WHEN PARENTS CAN CHOOSE TO HAVE THE “PERFECT” CHILD: WHY FERTILITY CLINICS SHOULD BE REQUIRED TO REPORT PREIMPLANTATION GENETIC DIAGNOSIS DATA

Laura Damiano*

Preimplantation Genetic Diagnosis (PGD) is a procedure used to screen embryos for certain genetic conditions before implantation via in vitro fertilization (IVF) so the desired embryos can be chosen for implantation. The procedure was originally used to prevent the birth of children with deadly genetic disorders, but it is now used for more controversial reasons, such as to select for sex. Limited information is available regarding how PGD is used in the United States and there are many ethical concerns surrounding the practice of PGD, most notably that it could lead to the creation of designer babies and eugenic practices. This Note proposes amending a federal act to require fertility clinics to report PGD data through an existing web-based system. This data can then be used by policymakers to federally regulate PGD practices.

Keywords: preimplantation genetic diagnosis; genetic testing; assisted reproductive technology; bioethics; parental choice

I. INTRODUCTION

Consider the following hypothetical scenarios: four couples schedule consultations with Dr. Smith, a well-known infertility specialist. Given the increasing number of couples seeking infertility treatment in the United States, this alone is not surprising; however, what is unique about these four couples is that none of them have infertility issues. They are seeking consultation because they believe Dr. Smith can help them conceive the “perfect” child.

Adam and Barbara have the first consultation. They have been married for seven years and are both carriers for Tay-Sachs disease, a devastating disorder that typically results in death during the first few years of life. They have a 25% chance of passing this disorder on to their children. Three years ago, the couple had their first child, Michael, who was born with Tay-Sachs disease. After a gruesome six months of suffering, their son died. The couple desperately wants to have another child but does not want to bear the pain of losing another child or have a child that will suffer for the entirety of his or her life the way Michael did.

Christa and Dan have the second consultation. They are an unmarried couple whose five year old daughter, Jennifer, has leukemia. Jennifer’s doctors believe that they can best treat her with a stem cell transplant, typically performed by transplanting stem cells found in an umbilical cord. Despite the couple’s recent separation, Christa and Dan want to have another child as a “savior sibling,” a child conceived with a particular genetic makeup so the stem cells from that child’s umbilical cord can be used to save the older sibling’s life. They are worried, however, that the child will not be a genetic match for Jennifer and they will not be able to use the stem cells for Jennifer’s benefit.

Elizabeth and Frank have the third consultation. The couple has four healthy daughters but they have always wanted a son. Elizabeth and Frank would like to have another child, with the hopes of finally having a boy. Elizabeth is getting older and is worried that if they do not have a son this time around they may never have one.

George and Holly have the last appointment. These newlyweds are eager to have their first child. The couple met in London during fashion week where Holly worked as a runway model and George worked as an investment banker after recently completing his studies at Harvard and Oxford. The couple

Correspondence: lddamiano@gmail.com
dreams of having beautiful, smart children with Holly’s blonde curly hair, green eyes, and olive skin and George’s 170 IQ. They will do anything they can to make their dreams a reality.

So what do these couples have in common? They are all seeking Dr. Smith’s help to have the “perfect” child. Dr. Smith assures each couple that he will be able to help them in some way. With the exception of testing for intelligence, the procedures alluded to in the aforementioned hypothetical cases are all scientifically feasible through preimplantation genetic diagnosis (PGD)⁷ and scientists are in the process of looking for genes that code for intelligence.⁸ Given that this technology exists, the question now becomes whether any of the couples should be able to use PGD.

In these hypothetical scenarios, the couples are each enquiring about having the “perfect” child, however, their definition of the ideal child and the reasoning behind their desires seem to differ greatly. Adam and Barbara want to have a healthy child that will not have to suffer through the same devastating disorder that took their first son. Dan and Christa want to save their five year old daughter Jennifer, but it is unclear whether they would actually want to have another child if Jennifer was not sick. Elizabeth and Frank want to have a son, but it is unclear why; perhaps to simply balance their family, or perhaps because many people have an inherent desire to have a son to carry on the family name.⁹ George and Holly seem concerned only with having children who are aesthetically and intellectually superior to their peers.

The four scenarios evoke different moral and ethical reactions, but should that affect whether or not Dr. Smith performs these procedures? The ultimate goal in these four scenarios is essentially the same. Nonetheless, their intentions for seeking PGD differ. Their different intentions raise ethical questions that policymakers should consider in deciding whether PGD should be regulated and, if so, how it should be regulated.

