THE IMPLICATIONS OF THE DUE PROCESS CLAUSE ON THE FUTURE OF HUMAN EMBRYONIC GENE THERAPY

Amber Stine*

I. INTRODUCTION

The goal of gene therapy is to correct genetic defects through a process of transferring nucleic acids to an individual's somatic cells.[1] Gene therapy is advantageous over other medical treatments due to its potential for correcting genetic causes of a disease, its ability to selectively treat affected cells and tissues, and its capacity for long-term treatment.[2]

As the practice of gene therapy becomes more refined and predictable, our society will struggle with the implications of this expansive scientific technology. The potential abuses that can occur in the absence of state regulation should be carefully considered.

As regulations on gene therapy are passed by the states and subsequently challenged in court, the judiciary will determine the constitutionality of such state action. This Note supports the contention that while therapeutic embryonic gene therapy might be regulated, state governments cannot completely ban gene therapy due to the individually protected right to procreate. This Note further supports the argument that states may regulate nontherapeutic or enhancement gene therapy more stringently.

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1. *See* Gabor M. Rubanyi, *The Future of Human Gene Therapy*, 22 MOLECULAR ASPECTS MED., 113, 113–14 (2001).

2. *See id.* at 114.

Both germ-line gene therapy and somatic gene therapy[3] involve the process of introducing one or more genes within cells for the purpose of treating, diagnosing, or preventing diseases related to genetic abnormalities.[4] These genetic defects are caused by a mutation.[5] A mutation causes the protein resulting from the gene to be absent or to be altered so that the functions of certain cell types in the body are affected.[6] These modifications in cellular functioning affect proper organ functioning.[7] Introducing a functional gene into a cell may correct cellular imbalances[8] resulting from missing or altered biochemical activity.[9]

Somatic and germ-line gene therapies are distinguishable from one another on the basis of cell type in that somatic gene therapy targets somatic cells while germ-line gene therapy targets germ-line cells.[10] Germ-line cells are gametes, zygotes, and the undifferentiated cells of embryos during the early developmental stages, which function in the contribution of genetic material to children.[11] Somatic cells, on the other hand, may be changed via gene therapy and such changes are not passed on to the subject's progeny.[12] Because germ-line gene therapy attempts to eliminate the genetic abnormality permanently so that it cannot be passed on to future generations, germ-line gene therapy is far more controversial than somatic gene therapy.[13] Somatic gene therapy, unlike germ-line gene therapy, does not involve changes that affect the genome of future generations.[14] Therefore, somatic gene therapy is arguably not much different from

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3. *See* Charles F. De Jager, *The Development of Regulatory Standards for Gene Therapy in the European Union*, 18 FORDHAM INT'L L.J. 1303, 1306 (1995) (citing JAMES D. WATSON ET AL., RECOMBINANT DNA (Scientific American Books 2d ed. 1992)), which describes germ-line gene therapy as targeting germ-line cells: gametes, zygotes, and early embryos. Somatic gene therapy is described as targeting somatic cells; i.e., all other cells besides germ-line cells. *Id.*

4. *See id.*

5. *See* WATSON ET AL., *supra* note 3, at 34 (explaining that a mutation is a change in the character of a gene that is perpetuated in subsequent divisions of the cell in which it occurs).

6. *See* Julie L. Gage, *Government Regulation of Human Gene Therapy*, 27 JURIMETRICS J. 200, 200–01 (1987).

7. *See id.*

8. *See* WATSON ET AL., *supra* note 3, at 569 (describing replacement of mutant genes by normal genes).

9. *See* Gage, *supra* note 6, at 200.

10. *See* WATSON ET AL., *supra* note 3, at 569 (describing the difference between genetic manipulations involving somatic cells and those involving germ-line cells).

11. *See* WATSON ET AL., *supra* note 3, at 569 (explaining that changes resulting from germ-line gene therapy are passed on to subject's offspring); Gage, *supra* note 6, at 201 (defining gametes as the sex cells containing genetic information to be transmitted to the offspring. Spermatozoa are the male gametes while ova are the female gametes).

12. *See* Gage, *supra* note 6, at 201. "The outcome [of somatic gene therapy] is a genetic alteration that is restricted to the treated patient . . . ." *Id.* Germ-line gene therapy corrects genetic defects in germ-line cells, affecting the individual and its offspring. *See id.*

13. *See* Theodore Friedmann, *Progress Toward Human Gene Therapy*, 244 SCI. 1275, 1280 (1989).

