THINKING HYPOTHETICALLY REALISTICALLY: PREIMPLANTATION GENETIC DIAGNOSIS AND THE LEGAL LANDSCAPE

by
John Gehring

Submitted in partial fulfillment of the requirements of the
King Scholar Program
Michigan State University College of Law
Under the direction of
Professor Melanie B. Jacobs
Fall, 2010

ABSTRACT

Discussion of the future of genetic selection of children often focuses on genetic engineering and "designer babies." Such technology may never come to fruition. In this paper, I would like to focus on something that is more realistic: preimplantation genetic diagnosis (PGD) for complex traits. PGD has important limitations compared to genetic engineering: the number of embryos available to choose from is limited, and the embryos themselves are limited to the genetic contributions of the potential parents. Choosing for complex traits will inevitably force some parents utilizing PGD to make trade-offs between one complex trait and another. This paper will introduce PGD as it stands today, and then examine constitutional arguments regarding procreative liberty and if they apply to PGD for complex traits. After discussing some of the concerns regarding the current uses of PGD and how it is regulated in different counties, I will conclude with a discussion of whether and how PGD for complex traits should be regulated. While concluding that PGD for complex traits is not a constitutionally protected fundamental right and thus open to significant regulation, I argue that future regulation, at least initially, should be limited to ensuring government receives comprehensive data on testing being conducted, rigorous informed consent is utilized, and appropriate standards for testing are set.

INTRODUCTION: WHAT IS PREIMPLANTATION GENETIC DIAGNOSIS?

Preimplantation Genetic Diagnosis (PGD) involves in vitro (outside the body) testing of embryos or oocytes, historically for various genetic abnormalities, rather than relying on pre-natal diagnosis and potential abortion.[1] First demonstrated in rabbits in 1968, development of in vitro fertilization (IVF) and technological advances enabling genetic diagnosis of singe cells led

[1] JPM Geraedts & GMWR De Wert, *Preimplantation Genetic Diagnosis*, 76 CLINICAL GENETICS, 315, 315 (2009).

to the first instance of PGD in the human context in 1989.[2] PGD is one step of the assisted reproduction process, which begins with stimulation of the ovaries, oocyte retrieval, and then fertilization.[3] PGD testing is performed on either a polar body[4] or a cell or cells removed from the embryo at three to five days after fertilization.[5] Embryos that are deemed desirable by PGD are not necessarily implanted. Embryos must also be embryologically viable.[6] PGD does not alter the genetic makeup of an embryo and is thus not genetic engineering.[7] PGD only allows parents to choose among the genetic variations they were able to produce.[8]

Currently, the reasons for utilizing PGD generally falls into one of seven categories: monogenic disorders (disorders caused by a defect in a single gene), structural chromosomal abnormalities (for example, part of one chromosome being located on a different chromosome), aneuploidy (three or one copy of a chromosome rather than two), mitochondrial disorders, stem cell transplantation ("savior sibling") sexing for X-linked disorders (disorders associated with genetic defects on the X chromosome that affect males), and sexing for social reasons such as family balancing.[9] While PGD is not currently utilized for complex traits, in 2009 a fertility

---

[2] *Id*.
[3] *Id*.
[4] The polar body is a byproduct of oogenesis, and contains the genetic material of the mother only.
[5] Geraedts & De Wert, *supra* note 1, at 316.
[6] Kathryn Ehrich & Clare Williams, *A 'Healthy Baby': The Double Imperative of Preimplantation Genetic Diagnosis*, 14 HEALTH 41, 50 (2010).
[7] GENETICS & PUBLIC POLICY CENTER, PREIMPLANTATION GENETIC DIAGNOSIS: A DISCUSSION OF CHALLENGES, CONCERNS, AND PRELIMINARY POLICY OPTIONS RELATED TO GENETIC TESTING OF HUMAN EMBRYOS 4 (2004).
[8] *Id*. at 3.
[9] Geraedts & De Wert, *supra* note 1, at 317-20.

clinic in Los Angeles began advertising the forthcoming availability of PGD for eye color, hair color, and complexion.[10] This claim, however, has not yet come to fruition.[11]

The most recent data available on the use of PGD is from 2006 in Europe and 2007 in the United States. Data available on the use of PGD in the U.S. is limited. Data from the CDC indicate that PGD was utilized in approximately 5% of the 142,435 Assisted Reproduction Technology (ART) cycles performed in 2007, which would equate to approximately 7,000 ART cycles utilizing PGD.[12] One reference laboratory performing testing on biopsied embryos reported 246 instances of PGD for non-therapeutic sex selection between January of 2006 and August of 2007.[13] This would equate to roughly 148 instances of non-therapeutic sex selection per year. As this is only an unknown fraction of non-therapeutic sex-selection conducted in the United States, it appears PGD for this purpose is significantly more common in the United States than in Europe, where there were only 82 PGD cycles for social sexing in 2006.[14]

---

[10] William Saletan, *Color ID: Screening embryos for eye, hair, and skin color*, SLATE (Fe. 17, 2009, 8:10 AM), http://www.slate.com/id/2211390.

[11] The link advertising hair color, eye color, and complexion selection provided in the above article from slate.com currently directs to the clinics "what's new" page. There is currently no mention on the website of selection of eye color, hair color, or complexion. *See* THE FERTILITY INSTITUTES, http://www.fertility-docs.com/news_events.phtml?ID=22 (last visited November 18, 2010).

[12] CENTERS FOR DISEASE CONTROL AND PREVENTION, 2007 ASSISTED REPRODUCTION TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 5, 91 (2009). An ART cycle is defined as when a woman begins taking drugs to stimulate egg production. *Id*. at 4.

[13] Pere Colls et al., *Preimplantation genetic diagnosis for gender selection in the USA*, 19 Sup. 2. REPRODUCTIVE BIOMEDICINE ONLINE 16, 18 (2009). The laboratory receives embryo biopsies from referring facilities across the country, and the study was based on PGD cycles performed for 53 IVF centers.

[14] V Goossens et al., *ESHRE PGD Consortium Data Collection IX: Cycles from January to December 2006 with pregnancy follow-up to October 2007*, 24 HUMAN REPRODUCTION 1786, 1804 (2009).

Data available from Europe is more comprehensive. In Europe, there were 5,858 PGD cycles in 2006.[15] Aneuploidy (also known as PGS in Europe) screening is utilized for women undergoing IVF in an attempt to identify normal embryos for transfer, and thus increase the chances of a successful pregnancy.[16] The Genetics and Public Policy Center speculated that aneuploidy screening would soon constitute the majority of PGD procedures,[17] and in Europe this has been the case, where aneuploidy screening accounted for nearly two-thirds of all PGD testing in Europe.[18] Recent randomized control trials have not shown that aneuploidy screening increases the chances of a successful pregnancy and may even reduce live birth rates; the American Society of Reproductive Medicine and the British Fertility Society do not support aneuploidy screening.[19]

In addition to social sexing, the other more controversial types of PGD are also performed at very low levels. In 2006, there were 29 PGD cycles for "savior siblings."[20] There were only three cycles of PGD for pre-disposition to breast cancer.[21]

There is no guarantee that a PGD cycle will result in the birth of a child. Success rates are currently quite modest. For example, 2006 data from Europe indicate there were 812 oocyte retrieval procedures for chromosomal abnormalities, yielding 11,411 oocytes.[22] This yielded

---

[15] *Id*. at 1788.
[16] Geraedts & De Wert, *supra* note 1, at 320.
[17] GENETICS & PUBLIC POLICY CENTER, *supra* note 7, at 3.
[18] V Goossens et al., *supra* note 14, at 1789.
[19] Geraedts & De Wert, *supra* note 1, at 320.
[20] *Id*. at 1791.
[21] Human Reproduction, *SupplementaryTable IIIc*, http://humrep.oxfordjournals.org/content/suppl/2009/04/29/dep059.DC1/Table_IIIC.pdf
[22] Geraedts & De Wert, *supra* note 1, at 321.

