

THE AMBIGUOUS ROLE OF PGD IN SOCIETY: AN ANALYSIS OF PREIMPLANTATION GENETIC DIAGNOSIS POLICY AND ITS PUBLIC PERCEPTION

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ABSTRACT: Gabriel Rubell Bergero's wrongful life lawsuit against the University of Southern California Keck School of Medicine in 2004 shed new light onto the issue of Preimplantation Genetic Diagnosis. While PGD has proven benefits, it also has the potential to raise serious legal, social, and ethical controversies--ones that regulators have yet to seriously address. Bergero's case in particular exhibits just some of these controversies, and reveals the dire need for regulation especially with regard to patient-doctor relationships. These regulations include both federal and state mandates designed to better educate and inform patients about PGD and ensure adequate funding for those who opt to use such procedures.

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In 2004, Gabriel Rubell Bergero filed a wrongful life lawsuit against the University of Southern California Keck School of Medicine. He was one year old. Gabriel's mother, Eve Rubell was undergoing IVF treatment in 2003 with USC Keck School of Medicine when she learned she was a carrier for Fabry disease. Fabry causes pain, especially for boys, from an early age in the hands and feet. In adulthood, Fabry leads to kidney failure, heart failure, and stroke. Rubell had never heard of Preimplantation Genetic Diagnosis (PGD), but her genetic counselor and doctor encouraged her to try the new procedure to implant only an embryo that was free of the Fabry gene. The doctor and genetic counselor wrote strong letters to Rubell's insurance Kaiser to convince them to cover the procedure. In it they described the benefits of PGD and the savings that Kaiser would make over time by not covering a sick child with Fabry. The company agreed. Rubell signed waivers that noted the 3-4% risk in the procedure. After PGD, scientists separated the embryos that had and did not have the Fabry trait. They claimed to implant the non-Fabry embryo, but three months into her pregnancy, Rubell learned through amniocentesis that her child had the disease. Shortly after Gabriel Rubell Bergero was born, Rubell and her husband filed the suit on behalf of their son suggesting negligence in PGD. In 2009 the court of appeals sided with the doctors from the University, who had gotten Rubell's written consent before the procedure. Gabriel is now eight years old and must live with Fabry, though his parents tried their best to de-select his birth.

Gabriel Rubell Bergero's case raises questions about the ethics of Preimplantation Genetic Diagnosis (PGD). While the case was ultimately fought as a "wrongful life" suit, it also discusses the broader issues surrounding genetic diagnosis: the concept of informed consent, misunderstandings between patients and medical experts, and errors in gray regulatory areas. This case may serve as a cautionary tale of the potential outcomes that arise from using this relatively new technique. While there are many stakeholders in the conversation on PGD, this paper will focus on the tension between patients and medical professionals (i.e. genetic counselors and doctors) raised by the Bergero case. Medical professionals play a significant role through the whole process of electing to use PGD: they inform patients about the very option to use PGD, choose which embryo diagnosis methodology to use, and actually implant the embryos. Given little regulatory oversight in the United States, the decisions about PGD fall mainly on the shoulders of professionals and patients; therefore, the tension in their relationships is a timely and important issue to discuss. Opportunities for regulation exist in providing greater education to patients, redefining standards for obtaining consent, and establishing guidelines to minimize human error during the procedure.

The dependence of patients on medical professionals for information about the existence and limitations of PGD creates a power dynamic that regulators may want to standardize. The legal, social, and ethical controversies surrounding PGD give it a precarious placement in the medical community. Religious values, political values, moral values, values of fairness, and long-

term societal wellbeing inform views both for and against PGD. The potential to eradicate genetic diseases for IVF children could positively impact on the economy and overall health of the nation; however, misuse of the technology could lead to a new social class segregated by genetic engineering or contribute to a crisis questioning the definition of human life. Inherent in the two views is the tension between accepting the benefits and risks to society associated with using PGD.