14. *See* WATSON ET AL., *supra* note 3, at 569.

other technologically advanced therapies, such as organ or bone marrow transplants.[15]

The progress of gene therapy has been relatively slow, and it remains a "pioneering new" therapy.[16] Incomplete knowledge of the genes involved in various diseases has limited scientists' abilities to create clinically successful gene therapies.[17]

However, in April 2000, *Science Journal* reported some promising results regarding gene therapy with two patients diagnosed with Severe Combined Immunodeficiency Disease (SCID).[18] SCID, commonly known as "bubble boy" disease, includes rare, sometimes fatal, congenital disorders that result in a weakened immune system.[19] SCID is an inherited disease that often results from a mutation in the interleukin-2 receptor gamma (IL2RG) gene. The central characteristic of SCID is a defect in the specialized white blood cells (B- and T-lymphocytes), which defend the human body from infection by viruses, bacteria and fungi. Without an efficient immune system, SCID patients are at risk for recurrent infections, and can die before the first year of life.[20] Now there is optimism that human gene therapy will be able to correct this fatal disease.[21]

A group of scientists conducted a gene therapy trial on two patients, aged eleven months and eight months.[22] Clinical improvement, such as healing extensive skin lesions, was observed in each patient due to the improvement and maintenance of each patient's immune system. Both children were able to leave protective isolation after approximately ninety days and were sent home. As of April 28, 2000, both children had been living at home for at least ten months following gene therapy and without further treatment. In April 2000, both children were enjoying normal growth and development and neither of the children were experiencing side effects.[23]

Despite its potential outstanding benefits, gene therapy has developed into a controversial issue in bioethics due to its ethical and legal ramifications.[24] The ethical ramifications will be explored by comparing gene therapy to human

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15. *See id.* Somatic gene therapy "is analogous to the treatment of genetic disorders by organ or tissue transplantation" in that all of these therapies replace defective genetic material with functioning genetic material. *Id.* The scope of this Note is limited to the legal considerations of somatic gene therapy.

16. *Id.* at 135.

17. *See id.*

18. *See* Marina Cavazzana-Calvo et al., *Gene Therapy of Human Severe Combined Immunodeficiency (SCID)-X1 Disease*, 288 SCI. 669, 669–72 (2000).

19. *See* NAT'L CTR. FOR BIOTECHNOLOGY INFO., GENES AND DISEASE, *at* http://www.ncbi.nlm.nih.gov/disease/SCImm.html (last visited Jan. 21, 2002).

20. *See id.*

21. *See* WATSON ET AL., *supra* note 3, at 670–71.

22. *Id.* at 670.

23. *Id.*

24. *See* SEC'Y'S ADVISORY COMM. ON GENETIC TESTING, ABOUT SACG, *at* http://www4.od.nih.gov/oba/sacgt/aboutsacgt.htm (last visited Jan. 29, 2002).

cloning.[25] Prominent geneticist, Dorothy C. Wertz,[26] stated, "The major argument against cloning is that it would rob individuals of their uniqueness, a uniqueness that some consider ordained by God or Nature."[27] Some members of the general public, as well as members of the scientific community, view cloning as a technique capable of threatening human diversity.[28] Some critics argue that cloning would enable scientists to control society through gene manipulation, by allowing them to play God.[29] Gene therapy, like cloning, allows scientists to be active in the role of creating humans.[30]

Given the inevitable future availability of human gene therapy, this Note attempts to analyze the legal implications of conducting gene therapy. While there are undoubtedly supporters for banning human gene therapy, there are possible constitutional obstacles to realizing such bans. Part II of this Note focuses on the likelihood of success of such constitutional challenges under the Due Process Clause of the Fifth and Fourteenth Amendments. Part III describes the basics behind human gene therapy and explores how gene therapy differs from other reproductive technologies such as cryopreservation and preimplantation screening. Part IV addresses some of the commonly feared abuses associated with human gene therapy and legislative measures that may prevent such abuses from occurring. Part V discusses the different levels of judicial review that may be applied in a constitutional challenge on the practice of gene therapy. Part V will also consider the potential governmental interest in regulating human gene therapy. This Note concludes that constitutional challenges to the practice of gene therapy are likely to fail in cases where gene therapy is being used for therapeutic purposes—to correct genetic abnormalities. Constitutional challenges may succeed, however, in preventing various abuses of gene therapy technology.

