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## A Parent's Choice v. Governmental Regulations: A Bioethical Analysis in an Era of Preimplantation Genetic Diagnosis

Michael Gortakowski

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**A PARENT'S CHOICE v. GOVERNMENTAL  
REGULATIONS: A BIOETHICAL ANALYSIS IN AN ERA  
OF PREIMPLANTATION GENETIC DIAGNOSIS**

MICHAEL GORTAKOWSKI<sup>†</sup>

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For most people November 18, 2005 was just another Friday, but for Jenifer and Angelo Magliocco, it was a day they would remember for the rest of their lives. At 2:43 pm, blue-eyed

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Angelo James was introduced to the world, weighing seven pounds and measuring almost twenty one inches long. Tears of joy filled the eyes of the Maglioccos when Angelo James cried for the first time. By Sunday, Dr. Esposito, the family's pediatrician, cleared Angelo James to go home to his safari themed nursery. The Maglioccos went through the process of changing, feeding, and bathing Angelo James and loved every minute of being new parents. The next few weeks were amazing for the Magliocco family, but fear grew when they noticed that Angelo James seemed extremely calm and relaxed compared to other newborns. The Maglioccos called Dr. Esposito for reassurance that Angelo James was fine. On December 18, one month after his birth, Angelo James was back in a hospital, but this time there was no reason to celebrate. Shortly thereafter, the Maglioccos received devastating news. There was a strong possibility that Angelo James suffered from Spinal Muscular Atrophy ("SMA"), a fatal disease. Three weeks later, on their way to see another physician, Jenifer received a phone call confirming her worst fears, the DNA tests were positive for SMA Type 1. Angelo James passed away after eight short weeks of life.<sup>1</sup>

In 2006, National Public Radio reported that the Maglioccos, with the help of a Yale University geneticist and a technique known as preimplantation genetic diagnosis ("PGD"), were attempting to have a child free of SMA.<sup>2</sup>

## INTRODUCTION

The late 1970s saw the first child born from *in vitro* fertilization ("IVF").<sup>3</sup> About ten years later, a procedure known as

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<sup>1</sup> This is a true story. The Magliocco family experienced the joy of life and the pain of death within a short two-month period. *Angelo's Story*, THE ANGELO JAMES MAGLIOCCO FOUNDATION, [http://www.angelojamesmagliocco.org/angelos\\_story.html](http://www.angelojamesmagliocco.org/angelos_story.html) (last visited Feb. 25, 2011).

<sup>2</sup> Joe Palca, *Screening Embryos for Disease*, NPR.org, (Dec. 20, 2006), <http://npr.org/templates/story.php?storyId=6653837>.

<sup>3</sup> Peggy Orenstein, *The Way We Live Now: In Vitro We Trust*, N.Y. TIMES MAGAZINE (July 20, 2008), <http://www.nytimes.com/2008/07/20/magazine/20wwln-lede-t.html>.

PGD<sup>4</sup> that analyzed the genetic make-up of two and one half day pre-embryos<sup>5</sup> created through IVF before implantation *in utero*,<sup>6</sup> was allowing parents to make critical decisions about the futures of their unborn children.<sup>7</sup> Within twenty five years, the completion of the Human Genome Project has mapped over three billion base pairs of DNA and more than 1,400 disease genes within the human body with an accuracy of 99.9%.<sup>8</sup> As scientists uncover new areas of genetic understanding within the human genome, as it pertains to disease and non-disease genes, legislatures will face increased pressure to pass laws regarding the ethical dilemmas associated with PGD. The combination of all three scientific discoveries has led to increased concern for a future filled with assisted reproductive technology (“ART”) and overzealous parents wanting only the best for their child at any cost.

This paper begins by analyzing the ethical considerations involved in a parent’s choice for PGD in the process of procreation. This paper then focuses on a line of Supreme Court cases to analyze whether a right to autonomous choice is recognized by the Constitution and if it can be asserted as a protected liberty. Section II looks at the current field of PGD

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<sup>4</sup> For the purpose of this paper, the term PGD will encompass preimplantation genetic diagnosis, preimplantation genetic screening (“PGS”), and preimplantation genetic screening and selection (“PGSS”). Although authors have suggested definitions for all three, this paper does not attempt to draw a distinction.

<sup>5</sup> See *Davis v. Davis*, 842 S.W.2d 588, 592-94 (Tenn. 1992). The Tennessee Supreme Court determined that in the case before them the “frozen embryos” of four-to-eight-cells were to be referred to as “pre-embryos” rather than “embryos.”

<sup>6</sup> See Donrich W. Jordaan, *Preimplantation Genetic Screening and Selection: An Ethical Analysis*, 22 BIOTECHNOLOGY L. REP. 586, 586-87 (2003).

<sup>7</sup> J. A. Robertson, *Extending Preimplantation Genetic Diagnosis: Medical and Non-Medical Uses*, 29 J. MED. ETHICS 213, 213 (2003), available at <http://jme.bmj.com/cgi/reprint/29/4/213>.

<sup>8</sup> Nat’l Inst. of Health News, *International Consortium Completes Human Genome Project* (Apr. 14, 2003, 1:00 PM), <http://www.nih.gov/news/pr/apr2003/nhgri-14.htm>.

regulation to see how the ethical question of regulation versus choice is handled by both international nations as well as the United States. Section III examines the bioethical principles of a parent's autonomous choice and the governmental interest in promoting justice through regulation regarding PGD. Next, hypothetical situations where one bioethical principle is chosen over another are presented and subsequently rejected as unethical in either circumstance. Section IV takes the stance that the combination of a central government agency protecting safety and efficacy and professional organizations weighing autonomy and justice for PGD creates an ethical solution suitable for the United States. Finally, this paper argues that both bioethical principles of autonomy and justice must be taken into consideration with the creation of governmental regulation for PGD because balancing these principles is the best solution to creating the most ethical result.