PGD was developed in the early 1990s at a time when in vitro fertilization was becoming a more widely accepted, understood, and utilized service. Meanwhile, genetic testing was becoming more affordable, prompting some individuals who had formerly left genetic inheritance to fate to seek information about their own conditions and the ways they could pass their genetic material to their offspring. Despite its creation in 1990, PGD was used relatively few times in its first decade: some cite doctor's reluctance to "play god" and introduce a more controversial fertilization service to patients while others describe a larger lack of knowledge around the technology across the medical community.¹

Moral, legal, and political controversy surrounds the broad use of PGD in society. Once used only to test for single gene disorders, PGD now has the capacity to test for non-medical traits such as gender, eye color, or deafness. The latter category generates moral confusion as parents may ask doctors to select embryos that *have* disorders like deafness or dwarfism so that they may share an

1 Amy Harmon, "Couples Cull Embryos to Halt Heritage of Cancer," *New York Times*, September 3, 2006.

identity with the parents.² The former group brings about ethical questions of “designer babies” that may someday be engineered to have socially desirable traits of beauty, intelligence, or height.³

I. INFERTILITY

Approximately one in eight couples in the U.S. has attempted fertility treatment to assist them in pregnancy.⁴ Treatment can range from taking pills to stimulate ovulation to more invasive in vitro fertilization, in which zygotes are joined in a lab and several embryos are inserted into a woman’s uterus for pregnancy. Fifteen states in the U.S. require insurers to cover infertility diagnosis and treatment.⁵ One cycle of IVF costs from approximately \$11,000-\$13,000 for medication and implantation. For an additional \$3,000 (not covered by insurance), parents can opt for additional procedures to specifically choose which embryos get implanted and which do not get implanted in the uterus.⁶

II. PREIMPLANTATION GENETIC DIAGNOSIS

PGD allows doctors to test embryos created in vitro for certain genetic characteristics. Only the embryos with desired genetic traits are implanted in the womb. The process occurs two to four

2 Darshak Sanghavi. *New York Times*, “Wanting Babies Like Themselves, Some Parents Choose Genetic Defect,” December 5, 2006.

3 B. Stankovic, “‘It’s a designed baby!’ - opinions on regulation of preimplantation genetic diagnosis.” *UCLA Journal of Law & Technology*, 3, 2005, 1.

4 National Conference of State Legislatures, 2012

5 Ibid.

6 Amy Harmon suggests that the out of pocket expenses for IVF and PGD are around \$25,000. See “Couples Cull Embryos to Halt Heritage of Cancer.” *New York Times*. September 3, 2006.

days after the egg has been fertilized when embryos consist of roughly eight cells. Geneticists remove one to two cells by biopsy. There are various methods to obtain samples: polar body biopsy, cleavage stage biopsy, and blastocyst biopsy.⁷ In the first method, scientists take the cells that have been “cast off” by the egg as it matures. Scientists use these “polar body cells” to understand the characteristics of the egg.⁸ A limit to this method is that these cells will only include genetic material from the mother and cannot test for paternally inherited diseases. In the other methods of extraction, scientists wait two to four days after the egg has been fertilized for the embryo to develop, and then they remove one to two cells. In cleavage stage biopsy, the most commonly used method, a laser is used to create a hole to access the blastomeres, which are often removed by pipette. The last method is called blastocyst biopsy. The benefit is that the blastocyst stage provides more cells for analysis; most cells in vitro do not make it to this stage and if they do they have little time to be analyzed.⁹

Once cell particles are removed from the embryo, there are two ways to analyze the extracted material: “FISH” (fluorescent in-situ hybridization), which allows researchers to determine the number and structure of chromosomes, and “PCR” (polymerase chain reaction), in which researchers make copies of individual

7 Karen Sermon, “Current Concepts in preimplantation genetic testing diagnosis (PGD): a molecular biologist’s point of view,” *Human Reproductive Update*, 2002, 12.

8 Genetics & Public Policy Center.

9 Karen Sermon, “Current Concepts in preimplantation genetic testing diagnosis (PGD): a molecular biologist’s point of view,” *Human Reproductive Update*, 2002, 13.

genes to examine their DNA sequences.¹⁰ FISH, used to determine the sex of embryos, has a 10% error rate.¹¹ PCR has been used to reduce the likelihood of having a child with genetic disorders. PCR testing now extends to test the status of many diseases ranging from Alzheimer's to Breast Cancer to Cystic Fibrosis to Fabry. The Reproductive Genetic Institute boasts positive testimonials on its website: "Benjamin is the first child ever to be born using PGD to prevent another life from being burdened with dystopia," signed by "Happy Parents." For couples that fear passing genetic disorders on to their children, PGD provides a better alternative to prenatal testing, abortion, or caring for a sick child.¹² However, many people are concerned about the ethical implications of using FISH to select the sex of babies and other non-medical characteristics such as eye color or hair color. Bratislav Stankovic describes people's fears of "Designer Babies" that are selected for non-medical traits.¹³ This paper will focus on electing PGD for medical purposes because this one option has enough disagreement for a whole paper to itself.

