

“IT’S A DESIGNER BABY!” – OPINIONS ON REGULATION OF
PREIMPLANTATION GENETIC DIAGNOSIS

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“Dear Designer Baby, Your mother and I created you but then decided to give you a little help by inserting some desired genes. We thought you should look as nice as possible, so you’re quite handsome now. We thought it might help if you were a little smarter than others, and so you are. And you should be slim, not fat. We love you, so we made you a better person. Hope you like yourself. Love, Dad.”

--Austin E. Sakong, Woodbridge, N.J.¹

I. INTRODUCTION

Preimplantation Genetic Diagnosis (PGD) is a procedure that identifies genetic defects in early embryos conceived via *In Vitro* Fertilization (IVF) techniques.² PGD involves the removal

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¹ *Letters*, TIME MAG., Feb. 1, 1999.

² Richard J. Tasca & Michael E. McClure, *The Emerging Technology and Application of Prenatal Genetic Diagnosis*, 26 J.L. MED. & ETHICS 7 (1998); *see also* Stephen S. Hall, *U.S. Panel About to Weigh In on Rules for*

of one or two cells (blastomeres) on day three of development, when the blastocyst contains only six to ten cells. Most commonly the procedure is performed when the risk of passing a serious (i.e., lethal or deforming) genetic disorder to the offspring is high.³ Available data suggests that PGD does not incur additional risks to the fetus or the child.⁴ Since the first PGD report 15 years ago,⁵ physicians have performed more than 3,000 PGD procedures. The reported pregnancy rate of 24% is comparable to assisted reproduction practices not involving biopsy.⁶

PGD is currently used primarily, if not exclusively, for medical purposes. As the array of possible applications of PGD is expanding, some of the projected uses of genetic screening are controversial, especially those involving non-medical motivations. For instance, PGD can be performed for selection and subsequent implantation of embryos based on gender preference.⁷ PGD has been used to create a donor offspring (i.e., the conception of a human leukocyte antigen-matched child to “design” a donor for a preexisting sibling in need of a stem cell

Assisted Fertility, N. Y. TIMES, Mar. 30, 2004, at F1 (noting that twenty-five years after the birth of Louise Brown, the first test-tube baby, approximately 1.2 million babies have been born through *in vitro* fertilization techniques).

³ Over one thousand genetic tests exist today. See Kathy Hudson, *A Discussion of Challenges, Concerns and Preliminary Options Related to the Genetic Testing of Human Embryos*, PGD PRELIMINARY POLICY OPTIONS REP., available at <http://www.dnapolicy.org/policy/pgdOptions.jhtml> (last accessed April 10, 2004).

⁴ *ESHRE Preimplantation Genetic Diagnosis (PGD) Consortium: Data Collection II (May 2000)*, 15 HUM. REPROD. 2673 (2000) (children born after PGD do not have a higher incidence of congenital malformations or neonatal problems than children born after intracytoplasmic sperm injection); see also *ESHRE Preimplantation Genetic Diagnosis (PGD) Consortium: Data Collection III (May 2001)*, 17 HUM. REPROD. 233 (2002).

⁵ A.H. Handyside et al., *Biopsy of Human Preimplantation Embryos and Sexing by DNA Amplification*, 1 LANCET 347, 349 (1989).

⁶ John A. Robertson, *Extending Preimplantation Genetic Diagnosis: Medical and Non-Medical Uses*, 29 J. MED. ETHICS 213, 216 (2003).

⁷ Note the difference between selections based on solely gender preference (non-medical use) and selection in the case of sex-linked diseases (medical use).

transplant),⁸ or to deliberately create a disabled child.⁹ The prospect of application of PGD for “unnatural selection” has become the subject of debates, conferences, and commentaries on possible PGD regulatory oversight, brimming with a diversity of opinions.¹⁰

This Article examines the legal, social, and policy issues surrounding preimplantation genetic diagnosis (PGD). Accordingly, this Article gives an overview of the timeliness and serious need for PGD regulation. In particular, the possibility of statutory regulation of PGD is analyzed. The Article addresses the ramifications of such statutory regulation, its scope, benefits, pitfalls, and criticisms. Particularly careful considerations are taken to draft a statute that should survive constitutional challenge, which could be difficult in light of the issue presented--genetic testing. In view of controlling case law, virtually insurmountable constitutional hurdles surrounding potential statutes constituting a form of “moral legislation” are presented. Finally, as an alternative, a holistic approach toward PGD regulation is proposed.

⁸ This is the widely publicized story of the Nash family from Denver, Colo. See Alice Park, *Designer Baby: Parents Use Genetic Testing to Get the Child they Need*, TIME MAG, Oct. 16, 2000, at 102; see also Susan M. Wolf, et al., *Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines & Limits*, 31 J.L. MED. & ETHICS 327 (2003); G. Pennings, et al., *Ethical Considerations on Preimplantation Genetic Diagnosis for HLA Typing to Match a Future Child as a Donor of Haematopoietic Stem Cells to a Sibling*, 17 HUM. REPROD. 534 (2002).

⁹ Julian Savulescu, *Deaf Lesbians, “Designer Disability,” and the Future of Medicine*, 325 BRIT. MED. J. 771 (2002).

¹⁰ See The Ethics Committee of the American Society of Reproductive Medicine, *Sex Selection and Preimplantation Genetic Diagnosis*, 72 FERTILITY & STERILITY 595 (1999) (arguing that preimplantation sex selection is not acceptable when used solely for nonmedical reasons); cf. The Ethics Committee of the American Society of Reproductive Medicine, *Preconception Gender Selection for Nonmedical Reasons*, 75 FERTILITY & STERILITY 861 (2001) (reversing the earlier position and suggesting that sex selection should not be prohibited or condemned as unethical in all cases); see also Jason C. Roberts, *Customizing Conception: A Survey of Preimplantation Genetic Diagnosis and the Resulting Social, Ethical, and Legal Dilemmas*, 2002 DUKE L. & TECH. REV. 12 (2002); John A. Robertson, *Extending Preimplantation Genetic Diagnosis: Medical and Non-Medical Uses*, 29 J. MED. ETHICS 213 (2003) (stating that speculations about potential future uses of PGD should not prevent otherwise acceptable current uses of PGD); Unnatural Selection: Should California Regulate Pre-Implantation Genetic Diagnosis? Stanford Law School, (Law & Bioscience Conference), Feb. 27, 2004, available at <http://www.law.stanford.edu/programs/academic/1st/bioscience/pgd>.

II. REGULATION OF PREIMPLANTATION GENETIC DIAGNOSIS

U.S. federal law does not regulate PGD, and at this time fertility specialists and the general public are divided over the issue of whether or not selecting an embryo's genetic makeup is acceptable.¹¹ Supporters of genetic testing state that parental reproductive choice extends to the use of PGD and should be safeguarded against government intrusion.¹² Opponents caution against unwarranted loss of embryonic life and disrespect for the serendipity that has traditionally accompanied childbearing.¹³ Critics associate the screening for selection of non-essential (enhanced, cosmetic) traits with eugenic practices.¹⁴ Their argument is that in the post-human genome era, the capacity to perform genetic testing can be expected to grow exponentially, and in concert, PGD will enable embryo selection based on trivial traits. This would lead to legitimizing a new form of individual, consumer eugenics.¹⁵ In the extreme interpretation of this line of logic, children could come to be regarded as made-to-order products.