When determining whether governmental regulation for PGD is ethical, this paper relies on the questions: What is the issue? Who are we protecting and how are they perceived? What ethical principles apply? Are the actions taken ethical? Is the action ethically based on the balancing of applicable principles? And if the action were unethical, what would make it ethical?<sup>9</sup>

This Author notes that the analysis of the third bioethical principle, beneficence,<sup>10</sup> is not left out of this paper because of a lack of oversight, but because the concepts of autonomy and justice take center stage. Realistically speaking, questions of parental intent, actions of the physician, and the instituted regulations all raise valid concerns of beneficence toward one

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<sup>9</sup> This paper relies on class discussion of bioethical principles with Professor Ruqaiijah A. Yearby.

<sup>10</sup> See generally TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 165-214 (5th ed. 2001). If the bioethical principle of beneficence was applied, the appropriate topics would include: 1) actions taken by the parents to benefit their child, 2) actions taken by the physicians to benefit the parents and the child, and 3) the actions of the government taken to benefit all three. *Id.*

another and the future child.<sup>11</sup> But an assumption that all participants are acting in the best interests of one another is necessary in order to focus on what this Author believes is most essential- autonomy and justice.<sup>12</sup> This paper focuses on a parent's choice to use PGD and the bioethical principles a government must address when considering regulation, rather than the future child.

## I. PGD AND AUTONOMOUS PROCREATION

Determining whether a parent's choice for PGD is ethical relies heavily on the weight given to their autonomous choices.<sup>13</sup> An autonomous choice focuses on the actual self-governance of decisions rather than the individual's capacity to make those decisions.<sup>14</sup> A person can only make an autonomous choice when he is acting intentionally with understanding and is substantially free from controlling influences.<sup>15</sup> Although an action is either intentional or not, the understanding and influences that determine an autonomous action can be measured in varying degrees.<sup>16</sup> It is almost impossible to say that a person has complete understanding or is without controlling influences when making a decision, but marking a point on the spectrum of understanding and influence can help to determine the level of autonomy behind a choice made and whether that action can be deemed ethical.<sup>17</sup>

Do society's laws shape our moral principles or do our moral principles shape society's laws? This Author suggests that although the legality of our actions does not always necessarily correspond to whether our actions are ethical, it is a good starting point for trying to uncover how today's society views morality and the ethical principles of autonomy and justice. Therefore, this

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<sup>11</sup> *See id.*

<sup>12</sup> *See id.*

<sup>13</sup> *See id.* at 121.

<sup>14</sup> *See id.*

<sup>15</sup> *See id.* at 123.

<sup>16</sup> *See id.*

<sup>17</sup> *See id.*

paper begins with a closer look at whether the Supreme Court of the United States has interpreted a protected fundamental right for PGD.

### A. Is There a Protected Fundamental Right for PGD?

*“Ultimately, decisions about how to use or not use genomics in human reproduction will be determined, not by biological necessity or evolutionary theory, but by how those uses fit into the fabric of rights and interests of individual and social choice and responsibility that particular societies recognize.”*<sup>18</sup>

*-John A. Robertson*

What if the United States has yet to directly address the rights and interests that genomic uses in human reproduction will raise? What then is the best gauge for predicting where our individual interests will lie on society’s spectrum of protected rights in the coming age of “reprogenetics”?<sup>19</sup> Two authors, John A. Robertson and Dov Fox, suggest that it is plausible to extrapolate a constitutionally protected right that might include procreative liberty,<sup>20</sup> and genetic engineering<sup>21</sup> in reproduction within the United States from a line of past Supreme Court cases.

In *Griswold v. Connecticut*,<sup>22</sup> Justice Douglas delivered the Court’s opinion regarding whether a Connecticut statute prohibiting the use and aiding and abetting the use of

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<sup>18</sup> John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 452 (2003).

<sup>19</sup> *Id.* at 481 (reprogenetics means the use of genetics in reproduction).

<sup>20</sup> *See id.* at 452-55. “Procreative liberty is best understood as a liberty or claim-right to decide whether or not to reproduce. As such, it has two independently justified aspects: the liberty to avoid having offspring and the liberty to have offspring.” *Id.* at 447.

<sup>21</sup> Dov Fox, *Silver Spoons and Golden Genes: Genetic Engineering and the Egalitarian Ethos*, 33 AM. J.L. & MED. 567, 577-79 (2007).

<sup>22</sup> 381 U.S. 479 (1965).

contraceptives was unconstitutional.<sup>23</sup> The Court held that the Connecticut statute was unconstitutional under the Due Process Clause of the Fourteenth Amendment.<sup>24</sup> Justice Goldberg drew upon prior Court decisions in his concurrence, to interpret that the Due Process Clause “protects those liberties that are ‘so rooted in the traditions and conscience of our people as to be ranked as fundamental,’” such as marital privacy.<sup>25</sup> In regards to prohibiting the use of contraceptives, Justice Goldberg stated that it would astonish him if “personal liberty guaranteed by the Constitution does not include protection against such totalitarian limitation of family size, . . .” which can be regarded under the concept of marital privacy.<sup>26</sup> Although *Griswold* does not directly address whether a fundamental right exists for a parent to make an autonomous choice regarding non-coital reproduction, the case creates a framework upon which to build a procreative right.

In *Eisenstadt v. Baird*,<sup>27</sup> Justice Brennan delivered Court’s opinion on the issue of whether a Massachusetts law prohibiting the use or distribution of contraceptives to unmarried individuals was unconstitutional.<sup>28</sup> The Court held that the Massachusetts law violated the Equal Protection Clause of the Fourteenth Amendment, and was therefore unconstitutional.<sup>29</sup> The Court revisited the *Griswold* decision when discussing the protection of the right of privacy and made the statement that “[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

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<sup>23</sup> *Id.* at 480.

