CUSTOMIZING CONCEPTION: A SURVEY OF PREIMPLANTATION GENETIC DIAGNOSIS AND THE RESULTING SOCIAL, ETHICAL, AND LEGAL DILEMMAS

One in six American couples experience difficulties conceiving a child. With fertility rates at an all time low, the business of treating infertility is booming. However, due to the United States prohibition on government funding for embryonic research, the $4 billion industry of assisted reproductive technologies (ART) has been incompletely monitored and largely removed from oversight. Additionally, due to the fervent abortion debate, in vitro *fertilization (IVF) was introduced in the United States without a research phase and procedures have been forced to evolve in the private sector. Thus, the checks and balances on medical innovation that are generally imposed by the federal government for consumer protection are lacking. Decisions about when to go from the laboratory to the clinic are often left solely to the discretion of private physicians. Preimplantation genetic diagnosis (PGD) is just one of many such treatments offered by these clinics. This iBrief examines how, why, and to whom the reproductive procedure of PGD is offered. In addition, it evaluates the prospective effects to society that arise when PGD is used for sex selection and for nontherapeutic or enhancement purposes. Finally, it explores whether and how to regulate PGD in the United States by investigating approaches to policy making that have been adopted by the United Kingdom.*

The great challenge to mankind today is not only how to create, but to know when to stop creating.

—*Lord Emmanuel Jacobvitz, former chief rabbi of Britain.*

Attending to her father and witnessing two siblings progressively deteriorate from the agonizing dementia that is characteristic of Alzheimer's disease recently led a Chicago woman in her early thirties to vow this dreadful fate would not be passed along to her child. The patient—who will almost certainly develop the disease by age forty—stood a 50% chance of having a child who would inherit the genetic anomaly. This led her to a specialist at Chicago's Reproductive Genetics Institute, where she was introduced to the possibility of preimplantation genetic diagnosis. Using *in vitro* fertilization techniques, doctors trained in reproductive medicine were able to fertilize thirteen of her eggs in petri dishes with the father's sperm. PGD then allowed them to screen these embryos for the six that were free from the defect. They implanted four of the six, which resulted in the birth of a healthy baby girl free from the fate bestowed on her

grandfather and her mother's siblings. Although PGD has been used to screen for genetic abnormalities for over a decade, this was the first known PGD procedure used to detect inherited early-onset Alzheimer's disease, which resulted in a clinical pregnancy and the birth of a child free from the disposition.

Human genomic research has led to innovations in reproductive technologies that are altering our attitudes towards procreation, and publicized success of cases like this will ultimately increase the demand for access to PGD. Although most agree that screening for Alzheimer's disease is auspicious in itself, PGD does have the potential to open the floodgates to selecting for a wider array of traits or essentially "customizing conception." Presently, it is not practicable to use PGD as a means of selecting physical characteristics, behavioral traits, or intelligence. However, the genetic components of these expressions are being investigated, and it is only a matter of time before technology will allow parents to select traits for their children that are most desirable to them. The potential for impacting future generations makes this a revolution that could be in danger of becoming a more politically sensitive matter than abortion.

Procreative autonomy or reproductive choice is often the principal argument advanced to discourage governmental oversight. Others believe that regulation would stifle debate and discourage a moral consensus, or that legislation encompassing these new technologies may not be desirable where it would "run contrary to basic human rights and freedoms." However, the laissez-faire approach currently practiced in the United States—while allowing for individual agendas of reproductive choice based on religion, culture, philosophy, and wealth—leaves open the door to eugenic practices, and could ultimately exacerbate the rift between the affluent and the underprivileged.

Section I. Who is likely to benefit from PGD?

Catastrophic reproductive history, genetic risk and aversions to abortions are the primary reasons specified for undertaking PGD.[1] Reproductive histories of patients surveyed showed that the majority of patients have had one or more pregnancies, yet very few of those couples have any healthy children.[2] Approximately 25% of those couples have had at least one child affected with a serious genetic disorder, and a greater number reported spontaneous abortions or terminations of pregnancies after an abnormality was detected through prenatal diagnosis.[3]

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[1] ESHRE, *Preimplantation Genetic Diagnosis Consortium: Data Collection III*, HUM. REPROD., May 2001, at 246.
[2] *Id.* at 246.
[3] *Id.* at 247.

Before the advent of PGD, testing was performed prenatally in the first trimester by using chorionic villus sampling (a biopsy on a small sample of the placenta), ultrasound (using sound waves to look at internal structures), or by amniocentesis (the withdrawal of amniotic fluid from around the fetus) during the second trimester. Currently, there are more than 500 different conditions that can be diagnosed prenatally, and this number continues to grow significantly each year.[4] These prenatal approaches, however, leave the couple faced with a decision of whether to undergo a "genetic abortion" as late as twenty-four weeks into the pregnancy. Genetic or therapeutic abortions often place the mother at risk and are frequently accompanied by a tremendous amount of guilt or grief arising out of the couple's own genetic status.

Predictive medicine, such as PGD, while attempting to prevent the passing along of genetic susceptibilities, can also eliminate the need to abort a fetus. IVF provides access to the egg and embryo, making it possible to examine the DNA of individual embryos. Infertile couples using IVF, couples at risk for a genetic disease, or those who are aware that one parent is a carrier can take advantage of the opportunity to screen their embryos for chromosomal abnormalities prior to implantation. Electing to terminate an embryo after PGD shows an abnormality is often an easier decision than abortion, and is less risky to the woman's health.

