Designer Babies: The Need for Regulation on the Quest For Perfection

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Imagine a society where the ability to create the “perfect child” is a possibility. With recent advances in reproductive medicine, parents may one day be able to customize their child’s embryos. In 2004 the term “designer baby” was added to the Oxford English Dictionary, where it is defined as “a baby whose genetic makeup has been selected in order to eradicate a particular defect, or to ensure that a particular gene is present.” At this time, the creation of designer babies is not yet possible. However, in the future by using Preimplantation Genetic Diagnosis (PGD) in conjunction with In Vitro Fertilization (IVF) doctors may have the ability to create “designer babies.”

Assisted Reproductive Technologies (ART), such as IVF and PGD, are most often enlisted by infertile couples. PGD can determine which embryos are affected by which genetic conditions before implantation. This process ensures that only embryos that test clear of inheritable diseases are transferred to the uterus using IVF. While those that carry the harmful genes will be discarded prior to implantation. Currently, PGD and IVF have been used to prevent couples from giving birth to a child afflicted with genetic disease. This has created many concerns surrounding the possibility of these techniques being used to hand select certain genetic traits for non-therapeutic reasons. As a result, fertile couples may begin to undergo treatments as ART increases the ability to control offspring’s genetic traits prior to fertilization.

While there are numerous positive aspects of PGD, it is necessary to consider the many ethical implications of using such techniques for non-therapeutic purposes. One can only wonder what will happen to society when it becomes possible for parents to screen embryos and hand

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pick genes for their children from an enormous range of attributes including gender, hair color, eye color, height, weight, intellect, personalities, athletic ability or musical talent. At present, neither state nor federal law regulates PGD; therefore guarding against the possible exploitation and objectification of children is a major concern for the future.\(^2\)

The ethical and social concerns regarding the expansion of PGD demonstrate the necessity for oversight by the United States government. PGD may be a beneficial procedure but when considering its ability to select for cosmetic genetic traits, it becomes evident the potential for manipulation requires the government to regulate these parents on their question for perfection.

This paper will begin by outlining the current methods of ART, including IVF and PGD. Section II will illustrate the benefits of using ART exclusively for medical purposes for both early and late onset genetic disorders. The therapeutic uses of PGD will be distinguished from the non-therapeutic uses. Section III will explore the various social, ethical and legal questions regarding PGD. Specifically, this section will examine such dilemmas as sexism, autonomy, legal liability issues, distributive justice concerns, genetic elimination, and discrimination in the context of selecting for genetic traits. Section IV will discuss the need for oversight of ART by the United States government to prevent children from becoming objects and commodities.

**I. Assisted Reproductive Technology’s Creation of Designer Babies**

Today nearly three out of every 100 babies born in the United States are the product of an assisted conception.\(^3\) Assisted Reproductive Technologies (ART) encompasses a range of fertility therapies, where the egg and sperm are manipulated to achieve pregnancy. These procedures are primarily used as fertility treatments. However, PGD and IVF may be used by

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fertile couples for genetic reasons. IVF consists of surgically removing eggs from a woman’s ovaries, fertilizing the egg outside the body and then transferring the fertilized egg back into the woman’s uterus. PGD is a process that can analyze the genetic make-up of the embryos created through IVF before implantation in utero. Together these two procedures can be used to genetically engineer a designer baby.

A. Assisted Reproductive Technologies

ART consists of numerous methods that are usually combined for the purpose to aid in achieving pregnancy by artificial or partially artificial means. ART enables pregnancy without sexual intercourse by surgically removing the eggs from the woman ovaries and fertilizing them in the laboratory. ART has been used in the United States since 1981 as a means to help women become pregnant.

In the past decade, many ART techniques have gained rapid acceptance in the medical community and have contributed to over five million births worldwide. ART is most often used to help infertile couples conceive a child. However, with the advancements in reproductive medicine these methods could eventually be combined to manipulate the embryo to the point of customization. Many more couples will begin to use ARTs for these genetic possibilities. This paper will focus on those methods, including IVF and PGD.

B. In-Vitro Fertilization

IVF is a process that ultimately fertilizes the egg with the sperm in a laboratory. IVF involves manipulating biological events that occur within a woman's body. The process begins

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4 Assisted Reproductive Technology (ART), CENTER FOR DISEASE CONTROL AND PREVENTION (last updated Nov. 27, 2013), http://www.cdc.gov/art/index.htm [hereinafter ART].
6 ART, supra note 4.
7 Daar, supra note 3.
8 Knaplund, supra note 5, at 904.
by promoting ovulation. Normally a woman only produces one egg a month, however fertility drugs create an increase in production.\textsuperscript{10} Researchers have found that by administering certain hormones, it is possible to cause several follicles to mature, thereby causing the woman's body to produce a larger number of eggs.\textsuperscript{11} After around two weeks of daily hormone injections and blood tests the doctors remove the eggs.\textsuperscript{12} This second step is known as egg retrieval. This can be done either by a laparoscopic procedure or by an ultrasound procedure.\textsuperscript{13} In either scenario a minor surgery, called follicular aspiration, is done to remove the eggs from the woman’s ovaries.\textsuperscript{14} A thin needle is inserted through the vagina and into the ovary; the needle is connected to a suction device, which pulls the eggs and fluid out of each follicle.\textsuperscript{15} The procedure is then repeated on the other ovary.\textsuperscript{16} By increasing the number of eggs produced this allows more eggs to be collected during the procedure, increasing the chance of a successful pregnancy.