II. LEGAL RAMIFICATIONS UNDER THE DUE PROCESS CLAUSES OF THE FIFTH AND FOURTEENTH AMENDMENTS

The due process clauses of the Fifth and Fourteenth Amendments prohibit federal and state governments from depriving any individual of "life, liberty, or

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25. *See* Dorothy C. Wertz, *Germ-line Gene Therapy: Is it Almost Here?*, GENE LETTER, *at* http://www.geneletter.com/archives/cloning1.html (last visited February 4, 2002).

26. Dr. Wertz is Senior Scientist in the Division of Social Science, Ethics, and Law at the Shriver Center for Mental Retardation in Waltham, MA. *Id.* Since 1981, she has researched social and ethical aspects of human genetics, most notably through international surveys of geneticists' viewpoints in thirty-seven nations, as well as patients' views in North America. *Id.*

27. Dorothy C. Wertz, *Cloning Humans: Is it Ethical?*, GENE LETTER, Mar. 1, 1997, *at* http://www.geneletter.com/archives/cloning1.html (last visited February 4, 2002).

28. *See id.*

29. *See* Dorothy C. Wertz, *Twenty-One Arguments Against Human Cloning, and Their Responses*, GENE LETTER, Aug. 1, 1998, *at* http://www.genesage.com/professionals/geneletter/archives/twentyonearguments.html (last visited Mar. 16, 2003).

30. *See* Wertz, *supra* note 27.

property without due process of law."[31] Traditionally, the Supreme Court has been cautious in expanding substantive due process rights.[32] The Supreme Court in *Washington v. Glucksberg*,[33] cautioned against extending substantive due process rights beyond the protection of "traditional" rights, stating that:

> By extending constitutional protection to an asserted right or liberty interest, we, to a great extent, place the matter outside the arena of public debate and legislative action. We must therefore "exercise the utmost care whenever we are asked to break new ground in this field," lest the liberty protected by the Due Process Clause be subtly transformed into the policy preferences of the Members of this Court.[34]

The Supreme Court in *Glucksberg* developed a two-part test to apply substantive due process analysis: (1) a "careful description" of the asserted liberty interest; and (2) consideration of whether the challenged activity is "deeply rooted" in the country's history and tradition, restricting protection to liberties that are objectively "deeply rooted."[35] This Note will apply the *Glucksberg* two-part test to the practice of gene therapy to determine whether substantive due process rights should encompass the practice of embryonic gene therapy.

A. Careful Description

The *Glucksberg* Court's first substantive due process requirement, a "careful description" of the asserted liberty interest, provides support for the argument in favor of a constitutional right of procreation.[36] Individuals have a constitutionally protected right to prevent procreation, including the right to use

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31. U.S. CONST. amends. V & XIV, § 1. The Due Process Clause of the Fifth Amendment limits the power of the federal government. *See* Boylan v. United States, 310 F. 2d 493, 498 (9th Cir. 1962). The Due Process Clause of the Fourteenth Amendment limits the power of the states as against individual citizens. *See* Sandin v. Conner, 515 U.S. 472, 493 (1995). The Due Process Clauses of the Fifth and Fourteenth Amendments have been interpreted to have essentially the same meaning. *See* Paul v. Davis, 424 U.S. 693, 702 n.3 (1976).

32. These clauses have traditionally been interpreted not only to provide protection against procedural unfairness, but also substantive protection against governmental action to deprive life, liberty, or property. *See* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 846 (1992) (stating that the Due Process Clause of the Fourteenth Amendment "has been understood to contain a substantive component as well, one 'barring certain government actions regardless of the fairness of the procedures used to implement them'") (citations omitted).

33. 521 U.S. 702, 731–34 (1997) (holding that Washington's assisted-suicide ban was rationally related to legitimate government interests such as preservation of human life, preventing suicide, and maintaining integrity and ethics of medical profession; thus, it did not violate due process clause).

34. *Id.* at 720 (citation omitted).