III. IMPACT OF PGD ON CHILD HEALTH

Though relatively few PGD procedures and births have

10 Genetics & Public Policy Center, 2006, and Sermon, 2002.

11 Karen Sermon et al., "Preimplantation Genetic Diagnosis," *The Lancet*, Vol. 363, 2004.

12 B. Tur-Kaspaa et al. "PGD for all cystic fibrosis carrier couples: novel strategy for preventive medicine and cost analysis," *Reproductive Biomedicine Online*, 2010.

13 B. Stankovic, "'It's a designed baby!' -Opinions on Regulation of Preimplantation Genetic Diagnosis," *UCLA Journal of Law & Technology*, 3, 2005, 2.

occurred, early research shows promising signs for children. As of 2006, between 1000 and 2000 children were born after PGD.^{14, 15} Exact estimates of the number of PGD children born vary, but this number is quite small relative to the 1 million children born through in vitro fertilization.^{16, 17} Studies show that babies who underwent PGD show signs of similar health to other babies conceived in vitro as well as naturally conceived babies. Researchers note that children born from multiple pregnancies (twins, triplets or more) have higher risks for health conditions.¹⁸

Given that the risks associated with PGD are low and that the reward of giving birth to a child without genetic disorder is so high, many parents with the means necessary pursue the technology. PGD has been used to help parents bear children that are free of a range of hereditary diseases. We will now look closely at one

14 Genetics & Public Policy Center, 2006

15 According to Andrew LaBarbera, president of the American Society for Reproductive Medicine, as quoted by Nicholas Wade in *In New Methods for Stem Cells, Viable Stem Cells: Objection to Use*, NYT, about 2000 babies were born from PGD as of 2006. The 100% discrepancy in total number of children born after PGD shows the lack of formal data gathering and registration across the medical community.

16 Preimplantation Genetic Diagnosis: A Discussion of Challenges, Concerns, and Preliminary Policy Options Related to the Genetic Testing of Human Embryos. Genetics & Public Policy Center. <http://www.dnainpolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf>

17 According to the 2012 Reproductive Genetics Institute website around 1500 children have been born to date after PGD. To put these numbers in perspective, consider the fact that couples in the U.S. gave birth to 61,000 babies conceived through IVF in 2008 alone (NCSL, 2012). PGD is being done on a much smaller scale due to costs, technology, and lack of awareness of the procedure, possibly driven by doctors' fears of personal and social impact.

18 L. Liebaers, "Report on a consecutive series of 581 children born after blastomere biopsy for preimplantation genetic diagnosis," *Human Reproduction*, 2010.

of those diseases, Fabry, which was the core of the Bergero case.

IV. FABRY DISEASE

Fabry disease is an X-linked recessive disorder. The gene creates reduced amounts of the enzyme alpha galactosidase, which prevents buildup of lipids in cells throughout the body.¹⁹ Without the enzyme, lipids build up to harmful levels in eyes, kidneys, the autonomic nervous system, and the cardiovascular system.²⁰ Symptoms begin in childhood and include a burning feeling in the hands and feet, skin blemishes, cloudiness of cornea, and impaired circulation.²¹ These symptoms are associated with an increase in heart attack or stroke. Approximately 1 in 40,000 to 60,000 males have the disease.²² In a study of individuals in the Fabry Registry, the life expectancy of men with Fabry disease was 16.5 years lower than that of men in the general population. The most common cause of death of people within that group was cardiovascular disease.^{23,24} Lastly, all individuals who died early as a result of Fabry had the common theme of late diagnosis of Fabry.²⁵ The FDA has approved enzyme replacement therapy to