5062 biopsied embryos, and 1126 of those were transferable.[23] There were 493 embryo transfer procedures and 126 deliveries, for an overall delivery rate of 15%.[24]

CONSTITUTIONAL QUESTIONS: BECAUSE PGD FOR COMPLEX TRAITS IS FAR REMOVED FROM THE MORE BASIC DECISION OF WHETHER OR NOT TO PROCREATE, THE SUPREME COURT IS UNLIKELY TO IMPOSE HEIGHTENED SCRUTINY ON PGD FOR COMPLEX TRAITS

As use and uses of PGD increase, so too will calls for its regulation in the United States. The following section examines whether PGD, in particular PGD of complex traits, may avoid heightened constitutional scrutiny. Proponents of viewing PGD as a fundamental right take a broad view of procreative liberty, arguing that where differences in the traits of offspring affect the relational experience of parent to child, parents have the right to effectuate those preferences, and that the potential harms are too speculative to justify infringing upon procreative liberty.[25] Skeptics point out that there is a total absence of Supreme Court precedent in the area of reproductive technologies, and while the Supreme Court would presumably recognize a constitutional right to reproduce, and quite possibly the right of infertile couples to utilize reproductive technologies, a very expansive reading of Supreme Court precedent is required to find a fundamental right to select offspring characteristics.[26] I will argue that current Supreme Court precedent is unlikely to support a fundamental right to PGD for complex traits.[27]

---

[23] *Id*.
[24] *Id*.
[25] John A. Robertson, *Preconception Gender Selection*, 1 THE AMERICAN JOURNAL OF BIOETHICS 2, 6-7 (2001).
[26] Carl H. Coleman, *Is There a Constitutional Right to Preconception Sex Selection?*, 1 THE AMERICAN JOURNAL OF BIOETHICS 27, 27-28 (2001).
[27] Much of the discussion of case law in this section will follow the framework from Dov Fox, *Silver Spoons and Golden Genes: Genetic Engineering and the Egalitarian Ethos*, 33 AM. J. L. & MED. 567, 574-79 (2007).

The Supreme Court has a History of Protecting Basic Decisions Regarding Reproduction.

The history of Supreme Court jurisprudence in regards to procreation begins with a rejection of the notion that the right to procreate is a fundamental liberty interest protected by due process.[28] In a rather abbreviated opinion, the Court upheld a Virginia statute that allowed the State to sterilize Carrie Buck, a woman judged "feeble minded."[29] The statute allowed the superintendent of state mental institutions to sterilize individuals when he determined it was in the best interests of the patient and society.[30] In conclusion, Justice Holmes authored the now infamous phrase, "[t]hree generations of imbeciles are enough."[31] The Court's attitude toward government mandated sterilization made a distinct shift in *Skinner v. State of Oklahoma*.[32] The Court struck down Oklahoma's Habitual Criminal Sterilization act that allowed Oklahoma to sterilize individuals convicted of three felonies involving "moral turpitude."[33] The Court characterized the statute as one involving "the basic civil rights of man" and fundamental to existence.[34] While basing its decision on equal protection rather than due process grounds, the court concluded any statute giving a state the power to sterilize its citizens must meet strict scrutiny.[35]

The concept of constitutional protection for procreational privacy begins with *Griswold v Connecticut*.[36] *Griswold* recognized a constitutionally protected privacy interest in the marital

[28] *Buck v Bell*, 274 U.S. 200 (1927).
[29] *Id*.
[30] *Id*. at 206.
[31] *Id*. at 207.
[32] *Skinner v. State of Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942).
[33] *Id*. at 536.
[34] *Id*. at 541.
[35] *Id*.
[36] *Griswold v. Connecticut*, 381 U.S. 479 (1965).

home, striking down a Connecticut statute that prohibited the use of contraceptives.[37] Perhaps significantly for an analysis of a proposed constitutionally protected liberty interest, the Court found that while it was not their place to judge the wisdom of laws relating to economics or social conditions, "this law, however, operates directly on an intimate relation of husband and wife and their physician's role in one aspect of that relation."[38] The Court found decisions relating to contraception in the marriage relationship lied in "zones of privacy created by several fundamental constitutional guarantees," ultimately concluding, "[w]ould we allow the police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives? The very idea is repulsive to the notions of privacy surrounding the marriage relationship."[39]

Procreational privacy was then broadened from the marriage context in *Eisenstadt v. Baird*.[40] The Court struck down a Massachusetts law that made dispensing contraception to anyone other than married persons a felony.[41] In striking down the law on Equal Protection grounds, the court recognized that a marital couple is not an entity unto itself, but represents two individuals. Therefore, "[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."[42]

The year after the *Eisenstadt* decision, the Court extended the right of privacy and personal liberty under the due process clause to a woman's decision whether or not to have an

---

[37] *Id*. at 485-86.
[38] *Id*. at 482.
[39] *Id*. at 485-86.
[40] *Eisenstadt v. Baird*, 405 U.S. 438 (1972).
[41] *Id*. at 454-55.
[42] *Id*. at 453 (citing *Stanley v. Georgia*, 394 U.S. 557 (1969); *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942); *Jacobson v. Massachusetts*, 197 U.S. 11, 29 (1905)).

abortion.[43] The court found that this right was "not unqualified" and thus adopted a trimester-based framework to accommodate the State's interest in the health of the mother and potential life.[44] The right was then modified in *Planned Parenthood v. Casey*, removing the trimester framework, holding that, prior to viability of the fetus, the State may express a preference for childbirth, so long as state regulation does not impose an "undue burden on a woman's ability to make this decision."[45] In affirming the essential holding of *Roe*, the court framed the liberty interests protected by due process in broad terms:

> Our law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education. … These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.[46]

If read narrowly, the case-law protects against state interference with specific acts: avoiding an unwanted pregnancy, terminating an unwanted pregnancy, and the decision of the state that an individual should not reproduce.[47] There is a good case to be made, however, that the Court would interpret the principles of these cases more broadly.

In striking down a Texas criminal statute prohibiting sodomy in 2003, the Court in *Lawrence v. Texas* held that "liberty gives substantial protection to adult persons in deciding how to conduct their private lives in matters pertaining to sex."[48] The court justified this broad

---

[43] *Roe v. Wade*, 410 U.S. 113, 153 (1973)
[44] *Id.* at 154, 163-64.
[45] *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 874 (1992).
[46] *Id.* at 851.
[47] Fox, *supra* note 26, at 577.
[48] *Lawrence v. Texas*, 539 U.S. 558, 559 (2003).

language specifically by referring to *Casey* and the language quoted above.[49] Similarly, the Court may interpret liberty to give protection to individuals in "deciding how to conduct their private lives" in matters pertaining to procreation.[50] But even if interpreted broadly, would the Court realistically find a fundamental liberty interest in PGD for complex traits? It is important to note that while the statute in *Lawrence* was struck down, a fundamental right triggering heightened scrutiny was not announced, as the statute did not further any legitimate state interest.[51] While it may be likely that the Supreme Court would interpret due process to give individuals "the freedom to decide whether or not to have offspring and to control the use of one's reproductive capacity"[52] expecting the Supreme Court to deem PGD for complex traits constitutionally protected may be a field too far.

The argument focuses on the *Casey* protection for "choices central to personal dignity and autonomy."[53] Proponents argue there is a broad concept of procreative liberty allowing individuals almost complete autonomy of their reproductive capacity.[54] This broad reading for procreative liberty is justified by "parental interest in self-expression in matters of reproductive selection and design."[55] The choice to reproduce or not is central to one's sense of self, and if the choice to reproduce is a fundamental right, then pre-birth control over offspring characteristics should follow from that.[56] This follows, it is argued, because individuals seek or avoid

---

[49] *Id*. at 559, 574.
[50] Fox, *supra* note 26, at 577.
[51] *Lawrence*, 539 U.S. at 578.
[52] JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES 16 (1994).
[53] *Casey*, 505 U.S. at 851.
[54] Fox, *supra* note 26, at 578.
[55] *Id*.
[56] John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 425-27 (1996).

reproduction because of the experience it will provide.[57] "If a couple would not reproduce if a child had gene A but would if it had gene B, procreative liberty should protect their decision not to reproduce in the first case and to reproduce in the second. Denying them information about A or B, or denying them the ability to make reproductive choices based on that information, will interfere with their procreative liberty."[58]

Because of the Deep Split Within the Supreme Court Regarding How Fundamental Rights Should be Defined, it is Unlikely the Court Would Expand Procreational Privacy Far Enough to Include PGD for Complex Traits.