Following the removal of the eggs, they are taken to the laboratory, where they are combined with the sperm.\textsuperscript{17} If there is no problem with the sperm, a process known as insemination takes places and the sperm and egg are combined in a petri dish.\textsuperscript{18} If sperm parameters are abnormal doctors usually use a process known as intracytoplasmic sperm injection (ICSI) to directly inject a single sperm into the egg to increase the chances of success.\textsuperscript{19} Around 16-18 hours after insemination or ICSI, fertilization is assessed.\textsuperscript{20}

\begin{itemize}
  \item \textsuperscript{9} Keith Alan Byers, \textit{Infertility and in Vitro Fertilization A Growing Need for Consumer-Oriented Regulation of the in Vitro Fertilization Industry}, 18 J. LEGAL MED. 265, 276-77 (1997).
  \item \textsuperscript{10} Knaplund, supra note 5, at 904.
  \item \textsuperscript{11} Id.
  \item \textsuperscript{12} Id.
  \item \textsuperscript{13} Byers, supra note 9, at 278.
  \item \textsuperscript{14} Id.
  \item \textsuperscript{15} Id.
  \item \textsuperscript{16} Id.
  \item \textsuperscript{17} Id.
  \item \textsuperscript{19} Id.
  \item \textsuperscript{20} Id.
\end{itemize}
occurs and the fertilized ova have been allowed to incubate or grow for approximately 48 to 72 hours, doctors transfer the fertilized egg into the uterus in the hopes of achieving a successful pregnancy.\textsuperscript{21} The entire process takes around two to three days.\textsuperscript{22}

C. Preimplantation Genetic Diagnosis

PGD is a technique used to identify genetic defects in embryos, which are created through IVF.\textsuperscript{23} Based on the fact that one or both parents have that known abnormality, PGD will be used to test an embryo to determine if it also carries a genetic abnormality.\textsuperscript{24} PGD dates back to 1968, when it was first successfully used on rabbit embryos.\textsuperscript{25} By 1989 the first unaffected child was born using PGD to test for an X-linked disorder.\textsuperscript{26} Throughout the 1990s, PGD was used to screen for severe, irreversible, genetic conditions.\textsuperscript{27} As of today, PGD is available for most known genetic conditions.\textsuperscript{28}

The PGD process begins after the IVF process of fertilization. Embryos must be grown in the laboratory for about two to three days and divide into around eight cells before PGD treatment can begin.\textsuperscript{29} When the embryos are ready an embryologist removes a single blastomere from the developing embryo for genetic evaluation.\textsuperscript{30} DNA is extracted from the blastomere, and tested for chromosomal abnormalities or genetic mutations.\textsuperscript{31} Genetic evaluation is performed using polymerase chain reaction (PCR), or fluorescence in situ hybridization (FISH), depending

\begin{thebibliography}{99}
\bibitem{vacco} Lindsey A. Vacco, \textit{Preimplantation Genetic Diagnosis: From Preventing Genetic Disease to Customizing Children. Can the Technology Be Regulated Based on the Parents' Intent?}, 49 ST. LOUIS U. L.J. 1181, 1228 (2005)
\bibitem{dayal} Id.
\bibitem{weise} Id.
\bibitem{weise} Id.
\bibitem{weise} Id.
\bibitem{weise} Id.
\bibitem{weise} Id.
\bibitem{weise} Id.
\bibitem{weise} BONNIE STEINBOCK, \textit{Preimplantation Genetic Diagnosis and Embryo Selection, in A Companion to Genethics} 175 (Justine Burley & John Harris eds., 2002).
\end{thebibliography}
on the genetic condition being studied.\textsuperscript{32} Cells from the embryo are tested to see if the embryo contains genetic conditions. A diagnosis is typically obtained within 24 hours, and then only the unaffected embryos are transferred into the woman’s uterus, in hopes of developing into a successful pregnancy.\textsuperscript{33}

PGD is used to determine genetic defects in embryos.\textsuperscript{34} This technology when combined with IVF can prevent implantation of embryos that contain genetic diseases or other undesirable traits. After the embryos that carry the genetic diseases or other undesirable traits are discarded, the healthy embryos, those that are free of disease, will be implanted into the woman’s uterus.\textsuperscript{35}

Unfortunately, there are some risks associated with PGD. Even after a successful procedure pregnancy is not a guarantee. The probability of getting pregnant from a PGD and IVF treatment is low.\textsuperscript{36} This is for two reasons: a relatively large number of embryos found maybe abnormal, thus leaving only a few or no healthy embryos for transfer and the PGD procedure itself may damage the embryo.\textsuperscript{37} Therefore, in both circumstances there are fewer embryos left for implantation.\textsuperscript{38} This results in fewer embryos to fertilize which decreases the chances of pregnancy.

\textbf{II. Benefits of PGD Exclusively for Therapeutic and Medical Purposes}

PGD is currently used to analyze embryos created through IVF to avoid transferring to the mother's uterus an embryo affected by a mutation or chromosomal abnormality.\textsuperscript{39} Since PGD can prevent genetic conditions in future children, PGD reduces the chance that the parents will

\textsuperscript{32} Dayal, \textit{supra} note 23.
\textsuperscript{33} Vacco, \textit{supra} note 21, 1184-86.
\textsuperscript{34} Steinbock, \textit{supra} note 31.
\textsuperscript{35} \textit{Id.}
\textsuperscript{36} \textit{RUTH DEECH & ANNA SMAIDOR, From IVF to Immortality: Controversy in the Era of Reproductive Technology} 57 (2007).
\textsuperscript{37} \textit{Id.}
\textsuperscript{38} \textit{Id.}
be faced with a difficult decision of whether to terminate the pregnancy. Therefore, PGD has
been widely accepted for its therapeutic uses, which include selection against serious early-onset
illnesses, and late-onset disorders.

A. Early Onset Genetic Diseases

IVF and PGD technologies are most commonly used to screen for particular diseases and
select against implantation of any embryo with a given genetic condition. PGD has the ability to
diagnose many severe genetic disorders including, but not limited to, Cystic fibrosis, Tay-Sachs
disease, Duchenne's muscular dystrophy, Fragile X syndrome, Down syndrome, and even some
cancer genes. The benefit of PGD in comparison to other existing prenatal screening is the
embryos are scanned for genetic conditions prior to implantation and all infected or disease
embryos are discarded. As a result, couples are not faced with the problem of aborting the fetus
later on during prenatal testing if a genetic condition is detected. Therefore, some view PGD as
an ethical alternative to termination of a pregnancy.

The benefits of PGD can be observed in the example of Jeffrey and Melanie Sowers, a
California couple whose first child was diagnosed with a form of muscular dystrophy. Couples
like the Sowers use PGD to avoid the chance of passing genetic diseases, like muscular
dystrophy, on to any future children. Before giving birth to their second child, the Sowers used
PGD to detect genes that carry the genetic disease and then used IVF technologies to implant the

40 Richard J. Tasca & Michael E. McClure, The Emerging Technology and Application of Preimplantation Genetic
41 Deech & Smajdor, supra note 36, 63.
42 Steinbock, supra note 31.
43 Amy Dockser Marcus, Ensuring Your Baby Will Be Healthy: Embryo Screening Test Gains in Popularity and
http://www.geneticsandsociety.org/article.php?id=104
44 Id.
unaffected embryos that were not carriers for the disease into Mrs. Sowers. This way they were guaranteed to give birth to a child unaffected with muscular dystrophy.

