndrome, the most common genetic condition. National Down Syndrome Society, *Questions and Answers About Down Syndrome*, <http://www.ndss.org/content.cfm?fuseaction=NDSS.article&article=194> (last visited Oct. 26, 2005).

⁷⁹ Prenatally and Postnatally Diagnosed Conditions Awareness Act, S. 1810, 110th Cong. (2007), available at GovTrack.us (database of federal legislation), <http://www.govtrack.us/congress/bill.xpd?bill=s110-1810> (last visited Aug 8, 2008).

⁸⁰ See, e.g., *Hearing on Prenatal Genetic Testing Tech. Before the Subcomm. on Sci., Tech. & Space of the S. Comm. on Commerce, Sci. & Transp.*, 108th Cong. (2004) (statement of Andrew J. Imparato, President and Chief Executive Officer, American Association of People with Disabilities).

testing.⁸¹

Asch argues that the same arguments apply to PGD: “As currently practiced and justified, prenatal testing and embryo selection cannot comfortably coexist with society’s professed goals of promoting inclusion and equality for people with disabilities.”⁸² Parents could be pressured to use PGD, even if they find the procedure unnecessary or objectionable. Pressures from family members or the larger community to use PGD for sex selection or to save an ill sibling could arise. Like the use of prenatal testing for Down syndrome, the use of PGD for less serious genetic characteristics could ultimately perpetuate discrimination and inequity. Other observers have disagreed with this characterization, arguing that PGD is best viewed as a preventive decision by parents rather than an act of discrimination.⁸³

V. PGD OVERSIGHT

These numerous and critical issues of ethics and equality—whether arising from PGD or prenatal testing—are difficult to address through direct oversight or regulation of PGD. This difficulty arises largely from the utter lack of societal consensus on the appropriateness of particular applications of PGD.

Ethical issues in PGD would be extremely difficult for existing U.S. federal and state governmental structures to address. As in the policy and political struggles over abortion—to which genetic testing of embryos is often tied—questions of ethical use are both politically and constitutionally challenging. The very personal and private reproductive decisions of adults and prospective families traditionally are left alone, although recent court decisions may have

⁸¹ Erik Parens & Adrienne Asch, *The Disability Rights Critique of Prenatal Genetic Testing: Reflections & Recommendations*, 29 THE HASTINGS CTR. REP. (SPECIAL SUPP.) S1, S1-S2 (1999).

⁸² Adrienne Asch, *Disability Equality and Prenatal Testing: Contradictory or Compatible?*, 30 FLA. ST. U. L. REV. 315 (2003).

⁸³ See B. Steinbock, *Preimplantation Genetic Diagnosis and Embryo Selection*, in A COMPANION TO GENETICS 175-90 (Justine Burley & John Harris eds., 2002); see T.S. Petersen, *Just Diagnosis? Preimplantation Genetic Diagnosis and Injustices to Disabled People*, 31 J. MED. ETHICS 231, 231-34 (2005).

limited that approach.⁸⁴ Still, there have been few attempts to regulate the *reasons* abortions take place. For example, only Pennsylvania and Illinois have passed legislation to regulate abortions for sex selection, and these laws have not been enforced.⁸⁵ Similarly, the attempt to limit the *reasons* why PGD takes place would raise constitutional concerns to the extent that reproductive choices would be limited.

Thus, such oversight of PGD as exists in the United States is indirect and related to safety and effectiveness rather than ethical use. There are few legal limitations on how prospective parents may use PGD. Decisions about appropriate and permissible uses of PGD generally are left to parents and to IVF and PGD providers. Three federal agencies within the U.S. Department of Health and Human Services have some authority in PGD-related matters.⁸⁶

First, the 1992 Fertility Clinic Success Rate and Certification Act (FCSRCA) requires that all U.S. IVF clinics annually report pregnancy success rates to the Centers for Disease Control and Prevention (CDC), which lists the data as well as names of non-reporting clinics.⁸⁷ However, the FCSRCA does not require IVF clinics to report any data related to PGD.