19 Bergero v. USC Keck School of Medicine, 2009

20 National Institute of Neurological Disorders and Stroke, 2010. <http://www.ninds.nih.gov/disorders/fabrys/fabrys.htm>

21 Ibid.

22 Genetics Home Reference, 2013. <http://ghr.nlm.nih.gov/condition/fabry-disease>

23 Waldek, S. "Life expectancy and cause of death in males and females with Fabry disease: findings from the Fabry Registry." *Genetic Medicine*, 2009, 1. <http://www.ncbi.nlm.nih.gov/pubmed/19745746>

24 Waldek et al. used data from 2848 patients in the Fabry Registry. As of 2008, the authors found that 75 of 1422 men and 12 of 1426 women registered in the Fabry Registry had died.

25 The median age of diagnosis was age 40 for men and age 55 for women.

reduce lipid build up in organs. Other interventions include medications, renal replacement therapy, and kidney transplant.²⁶

Because of the painful outcomes associated with Fabry disease, parents may seek genetic counseling. As stated above, Fabry is an X-linked recessive disorder. If a female carrier has a child, a boy will have a 50% chance of inheriting the disorder and a girl will have a 50% chance of being a carrier.²⁷ If a father is a carrier, all of his female children will inherit the gene and none of his male children will inherit the gene.²⁸ Since women have two X-chromosomes, the normal gene on the unaffected X-chromosome may produce enough of the necessary enzyme to compensate for the deficient gene on the other chromosome.²⁹ Thus, the effects of Fabry in females are milder.

Like many other parents who are aware of genetic disorders they may carry, Eve Rubell wanted to avoid passing the gene to her potential offspring. Rubell had previously attempted treatment for infertility when she learned that she was a carrier for Fabry after a routine eye exam showed swirling around the cornea.³⁰ Afraid that a child would inherit the gene, she and her husband sought counseling. A genetic counselor from Kaiser suggested PGD as one of three options and recommended specialist Dr. Hughes. Rubell

Because of diagnosis at this point in mid-late adulthood, the disease had progressed a good deal before it was treated.

26 National Institute of Neurological Disorders and Stroke, 2010. <http://www.ninds.nih.gov/disorders/fabrys/fabrys.htm>

27 Ibid.

28 "What is Fabry Disease?" Fabry Support & Information Group. <http://www.fabry.org/fsig.nsf/pages/fabry>

29 *Bergero v. USC Keck School of Medicine*, 2009

30 Ibid.

could do PCR (used to study genes; commonly used to determine presence of a single gene diseases) or FISH (used to study chromosomes; commonly used to test gender). Hughes recommended using PCR because if they did FISH they would have to get rid of all male embryos (since FISH would not be able to distinguish which embryos were affected with Fabry). Rubell understood this to mean that she would have more embryos to implant with PCR than FISH, and so she chose PCR to increase the odds of having a successful pregnancy.

After PCR, Hughes found that all six of the embryos were affected with the Fabry gene. Two were female, two were male, and two were inconclusive. Given the much milder health outcomes in women with Fabry (due to the extra X chromosome to combat the enzyme deficiency), Rubell asked Dr. Hughes to implant the two known female carriers. Twelve weeks after getting pregnant, Rubell learned that the fetus was a boy with Fabry. Rubell later told the court that her top priority was to not conceive a male child with Fabry. However, she testified that she could not remember whether she had made the statement to her genetic counselor. Knowledge of this goal might have led Dr. Hughes to recommend FISH, which has a better accuracy for gender. Rubell

also lamented that no one had ever verbally reviewed the consent form with her and that they concealed the center's lack of experience with PGD from her.

The Rubell-Hughes misunderstanding serves as a warning of the potential outcomes of mismanaged expectations and end-goals of patients and their doctors. According to the case notes, "consensus among the genetic community" suggested that two people be present at the time of the embryo transfer to ensure that the correct one be implanted in the mother. However, no formal regulation on PGD existed or exists today.

V. REGULATION

There is little regulation on PGD in the United States.^{31, 32} However, members of the American Society for Reproductive Medicine claim that Assisted Reproductive Technologies (ART) is "already one of the most highly regulated of all medical practices in the U.S."³³ The report cites federal government, state government, and professional self-regulation as the watchdogs on ART.