Another couple, the Dunthores, gave birth to a child with cystic fibrosis, who died a few months later. The couple was originally unaware they were carriers for the disease and feared that they would give birth to another child who would suffer from cystic fibrosis. The couple decided to use PGD to have their embryos tested. Embryologists tested the cells for the cystic fibrosis gene. Those that were affected with cystic fibrosis were discarded. Those that were unaffected were placed in the uterus. Eventually, Susan gave birth to a child unaffected with cystic fibrosis.

As you can see in the two examples above, PGD is a beneficial alternative for couples that are carriers for genetic diseases. Often times these couples may be forced to remain childless, may question adoption, or even sometimes endure the stress of terminating the pregnancy. However, now these at-risk couples are provided with alternatives due to the benefits of PGD. These parents who undergo PGD treatment no longer need to worry that their children will be born with a genetic condition and have to undergo years of testing and monitoring, treatment, or even death.

B. Late Onset Genetic Diseases

PGD can also be used to prevent late onset diseases including Alzheimer’s, Huntington’s disease and potentially even cancer. Many late onset diseases include an inevitable process of

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45 Id.
46 Deech & Smajdor, supra note 36, 53.
47 Id.
48 Id.
49 Id.
50 Id.
51 Id.
slow mental and physical deterioration, which eventually leads to death. PGD could prevent the birth of children with late onset diseases who would spend their lives being closely monitored, having to undergo multiple surgeries and other preventive measures or dying as a result of the disease. PGD provides parents with a sense of security knowing their children will not spend their adult lives suffering from a genetic condition.

The Kingsbury’s story illustrates the benefits of using PGD in regards to late onset genetic conditions. The Kingsbury’s are a couple that lost his mother, her father and her two brothers, all to an inherited form of colon cancer. Therefore, they decided to conceive their child using PGD technology to ensure the child would never have to suffer from colon cancer. The Kingsbury’s used PGD to detect a predisposition to colon cancers that may or may not have developed later in their child’s life. PGD allowed the Kingsbury’s to give birth to a baby girl who will grow up be unaffected by colon cancer.

The ability to prevent late onset diseases serves an important function for society and would greatly decrease the population of people who become ill. However, many question if as a society we should have the right to say that embryos that suffer from genetic conditions do not deserve to be born. Especially, since many times people born with late onset diseases can live very fulfilling lives for a long period of time. Therefore, an ethical dilemma exists whether reproductive medicine should prevent a child from being born who will only become ill toward the end of their lives. Society must decide whether the desire to prevent suffering that is not certain to occur justifies the conscious destruction of an embryo that carries the defective gene.

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53 Id.
55 Id.
56 Id.
57 Id.
58 Id.
There are benefits of using PGD exclusively for medical purposes to select against serious or life-threatening genetic conditions. At this time PGD has been utilized for selection against medical traits. PGD has been used for implantation of embryos based on gender preferences. However, many people are horrified by the thought of potential parents being able to select their children’s genes for cosmetic trivial traits. The prospect of PGD for “unnatural selection” or selection of cosmetic, non-therapeutic traits is the subject of numerous debates.

**III. Ethical Arguments Regarding Genetic Enhancement**

To date, PGD has only been used to treat serious, life-threatening genetic conditions and in some cases sex selection. However, as technology advances, the possible uses for PGD begin to move towards selecting for a trait instead of selecting against a genetic condition. Currently, technology makes it possible to select gender, and soon it will be able to select for appearance, personality, and IQ. Some believe that parents will inevitably want to choose their children’s genes, thus creating designer babies. As the potential uses for PGD technology expands so do the ethical and social concerns. Often, these non-therapeutic uses of PGD for selection of sex, cosmetic traits or performance traits are referred to as “positive eugenics” or “non-therapeutic enhancement.”

Unlike therapeutic uses for PGD, non-therapeutic enhancement offers parents the hope of using embryonic genetic therapy to create children with attributes likely to improve their chances for a “fruitful and rewarding life”. However, simply because technology makes it possible the question still remains whether or not potential parents should be given the right to alter their children’s genes according to their own preference and liking. By affording parents this right it raises many social, ethical and legal questions.

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59 Knox, *supra* note 2, at 440.
A. Sexism and its Affects on Altering the Population

Recent advances in ART provide parents with an accurate method of selecting the sex of their children prior to conception. Proponents of this technology argue that families are simply seeking a balance. However, rejecting a boy or girl when there is no medical need seems morally reprehensible. Discarding an embryo simply based on its sex is an entirely new form of sex discrimination. There is also a concern that this type of genetic selection is all too similar to forms of selective abortion, which are still being practiced in societies like China or India. Both of those countries condone the killing of female embryos because they are the undesirable sex. These countries have long practiced infanticide, where infants are suffocated shortly after birth, or have used selective abortions to terminate female fetuses. In an attempt to avoid such scenarios, many countries have implemented types of regulation saying after you have “x” number of children that are one gender you can use PGD to make sure you have a child of the other gender. However, the ethical question remains what number should “x” be.

For example, a California woman with three sons used PGD because she wanted to ensure her next pregnancy was a girl. After three children all of the male sex, she was able to use PGD to select for female embryos. Many parents similar to this California woman all state that their motives are part of their desire to have a “balanced family.” This term is used to describe families that have children of all one sex and desire their last child to be of the opposite sex. The argument of family balancing seems to be a weak one; you are not really balancing

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62 Id.
63 Id.
64 Vacco, supra note 21, 1196-98.
65 Remaley, supra note 61.
66 Vacco, supra note 21, 1196-98.
67 Id.
68 Id.
anything at all but rather sexually discriminating against one gender and discarding an otherwise healthy embryo.  