<sup>24</sup> *See id.* at 486 (Goldberg, J., concurring).

<sup>25</sup> *Id.* at 487 (quoting *Snyder v. Com. of Massachusetts*, 291 U.S. 97, 105 (1934), *overruled in part by Malloy v. Hogan*, 378 U.S. 1 (1964) (regarding a 5th amendment violation)).

<sup>26</sup> *Id.* at 497.

<sup>27</sup> 405 U.S. 438 (1972).

<sup>28</sup> *Id.* at 446-47.

<sup>29</sup> *Id.* at 454-55.



whether to bear or beget a child.”<sup>30</sup> Fox notes that the Court’s positions in *Griswold*, *Eisenstadt*, and *Casey* culminate in the conclusion that the “fundamental right to make childbearing decisions free from state interference” is a matter of due process.<sup>31</sup>

In *Roe v. Wade*,<sup>32</sup> Justice Blackmun delivered the opinion of the Court regarding whether a Texas statute that criminalized abortion was unconstitutional.<sup>33</sup> The Court held that the criminal abortion statute in Texas, and others like it, violated the Due Process Clause of the Fourteenth Amendment and was therefore unconstitutional.<sup>34</sup> The Court recognized certain instances regarding a “right of personal privacy” of an individual where there are “zones of privacy [that do] exist under the Constitution.”<sup>35</sup> The Court went on to say that case history has established that the protected privacy right extends to the activities of procreation and child rearing.<sup>36</sup> However, the Court held that although a woman does have a privacy right related to pregnancy and the decision to terminate, that right is not absolute; upon a showing of a ‘compelling state interest,’ the State may limit those rights.<sup>37</sup> An important distinction was drawn between a pregnant woman’s privacy right and the privacy aspects of other rights such as procreation, due to the involvement of a third party (the fetus) during pregnancy.<sup>38</sup> Arguably, the Court has placed a lower burden

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<sup>30</sup> *Id.* at 453.

<sup>31</sup> Fox, *supra* note 21, at 576. Fox notes that the *Casey* Court draws from dictum of *Eisenstadt* to establish a substantive due process right that protects personal privacy.

<sup>32</sup> 410 U.S. 113 (1973).

<sup>33</sup> *See id.* at 116.

<sup>34</sup> *See id.* at 164.

<sup>35</sup> *Id.* at 152.

<sup>36</sup> *See id.* at 152-53 (citing *Skinner v. Oklahoma*, 316 U.S. 535, 541-42 (1942) (procreation); *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 535 (1925) (child rearing)).

<sup>37</sup> *See id.* at 154-55 (quoting *Kramer v. Union Free Sch. Dist.*, 395 U.S. 621, 627 (1969)).

<sup>38</sup> *See id.* at 159.

on the State to show an interest necessary to limit a pregnant woman's right to privacy compared to her right to procreate.<sup>39</sup>

In *Casey v. Planned Parenthood of Southeastern Pennsylvania*,<sup>40</sup> Justice O'Connor, Justice Kennedy and Justice Souter delivered the opinion of the Court regarding the constitutionality of the Pennsylvania Abortion Control Act of 1982.<sup>41</sup> *Casey* was an opportunity for the Court to revisit and redraw the boundaries for the circumstances under which the State could limit the fundamental right of a woman to terminate her pregnancy as decided in *Roe v. Wade*.<sup>42</sup> The Court determined that the main holding of *Roe* should be kept intact but changed the "rigid trimester framework" to an "undue burden analysis" – balancing the State's interest to preserve and promote life against a woman's constitutionally protected rights.<sup>43</sup> Although the standard seems to have lessened from a compelling State interest to a showing of undue burden, the Court did note that the constitutional protection to personal decisions, such as procreation, family relationships, and child rearing, "involv[e] 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."<sup>44</sup>

In *Lawrence v. Texas*,<sup>45</sup> Justice Kennedy delivered the opinion of the Court regarding the constitutionality of a Texas statute criminalizing the intimate sexual conduct of two members of the same sex.<sup>46</sup> Overruling its decision in *Bowers v. Hardwick*,<sup>47</sup>

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<sup>39</sup> *See id.* ("The situation [of pregnancy] therefore is inherently different from marital intimacy, . . . or procreation, . . . with which Eisenstadt and Griswold, . . . [and] Skinner . . . were respectively concerned.").

<sup>40</sup> 505 U.S. 833 (1992).

<sup>41</sup> *Id.* at 843-45.

<sup>42</sup> *See id.* at 853.

<sup>43</sup> *Id.* at 878-79.

<sup>44</sup> *Id.* at 851.

<sup>45</sup> 539 U.S. 558 (2003).

<sup>46</sup> *Id.* at 562.

<sup>47</sup> *See id.* at 578-79.

the Court held that under the Due Process Clause of the Fourteenth Amendment the Texas statutes were unconstitutional for violating the privacy liberty of individuals in making a decision about their sexual practices. Both Fox and Robertson identify *Lawrence* as the Court's expansion of protected privacy rights associated with personal choices considered extremely intimate. Therefore, *Lawrence* creates the possibility of a broader interpretation into reproductive rights involving genetics in ART.<sup>48</sup>

In *Gonzales v. Carhart*,<sup>49</sup> Justice Kennedy delivered the Court's opinion regarding the constitutionality of the Partial-Birth Abortion Ban Act of 2003.<sup>50</sup> The Court held that the Act's prohibition of the "intact" dilation and evacuation ("D & E") procedure, used for pre-viability second trimester abortions, was constitutional because it was neither vague nor did it place an undue burden on women.<sup>51</sup> The Court further stated that "[t]he government may use its voice and its regulatory authority to show us profound respect for the life within the woman," seemingly limiting certain actions, such as "intact" D & E which might devalue that respect.<sup>52</sup> Although the Court's decision in *Gonzales* prohibits a certain type of abortion, the Court recognized that the constitutional right for a woman to terminate a pregnancy is still available in other forms.<sup>53</sup>

### B. Varying Opinions

An individual's actions regarding his "procreative liberty's" constitutional protection against state interference "depend upon whether they were centrally or intimately connected with reproductive decision-making."<sup>54</sup> Robertson suggests that the closer the actions of an individual are linked to the fundamental right to reproduce, the further the constitutional presumption of

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<sup>48</sup> See Fox, *supra* note 21, at 577; Robertson, *supra* note 18, at 454-55.