Unfortunately, policymakers do not yet have enough information about how PGD is used by fertility clinics to make thoughtful decisions about the regulation of PGD in the United States. This Note thus proposes amending federal legislation to mandate reporting by fertility clinics of additional information regarding their practices, including requiring clinics to report details about their use of PGD. This information can then be used by policymakers to examine how and when these procedures are performed in the United States and the ethical implications that arise from these procedures so they can create appropriate legislation regulating and limiting the use of PGD in the United States.

Part II of this Note will provide background information on PGD. Part III of this Note will outline the current state of the laws and regulations regarding PGD and parental choice. It will also discuss how PGD is regulated in other countries. Part IV of this Note will outline the ethical issues associated with PGD. Part V of this Note will propose an amendment to a federal act that will require fertility clinics to report PGD data, making it possible for policymakers to assess the need for governmental regulation. Part VI presents counterarguments to the proposal and offers solutions to address these counterarguments. Part VII offers a conclusion.

II. BACKGROUND ON PREIMPLANTATION GENETIC DIAGNOSIS

A. WHAT IS PREIMPLANTATION GENETIC DIAGNOSIS?

Preimplantation Genetic Diagnosis (PGD) is a procedure in which fertilized embryos are tested for certain genetic indicators before implantation via in vitro fertilization (IVF).¹⁰ The purpose of PGD is to ensure that only the embryos with the parents’ desired genetic makeup are selected for implantation.¹¹ Given the nature of the procedure, even fertile couples must undergo the fertility treatments necessary for IVF.¹² The procedure is typically performed three days after fertilization.¹³ At that point, a single cell is removed from the embryo using a straw with a diameter one-twenty-fifth the size of a human hair.¹⁴ That cell is then tested for certain genetic indicators.¹⁵ Once the “healthy” embryos are identified, they are implanted into the mother or surrogate.¹⁶ PGD is currently available for over 100 conditions, including almost all known chromosomal genetic defects.¹⁷ PGD is an expensive procedure, with the total cost of PGD and IVF being approximately $18,000 per cycle.¹⁸
B. ALTERNATIVES TO PGD

For decades, soon-to-be parents longing for a “perfect,” healthy baby have turned to science, through prenatal testing, to assuage any fears about pending pregnancies. Carrier testing is one of the more common methods, which involves testing both parents for genetic conditions before they begin trying to conceive to determine the chance they have of passing on any disorders to their children. Typically, couples who are at high risk for passing on a genetic condition because of a family history of the disorder or because of ethnicity will seek carrier testing. Before PGD was developed, couples who tested negative for the condition could begin trying to conceive with no fears, while couples who tested positive had to decide whether they wanted to risk conceiving a child with that genetic disorder. Now these couples can use PGD to avoid such risk.

Other alternatives to PGD that may also be used to ensure the birth of “healthy” babies include amniocentesis and chorionic villus sampling (CVS). Both procedures involve screening the fetus during gestation, as opposed to PGD which screens embryos before implantation. These procedures are beneficial; however, they cannot test for all of the conditions that PGD can. When amniocentesis or CVS test results indicate that the fetus has a certain genetic condition, parents are faced with difficult decisions regarding how and if they should continue the pregnancy. Some parents may choose to terminate the pregnancy by opting for a selective abortion. Many ethicists argue that PGD could eliminate the need for parents to make the difficult decision to have a selective abortion by testing embryos before pregnancy.

C. CURRENT AND FUTURE UTILIZATION OF PGD

Today, PGD is primarily used by prospective parents to test embryos in order to avoid serious inherited genetic disorders, to avoid adult onset disorders, and, more controversially, to select for sex. PGD is also used, though probably less frequently, for Human Leukocyte Antigen (HLA) matching to create a “savior sibling” and to select for disability. Scientists are continuously working to discover genes that code for additional disorders, as well as for genes that code for purely aesthetic traits, such as hair color, which will increase the possible uses of PGD.

1. Avoiding Serious Inherited Genetic Disorders

The original purpose of PGD, and one of its main uses, is to avoid serious inherited genetic disorders, such as cystic fibrosis, Tay-Sachs disease, sickle cell anemia, and Duchenne muscular dystrophy. By testing embryos for these disorders, couples are able to avoid having children with devastating illnesses that will often result in death at an early age. Alternative screening procedures for inherited genetic disorders, which take place during pregnancy, may require parents to make the difficult decisions of whether or not to opt for a selective abortion. Since PGD occurs before pregnancy, it prevents couples from having to make this difficult decision.

2. Avoiding Adult Onset Disorders and Predisposition

Another use of PGD is to avoid adult onset disorders such as Huntington’s disease or early onset Alzheimer’s. PGD is also being used to screen for a predisposition to certain conditions, such as screening for the BRAC1 gene, which puts individuals at a higher risk of developing breast cancer. In many cases, breast cancer is curable and some individuals with this gene can live their whole lives without ever developing cancer. Therefore, it remains controversial whether clinicians should perform PGD to test for this predisposition. Policymakers must consider whether it is ethical for clinicians to avoid implanting some embryos that would live perfectly healthy lives and never develop the condition to which they are predisposed.