The vast potential of PGD, as well as fear elicited by the specter of its abuse, have triggered initiatives to introduce proposals for law and policy assurances aimed at regulating the

¹¹ Claudia Kalb & Karen Springen, *Brave New Babies*, NEWSWEEK, Jan. 26, 2004, at 44; see also Michele Grygotis, *Higher Level of Embryo Testing Raises Questions About Possibility of Creating "Designer Babies"*, TRANSPLANT NEWS, Jun. 30, 2001 at 12.

¹² See Julian Savulescu, *Sex Selection: The Case For*, 171 MED. J. AUSTL. 373 (1999); David McCarthy, *Why Sex Selection Should Be Legal*, 27 J. MED. ETHICS 302, 306 (2001); Scott Gottlieb, *US Doctors Say Sex Selection Acceptable For Non-Medical Reasons*, 323 BRITISH MED. J. 828 (2001).

¹³ Michael D. Lemonick, *Designer Babies: Parents Can Now Pick a Kid's Sex and Screen for Genetic Illness. Will They Someday Select for Brains and Beauty Too?*, TIME MAG., Jan. 11, 1999, at 64; see also Kelly M. Plummer, *Ending Parents' Unlimited Power to Choose: Legislation is Necessary to Prohibit Parents' Selection of Their Children's Sex and Characteristics*, 47 ST. LOUIS L.J. 517 (2003).

¹⁴ Eugenic purpose is discriminatory and is subject to fourteenth Amendment equal protection scrutiny.

¹⁵ Some eugenic practices witnessed through history had "for the benefit of society" arguments.

safe and responsible practice of reproductive medicine without unduly burdening rights of procreative liberty.¹⁶ The introduction of any proposed bill limiting the use of PGD to specific medical scenarios will likely be challenged. Potential legislation in this area is controversial, and has attracted constitutional attention. The relevant issues are addressed below with attention to their distinct, yet overlapping legal, political, ethical, and pragmatic concerns. Strong criticism of a proposed bill can be expected: particularly in the areas related to parental entitlements, the scope of state's right to regulate in the area of reproduction, and interference in the physician-patient relationship.

1. U.S. Regulatory Framework

The U.S. *laissez-faire* approach to reproductive issues has resulted in the absence of federal statutory authority for the regulation of prenatal genetic diagnosis, and no common law precedents on the point exist to serve as guidance. The Framers of the Constitution did not express a specific opinion on reproductive technologies. However, a few states have enacted laws that regulate human embryo research.¹⁷

¹⁶ Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past – Present, and Future?*, 36 CONN. L. REV. 125 (2003); see Plummer, *supra* note 13.

¹⁷ At least nine states have enacted laws regulating embryo research; some include felony penalties for violations. For instance: Louisiana law that defines “viable *in vitro* fertilized human ovum” as “embryo,” outside the womb as a juridical person that “shall not be intentionally destroyed by any natural or other juridical person or through the actions of any other such person.” LA. REV. STAT. tit. 9, § 129 (2004); Maine law that prohibits the use of any human fetus, “whether intrauterine or extrauterine...for scientific experimentation or for any form of experimentation (ME. REV. STAT. tit. 22 §1593 (2004); Michigan law, providing that human embryos should not be used for nontherapeutic research if the research “substantially jeopardizes the life or health of the embryo.” MICH. COMP. LAWS § 333.2685 (2004); Minnesota law that prohibits the use of “a living human conceptus for any type of scientific, laboratory research or other experimentation except to protect the life or health of the conceptus.” MIN. STAT. § 145.422 (2004); Pennsylvania law that prohibits “any type of nontherapeutic experimentation or nontherapeutic medical procedure...upon any unborn child.” 18 PA. CONS. STAT. § 3216 (2004).

The dearth of federal public policy guidance in reproductive matters extends to a lack of professional PGD self-regulation. No national regulations are officially sanctioned, although opinions and recommendations of reproductive medicine agencies have been published. Heterogeneity of clinical liability exists on a national level resulting from clinics in different states performing discrete steps of the IVF-PGD procedures. In such a heterogeneous environment of plausible deniability, a regulatory gap exists. This gap is partially filled by a voluntary mandate against the performance of procedures that are morally repugnant.

Precedent for the regulation of biologics exists under the auspices of the Food and Drug Administration (FDA).¹⁸ The FDA could theoretically claim jurisdiction over PGD procedures, similar to what it has done in embryo transfer (defining it as “tissue transplantation”). But FDA oversight of PGD is impractical; the FDA does not regulate fertility procedures, nor does it oversee the operations of the fertility clinics.

Through the seminal rulings on sexuality, abortion and fetal experimentation statutes, U.S. courts have established a limited framework against which the constitutionality of any proposed bill can be analyzed. Courts have typically focused on the interests and burdens of the parties when determining the effect of a statute. Statutes have been deemed unconstitutional on the basis of violated fundamental liberty interest (abortion statutes), or on grounds of vagueness (embryo experimentation statutes).¹⁹ Among the most relevant is the 2003 U.S. Supreme Court’s holding enunciated in *Lawrence v. Texas*.²⁰ Notably downplaying key phrases such as

¹⁸ The FDA has the authority to regulate biological products, under the biologics provisions of the Public Health Service (PHS) Act. A final rule that established the criteria for regulation of human cells, tissues, and cellular and tissue based products, including reproductive cells and tissues, was published on January 19, 2001 (66 FR 5447).

¹⁹ See *infra* notes 40-43 and accompanying text.

²⁰ *Lawrence v. Texas*, 539 U.S. 558 (2003).

“fundamental rights,” the *Lawrence* Court spoke of protection of liberty, privacy, and decided the case as a matter of policy and justice. Extended beyond the sexuality discussion, *Lawrence* drastically limits the state’s power to regulate personal decisions, counseling “against attempts by the State, or a court, to set boundaries absent injury to a person or abuse of an institution the law protects.”²¹ A state regulation will be stricken unless an identifiable vulnerable party is affected.

The question of personhood is central to treatment of reproductive issues, and at the core of debates is the disagreement over when human life begins. The currently accepted term for the zygote immediately after division is “pre-embryo” and this term applies up until 14 days after fertilization. At about 14 days, the cells begin to differentiate in a process leading to development of different body parts, resulting in development of an individual.²² At that point the proto-human becomes defined as an embryo. The American Fertility Society supports this delineation.²³

²¹ *Id.*; The court emphasized the dissenting opinion of Justice Stevens in an earlier case, *Bowers v. Hardwick*, 478 U. S. 186 (1986), quoting “the fact that the governing majority in a State has traditionally viewed a particular practice as immoral is not a sufficient reason for upholding a law prohibiting the practice.”

²² *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992). The biological definition of embryo in vertebrate animals is the developmental stage from after the long axis appears until all major anatomical structures form. In human development, this is from about two weeks after fertilization until the seventh or eighth week of pregnancy.