Federal Regulation has been limited in its scope. As established by the 1992 Fertility Clinic Success Rate and Certification

31 See B. Stankovic. "'It's a designed baby!' -Opinions on Regulation of Preimplantation Genetic Diagnosis." *UCLA Journal of Law & Technology*, 3, 2005, 5-7.

32 In England, a committee was chartered in a 1990 law to promote and regulate the research on embryonic cells, transfer of cells for IVF, and other genetically related procedures. Italy banned PGD, Israel promotes it (since it is a good alternative to abortion, which is prohibited by Jewish doctrine), and France is still figuring out what it should do with PGD given differences in public opinion.

33 "Oversight of Assisted Reproductive Technology," American Society for Reproductive Medicine. May 25, 2012, 3.

Act, the Centers for Disease Control created standard definitions for methods used in fertility clinics and required standard reporting of ART data. The FDA has jurisdiction over medications as well as the screening and testing of reproductive tissues. The Centers for Medicaid and Medicare and Clinical Lab Improvement Act handle diagnostic testing and regulation of embryology labs.³⁴ These organizations audit labs by sending blank samples that need to be identified; labs with consistently high percentages of error lose their accreditation. Authors are torn on the role of regulation, citing the impact regulation might have on different stakeholders.³⁵

There are many stakeholders in a conversation about access to PGD: parents, doctors, scientists, drug companies, insurers, government agencies, and society at large. This paper focuses on the tension between patients and their medical professionals. In this paper, I conflate doctors and genetic counselors, since they as a group have more information about the technology of PGD than most patients. A separate analysis would show the differences in concerns between these two stakeholders, but due to its scope, this article will focus on the asymmetric information between patients and their medical-advisors. *New York Times* science correspondent and Pulitzer Prize winner Amy Harmon notes, "In the U.S., where technology is not regulated, decisions about when it is appropriate are left largely to fertility specialists and their

34 Ibid. 6-7.

35 Dorothy Roberts. "Race, gender, and genetic technologies: A new reproductive dystopia?" *Signs*, 34(4), 2009, 784.

patients.”³⁶ Because there is little regulation in the U.S., many decisions regarding PGD are left up to doctors and counselors. Therefore, the tension between doctors and patients is extremely relevant in the U.S. right now.

VI. PATIENTS

Since PGD is a relatively new technology, many people are unaware of having an option to prevent passing on a hereditary trait to children. Genetic diseases have different emotional and social meanings for different people. Some people like Eve Rubell are carriers for a disease but have never been physically affected by the genetic disorder; because she was undergoing IVF and discussed the disease diagnosis with her genetic counselor, she thought that she could prevent future suffering of her child by deselecting embryos with the Fabry gene. For others, having a disease is strongly linked with personal and familial identity. Women who have seen scores of family members die from breast cancer may learn about PGD and see it as a chance to overcome a plague that has befallen generations and prevent tragedy for future genetic lines. Some breast cancer survivors who have not been presented the option of PGD feel they have been “cheated” out of an opportunity to have a cancer-free future for their children. Indeed, Offit et al. suggest that patients with various types of cancer are increasingly asking about the option to select PGD and avoid passing cancer genes to children.³⁷ Others experience

36 Amy Harmon, “Couples Cull Embryos to Halt Heritage of Cancer,” *New York Times*, September 3, 2006, <http://www.nytimes.com/2006/09/03/health/03gene.web.html?pagewanted=all&r=0>.

37 Offit et al., “Cancer genetic testing and assisted reproduction,” *Journal of*

genetic diseases as cultural identities.

Consider the Dor Yeshorim program used to eliminate Tay-Sachs in the New York City Jewish community in the 1980s. In the program, the trusted community Rabbi signed off on every marriage. With access to genetic information about community members, Rabbi Josef Ekstein would disallow marriages where both individuals were Tay-Sachs carriers.³⁸ The program successfully decreased the prevalence of Tay-Sachs in the community. The Dor Yeshorim was popularly accepted because Rabbi Josef Ekstein was a trusted and respected figure within the community. While the Dor Yeshorim served as a community-led mating process to avoid passing deadly Tay-Sachs genes to offspring, PGD may be seen as a more invasive form of ensuring that a healthy child is produced. PGD is supported by genetic counselors who are not as engrained and attuned to cultural traditions as a community leader. Lastly, the Dor Yeshorim was successful because the group of individuals affected became educated and acted together to eradicate this disease.³⁹

Clinical Oncology, July 13, 2006, 4775.