Second, the Food and Drug Administration (FDA), under the Federal Food, Drug, and Cosmetic Act (FDCA), regulates drugs and devices, including those used in IVF treatments.⁸⁸ The clinical validity of the genetic analysis, however, is subject to premarket review by FDA only when the test is sold as an in vitro diagnostic

⁸⁴ See *Roe v. Wade*, 410 U.S. 113 (1973); see *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992); see *Gonzales v. Carhart*, 550 U.S. 124 (2007); see *Gonzales v. Planned Parenthood Fed'n of Am., Inc. (Carhart II)*, 550 U.S. 124 (2007).

⁸⁵ Abortion Control Act, 18 PA. CONS. STAT. ANN. § 3204(c) (West 2008); Illinois Abortion Law of 1975, 720 ILL. COMP. STAT. ANN. 510/6(8) (West 2008).

⁸⁶ For a complete analysis of the current oversight of PGD, see Susannah Baruch et al., *Reproductive Genetic Testing: Issues and Options for Policymakers*, Genetics & Pub. Pol'y Center (2004), <http://www.dnapolicy.org/images/reportpdfs/ReproGenTestIssuesOptions.pdf> and THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES, *supra* note 25.

⁸⁷ Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1 (1992).

⁸⁸ For example, medicines used to stimulate ovulation are classified as "drugs" subject to the FDCA and therefore must be approved by the FDA before they are marketed in the United States. Similarly, culture media used to grow human embryos in the laboratory prior to implantation are classified as "devices" subject to premarket approval or clearance. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938).

device or “test kit.”⁸⁹ The FDA does regulate certain components laboratories use to make genetic tests.⁹⁰ The FDA also regulates facilities handling human tissues intended for transplantation, including eggs and sperm under certain circumstances.⁹¹ In addition, the FDA regulates the safety and effectiveness of certain human-tissue therapies, called “biological products,” which are tissues manipulated extensively or used in a manner different from their original function in the body. If the FDA determined that reproductive tissues are biological products when used for IVF or PGD procedures, those tissues could be subject to premarket review and approval. However, it is not clear if the FDA has the legal authority to categorize these tissues as such or whether the FDA would assert such authority if it had it.⁹²

Finally, the Centers for Medicare and Medicaid Services (CMS) oversee and administer the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which include standards and testing to monitor laboratory performance.⁹³ CMS has taken the position that PGD is not covered by CLIA but rather “is an assessment of a product and therefore falls under FDA’s oversight of reproductive

⁸⁹ Of the more than 1,000 diseases for which genetic tests are used clinically, test kits are available for only about a dozen; the rest are developed as in-house or “home brew” tests by clinical laboratories and are not reviewed by the FDA before they are offered clinically. Genetics & Pub. Pol’y Center, News Releases, New Publication – “In Search of a Coherent Framework: Options for FDA Oversight of Genetic Tests”, http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=87 (last visited Oct. 18, 2008). In contrast, pharmaceuticals and medical devices must undergo premarket review by the FDA to demonstrate their safety and effectiveness. See generally 21 C.F.R. §§ 314.1-314.650, 814.1-814.47 (2008).

⁹⁰ See, e.g., 21 C.F.R. §§ 809.10(e), 809.30 (2005) (establishing labeling requirements and restrictions on the sale, distribution, and use of analyte specific reagents); see also §§ 864.4010(a), 864.4020 (2005) (defining general purpose and analyte specific reagents).

⁹¹ Human Tissue Intended for Transplantation, 21 C.F.R. §1270 (2000); Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001) (codified at 21 C.F.R. § 1271.1 et seq. (2005)).

⁹² See Food and Drug Administration, *Proposed Approach to Regulation of Cellular and Tissue-Based Products* 6 (Feb. 28, 1997), available at <http://www.fda.gov/cber/gdlns/celltissue.pdf>; see also Public Health Service Act, ch. 373, § 2, 58 Stat. 682 (1944) (current version at 42 U.S.C. § 201 (2008)). The biologic provisions of the Act are codified at 42 U.S.C. § 262 (2008).