²³ *Id.* at 593 (American Fertility Society’s June 1990 report on Ethical Considerations of the New Reproductive Technologies indicates that: “Each blastomere, if separated from the others, has the potential to develop into a complete adult... Stated another way, at the 8-cell stage, the developmental singleness of one person has not been established. Beyond the 8-cell stage, individual blastomeres begin to lose their zygote-like properties. Two divisions after the 8-cell stage, the 32 blastomeres are increasingly adherent, closely packed, and no longer of equal developmental potential. The impression now conveyed is of a multicellular entity, rather than of a loose packet of identical cells.”); see also John A. Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437 (1990) (a similar description of the biologic difference between a preembryo and an embryo).

A state can define what a person is, as long as the definition does not contradict constitutional norms.²⁴ In 1973, the Supreme Court held²⁵ (and two decades later reaffirmed²⁶) that, historically, fetuses were never considered to be a “person” under the law. Such a definition constitutes a problem for any proposed PGD bill, especially if one of the bill’s arguments is protection of its citizens. To counter this view, a proposed PGD bill needs to point out that PGD for non-medical purposes encourages commodification of entities that are closely connected to our sense of personhood.²⁷

2. *Construction of a Statute Regulating Preimplantation Genetic Diagnosis*

One way to regulate PGD practices is to focus efforts at the state level. A proposed PGD regulation statute needs to be constructed in a way that will avoid it being thwarted by negative precedents. It is important to name the proposed PGD statute (hereafter “bill”) and define the issues in such a way that the court will recognize legitimate, compelling rational interest in the state’s regulation of both the health profession (specifically the area of reproduction) and the biological existence of its citizens.²⁸ The bill should emphasize that it aims to regulate one type

²⁴ See Ronald Dworkin, *Unenumerated Rights: Whether and How Roe Should be Overruled*, 59 U. CHI. L. REV. 381, 400 (1992) (“Laws designed to protect fetuses may be drafted in language declaring or suggesting that a fetus is a person, or that human life begins at conception. The Illinois abortion statute begins, for example, by declaring that a fetus is a person from the moment of conception. There can be no constitutional objection to such language, so long as the law does not purport to curtail constitutional rights.”).

²⁵ *Roe v. Wade*, 410 U.S. 113 (1973).

²⁶ *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992).

²⁷ Suzanne Holland, *Contested Commodities at Both Ends of Life: Buying and Selling Gametes, Embryos, and Body Tissues*, 11 KENNEDY INST. ETHICS J. 263 (2001).

²⁸ The bill should emphasize that beneficiaries are children, future productive citizens. A cynical remark is that statutes that purport to benefit children are favorably viewed.

of practice in the medical profession, and to preserve human life. The state should claim its interest in protecting vulnerable groups from abuse, neglect, and mistakes. PGD should only be offered as an option to prevent inheritance of genetically fatal diseases, and not for reasons of selecting a child that conforms to parents' whims. In a seminal decision, the U.S. Supreme Court held in *Roe* that a state can "assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life."²⁹ The *Casey* Court stated that the state has a substantial interest in potential life from the time of conception until birth.³⁰

The statute must be written to lend substantial weight to the state's interest, while avoiding issues regarding parents' right to privacy and procreation choices. Regulation of prenatal genetic testing falls within the realm of social and health affairs, which are already considered to be within the state's authority to regulate.³¹ The bill should emphasize its aim to regulate extrauterine medical practice, while maintaining proper distance from issues involved when the health and body of the mother are also present. Importantly, because the bill does not attempt to regulate fundamental rights (e.g., privacy, abortion), the state merely has to demonstrate a rational connection between its asserted interest and the regulation. The Supreme Court's review of the bill's constitutionality will likely be conducted under a rational basis test, as opposed to strict scrutiny.³² Narrow and fact-specific characterization of the issue stands a better chance of avoiding unfavorable precedents for the Court's potential negative opinion.

²⁹ *Roe*, 410 U.S. at 154.

³⁰ *Casey*, 505 U.S. at 876.

³¹ *Wynn v. Scott*, 449 F. Supp. 1302, 1322 (N.D. Ill. 1978) (state has the authority to regulate where not infringing on a fundamental right)

³² There is no suspect class in this case, meaning that strict scrutiny review cannot be obtained on that ground.

Of paramount importance are the legal definitions of (pre)embryo and blastocyst, as the designations will likely be determinative of the concomitant legal rights assigned to the entity. Use of biological definitions to form strict legal categories introduces definitional uncertainties that are foreign to law.³³ Neither belief systems,³⁴ nor state laws³⁵ or courts,³⁶ are consistent in the use of terminology relative to the stages of embryo development. But often during review of statutes, the final decision turns on aspects of nomenclature, rather than the stated issue *per se*.³⁷ To avoid problems associated with “vagueness,” the bill must have a core meaning³⁸ and should clearly define the entity it intends to protect. That entity can be defined as “embryo,” “unborn

³³ The notion of life is not entirely based on biology; it is also based on belief systems. What we try to define is “morally significant life”; *See Casey*, 505 U.S. at 913 (Stevens, J., concurring). (“As a matter of federal constitutional law, a developing organism that is not yet a ‘person’ does not have what is sometimes described as a ‘right to life.’”)

³⁴ The Vatican recognizes the embryo as person from the time of fertilization. *See INSTRUCTION ON RESPECT FOR HUMAN LIFE IN ITS ORIGIN, AND ON THE DIGNITY OF PROCREATION, REPLIES TO CERTAIN QUESTIONS OF THE DAY*, (Vatican 1987), available at http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html (last visited Mar. 14, 2005) (“The human being must be respected - as a person - from the very first instant of his existence”). For Islam, the important principles are the moment when the embryo acquires a life of its own and respect for descentance (40 or 120 days before the soul (ruh) enters the embryo; there is a disagreement). The Islamic tradition accepts prenatal screening, but would make decisions on a case-by-case basis. Muslims have attempted to maintain the tenuous distinction between therapeutic uses and “enhancing” uses of genetic engineering, albeit without a bright-line rule demarcating the boundary between these two categories. *See* Mohammad Fadel, *Islam and the New Genetics*, 13 ST. THOMAS L. REV. 901 (2001).

³⁵ *See, e.g.*, MINN. STAT. §145, 421 (2004), defining “human conceptus” as “any human organism, conceived either in the human body or produced in an artificial environment other than the human body, from fertilization through the first 265 days thereafter; 18 PA. C.S. §3203 (2004), defining “unborn child” as “an individual organism of the species *homo sapiens* from fertilization until live birth”; S.D. CODIFIED LAWS §34-14-20 (2003), defining “human embryo” as a living organism of the species *Homo sapiens* at the earliest stages of development (including the single-celled stage) that is not located in a woman’s body.” § 34-14-20.

³⁶ *See Davis*, 842 S.W.2d 588 (using the term “embryo” for cryopreserved fertilized ova); *cf. A.Z. v. B.Z.*, 725 N.E.2d 1051 (Mass. 2000) (using the term “pre-embryo” for cryopreserved fertilized ova); *J.B. v. M.B.*, 783 A.2d. 707 (N.J. 2001) (using the term “pre-embryo” for cryopreserved fertilized ova).

³⁷ Note that *Glucksberg* was decided at the moment when the court called the issue “the right to assist suicide.” *Washington v. Glucksberg*, 523 U.S. 702, 721 (1997). The *Davis* court was deciding whether the 4- to 8-cell entities should be referred to as “embryos” or as “preembryos,” with resulting differences in legal analysis. *Davis*, 842 S.W. 2d 588.