3. HLA Matching to Save an Older Sibling

HLA matching is performed through PGD to select for a child that will be an immunological, genetic match for an older sibling who is sick. The stem cells from the umbilical cord of the child
conceived after PGD can then be transplanted into the affected sibling, hopefully saving his or her life. This procedure can be done to simultaneously ensure that the implanted embryo does not suffer from the same condition as his or her sibling. It can also be performed when the older sibling’s condition is not genetic and the procedure would have no medical benefit to the embryo.

4. Non-Medical Sex-Selection

Non-medical sex-selection involves selecting embryos for the sole purpose of having a child of the desired gender, as opposed to selecting for gender to avoid a sex-linked disorder. A Johns Hopkins University study found that almost half of fertility clinics in the United States would offer non-medical sex-selection for any purpose, while other clinics would only perform this procedure for a second or third child to achieve “family balancing.” Sex-selection via genetic testing has had mixed reactions from the public, and has resulted in a great deal of criticism from individuals who argue that the practice promotes gender discrimination and could lead to gender imbalance in the population.

5. Selection for Disabilities

In rare cases, embryos are tested for certain genetic disabilities and the embryos that test positive for the condition are the ones chosen for implantation. This procedure has been performed to select for deafness and dwarfism. Parents who have opted for this procedure as well as many disability rights activists argue that it is in the best interest of a child to be raised in an environment where they can identify with their parents. For example, there is a great sense of camaraderie within the deaf community and a hearing child born to deaf parents may feel excluded from that world. On the other hand, there is concern that these procedures may not be in the best interest of the child. There is also concern that the procedure will be used in the future to select for other, more debilitating disorders. As long as PGD is legal and unregulated in the United States, it will be difficult to prevent its use to select for serious medical conditions.

6. Future Uses of PGD

The demand for PGD to test for non-medical conditions, such as selection based on gender or aesthetic traits, seems to be increasing. Clinics such as the Fertility Institutes, a private company with offices in California and New York, plan to offer PGD for non-medical, physical characteristics, including eye, hair, and skin color, in the near future. Although the technology is being developed, the Fertility Institutes have delayed offering the procedure for purely aesthetic based child selection due to the pushback they have received from the public. In addition, scientists are exploring possible genetics indicators for intelligence, which could lead to a controversial process of screening embryos based on intelligence.

D. LIMITED STATISTICS ON THE UTILIZATION OF PGD

Over the past several decades, society’s perception of the family has shifted from a traditional view to a more modern, contemporary one which includes single parents, same-sex couples, and surrogates. Many factors have contributed to this shift in perception, including the increased use of Assisted Reproductive Technology (ART) to conceive children and the impact this technology has on parental choice and the familial structure. Today, over 1% of children born in the United States are conceived through ART. As these technologies continue to improve, they can be offered at lower costs. Thus, the demand for ART and the numbers of cycles performed each year continues to increase. In 2008, there were 148,055 ART cycles performed, resulting in 46,326 live births and 61,426 infants compared to in 2007, when there were 142,435 ART cycles performed, resulting in 43,412 live-births and 57,569 infants.
There is a great deal of information available regarding the success rates of ART, however, there is surprisingly little information available regarding how often fertility clinics perform PGD and, if they do, what indicators they test for. The Centers for Disease Control and Prevention (CDC) publishes an annual report, the Assisted Reproductive Technology Success Rates National Summary and Fertility Clinic Reports, based on mandated fertility clinic success rate reporting. The most recent publication includes some data on which fertility clinics offered PGD. Those data, however, are extremely limited and only include whether the clinics performed PGD and what percentage of the IVF procedures they performed involved PGD. It is difficult to analyze this information because it does not specify which conditions were tested for and their success rates. There is a wide range of disorders that can be tested for using PGD and there are many bioethical considerations associated with testing for certain conditions. More information is needed to analyze the current practice of PGD in the United States.

There is some information available about the use of PGD in United States ART clinics. A survey conducted by Johns Hopkins University, which was approved by their Institutional Review Board (IRB), surveyed 415 ART clinics regarding their use of PGD, with a response rate of 45%. This survey found that PGD occurs in 4–6% of IVF cycles and 74% of clinics surveyed provided PGD to their patients. Clinics reported that they perform PGD primarily to avoid genetic disorders and to help increase a woman’s chance of success during IVF. Clinics also indicated that they offer PGD for other purposes. Of the clinics surveyed, 28% performed PGD to avoid adult-onset diseases, such as breast cancer or Huntington’s disease, 24% performed PGD for HLA matching to save an affected sibling, 42% provided PGD for nonmedical sex-selection, and 3% performed PGD to select for a disability such as deafness or dwarfism.