38 Keith Wailoo and Stephen Pemberton, *Ethnicity and Innovation in Tay-Sachs, Cystic Fibrosis, and Sickle Cell Disease: The Troubled Dream of Genetic Medicine*, The Johns Hopkins University Press, 2006, 20.

39 Because the community of cancer survivors is much larger and more heterogeneous, it might be difficult to get a group even as committed to eradicating cancer as them to promote use of PGD to deselect genes with the BRCA1/2 genes. Indeed, much research and literature has recently shown that researchers are thinking about the relationship between PGD and cancer prevention. The growing concern between cancer and PGD may be due to the large number of people in the U.S. affected by cancer in some way or because of its racially and economically free characterization: no race, ethnicity, or income status is barred from cancer. Whereas other diseases may be more specific to certain groups, getting donors to support cancer-PGD research may be easier.

In all cases, patients are trying to avoid the future suffering of their children and hoping to give birth to healthy children, whatever their fertility motivations may be. Since the majority of people considering PGD have tried IVF and have dealt with the sadness of infertility, their overriding desire is to have a successful pregnancy and give birth to a healthy child. Definitions of healthy, however, vary across patients. Some parents have, as a secondary goal, a desire to have a child similar to his or her parents. In 2006 Darshak Saghavi described the practice of parents selecting embryos with known deficiencies so that they can fit in with the family or be part of a disabled community. According to Susannah Baruch at Johns Hopkins Medical Center, 3% of couples deliberately used PGD to select an embryo with a disability.⁴⁰ These desires present a tension between individual values and collective values. Many doctors refuse to do such procedures because of the social value on "wellness."

Patients may see PGD as a way to improve fertility by selecting embryos with a higher rate of survival or as a way to avoid passing on a deadly genetic disease while conforming to religious norms. Women who were studied in Israel saw PGD as a positive option to have in trying to have a healthy child, since many women had religious beliefs preventing them from aborting fetuses.⁴¹ Religious values can influence patients' desires in the other way, as well. Some conservative Christians may not believe in

40 Darshak Sanghavi, "Wanting Babies like Themselves, Some Parents Choose Genetic Defects," *New York Times*, December 5, 2006, <http://www.nytimes.com/2006/12/05/health/05essa.html>.

41 M. Sagi et al. Preimplantation Genetic Diagnosis for BRCA1/2- a novel clinical experience, *Prenatal Diagnosis*. May 29, 2009, 511.

IVF because it separates the act of procreation from sex, denying a sacred part of human creation. In addition, PGD may create an even bigger moral dilemma than abortion because of the question of what to do with the multiple leftover embryos not selected for implantation. However, PGD has been found, broadly, to decrease the number of abortions of fetuses with genetically inherited diseases: Verlinsky et al found that PGD “reduces by fourfold the spontaneous abortion rate in couples carrying translocation.”⁴² Thus, pro-life individuals might support PGD, depending upon their beliefs regarding the extraneous embryos. Religious values may create political complications for any regulations surrounding PGD; for example, would religious hospitals or insurance agencies have to cover expenses for IVF and PGD? The current skepticism around women’s reproductive rights in the political forum will undoubtedly influence policy decisions around PGD.

As the parents of future children, patients have a large stake in determining the outcome of their potential progeny. PGD allows many couples who would otherwise be infertile to have the opportunity to have a child and continue their genetic ancestry. PGD may also prove burdensome, as parents who do not elect to use the technology may feel guilt if they see their child suffer later in life and think about what they could have done to prevent that pain. Patients may lack understanding of their own disease, of the powers of PGD, or may misunderstand the probabilities for misdiagnosis.

42 Verlinsky et al., “Over a decade of experience with preimplantation genetic diagnosis: a multicenter report,” *Fertility and Sterility*, August 2004, 293.