³⁸ *Margaret S. v. Edwards*, 794 F.2d 994 (5th Cir. 1986).

child,” “living human conceptus,” or the like, and should be further specified as a human organism which from the moment of conception is recognized as a legal person. Statutory precedents exist for this statement, as an extrauterine embryo conceived by IVF in some states is deemed an unborn child and furthermore is an existing legal person for statutory purposes.³⁹ The bill will prohibit nontherapeutic medical procedures on that defined legal entity, specifically nontherapeutic experimentation and/or research that might jeopardize the life of the entity. Additionally, the bill should specify which procedures are allowed (such as harmless procedures, diagnostic procedures, and procedures that do not threaten the entity’s life).

Clear definitions of all terms used in the statute are essential, to avoid vagueness, and to minimize the danger of the statute being stricken because of failure to specify a standard of conduct.⁴⁰ The statute should narrowly focus on regulation of genetic testing of extrauterine embryos. Because the egg is fertilized outside of a body, the statute would avoid issues regarding mother’s health, pregnancy interest, or infringement of mother’s privacy or fundamental rights.

Different standards for vagueness are used depending on the type of statute involved. If a statute imposes a civil penalty, it is unconstitutionally vague only when it is “vague in all of its

³⁹ *See, e.g.* 720 ILL. COMP. STAT. ANN. 510/1 (2004) (declaring that “the unborn child is a human being from the time of conception and is, therefore, a legal person for purposes of the unborn child’s right to life and is entitled to the right to life from conception under the laws and Constitution of this State.”); *see also* CAL. CIV. CODE § 43.1 (2005) (“A child conceived, but not yet born, is deemed an existing person ...”).

⁴⁰ *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill. 1990) (holding that because a statute prohibiting nontherapeutic experimentation on fetuses did not define the terms “experiment” and “therapeutic,” it failed to define unlawful conduct, and was held unconstitutionally vague); *Margaret*, 794 F.2d 994 (holding that Louisiana’s law prohibiting experimentation on unborn children violated the Due Process Clause of the XIVth Amendment, because it failed to specify a standard of conduct; hence, a physician would not be able to distinguish whether a procedure was an “experiment” or a “test”).

applications.”⁴¹ In contrast, when a statute imposes a criminal penalty, it is considered unconstitutionally vague “even when it could conceivably have had some valid application.”⁴² Should the statute attempting to regulate PGD contain a criminal penalty, its vagueness will probably be analyzed under a stricter interpretation.⁴³

3. *Substantive Due Process and Fundamental Rights*

To survive legal challenges, a bill to regulate PGD should be narrowly construed and should rationally relate to a legitimate government interest (regulation of public health), but should not “shock the conscience,” or violate the Due Process Clause of the XIVth Amendment. The bill should not violate fundamental rights, including those enumerated in the Bill of Rights, or other unenumerated rights that are occasionally announced.⁴⁴ Constitutionality of laws that limit fundamental rights receives “heightened level of judicial scrutiny.” This makes it more difficult for states to regulate fundamental rights, because they need to demonstrate “compelling state interest” for the regulation.⁴⁵ To survive constitutional challenge, the bill needs to highlight the state’s compelling interest in preservation of potential human life, without violating the constitutional liberties of prospective parents. To avoid being embroiled in a debate about

⁴¹ *Chicago v. Morales* (97-1121) 527 U.S. 41 (1999) 177 Ill. 2d 440, 687 N. E. 2d 53. For a discussion of the “void-for-vagueness” constitutional doctrine in the area of fundamental rights see Anthony Amsterdam, *The Void-For-Vagueness Doctrine in the Supreme Court*, 109 U. PA. L. REV. 67 (1960).

⁴² *Jane L. v. Bangerter*, 61 F.3d 1493 (10th Cir. 1995) (reversed by *Lewitt v. Jane*, 518 U.S. 137).

⁴³ Note that the criminal penalty provision in the statute is in line with similar penalty provisions enunciated in federal statutes. See, e.g., 18 U.S.C.S. § 1531, Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108-105(S.3)

⁴⁴ *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965) (Goldberg, J., concurring) (“...the concept of liberty protects those personal rights that are fundamental, and is not confined to the specific terms of the Bill of Rights”).

fundamental rights, it remains critical that the bill should not be vague and undefined, especially where such issues are involved.⁴⁶

An anticipated area of conflict with the imperatives above involves the choice of embryo sex/gender. Making sex selection illegal can be seen as restriction of fundamental liberties.⁴⁷ Critics could argue that such a bill would invade privacy. “Privacy” has come to represent a bundle of individual rights and liberties that are derived from the Due Process Clause. Conflict arises when the protection of privacy interferes with the exercise of rights of a developing human life.⁴⁸ Critics might argue that in a democratic society, there is always a presumption in favor of liberty, including rights to privacy and to procreative autonomy.⁴⁹ PGD will reveal information on inherited traits, both pleasant and shied away from. Sensitive private information will be revealed about the parents, siblings, and close relatives. Our society is aware of the potential for misuse of personal genetic information – by health and life insurance agencies, employers, etc. The burden therefore falls on the proponents of a proposed bill to justify the reasons for the constraint of any liberties. The state would need to support the bill by specifically and rationally

⁴⁵ *Roe v. Wade*, 410 U.S. 113, 155 (citing several cases).

⁴⁶ *Lifchez*, 735 F. Supp. 1361 (discussing of three ways in which vagueness violates due process: a) lack of notice of exactly what conduct is unlawful; b) indefinite terms that allow for arbitrary and capricious enforcement; c) possibility of arbitrary enforcement, which has a chilling effect because people will want to avoid facing arrest).

⁴⁷ *See id.* (holding that a provision of Illinois law, which stated that no person shall sell or experiment upon fetus produced by fertilization of human ovum by human sperm, unless such experimentation is therapeutic to fetus thereby produced, was unconstitutional because it restricted woman’s fundamental right of privacy to make free reproductive choices).

⁴⁸ *Planned Parenthood of Pennsylvania v. Casey*, 505 U.S. 833, 915 (1992) (“[T]he state interest in [protecting] potential human life is not an interest *in loco parentis*, for the fetus is not a person . . . [This interest] is not grounded in the Constitution. It is an indirect interest supported by both humanitarian and pragmatic concerns The State may also have a broader interest in expanding the population, believing society would benefit from the services of additional productive citizens -- or that the potential human lives might include the occasional Mozart or Curie. These are the kinds of concerns that comprise the State’s interest in potential human life.”).

⁴⁹ David McCarthy, *Why Sex Selection Should Be Legal*, 27 J. MED. ETHICS 302, 306 (2001).

describing how the benefits of the bill to the protected entity and the interests of the state outweigh its burden.

As of 2003, the U.S. Supreme Court does not allow infringement of fundamental rights by the government based only on the desire of the majority to impose its moral beliefs on the personal lives of individuals.⁵⁰ Put bluntly in the dissenting view of Justice Scalia, *Lawrence* “effectively decrees the end of all morals legislation.”⁵¹ Accordingly, to avoid being constitutionally stricken, the bill should refrain from discussing societal moral norms.