Sex selection has also sparked debate over whether parents' procreative freedom to choose their child's gender outweighs society's greater concern regarding gender stereotypes and equality. Proponents argue families should be entitled to select embryos of the desired sex. However, sex selection would contribute to sex ratio imbalances, and would only reinforce sexism toward women. Over time sex selection will lead to a changed sex ratio, with fewer women than men, thus leading to inequality for women. It is speculated that selection for a first child would favor males, which if executed on a large scale could lead to great disparities in the sex ratio of the population. Sex selection is essentially sex discrimination.

B. Autonomy

In reality parents already possess a high degree of control over the outcome of their children’s lives. If technology continues to progress to allow such intense preimplantation manipulation it would be irresistible for parents who could afford this technology to give their children a genetic head start. The important question that arises is whether there is really an ethical distinction between being able to paying for the best coach for your child or the best SAT tutor and simply being able to pay for that desired trait of athleticism or intellect. Providing coaches and tutors is simply considered as parents doing what is best for their children; all parents want to give their children the best life and provide them with the most advantages. However, there is a difference between paying for the gene for your child to be musically

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70 Vacco, supra note 21, 1196-98.
71 Id.
72 McCarthy, supra note 69.
73 Robertson, supra note 52, 214.
inclined versus signing them up for music classes or taking them to concerts on a regular basis. Now being the best parent means you have genetically engineered your child to perfection. This is very problematic for society and a very slippery slope. However, in today’s society where colleges and little league games are so competitive it is a very appealing option that can be easily taken advantage of. And the irony of the situation is those parents who do not take advantage of PGD technology will be viewed as the neglectful or bad parents. 75

Many advocates argue that it is the parent’s right to equip their children with certain traits and provide them with the tools to be successful in life. 76 The children who were genetically engineered will most likely have a tendency to achieve more than their “unenhanced cohorts.”77 Although it may be parent’s right to provide their children with the opportunity to succeed, children’s futures may be harmed by parent’s pre-birth intervention. Genetic engineering may eventually allow parents to choose cosmetic, intellectual, and physiological enhancements for their child before the child is even born. In reality, it is impossible for a parent to know entirely what is best for a child before they are born. There are simply too many factors science cannot take into consideration. Parents are unable to know that providing their child with the skills to be musically inclined is in fact what is best for the child. Parents are unable to predict that just because they provide their child with the genes to be a great athlete that their child will enjoy sports. Parent providing their child with these hand picked genes have no idea if they will actually benefit their child. Therefore, any decisions to provide genetic enhancements for a child is only motivated by life choices that the parents themselves have chosen.78

75 Id.
77 Fox, supra note 74.
78 Long, supra note 76.
Parental autonomy is the liberty to decide for their children what the parents judge is best. However, we must question what would happen if parental autonomy goes too far. It would seem at some point society would begin to lack free choice. Genetic enhancements would make it impossible for a child to determine their own success or decide what would make them happy. But even if society were to lack free choice, pre-determined society would still have the ability to make choices for the child. Genetic enhancements would make it impossible for a child to determine their own success or decide what would make them happy. Everything would be predetermined for them before birth. A child would be unable to practice an instrument or play a sport unless their parent had specifically paid for that gene. Eventually, a child may be forced to become a musician because his or her parents paid for the musicality gene, when in fact the child would have rather been an athlete. At some point children will resent their parents for having made them this way.

An additional concern is that parents who have engaged in cosmetic genetic enhancements will be unable to accept their children as they are and these parents will be “less tolerant of imperfections and deviations from the norm.” Eventually this lack of tolerance will lead to parents imposing an absurd about of pressure on their child to be perfect. Or expect their children to excel in the traits the parents have genetically enhanced. For example, if the child is born with enhanced intelligence the child may feel compelled to perform exceptionally well in school. The parent-child relationship changes into one where the child is conceived to fulfill the parental expectations that the parents have chosen and paid for.

Thus, parents will begin to place excessive expectations on their customized children, their designer products. PGD will increase intolerance of imperfections and as a result parents will settle for nothing less than perfection. Parents may begin to harbor resentment towards the

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79 Id.
80 Vacco, supra note 21, 1196-98.
82 Id.
83 Fox, supra note 74.
child if they did not turn out how they expected them to. However, unlike other commodities, a designer baby is not returnable.

C. Legal Liability Claims

Designer children create a culture of consumerism. You pay for a trait, and you expect that trait. Allowing parents to have the ability to select the best embryos and the best traits for their children will lead to the commodification of children.\(^\text{84}\) “Consumer-driven parents may feel as though they paid for a perfect child and that anything less than perfect would be unacceptable.”\(^\text{85}\) For example, you purchase the gene for athleticism but your child or your product is not athletic, in fact far from athletic, your child is clumsy. Now the parents, or the consumers, are upset, and rightfully so since they did not get what they paid for. When your customized child does not meet your expectations, there is unfortunately no return policy.

In a society where lawsuits are so common, this commodification of children may give rise to product liability issues. In reality, PGD technology is not perfect. Mistakes in diagnosis have occurred. In these circumstances, wrongful birth lawsuits emerge, as do issues of medical malpractice and professional negligence. “Wrongful birth” claims are brought by parents alleging that, but for the defendant’s negligence, they would have aborted or never conceived the child.\(^\text{86}\) “Wrongful life” claims are those brought by the unhealthy child alleging that, but for the defendant’s negligence, they would not have been born.\(^\text{87}\) In cases like these claims for wrongful birth and wrongful life would be brought against the physicians who performed PGD testing, and hospitals or medical practices that employed such physicians. These parents would claim

\(^{84}\) Id.
\(^{85}\) Id.
\(^{87}\) Id.
damages asking for reimbursement for the costs of all the PGD treatments, as well as the future cost of bearing and rearing a child with a genetic condition.