It seems unlikely the Supreme Court would frame the issue quite so broadly. When examining this question, one must think about the disagreement within the court on how fundamental rights are identified, and their boundaries determined. The case of *Michael H. v. Gerald D.* is illustrative.[59]

Michael H. had an affair with Victoria, a married woman, who subsequently gave birth to a child that blood tests showed a 98% probability Michael was the child's father, and Michael had an ongoing relationship with the child. When Michael was no longer allowed to see the child, he filed a filiation action in California to establish paternity and visitation rights. California law, however, stated that – unless important or sterile – a husband cohabitating with his wife is the presumptive father of any child, and that presumption could only be rebutted by the mother or the husband.[60] The court upheld the statute, a plurality of the court finding the

[57] *Id.* at 427.
[58] *Id.*
[59] *Michael H. v. Gerald D.*, 491 U.S. 110 (1989)
[60] *Id.* at 113-15.

interest present was not a fundamental right rooted in the traditions and conscience of the nation.[61]

Writing for the plurality, Justice Scalia framed the issue as "whether the relationship between persons in the situation of Michael and Victoria has been treated as a protected family unit under the historic practices of our society."[62] Framed in this fashion, Justice Scalia found no support for the power of a natural father to assert parental rights to a child born into a woman's marriage with another man.[63] In a footnote joined only by the Chief Justice, Justice Scalia outlined his method for identifying fundamental rights: examining the rights historically afforded an adulterous natural father with respect to the marital family was the correct inquiry, rather than dissent's inquiry into protection afforded to parenthood generally, because he argued there was no basis for that level of generality. Examining the rights afforded adulterous natural fathers, on the other hand, was the most specific level at which a tradition is found, and protection was clearly *denied* historically.[64] Allowing judges to choose the level of generality to assess a right, argued Justice Scalia, "leav[es] judges free to decide as they think best" and "a rule of law that binds neither by text nor by any particular, identifiable tradition is no rule at all."[65]

Writing in dissent, Justice Brennan questioned Justice Scalia's assertion that tradition could yield definitive contours to liberty, arguing that tradition was an equally "malleable and elusive" concept with no objective means to define it.[66] The plurality chose not to focus on the protection parenthood has historically received by the courts because it was too clear for

---

[61] *See id*. at 124.
[62] *Id*.
[63] Indeed, Justice Scalia found quite the opposite. *Id*. at 124-26.
[64] *Id*. at 127, n. 6.
[65] *Id*.
[66] *Id*. at 137 (Brennan, J. dissenting).

dispute.[67] Justice Brennan argues that drilling down to the specific variety of parenthood ignored precedent: cases such as *Eisenstadt* and *Griswold* would have reached different results under this method of analysis.[68] Further, Justice Brennan argued that there was good reason to limit the use of tradition in interpreting the "deliberately capacious" language of due process.[69] By requiring specific approval from history and focusing on whether an interest has been traditionally protected "rather than one that society traditionally has thought important (with or without protecting it)," substantive due process is reduced to protecting the already protected, making due process a redundancy.[70]

In contrast to *Michael H*, the Court in *Lawrence* did not frame the constitutional question nearly so narrowly. The Court explicitly rejected the framing of the issue advanced in *Bowers v. Hardwick*, a previous case involving a criminal statute prohibiting sodomy, where the issue was stated as "whether the Federal Constitution confers a fundamental right upon homosexuals to engage in sodomy."[71] The majority concluded this framing of the issue "demeans the claim" and instead focused on the statutes "more far reaching consequences, touching upon the most private human conduct, sexual behavior, and in the most private of places, the home."[72]

And so the debate rages on, with no particular agreement on the methodology to identify fundamental rights and their scope. How would the court define procreative liberty? Certainly the affirmative decision to have a child would seem to fall under the rubric of choices "central to personal dignity and autonomy" of *Casey*, but how would the Court define its outer boundaries? Following Justice Scalia's mode of analysis from Michael H would suggest a rather narrow

---

[67] *Id*. at 139.
[68] *Id*. at 139-40.
[69] *Id*. at 140.
[70] *Id*.
[71] *Lawrence*, 539 U.S. at 566 (quoting *Bowers v. Hardwick*, 478 U.S. 186, 190 (1986)).
[72] *Id*. at 567.

boundary. There is arguably no deeply rooted historical tradition of ART since it simply is so recent. Given this fact, following Justice Scalia's analysis would likely limit procreative liberty to coital reproduction. This arguably illustrates some of the shortcomings of Scalia's analysis elucidated by Justice Brennan. ART has been with us for thirty years, PGD for twenty. At what point do they become sufficiently rooted in our history to become traditions relevant to liberty? Fifty years? 200 years? That decision seems to hand judges as least as much discretion as choosing the level of generality that an issue is framed. Such a strictly defined definition of procreative liberty would give the State the power to consign couples with a high risk of conceiving a child doomed to early death because of a genetic disorder with the option to either forgo reproduction or choose prenatal diagnosis and abortion of the affected fetus. Constitutional protection to abort an affected fetus with simultaneous denial of constitutional protection to choose an unaffected embryo would seem extremely anomalous.

On the other side of the coin, a constitutional right to select an embryo based on whatever criteria one desires seems equally untenable. This takes the procreative decision outside of something central to autonomy to something perhaps quite trivial. Given the limited number of embryos from which to choose, limited by the genetic material of the progenitors, PGD for complex traits will inevitably involve tradeoffs. Should a parent who wants to maximize a child's intelligence choose the embryo with the greatest odds for superior academic achievement, even though that same embryo harbors an increased risk for heart disease compared to other embryos? What about if the parent was most interested in hair color, or skin tone? The decision to have a child is fundamentally different from preferring certain characteristics for that child. New technologies should not be enshrined in the constitution and subject law addressing it to heightened judicial scrutiny simply because they relate to procreation. The State should have the

authority to take a precautionary approach if it so desires. When facing a new technology, potential harms to individuals or society is necessarily speculative, and the State may decide the risks rational enough to impose limits before the speculated harm materializes. Expanding procreative liberty in such drastic fashion would certainly give credence to Justice Scalia's criticism that allowing judges to determine the correct prism of generality gives them too much authority to impose their own preferences.

Professor John Roberts, using the example of PGD for perfect pitch, argues that selection of embryos should be allowed for such a purpose if the couple can demonstrate it is of great importance:

> Ultimately, the judgment of triviality or importance of the choice within a broad spectrum rests with the couple. If they have a strong enough preference to seek PGD for this purpose and that preference rationally relates to understandable reproductive goals, then they have demonstrated its great importance to them. Only in cases unsupported by a reasonable explanation of the need—for example, perhaps creating embryos to pick eye or hair colour, should a person's individual assessment of the importance of creating embryos be condemned or rejected.[73]

While this may be a fine policy argument, as Justice Scalia might say, "this is not the stuff of which fundamental rights … are made."[74] It would not be possible to hinge the extent of procreative liberty based on each individual's personal preferences on equal protection grounds. Therefore, if it's feasible that a couple could demonstrate a strong preference related to reproductive goals for a particular trait, PGD for that trait would be constitutionally protected, a reading of procreative liberty that strikes the author as seriously overbroad and that a swing vote on the Court would be unlikely to adopt. For example, in *Lawrence*, Justice Kennedy focused on

---

[73] John A. Robertson, *Extending Preimplantation Genetic Diagnosis: Medical and Non-Medical Uses*, 29 J. MED. ETHICS 213, 215 (2002).

[74] *Micheal H.*, 491 U.S. at 127. I do not mean to imply that professor Roberts is making a constitutional argument in the cited article. His argument is an ethical one.

the fact that the case did not involve minors or formal government recognition of homosexual relationships: in short, "[t]he petitioners are entitled to respect for their private lives." PGD, on the other hand, involves the testing and selection of embryos that, if implanted successfully, the State has a legitimate interest in from the outset of the pregnancy.[75] Six years prior to *Lawrence*, the Court declined the opportunity to give an expansive reading to personal autonomy, upholding a Washington law banning assisted suicide.[76] The majority specifically rejected the respondents reliance on *Casey*: "[t]hat many of the rights and liberties protected by the Due Process Clause sound in personal autonomy does not warrant the sweeping conclusion that any and all important, intimate, and personal decisions are so protected."[77] Given the State's immediate interest in the product of PGD, it seems unlikely that a swing vote on the Court would find regulation of PGD for complex traits subject to heightened scrutiny.