VII. MEDICAL PROFESSIONALS

Medical professionals present another group within the conversation on stakeholders in the discussion on PGD. Doctors and genetic counselors want, broadly, to produce healthy children. They are responsible for conducting PGD and are held responsible if something goes wrong along the way. Doctors have stakes in maintaining their businesses, making money, and promoting healthy babies. They also have their own social, religious, or moral beliefs that may influence their decisions. For example, many doctors refused the patients who asked them to select embryos with deafness or dwarfism because of their own values of what it means to be healthy and “normal” in society.⁴³ Genetic counselors have stakes in keeping the field of genetics popular and lucrative; hopefully, they have it in the best interest of their patients to produce healthy children. Should they bend to the desires of their patients?

Medical professionals are essentially the gatekeepers to PGD. Whom do they choose to inform about the procedure and assist in getting coverage? Is it ethical that some parents are aware of the procedure—let alone have access to it—while others do not? Eve Rubell’s genetic counselor fought hard to get coverage from Kaiser insurance for the expensive procedure.⁴⁴ What was that counselor’s motive in fighting for the money despite USC’s low level of experience with the procedure? How much responsi-

43 Darshak Sanghavi, *New York Times*, “Wanting Babies Like Themselves, Some Parents Choose Genetic Defect,” December 5, 2006. <http://www.nytimes.com/2006/12/05/health/05essa.html>

44 *Bergero v. USC Keck School of Medicine*, 2009

bility do professionals have in reaching out to communities that are currently underrepresented in PGD? Dorothy Roberts suggests that culture, history, and economics influence a distrust of genetic specialists that explains the low number of African American women who receive PGD: "Blacks may find it emotionally difficult to discuss their problem with a physician, especially considering the lack of Black specialists in this field. They may also harbor a well-founded distrust of technological interference with their bodies and genetic material at the hands of white physicians."⁴⁵ Thus, genetic counselors, doctors, and specialists must overcome this distrust if they hope to reach a wider group of individuals.

Tensions exist between patients and their medical professionals because of incentives on either end: patients with disabilities may seek harmonious family life, which motivates their desire to select certain embryos. Professionals may seek to maximize the chance of pregnancy or may act in the best interest of protecting the clinic. All of these stakeholders have different values guiding their decisions, and they have one thing in common: each needs the other. Patients could not avoid passing genetic disorder to their offspring through PGD without the help of medical professionals, and, medical professionals would have no line of business if they did not have patients.

VIII. MORAL, POLITICAL, AND RELIGIOUS VALUES

PGD raises many issues. Morally, people are concerned with picking which lives get to live. Controversies include using PGD

45 Dorothy Roberts, "Race and the New Reproduction," *Hastings Law Journal*. Vol. 47, 1995-1996: 941.

as a means for an end. For example, parents may select certain embryos that have an "immunological match for a sick sibling."⁴⁶ PGD may be favorable to individuals who oppose abortion. By limiting the embryos that can lead to a pregnancy to only those of healthy quality, then women avoid the question of aborting a pregnancy.

Social and political values consider who can access PGD and whether it will give certain families unfair advantages. Dorothy Roberts discusses the double-edged sword of making IVF and PGD more accessible to all people. As current policy stands, there is little regulation of the IVF business, so the majority of women who have access to the processes are independently wealthy.⁴⁷ Roberts notes also that the vast majority of women undergoing reproductive assistance are white women.⁴⁸ While some might welcome government regulation to provide access to fertility services for low-income women and black women, the very act of regulation on reproduction may be a cause for political concern for others.

Other legal concerns question the autonomy of the fetus. Should parents deselect for diseases that do not appear until later in life or for heightened but uncertain risks such as breast cancer? In Israel, the Genetic Information Law of 2000 makes it illegal for parents to seek the genetic information of children after birth.⁴⁹

46 Genetics and Public Policy Center.

47 Dorothy Roberts. Race, gender, and genetic technologies: A new reproductive dystopia? *Signs*, 34(4), 2009, 784.

48 Dorothy Roberts, "Race and the New Reproduction." *Hastings Law Journal*. Vol. 47, 1995-1996: 937.

49 M. Sagi et al. Preimplantation Genetic Diagnosis for BRCA1/2- a novel

The U.S. may look to other countries as it begins to craft its own policies on the subject.

IX. Policy Recommendations

Based on the models that have been studied in different countries, the values shared by many stakeholders, and on the experiences represented in the Bergero case, I would recommend three changes to current policy.