Provided the parents are not hindered by their view of the moral status of the embryo, PGD can obviate the 25% to 50% risk of passing on specific genetic abnormalities by offering couples the opportunity to terminate in vitro derived embryos that manifest genetic abnormalities prior to implantation. Moreover, PGD restores confidence when the embryo is healthy, and offers diagnosis and alternatives when a severe abnormality is present. It is, therefore, natural to see why many have elected to use this technology to avoid the possibility of abortion after traditional prenatal diagnosis shows that the fetus has the genetic defect. If use of PGD becomes widespread it has the potential to reduce the occurrence of many of these genetic diseases worldwide. Due to the fact that treatments can easily cost many millions of dollars over the lifetime of a single individual, there appears to be a substantial and justifiable interest in preventing the occurrences of these traits by employing PGD for therapeutic screening of embryos.

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[4] LORI B. ANDREWS, FUTURE PERFECT 23 (2001).

Section II. Arguments against using PGD to select for serious diseases

Moral status of the embryo

There are relatively few arguments against using PGD to screen for serious diseases. The most often cited seems to be related to the moral status of the embryo. The argument centers on the effect that screening and subsequent termination of embryos has on prenatal life. Pro-life activists argue that life begins at fertilization, not conception. Thus, the embryos would be entitled to the same legal protections that are afforded to individuals. Therefore, they believe that the embryos should not be deprived of any likelihood of implantation, and that they should not be subjected to screening that would lessen their chance of survival.[5] However, the majority of practitioners view this simply as the lesser of two evils. By allowing for screening prior to implantation, PGD has the potential to reduce the amount of abortions that carry greater medical and emotional consequences. Additionally, it is argued that because embryonic cells are nondifferentiated–often undergoing spontaneous twinning–the embryo is not clearly individual.[6] Thus, it is contended no life actually taken by the termination of these preembryos.

The United Kingdom's licensing and regulatory body for assisted reproductive technologies, the Human Fertilization and Embryological Authority (HFEA), has taken the position that "a collection of four or sixteen cells is so different from a full human being … that it might quite legitimately be treated differently."[7] Consequently, they determined that the time to be adopted for regulation of research on embryos is at the appearance of the "primitive streak" at about day 14 or 15.[8] This "primitive streak" is the visible site of invagination formed by the interpositioning of the mesoderm with the endoderm and the ectoderm.[9] This view has been held to be consistent with the theological view of continuous creation as opposed to the infusion of a human soul at a particular moment.

Late-onset diseases

While many genetic diseases are progressive and disabling, a late-onset disease allows many years of good health. However, variations in penetrance can frequently generate stress and a feeling of uncertainty. The costs of rearing a child with a late-onset disease may be financially

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[5] ESHRE Task Force on Ethics and Law, *The moral status of the preimplantation embryo*, 16 HUM. REPROD. 1046-1048 (2001).
[6] John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 449 (1996).
[7] Stenger, R., *The Law and Assisted Reproduction in the United Kingdom and United States*, 9 J.L. & HEALTH 135, 141 (1995).
[8] *Id.* at 144.

and emotionally significant. Thus, the presence of a genetic disposition for a late-onset disease may go to the heart of the couple's decision of whether to reproduce at all. In a case where PGD reveals a predisposition for a late-onset disease such as Alzheimer's or Huntington's disease, a couple may elect to terminate those embryos that are affected. Some argue that patients suffering from these diseases that will not manifest any symptoms for thirty to forty years should not be allowed to terminate the affected embryos because they feel that by that time a cure may have been developed. The HFEA acknowledges that while the age of onset is one factor, the seriousness of the disorder and the circumstances of the individual couple and family may be equally relevant. They have suggested that age of onset, "should be one of a number of factors, but not an overriding factor, in determining whether PGD should be offered."[10]

Disability discrimination claim

The disability discrimination claim maintains that prenatal or preimplantation screening for disabilities results in discrimination against those with the disability by reducing the numbers of people affected. Moreover, they believe that by terminating the fetus or embryo we are sending a message that a life with the disability is not worth living at all. It is also argued that developing remedies is hindered by the ability to select against diseases either by PGD or abortion. Millions of people who are currently affected with these disorders are living happy and productive lives. These individuals argue that identifying people based on their circumstances has the tendency of perceiving abnormalities as inconveniences. In addition, they believe that "PGD and embryo selection against these traits will reinforce beliefs that they are inferior."[11] However, one commentator cautions, "it would be a drastic step in favor of equality to inflict a higher risk of having a child with a disability on a couple (who do not want a child with a disability) to promote social equality…. To attempt to prevent accidents which cause paraplegia is not to say that paraplegics are less deserving of respect."[12] It is important to distinguish between disability and persons with disabilities. Selection reduces the prevalence of the former, but is silent with respect to the value of the latter. Consequently, we must evaluate our social institutions and beliefs regarding the disabled, but we should not restrict the use of PGD to screen for severe genetic disorders solely on the basis of disability rights.

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[9] *Id.* at 147.
[10] Julian Savulescu, *Procreative Beneficence*, 15 No. 5/6 BIOETHICS 423 (2001).
[11] LEE SILVER, REMAKING EDEN: CLONING AND BEYOND IN A BRAVE NEW WORLD 221 (1997).
[12] Savulescu, *supra* note 10, at 423.