Our society’s commitment to liberty and to freedom of expression is not absolute. In defense of the proposed bill, the Supreme Court has already stated “that 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.”⁵² Therefore, the parents’ reproductive choices need to be viewed as limited.⁵³

A bill to regulate PGD aims to regulate practices in the medical profession (reproductive medicine). That is not unusual. A state may outlaw medical practices for the preservation of public health or for fiscal reasons. If PGD were available to all prospective parents, and was subsidized by the government, the state would quickly go bankrupt. The Due Process Clause does not confer an affirmative right to governmental aid, even where such aid may be necessary

⁵⁰ *Lawrence v. Texas*, 539 U.S. 558 (2003).

⁵¹ *Id.* at 599 (Scalia, J., dissenting).

⁵² *Washington v. Glucksberg*, 521 U.S. 702, 727 (1997).

⁵³ Martha A. Field, *Killing “the Handicapped” – Before and After Birth*, 16 HARV. WOMEN’S L.J. 79 (1993) (arguing against parental discretion to control the newborn’s fate, when that fate is ending the newborn’s life).

to secure life, liberty, or property interests of which the government may not deprive the individual.⁵⁴

As referred to above, the bill to regulate PGD must be distinguished from bills that regulate reproductive choices. Importantly, such a bill should not: (i) curtail abortion rights; (ii) attempt to undermine the *Roe*⁵⁵ and *Casey*⁵⁶ decisions; (iii) attempt to regulate personal autonomy and bodily integrity. The bill should focus on regulation of practices in the health profession, and protection of the state interest in potential life. By proposing that PGD is a practice requiring regulation, the burden falls to the state to demonstrate probability of harms incurred by genetic screening. These harms could include but are not limited to: destruction of embryos, commodification of human life, gender- and disability- based discrimination, and easing the way to non-medical enhancement.⁵⁷ They can also be viewed as: 1) comparative (relative) harms; 2) status harms (*harms per se*).

4. *Equal Protection Issues*

Equality of treatment and the due process right are linked in important respects. Under the Supreme Court's rational basis standard of review, "legislation is presumed to be valid and

⁵⁴ *Webster v. Reprod. Health Services*, 492 U.S. 490, 491 (1989) (holding that the restrictions in Missouri statute on the use of public employees and facilities for the performance or assistance of nontherapeutic abortions do not contravene the U.S. Supreme Court's abortion decisions). *See id.* ("[A] government's decision to favor childbirth over abortion through the allocation of public funds does not violate *Roe v. Wade*. A State may implement that same value judgment through the allocation of other public resources, such as hospitals and medical staff.").

⁵⁵ 410 U.S. 113 (1973).

⁵⁶ 505 U.S. 833 (1992).

⁵⁷ John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 429 (1996).

will be sustained if the classification drawn by the statute is rationally related to a legitimate state interest.”⁵⁸ A bill to regulate PGD needs to state its aims - to prevent social harm, imbalance of the sex ratio through preferential choice of baby boys as opposed to baby girls, and the creation of “designer babies.” Opponents of the bill might argue that these concerns are based on limited evidence.

There is concern about the inherent potential for gender discrimination posed by the practice of sex selection. Proponents of unfettered PGD testing invoke studies that suggest that in developed liberal democracies such as the U.S.⁵⁹ and the U.K.,⁶⁰ non-medical sex-selection should not disturb the gender ratio in the society. These conclusions do not consider the dynamic nature of U.S. demographics, and the fact that two ethnic groups that are on the rise (immigrants from the Asian subcontinent and China) have a tradition of overwhelmingly favoring male offspring.⁶¹ Allowing sex selection will introduce inequality along both gender and ethnic lines in our society.⁶² While motivations for desiring a child of a particular sex may vary, by definition there are no non-sexist reasons for sex selection except in cases of preventing sex-linked diseases.

⁵⁸ *Lawrence v. Texas*, 539 U.S. 558, 579 (2003) (O’Connor, J., concurring (quoting *Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432, 439 (1985))).

⁵⁹ Joel H. Batzofin, *XY Sperm Separation for Sex Selection*, 14 *UROLOGIC CLINICS N. AM.* 609, 616 (1987).

⁶⁰ P. Liu & G. Alan Rose, *Social Aspects of >800 Couples Coming Forward for Gender Selection of Their Children*, 10 *HUM. REPROD.* 968, 970 (1995).

⁶¹ *Id.* at 970.

⁶² One episode is particularly telling. Concurrent with ASRM’s 2001 approval of PGD for sex selection, *see* sources cited *supra*, note 10, advertisements placed by fertility practitioners offering sex selection targeted the South Asian community in the U.S. The marketing of this service capitalized on the strong son preference in India and China. Such choices can lead to gender discrimination with alarming gender imbalance consequences in the population. India’s experience with sex selection demonstrates that the methods of sex selection are abusive and discriminatory. *See* Susan Sachs, *Clinics’ Pitch to Indian Émigrés: It’s a Boy*, *N.Y. TIMES*, Aug. 15, 2001, at A1.

Allowing non-medical uses of PGD takes us on a slippery slope, because it is difficult to prescribe fairness against a backdrop of inequity. On the demand side of the issue, one of the inequities that underlie PGD is the pricing. PGD is only available to the elite, and encourages a subculture of selectivity and discrimination. If we allow sex selection today, tomorrow it will be different personality traits, phenotype, intelligence, sexual appeal, etc. Genetic enhancement being available primarily to the rich will increase unequal treatment, which is what the Equal Protection Clause intends to prevent. On the supply side of the issue, the fact that some clinics are willing to exploit medical practices for pecuniary gain irrespective of ethical considerations should act as a warning to proceed with extreme caution in genetic screening. Fertility specialists who offer potentially lucrative yet ethically-problematic services threaten to erode public trust in the fertility field as a whole. The state has an argument in stepping in and regulating market monopoly and consumer choices.

Taken together, both supply and demand related issues related to genetic testing, PGD based selection, and IVF support the proposed need for regulation. This includes the means, materials and accessibility to new reproductive techniques that threaten to undermine the equality and peaceful coexistence of our state's disparate socio-economic-ethnic components.

5. Interference in Health Professional-Patient Relationship

Strong criticism of a bill to regulate PGD can be expected from the advocates of increased personal freedom in the decision-making area of medical practice. Bill opponents will

likely argue that enactment of legislation regulating PGD will be seen as imposition into the “sacred” physician – patient relationship and patient privacy issues.⁶³

In support of the bill, the state could argue that PGD regulation relieves the physicians of a difficult gate-keeping task. Once the government has drawn a line, the physicians do not have to conduct a case-by-case assessment of the parents’ desires that in reproductive context might sometimes be unrealistic. Prenatal genetic testing is offered to prospective parents, with the implicit expectation that they are engaged in dialogue about their procreative decisions. When embryos are genetically tested for health reasons, the state should concede the decision-making to prospective parents. But when the reasons are not health-related, then regulation becomes a legitimate state function.

The state could assuage these interference concerns by advocating, or perhaps requiring, the deliberative model of physician-patient interaction.⁶⁴ Physicians should assist the prospective parents in choosing health-related values of their offspring. At the same time, the physicians should emphasize the risks, unknowns, unexamined preferences or examined values, alternative values, worthiness, and implications related to making reproductive choices based on PGD testing.