III. PGD AND THE CURRENT STATE OF THE LAW

A. PGD REMAINS UNREGULATED IN THE UNITED STATES

PGD is legal in the United States and there are no state or federal laws regulating its use, nor have there been legislative proposals to governmentally regulate its use. Professional organizations, such as the American Society for Reproductive Medicine (ASRM), have provided limited guidance on the ethical uses of PGD. The ASRM stated that “PGD should be regarded as an established technique with specific and expanding applications for standard clinical practice” and that “while the use of PGD for the purpose of preventing sex-linked diseases is ethical, the use of PGD solely for sex selection is ‘discouraged.’ ” Aside from these non-binding, advisory guidelines, decisions regarding how PGD should be used are left to fertility clinic providers and their clients.

B. PGD IN OTHER COUNTRIES IS MORE RESTRICTIVE

Other countries have addressed the ethical issues raised by using PGD by prohibiting it completely, limiting it for medical purposes only, or regulating its use through a government agency. Countries that prohibit the practice of PGD include Germany, Austria, Italy, Switzerland, and Ireland. In other countries, such as India and China, PGD is allowed, but sex-selection is prohibited, given the difficulties these countries are facing with gender balancing. In Canada and Australia, PGD is allowed, but sex-selection is prohibited for non-medical purposes and is only allowed to prevent sex-linked genetic disorders. In the United Kingdom, the practice of PGD is regulated by the Human Fertilisation and Embryology Authority (HFEA), a statutory body which requires each clinic to obtain a separate license for each condition it wishes to test for using PGD. The license must be obtained before PGD is used for a patient, allowing HFEA to determine beforehand whether or not a procedure is appropriate. A similar regulatory scheme could be effective in the United States, where there is essentially no government oversight.
C. THE FERTILITY CLINIC SUCCESS RATE AND CERTIFICATION ACT OF 1992

Fertility clinics are already subject to some regulation by the federal government. The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRSA) states that “each assisted reproductive technology program shall annually report to the Secretary through the Centers for Disease Control . . . pregnancy success rates achieved by such program through each assisted reproductive technology.”88 It does not, however, require clinics to report any information regarding the use of PGD.89 The FCSRSA was passed to increase transparency in the industry so that the data collected could be used by families seeking treatment to make informed decisions, by clinicians to evaluate their success rates, and by policymakers and the Secretary of Health and Human Services (HHS) to create certification requirements for fertility clinics.90 Clinics can use the National ART Surveillance System (NASS), a web-based ART data reporting system, to report their success rates and be in compliance with the FCSRSA.91 There are no significant penalties for failure to comply with the FCSRSA; the only penalty is that a noncompliant clinic will be listed on the CDC’s website.92

D. PGD COULD BE A NATURAL EXTENSION OF PARENTAL CHOICE

The right to procreate, regardless of marital status, is generally considered to be a fundamental right under the Constitution.93 The issue of whether the right to procreative choice extends to the parental decision making involved in PGD is a more complicated issue because it not only deals with the right to have a child, but also with the right to “choose” a child’s traits.94 Proponents of PGD argue that parents have engaged in similar processes for years through the use of prenatal testing and selective abortion95 and that choosing gender or other traits could be considered a natural extension of reproductive choice since it correlates with the right to procreate.96 Alternatively, Harvard philosopher Michael Sandel argues that PGD is not a natural extension of parental choice.97 He purports that allowing parents to choose the “perfect” child is undignified since parents should love the child despite any genetic disabilities and regardless of gender or physical characteristics.98 Governments exist to regulate practices where there is wide ranging disagreement and no clear moral answer.99 Given the controversy surrounding this issue, policymakers should create regulations regarding the use of PGD to ensure that the practice is not abused.

IV. BIOETHICAL ISSUES THAT MUST BE CONSIDERED

As PGD becomes more widely practiced in the United States, the lack of regulation has led to a myriad of legal, regulatory, and ethical issues.100 The purpose of this section is to identify what those issues are, not to resolve them. This section will list the arguments for and against the use of PGD to achieve key goals for parents. The discussion will demonstrate that the issues raised by PGD regulation are too complex for easy resolution and we need data so that policymakers can make informed decisions about whether and how to regulate PGD. There appear to be clear benefits associated with many practices of PGD, such as selecting for an embryo that does not carry a devastating, life-threatening disorder.101 The benefits are less clear when parents choose embryos based on non-medical traits, such as sex.102 This unregulated practice has resulted in fear that new advances in the technology will lead to parental choice that is not in the best interest of the offspring103 by allowing them to select for non-medical traits, such as hair and eye color. This could lead to parents commodifying children, which could have a significant psychological impact on the children and could also lead to eugenic practices.104