35. *Id.* at 703, 720–21 (explaining that "deeply rooted" is something that is "objectively" found to be part of our "Nation's history and tradition") (citations omitted).

36. *Id.* at 721–22 (noting that the Court's substantive due process jurisprudence defines liberty as having "at least been carefully refined by concrete examples involving fundamental rights found to be deeply rooted in our legal tradition").

contraceptives[37] and to abort prior to fetal viability.[38] A right to procreate may be reasonably inferred from Court decisions addressing whether a state may attempt to prevent conception.[39] Most legal commentators agree that there is an affirmative right of procreation. However, they disagree as to the content and scope of this right.[40]

The Supreme Court's 1923 decision in *Meyer v. Nebraska*[41] implies, through dicta, the existence of an affirmative right of procreation. In *Meyer*, the Supreme Court struck down a Nebraska law that prohibited the teaching of any language other than English to elementary school children.[42] The Court held that the law violated the "liberty" interest protected by the Due Process Clause of the Fourteenth Amendment,[43] stating in dicta:

> Without doubt, [the liberty interest of the Due Process Clause] denotes not merely freedom from bodily restraint but also the right of the individual . . . to marry, establish a home and bring up children . . . and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.[44]

Thus, the Due Process Clause was interpreted by the Court to include not only protection from physical restraint, but also affirmative rights to the essentials of happiness: marriage, establishing a home, and raising children.[45]

In *Skinner v. Oklahoma*, the Supreme Court addressed the right of procreation more directly by invalidating an Oklahoma statute requiring sterilization for criminals convicted two or more times for felonies involving "moral turpitude."[46] *Skinner* is an Equal Protection Clause case, rather than a due

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37. *See* Griswold v. Connecticut, 381 U.S. 479, 507 (1965).

38. *See* Roe v. Wade, 410 U.S. 113, 163–64 (1973).

39. *See* Skinner v. Oklahoma, 316 U.S. 535 (1942) (holding that the state deprived a category of criminals of "a right which is basic to the perpetuation of a race—the right to have offspring." The state court had ruled that embezzlers who committed larceny were not required to have vasectomies pursuant to the state's Habitual Criminal Sterilization Act, while other criminals who committed larceny were.).

40. *See* Ronald Chester, *To Be, Be, Be . . . Not Just to Be: Legal and Social Implications of Cloning for Human Reproduction*, 49 FLA. L. REV. 303, 313 n.33 (1997) (arguing that the Supreme Court in *Skinner*, 316 U.S. 535, recognized a right to procreate); Elizabeth Price Foley, *Constitutional Implications of Human Cloning*, 42 ARIZ. L. REV. 647, 703 (2000) (asserting that there may be an affirmative right of procreation and that this right may legally extend to non-traditional forms of reproduction, such as cloning) (citations omitted); Lawrence Wu, *Family Planning Through Human Cloning: Is There a Fundamental Right?*, 98 COLUM. L. REV. 1461, 1473–74 (1998) (arguing that married persons have a fundamental right to procreate through the use of cloning technology and various artificial reproductive technologies).

41. 262 U.S. 390 (1923).

42. *See id.* at 400–03.

43. *See supra* note 32 and accompanying text (regarding the Due Process Clause).

44. *Meyer*, 262 U.S. at 399.

45. *See id.*

46. Skinner v. Oklahoma, 316 U.S. 535, 536 (1942).

process case, because the Court invalidated the Oklahoma statute because it only mandated sterilization for a certain class of convicted felons.[47] However, the Supreme Court treated procreation as a fundamental right by invoking strict scrutiny, stating that "marriage and procreation are fundamental to the very existence and survival of the [human] race,"[48] and concluded that the statute in question, which prevented procreation, interfered with "one of the basic civil rights of man."[49] The Supreme Court further clarified this procreational right in *Stanley v. Illinois* by citing *Skinner* as asserting a right to "conceive and to raise one's children."[50] In *Skinner*, the Court described this right as "far more precious . . . than property rights."[51]