6. Interest and Rights of the Future Child

Any proposed PGD regulation should assuage concerns that genetic screening might lead to “designer babies.” PGD carries risks as it involves the testing and possible destruction of

⁶³ For interesting stories on physicians’ clinical-moral dilemmas see generally S.R. Kaufman, *Construction and Practice of Medical Responsibility: Dilemmas and Narratives from Geriatrics*. 21 CULTURE, MEDICINE AND PSYCHIATRY 1-26 (1997).

embryos. Used for non-medical reasons, PGD is a causal agent in the creation of individual harm.⁶⁵ The harm can be classified as intentionally caused loss of life.⁶⁶ The state's interest in protecting human life does not come into existence only at point of viability; there is no rigid line allowing state regulation of abortion after viability but prohibiting regulation before viability.⁶⁷

Our legal system recognizes parental duties to children, to care for the children as much as possible. In the context of frozen embryos, focus on the child's "best interest" recently received support in the courts.⁶⁸ Arguably, the state can step in and legislatively protect the child's best interest. The choice in genetic screening is not as delicate as in the abortion cases – there is no issue with a woman's right to make a choice for a fetus that she is carrying. PGD is about making choices with extrauterine embryos. The "best interest of the child" standard in this instance might counterweigh the reproductive rights that parents might have, especially if PGD is used to treat the child as a mere means to the ends of another person.⁶⁹

⁶⁴ Ezekiel J. Emanuel & Linda L. Emanuel, *Four Models of the Physician-Patient Relationship*, 267 JAMA 2221, 2222 (1992).

⁶⁵ To further complicate the matter, in PGD context harm can be analyzed as: 1) harm to the child who was going to develop from the blastocyst and was destroyed because of the blastocyst's unfavorable genetic profile; 2) harm to the twin who could have been developed from the cell(s) removed and used for PGD, and thereby destroyed.

⁶⁶ Arguably, the deliberate choice of having a disabled child results in that child being better off than if the parents selected a different embryo, because in that case the disabled child wouldn't have existed at all.

⁶⁷ *Webster v. Reproductive Health Services*, 492 U.S. 490 (1989).

⁶⁸ *Davis v. Davis*, 842 S.W.2d 588, 597 (Tenn. 1992).

⁶⁹ This issue is complicated, with arguments ranging from the fact that PGD might be utilized for creating a child that will be used for the parts (organs) it may yield, to arguments that such practice is acceptable if there is no harm to the donor. For instance, the embryo that gave rise to Adam Nash was selected after negatively testing for both Falconi Anemia and for HLA compatibility with his ailing sister. A critical view of such screening is that the parents eliminated multiple healthy (FA negative) embryos. See sources cited *supra*, note 8. From a different viewpoint, but for Adam's HLA compatibility with his sister, he wouldn't have been born at all. Furthermore, we have no established principles for evaluating parents' motivations to have children.

The traditional reason for bringing a child into the world is love, which is best perceived as unconditional love, with no wish to control or infringe the child's autonomy. A child's sex or genetic makeup is fundamental to his/her identity and personality. Choosing a child's genetic characteristics for reasons other than medical necessity turns the process of having child into a consumer experience, giving it a measurable, commodified value. PGD for trivial reasons will exacerbate parental egocentrism. Some people who choose to undergo IVF "often seem to be fixated on having, in the sense of possessing, a child, rather than being a parent."⁷⁰ The prospect of having "designer babies" will only worsen this type of abuse.

Genetic screening shifts the process of reproduction from the bedroom to the laboratory, with an implicit assurance of precision. However, genetic tests are not completely accurate, with an error margin of false positives – and the prospects of having less-than-desired children – of about 3%. Therefore, some parents will end up with "handicapped" children. In such a case of wrongful life, the courts are faced with the impossible task of measuring harm of what would have been (non-existence) *vs.* what is (existence with a disability). It is also difficult to draw a line to decide when "genetic enhancements" might start imposing more than minimal risk in the children. The government has an argument that a legislative act will help regulate that predicament.

A bill designed to regulate PGD must aim to protect bodily autonomy, from the point of view of the embryo. Invasion of the embryo's bodily autonomy through genetic testing might be subject to several state laws. From the embryo's point of view, genetic testing might constitute

⁷⁰ GINA MARANTO, *QUEST FOR PERFECTION* (2000).

trespassing. This is derived from the notion of quasi-property ownership of human bodies.⁷¹

Genetic testing might be viewed as a tort of battery. The state has legitimate interests in protecting its citizens against torts. Inherent difficulty in this argument exists in the subjective value judgments of what constitutes a living being.

Proponents of the bill will argue for prevention of the new problem of “designer disability.”⁷² Selection of disabled or disfavored offspring is not only morally repugnant; it creates fertile ground for a flood of wrongful life lawsuits. Designing children can have adverse psychosocial effects, on the child’s own cognition, and parent-sibling, and on sibling-sibling bonds.⁷³ Arguably, it is a legitimate state interest to act with the objectives of: (i) protecting the health and well being of its citizens; (ii) preventing future wrongful life lawsuits.⁷⁴

Opponents of the bill will argue the case for limited sex selection for family balancing and possible contribution to the happiness of the family.⁷⁵ Some people may feel that there is something better about having a family with children of both sexes. Such arguments are countered by revealing the possibility of preferential or prejudicial treatment to fit parental expectations, or the potential for favoritism and neglect of existing children. If the birth of a

⁷¹ For an extensive discussion on autonomy and ownership of human bodies, see Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U. L. REV. 359 (2000).

⁷² E.g. M. Spriggs, *Lesbian Couple Create a Child Who is Deaf Like Them*, 28 J. MED. ETHICS 283 (2002).

⁷³ Patrik S. Florencio, *Genetics, Parenting, and Children’s Rights in the Twenty-First Century*, 45 MCGILL L.J. 527 (2000); see also Dena Towner & Roberta Springer Loewy, *Ethics of Preimplantation Diagnosis for a Woman Destined to Develop Early-Onset Alzheimer Disease*, 287 JAMA 1038 (2002) (discussion of the ethics of providing PGD to a woman who with relative certainty will not be able to recognize that child within the matter of a few years).

⁷⁴ Wrongful life claims arise from a child who asserts birth in impaired condition. See, e.g., *Daniels v. Delaware*, 120 F. Supp. 2d 411 (D. Del. 2000).

⁷⁵ G. Pennings, *Family Balancing As a Morally Acceptable Application of Sex Selection*, 11 HUM. REPROD. 2339 (1996) (noting even these proposals include a number of restrictions, e.g., selection cannot be used for the first child, the selected sex must be of the outnumbered sex).

child of undesired sex occurs as a result of a misdiagnosis, the child might suffer from parental disappointment. Popularization of genetic testing in reproductive practices could lead to a redefinition of parenthood, magnifying “genetic ties” to the exclusion of other forms of family relationships.⁷⁶ All of these concerns warrant regulation.

7. *Public Policy Considerations*

A state can argue that reproductive genetic technologies in the U.S. need to be regulated as a matter of public policy. Public support for such a policy has been demonstrated by recent surveys that indicate Americans support genetic technologies for healthy babies, but for not designer babies.⁷⁷ This finding is similar to a public survey in the U.K., which suggested that PGD is perceived as inherently eugenic.⁷⁸ Despite the widespread support for PGD-based selection of healthy embryos, the public is worried about the wider implications of the technique.⁷⁹

The economics of genetic testing (price paid vs. benefit of testing) further supports PGD regulation. PGD currently costs thousands of dollars, and if used solely for sex selection will divert medical resources from genuine medical need. It is unclear who will bear the costs of

⁷⁶ Suzanne Holland, *Selecting Against Difference: Assisted Reproduction, Disability and Regulation*, 30 FLA. ST. U. L.R. 401, 408 (2003).