It seems most likely that, as is the case with abortion, the Court would strike an uneasy middle ground. The Court may protect as a fundamental a right of access to PGD that has a real and undeniable effect on the decision to procreate: PGD for genetic disorders that result in early death or severe disability. Parents at significant risk of conceiving a child consigned to an early death or severe disability face a true constraint on their ability to procreate: accept the likelihood of conceiving and perhaps aborting a child that is doomed or simply choose not to conceive. This offers the benefit of a relatively bright line.[78] PGD for complex traits, however, is unlikely to effect the fundamental decision of whether to procreate or not, and the Court should not subject laws regulating it to heightened scrutiny. The number of individuals who would forgo

---

[75] *Casey*, 505 U.S. 846.
[76] *Washington v. Glucksberg*, 521 U.S. 702, 736 (1997).
[77] *Id.* at 727.
[78] There would, of course, likely be significant disagreement on the margins of what is sufficiently severe, and what death sufficiently early.

having a child because they could not, for example, choose an embryo more likely to have high academic achievement, is likely vanishingly small to non-existent. This flexibility allows States to be responsive to legitimate concerns of a technology whose effects are unknown.

Another avenue for asserting a fundamental right to PGD for complex traits would be by analogy to the "right of parents to make decisions concerning the care, custody, and control of their children."[79] The Court has characterized this right as "perhaps the oldest of the fundamental liberty interests recognized by this Court."[80] The argument, then, is if parents have extensive freedom to shape their children through how they rear them, what is the difference between shaping them through decisions about their child's genetics?[81] Childhood influences can ingrain characteristics in a child while they are too young to contest it, and in that sense are no less permanent than selected genetic characteristics.[82]

Analogy to the Right of Parents to the Care, Custody, and Control of Their Children is Unpersuasive Because it Gives the Embryo the Same Status as the Child.

Regardless of the merits of the analogy, it appears to contain a significant flaw that renders the analogy a nullity: under the above reasoning, an embryo is given the same status as a living, breathing child. Once the embryo is given the same status as a child, the logic of the whole system clearly breaks down. If the parent's interest in control of the child extends to the embryo, then by the same analogy the State's own compelling interest in preservation of the child's life should extend to each and every embryo. At this point, the state could ban ART entirely and still pass strict scrutiny. Alternatively, if the embryos are considered merely property, then the process of PGD is reduced to nothing more than an economic transaction,

[79] *Troxel v. Granville*, 530 U.S. 57, 66 (2000) (citations omitted).
[80] *Id.*
[81] Fox, *supra* note 26, at 578-79.
[82] *Id.*

something the Supreme Court long ago got out of the business of applying heightened scrutiny to.[83] Another alternative argument could be that the parents have a heightened interest while the State does not due to the parents' exercise of their procreational rights to control the embryo just as they control the resulting child. But now the argument has come full circle: it is substantively no different than the previously discussed argument regarding reproductive autonomy.

While PGD for complex traits would undoubtedly be a highly complex, personal, and individualized decision, this does not automatically grant that decision protection as a due process liberty interest. Even considering the court's more expansive reading of liberty in *Lawrence*, the context of that case and the Court's general reluctance to grant sweeping protected liberty interests ultimately indicate that constitutional protection for PGD is unlikely to extend to complex traits.

CURRENT CONTROVERSIAL USES OF PGD: SOCIAL SEXING AND HEREDITARY BREAST AND OVARIAN CANCER

This section discusses two of the more controversial aspects of PGD: social sexing and hereditary breast and ovarian cancer (HBOC). Concerns surrounding both of these techniques are relevant to a discussion of PGD for complex traits. Social sexing is the first example of using PGD for selection relating to non-disease genes. PGD for HBOC identifies embryos at markedly increased risk for cancer, but the cancer does not develop until adulthood, if it develops at all.

Social Sexing Raises Concerns About Reinforcing Sexism and Genetic Control of Offspring that Supporters Contend are Overblown or too Speculative.

Arguments against social sexing can be separated into four categories: increasing sexism, societal sex-ratio imbalances, the welfare of children expected to act in conformance with their

[83] *See* e.g., *Williamson v. Lee Optical Co.*, 348 U.S. 483 (1955).

gender, and sliding further down the slope of genetic control of offspring.[84] Those concerned with the propensity for sex selection to lead to sexism state that history shows that gender selection has promoted and reinforced discrimination against females.[85] Pre-conception sex selection, then, can be seen as unjust because it could serve to perpetuate gender discrimination, allowing parents to use gender as a measure of a child's worth.[86] These concerns are particularly heightened when selecting the sex of a first-born child, as opposed to family balancing.[87] Closely related to arguments regarding sexism is that as a consequence of sexism in preconception gender selection, sex-ratio imbalances could result.[88] For example, new technologies enabling selective abortion of female fetuses have exacerbated already present sex-ratio imbalances in countries such as China, South Korea, and India.[89]

Another concern is that sex selection could affect the welfare of children where selection is purely for social reasons. Helping people have a particular kind of child is very different from helping people conceive generally.[90] Whether it is for diversity or selection of the gender of a first-born child to obtain a specific rearing experience, sex selection could have the capacity to reduce children to something more akin to products.[91] It would follow from this assertion that parents would then potentially be less willing to accept the shortcomings of their children.[92] This

---

[84] Robertson, *supra* note 25, at 4.
[85] Jenny Dai, *Preconception Sex Selection: The Perspective of a Person of the Undesired Gender* 1 THE AM. J. OF BIOETHICS 37, 37 (2001).
[86] *Id*.
[87] Robertson, *supra* note 73 at 214.
[88] *Id*.
[89] Giuseppe Benagiano & PaoloBianchi, *Sex Preselection: An Aid to Couples or a Threat to Humanity?* 14 HUMAN REPRODUCTION 868, 869 (1999).
[90] Rebecca Dresser, *Cosmetic Reproductive Services and Professional Integrity*, 1 THE AM. J. OF BIOETHICS 11, 11 (2001).
[91] Carson Strong, *Can't You Control Your Children?* 1 THE AM. J. OF BIOETHICS 12, 13 (2001).
[92] *Id*.

could undercut the child's self-esteem, which children may blame on their parents, and undercut family ties.[93]

Concerns about child-welfare, then, are fundamentally intertwined with concerns over greater genetic control of offspring. Sex selection moves society ever closer to genetically engineered offspring, and those already committed to ART are the ones most likely to take advantage of this technology since it can be added relatively cheaply.[94] This self-selected pool, already committed to pre-birth control of their offspring, may be at the greatest risk for a poor outcome if sex selection fails.[95] Parents less tolerant of shortcomings in their own children due to pre-birth selection may also have less compassion for the handicapped.[96] Sexism issues are also woven into the fabric of concerns about genetic enhancement. Being male confers advantages in our male-dominated society, and allowing parents to select a first-born male child inevitably allows some parents fulfill a vision of genetic enhancement.[97] In essence, the argument is that sex selection already puts society well down the proverbial slippery slope.[98] Therefore a better understanding of where this technology could take us is necessary before proceeding.[99]

Supporters of sex selection note that there is a difference between concluding a particular person's choice of sex selection is unethical and deciding all such decisions should be circumscribed.[100] Males and females are different, and it is not inherently sexist to seek variety

---

[93] *Id*.
[94] Nancy King Reame, *Gender by Design: Not Yet Ready for Prime Time*, 1 THE AM. J. OF BIOETHICS 29, 30 (2001).
[95] *Id*.
[96] Strong, *supra* note 91 at 13.
[97] *Id*.
[98] *Id*.
[99] *Id*.
[100] Rosamond Rhodes, *Acceptable Sex Selection*, 1 THE AM. J. OF BIOETHICS 31, 32 (2001).