Section III. Sex selection of embryos

Historically, cultures have practiced sex selection using a variety of means from timing of coitus to infanticide. Infanticide (a form of genetic selection where infants are often suffocated soon after birth) has often been practiced in countries such as India and China where families place a premium on producing a baby boy. Continued lineage and economic survival of the family are the two principal reasons advanced for undertaking this practice. And although selective female infanticide has been outlawed in India since 1996, the procedure is still widespread.[13]

However, as prenatal screening technologies such as ultrasound, genetic diagnosis by amniocentesis, and chorionic villus sampling have become more readily available, the practice of infanticide has declined and many couples are choosing selective abortion as the preferred method of ensuring the sex of their children.[14] In fact, technicians in China, Taiwan, Bangladesh and India travel from village to village with portable ultrasound devices to screen pregnant women who pay them to discover the sex of their fetuses.[15] As a result, one study conducted in India reported that out of 8000 abortions performed, 7999 of the fetuses were females.[16] Recent developments such as prefertilization separation of X-bearing spermatozoa and PGD followed by sex selection have the potential to eliminate theses conventional practices of "gynecide."

Prefertilization sex selection techniques, although currently available to humans, are still experimental and unreliable. PGD, on the other hand, has opened the doors to sex selection by providing couples with the opportunity to screen embryos for the preferred sex before a pregnancy is initiated. If a single piece of DNA on the Y chromosome is identified then the sex of the embryos obtained can be determined with 85-95% accuracy.[17] Nevertheless this still provokes ethical concerns relating to the perpetuation of gender oppression, the appropriateness of expanding control over nonessential characteristics of children, and unfair expenditure of limited medical resources.[18]

In May 2001, the Ethics Committee of the American Society for Reproductive Medicine (ASRM)–a group that sets fertility clinic standards nationwide–said it could be ethical for parents

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[13] A. Malpani, *Preimplantation Sex Selection for Family Balancing in India*, 17 HUM. REPROD. 11, 12 (2001).
[14] Ethics Committee of the American Society of Reproductive Medicine, *Sex Selection and Preimplantation Genetic Diagnosis*, 72-4 FERTILITY & STERILITY 595 (1999).
[15] LORI B. ANDREWS, THE CLONE AGE 143 (1999).
[16] *Id.*
[17] Reproductive Specialty Medical Center, *Preimplantation Genetic Diagnosis*, *at* http://www.drary.com/pgd.htm.
[18] Ethics Committee of the American Society of Reproductive Medicine, *supra* note 14, at 595.

to choose their children's sex for non-medical reasons.[19] They stated that they did not feel that it would be unethical for parents to utilize this technology to select for a child "of the gender opposite that of an existing child or children."[20] Likewise, they acknowledged, "it would not be unethical for parents to prefer that their first-born or only child be of a particular gender because of the different meaning and companionship experiences that they expect to have."[21]

Although the committee was referring to pre-conception sperm sorting techniques, this statement opened the floodgates for the use of PGD for sex selection. The attitudes of some clinicians were that if it is ethically sound to select for sex using a technique that can merely improve the odds of gender selection, then logically it follows that it must also be acceptable to do so using PGD, which is nearly 100% effective in determining the sex of an embryo. As a result, CHR–one of the largest providers of fertility treatments in the United States–announced plans to begin offering sex selection for nonmedical referrals to patients at their New York and Chicago clinics.[22] However, other commentators did not see this as a logical extension of the endorsement on sex selection. Jeffery Kahn, who is the Director of the Center for Bioethics at the University of Minnesota argues, "[s]orting sperm is one thing—it's quite another to create and test embryos before they are implanted in a woman's womb and discard those of the "wrong" gender, at least for many professionals and members of the public."[23]

Accordingly, after an uproar from members of the public and the press, the Chairman of the Ethics Committee John A. Robertson announced an updated opinion in a letter dated September 17, 2001.[24] In summary, the position of the committee was that clinics could ethically offer PGD solely for sex selection if there is "good reason to think that the couple is fully informed of the risks of the procedure, and are counseled about having unrealistic expectations about the behavior of children of the preferred gender."[25] Shortly after, however, in a letter dated February 7, 2002, the opinion was again revised to read "the Committee reaffirms its previous conclusion that initiating IVF and PGD solely for non-medical gender selection, e.g., for the first

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[19] Ethics Committee of the American Society for Reproductive Medicine*, Preconception gender selection for nonmedical reasons*, 75 FERTILITY & STERILITY 5 (2001).
[20] *Id.*
[21] *Id.*

[22] The Center for Human Reproduction, *New York City and Chicago-Based Infertility Center Announces New Gender Selection Program*, *at* http://www.centerforhumanreprod.com/about_pressRelations.jsp?EventId=6&action=pr.

[23] Jeffery P. Kahn, *The Questionable Future of Unregulated Reproduction, at* http://www.cnn.com/2002/HEALTH/02/18/ethics.matters/index.html.
[24] Jeffery P. Kahn, *High-Tech Sex Selection, at* http://www.cnn.com/2001/HEALTH/10/01/ethics.matters/index.html.

child, should be discouraged. It also concludes that initiating IVF and PGD solely to create gender variety in a family should at this time also be discouraged."[26]

Although there is currently little reporting on the use of PGD for sex selection in the United States, of the twenty-one centers that submitted data to the European Society of Human Reproduction and Embryology (ESHRE) Consortium, fifteen reported that they were against social sexing and only four replied that they were in favor of the procedure.[27] The arguments for social sexing other than the prevention of sex linked genetic disease include: the right to self-regulation of countries, individual rights of procreative choice, and that the elimination of embryos of the unwanted sex is a preferred alternative to abortion.[28] Couples in favor of sex selection maintain that the choice of offspring gender is significant in their decision of whether or not to reproduce. If this argument were accepted then their decision would presumptively be protected as a fundamental right and could not be restricted without the showing of a compelling state interest. This aspect of procreative autonomy is the focus of section V.