<sup>49</sup> 550 U.S. 124 (2007).

<sup>50</sup> See *id.* at 132.

<sup>51</sup> See *id.* at 168.

<sup>52</sup> *Id.* at 157.

<sup>53</sup> See *id.* at 181-82 (Ginsburg, J., dissenting).

<sup>54</sup> Robertson, *supra* note 18, at 454.

protection against state interference will extend under a concept of procreative liberty.<sup>55</sup> However, Robertson notes that this constitutionally extended presumption will only go as far as the actions are viewed as necessary to reproduction and no great harms are imposed on others.<sup>56</sup>

Relying on the interpretation of *Lawrence* as an indication that the Supreme Court will broaden the childbearing jurisprudence, Fox suggests possible ways in which the Supreme Court might find a protected liberty interest in genetic reproduction.<sup>57</sup> The first approach, an autonomy defense, reads the dictum of *Casey* as recognizing that the autonomous choices an individual makes throughout his lifetime are so personal that he inherently demands protection as a fundamental right.<sup>58</sup> One could argue that within reproduction is the liberty to use genetics in ART.<sup>59</sup>

The second approach, an analogical defense, relies on the *Washington v. Glucksberg*<sup>60</sup> analysis of an asserted right's proximity to other fundamental rights that have already been established.<sup>61</sup> Fox argues that under safe conditions it is reasonable to draw a parallel between the affects of a parent's choice in early child development after birth and genetic intervention before birth, both being extremely important to the childrearing experience and therefore, extend protection to genetic engineering in ART.<sup>62</sup>

Contrary to the possible extensiveness of procreative liberty as a right extrapolated from previous Supreme Court cases as noted by Fox and Robertson, King suggests that the ruling in *Gonzales* expands the State's right to regulate the medical profession to promote the interest of life possibly even to pre-

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<sup>55</sup> *See id.*

<sup>56</sup> *See id.*

<sup>57</sup> *See Fox, supra* note 21, at 577-79.

<sup>58</sup> *See id.* at 577-78.

<sup>59</sup> *See id.*

<sup>60</sup> 521 U.S. 702 (1997).

<sup>61</sup> *See Fox, supra* note 21, at 577-79.

<sup>62</sup> *See id.*

embryos outside the uterus.<sup>63</sup> In light of *Gonzales* and in accord with King's view, Robertson suggests “. . . it is not a stretch to think that a future Supreme Court majority would allow states to protect human life from fertilization onward, whether the entity at stake is inside or outside the body[,]” with the qualification that the Court “found no other reproductive or liberty rights violated.”<sup>64</sup> Of course only speculation can be made as to the breadth of protection an individual has to PGD for reproduction under the Constitution without the Supreme Court addressing that specific question.

## II. GOVERNMENTAL REGULATION OF PGD

The concept of justice gives weight to an ethical analysis of governmental regulation to ensure “fair, equitable, and appropriate treatment in light of what is due or owed to persons,” within a society.<sup>65</sup> A government that does not center its foundation on a free-market distribution of goods and attempts to act equitably toward prospective parents, might base restrictive regulation of PGD on a philosophy of distributive justice.<sup>66</sup> A government in a free-market structure, such as the United States, might rely more heavily on a libertarian theory of justice where individuals' rights and property are protected to allow PGD to be used to improve their reproduction and childrearing environment.<sup>67</sup> However, an underlying sense of egalitarian attitudes of justice that provides fairness to all members of a society might be used to weigh regulation versus autonomous choice for PGD.<sup>68</sup> It is informative to see how this difficult question is dealt with on an international level when trying to make a prediction of how the United States may regulate PGD.

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<sup>63</sup> See Jamie King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL'Y L. & ETHICS 283, 328 (2008).

<sup>64</sup> John A. Robertson, *Assisting Reproduction, Choosing Genes, and the Scope of Reproductive Freedom*, 76 GEO. WASH. L. REV. 1490, 1497 (2008).

<sup>65</sup> See BEAUCHAMP & CHILDRESS, *supra* note 10, at 226.

<sup>66</sup> See *id.* at 327-28.

<sup>67</sup> See *id.* at 337.

<sup>68</sup> See *id.* at 339-40; see also Fox, *supra* note 21, at 573.

### **A. A Perspective of International Regulation for PGD**

The international landscape of PGD is a hodgepodge of regulation ranging from absolute bans to negligible intervention.<sup>69</sup> As noted by Soini, no specific “international governmental instruments” exist to regulate PGD other than the advice of national ethics committees in the forms of recommendations and reports.<sup>70</sup> Even the European Union is able to skirt the responsibility of regulating PGD because matters of health policies belong to the sovereign nations under the EC Treaty.<sup>71</sup> This leaves PGD regulation dependant on the suggestions of professional organizations and the laws of individual nations.