A. PGD COULD LEAD TO EUGENIC PRACTICES

Most individuals who argue against the use of PGD do not believe it should be prohibited completely, but rather believe it should be permitted only in certain situations to prevent medical
disorders. The major fear associated with PGD is that as it is used to test for more conditions, it will lead to the creation of designer babies and a form of eugenics. Once policymakers allow PGD for serious physical impairments, it becomes difficult to differentiate impairments that are solely aesthetic. This could lead to the use of genetic modification and the creation of a homogeneous race. Allowing parents to choose their child’s non-medical traits could influence society’s perception of how children should be, potentially ostracizing children who are not born with these characteristics and establishing a value system that focuses on an individual’s genetic makeup rather than his or her intrinsic worth.

B. PGD INVOLVES THE CREATION OF EMBRYOS THAT WILL BE DESTROYED OR DISCARDED

Given the nature of PGD, it is almost certain that there will be embryos created that are found to have the unwanted condition and will thus be destroyed or discarded. Although the law does not recognize embryos as persons, this remains a major concern for many individuals, specifically pro-life activists, who believe that embryos are persons and their destruction is murder. The law has taken certain steps to address these moral concerns. The Dickey-Wicker Amendment prohibits the use of federal funding for research “in which human embryos are created, destroyed, discarded, or knowingly subjected to risk of injury or death greater than allowed for research on fetuses in utero.” However, since clinics that offer PGD are not funded by the federal government and are not performing research, they are not prohibited from performing PGD under the Dickey-Wicker Amendment.

C. UNREGULATED PGD HAS LED TO AN INCREASE IN REPRODUCTIVE TOURISM

The United States is one of the few countries that does not prohibit PGD for sex-selection. This lack of regulation has lead to an increase in reproductive tourism, bringing women from countries where PGD is prohibited for sex-selection, such as the UK, Canada, and India, to the United States to have the procedure. Many of these women are originally from countries, such as India and China, where males are considered the superior gender and women are pressured to give their husband a son. This cultural exploitation also raises issues of informed consent when coercion from the family can be subtle. Some fertility clinics seem to be encouraging this culturally-based discrimination against women by taking advantage of this inherent cultural pressure. Clinics have used cultural exploitation to target advertisements by promoting guaranteed sex-selection procedures in US published Indian newspapers and directly to individuals in India and China through print publications and the Internet. PGD is not currently performed on a large-scale and data is not available regarding how often this procedure is performed to select for gender, however, there is concern that it could lead to a gender imbalance in the US in the future. This is an issue that needs to be addressed.

D. PGD MAY HARM INDIVIDUALS WITH DISABILITIES

Many disability rights’ activists do not support the use of PGD, and believe that selecting against certain disabilities will harm existing individuals with those disabilities. As Adrienne Asch, Professor of Bioethics at Yeshiva University, notes, “as currently practiced and justified, prenatal testing and embryo selection cannot comfortably coexist with society’s professed goals of promoting inclusion and equality for people with disabilities.” Selecting against a disability could stigmatize the disabled community. In addition, using PGD in an attempt to eliminate certain disabilities will likely lead to a decrease in services and treatments available for individuals with those disabilities. Given the potential discrimination and inequality issues that PGD may cause for individuals with disabilities, it is necessary to assess whether the benefits to the future offspring outweigh the potential harms to the disabled community.
E. INCREASED UTILIZATION OF PGD COULD INCREASE WRONGFUL-BIRTH LAWSUITS

Although courts traditionally rejected wrongful-birth lawsuits, in 1973 the Supreme Court’s decision in Roe v. Wade led many state courts to recognize wrongful-birth lawsuits. Since many states recognize that parents with impaired children have a right to sue physicians for wrongful-birth, as the use of PGD increases, it may lead to an increase in wrongful-birth lawsuits since the technology is not always 100% accurate. Wrongful-birth lawsuits are extremely controversial since they rely on the notion that some individuals would have been better off never being born. One court suggests that the moral and ethical issues deeply rooted in wrongful-birth cases should not be handled by the courts, and that the issues of “whether it is better never to have been born at all than to have been born even with gross deficiencies is a mystery more properly to be left to the philosophers and the theologians.”

Regardless, wrongful-birth lawsuits are permitted in many states, but it is unclear how they will be analyzed when the wrongful-birth in question involves PGD. Also, if PGD becomes widespread, children born through natural conception with serious genetic disorders that could have been prevented through PGD may want to sue the doctor, or their parents, for wrongful-life since the condition could have been prevented.