With respect to the argument that the termination of embryos of the unwanted sex is a lesser evil than selective abortion, Jeffery Kahn responds, "[i]n the case of using in vitro fertilization for sex selection, couples test embryos and discard those of the unwanted gender–a process that seems to discount or even ignore the seriousness of the ethical issues it raises."[29] Therefore, if the embryo is to be given any moral status whatsoever, terminating healthy embryos because they are of the wrong sex seems to be as immoral as it is unethical.

Other more attenuated arguments in favor of PGD for sex selection include: that allowing families to select embryos of the desired sex contributes to population control (these couples will no longer be compelled to reproduce until they conceive a child of the ideal gender), gender balancing within the family (they have one or more children of one sex and would like to parent the other sex), and a desire for parental companionship by raising a child of the same gender.[30] The Ethics Committee of the ASRM believes that although population control is a key

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[25] *Id.*
[26] The Center for Human Reproduction, *Fertility Center Follows Most Recent Ethics Opinion on the Use of IVF/PGD for Gender Selection*, *at* http://www.centerforhumanreprod.com/about_pressRelations.jsp?EventId=10&action=pr.
[27] ESHRE, *Preimplantation Genetic Diagnosis Consortium: data collection III*, HUM. REPROD., May 2001 at 246.
[28] American Society for Reproductive Medicine, *supra* note 18.
[29] Kahn, *supra* note 23.
[30] American Society for Reproductive Medicine, *supra* note 18, at 596.

issue in many countries, the limited use of PGD and sex selection in the United States cannot be currently justified solely on the basis of population limitation.[31]

Inherent gender discrimination is the primary reason advanced for prohibiting sex selection of embryos. However, this argument seems to be more compelling when applied in countries where gender is tied to economic independence and equal rights. Presently, there is no data that suggests that gender discrimination practiced in the Middle East and Asia would occur if we allowed for sex selection in the United States. Further arguments against using PGD for sex selection other than the potential for inherent gender discrimination include: the use of medical resources for sex selection may result in an unfair allocation of medical resources, that inappropriate control over trivial characteristics may lead to commodification of children, and that widespread use of sex selection may lead to an imbalance of the overall sex ratio within society.[32]

The decentralized health care system in the United States makes it unlikely that couples choosing to take advantage of PGD for sex selection will, as a result, deprive others of limited medical resources. However, if argued in the aggregate, these individual decisions could ultimately have some impact on the overall allocation of medical resources. The argument against commodification of children seems to present the strongest case against using PGD for sex selection. As the possible list of genetic tests grow, there will be a greater temptation to select for physical traits and behavioral characteristics. Furthermore, as more and more clinics begin to offer PGD the relative demand for standard screening will diminish, and there is some concern that existing clinics will begin to offer these supplementary services to remain competitive in the marketplace.

While many commentators argue that PGD for social sexing will produce an unbalanced sex ratio, Dr. Malpani at the Malpani Infertility Clinic in Mumbai, India, dismisses these claims by stating that the "expense, limited availability and comparative inefficiency of sexing by embryo biopsy" make it unlikely to significantly impact the gender ratios of any populations.[33] Moreover, he recommends that in countries like India where cultural preferences for males are great, that safeguards should be implemented to restrict PGD for sex selection to only couples that already have a child.[34] However, even before PGD became available–when the one-child policy was being enforced in India–the sex ratio was altered to 153 males for each 100 females.[35]

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[31] *Id.* at 597.
[32] *Id.* at 596.
[33] Malpani, *supra* note 13, at 12.
[34] *Id.*
[35] ANDREWS, *supra* note 15, at 142.

In the US, sex selection is generally sought for a third or later child of the opposite sex than those already produced by the couple.[36] One survey reported that 34% of geneticists stated that they would perform sex selection for families seeking to have a son, and another 28% said that they would refer the couple to a doctor who would.[37] Dr. John Stephens's clinics in California, Washington, and New York, already offer couples the opportunity to undergo prenatal testing for sex selection.[38] Twenty-five percent of American couples surveyed have said that they would utilize these sex selection techniques.[39] And although Western societies attitudes towards women differ significantly from other parts of the world, the demand for male offspring is still apparent with 81% of men and 94% of women stating that they would desire to ensure their first child was a boy.[40] This survey tends to legitimize fears of a potential gender imbalance that the ASRM's Ethics Committee is dismissing as a "remote consequence … remaining too speculative to place seriously in the balance of ethical assessments of the techniques."[41]

Section IV. PGD used to select for nonmedical traits

Today, we may only be selecting for gender, but as the technology catches up with our suspicions we may soon be faced with hundreds of alternatives that could fall under the rubric of family balancing. For example, suppose that thirteen embryos have been biopsied, six are found to be free of the specific disorder in question and the doctor is only willing to transfer four of them (due to the health risks with multiple pregnancies). What are the criteria by which the remaining two are terminated? Should we allow sex selection at this point, or what about selecting for physical or behavioral preferences? "There's a big difference between curing infertility, on the one hand, and trying to make sure that your child inherits your curly hair on the other," says Princeton bioethicist and author Lee Silver.[42]