#### **1. International Professional Organizations**

It is appropriate to start the analysis of international regulation of PGD with the “regulation” that holds no legal authority, hence the term professional organization “guidelines.” The International Bioethics Committee (“IBC”) of the United Nations Educational, Scientific and Cultural Organization (“UNESCO”) released a report analyzing the ethical use of PGD and germ-line intervention in 2003, and came to the following conclusions, among others: 1) PGD should be limited to medical uses, 2) PGD testing for normal mental and physical characteristics should be rejected, and 3) PGD for selecting pre-embryos with genetic disease or condition similar to a parent is unethical.<sup>72</sup> In addition to the UNESCO IBC’s guidelines released in 2003, the Preimplantation Genetic Diagnosis International Society

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<sup>69</sup> See S. Soini, *Preimplantation Genetic Diagnosis (PGD) In Europe: Diversity of Legislation a Challenge to the Community and Its Citizens*, 26 *MED. & L.* 309, 317 (2007).

<sup>70</sup> See *id.* at 319-20.

<sup>71</sup> See *id.* at 321.

<sup>72</sup> See UNESCO Int’l Bioethics Comm. [IBC], *Reports of the IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention*, at 14-15, UNESCO Doc. SHS-2003/WS/26 (Apr. 24, 2003), available at <http://unesdoc.unesco.org/images/0013/001302/130248e.pdf>.

(“PGDIS”) released guidelines for practice in 2004 and the European Society of Human Reproduction and Embryology (“ESHRE”) released their Best Practice Guidelines in 2005.<sup>73</sup> Although Soini claims that Article 4 of the Biomedicine Convention (1997) provides a “special value” to the guidelines, there are still questions as to how thoroughly, if at all, these suggestions and recommendations are actually followed in practice.<sup>74</sup>

## 2. Individual Nations

### a. Strict Ban

Some countries have ended the discussion of PGD within their borders by banning PGD through legislation.<sup>75</sup> Germany, Austria and Italy are among the countries that have banned the practice of PGD.<sup>76</sup> Soini points out that although these countries have banned the use of PGD within their borders, patients can easily travel to nearby countries with less restrictive regulations to receive the PGD treatment they want.<sup>77</sup>

### b. Restricted Use

Other countries have taken a more moderate approach to PGD and allow its use with certain limitations.<sup>78</sup> Countries such as France, Denmark, Norway, New Zealand, Japan, Canada, the Netherlands, Australia, and the United Kingdom have allowed PGD under specific circumstances.<sup>79</sup> France, Denmark and Norway have passed legislation that allows PGD-Human Leukocyte Antigen (“PGD-HLA”) for tissue typing to match a

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<sup>73</sup> See Soini, *supra* note 69, at 320-21.

<sup>74</sup> See *id.* at 321.

<sup>75</sup> See King, *supra* note 63, at 318; Soini, *supra* note 69, at 318.

<sup>76</sup> See King, *supra* note 63, at 318; Soini, *supra* note 69, at 318 (noting that although a restrictive ban of PGD exists in Germany, the public attitude is more liberal).

<sup>77</sup> See Soini, *supra* note 69, at 318.

<sup>78</sup> See King, *supra* note 63, at 318; Soini, *supra* note 69, at 318.

<sup>79</sup> See King, *supra* note 63, at 318; Soini, *supra* note 69, at 318; C. Thomas, *Preimplantation Genetic Diagnosis: Development and Regulation*, 25 *MED. & L.* 365, 370-71 (2006).

seriously ill brother or sister.<sup>80</sup> Japan has not passed legislation restricting PGD, but the professional organization, the Japanese Society of Obstetricians and Gynecologists, weighs the social impact PGD would have on effected groups before issuing a license to a specific clinic to use PGD.<sup>81</sup> The Netherlands will only allow PGD for “serious conditions.”<sup>82</sup> The Australian Medical Association has guidelines that state PGD should only be used to prevent permanent diseases.<sup>83</sup> New Zealand’s National Ethics Committee on Assisted Human Reproduction established guidelines that leave the decision of PGD not to the family, but rather to the consensus of genetic counselors and PGD providers in a case-by-case determination of whether a familial disorder will be serious in the future child.<sup>84</sup>

The United Kingdom (“UK”) established the Human Fertilisation and Embryology Authority (“HFEA”) to oversee the use of PGD.<sup>85</sup> A clinic must receive a license from the HFEA to use PGD.<sup>86</sup> The HFEA lists most of the conditions under which they will allow PGD on its website.<sup>87</sup> However, if the HGEA does not already allow PGD in a situation, a clinic may submit an application for that specific PGD use.<sup>88</sup> Before deciding whether or not to allow the use of PGD, HFEA will review the application using scientific, legal, ethical, and medical information.<sup>89</sup> The HFEA is continuously changing PGD’s acceptable uses as new

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<sup>80</sup> See Soini, *supra* note 69, at 318.

<sup>81</sup> See King, *supra* note 63, at 318. King notes that, to date, PGD use in Japan has been extremely limited.

<sup>82</sup> *Id.* at 347 (citation omitted).

<sup>83</sup> *Id.*

<sup>84</sup> Thomas, *supra* note 79, at 370-71.

<sup>85</sup> See King, *supra* note 63, at 318.

<sup>86</sup> Soini, *supra* note 69, at 318.

<sup>87</sup> Human Fertilisation & Embryology Authority Home Page, <http://www.hfea.gov.uk/cps/hfea/gen/pgd-screening.htm> (last visited Feb. 25, 2011).

<sup>88</sup> *Id.*

<sup>89</sup> See Soini, *supra* note 69, at 318.



technologies emerge and a greater understanding is reached on how certain conditions manifest.<sup>90</sup>

In 2006, the HFEA changed its policy allowing PGD screening for non-lethal genes that are linked to cancer risk in adulthood.<sup>91</sup> The HFEA departed from its 2001 policy, limiting PGD use based on the parents' intentions for the child after birth<sup>92</sup> because the House of Lords determined that the HFEA's role is limited to the extent of pre-embryo selection.<sup>93</sup>

## **B. No Regulation of PGD – The United States**

“No Regulation” is a slight misnomer when referring to the United States because certain agencies have discretion to regulate aspects of PGD; however, no agencies or statutes have direct control over the process.<sup>94</sup>

### **1. Professional Organizations**

Professional organizations such as the American Society of Reproductive Medicine (“ASRM”) and the Society for Assisted Reproductive Technology (“SART”) have developed guidelines, and they offer informational services for clinics involved with PGD.<sup>95</sup> For example, ASRM ethics committee suggests that PGD not be used for sex selection unless for preventing a serious sex-linked disease, and ASRM found that PGD was a suitable substitute for postconception diagnosis and pregnancy

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<sup>90</sup> See *id.*; Thomas, *supra* note 79, at 372-73.