⁷⁷ See Genetics and Public Policy Center at John Hopkins University, Highlights From ASRM 2003, the 59th Annual Meeting of the American Society for Reproductive Medicine, available at <http://www.asrm.org/Media/Press/gentechhealthy.html> (last accessed Mar. 13, 2005).

⁷⁸ These concerns might be well justified. See *Stem Cells from Genetically Screened Test Tube Baby Used to Treat Sister*, 19 TRANSPLANT NEWS, Oct. 6, 2000 (describing parents that screened and selected an embryo in order to find a suitable tissue donor for a sick sibling).

⁷⁹ Celia Hall, “Wide Support” for Genetic Diagnosis, THE DAILY TELEGRAPH, Nov.15, 2001, at 14.

genetic testing if it becomes widespread, especially for trivial reasons. Each health insurance benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps. Testing for non-medical reasons such as sex selection is not in the category of health care, and states shouldn't be subsidizing it. Advancing a fairness argument, it would be appropriate that individualized health insurance premiums go up. The economics of genetic testing might change some day; at that time individualized health insurance (akin to car insurance) might be obtainable.⁸⁰ The state can argue that, until better regulations are put in place, the proposed bill will ensure that the health care funds are directed toward real health care needs of the population.

A statute regulating PGD should indicate that the state's policy is to protect the life of every unborn child, from fertilization until birth, regardless of their degree of biological development, to the extent permitted by the state and federal constitutions. The bill would need to be in line with the recent report released by The President's Council on Bioethics, which recommends increased government scrutiny and regulation of the medical field of assisted reproduction.⁸¹ Careful, broader legislation is needed. The ESHRE PGD Consortium suggested

⁸⁰ For instance, Wisconsin already regulates nontherapeutic abortion in such a way. WIS. STAT. § 40.98(2)(bm) (2003) ("No health care coverage plan under the health care coverage program may provide coverage of a nontherapeutic abortion except by an optional rider or supplemental coverage provision that is offered and provided on an individual basis and for which an additional, separate premium or charge is paid by the individual to be covered under the rider or supplemental coverage provision . . .").

⁸¹ In a report released on April 1, 2004, bioethics advisers to President Bush urged restraints on the largely unregulated test-tube baby business. The President's Council on Bioethics recommended studies of assisted fertility treatments that track mothers and children for long-term health effects. The council also recommended placing time limits on the research use of embryos left over from in vitro fertilization. The council urged those engaged in reproductive medicine to step up their oversight and self-regulation. See THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY, *available at* <http://www.bioethics.gov/reports/reproductionandresponsibility/index.html> (last visited Mar. 13, 2005).

formulation of guidelines specific for the practice of PGD.⁸² On the other hand, the pronouncements of the FDA on jurisdiction over human cloning are not only dubious; they are not helpful, as they take the pressure off Congress to come up with a broader legislation.⁸³

A large problem of genetic tests is the potential for institutional abuse. Fears lie in the use of test results by the state, employer and insurance companies. Widespread administration of PGD can lead to selecting individuals using criteria such as wanted/unwanted characteristics. Reducing the human individual to genes and passing judgment on behavioral traits is demeaning to humanity, and might have terrible consequences for the sick and disabled in our society.

Capricious use of PGD might further exacerbate the unresolved, hot potato issue of the disposition of unused embryos.⁸⁴ Current opinion favors personal (parental) choice, as opposed to state regulation.⁸⁵ The personal choice implied in contract law regarding disposition of embryos suggests that the state's policy regarding embryo disposal is subservient to the parental rights related to their embryos. Unsupervised and unlimited use of PGD might create an avalanche of spare embryos, whose fate and status will further fuel the societal debate over the embryos' fate.

In certain cases, such as prevention of epidemics, the state could institute mandatory genetic screenings to preserve health of the populus. The state could invoke a violation of human rights argument. The state can seek to institute a precautionary principle, allowing

⁸² ESHRE Preimplantation Genetic Diagnosis (PGD) Consortium, *Data Collection III (May 2001)*, 17 HUM. REPROD. 233 (2002).

⁸³ *Legislate Carefully*, BOSTON HERALD, Jan. 24, 1998, at 14 (stating that it is hard to see a role for FDA's regulatory authority when no new drugs are used).

⁸⁴ Susan C. Clock et al., *The Disposition of Unused Frozen Embryos*, 345 NEW ENG. J. MED. 69 (2001).

⁸⁵ See *Davis v. Davis*, 842 S.W. 2d 588 (Tenn. 1992); G. Pennings, *The Validity of Contracts to Dispose of Frozen Embryos*, 28 J. MED. ETHICS 295 (2002).

genetic testing for medical benefits, while keeping a balance in the weighing of the benefit-harm (risk) ratio.

8. *Who Decides*

People's reasons for choosing characteristics of an offspring may have less-than-noble motivations, or may even be frivolous. A critical element in the construction of the bill relates to who decides what tests can be done using prenatal genetic diagnosis. One possibility is the doctor, as is already done in conventional reproductive technologies. Another possibility is that the government will regulate the types of PGD tests that might be performed. The U.S. Supreme Court has held that "States are free to enact laws to provide a reasonable framework for a woman to make a [reproductive] decision...The State may promote its preferences by funding childbirth, by creating and maintaining alternatives to abortion, and by espousing the virtues of family..."⁸⁶

The state can and does delegate public health-related decisions to the state health department. In this instance, the department will be given the authority to issue a list of permissible conditions for which PGD can be done by the state's doctors. This will shift the gatekeeping function to the state, rather than the doctors. Prospective parents are ill suited to make decision about the fate of embryos. Due to the conflict of interest in the decision-making, the state might argue that it would be appropriate for parents to recuse themselves when making decisions about the fate of their embryos in non-medical context.

Although genes influence behavior, we have just begun to understand the mono-, oligo-, or polygenic bases of human behavioral traits. Furthermore, even though there is a genetic basis

⁸⁶ *Planned Parenthood of Pennsylvania v. Casey*, 505 U.S. 833, 916 (1992).

for many conditions, complex behavioral traits are the product of multiple genetic and environmental antecedents.⁸⁷ The state can argue that the bill's objective for regulation of genetic screening in reproductive technologies is legitimate, due to the potential for detrimental social impact of poorly-made parents' choices. Stated differently, it would be wrong to allow parents to make life-or-death decisions based on incomplete understanding of human behavioral genetics.

9. *Requirement of Informed Consent*

In assisted reproduction, informed consent is one of the key tools to help avoid disputes over embryo fate and disposition. Before requesting PGD, prospective parents should consult a geneticist or genetic counselor to evaluate the risk of transferring their genetic abnormality to offspring. Tests should be performed to confirm the diagnosis of the affected parent, to pinpoint the genetic change leading to the condition in question, and to ensure that the currently available technology can identify that genetic change in a blastomere biopsy sample.