Courts have addressed a variety of cases relating to assisted reproduction, but only a few concerning PGD. For example, in Doe v. Illinois Masonic Med. Ctr., 88 parents sued the institution where they underwent PGD treatment after their child was born with cystic fibrosis. In that case, the parents' claimed a “loss of consortium” and “wrongful life” claim on behalf of the child. 89 Although in that case the court rejected both claims concluding that the defendants could not be held legally liable, future scenarios may prove successful. 90

In Doolan v. IVF Am. (MA), Inc., 91 the parents of a child born with cystic fibrosis following PGD, as well as the child, sued those involved with the embryo screening for failing to detect the condition. 92 The parents made the claim of “loss of consortium,” meaning the loss of the companionship they would otherwise have had with a healthy, non-affected child. 93 The court rejected this claim reasoning that defendants were not legally responsible for causing the child to suffer from a genetic disease. 94 The court also rejected the child’s claim of “wrongful life,” which alleged that the defendants’ negligent failure to detect the genetic condition denied his parents an opportunity not to give birth to him. 95 Most courts reject such wrongful life claims because otherwise courts would be accepting the proposition that there can be instances in which an impaired life is worse than no life at all. 96 In the future PGD may give rise to product liability

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89 Vacco, supra note 21, 1228.
90 Id.
92 Id.
93 Id at 4.
94 Id at 2.
95 Id.
96 Id at 3.
cases where parents begin to sue doctors for fraud, misrepresentation, or false advertising. It would seem the possibilities are endless.

Not only could parents and children have claims against their providers, children may have claims against their parents. Using PGD, parents could intentionally choose embryos with disabilities. Parents may select genetic traits that run in the family for example traits such as deafness or Achondroplasia (dwarfism).97 Parents would argue that they are better suited to handle children who are more like them. If this is the case children maybe able to hold their parents liable in tort for making genetic decisions that disfavored them.98 Children would be able to sue their parents for engaging in certain direct genetic interventions. Parents' preimplantation genetic choices would limit a child's ability to pursue a variety of different life paths and tort law would protect a child's moral right to an open future.99

D. Distributive Justice

The social argument against designer babies is that if this technology becomes a realistic and accessible medical practice, then it would create a division between those that can afford the service and those that cannot. Using PGD to screen for non-medical traits could cause further division between the wealthy and the poor.100 The poor will face further disadvantages because they cannot afford the procedure.101 As it is, wealthier individuals already possess social advantages such as “money, status and access to information concerning new

98 Id.
99 Id.
100 Vacco, supra note 21, 1196.
101 Id.
biotechnologies.”¹⁰² The advantages of PGD technology will eventually lead to an “even wider gap between the haves and the have nots.”¹⁰³

Over time, affluent parents may have children who are less prone to disease. Wealthy parents may be able to select traits for happiness, creativity and physical talents, while disorders such as obesity, heart disease, alcoholism and mental illness will be left to those who are not genetically enhanced.¹⁰⁴ Now not only is there monetary distinction between the wealthy and those of lower socioeconomic standing but these groups of people now have genetic distinctions. The upper classes’ ability to manipulate embryos preimplantation will circumvent the natural process of evolution. If PGD continues to only be used by the wealthy it would appear that the two different economic classes could grow into two different races. Genetic engineering would eventually result in “biological divergence and social polarization.”¹⁰⁵ Molecular biologist Lee Silver, as well as many others, fear that “disparate access to genetic technologies will drive a wedge between enhanced and unenhanced classes of people, which will live in segregated social worlds where there is little chance for contact between them.”¹⁰⁶

E. Discrimination

Genetic engineering may result in fostering prejudice and stereotypes.¹⁰⁷ If PGD is continually utilized to select for the genetic trait of height, subconsciously people will begin to have biases for short people, the “undesirable trait.” And now it would be obvious to the naked eye whom the wealthy and elite members of society. This technology would create an entirely new type of discrimination. The ability to choose desirable genetic traits will unintentionally

¹⁰³ Fox, supra note 74, 595.
¹⁰⁴ Id.
¹⁰⁵ Id. at 572.
¹⁰⁶ Id.
¹⁰⁷ Long, supra note 76, 221-22.
result in the devaluing those persons without those traits or a belief that those individuals are abnormal. Inevitably, PGD technology will lead to discrimination against those who do not have the opportunities to utilize gene selection technologies.

PGD may also change social attitudes toward those who are born with genetic diseases. As a result of PGD technologies, fewer people with disabilities are born. This will affect how society views those who are disabled. If fewer people are born with disease society will have a reduced need to find cures for genetic conditions. Another concern is that where there are fewer people who suffer from certain conditions, their voices are less likely to be heard. The number of individuals born with diseases will be drastically limited, it will no longer be important for society to look for cures or for health insurance to pay for their care. PGD technology will also cause discrimination against those who are disabled and create the notion in society that those who are disabled are not worthy of even being born.

After enough time using this technology to select for genetic traits, PGD has the ability to wipe out certain traits entirely. If certain traits are widely disfavored, over time this will lead to fewer people with those traits, resulting in a lack of diversity. This could lead to a type to genetic elimination. If over time the trend is to always choose a child with blonde hair and blue eyes, then eventually brown haired and brown-eyed children will no longer exist.

Over time, perfectly healthy embryos will be destroyed based on dislike for certain traits. The resulting lack of diversity will be problematic. It will create a society that is intolerant to those who are different. As such traits or disabilities become more rare, societies lack of

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108 Id.
109 Id.
110 Id.
111 Deech & Smajdor, supra note 36, 58.
112 Id.
113 Id.
114 Garcia, supra note 60, 500.
experience with these traits will increase our ignorance towards individuals who have those traits. The ultimate fear is that such intolerance towards those traits will reinforce the prejudices against these traits and eventually the trait will become extinct entirely. Obviously this is not an immediate concern of PGD technology, but is still one that needs to be taken into consideration for the drastic effects it could have on the future.

The ethical, social and legal concerns regarding the expansion of reproductive medicine demonstrate the necessity for oversight by the United States government. At present, neither state nor federal law regulates ART. It is critical to consider the ethical implications of PGD before it becomes possible to select for specific genetic traits. A lack of regulation may lead to unethical applications and unforeseen consequences. Therefore, governmental oversight is necessary.

**IV. Oversight of Designer Babies**

There is currently very little oversight of PGD in the United States. Most often decisions regarding PGD are left to patients and healthcare providers, who, together determine if PGD is appropriate in particular situations. At the rate technology is progressing the government can no longer allow PGD regulation to be at the discretion of couples and their individual medical providers. Even though the ability to fully customize children may still be years away, it is important that the government realize that these technologies could vastly impact society and there are numerous ethical concerns that need to be addressed.