⁹³ United States Dep’t of Health & Hum. Services, Centers for Medicaid & Medicare Services, Clinical Laboratory Improvement Amendments of 1988, <http://www.cms.hhs.gov/CLIA/> (last visited Mar. 22, 2005).

tissue.”⁹⁴ Thus, laboratories that perform genetic analysis for PGD are not regulated as clinical laboratories under CLIA. If they were, PGD laboratories would be required to demonstrate proficiency under CLIA’s general proficiency testing requirements for laboratories performing high complexity tests. However, CMS has not yet established specific proficiency testing requirements for molecular genetic testing; thus, the responsibility of ensuring proficiency for genetic testing rests with the individual laboratory.⁹⁵

In this way, the current regulatory approach taken by federal agencies in the United States addresses some issues of safety and accuracy of PGD but leaves others untouched. One possibility for the future would be expansion of existing federal agency authority. As Kathy Hudson and Gail Javitt have recently argued, both FDA and CMS could play a more active role in overseeing the safety and effectiveness of genetic tests and the proficiency of the laboratories that perform the tests.⁹⁶ However, neither agency seems well situated to oversee the particular indications for which PGD is used or the ethical dilemmas arising from such uses. And while any PGD research receiving federal funds theoretically would be subject to human research subjects protections, these regulations do not apply to PGD in practice.⁹⁷ These protections govern research carried out at institutions supported with federal funds or research conducted to support an application to the FDA for product approval.⁹⁸ However, there is a law against providing federal funding for research in which embryos are created or destroyed,⁹⁹ and the FDA does not currently

⁹⁴ Letter from Judith A. Yost, Director, Division of Laboratory Services, Survey & Certification Group, Centers for Medicare & Medicaid Services, to Dr. Gary R. Cutting, DNA Diagnostic Laboratory, Institute of Genetic Medicine, Johns Hopkins University (April 22, 2005) (on file with Genetics & Public Pol’y Center).

⁹⁵ Genetics & Pub. Pol’y Center., *The Regulatory Environment for Genetic Tests*, <http://www.dnapolicy.org/policy/genTests.jhtml.html#clia> (last visited Feb. 23, 2006).

⁹⁶ Gail H. Javitt, *In Search of a Coherent Framework: Options for FDA Oversight of Genetic Tests*, 62 FOOD & DRUG L.J. 617, 646-47 (2007); Gail H. Javitt & Kathy Hudson, *Federal Neglect: Regulation of Genetic Testing*, 22 ISSUES IN SCI. & TECH. 59, 66 (2006).

⁹⁷ 45 C.F.R. pt. 46.

⁹⁸ Dep’t of Health and Human Svc’s, Regulations for the Protection of Human Subjects, 45 C.F.R. 46 (2004); Food and Drug Admin., Regulations for the Protection of Human Subjects, 21 C.F.R. pts. 50, 56 (2004).

⁹⁹ Every year since 1996, Congress has imposed a ban on federal funding for all research in which human embryos are created, destroyed, or discarded. H.R. 3610, 104th Cong. (1996).

require premarket approval for PGD.¹⁰⁰ In addition, embryos generally are not considered “human subjects” as contemplated by federal regulations.¹⁰¹ Thus, federal human subjects protections—which could provide some governmental evaluation of the risks and benefits of the procedure – generally do not apply. However, some clinics have declared PGD to be “experimental” and provide it under research protocols approved by an Institutional Review Board – an alternative to government oversight, albeit one left entirely up to the clinics offering the technique.¹⁰² Furthermore, state laws nor court decisions have provided oversight regarding uses of ethical use of PGD.¹⁰³

In sum, the determination of appropriate uses for PGD in the U.S. is primarily left to providers and parents.¹⁰⁴ Policies in other countries, however, are evolving. For example, for many years the United Kingdom permitted HLA matching only when the disease affecting the older sibling had an inherited genetic basis, and thus there would be a benefit to screening the embryos for the same disease. Under such a policy, HLA matching would not have been permitted for a sibling affected with a disease such as leukemia, which does not have an inherited basis. Now, the U.K. policy permits

¹⁰⁰ Medical Devices; Classification/Reclassification; Restricted Devices; Analyte Specific Reagents, 61 Fed. Reg. 10,484 (Mar. 14, 1996).

¹⁰¹ Office for Human Research Protections, *Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells and Stem Cell-Derived Test Articles* (March 19, 2002), available at <http://stemcells.nih.gov/StaticResources/news/newsArchives/stemcell.pdf>.