<sup>91</sup> Laura Blackburn, *U.K. Embryos May be Screened for Cancer Risk*, 312 SCI. 984 (2006).

<sup>92</sup> See, e.g., Thomas, *supra* note 79, at 372-73 (a parent was limited to only using the child's cord blood for an ill sibling, not bone marrow).

<sup>93</sup> *Id.*

<sup>94</sup> See Rebecca Dresser, *Preimplantation Genetic Diagnosis as Medical Innovation: Reflections From The President's Council on Bioethics*, 85 FERTILITY & STERILITY 1633, 1634 (2006); Kathy L. Hudson, *Preimplantation Genetic Diagnosis: Public Policy and Public Attitudes*, 85 FERTILITY & STERILITY 1638, 1638-39 (2006); King, *supra* note 63, at 333; Note, *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574, 579 (2006).

<sup>95</sup> See King, *supra* note 63, at 324.

termination.<sup>96</sup> However, similar to international professional organizations, professional organizations within the United States are voluntary with no legal standing against violators.<sup>97</sup> Although organizations such as SART can require their members to follow certain guidelines and procedures, such as being accredited and filing success rate information, failure to follow SART guidelines and procedures cannot result in prosecution; the penalty for failure to abide by SART guidelines is merely a revocation of membership.<sup>98</sup> Membership in these professional organizations, at least in the United States, is not required to operate ART clinics or use PGD.<sup>99</sup>

## 2. Federal Agencies

The authority of the Food and Drug Administration (“FDA”) does not encompass regulating a physician’s medical practices with patients.<sup>100</sup> Although the FDA does have the ability to regulate devices for efficacy and safety that might be used during PGD, such as genetic tests, the FDA commonly takes a “hands off” approach.<sup>101</sup>

The Center for Medicaid and Medicare Services (“CMS”) does not have direct authority to regulate any ART or PGD procedures, but through the Clinical Laboratory Improvement Act (“CLIA”) CMS has the authority to grant a specialty certification license required to practice those specialty procedures.<sup>102</sup>

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<sup>96</sup> Hudson, *supra* note 94, at 1640.

<sup>97</sup> See King, *supra* note 63, at 325.

<sup>98</sup> See *id.*

<sup>99</sup> See *id.*

<sup>100</sup> See Dresser, *supra* note 94, at 1635; Hudson, *supra* note 94, at 1638-39; *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 94, at 579.

<sup>101</sup> See King, *supra* note 63, at 335 (noting the majority of genetic test regulation is left to the CMS because most laboratories were creating their own genetic tests that were not being commercialized, however, the genetic test landscape is changing).

<sup>102</sup> See *id.* at 334.

However, CMS has not created a specialty certification for genetic testing laboratories to hold the genetic testing associated with PGD to a higher quality standard.<sup>103</sup> CMS does not classify PGD laboratories as “clinical laboratories” under the CLIA, and therefore these laboratories do not require a specialty certification license to practice.<sup>104</sup>

The Centers for Disease Control and Prevention (“CDC”) under the Fertility Clinic Success Rate and Certification Act (“FCSRCA”) requires IVF providers to report annual success rates for publication by the CDC.<sup>105</sup> Failure by IVF providers to report annual success rates, however, only results in the minor punishment of being put on a list of providers who failed to report, and no further penalty is imposed.<sup>106</sup> King comments that under the current CDC structure for dealing with ART and PGD related activities, or lack thereof, the CDC has even less authority than professional organizations.<sup>107</sup>

### III. ETHICAL ANALYSIS: PARENT'S CHOICE v. GOVERNMENTAL REGULATION

Under what circumstances is it ethical for a parent to use PGD for procreative purposes? Under what circumstances is it ethical for a government to prohibit the use of PGD for procreative purposes? Is one ethical claim greater than the other? Which principle wins in the ethical balancing act of autonomy versus justice? This Author submits that not only is there no clear-cut answer to any of these questions, but in varying circumstances both autonomy and justice have an equal chance to prevail.

First, an argument for autonomous choice in procreation will be made. Second, an argument will be made for governmental regulation based on theories of justice. Finally, two hypothetical situations, where both scenarios are taken to the extreme, will

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<sup>103</sup> *Id.* at 334-35.

<sup>104</sup> *See* Hudson, *supra* note 94, at 1639.

<sup>105</sup> *Id.* at 1638.

<sup>106</sup> *Id.* at 1638-39.

<sup>107</sup> *See* King, *supra* note 63, at 334.

demonstrate how taking either bioethical principle without the other can never be ethical, with the ethical implications of everything in between relying on a balance of the two.