Interpreted narrowly, *Skinner* at least supports the contention that individuals have a fundamental right to coital procreation.[52] The question surrounding the use of gene therapy, in light of *Skinner*, is whether gene therapy is a form of procreation when it is used to "bear and beget" a normal, healthy child.[53] The cases decided by the Court thus far have dealt with coital reproduction; therefore, it is unclear whether the Court's language regarding "procreation" and "bear[ing] or beget[ing] a child" includes noncoital forms of procreation. The Court's language regarding "procreation" and "bear[ing] or beget[ing] a child" is broad, and it could reasonably be inferred that the fundamental right of procreation is extended to noncoital forms of procreation as well.[54] Since there appears to exist a right of procreation, as outlined in *Skinner* and its progeny, gene therapy might be protected when used as a means of procreation, particularly because the Court's language regarding "procreation" and "bear[ing] or beget[ing] a child" is broad and has not been defined by the Court.[55]

In *Cameron v. Board of Education*, a public school teacher sued her employer for discrimination, alleging that she was terminated due to her decision to become a single mother through the use of artificial insemination.[56] Addressing the substantive due process issue, the Supreme Court held that, pursuant to their decisions in prior reproductive privacy cases, "[a] woman has a constitutional

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47. *See id.* at 538–39.
48. *Id.* at 541.
49. *Id.*
50. Stanley v. Illinois, 405 U.S. 645, 651 (1972).
51. *Id.* at 651.
52. *See id.*
53. Eisenstadt v. Baird, 405 U.S. 438, 453 (1972) ("If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child"); WEBSTER'S NINTH NEW DICTIONARY 137,140 (9th ed. 1989) (defining "bear" as, among other things, "to give birth to" and defining "beget" as "to procreate as the father.").
54. *See* Cameron v. Bd. of Educ., 795 F. Supp. 228, 237 (S.D. Ohio 1991) (stating that a woman has a "constitutional privacy right" regarding her reproductive capacity, including a right to become pregnant through artificial insemination).
55. *Cf.* Foley, *supra* note 40, at 695 (arguing that "[b]ecause cloning is merely an asexual form of procreation, it is arguably as much a fundamental constitutional right as our right to procreate by either passion or the petri dish").
56. *See Cameron*, 795 F. Supp. at 234.

privacy right to control her reproductive functions. Consequently, a woman possesses the right to become pregnant by artificial insemination."[57]

In re Baby M also supports the argument that there is an affirmative right of procreation and that this right includes the use of Artificial Reproductive Technologies (ARTs).[58] In *Baby M*, a surrogate mother agreed to be artificially inseminated with Mr. Stern's sperm and to relinquish her parental rights to the baby following its birth so that Mr. and Mrs. Stern could raise the baby.[59] When the surrogate mother refused to relinquish her rights to the baby according to the terms of the contract, the biological father and his wife brought an action to enforce the contract. While the New Jersey Supreme Court denied the Stern's claim, the court stated that "[t]he right to procreate very simply is the right to have natural children, whether through sexual intercourse or artificial insemination."[60] The New Jersey Supreme Court stated that the fundamental right of procreation includes the right to use ARTs, such as artificial insemination.[61] The Court simply did not extend procreative liberty to include a right of custody.[62]

B. Deeply Rooted

Procreation is deeply rooted in the nation's history and traditions. The relevant inquiry is whether bearing and begetting a normal and healthy child through the use of gene therapy is qualitatively different from reproduction by other existing means.[63] This inquiry concerns the *Glucksberg* Court's second prerequisite for finding that a liberty interest is protected by substantive due process, namely, whether the interest is "deeply rooted" in the nation's history and traditions.[64] In *Palko v. Connecticut*, the Court indicated that in order for an asserted interest to be fundamental under due process analysis, it must be "so rooted in the traditions and conscience of our people as to be ranked

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57. *Id.* at 237. The *Cameron* Court referred to *Cleveland Board of Education v. LaFleur*, 414 U.S. 632 (1974), *Eisenstadt*, 405 U.S. 438, *Roe v. Wade*, 410 U.S. 113, 153 (1973), and *Griswold v. Connecticut*, 381 U.S. 479, 485–86 (1965), in their holding. In *LaFleur*, the Court declared that "[t]his Court has long recognized that freedom of personal choice in matters of marriage and family life is one of the liberties protected by the Due Process Clause of the Fourteenth Amendment." 414 U.S. at 639. In *Eisenstadt*, the Court stated that there is a right "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision as to whether to bear or beget a child." 405 U.S. at 453. In *Roe*, the Court held that a woman's right to privacy includes the right to terminate a pregnancy. 410 U.S. at 153. In *Griswold*, the Court struck down a Connecticut statute criminalizing the purchase of contraceptives as violative of a person's right to privacy. 381 U.S. at 485–86.