in the rearing experience or prefer one experience to the other.[101] It is difficult to imagine any detectable demographic effect on sex ratios in the United States.[102] Research appears to support this conclusion that sex selection, in the aggregate, has not favored males over females.[103] Logically, it would seem that if male embryos are not preferred, fears over sexism should be assuaged. However, even if males are not preferred overall in sex selection in the United States, there is evidence males are preferred by certain ethnic groups.[104] Still, regulation of sex selection is unlikely to have any impact on controlling gender discrimination generally, and is a less harmful proposition than abortion.[105]

Arguments concerning the welfare of children ignore potential benefits and focus on harms that are highly speculative. Tangible benefits of sex selection include not exacerbating overpopulation problems by forcing parents to "try again" to have a child of the desired gender, and the corresponding ease in the economic burdens of providing for a large family.[106] In cases where a child of a certain gender is desired for discriminatory reasons, sex selection could prevent the psychological suffering of a child of the unwanted gender.[107] From a different perspective, prohibiting sex selection inherently cannot serve the best interests of the child because even if a female child was born where the parents desired a male, the resulting child can't be worse off than she should have been otherwise, because without the attempt at sex selection, the parents would have conceived a different child.[108]

---

[101] Robertson, *supra* note 73, at 214.
[102] *Id*.
[103] Colls et al., *supra* note 13, at 21 (2009).
[104] *Id*. at 18.
[105] Dai, *supra* note 85, at 38.
[106] Rhodes, *supra* note 100, at 31.
[107] *Id*.
[108] Julian Savulescu, *In Defense of Selection for Nondisease Genes* 1 THE AM. J. OF BIOETHICS 16, 17 (2001). Of course, from this perspective, the previously mentioned benefit of

Proponents of sex selection heavily emphasize the vital interest of personal autonomy and procreative liberty, arguing that personal satisfaction is an important moral consideration.[109] Sex selection is just one example of reproductive technology allowing parents to rear children with the qualities they value, be it health of otherwise.[110] People are motivated to have children by the personal satisfaction associated with being a parent: they are in the best position to evaluate what sort of rearing experience they want, and parents choosing their child's gender may be more likely to nurture that child well, increasing child welfare on the whole.[111] Prohibiting sex selection has an inherent conflict with a woman's rights concerning her reproductive choices: if a woman can choose to abort due to the gender of the fetus, it makes little sense to prevent her from exercising that same choice before the pregnancy even begins.[112] Procreative liberty should not be impinged merely because of theoretical harms that may or may not come to fruition.[113] "Allowing people to live their lives by their own lights and even to make some bad or even unethical decisions is inherent in our valuing liberty. A demonstration of actual overriding harms is the only legitimate justification for constraining liberty."[114]

---

avoidance of psychological harms to unwanted children would be obviated. The psychological consequences to that particular child would not affect the best interests of *that* child, because if the parents chose sex selection the child would not have been born, and presumably the child is better off having been born, even if her life is not as good as if she had been a male child. This represents a difference is perspective: the welfare of the particular child, or the welfare of children as a whole from the perspective of society.

[109] Rhodes, *supra* note 100, at 32.

[110] Gregory Stock, *Chance or Choice − Why Not Pick Our Children's Gender?* 1 THE AM. J. OF BIOETHICS 31, 32 (2001).

[111] Rhodes, *supra* note 100, at 31-32.

[112] Stock, *supra* note 110, at 31.

[113] *Id*.

[114] Rhodes, *supra* note 100, at 32.

PGD for HBOC Elicits Concerns Over Testing For Traits that Have no Effect on Offspring as Children, While Supporters Regard Age of Onset as Irrelevant.

PGD for HBOC raises its own concerns. The large majority of hereditary breast and ovarian cancer is associated with mutations in the BRCA1 and BRCA2 genes, giving rise to an estimated 50% to 80% lifetime risk of breast and ovarian cancer.[115] HBOC accounts for less than 10% of all cases of breast and ovarian cancer.[116] Ethical analysis of PGD for HBOC requires a balancing act: are the burdens on parents and children of carrying susceptibility genes great enough to justify the burdens of PGD to screen out affected embryos.

Skeptics point out that unlike other applications of PGD, where screening is for conditions causing death or severe disability in early childhood, PGD for HBOC screens for mutations that have no affect on the pregnancy, or on the offspring as children.[117] Treatments, from earlier and more aggressive screening, to chemoprevention or prophylactic surgery, are available to reduce the risk to a carrier.[118] If an individual is diagnosed with cancer, their quality of life both before and after diagnosis can be good.[119] Unlike sex selection, because there is no outward difference in the child ultimately produced, PGD for HBOC would not impact the day-to-day rearing experience of parents. PGD is costly, often failing to result in pregnancy. These realities justify at least caution, and taking measures to ensure adequate counseling of those considering PGD for HBOC without pressure to choose in favor of screening.[120]

---

[115] Ray Noble, *Pandora's Box: Ethics of PGD for Inherited Risk of Late Onset Disorders*, 17 Sup. 3 REPRODUCTIVE BIOMEDICINE ONLINE, 55, 56 (2008).
[116] G. F. Quinn et al., *Decisions and Ethical Issues Among BRCA Carriers and the Use of Preimplantation Genetic Diagnosis*, 100 MINERVA MEDICA 371, 372 (2009).
[117] Noble, *supra* note 115, at 36.
[118] *Id*.
[119] Tara Clancy, *A Clinical Perspective on Ethical Arguments Around Prenatal Diagnosis and Preimplantation Genetic Diagnosis for Later Onset Inherited Cancer Predispositions*, 9 FAMILIAL CANCER 9, 11 (2010).
[120] Noble, *supra* note 115, at 36.

Proponents argue that age of onset is irrelevant.[121] There simply is no good time to be afflicted by a genetic condition or any principled way to distinguish what age of onset should be deemed sufficiently serious.[122] Parents have a strong interest in having healthy children.[123] In families where most to all female members are affected, the fear of cancer is extreme, and prophylactic removal of the breasts or ovaries have significant physical and emotional costs.[124] None of the preventive measures listed above eliminates the risk of HBOC and research indicates parents have an interest in and a sense of responsibility for avoiding long-term health consequences for their children.[125] Given that these mutations are a major source of suffering for generations of families, that disease occurs later in life is not morally significant; the creation and destruction of embryos to eliminate the risk of HBOC is therefore far from frivolous.[126]

EXISTING REGULATION: REGULATION OF PGD RUNS THE GAMUT FROM TOTAL BANS TO THE ABSENCE OF ANY DIRECT REGULATION

Given the controversial nature of PGD, PGD is heavily regulated or banned in a number of countries. There are four general systems of regulation of PGD: constitutional or statutory bans, licensing and regulation through statute, regulation limited to professional organizations, and no regulation.[127]

---

[121] *See generally* Timothy Krahn, *Preimplantation Genetic Diagnosis: Does Age of Onset Matter (Anymore)?*, 12 MED. HEALTH CARE & PHIL. 187 (2009).
[122] *Id*. at 192.
[123] John A. Robertson, *Extending Preimplantation Genetic Diagnosis: The Ethical Debate*, 18 HUMAN REPRODUCTION 465, 467 (2003).
[124] Quinn, *supra* note 116, at 373.
[125] *Id*.; Clancy, *supra* note 119, at 11.
[126] Robertson, *supra* note 123, at 467.
[127] Aaron R. Fahrenkrog, *A Comparison of International Regulation of Preimplantation Genetic Diagnosis and a Regulatory Suggestion for the United States*, 15 TRANSNATIONAL LAW & CONTEMPORARY PROBLEMS 757, 762 (2005-2006).