### A. Argument for a Parent's Choice

Respect for a person's right to make an autonomous choice is deeply engrained in the ideological foundations of the United States and further reflected in a line of Supreme Court decisions interpreting the Fourteenth Amendment.<sup>108</sup> The importance of autonomous choice in reproduction has a long history supported by "[l]aws, ethical norms, and institutions [that] protect and support human desires to have or avoid having offspring, and the rearing that follows".<sup>109</sup> The Supreme Court recognized in *Skinner v. Oklahoma*<sup>110</sup> that "[m]arriage and procreation are fundamental to the very existence and survival of the race[,] and further noted the importance of reproduction in its discussion of legislation that would force sterilization of a man convicted two or more times of a felony as "dealing . . . with legislation which involves one of the basic civil rights of man."<sup>111</sup>

A government that decides against regulation of PGD is attempting to protect the principles of parental autonomy during reproductive decision-making.<sup>112</sup> The Government assumes that the perspective parents are not only capable of acting intentionally and are not substantially influenced by controlling factors, but also

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<sup>108</sup> See cases cited *supra* notes 22, 27, 32, 40, 45; see also BEAUCHAMP & CHILDRESS, *supra* note 10, at 57 ("Respect for the autonomous choices of other persons runs as deep in common morality as any principle . . ."); see generally *Washington v. Glucksberg*, 521 U.S. 702, 727 (1997) (citing *Planned Parenthood Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 851 (1992) (recognizing prior cases where personal activities and decisions have been protected by the Fourteenth Amendment)).

<sup>109</sup> Robertson, *supra* note 18, at 451.

<sup>110</sup> 316 U.S. 535 (1942).

<sup>111</sup> *Id.* at 541.

<sup>112</sup> See Sonia M. Suter, *A Brave New World of Designer Babies*, 22 BERKELEY TECH. L.J. 897, 949 (2007).

that they are using that capacity to make a well informed and reasonable choice when deciding to reproduce using PGD.<sup>113</sup> Governmental regulation of PGD in the broadest sense could lead to an arbitrary limitation restricting a parent's most powerful interests when deciding to have a child.<sup>114</sup> Only in the most extreme conditions having a direct relation to inequality and discrimination should governmental regulation play a role in limiting a parent's autonomous choice in ART involving PGD.

### **B. Argument for Governmental Regulation**

Although under the Due Process Clause of the Fourteenth Amendment the Supreme Court has found protection for autonomous choices involving reproduction, it is clear that this right, like any other, is not above regulation, as shown in the infamous eugenics case of *Buck v. Bell*.<sup>115</sup> In *Buck*, the Supreme Court upheld the constitutionality of a Virginia sterilization law that enabled the superintendent of certain institutions to force sterilization of patients.<sup>116</sup> The Virginia Act justified limiting an autonomous choice to reproduce by stating "that the health of the patient and the welfare of society may be promoted in certain cases by the sterilization of mental defectives . . ."<sup>117</sup> Justice Holmes rationalized the State's limitation of autonomous choice by comparing the lives given up by "the best citizens" for the public welfare versus the "lesser sacrifice" of people such as Carrie Buck.<sup>118</sup> *Buck* has yet to be overruled and therefore, as horrific the thought of forced sterilization may seem, the case serves as a reminder that under certain circumstances governmental regulation of our autonomous choices can be held constitutional.<sup>119</sup>

A government that institutes regulation of PGD is attempting to protect persons already born with disabilities or

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<sup>113</sup> See BEAUCHAMP & CHILDRESS, *supra* note 10, at 58-60.

<sup>114</sup> See Robertson, *supra* note 18, at 450-53.

<sup>115</sup> 274 U.S. 200 (1927).

<sup>116</sup> See *id.* at 207.

<sup>117</sup> *Id.* at 205.

<sup>118</sup> *Id.* at 207.

<sup>119</sup> See *id.* at 208.

genetic diseases from increased discrimination and persons unable to afford PGD from increased inequality.<sup>120</sup> Arguments have been made that “[b]y promoting technologies to avoid the birth of children with genetic conditions or unwanted traits, we define the ‘unfit’ in terms of that disability or trait,” therefore, increasing discrimination and inequality toward persons already living with such conditions.<sup>121</sup> Certain circumstances of PGD could call for governmental regulation because allowing a parent’s unregulated decision could run afoul of an egalitarian society’s interest in decreasing discrimination and inequality.<sup>122</sup>

### **C. Hypothetical Situations**

#### **1. No Governmental Regulation**

A child is born through what was once considered a “natural” conception. He is born already knowing his flaws and weaknesses through genetic tests. Stricken with a noticeably below average stature, receding hair line, non-symmetrical facial features, and a genetic disease most people thought to be non-existent; where PGD is the norm, he is shunned by society for his parent’s failure to do what any loving parent would, be tested through PGD for medical screening and non-medical selection of specific traits.

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<sup>120</sup> See Fox, *supra* note 21, at 584-87. Fox argues that the egalitarian ethos of compassion towards other members of society must be protected. See *id.* at 593 (“Compassion helps us make sense of the suffering of others, and motivates us to try to relieve it.”).

<sup>121</sup> Suter, *supra* note 112, at 955.

<sup>122</sup> See Fox, *supra* note 21, at 572; see also THE PRESIDENT’S COUNCIL ON BIOETHICS, THE CHANGING MORAL FOCUS ON NEWBORN SCREENING: AN ETHICAL ANALYSIS, 77-82 (2008), available at [http://bioethics.georgetown.edu/pebe/reports/newborn\\_screening](http://bioethics.georgetown.edu/pebe/reports/newborn_screening) (“If we test an infant, not in the hope of providing treatment for his or her condition, but with a view to making sure that no further children come into the family with the same defect, are we not in effect telling the child that he or she was, in some ways, a regrettable mistake . . .”).

## 2. Strict Governmental Regulation

A child is born with a genetic disease. His parents were unaware that they were both carriers. He lives a relatively normal childhood except for the medication, long weekend trips to the doctor for needed checkups, and the chronic pain he suffers. Eventually he will learn that his disease drastically shortens his life expectancy and his chance of passing that disease on to his future children is relatively high. As a result of their son's birth, both parents decide that without a way to prevent passing on the disease, they will not try to have another child.