So then, on what basis should we ascribe impairment? Most commentators agree that pre-natal and pre-implantation diagnosis should only be used to screen for serious disorders.43 The "best interests of the child principle" is fundamental to legislation of assisted reproductive

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[36] ADELE E. CLARKE, DISCIPLINING REPRODUCTION: MODERNITY, AMERICAN LIFE SCIENCES, AND THE PROBLEMS OF SEX 250 (1998).
[37] ANDREWS, *supra* note 15, at 143.
[38] *Id.* at 142.
[39] *Id.* at 143.
[40] *Id.*
[41] American Society for Reproductive Medicine, *supra* note 18, at 597.
[42] SILVER, *supra* note 11, at 75.
[43] JOHN HARRIS & SOREN HOLM, THE FUTURE OF HUMAN REPRODUCTION: ETHICS, CHOICE, AND REGULATION 182 (1998).

technologies in Australia and the United Kingdom.[44] This principle provides that the welfare and interests of the child are paramount. Parents are prohibited from requesting inappropriate nontherapeutic treatments if they are contrary to the best interests of the child. On the other hand, if two alternatives are considered to be equally viable, the parental choice will be upheld. This approach offers protection for children who cannot help themselves versus offering protection to those who may bear the burden of caring for them.

The English Abortion Act of 1967 provides for a lawful termination of the pregnancy if "two registered medical practitioners are of the opinion, formed in good faith ... that there is a substantial risk that if the child were born it would suffer from such physical symptoms or mental abnormalities as to be seriously handicapped."[45] What then should be considered to be severe? Can some conditions be severe in some geographical locations and not in others based on climate and treatments offered? Should parents abort a fetus that has a treatable disorder because of expense? Severity is not always determined in the medical sense and can be accessed differently among diverse family structures.[46] Professor Silver suggests three factors to determine severity: impact on quality of child's health (survival suffering and limitations on function), age of onset, and probability that genotype will influence phenotype.[47]

Even if these standards are applied through legislation, there remains a threat that more and more conditions will be classified as severe as a result of pressure to get access to PGD.[48] Perhaps the use of PGD could be limited by allowing couples to select only against traits that would impair one's "well-being." However, selecting against traits that have the potential to limit an individual's well-being naturally suggests that we must select only positive traits. A positive trait may encompass both disease and nondisease genes; thus, the line is again blurred.

When one screens multiple embryos, however, there is an inherent pressure to select only the most desirable traits. Consequently, PGD has a far greater eugenic potential than prenatal genetic testing. Essentially what would be screened for is a gene that predisposes some physical or psychological state such as intelligence, height, or even musical talent.[49] Although selecting for physical and behavioral traits is not currently possible, the demand seems to exist as evidenced by donor catalogs for artificial insemination that allow couples to select for these traits by providing information on "ethnicity, hair color and texture, eye color, height, weight, blood

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[44] Savulescu, *supra* note 10, at 429.
[45] Abortion Act of 1967 § (1)(1)(d) (Eng.).
[46] HARRIS & HOLM, *supra* note 43, at 184.
[47] SILVER, *supra* note 11, at 57.
[48] HARRIS & HOLM, *supra* note 43, at 184.
[49] Savulescu, *supra* note 10, at 415.

type, skin tone, years of education, and occupation (or major in college)."[50] The central logic behind reform eugenics of the 1930s was that "the human race was faced with genetic deterioration unless we actually intervened in reproductive decisions."[51] Ideas about biological variations have been the foundation of many of the global atrocities in the past; therefore, we should be particularly cautious of distinguishing potential humans on the basis of behavior, personality or genetic predispositions to genetic disease.

Researchers involved in behavioral genetics are seeking to link genes to complex patterns of behavior such as alcoholism, bipolar disorders, intelligence, and homosexuality.[52] Behavioral genetic research can be categorized as the study of "behavioral illness" (depression, schizophrenia, Alzheimer's, and attention-deficit disorder), "deviant characteristics" (alcoholism, criminal behaviors, and homosexuality), cognitive characteristics (reading disabilities and intelligence), or "basic personality dispositions" (shyness, self-esteem, and social attitudes).[53] However, the problem with analyzing this data is that most of these traits are apparently polygenic and also significantly influenced by nongenetic environmental factors. Therefore, predisposition testing has a great potential for abuse because it cannot accurately predict whether or when these behavioral characteristics will actually express themselves.

The fear of misinterpreting or misapplying these correlations is that society may view non-genetically influenced behavior as the product of "free will," whereas non-genetically influenced behavior will likely be held beyond the control of the individual.[54] In fact, criminal defense attorneys seized upon one such study published in 1993, which attempted to link the MAOA gene with abnormal aggressive behavior, as a way by which to exculpate their clients that were serving death row sentences.[55]

The principle of procreative autonomy claims that couples should be free to determine when and how to have children, and many see selection of nonmedical traits as a logical extension of this principle. They further support this argument by stating that if people are free to choose whether to procreate, and if these behavioral characteristics are central to that decision, then couples should be able to select for nonmedical traits as well. Proponents of selecting for nondisease genes often equate their argument to selecting for disease genes by stating "it is not

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[50] FURROW, ET AL, BIOETHICS: HEALTH CARE LAW AND ETHICS 102 (1997).
[51] BRYAN APPLEYARD, BRAVE NEW WORLDS: STAYING HUMAN IN THE GENETIC FUTURE 48 (1998).
[52] Savulescu, *supra* note 10, at 416.
[53] Patrik Florencio, *Genetics, Parenting, and Children's Rights in the Twenty-First Century*, 45 MCGILL L.J. 532 (2000).
[54] *Id.* at 537.
[55] *Id.* at 529.

disease which is important but its impact on well-being."[56] This implies that if intelligence affects one's well-being then parents should select for it without regard to social inequality.