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115 Suter, *supra* note 81, 956.
A. Lack of United States Oversight

Currently, ART is largely unregulated in the United States.116 The government typically does not regulate the practice of medicine.117 There are a variety of mechanisms that governmental agencies use to regulate the safety and efficiency of health care services including safety requirements, reporting requirements and oversight of clinical research.118 However, PGD as a scientific process does not fall into these categories. At this time the government does not currently regulate PGD nor does any governmental body issue ethical recommendations.119 However, it is critical to consider both the ethical and social implications of PGD technology discussed in Part III.120 As PGD technology becomes more accessible to the public, a lack of regulation may lead to unethical applications and unforeseen consequences.121

The United States is one of the few countries that lack PGD oversight. Germany, Austria and Italy have a strict statutory ban on all PGD uses.122 A complete ban can be justified by strong moral concerns about the status of the embryo.123 A ban is grounded on the premise that the right to life is the most important, therefore performing PGD is unacceptable because will result in the destruction of those embryos that carry disease-linked genes.124 A strict statutory ban however is not necessarily related to the ethical concerns surrounding PGD but rather focuses on the status

118 Id.
119 Id.
120 Id.
121 Id.
124 Id.
of the embryo.125 A strict ban allows protection for stored or discarded embryos after genetic testing.126 However, total prohibition seems to be neither a viable option nor an intelligent one since PGD has many benefits to society, which should be recognized and utilized.127

The United Kingdom and France require a clinic to obtain a license before it can perform preimplantation testing.128 In the United Kingdom, preimplantation testing is regulated by the Human Fertilisation and Embryology Act 1990 (HFE Act), which requires any clinic that creates embryos to obtain a license.129 Under the HFE Act, any person who “brings about the creation of an embryo, or keeps or uses an embryo, except in pursuance of a license is criminally liable.”130 Additionally, criminal liability attaches to any person who knowingly or recklessly provides false or misleading information in order to obtain a license.131 The HFE Act also established the Human Fertilization and Embryology Authority (HFEA), which issues licenses to clinics.132 The HFEA’s purpose is to safeguard the interests of patients, children, the general public, doctors, service providers, the scientific community, and also future generations, as well as regulate the storage of embryos. HFEA also issues a Code of Practice, which requires clinics to submit a new application to HFEA for each new condition they want to test for and for each new test they want to use.133 The premise of the United Kingdom’s system is by making licenses very limited in scope, HFEA maintains substantial control over the use of PGD.134 Currently, the United

125 Id.
126 Id.
127 Id.
128 Id. at 765.
129 Id.
130 Id. at 766-67.
131 Id.
132 Id. at 765.
133 Id.
134 Id.
Kingdom does not allow gender selection for non-therapeutic purposes.\textsuperscript{135} However, HFEA allows tissue-typing (HLA matching) for the creation of savior siblings, subject to strict criteria.

Other countries have taken a more moderate approach to PGD. For example, both the Netherlands and Australia only allow PGD for “serious conditions.”\textsuperscript{136} However, drafting such guidelines may be difficult due to the ambiguity of words like “serious.” Thus, attempts to draft regulatory guidelines may suffer from ambiguous or uncertain language and the difficulty of trying to interpret such language.\textsuperscript{137}

Some countries like Japan or New Zealand regulate through guidelines issued by professional organizations.\textsuperscript{138} Both countries have implemented professional organizations that are responsible for establishing guidelines and reviewing ethical concerns before issuing licenses to use PGD.\textsuperscript{139} Presently, there are two professional organizations in Japan, the Japan Society of Obstetrics and Gynecology (JSOG) and the Japan Society of Fertility and Sterility (JSFS), which have issued guidelines concerning many ARTs, including IVF, embryo transfer, and PGD.\textsuperscript{140} Approval for the use of PGD must be sought through application to the JSOG and the guidelines require that PGD only be applied to “serious hereditary disorders.”\textsuperscript{141} Failure to abide by any of these guidelines may result in the withdrawal of a clinic’s membership in the organization.

\textbf{B. CDC Reporting}

The Centers for Disease Control (CDC) is a federal agency under the Department of Health and Human Services that protects the public health and safety through the control and

\begin{footnotesize}
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\item Id.\textsuperscript{135}
\item Gortakowski, \textit{supra} note 122, 89.\textsuperscript{136}
\item Fahrenkrog, \textit{supra} note 123, 769-70.\textsuperscript{137}
\item Gortakowski, \textit{supra} note 122, 89.\textsuperscript{138}
\item Id.\textsuperscript{139}
\item Fahrenkrog, \textit{supra} note 123, 767-68.\textsuperscript{140}
\item Id.\textsuperscript{141}
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prevention of disease, injury, and disability.\textsuperscript{142} Congress enacted the Fertility Clinic Success Rate and Certification Act (FCSRCA) in 1992 mandating that all ART clinics report success rate data to the federal government.\textsuperscript{143} Currently, this is the only mechanism for reporting of ART use in the United States.\textsuperscript{144} FCSRCA requires clinics performing ART to annually provide data for all procedures performed to the CDC.\textsuperscript{145} The CDC is required to use the data to report and publish clinic-specific success rates and certification of embryo laboratories.\textsuperscript{146}

Specifically, FCSRCA requires clinics that provide IVF services to report pregnancy success rates annually to the federal government.\textsuperscript{147} The FCSRCA requires clinics to report data concerning the type of ART used, the medical diagnosis leading to IVF treatment, the number of cycles of IVF attempted, whether fresh or frozen embryos were used, the number of embryos transferred in each cycle, the number of pregnancies achieved and the number of live births.\textsuperscript{148} However, FCSRCA does not require clinics to report the health status of babies born as a result of the procedure or the use of diagnostic tests such as PGD.\textsuperscript{149}

Under the FCSRCA, CDC developed a model state program for certifying laboratories that work with human embryos.\textsuperscript{150} It includes standards for procedures, record keeping and laboratory personnel and criteria for inspection and certification.\textsuperscript{151} However, the model program is voluntary and has yet to be adopted or implemented by any state.\textsuperscript{152} To actually be beneficial

\textsuperscript{142} ART, supra note 4.
\textsuperscript{143} Id.
\textsuperscript{144} Fahrenkrog, supra note 123,767-68.
\textsuperscript{145} ART, supra note 4.
\textsuperscript{146} Id.
\textsuperscript{147} PGD, supra note 4.
\textsuperscript{148} Id.
\textsuperscript{149} Id.
\textsuperscript{150} ART, supra note 4.
\textsuperscript{151} Id.
\textsuperscript{152} Id.
and prevent the abuse of ART, the reporting requirements would need to be greatly improved. Therefore, currently all US oversight starts and ends with reporting requirements.