58. 537 A. 2d 1227, 1242–43 (N.J. 1988).

59. *See id.* at 1234–35.

60. *Id.* at 1253.

61. *See id.* (stating that the "right to procreate very simply is the right to have natural children, whether through sexual intercourse or artificial insemination").

62. *See id.* at 1254 ("There is nothing in our culture or society that even begins to suggest a fundamental right on the part of the father to the custody of the child as a part of his right to procreate when opposed by the claim of the mother to the same child.").

63. *See* Foley, *supra* note 40, at 695.

64. 521 U.S. 702, 720–21 (1997).

fundamental."[65] The Court further asserted that the interest must be implicit in the concept of liberty such that "neither liberty nor justice would exist if [it were] sacrificed."[66]

Since there appears to be a protected procreative liberty interest, this liberty interest should extend to the use of gene therapy in order to bear and beget an average, healthy child. The issue becomes whether a procreative liberty interest ends upon conception or whether it extends to include the practice of gene therapy to alter the fetus, correcting for genetic abnormalities, after conception.[67]

One obstacle is meeting the "deeply rooted," or "history and tradition," prong of the *Glucksberg* test.[68] The practice of gene therapy has only existed for a few years and remains in experimental stages.[69] However, where the asserted right is itself "new" so that it has not been considered fundamental to liberty historically and traditionally, Justice Scalia has suggested that the right could still be deemed a protected liberty interest.[70] Rather, the Court should "refer to the most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified."[71]

Interestingly, "[t]he University of Michigan revealed that sixty to seventy percent of individuals believed that parents should be morally free to pursue whatever ARTs are available to avoid the birth of a child with a serious genetic disorder."[72] Such prevalent public support suggests that a majority of U.S. citizens may consider the use of ARTs to be a fundamental aspect of procreative liberty, at least in the context of correcting genetic abnormalities.[73]

Even if there is a lack of demonstrable public acceptance, neither the state nor federal governments have immediately attempted to prohibit genetic

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65. 302 U.S. 319, 325 (1937) (citations omitted) (holding that the right to trial by jury and the immunity from prosecution except as the result of an indictment may be important, but that a statute that abolishes them does not violate a principle so rooted in the traditions of our nation as to be considered fundamental).

66. *Glucksberg*, 521 U.S. at 721.

67. *See supra* note 53 and accompanying text (regarding the definition of bearing and begetting); *cf. supra* note 40 and accompanying text (stating that cloning is a form of procreation that is arguably as much a fundamental constitutional right as more traditional forms of procreation).

68. *See supra* notes 35–36 and accompanying text (explaining the meaning of deeply rooted and tradition).

69. *See* Rubanyi, *supra* note 1, at 114 (stating that human gene therapy is a new type of therapy emerging from the molecular biology and biotechnology revolution).

70. *See* Michael H. v. Gerald D., 491 U.S. 110, 127 n.6 (1989) (Scalia, J., writing for the plurality).

71. *Id.*

72. Foley, *supra* note 40, at 699–700 (quoting from LEONARD M. FLECK, GENOME TECHNOLOGY AND REPRODUCTION: VALUES AND PUBLIC POLICY (1996) (Executive Summary, Item No. 6)).

73. *Cf. Michael H.*, 491 U.S. at 127 (explaining that a "new" right may be a liberty interest protected by the Due Process Clause of the Fourteenth Amendment if a similar and relevant tradition, which is clearly protected by the Fourteenth Amendment, can be identified).

engineering.[74] This "history and tradition" of acceptance may indicate that Americans consider the use of ARTs to be fundamental to procreative liberty.[75] As Justice Scalia stated in *Michael H. v. Gerard D.*, for an asserted liberty interest to obtain protection under either Due Process Clause, the interest must be "fundamental" and also must be an interest that has been "traditionally protected by our society."[76] Such protection "need not take the form of an explicit constitutional provision or statutory guarantee, but it must at least exclude . . . a societal tradition of enacting laws *denying* the interest."[77] The absence of a tradition denying the use of ARTs is therefore a relevant factor in determining the existence of substantive due process protection.[78] Presently, no bans exist on the practice of gene therapy. Therefore, it is possible for the practice to achieve indirect acceptance by the public, as did ARTs.[79] Another possibility is that gene therapy will be considered another form of ART and gain public acceptance through this classification.[80]

III. THE RIGHT TO PRIVACY UNDER THE DUE PROCESS CLAUSE

The Due Process Clause[81] protects one's fundamental right to life[82] and liberty.[83] At least one authority, after reviewing the Council of Europe, Convention

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74. Foley, *supra* note 40, at 700.