Others suggest that if we allow selection of embryos based on intelligence, physical, and psychological traits then we will be contributing to inequality in society. These critics argue that by selecting the best embryos we are circumventing the natural random process of evolution, and that selecting for non-disease traits will lead to commodification of children.[57] They fear that consumer-driven parents may feel as though they paid for a perfect child and that anything less than perfect would be unacceptable. Thus, parents might place excessive expectations on their customized children.

While the current effects on society from the use of PGD are minute, Professor Silver feels that in time affluent parents will have children who are less prone to disease.[58] Moreover, he believes that this effect will combine with the increased chance for success already possessed by children raised under better environments, which will eventually lead to an even wider gap between the "haves" and the "have nots."[59] In other words, while wealthy parents are able to select traits for happiness, creativity and physical talents, disorders such as obesity, heart disease, alcoholism and mental illness will be left to "drift randomly among the families of the underclass."[60] Bioethicist, George Annas, has stated,

> [t]o try to give your child a genetic head start would, I think, be irresistible for parents who could afford to pay for it …. This could be very problematic for society. It's a road I don't think we should go down. But it's one I could see us going down very quickly as a result of advertising, peer pressure, and so on ... and that parents who don't "take advantage" of the new genetics will soon be seen as bad or even neglectful parents."[61]

Section V. Legislation of PGD

Rights-based Arguments

Arguments in favor of using PGD are generally founded on principles of procreative autonomy. Therefore, any public attempts to regulate this technology would likely be attacked on that basis. The Supreme Court has examined the principle of procreative autonomy associated

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[56] Savulescu, *supra* note 10, at 423.
[57] *Id.*
[58] SILVER, *supra* note 11, at 225.
[59] *Id.*
[60] *Id.*
[61] George Annas, *Turning Point for the Human Species: Trial Lawyers Should Prepare for the Brave New World of Genetic Research and Human Cloning*, TRIAL 29 (2001).

with the right to privacy protected by the Fourteenth Amendment's Due Process Clause. Although the Court has never overtly acknowledged an affirmative right to procreate using IVF, *Skinner v. Oklahoma* recognized, in dicta, that "marriage and procreation are basic civil rights of man" and declared procreation to be "a fundamental right essential to the existence and survival of the race."[62] Furthermore, Mr. Justice Brennan stated in *Eisenstadt v. Baird*, "[i]f 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 so fundamentally affecting a person as the decision whether to bear or beget a child."[63] However, *Skinner* and its progeny involved only coital reproduction, and it is uncertain whether this inferred right that stems from a right of privacy would be applied to noncoital reproduction.

Where certain fundamental rights are involved, the Court held in *Roe v. Wade* "that regulations limiting these rights may be justified only by a compelling state interest."[64] The Court specifically noted the burdens of carrying, delivering and raising a child and concluded that a mother's interests in avoiding these burdens were significant enough to outweigh the state's interest of protecting the embryo.[65] Therefore, it seems logical that this analysis would extend to the decision to use PGD to select for serious medical conditions that may give rise to such burdens, and that a standard of strict scrutiny would be applied to ensure that the state is "pursuing a goal important enough to warrant use of a highly suspect tool."[66] However, the decision may be more complex because IVF separates the embryo from the womb. Therefore, if the embryo is viewed as a separate and physically discrete unit, it may be held to have rights independent of the mother.[67] Nevertheless, this standard of strict scrutiny that the court applies when a state attempts to regulate requires a showing of a "proximate and inherently dangerous degree of harm."[68] If such a compelling state interest does exist, the Court has stated that the restrictions that attempt to accomplish these interests must be narrowly tailored so as not to be overly inclusive.[69]

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[62] Skinner v. Oklahoma, 316 U.S. 535 (1942).
[63] Eisenstadt v. Baird, 405 U.S. 438, 453 (1972).
[64] Roe v. Wade, 410 U.S. 113 (1973).
[65] *Id.*
[66] City of Richmond v. J.A. Croson Co., 488 U.S. 469, 493 (1989).
[67] HARRIS & HOLM, *supra* note 43, at 111.
[68] Rachel Remaley, *The Original Sexist Sin: Regulating Preconception Sex Technology*, 10 HEALTH MATRIX 283 (2000).
[69] Owen D. Jones, *Sex Selection: Regulating Technology Enabling the Predetermination of a Child's Gender*, 6 HARV. J.L. & TECH. 1, 3-7 (1992).

Supporters of prebirth selection rest their arguments on the connection between the expected characteristics of offspring and the decision of whether or not to reproduce.[70] If PGD is used to select what is merely a preferable trait as opposed to a trait that vitally affects the decision of whether or not to reproduce at all, then it may not be viewed within the ambit of procreative autonomy or as a fundamental right. Thus, the state may regulate to further any rational interest. This rational interest seems to exist where policy is based on the "best interests of the child" principle. Using PGD for sex selection or for selecting for nonmedical traits does not deal directly with the decision of whether an individual can reproduce, but rather it deals with the product of their decision to reproduce. Because of the Supreme Court's reluctance to recognize new rights, these types of decisions would appear to fall outside the scope of the substantive due process doctrines founded upon rights traditionally protected within our society.