C. Reproductive Liberty

The biggest obstacle for having a uniformed system of oversight regarding ART is the constitutional limitations of parental autonomy and first amendment liberties. The concern is that US oversight would restrict fundamental liberties including invasion of privacy and procreative autonomy.\textsuperscript{153} Determining whether a parent’s choice for PGD is ethical relies heavily on whether the Supreme Court of the United States has interpreted a protected fundamental right for PGD.\textsuperscript{154}

In \textit{Eisenstadt v. Baird},\textsuperscript{155} the Court’s held the Massachusetts law prohibiting the use or distribution of contraceptives to unmarried individuals unconstitutional.\textsuperscript{156} The Court reasoned that the Massachusetts law violated the Equal Protection Clause of the Fourteenth Amendment, and was therefore unconstitutional.\textsuperscript{157} The Court made the statement that “if the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters affecting a person’s decision whether to bear a child.”\textsuperscript{158}

The Supreme Court has made it clear that parenting decisions “concerning education, religion, and procreation are constitutionally protected interests because they involve the most intimate and personal choices a person can make.”\textsuperscript{159} For example, in \textit{Planned Parenthood of Se. Pennsylvania v. Casey},\textsuperscript{160} the Court revisited the boundaries for the circumstances under which the State could limit the fundamental right of a woman to terminate her pregnancy as decided in

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\item \textsuperscript{153} Stankovic, \textit{supra} note 116, 20.
\item \textsuperscript{154} Gortakowski, \textit{supra} note 122, 89-90.
\item \textsuperscript{155} 405 U.S. 438 (1972).
\item \textsuperscript{156} Gortakowski, \textit{supra} note 122, 89-90.
\item \textsuperscript{157} \textit{Id}.
\item \textsuperscript{158} 405 U.S. 438 (1972).
\item \textsuperscript{159} 505 U.S. 833 (1992).
\item \textsuperscript{160} \textit{Id}.
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Roe v. Wade.¹⁶¹ The Court noted that the constitutional protection to personal decisions, such as procreation, family relationships, and child rearing, “involve the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment.”¹⁴⁴

In Lawrence v. Texas¹⁶² the Court again held that “personal autonomy is a core liberty interest at the heart of the due process clause.”¹⁶³ Regarding the constitutionality of a Texas statute criminalizing the intimate sexual conduct of two members of the same sex, the Court held that under the Due Process Clause of the Fourteenth Amendment the Texas statute was unconstitutional for violating the privacy liberty of individuals in making a decision about their sexual practices.¹⁶⁴ In Lawrence, the Court expanded protected privacy rights associated with personal choices. Therefore, Lawrence, creates the possibility of a broader interpretation into reproductive rights involving genetics in ART.¹⁶⁵

In Washington v. Glucksberg,¹⁶⁶ the Court downplayed the role of autonomy stating “that many of the rights and liberties protected by the due process clause sound in personal autonomy do not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected.”¹⁶⁷

In fact the Supreme Court has already determined in Maher v. Roe, that a woman has a fundamental reproductive right to decide when to have a child.¹⁶⁸ The court stated a woman has a reproductive right of “procreation without state interference,”¹⁶⁹ This includes the right to

¹⁶¹ 410 U.S. 113 (1973).
¹⁶³ Id.
¹⁶⁴ Id.
¹⁶⁵ Gortakowski, supra note 122, 89-90.
¹⁶⁷ Long, supra note 76, 215.
¹⁶⁹ Id.
decide when to get pregnant, and the right to terminate a pregnancy.\textsuperscript{170} However, the Supreme Court has not recognized that the rights of procreative liberty and family discretion extend so far as to protect all parental decisions relating to preconception selection.\textsuperscript{171} Therefore, procreative liberties may not extend towards genetic testing, screening and manipulation. Especially since the ethical concerns that face prenatal genetic manipulation are different from fundamental reproductive rights. As a result regulations dealing with these ethical concerns would not be unconstitutional.

Additionally, the Supreme Court could easily find a compelling state interest in regulating the health and safety of embryos and their mothers. The state has an interest in regulating PGD procedures to the extent that they are motivated by and promote discrimination.\textsuperscript{172} The state could also regulate prenatal technologies using its police powers to the extent that prenatal procedures will be harmful to public welfare or health.\textsuperscript{173} Therefore, federal oversight is constitutional.

D. The Need for National Oversight

The current system is decentralized and lacks regulation.\textsuperscript{174} The most effective way to regulate PGD would be at the federal level, because such a system provides the most uniformity.\textsuperscript{175} A nationwide approach would likely lead to the most uniform regulation, thereby minimizing delegating state legislatures competing for medical tourism by enacting minimal regulations to attract patients seeking PGD treatment.\textsuperscript{176}

\textsuperscript{170} Id.
\textsuperscript{171} Vacco, supra note 21, 1228.
\textsuperscript{172} Long, supra note 76, 222-27.
\textsuperscript{173} Id.
\textsuperscript{174} Fahrenkrog, supra note 123, 780.
\textsuperscript{175} Id.
\textsuperscript{176} Id.
National oversight can be imposed either by federal legislation or through professional organizations. Oversight performed on a nationwide level by a statutorily created body with legal authority to attach criminal liability to violators of the statute, would provide the benefits of uniform regulation, flexibility, and compliance with regulatory guidelines. A licensing system similar to that of the United Kingdom's would strike a balance between ethical concerns and the progress of science and medical technology. Violations of the statutory licensing system could include administrative measures such as suspension or termination of licenses or a prohibition on a clinic's ability to receive licenses in the future, or criminal punishments such as fines or imprisonment. Professional organizations present another opportunity for oversight of PGD. Professional organizations are comprised of members of a particular occupation or specialty, therefore they have more specialized expertise. Most importantly, professional organizations can develop and amend guidelines much faster than legislatures, which is particularly important in an area of rapidly advancing technology such as PGD.