F. UNEQUAL ACCESS TO PGD WILL WIDEN THE DISPARITY GAP BETWEEN THE RICH AND POOR

PGD and other genetic technologies will increase inequalities between the rich and poor, expanding an already significant disparity gap. Given the high cost of PGD, it is a procedure that will be utilized by wealthy individuals who can afford it, and will not likely be used by poorer individuals. In the long term, this could result in certain disabilities becoming a stigmatized condition of the poor. As PGD is developed for more non-medical conditions, such as intelligence, the technology could result in rich individuals creating children with “superior” traits, putting them at an even greater advantage.

G. IS THERE A POTENTIAL NEGATIVE IMPACT ON CHILDREN?

There has been little research done on the impact PGD for non-medical purposes has on the child. There has not been conclusive evidence that PGD has a negative psychological impact on children conceived through the procedure, but there are concerns that PGD for non-medical purposes commodifies children and could result in long-term psychological harm. There is also a fear that if parents choose embryos that do not live up to their expectations, it will put a strain on the parent-child relationship. Paul Freund, Professor at Harvard Law School, argues that “human dignity is compromised when individuals know that they are the product of genetic manipulation” because they are perceived based solely on their genetic makeup rather than their intrinsic worth.

V. PROPOSAL FOR MANDATING PGD DATA REPORTING AND CREATING A FEDERAL REGULATION

Given all these complex issues, we need more information to create intelligent regulation of this emerging technology. Congress should amend the FCSRCA to create additional reporting requirements that mandate fertility clinics report PGD data to the CDC. By doing so, Congress will make it possible for organizations to learn how fertility clinics are utilizing PGD technologies, and policy makers will be able to use this data to create necessary regulations to protect the best interest of future offspring and prevent practices that could lead to designer babies and eugenics. This amendment should also require the CDC to publish this data and require the CDC to implement penalties for noncompliance.
A. THE PROPOSED REPORTING REQUIREMENTS

The specific data fertility clinics should be required to report regarding PGD are:

- when PGD is performed;
- how often PGD is performed;
- what genetic indicators are being tested for;
- how many embryos are tested;
- how many embryos test positive for each condition;
- how many embryos test negative for each condition;
- which embryos are chosen for implantation;
- how many embryos are implanted; and
- fertility success rates, which are already required under the current law.

This data will identify how fertility clinics are utilizing PGD and which conditions are most commonly tested for, allowing clinicians, policymakers, and bioethicists to assess the information and determine how it should be regulated.

B. THE PROPOSAL CAN BE IMPLEMENTED THROUGH THE EXISTING REPORTING SYSTEM

Fertility clinics will be able to report PGD data through the existing, web-based, National ART Surveillance System (NASS). Only minor programming adjustments to add new reporting fields will be needed. NASS is already approved by the CDC for use by fertility clinics to ensure compliance with the FCSRCA. Clinics can access the system and report their data via the internet with a username and password. Since this is the same system currently used by fertility clinics to report annual success rates, adoption of the new process should be seamless. The proposed amendment should also create monetary penalties for failure to comply with the act each year, with multiple violations resulting in the fertility clinic losing its certification. This will ensure that all clinics report PGD data, allowing clinicians and policymakers alike to analyze the data to determine how the practice should be regulated.

C. THE PGD DATA REPORTED SHOULD BE USED TO CREATE A FEDERAL REGULATION LIMITING ITS USE

Mandatory reporting will give policymakers a better understanding of how PGD is being used in the United States so they can create appropriate regulations limiting its use. Until policymakers are able to assess how and when PGD is being used, it will be difficult for them to implement and enforce any proposed regulations. By collecting PGD data from clinics and considering the ethical problems described in this Note, it will be possible to create fair governmental regulations that balance reproductive liberties and free choice, with concerns that PGD will lead to the creation of designer babies and may not be in the best interest of offspring.