Issues of family law have been traditionally left to the states, and most states allow the industry to regulate itself.[71] The Society for Assisted Reproductive Technology calls itself a "governmental watchdog for assisted reproductive technologies."[72] The society collects and validates the outcomes of clinical data and requires accreditation of embryology laboratories. Nonetheless, membership in SART is voluntary and many establishments do not subscribe. The American Society of Reproductive Medicine (ASRM) also has formed an ethics committee that publishes guidelines for its members, but again, membership is voluntary.

Ten states have enacted legislation that prohibits some forms of embryonic research; however, six of those have specifically exempted PGD.[73] The remaining four only allow PGD when it can be shown that it causes no harm to the embryo and is proved to be beneficial.[74] Moreover, there are no state or federal laws directly assessing the nontherapeutic use of PGD.[75] Federal courts in Illinois, Louisiana, and Utah have considered the constitutionality of embryological research prohibitions.[76] The *Lifchez* court held that "the constitutional choices that include the right to abort a fetus within the first trimester must also include the right to submit to a procedure designed to give information about that fetus which can then lead to a decision to

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[70] John A. Robertson, *Preconception gender selection*, AM. J. BIOETHICS 8211 (2001).
[71] ROBERT LEE, & DEREK MORGAN, BLACKSTONE'S GUIDE TO THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990 287 (1991).
[72] Phil McNamme, *What does SART do anyway?*, *at* http://www.sart.org/.
[73] June Coleman, *Playing God or Playing Scientist: A Constitutional Analysis of State Laws Banning Embryological Procedures*, 27 PAC. L.J. 1331, 1354 (1996).
[74] *Id*.
[75] Remaley, *supra* note 58, at 282.
[76] Lifchez v. Hartigan, 735 F. Supp 1361, 1376 (N.D. Ill. 1990); Margaret S. v. Treen, 597 F. Supp. 636, 673 (E.D. La. 1984), *aff'd sub nom.* Margaret S. v. Edwards, 794 F.2d 994 (5th Cir. 1986); Jane L. v. Bangerter, 61 F.3d. 1493, 1506 (10th Cir. 1995).

abort."[77] More specifically, in *Margaret S. v. Treen*, the court found that because fundamental rights encompass the entire process surrounding abortion, the prohibition of diagnostic testing would violate the fundamental rights of women to make reproductive choices.[78] However, none of these decisions have ruled specifically on the use of PGD.

Federal Regulatory Framework

Many believe that the inescapable expenditures of public monies in the direction of science and technology demand the introduction of a regulatory framework. Generally, medical procedures are researched and introduced though the NIH. Only after efficacy is established will procedures find their way into private practices. However, pro-life activists in the United States have historically campaigned to enforce the ban on federal funding to institutions conducting research on human embryos or assisted conception.[79] Consequently, these procedures are no longer carried out in governmentally-funded hospitals or universities. Thus, a market-driven, business oriented approach towards research and treatments for assisted reproduction has developed.

In addition to privatization, attempts at federal regulation have encountered numerous hurdles. Since antiabortion sentiments from the Reagan-Bush era led to the abandonment of the Ethics and Advisory Board in 1979, there have been only limited attempts at federal oversight of reproductive technologies. Harvard law professor Elizabeth Bartholet criticizes, "this country is the only country in our technological position that hasn't, as a society, faced up to the various social and ethical issues involved in this technology."[80] In 1992, Congress enacted Public Law 102-493 entitled the Fertility Clinic Success Rate and Certification Act.[81] The act called for clinics to report pregnancy rates to the Centers for Disease Control (CDC) and for the establishment of a model program for certifying embryo laboratories.[82] The CDC has developed a set of quality standards that are targeted at assuring the quality of embryo laboratory procedures. They include laboratory personnel qualifications, record maintenance procedures, and criteria for the certification and inspection of embryo laboratories.[83] However, the model program is voluntary and has yet to be adopted or implemented by any state. Congress

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[77] Lifchez, 735 F. Supp. at 1377.
[78] Margaret S., 597 F. Supp. at 673.
[79] LEE & MORGAN, *supra* note 71, at 287.
[80] ANDREWS, *supra* note 15, at 221.
[81] 42 U.S.C. § 263a(1)-(4) (1991).
[82] *Id.*

established the Biomedical Ethics Advisory Committee in 1988, and the NIH formed an advisory panel in 1994 to make recommendations regarding embryo research.[84] However, both of these bodies continued to be hindered by the divide on abortion issues.

The FDA claims authority over human cellular and tissue-based products, which include embryos, under the authority of section 361 of the Public Health Service (PHS) Act.[85] The PHS Act provides authority to enforce regulations necessary to "prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States."[86] However, the FDA's final rule provides an exception for reproductive tissues establishments that perform only "certain limited activities that raise limited communicable disease concerns."[87] PGD seems to fall under this exception for establishments that only "recover reproductive cells or tissue for immediate transfer into a sexually intimate partner of the cell or tissue donor."[88]

With the exception of the Fertility Clinic Success Rate and Certification Act, these agencies have been advisory in nature. Procedurally, we must consider the establishment of a separate and independent regulatory agency to review applications for the development and implementation of new applications of PGD. This agency should apply the principle of placing the burden of proof of efficacy and safety–in terms of the effects on the children and to society–to those clinics who wish to offer new techniques of PGD technologies. We must be particularly careful when attempting to implement this type of technique based legislation that is targeted at a particular technology (i.e. human cloning), because the line is often drawn to be overly conservative and may be unconstitutional. Moreover, broad sweeping legislation is not as adaptable to changing science and, thus, deals with innovation by halting it.