¹⁰² American Society for Reproductive Medicine and Society for Assisted Reproduction Technology Practice Committees, *Preimplantation Genetic Diagnosis*, 82 FERTILITY & STERILITY 120, 120–22 (2004).

¹⁰³ New York State has developed standards for laboratories that include oversight of the genetic tests associated with PGD. Wadsworth Center, Clinical Laboratory Evaluation Program § 5, available at [http://www.wadsworth.org/labcert/lep.html](http://www.wadsworth.org/labcert/clep/lep.html); see also Letter from Ellis Jacobs to Laboratory Directors (July 30, 2003) (on file with author). In one notable case, the parents of a child born with cystic fibrosis (CF) following PGD sued those involved with the PGD for failing to detect the condition. The parents made the claim of “loss of consortium,” meaning the loss of the companionship they would otherwise have had with a healthy child. The court construed their claim as one for “wrongful birth” and rejected it, finding that the alleged harm was too speculative. *Doolan v. IVF Am., Inc.*, 2000 Mass. Super. LEXIS 581 (Mass. Super. 2000).

¹⁰⁴ See generally Susannah Baruch et al., *Reproductive Genetic Testing: Issues and Options for Policymakers*, GENETICS AND PUB. POL’Y CTR. (2004); Andrea L. Kalfoglou et al., *PGD Patients’ and Providers’ Attitudes About the Use and Regulation of PGD*, 11 REPROD. BIOMED. ONLINE 486-96 (2005).

HLA matching is permitted even in cases where the future younger sibling is not screened for diseases.¹⁰⁵

Similarly, policymakers in the United Kingdom initially did not permit PGD for adult-onset genetic diseases; however, policymakers have recently determined PGD is appropriate for certain adult-onset conditions such as inherited breast, bowel, and ovarian cancers. Patients wishing to use PGD for this purpose apply to a license committee for permission on a case-by-case basis.¹⁰⁶ The HFEA has said that the decision permits PGD for conditions of lower penetrance and later onset than previous policies. The diseases in question are also to some extent treatable. According to the HFEA, "it is the fact that inherited breast and bowel cancer have a combination of all of these features that makes them different to others previously licensed by the HFEA."¹⁰⁷ As one commentator has noted, while there is no doubt PGD will reduce suffering in families where these diseases frequently occur, the change begs the question of where the line should be drawn and which additional diseases ought to be permissible targets of PGD.¹⁰⁸

The use of PGD for non-medical sex selection is not prohibited by the U.S. government although there have been some voluntary efforts among providers to discourage it.¹⁰⁹ In many other countries, the use of PGD to select sex for non-medical reasons has been prohibited.¹¹⁰ In the United Kingdom the use of PGD has been

¹⁰⁵ Press Release, Human Fertilization and Embryology Authority, HFEA Agrees to Extend Policy on Tissue Typing (July 21, 2004), available at www.hfea.gov.uk/PressOffice/Archive/1090427358 (last visited June 7, 2005); Ram NR. Britain permits controversial genetic test. 34 HASTINGS CTR. REP. 49 n.5 (2004).

¹⁰⁶ Human Fertilisation and Embryology Authority, Choices and Boundaries, <http://www.hfea.gov.uk/en/489.html> (last visited Nov. 27, 2007).

¹⁰⁷ Human Fertilisation and Embryology Authority, Frequently Asked Questions: Preimplantation Genetic Diagnosis, <http://www.hfea.gov.uk/en/910.html> (last visited Aug. 8, 2008).

¹⁰⁸ William Saletan, *Cut Off Genes: Our Gentle Descent Towards Eugenics*, SLATE, May 19, 2006, <http://www.slate.com/id/2141968/>.

¹⁰⁹ The Ethics Committee of the American Society for Reproductive Medicine, *Sex Selection and Preimplantation Genetic Diagnosis*, 72 FERTILITY & STERILITY 595, 598 (1999).