Germany has been described as the "quintessential example of restrictive regulation.[128] Embryos are given the right to life at the time of fusion of the sperm and the egg under both the German Constitution and statute.[129] The ban is based upon human dignity, and the concept that no one should be disadvantaged by a handicap.[130] Other reasons behind the ban not expressed by statute include the eugenics of the Nazi regime and concern that children born as a result of parents' preferences may be accepted not for their own sake, but for the preferences chosen.[131] Support for the ban is certainly not unanimous, as surveys have indicated support for some PGD procedures among the German public[132] and one of two parliamentary ethics committees favored allowing PGD.[133] A limited variation of PGD does exist in Germany. Under the law, an embryo is created after the fusion of the maternal and paternal nuclei, twenty-four hours after insemination.[134] This allows genetic testing in this timeframe by biopsy of the polar body, allowing for testing of the maternal genotype.[135] This practice has its own ethical problems.[136] Consequently, treatment is not viewed in Germany as being worthwhile, and while formal referral is not allowed, patients subsequently go abroad.[137]

---

[128] Erik Aarden et al., *Providing Preimplantation Genetic Diagnosis in the United Kingdom, The Netherlands and Germany: a Comparative In-Depth Analysis of Health-Care Access*, 24 HUMAN REPRODUCTION 1542, 1545 (2009).
[129] Fahrenkrog, *supra* note 127, at 764.
[130] *Id*. at 764-65.
[131] *Id*. at 765.
[132] *Id*.
[133] Aarden et al., *supra* note 128, at 1545.
[134] *Id*.
[135] *Id*.
[136] "Because polar body biopsy looks only at maternal DNA, all mutation carriers for recessive and sex-linked disorders will be discarded, although half of these will develop to be either unaffected carriers or healthy girls." *Id*. Polar biopsy is allowed but considered "difficult and less reliable." ANNIEK CORVELEYN ET AL., PREIMPLANTATION GENETIC DIAGNOSIS IN EUROPE 41 (European Commission Joint Research Centre) (2007).
[137] CORVELEYN ET AL., *supra* note 136, at 41.

Presumed bans or tight restrictions on PGD in other European counties have recently been successfully challenged. In Ireland, PGD was presumed to be banned because the Irish Constitution protects the right to life of the unborn.[138] The question of whether or not an embryo is an "unborn" under the Irish Constitution was addressed in the case of *Roche v Roche*, where the court determined that the term "unborn" in the Irish Constitution does not include un-implanted embryos.[139] This would appear to open the door for PGD to take place in Ireland. In Italy, PGD was only allowed to determine if an embryo had a genetic disease if "serious and actual danger for the physical and mental health of the woman" was shown.[140] Italian courts have since opted for a less restrictive reading of Italian law, and held that performing PGD when there is a risk of serious genetic disease is acceptable.[141]

The United Kingdom (UK) is probably the most well known system of comprehensive regulation of PGD by government. Performing PGD requires licensure from the Human Fertilisation and Embryology Authority (HFEA) under the Human Fertilisation and Embryology Act of 1990.[142] Clinics must apply for a license for each new condition and new test they plan to perform, and providing false information to obtain a license is a crime punishable by imprisonment.[143] The HFEA Code of Practice allows testing of an embryo for three primary reasons:

---

[138] *Id*. at 65.

[139] *Roche v Roche*, 2009 IESC 82. The case did not involve PGD, but rather frozen embryos of a couple that had since divorced. The court held the right was defined by the capacity to be born, which could only arise after implantation.

[140] E Turillazzi & V Fineschi, *Preimplantation Genetic Diagnosis: A Step by Step Guide to Recent Italian Ethical and Legislative Troubles*, 34 JOURNAL OF MEDICAL ETHICS e21 (2008).

[141] *Id*.

[142] CORVELEYN ET AL., *supra* note 136, at 53. The UK is currently scheduled to eliminate the HFEA by April of 2013 and roll its functions into the Care Quality Commission. Daniel Cressey, *UK Embryo Agency Faces the Axe*, 466 NATURE 674, 674 (2010).

[143] Fahrenkrog, *supra* note 127, at 766-67.

(a) establishing whether the embryo has a gene, chromosome or mitochondrial abnormality that may affect its capacity to result in a live birth,
(b) in a case where there is a particular risk that the embryo may have any gene, chromosome or mitochondrion abnormality, establishing whether it has that abnormality or any other gene, chromosome or mitochondrion abnormality,
(c) in a case where there is a particular risk that any resulting child will have or develop –
(i) a gender-related serious physical or mental disability,
(ii) a gender-related serious illness, or
(iii) any other gender-related serious medical condition, establishing the sex of the embryo
***
(2) A licence... cannot authorise the testing of embryos for the purpose mentioned in sub-paragraph (1)(b) unless the Authority is satisfied–
(a) in relation to the abnormality of which there is a particular risk, and
(b) in relation to any other abnormality for which testing is to be authorised under sub-paragraph (1)(b), that there is a significant risk that a person with the abnormality will have or develop a serious physical or mental disability, a serious illness or any other serious medical condition.[144]

Licensing is thus fairly limited in scope: "social sexing" is not allowed, and the creation of "savior siblings" is subject to strict criteria. However, the number of conditions licensed by HFEA has grown significantly in the past few years. In 2007, the number of conditions licensed for PGD was over fifty.[145] Currently more than 150 conditions are licensed for PGD by the HFEA, including testing for hereditary cancer syndromes.[146] Some clinics feel that the bureaucracy of the HFEA causes delays that negatively impact patients, while another notes that applications are not turned down, rendering regulation superficial.[147] Other European countries,

[144] HFEA, Code of Practice § 10 (8th ed. 2010) *available at* http://www.hfea.gov.uk/docs/8th_Code_of_Practice(2).pdf
[145] CORVELEYN ET AL., *supra* note 136, at 53.
[146] Human Fertilisation Embryology Authority, *PGD Condition Licensed by the HFEA – Testing and Screening* http://www.hfea.gov.uk/cps/hfea/gen/pgd-screening.htm (last visited December 15, 2010).
[147] CORVELEYN ET AL., *supra* note 136, at 54.

such as France and The Netherlands, have similar highly regulated, centralized licensing schemes.[148]

Other European counties have more liberal regulation of PGD. Spain, for example, universally allows PGD to select embryos that are histocompatible with siblings in need of a bone marrow transplant, i.e., the creations of "savior siblings."[149] Belgium, meanwhile, has no specific regulation of PGD, although regulation in other fields serves to prohibit social sexing.[150] Not surprisingly, Spain and Belgium are among the leaders in the number of foreign citizens receiving PGD services within their respective borders.[151]

In Japan, two professional organizations, the Japan Society of Obstetrics and Gynecology, and the Japan Society of Fertility and Sterility regulate PGD.[152] Their regulations only allow PGD, including sex selection, in the case of severe hereditary disorders.[153] A dearth of consequences for violating guidelines can make it difficult for professional organizations to deter violations.[154]

The United States has not imposed any kind of formal regulation of PGD at this time.[155] This, in turn, makes more controversial forms of PGD more widely available, although, as noted earlier, there is paucity of data available for the United States. In Europe, it is very uncommon for a center performing PGD to engage in social sexing: a survey of fertility centers in Europe found only one center indicating it performed PGD for social sexing.[156] In the United States, one

---

[148] *Id*. at 38, 45.
[149] *Id*. at 68.
[150] *Id*. at 61-62.
[151] *Id*. at 28.
[152] Fahrenkrog, *supra* note 127, at 767.
[153] *Id*.
[154] *Id*. at 772-73.
[155] *Id*. at 768.
[156] CORVELEYN ET AL., *supra* note 136, at 15.

laboratory alone performed PGD for social sexing 246 times in less than two years.[157] The relatively wide availability of PGD uninhibited by regulation in the United States leads to Europeans utilizing the United States for PGD services. For example, a British couple was able to have PGD for selection of a savior sibling in the United States after being rejected by the HFEA.[158]

REGULATING PGD FOR COMPLEX TRAITS: BECAUSE CONCERNS REGARDING PGD FOR COMPLEX TRAITS ARE LARGELY HYPOTHETICAL, REGULATION SHOULD FOCUS ON ENHANCING PROCREATIVE LIBERTY

Given the current lack of regulation in the United States, how, or if, PGD will be regulated in the future as the traits that can be tested for increase in number and complexity is an open question. Technology will not suddenly allow one day for "designer babies," if it is even possible at all. PGD for complex traits will develop along a continuum, with different traits or disease risks being developed with varying degrees of predictive ability. For example, testing might be able to give relatively accurate information on an embryo's predisposition towards type II diabetes: three to six times the average population risk, depending on various environmental factors. On the other end of the spectrum, maybe genetic testing on an embryo could show a predisposition towards anti-social behavior, but testing is unable to show more than a 20% increase in risk. Currently, genome-wide association studies have identified a myriad of genetic risk markers for a range of chronic diseases, but most are associated with small increases in risk.[159] Future studies may identify rarer genetic variants that have larger effects,[160] but, in its