## 3. Analysis – How Much Regulation is Ethical?

Both scenarios demonstrate a hypothetical situation in which one bioethical principle trumps the other with devastating consequences. In the first hypothetical situation where there is no governmental regulation, a parent's choice is completely free from limitations imposed by the government. As a result, society lacks compassion towards children born through coital reproduction.<sup>123</sup> In a way, not limiting a parent's autonomous choice for PGD could actually result in the destruction of autonomous procreation.<sup>124</sup> Allowing for absolute freedom with PGD will create a genetic arms race that could foster a sense of social pressure subjecting all prospective parents to feel a need for PGD in order to have a "normal" baby.<sup>125</sup> These pressures toward PGD would be a substantial controlling influence that would take away the self-governance of the parent, affecting what once was a parent's autonomous choice in reproduction by making it no choice at all. Also, an egalitarian theory of justice requires that a society allow

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<sup>123</sup> See Fox, *supra* note 21, at 589-94.

<sup>124</sup> See Suter, *supra* note 112, at 936-37 ("[T]he aggregate result of individual choices creates societal and cultural norms which substantially influence or limit the scope of autonomous decision making in regard to the use of genetic technology." (quoting AMA COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, CEJA REPORT A – A-91: ETHICAL ISSUES IN CARRIER SCREENING OF CYSTIC FIBROSIS AND OTHER GENETIC DISORDERS, 11 (1991))).

<sup>125</sup> See *id.* at 924-26.

its members equal opportunity to PGD access, which is unlikely with no government regulation of PGD procedures in a free-market economy like the United States.<sup>126</sup> Therefore, no governmental regulation of PGD would be unethical for violating an egalitarian theory of justice and ironically limiting a parent's autonomous choice through social pressures to undergo PGD.

In the second hypothetical situation, a government relying on principles of justice might eliminate the autonomous choice of parents wanting to reproduce. As a result, the government's attempt to discourage the possibility of discrimination and inequality not only violates autonomous procreation, but conflicts with other notions of justice.<sup>127</sup> Under a libertarian theory of justice, for instance, regulation of PGD deprives a parent of the freedom to use their wealth and property in their best interest.<sup>128</sup> A ban on all PGD would be unethical for consequently depriving a parent of their autonomous choice in reproduction and freedom under a libertarian theory of justice.

#### **IV. AN ETHICAL SOLUTION**

This Author suggests that the best method for regulation of PGD is a combination of many of the ideas previously discussed. As this paper demonstrates, the only way to make regulation of PGD ethical is to balance the interest of the parent's autonomous choice and the government's interest in justice. To balance these principles, a system involving a central government agency as well as more influential professional organizations will be necessary.

##### **A. Government Agency**

The government would best be served to institute a separate agency similar to the HFEA in the UK that is able to handle the

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<sup>126</sup> See BEAUCHAMP & CHILDRESS, *supra* note 10, at 233-41.

<sup>127</sup> See *id.*

<sup>128</sup> See *id.*



ever changing field of ART involving PGD,<sup>129</sup> but unlike the HFEA, this agency would focus on the safety and efficacy of PGD rather than the appropriate uses.<sup>130</sup> The easiest way to provide this new agency with the power to regulate is to take PGD out of the private sector through governmental funding.<sup>131</sup> Public grants would force PGD under the umbrella of governmental regulation and away from the costly private sector through the power of the purse.<sup>132</sup> Once monetary support for PGD is established through public funding, the government will be able to regulate PGD in instances where safety and effectiveness of procedures are a concern.<sup>133</sup> A governmental agency would be an ethical compromise because parents would be allowed to make autonomous choices to use a safe and effective means of PGD, while regulation in the interest of justice would only be instituted when clear signs of danger to the parent and child were found.

### B. Professional Organizations

Professional organizations would have the best opportunity to account for PGD's ethical considerations and shape a process for determining its acceptable uses.<sup>134</sup> Through collections of data from interaction with patient groups, ongoing studies of children born with PGD, public opinion, and feedback from those already affected with genetic diseases and disabilities, information can be gathered and passed on to perspective parents to further broaden their knowledge of the procedure and all the risk and benefits associated. The gathered information will reinforce parents' autonomous choice for PGD with increased self-governance and

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<sup>129</sup> See Soini, *supra* note 69, at 318; Thomas, *supra* note 79, at 372-73.

<sup>130</sup> See King, *supra* note 63, at 354; Soini, *supra* note 69, at 318-19; *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 94, at 595-96.

<sup>131</sup> See *Guiding Regulatory Reform in Reproduction and Genetics*, *supra* note 94, at 589-90.

<sup>132</sup> See *id.*

<sup>133</sup> See *id.* at 595.

<sup>134</sup> See Susannah Baruch, *Preimplantation Genetic Diagnosis and Parental Preferences: Beyond Deadly Disease*, 8 HOUS. J. HEALTH L. & POL'Y 245, 267-68 (2008).

substantial understanding.<sup>135</sup> Therefore, it would be ethical for professional organizations to make determinations about the acceptable uses of PGD because the organizations would protect the autonomous choices of parents while weighing those choices against signs of increased discrimination and inequality.

### CONCLUSION

With advances in technology associated with reproduction and a better understanding of the interplay of genes in human development, an increase in the use of PGD for medical screening and non-medical selection is bound to occur. This Author suggests that the United States attempt to institute a two tier system for regulation: 1) a federal agency capable of regulating the effectiveness and safety of PGD through monetary control, and 2) an increased influence on clinics to follow ethical guidelines established by professional organizations working in the field of ART including PGD. The need for legislatures in the United States to implement a plan to handle PGD is fast approaching. As legislatures wrestle with conflicting opinions regarding the use of PGD, it is imperative that legislators look toward the bioethical principles of autonomy and justice before making any definitive decisions. Too little or too much regulation could spell disaster when one principle, autonomy or justice, is sacrificed in the interest of the other.

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<sup>135</sup> *See id.* at 268-69.