Human emotions run particularly high when a married couple is attempting to overcome infertility problems. The applicability of parties' initial informed consent to assisted reproduction procedures is limited because of the near impossibility of anticipating, emotionally and psychologically, all the turns that events may take as the fertilization process unfolds. Provisions for later modification of the initial agreements may protect the parties against some of

⁸⁷ Charles C. Mann, *Behavioral Genetics in Transition*, 264 SCIENCE 1686 (1994).

the risks they face, or in case the relationship becomes sour. In absence of such agreed modification, the parties' prior agreements should be considered binding.⁸⁸

10. International View

In contrast to the U.S., other developed countries have decided to regulate PGD. For instance, in Austria, Germany, Ireland, and Switzerland, PGD is completely prohibited. In Belgium, France, Greece, Holland, Italy, Norway, and the United Kingdom, PGD is limited to medical uses. There is a transnational move toward regulation of reproductive technologies, toward comprehensive regulation. This movement has received strong support in the European countries, with emphasis on societal good, and greater latitude in government's regulation.

Even though these international treaties do not bind the U.S., the treaties can influence congressional acts. The World Medical Association's Declaration of Helsinki is especially relevant for the topic of PGD.⁸⁹ International opinions should be weighed in the balancing considerations, regardless of the U.S. ambivalent attitude consisting of the instinct as to what is good, while emphasizing individual fundamental rights and choices.

⁸⁸ *Davis*, 842 S.W. 2d at 597 (utilizing contract law analysis to support its holding); *J.B. v. M.B.* 783 A.2d 707, 719 n.35 (N.J. 2001) ("Despite the conditional nature of the [embryo] disposition provisions, in the large majority of cases the agreements will control, permitting fertility clinics and other like facilities to rely on their terms.").

11. Actions in Support of PGD Regulation

There is a need for greater public discussion of prenatal genetic diagnosis. To successfully regulate PGD, we should launch a public education campaign, to raise public awareness of the controversial non-medical genetic screening uses. We need to educate the public, including prospective parents, about genetic testing, about disabled people's lives, and improving financial and other support for disabled people and their families. One goal of this education will be to enable every member of the public to make an informed decision whether they want to undergo genetic tests. We need to explain that genetic causation and susceptibility are not well understood. Prospective parents might be tempted to terminate a pregnancy on the assumption that the child carries a disease rather than being susceptible to a disease.⁹⁰ Complex traits are a product of both genetic and environmental factors; hence the parents might be unnecessarily and prejudicially terminating the life of imperfect, but genetically insignificantly inferior child. In case of irreconcilable differences between the parents' points of view, a third party (expert arbitrator) could conduct an independent review and generate a ruling or a recommendation.

The government should fund studies to monitor the long-term health effects of PGD. There is a need for such studies in light of recent reports of slightly higher birth-defect rates with certain IVF techniques.⁹¹ The PGD dilemma needs to be viewed as a part of the bigger picture

⁸⁹ World Medical Association, *Declaration Of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects*, 277 JAMA 925 (1997).

⁹⁰ For a discussion on "genetic fatalism," see J.S. Alper & Jonathan Beckwith, *Genetic Fatalism and Social Policy: The Implications of Behavior Genetics Research*, 66 YALE J. BIOL. MED. 511 (1993).

⁹¹ See Michele Hansen et al., *The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and In Vitro Fertilization*, 346 NEW ENG. J. MED. 725 (2002); Laura A. Schieve et al., *Low and Very Low Birth Weight in*

of need for regulation of reproductive technologies. Paradoxically, periconceptual sex selection by “natural” means is legal, even if it relies on technology developed specifically for that purpose.⁹² Prenatal testing and termination of undesired-sex pregnancies is accepted practice. It is inconsistent to provide couples with information from prenatal testing which allows them to select sex and not allow them to select sex by PGD means.⁹³

A combination of scientific analysis, policy analysis, and research on public attitudes should weigh the potential harms and benefits. Clinical, legal, and ethical issues need to be resolved, and recommendations need to be devised. This could be done through formation of a multidisciplinary committee. The committee would include specialists in IVF, genetic counselors, cytogeneticists, molecular biologists, bioethicists, and policy analysts. Strict documentation requirements of the content system and of the protocol for the procedures involved would ensure implementation of the regulations.

III. CONCLUSION

Regulation of preimplantation genetic diagnosis through the institution of a bill that would limit its practice will probably not survive a court challenge, based on constitutional review. The violation of privacy rights should be of little concern for upholding the bill. However, other serious obstacles to state regulation of reproductive practices exist. The

Infants Conceived With Use of Assisted Reproductive Technology, 346 NEW ENG. J. MED. 731 (2002) (showing preliminary data that children born as a result of IVF are more likely to have birth defects and low birth weight, even if they are not the products of multiple births).

⁹² Robert P.S. Jansen, *Evidence-Based Ethics and the Regulation of Reproduction*, 12 HUM. REPROD. 2068 (1997).

⁹³ *Id.*; see also Julian Savulescu, *Sex Selection: The Case For*, 171 MED. J. AUSTRAL. 373 (1999).

Supreme Court will likely take the view that it is extraordinary for the government to regulate the health profession in terms of a rapidly evolving technology,⁹⁴ or to interfere in physician-patient relationships. The medical profession is far better situated to self-regulate health practices, including the morally debatable ones. The government should influence and encourage the appropriate professional societies to take action.

We would be sorry specimens if we did not have a core sense of what is right and what is wrong. However, the difficulty in seamlessly integrating our systems of values into jurisprudence lies in the fact that we don't share the same core values, so the determination of socially acceptable behavior becomes subjective.

The notable evolution and expansion in the Supreme Court's analysis of fundamental rights, equal rights, and unenunciated freedoms has culminated in *Lawrence*.⁹⁵ Strong arguments can now be made about judicially recognized preeminence of personal autonomy. Unless the *Lawrence* decision becomes tempered and relegated to a footnote, Justice Scalia was right – *Lawrence* did decree the end of all U.S. "morals legislation."⁹⁶ Absent showing of concrete injury to a person, to a vulnerable party, or abuse of an institution that the law protects, the regulation of PGD will not be able to pass constitutional muster.

With the booming array of possibilities associated with genetic screening, some kind of regulation of Preimplantation Genetic Diagnosis is necessary. The regulation should be carefully crafted, and should not be used as a vehicle to promulgate moral views disguised as a federal

⁹⁴ See generally Michael H. Shapiro, *Is Bioethics Broke?: On the Idea of Ethics and Law "Catching Up" with Technology*, 33 IND. L. REV. 17 (1999) (discussing whether law and ethics have lagged behind biotechnology).

⁹⁵ *Lawrence v. Texas*, 539 U.S. 558 (2003).

⁹⁶ Citing the irrationalism of morality announced in *Lawrence*, two sections of California's Family Code were recently found unconstitutional, "because they have no rational relation to a legitimate state purpose." Judicial Council Coordination Proceeding #4635, State of California (2005).

statute. Under current federal and state law, the decision to conduct prenatal genetic diagnosis tests for various purposes should be made by the couple, after informed consent. Only qualified doctors, with available indications and previous, comprehensive consultations should conduct genetic tests. The costs of PGD for health purposes should be carried by health insurance in order to prevent social inequalities. A competent authority should safeguard the quality of the genetic tests. Regulation and practice should be in a symbiotic relationship, and they should be constantly informing each other.