---

[157] Colls et al., *supra* note 13, at 18 (2009).
[158] CORVELEYN ET AL., *supra* note 136, at 71.
[159] Peter Kraft & David J. Hunter, *Genetic Risk Prediction — Are We There Yet?*, 360 NEW ENG. J. MED. 1696, 1697 (2009).
[160] David B. Goldstein, *Common Genetic Variation and Human Traits*, 360 NEW ENG. J. MED. 1701, 1701 (2009).

infancy, PGD for complex traits may involve relatively low predictive value. This is further complicated by how our genomes interact with our environment. For example, polymorphisms that are associated with disease in one environment can be protective in another.[161] Parents opting for PGD of complex traits would in most instances be choosing probabilities, rather than certainties. PGD for complex traits will tend to enhance some of the ethical and societal concerns identified previously for sex selection and HBOC. The following section examines how limited choice of embryos, the probabilistic nature of testing, and the subsequent trade-offs parents may be forced to make (should we select for height, or musical ability?) affect this analysis.

<u>While Legitimate, Concerns Regarding PGD for Complex Traits are Highly Speculative, and, Without More, Do not Justify the Infringement on Reproductive Autonomy.</u>

There may be greater concerns for psychological distress in offspring. Taking the example of parents selecting an embryo for greater musical ability, parents may excessively push the resulting child towards music, or be disappointed in their child if she does not show a predilection towards music, resulting in psychological distress for the child. "Having the way she is raised unduly affected by her parents' expectations consequent on their PGD decisions" could unduly restrict her "open future."[162] As discussed earlier, this is inconsequential to best interests of the child analysis, since the child is presumably better off having been selected and consequently born. Limiting the analysis to the best interest of the child, though, would be myopic. From the perspective of society, the welfare of children generally is certainly of

---

[161] *See e.g.* S. McLeish & S. W. Turner, *Gene–Environment Interactions in Asthma*, 92 ARCHIVES OF DISEASE IN CHILDHOOD, 1032, 1034 (2007) (Describing a polymorphism protective against asthma in a rural environment, but risk conferring in an urban environment).

[162] Rosamund Scott, *Choosing Between Possible Lives: Legal and Ethical Issues in Preimplantation Genetic Diagnosis*, 26 OXFORD J. LEGAL STUD. 153, 170 (2006).

consequence: if PGD for complex traits produced psychological distress in children that on the whole reduced the welfare of those children, this would be an important consideration. However, any hypothesized reduction in welfare is highly speculative. First, to assess the true negative consequences of PGD, one would need a measure of not only the effects of parental pressure on children chosen by PGD, but also pressure on children not a product of PGD. If a set of parents were sufficiently motivated to have a child with a high level of musical ability that they would choose the time and expense of PGD to achieve that goal, it seems likely that these parents would also exert a significant amount of pressure on *any* child to pursue music. It is not at all clear how much greater the pressure on a child of PGD would be, if at all. Balanced against the speculatively negative side of the equation must be the positive value to the welfare of children who, chosen for their predisposition for musical ability, do in fact share that interest, leading to a more fulfilling rearing experience. The extent of this positive side of the equation is also speculative. Such an unknown balance of harms and benefits is a weak argument for restricting access to PGD for complex traits.

Perhaps more persuasive are potential psychological consequences to parents who must make tradeoffs when choosing between embryos. For example, say a couple choosing PGD has two concerns: they desire a child predisposed to a high level of musical ability, and there is a family history of neural tube defects (NTDs).[163] The two best embryos have divergent characteristics: one has a lower probability of developing an NTD, but the genetic background

[163] Neural tube defects are birth defects of the brain and spinal cord. National Institute of Child Health and Human Development, *Neural Tube Defects (NTDs)* http://www.nichd.nih.gov/health/topics/neural_tube_defects.cfm/ (last visited November 18, 2010).
Neural tube defects result from a complicated milieu of genetic and environmental factors and their interactions. *See* Rebecca J. Schmidt et al., *Caffeine, Selected Metabolic Gene Variants, and Risk for Neural Tube Defects*, 88 BIRTH DEFECTS RESEARCH (PART A): CLINICAL AND MOLECULAR TERATOLOGY 560, 560 (2010).

does not show any particular predisposition towards musical ability; the other is three times as likely as the typical child to have high musical ability, but without a genetic background evincing protection against NTDs. Despite the family history of NTDs, the couple feels the absolute chances of having a child with an NTD are still low, and choose the embryo predisposed to musical ability. The child is born with spina bifida. What is the psychological effect on parents like this, who chose to take a risk and roll snake-eyes? When parents have to choose between different embryos predisposed towards different traits, parents may feel guilty or cheated having selected for one trait over another, only to not have the trait selected for realized. Of course it is also entirely speculative how often this sort of harm would occur, and its balance against the benefits to parents. These concerns may speak well to the idea of rigorous informed consent so individuals may pursue their reproductive autonomy in an informed manner, but are again a tenuous reason to restrict PGD.

Related to concerns over sexism in sex selection are concerns that PGD for complex traits could lead to discrimination against those with disabilities, or make it "more difficult to convince the successful to adopt a charitable moral posture toward those who are less fortunate."[164] These concerns are also blunted by the practical realities of PGD for complex traits, at least in its early stages. PGD will simply be unable to select "perfect" children. Even assuming scientific advances in embryo creation, the number of viable embryos to choose from will be limited, and the genetic content of the embryo is limited by the genetic diversity of the sperm and egg that created it. Prospective parents utilizing PGD for complex traits will face difficult decisions about what are, and are not, their priorities: musical ability or protection against high cholesterol; predisposed to above average height or analytical ability? Parents likewise will not be able to

[164] Fox, *supra* note 26, at 573.

eliminate all risks for disability. PGD cannot select an embryo guaranteed not to suffer a birth defect, because such an embryo simply does not exist. The genetic and environmental factors are simply too complex. Parents utilizing PGD will still have children with birth defects and other disabilities. It is possible that parents utilizing PGD, having faced the difficult choice of which embryo to implant, are *more* susceptible to having a charitable moral posture since they would have a very personal understanding of the limits of PGD and how much remains beyond their control. The largest impact of PGD on disabilities for the foreseeable future will be those caused by single gene disorders, which is a world we already inhabit. Given the availability of abortion, the impact of PGD on attitudes towards these disabilities is arguably negligible. In a world that comes up short of genetic engineering, concerns about discrimination against the disabled and more dismissive attitude towards the less fortunate are significantly blunted.

Related to these concerns are those of social inequality. Is it right to allow those with resources to utilize PGD to increase the welfare of their children while others are unable to access these services? The question in response, is how would those without access be helped by a ban on PGD for complex traits?[165] If we tolerate inequality in access to PGD for single gene disorders because of their effect on well-being (disease makes our lives worse), then selection of embryos for resistance to chronic disease or non-disease traits such as musical ability should be justifiable insofar as they have a positive effect on well-being.[166] In short, "Of the possible children they could have, couples should have the opportunity to have the child whose life will be best."[167]

---

[165] Cass R. Sunstein, *Keeping Up With the Cloneses*, THE NEW REPUBLIC, May 6, 2002 at 32, 40.
[166] Savulescu, *supra* note 108, at 18.
[167] *Id*.

Finally, and perhaps most fundamentally, arguments against genetic enhancement assert it takes us from "thick" to "think" humanity:

> Genetic enhancement pushes us … to a thinner view of ourselves: as bundled preferences that are identifiable, separable units, to be appraised, priced, purchased, traded in and upgraded. Genetic enhancement shifts us towards a mode of valuing our internal selves that is most associated with the appraisal of commodities in the marketplace. In so doing, we have more freedom to define ourselves, and yet the givenness, internality, and wholeness that sanctified this pursuit have vanished.[168]

PGD for complex traits may have the opposite affect. The inherent limits of limited number of embryos with limited variation and the resultant difficult choices it would yield could serve to emphasize our internal selves by starkly illustrating the limitations on how much we can shape our children by choosing embryos. While couples will strive to make their children's lives better, their children will still ultimately define themselves.