VI. COUNTERARGUMENTS—THE CLAIM THAT REPORTING PGD DATA AND GOVERNMENTAL REGULATION MAY NOT BE NECESSARY

A. CAN THE INDUSTRY REGULATE ITSELF?

Individuals in the fertility industry argue that the practice of PGD can be self-regulated and there is no need for governmental involvement or regulation. Providers argue that professional organizations, such as the American Society for Reproductive Medicine (ASRM) and the PGD International...
Society (PGDIS) could create voluntary ethical guidelines to self-regulate the industry. Despite these claims, there is not a consensus within the field about whether or not there should be limits on the use of PGD and, if there should be limits, what those limits should be. In any case, the data from mandatory reporting could be useful to professional organizations in shaping ethical guidelines. Dr. Jeffrey Steinberg of the Fertility Institutes, one of the leading clinics offering sex-selection in the United States, feels that he has an obligation to provide everything science offers to his patients, including PGD for sex-selection, and eventually PGD for aesthetic, non-medical traits. On the other hand, Dr. Mark Hughes, one of the original pioneers of PGD, disagrees, asserting that he developed the procedure to help root out serious disease, not gender. When asked whether he thought the use of PGD would become common practice he replied, “I hope not... just because you technically can do something doesn’t mean you should.” If two of the most prominent faces of PGD cannot agree on how it should best be utilized, it is unlikely that self-regulation will be effective. In addition, the ASRM has already issued ethical guidelines suggesting that clinics not perform non-medical sex-selection. Since almost half of clinics reporting in the Johns Hopkins study reported offering non-medical sex-selection, it does not appear that the guidelines are followed. It is likely that any additional guidelines issued by professional societies will be just as easily disregarded.

B. MANDATORY REPORTING WILL NOT BE AN UNNECESSARY BURDEN FOR CLINICS

Requiring fertility clinics to report additional information will create a new burden for fertility clinics, which they will likely argue is unreasonable. The burden, however, is minor since there is already an existing infrastructure for reporting and clinics should already have individuals trained to use this reporting system. Under this proposal, these individuals will need more time to input data into the system, however, the time needed and costs associated with paying these individuals is minimal.

VII. CONCLUSION

Adopting the proposed amendment requiring fertility clinics to report PGD data will provide policymakers with the information needed to create appropriate governmental regulation of this technology. Today, there is limited information available regarding how PGD is used, but there are many ethical concerns, particularly that the unregulated use of PGD will result in the creation of children through genetic modification. Until there is a clear understanding of how the technology is being used, it will be difficult to regulate. Mandated reporting is the first step toward ensuring that the practice of PGD is not abused.

NOTES

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1. The characters mentioned in these hypothetical scenarios are fictional monikers utilized solely for the purpose of this Note.


10. In vitro fertilization (IVF) is an artificial insemination procedure in which an egg and sperm are combined in a Petri dish, to create a fertilized embryo that is then implanted into the mother or a surrogate. Before IVF may occur, couples must undergo fertility treatments. This may include getting hormone injections, taking fertility drugs, having multiple ultrasounds, and completing blood and urine tests. American Pregnancy Association, In Vitro Fertilization: IVF, http://www.americanpregnancy.org/infertility/ivf.html (last visited Nov. 20, 2010).

11. eMedicine, Preimplantation Genetic Diagnosis, supra note 7.

12. Id.

13. Id.

14. 60 Minutes: Choose the Sex of Your Baby (CBS television broadcast Aug. 11, 2004).

15. Three techniques can be used to remove this single cell. Cleavage-state embryo biopsy is the most common and involves removing a cell on day three of fertilization as described in the body of this Note. Other techniques include polar body biopsy, which can only be used to test for female chromosomal disorders, and blastocyst biopsy, which occurs five days after fertilization. eMedicine, Preimplantation Genetic Diagnosis, supra note 7.

16. Id.

17. 60 Minutes, supra note 14.


21. Id.

22. Id.

23. Id.


25. Chorionic Villus Sampling is a procedure that involves removing “a small piece of placenta tissue (chorionic villi) from the uterus during early pregnancy to screen the baby for genetic defects.” This can be done through either the abdomen or cervix. Medline Plus, Chorionic Villus Sampling, http://www.nlm.nih.gov/medlineplus/taysachsdis.html (last visited Oct. 21, 2010).


28. Id.

29. Id.

30. Baruch, supra note 18, at 259.

31. Devolder, supra note 6, at 584.


33. 60 Minutes, supra note 14.