¹¹⁰ Franco Furger and Francis Fukuyama, *A Proposal for Modernizing the Regulation of Human Biotechnologies*, HASTINGS CTR. REP. 37, no. 4 (2007): 16-20; Human Fertilisation & Embryology Authority, *Sex Selection: Options for Regulations*, available at http://www.hfea.gov.uk/docs/Final_sex_selection_main_report.pdf (last visited August 8, 2008). For example, under French law PGD is allowed only if the relevant hereditary

limited to serious inherited conditions and sex selection is not permitted.¹¹¹ It appears that because the United States is one of the few countries in the world that permits non-medical sex selection, couples from other countries travel to the United States to seek it out.¹¹²

VI. A PROPOSAL FOR PGD OVERSIGHT IN THE UNITED STATES.

What is the optimal approach to government oversight of PGD? Franco Furger and Francis Fukuyama have proposed that Congress could delegate authority to oversee PGD—including appropriate uses—to a new or existing federal entity.¹¹³ There is precedent for this approach in other countries.¹¹⁴ However, as previously argued, given that Congress would need to create the proposed entity, its mission, and its authority, it is hard to envision a successful outcome. The political process is slow and unpredictable at best and the subject matter in this case guarantees intense scrutiny from every corner of the national abortion controversies.¹¹⁵

There is, however, a possible road forward in this area, an appropriate approach to ethical questions related to how PGD ought to be used. While there is a role for government in overseeing the safety and effectiveness of PGD, it is voluntary professional

predisposition has previously been demonstrated to exist in the parents, or in one parent, and only for the purpose of avoiding a severe genetic pathology. Canada recently enacted a law prohibiting PGD for sex selection in the absence of a sex-linked disease-causing mutation. See Bill C-6, "An Act Respecting Assisted Human Reproduction and Related Research" (Royal Assent received March 29, 2004); see also Genetics and Public Policy Center International Law Search, available at <http://www.dnapolicy.org/policy.international.php> (last visited Aug. 8, 2008).

¹¹¹ Human Fertilisation & Embryology Authority, *Sex Selection: Options for Regulations*, available at http://www.hfea.gov.uk/docs/Final_sex_selection_main_report.pdf (last visited August 8, 2008).

¹¹² Michael Kahn, *Reproductive Tourism A Growing Worry, Experts Say*, REUTERS, July 24, 2008 available at <http://www.reuters.com/article/lifestyleMolt/idUSL2492408820080724> (last visited Aug. 8, 2008); see also Guido Pennings, *Legal Harmonization and Reproductive Tourism in Europe*, 19 HUM. REPROD. 2689-94 n.12 (2004); Eric Blyth & Abigail Farrand, *Reproductive Tourism - A Price Worth Paying For Reproductive Autonomy?*, 25 CRITICAL SOC. POL'Y 91-114 (2005).

¹¹³ Furger & Fukuyama, *supra* note 110, at 16-20.

¹¹⁴ In 1990, the U.K. enacted the Human Fertilization and Embryology Act, which established the Human Fertilization and Embryology Authority (HFEA).

¹¹⁵ Susannah Baruch, *Needed: A Modest Proposal*, 37 THE HASTINGS CTR. REP. 5, 10 (2007).

societies—organizations of PGD providers—that are best situated to address issues about appropriate PGD uses. Medical and scientific professional organizations such as the American Society for Reproductive Medicine (ASRM) have issued several practice committee opinions on PGD.¹¹⁶ Although ASRM has also issued an ethics committee opinion cautioning against the use of PGD for sex selection in the absence of a serious sex-linked disease,¹¹⁷ it has not commented on other indications for PGD: it could and should do so. Two other professional organizations focused on PGD, the PGD International Society (PGDIS) and the European Society for Human Reproduction and Embryology (ESHRE), could similarly play a larger oversight role for PGD. Both have recently issued practice guidelines;¹¹⁸ however, these guidelines are not aimed at influencing the reasons for which PGD is used.