75. *Id.*

76. *Michael H.*, 491 U.S. at 122.

77. *Id.* at 123 n.2.

78. *Compare Michael H.*, 491 U.S. 110 *with* Bowers v. Hardwick, 478 U.S. 186, 192–93 (1986). In *Bowers*, the Court held that a law criminalizing sodomy did not violate substantive due process. The *Bowers* Court noted when the Fourteenth Amendment was ratified, all but five of the thirty-seven states criminalized sodomy, and that twenty-four states and the District of Columbia continued to do so at the time of the Court's decision in the mid-1980s. The Court stated with regards to the historical and traditional prohibition against sodomy, that "to claim that a right to engage in such conduct is 'deeply rooted in this Nation's history and tradition' or 'implicit in the concept of ordered liberty' is, at best, facetious." *Id.* at 194. The Court will revisit the issue this term in *Lawrence v. Texas*.

79. *See Michael H.*, 491 U.S. at 123 n.2 (plurality opinion) ("The protection need not take the form of an explicit constitutional provision or statutory guarantee, but it must at least exclude . . . a societal tradition of enacting laws denying the interest."); *see also* Foley, *supra* note 40, at 700 (quoting Scalia, J., in *Michael H.*, 491 U.S. 110).

80. *See* Foley, *supra* note 40, at 700 ("If reproduction using ARTs is indeed within the ambit of protected activity under substantive due process, cloning may also be protected, depending upon how one characterizes cloning. If cloning is viewed as merely another ART, then cloning would be constitutionally protected. If, on the other hand, cloning is viewed as qualitatively distinct from existing ARTs, then cloning would not be constitutionally protected by substantive due process.").

81. U.S. CONST. amends. V & XIV, § 1. These clauses have traditionally been interpreted to provide substantive protection against governmental action to deprive life, liberty, or property.

82. *See* Council of Europe, Convention for the Protection of Human Rights and Fundamental Freedoms, European Treaty Series No. 5, Nov. 4, 1950, at 1, *reviewed by* Nati Somekh, *The European Total Ban on Human Cloning: An Analysis of the Council of Europe's Actions in Prohibiting Human Cloning*, 17 B.U. INT'L L.J. 397, 419 (1999).

83. *See id.* at 2.

for the Protection of Human Rights and Fundamental Freedoms, has stated, "[A] person has the right to respect for his or her private and family life and no public authority may interfere with this right unless in the interest of national security, public safety, the prevention of crime, the protection of health and morals or the protection of the rights and freedoms of others."[84]

Generally, the Court has treated most of the interests it has found to be fundamental as falling within the broad category of the "right to privacy."[85] The right to privacy has been derived from the Fourteenth Amendment's Due Process Clause, as well as other areas of the Constitution.[86] The Supreme Court has addressed the right to privacy in the areas of reproductive choice,[87] marital relationships,[88] family relationships,[89] child rearing,[90] and education.[91]

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84. *Id.* at 4.

85. June Coleman, Comment, *Playing God or Playing Scientist: A Constitutional Analysis of State Laws Banning Embryological Procedures*, 27 PAC. L.J. 1331, 1362 (1996) (explaining that the Supreme Court has considered the "right to privacy" in areas such as "reproductive choice, marital relationships, family relationships, child rearing, and education").

86. *See* Roe v. Wade, 410 U.S. 113, 152 (1973) (finding a right to privacy from the penumbras of the Bill of Rights, the Ninth Amendment, and the Fourteenth Amendment); Griswold v. Connecticut, 381 U.S. 479, 484 (1965) (noting that the right to privacy is based on the Bill of Rights, including the First, Third, Fourth, Fifth and Ninth Amendments).