First, to empower patients and ensure that they are aware of all of their fertility options, medical professionals should educate known genetic carriers on the use of PGD. States could mandate that geneticists provide information about PGD (and provide counseling) to individuals over the age of 18 when they are diagnosed with diseases that can be passed on to children. This recommendation is inspired by the research of Sagi et al., who informed BRCA1/2 survivors of PGD and studied women's reactions in response to the option. In the study, all women said they appreciated having the option to use PGD to prevent implanting an affected embryo, but most did not choose to use the option.⁵⁰ In addition, the work of Kalfoglou and Quinn et al. shows that patients desire to know more about PGD as an option to prevent genetically passed disease traits, even if they do not ultimately use it as an option.^{51, 52} This recommendation is particularly easy

clinical experience, *Prenatal Diagnosis*. May 29, 2009, 512.

50 M. Sagi et al. Preimplantation Genetic Diagnosis for BRCA1/2- a novel clinical experience, *Prenatal Diagnosis*. May 29, 2009, 510.

51 Dwendolyn Quinn et al., "Conflict between values and technology: perceptions of preimplantation genetic diagnosis and women at increased risk for hereditary breast and ovarian cancer," *Familial Cancer*, 2009

52 Kalfoglou et al. PGD patients' and providers' attitudes to the use and

to implement for the cancer survivors and other genetic disease carriers who are already undergoing IVF treatment due to infertility issues. Geneticists and doctors who deliver news of diagnoses of genetic diseases would have to first learn more about the technologies of PGD and then articulate those options to their clients. Such a policy would inform patients of the full extent of fertility options.

Second, to ensure that patients who choose PGD are fully aware of the risks involved with the procedure once they decide to do it, regulation should require doctors to review consent forms verbally to ensure that their patients understand the information to which they are agreeing. Eve Rubell signed consent forms stating that she was aware PGD had an error rate of 3-5%. She received written word of the probabilities of misdiagnosis in emails, but her doctor stated that he did not review the forms with her verbally. Such a conversation may have prevented her from suing USC and may have helped her manage her expectations on the powers of PGD. Kalfoglou's research uncovered that women did not feel like "empowered consumers" of PGD and felt confused by their contractual agreements in consent forms.⁵³ Kalfoglou also shows that patients misunderstood the probabilities of having live births after PGD.⁵⁴ Better communication between providers and patients will improve the process by empowering patients. Edu-

regulation of preimplantation genetic diagnosis, *Reproductive BioMedicine Online*, 2005, 487.

53 Kalfoglou et al. "PGD patients' and providers' attitudes to the use and regulation of preimplantation genetic diagnosis," *Reproductive BioMedicine Online*, 2005, 490.

54 Ibid, 490.

cating patients about the limitations of PGD, in part by verbally discussing consent agreements, will clarify doctors' and patients' expectations.

Third, to reduce human error in PGD, states should regulate that two people check transfers at the time of single cell biopsy. In addition, having two people present at the transfer of the embryo will reduce speculation of human error in cases of misdiagnosis, which will help further develop our understanding of this technology and process. According to the notes from *Bergero v. USC Keck School of Medicine*, it is a commonly accepted practice within the "PGD community" to have two people present at the time of the transfer, but that did not happen in *Bergero*. Legislation could standardize this procedure.

Many problems still exist in regulating PGD. While most people support more equal access to the procedure, others are wary about the potential for bureaucratic processes to stifle growth in this area and would prefer to rely on self-regulation within the PGD community.⁵⁵ In addition, others are concerned about the precedent of having government further involved in reproductive politics, given abuse and oppression in the past.⁵⁶ Future research should consider fair access to PGD treatment and enforcement of the above regulations. Research should explore the possibility of expanded access through insurance coverage of PGD and the costs and benefits associated with such a policy.

Bergero serves as a good example of the tensions between

55 Ibid. 495.

56 Dorothy Roberts, "Race and the New Reproduction." *Hastings Law Journal*. Vol. 47, 1995-1996: 947.

patients and professionals in navigating the new waters of PGD. As society steers ahead with Preimplantation Genetic Diagnosis technology, professionals may be at the helm, but they will be best served if patients are by their sides.