The likely arguments against PGD for complex traits are based largely on speculated harms, most of which are made less likely by the inherent limitations of PGD. Balanced against this are arguments for procreative liberty that, while not constitutionally persuasive, should give us serious pause before imposing restrictions on PGD. A woman who makes the decision to go through arduous IVF procedures to have the child she wants has made an intensely personal decision. Uncertain harms should not be the basis of decisions society has learned it is best not to interfere with.[169]

---

[168] Daniel L. Tobey, *What's Really Wrong with Genetic Enhancement: A Second Look at our Posthuman Future*, 6 YALE J. L. & TECH. 54, 147 (2004).

[169] Savulescu, *supra* note 108, at 18.

Regulations can Help Enhance Procreative Liberty Through Reporting Requirements, Rigorous Informed Consent, Standards for Testing, and Encouraging Research.

While harsh regulation based on uncertain harms is unwise, regulation should have an important place in PGD for complex traits. As PGD for complex traits is introduced in the future, regulation can serve to *enhance* procreative liberty by protecting patients. To imagine some of the risks to procreative liberty inherent in unregulated PGD, one can look to current direct-to-consumer (DTC) genetic testing.

Companies such as 23andMe and Navigenics offer to analyze individuals' genomes and inform customers of their genetic risk for a wide variety of health conditions.[170] There currently is little to no federal regulation of these tests.[171] Recently, the Government Accountability Office had five donors send their DNA samples to four different companies.[172] Results were wildly inconsistent across the board: one individual's results stated that–depending on which companies results were consulted–he was at average, below average, or above average risk for prostate cancer and hypertension.[173] Of the fifteen conditions examined in the report, companies provided contradictory results for between nine and twelve conditions.[174] These differences occur because the companies rely on published studies to choose which markers to analyze, and

---

[170] *See Navigenics – Health Conditions We Offer*, NAVIGENCS.COM http://www.navigenics.com/visitor/what_we_offer/conditions_we_cover/ (last visited November 18, 2010; *Health and Traits – List of Conditions – 23andMe*, 23ANDME.COM https://www.23andme.com/health/all/ (last visited November 18, 2010).

[171] Katherine Drabiak-Syed, *Baby Gender Mentor: Class Action Litigation Calls Attention to a Deficient Federal Regulatory Framework for DTC Genetic Tests, Politicized State Statutory Construction, and Lack of Informed Consent*, 14 MICH. ST. U. J. MED. & L. 71, 72 (2010).

[172] GOVERNMENT ACCOUNTABILITY OFFICE, DIRECT-TO-CONSUMER GENETIC TESTS: MISLEADING TEST RESULTS ARE FURTHER COMPLICATED BY DECEPTIVE MARKETING AND OTHER QUESTIONABLE PRACTICES (2010), *available at* http://www.gao.gov/new.items/d10847t.pdf

[173] *Id*. at 6.

[174] *Id*. at 5.

different companies choose to rely on different studies and different genetic markers.[175] One company even provided differing predictions within their own results.[176] Some companies also made unrealistic claims, such as asserting children's DNA could be analyzed to determine which sports they would be good at.[177]

If the above practices were seen in PGD for complex traits, reproductive freedom would be curtailed without some sort of regulation. As PGD for complex traits debuts, embryos will be identified for selection based on probabilities of displaying a certain trait, and the probability could be relatively low or disputed. There would be obvious temptation on the part of providers to oversell the predictive powers of their testing. Prospective parents could be faced with a vast array of confusing contradictions. Looking at the same information, one PGD service may insist embryo A is the most predisposed for high intelligence and general good health, while another declares embryo B is the best choice, and because they base their testing on newer, better studies, they know embryo A actually shows an increased risk for heart disease. If PGD follows the same unregulated, standardless path of DTC genetic testing, procreative liberty could be inhibited by the resulting confusion of competing tests of uncertain validity.

To facilitate procreative liberty, regulation in this area must attempt to strike a balance between flexibility to adapt to rapidly developing technology but still ensure potential parents are well informed and not being sold the proverbial bill of goods. This goal could be served by a two-pronged approach. First, implement legislative requirements providing for rigorous data reporting and informed consent. Requirements for data reporting can allow government officials and the public to monitor the field and intervene if it is headed in a direction deemed undesirable.

---

[175] *Id*. at 7.
[176] *Id*. at 12.
[177] *Id*. at 16. An expert interviewed for the report called the claim "complete garbage."

Logical requirements for data reporting would include the number cycles of PGD, the number of pregnancies that result, the traits being selected for or against, and, perhaps most importantly, the clinical basis of testing. For each embryo and each trait being tested for, what markers are being used, and what methods are utilized to calculate the odds of a desired trait? Armed with this information, government can give the public a full picture of what is being tested for, who is doing the testing, and inform the public about its judgment of the clinical validity of the testing being offered. Equally important will be rigorous informed consent requirements, both before the process beings and before an embryo is selected, so potential parents have a firm grasp of what PGD for a complex trait will and will not be able to accomplish. To facilitate consent, clinics should be required to utilize genetic counselors or other genetics professionals when obtaining consent. Prior to beginning the IVF process, potential parents should be informed of the inherent limitations of PGD previously discussed of limited embryos to select from, limited to the genetic material they contribute. Parents should also be informed of the clinical validity of the trait(s) they are requesting testing for, and the that the nature of a probabilistic test means that their child may not display the trait desired. After testing has been conducted on embryos, parents should be informed of results for each embryo tested so parents may weigh their options if multiple traits are being considered, or weigh the chances of achieving a successful pregnancy because of the quality of the embryo with the varying odds for different embryos to show the desired trait.

The second prong should involve setting standards for testing of traits, so clinics utilize a consistent set of markers and potential parents avoid inconsistent information depending on what clinic they choose. Because testing would likely be a rapidly evolving field, these standards would most appropriately be set by a professional organization rather than a government agency.

A professional organization would have the ability to bring experts together and more rapidly make changes to standards for testing as new information became available. The drawback of this approach would be that these standards would not have the force of law. One way to encourage compliance with these standards is to tie them to the data-reporting requirements. Clinics following the standards of the professional organization could simply indicate that they were doing so, and avoid the time and expense of explicitly laying out their own testing regimes.[178] Of course, even standards set by a relatively flexible professional organization would likely slow the development of testing. This seems like a reasonable cost, however, of ensuring PGD for complex traits proceeds in an orderly fashion that does not take advantage of potential parents.

Finally, government should encourage research. The data reporting requirements discussed earlier are a first step. Another is requiring facilities offering PGD to allow academic researchers the access needed to recruit those seeking PGD services into approved research studies. From psychological costs to parents and children, to broader societal concerns of attitudes towards the disabled or less fortunate, PGD for complex traits does raise concerns that, while hypothetical, should be investigated. Assessing these concerns is likely to be highly challenging social and epidemiological research that could last generations. The research should begin now. As discussed earlier, PGD for sex and familial cancer raises concerns that are also reflected by PGD for complex traits. If thorough research on these families starts now, concerns that are now hypothetical could be substantiated or alleviated by the time PGD for complex traits becomes a practical reality.

[178] To ensure compliance, there would likely need to be periodic audits to ensure clinics are actually complying with the standards of the professional organization.

CONCLUSION

Long before genetic engineering of offspring becomes possible, if it ever does, PGD for complex traits will gradually come into existence. As the traits that can be selected for or against before birth increase, there will inevitably be calls to heavily limit or regulate this technology.

An examination of Supreme Court precedent reveals that it is unlikely that the court would expand procreative liberty to include PGD for complex traits. While not constitutionally protected, concepts of procreative liberty counsel caution in limiting PGD in the name of hypothetical consequences. That some would inevitably use PGD in ways most would find morally objectionable does not mean that it should be eliminated. The most appropriate role for government is to ensure adequate information is collected to inform the public and policymakers, and to ensure PGD actually serves to enhance procreative liberty, rather than inhibit it.