D. Professional Oversight

Medical and scientific professional organizations have the best opportunities to collect data and interact with patient groups based on this knowledge they have the ability to consider all ethical concerns and determine the acceptable uses for PGD. Professional organizations can educate members about advances in the field, develop guidelines addressing appropriate conduct and impose standards of adherence that are a prerequisite for membership.

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177 Id. at 779.
178 Id.
179 Id.
180 Id.
181 Id.
182 Id.
183 Id.
184 Id.
185 PGD, supra note 117.
186 Fahrenkrog, supra note 123, 773.
187 Gortakowski, supra note 122, 89-90.
188 PGD, supra note 117.
A few professional organizations already have the relevant expertise and either currently or could in the future develop PGD-specific guidelines or standards.\(^\text{185}\) For example, the American Society for Reproductive Medicine (ASRM) is a professional organization whose members are health professionals engaged in reproductive medicine.\(^\text{186}\) ASRM issues policy statements, guidelines and opinions regarding medical and ethical issues that reflect the thinking of the organization’s various practice committees.\(^\text{187}\) In fact, ASRM has already warned patients to be aware of potential diagnostic errors and the possibility unknown long-term consequences of PGD.\(^\text{188}\) 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.\(^\text{189}\)

Another Professional Organization is the Society for Assisted Reproductive Technologies (SART).\(^\text{190}\) SART administers the legislatively mandated reporting requirements for fertility clinics and then collects this data, which is then analyzed and reported by CDC.\(^\text{191}\) Compliance with the reporting requirements and guidelines is a requirement of SART membership.\(^\text{192}\) However, at this time the organization does not have any guidelines specifically addressing PGD.\(^\text{193}\)

Centers for Medicare and Medicaid Services (CMS) implemented the Clinical Laboratory Improvement Amendments of (CLIA) in 1988.\(^\text{194}\) CLIA was enacted in order to improve the quality of clinical laboratory services.\(^\text{195}\) CLIA includes requirements addressing laboratory

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\(^{185}\) Id.  
\(^{186}\) PGD, supra note 117.  
\(^{187}\) Id.  
\(^{188}\) Id.  
\(^{189}\) Id.  
\(^{190}\) Id.  
\(^{191}\) Id.  
\(^{192}\) Id.  
\(^{193}\) Id.  
\(^{194}\) Id.  
\(^{195}\) Id.
personnel qualifications, documentation and validation of tests and procedures, quality control standards and proficiency testing to monitor laboratory performance. \textsuperscript{196} However, CMS has not taken a position regarding whether laboratories engaged in IVF and PGD are “clinical laboratories” within the meaning of the statute. \textsuperscript{197} However, many argue since IVF and PGD are procedures that constitute the practice of medicine they are not within the scope of CLIA. \textsuperscript{198}

Other professional organizations that do not currently address PGD could take on additional functions in the future. The PGD International Society (PGDIS), was recently founded to promote PGD and to organize meetings and workshops on PGD research. \textsuperscript{199} The College of American Pathologists (CAP) has developed a voluntary certification program for reproductive laboratories that perform embryology testing and inspects clinical laboratories seeking certification under CLIA. \textsuperscript{200} American College of Medical Genetics (ACMG) develops laboratory standards and clinical practice guidelines for genetic tests. \textsuperscript{201}

The health and safety of women and children who use ART technologies is paramount to these professional organizations. Professional oversight has the ability to monitor the safety, efficacy and privacy guidelines associated with ART technologies. The organization can issue guidelines that make the distinction clear between what constitutes a serious genetic condition and what does not. The organization can limit PGD to medical uses and determine the acceptable uses of PGD.\textsuperscript{202} Therefore, the government can state that PGD should only be used if the condition constitutes serious or significant genetic condition.

\textsuperscript{196} Id.  
\textsuperscript{197} Id.  
\textsuperscript{198} Id.  
\textsuperscript{199} Id.  
\textsuperscript{200} Id.  
\textsuperscript{201} Id.  
\textsuperscript{202} Gortakowski, supra 122, 104-05.
Regulation through professional organizations may be difficult because of a lack of consequences for violating guidelines.\textsuperscript{203} Professional organizations typically do not have authority to sanction members for noncompliance. Generally, the only consequence of noncompliance with guidelines is the revocation of a clinic's membership, and the organization.\textsuperscript{204} Unless the organization is specifically authorized by the federal government to act on the government’s behalf in administering and enforcing government standards, actions of the professional organization do not have the force of law.

E. Proposed Solution

The ethical concerns surrounding PGD suggest that oversight is needed, and PGD should be regulated through guidelines issued by professional organizations.\textsuperscript{205} The professional organizations would be composed of PGD providers. Therefore, these groups would know the most about the use, limitations, risks and benefits of PGD. Through collections of data from interaction with patient groups, ongoing studies of children born with PGD, public opinion, and feedback from those already affected with genetic diseases and disabilities, information can be used to assess the risk and benefits associated with PGD.\textsuperscript{206} Through a new or existing professional society could create guidelines for acceptable uses of PGD faster than legislatures, which is important in such a rapid growing field.

Ethical concerns should be taken into account in issuing licenses and guidelines. However, these concerns need to be balanced against the interest of not foreclosing the advancement of technology, since PGD has the potential to greatly benefit society through the

\textsuperscript{203} Fahrenkrog, supra 123, 772.  
\textsuperscript{204} Id at 773.  
\textsuperscript{205} Id at 769.  
\textsuperscript{206} Gortakowski, supra note 122, 108.
reduction of genetic disorders. The professional organization would be able to correctly balance these dilemmas for the greater good of society. This approach provides the most flexibility for the development of science and technology. Additionally, by utilizing a professional organization, it avoids government intrusion in medical practices. Failure to abide by the guidelines ideally need to result in stricter punishments in order to increase compliance.

**Conclusion**

It is clear there is a need for oversight by the United States government in regards to PGD. Although parents may be morally and legally entitled to use PGD for customization of their children as part of the parental autonomy, as technology continues to advance we need the government to implement regulations to ensure risks of these advancements never outweigh the benefits. Without proper oversight children become products to be bought and sold. Without proper oversight the ethical and social concerns discussed could become a reality. In order for the necessary oversight to be functional the government should enlist or create a professional organization that has the ability to ensure that PGD and other prenatal technologies can only be used for medical purposes, and issue strict punishments for those who fail to comply.

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207 Fahrenkrog, *supra* note 123, 780.