Examining the governing body implemented in the United Kingdom offers some guidance in this area. The United Kingdom's Secretary of State for Social Services established a 16-member committee of inquiry in July of 1982, whose primary objective was to address the problem of relating legislation and morality to the business of assisted reproductive technology.[89] The committee issued the Warnock Report in 1984, which called for legislation and led to the

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[83] CDC, *Implementation of the Fertility Clinic Success Rate and Certification Act of 1992: A Model Program for the Certification of Embryo Laboratories*, *at* http://www.phppo.cdc.gov/dls/art/fcsrca_9907.asp.
[84] George Annas, *Human Cloning: A Choice or an Echo?*, 23 DAYTON L. REV. 247, 266 (1999).
[85] Public Health Services Act, 42 U.S.C. § 262 (2001).
[86] 42 U.S.C. § 361.
[87] *Id.*
[88] *Id.*
[89] Stenger, *supra* note 7, at 140.

creation of the Human Fertilization and Embryology Authority (HFEA) in 1990. The HFEA is a licensing authority that authorizes and regulates clinics that offer assisted reproductive procedures. The Authority conducts annual inspections of clinics, grants licenses for treatment services or research, and defines the boundaries beyond which treatment and research must not venture. The HFEA assures public representation by requiring that half of their members come from areas of specializations outside of medicine and research.[90] These members are recruited from outside the medical community via newspaper advertisements.[91] Their meetings are closed to the public and only skeletal minutes are published without individual comments.[92]

The HFEA has set forth training and assessment criteria for laboratories and for individuals carrying out the embryo biopsy part of the PGD procedure. They require each biopsy practitioner to be "individually inspected and assessed according to these criteria and their names registered centrally with the HFEA."[93] The guidelines specify methods of gaining experience and stipulate demonstrations of proficiency in using FISH and PCR techniques. Moreover, inspectors and peer reviewers are recruited to evaluate applications to carry out new PGD tests.[94] Clinics cannot perform any other tests or treat any individuals for new disorders without approval.[95] Additionally, once practitioners are licensed they are required to submit to annual inspections and to report the results of their progress.[96]

Section VI. Building on current regulations

The United States established the Recombinant DNA Advisory Committee (RAC) on October 7, 1974.[97] The goal of the RAC is to "consider the current state of knowledge and technology regarding recombinant DNA."[98] This includes reviewing human gene transfer trials, assessing the risks of potential transfer of genetic material to other organisms, and evaluating hypothetical hazards and methods for monitoring and minimizing risks.[99] The composition of

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[90] Brendan Koerner, *Embryo Police*, WIRED, Feb. 2002, at 53.
[91] *Id.*
[92] *Id.*
[93] HFEA, *HFEA Annual Report 2000*, *at* http://www.hfea.gov.uk/Downloads/Annual_Report/AnnualReport2000.pdf.
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] Recombinant DNA Advisory Committee, *About Recombinant DNA and Gene Therapy*, *at* http://www4.od.nih.gov/oba/rac/aboutrdagt.htm.
[98] *Id.*
[99] *Id.*

RAC is very similar to that of the HFEA as approximately one-third of the fifteen members do not have scientific backgrounds.[100]

The RAC has enacted guidelines to apply to "all NIH-funded projects involving recombinant DNA techniques as well as to all non-NIH funded research involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving such techniques."[101] Therefore, a logical place to implement regulatory authority seems to exist through expanding the committee's jurisdiction beyond that of publicly funded gene therapy to include the review of procedures developed for reproductive purposes. In the vein of the HFEA, the RAC would be both a rule-making and an adjudicatory authority. Their function would be to perform accreditation of laboratories and licensing of PGD in relation to each specific test and condition.

George Annas of Boston University believes that "a meaningful dialogue on such an important topic can't be left solely to experts; it needs public deliberation." A solution that provides this much-needed element of public transparency would be to establish an institutional review board (IRB) within the RAC. An IRB could require that every new test to be used and every new disorder to be tested for be approved in advance. The disorders should be defined down to the level of each different mutation, and then listed on a license under specific headings. The screening procedures should only be approved when there can be a compelling demonstration of a definite benefit to society and to the child. An IRB would place this burden of proof on parents to show these tests offer an immediate therapeutic benefit to the child and lack the potential to do significant harm to society. Immediate therapeutic benefits exist where preventative treatments or early interventions are available, and where these interventions would be more beneficial than they would be harmful. Accordingly, an IRB could deny access to tests that do not offer such benefits. Thus, IRB approval would, in effect, take the discretion away from clinicians–who often have a financial stake in offering new procedures–and place the issue up for evaluation by an impartial committee.

Developments in equipment and know-how will enable procedures such as IVF and PGD to be offered to a wider array of individuals. The potential this technology has to eliminate genetic disease and to extend life will have a substantial impact on future generations. Policymakers should act with deliberate speed in implementing the necessary substantive and procedural strategies that are essential to protect future parents and their children.

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[100] *Id.*

[101] Amy P. Patterson, M.D., *NIH Guidelines for Research Involving Recombinant DNA Molecules*, *at* http://grants1.nih.gov/grants/policy/recombinentdnaguidelines.htm.