34. Baruch, supra note 18, at 248.

35. Id.


37. Baruch, supra note 18, at 253.

38. Id.

39. Id.

40. Devolder, supra note 6, at 582.

41. Id.

42. Id.

43. Id.

44. Id. at 254.


46. Remaley, supra note 9, at 277.

47. Baruch, supra note 18, at 255.
48. Id.
49. Id.
51. Baruch, supra note 18, at 255.
52. Id.
53. Id.
56. Scientists state that they should soon be able to predict eye color with 80% certainty. 60 Minutes, supra note 14.
57. The Fertility Institutes, supra note 55.
58. Reproductive Health Technologies Project, supra note 8.
60. Id.
61. Centers For Disease Control and Prevention, supra note 2.
62. Id.
63. Id.
64. The significant difference between the number of live-births and infants each year occurs because many IVF pregnancies result in multiple births. Id.
65. The most recent publication data available was published in December 2009 and included data from the 2007 calendar year. Since ART success rates are based primarily on the number of live births resulting from ART cycles, pregnancies must be tracked and therefore comprehensive data is not immediately available. 2007 ART Report Commonly Asked Questions, http://www.cdc.gov/art/ART2007/faq.htm (last visited Nov. 20, 2010).
67. Id.
68. Id.
69. Baruch, supra note 18, at 245–46.
70. Baruch, supra note 45, at 1054.
71. Id.
72. Id.
73. Id. at 1056.
74. Id.
75. Typically, HLA matching and PGD to prevent the genetic condition affecting the older sibling are performed simultaneously. In some cases, HLA matching is performed when the older sibling’s condition is not inherited. Only 6% of clinics have provided PGD for HLA matching in these cases. Id.
76. Id.
77. Remaley, supra note 9, at 282.
78. Ethics Committee of the American Society for Reproductive Medicine, Preconception Gender Selection for Nonmedical Reasons, 82 FERTIL STERIL. 232–35 (2004); American Society for Reproductive Medicine and Society for Assisted Reproductive Technology Practice committees, Preimplantation Genetic Diagnosis, 82 FERTIL STERIL. 120–22 (2004).
79. Id.
82. Id.
83. Id.
84. Id.
86. Id.
87. Baruch, supra note 18, at 261.
88. Id.
90. Id.
92. Id.
93. See Skinner v. Oklahoma, 316 U.S. 535 (1942) (describing in dicta the fundamental right to have offspring); Griswold v. Connecticut, 381 U.S. 479 (1965) (holding that there is a constitutionally protected right to marital privacy); Eisenstadt v. Baird, 405 U.S. 438 (1972) (finding that the right to procreate extends to unmarried couples).

95. Id.


98. Id.

99. Although the United States may be reluctant to do so, this can be accomplished without compromising individual liberties or overturning Roe v. Wade. Spar, supra note 86, at 489.

100. Robertson, supra note 72, at 466.

101. Id. at 471.

102. Id.

103. Andrea L. Kalfoglou, Patients’ and Providers’ Attitudes to the Use and Regulation of Preimplantation Genetic Diagnosis, 11 REPROD. BIOMED. ONLINE 486 (2005).


105. Baruch, supra note 45, at 1057.

106. Id.

107. Saletan, supra note 54.


110. Id.; This concept is highlighted in the fictional film Gattaca, which depicts a future where individuals are created almost exclusively through ART and those who are not face genetic discrimination. GATTACA (Columbia Pictures 1997).

111. Reproductive Health Technologies Project, supra note 8.

112. Roe v. Wade, 410 U.S. 113 (1973) (holding that a woman’s constitutional right to privacy includes the decision to have an abortion, establishing a woman’s rights to choose to terminate a pregnancy).

113. Dolgin, supra note 104, at 523.


115. Id.


117. Reproductive Tourism is defined as “the movement of citizens to another state or jurisdiction to obtain specific types of medical assistance in reproduction that they cannot receive at home.” Guido Pennings, Legal Harmonization and Reproductive Tourism in Europe, 19 HUM. REPROD. 2689, 2690 (2004).


120. Remaley, supra note 9, at 250.

121. Sundaram, supra note 119.

122. Id.

123. Id.

124. Remaley, supra note 9, at 277–79.

125. Id.

126. Dolgin, supra note 104, at 526.


129. Id.

130. Baruch, supra note 18, at 261.


133. See Turpin v. Sortini, 643 P.2d 954, 955 (Cal. 1982) (noting that “the overwhelming majority of decisions in other jurisdictions recognize the right of the parent to maintain action” for wrongful birth when their child is impaired).


135. Id at 680.
137. Goebelmann, supra note 134, at 669.
139. Dolgin, supra note 104, at 526.
140. Reproductive Health Technologies Project, supra note 8.
141. Id.
143. Id.
144. Dolgin, supra note 104, at 524.
145. Remaley, supra note 9, at 270.
146. Id. at 273.
148. Id.
149. Baruch, supra note 18, at 268.
150. Id.
151. 60 Minutes, supra note 14.
152. The Fertility Institutes, supra note 55.
153. 60 Minutes, supra note 14.
154. Id.
155. Id.
156. Baruch, supra note 18, at 269.
157. See Baruch, supra note 45.

Laura Damiano is the Managing Editor of Notes and Comments for Family Court Review at Hofstra University School of Law. She graduated from Brandeis University with a B.A. in Health: Science, Society, and Policy. At Hofstra Law, she is a Health Law and Policy Fellow and former President of the Health Law Society. During her first summer of law school she interned at HealthDrive in the Office of Legal and Regulatory Affairs. During her second year, she interned at Weill Cornell Medical College in the Office of University Counsel. During her second summer of law school she interned at the Nemours Office of Child Health Policy and Advocacy in Washington, DC.