Similarly, patient groups, which typically are organized around particular diseases or conditions, could develop their own recommendations for appropriate uses of PGD and could educate genetic counselors and other health care professionals by including the perspective of those living with the genetic disease or condition. Moreover, parents considering PGD could be assured the opportunity to meet with individuals living with a particular genetic condition and their families, which is addressed by the new law originated by U.S. Senators Kennedy and Brownback.¹¹⁹

Despite the current lack of voluntary guidelines on the ethical use of PGD, leaders of PGD, including the leadership of ASRM and PGDIS, have endorsed the collection of comprehensive data on PGD

¹¹⁶ In 2001, ASRM called PGD a “viable alternative to post-conception diagnosis and pregnancy termination.” Am. Soc’y for Reprod. Med., *Preimplantation Genetic Diagnosis*, 82 FERTILITY & STERILITY S120, S121 (Supp. I Sept. 2004). In 2007, ASRM stated that the evidence does not support the use of PGS for infertile couples. The Practice Comm. of the Soc’y for Assisted Reprod. Tech. & the Practice Comm. of the Am. Soc’y for Reprod. Med., *Preimplantation Genetic Testing: A Practice Committee Opinion Corrected Proof*, 88 FERTILITY & STERILITY 1497-504 (2007).

¹¹⁷ The Ethics Committee of the American Society for Reproductive Medicine, *supra* note 109 at 598.

¹¹⁸ A.R. Thornhill et al., *ESHRE PGD Consortium ‘Best Practice Guidelines For Clinical Preimplantation Genetic Diagnosis (PGD) and Preimplantation Genetic Screening (PGS)’*, 20 HUM. REPROD. 35-48 (2005).

¹¹⁹ Prenatally and Postnatally Diagnosed Conditions Awareness Act, S. 1810, 110th Cong. (2007), available at GovTrack.us (database of federal legislation), <http://www.govtrack.us/congress/bill.xpd?bill=s110-1810> (last visited Aug 8, 2008).

to determine how often and for what reasons it is being used in the United States.¹²⁰ Indeed, it is striking how much we still do not know about the uses of PGD. While the Center's survey shows that some parents are using PGD for reasons beyond the avoidance of life-threatening genetic disease, it is still difficult to fully understand the scope of this practice. Better data collection in the form of a PGD database or registry will reveal how often PGD is used in these cases. Properly designed, such a database will permit future researchers to follow up with patients in order to study the impact of these uses on the children born following PGD, their families, and society at large.

To collect such data, the Fertility Clinic Success Rate and Certification Act (administered by the CDC, together with the Society for Assisted Reproductive Technology) could be expanded and enforced, requiring IVF clinics to report when PGD is used as part of an IVF procedure. Required information should include the purpose for which PGD was used, whether pregnancy occurred, and the outcome of such pregnancy. Analysis of this new data would allow providers and prospective parents to judge whether the risks of PGD are outweighed by the benefits in particular circumstances and aid development of government oversight of PGD safety and effectiveness. Longitudinal studies of women who have undergone IVF and children born following IVF and PGD would provide valuable information about the risks of IVF and embryo biopsy.¹²¹ Officials should also consider monetary and other penalties for failure to report. Currently, clinics that fail to report information on IVF procedures face no penalties.¹²²

Ultimately, follow-up studies on the use of PGD should include longitudinal, psychological studies of families who have used PGD and national surveys on attitudes toward the use of PGD as it continues to evolve. Among many benefits of such studies, this work could provide insight into the question of how PGD for non-deadly genetic conditions may change the perceptions of and resources available to people with disabilities.

¹²⁰ Baruch, *supra* note 5, at 667-70; Joe Leigh Simpson et al., *Prof'l Self-Reg. for Preimplantation Genetic Diagnosis: Experience of the Am. Soc'y for Reprod. Med. and Other Prof'l Soc'ys*, 85 *FERTILITY & STERILITY* 1653-60 (2006).

¹²¹ Hudson, *supra* note 27, at 117.

¹²² Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1(a) (2000).

VII. CONCLUSION

PGD is no longer simply an alternative to prenatal testing and termination as a way to avoid deadly genetic diseases in one's offspring. It is clear that PGD is already being used by prospective parents to choose embryos that will have the traits parents simply want. We need to know much more about how PGD is being used and its impact on individuals, families, and society. But government oversight of the ethical use of PGD would be extremely difficult—PGD providers are better situated to provide guidance on acceptable uses. In addition, better data would permit robust research into the long-term impact of PGD, a practical approach to the ethical questions arising from this still-evolving technology.