87. *See* Carey v. Population Servs. Int'l, 431 U.S. 678, 685 (1977) (addressing reproductive choice in the context of abortion); *Roe*, 410 U.S. at 153 (stating that a woman's right to privacy is a "fundamental right" under the Fourteenth Amendment and this right is "broad enough to encompass a woman's decision whether or not to terminate her pregnancy"); Skinner v. Oklahoma, 316 U.S. 535, 536 (1942) (holding that the state deprived a category of criminals of "a right which is basic to the perpetuation of a race—the right to have offspring").

88. *See* Griswold, 381 U.S. at 485 (stating that the Bill of Rights protects one's privacy interest and creates a penumbra, or zone of privacy, which extends to "marital bedrooms").

89. *See* Roberts v. United States Jaycees, 468 U.S. 609, 619–20 (1984) (upholding the limitation of state interference on family relationships and recognizing a "constitutional shelter" for such relationships because "individuals draw much of their emotional enrichment from close ties with others" and "is central to any concept of liberty"); Moore v. City of E. Cleveland, Ohio, 431 U.S. 494, 499 (1977) (stating that the government must not intrude "on choices concerning family living arrangements" unless important governmental interests are advanced and are "served by the challenged regulation"); Eisenstadt v. Baird, 405 U.S. 438, 453–54 (1972) (stating that the right of privacy includes the right of an individuals to be "free from unwarranted government intrusion" as to "the decision whether to bear or beget a child").

90. *See* Prince v. Massachusetts, 321 U.S. 158, 166 (1944) (stating that "the custody, care and nurture of the child resides first in the parents" and that the courts should respect "the private realm of family life which the state cannot enter") (internal citation omitted).

91. *See* Carey, 431 U.S. at 685; Pierce v. Soc'y of Sisters, 268 U.S. 510, 534–35 (1925) (stating that there is no general power of the state to force children to "accept instruction from public teachers only" and recognizing that parents have some freedom to make educational decisions regarding their children); Meyer v. Nebraska, 262 U.S. 390,

A. Background of Privacy Interests, As Defined in the Context of Preventing Procreation

The Supreme Court has consistently upheld the right of privacy regarding an individual's decision to prevent procreation. The Supreme Court stated in *Griswold v. Connecticut* that the Bill of Rights protects one's privacy interest regarding the use of birth control and creates a penumbra, or zone of privacy.[92] The Supreme Court further stated in *Eisenstadt v. Baird* that "[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted government intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[93] In *Carey v. Population Services International*, the Supreme Court stated that "[r]ead in light of its progeny, the teaching of *Griswold* is that the Constitution protects individual decisions in matters of childbearing from unjustified intrusion by the State."[94] The Supreme Court, in *Paris Adult Theatre I v. Slaton*, further asserted that the constitutionally protected privacy interest in procreation and childrearing "is not just concerned with a particular place, but with a protected intimate relationship. Such protected privacy extends to the doctor's office, the hospital, the hotel room or as otherwise required to safeguard the right to intimacy involved."[95] These cases indicate that based on the constitutional right of privacy, individuals possess the right to control their own reproductive functions without unwarranted governmental interference.

B. Extending the Privacy Analysis in the Context of Contraceptive Cases to Various Reproductive Technologies

The right of privacy has been discussed primarily in the context of contraception, marriage, and family. One relevant question is whether the right to privacy extends to reproductive technologies as well. Courts have discussed at least three types of reproductive technologies that are associated with procreation: cryopreservation, preimplantation screening, and gene therapy.[96] These reproductive technologies should be characterized as a means by which individuals exercise the more general right of procreation.[97]

400–03 (1923) (holding that the state court erred in upholding a statute that required teachers to instruct children only in English, recognizing that this statute infringed on parental rights, and stating that this statute was "arbitrary and without reasonable relation to any end within the competency of the state").

92. *See Griswold*, 381 U.S. at 484 (1965).

93. 405 U.S. 438, 453 (1972).

94. *Carey*, 431 U.S. at 687.

95. 413 U.S. 49, 67 n.13 (1973).

96. *See infra* notes 98, 100, & 103 and accompanying text for information about cryopreservation, preimplantation screening, and gene therapy, respectively.

97. *See* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 846, & 851–60 (1992) (protecting procreative liberty and defining a woman's interest in abortion as the specific "liberty" to choose abortion, rather than as a more general right to not procreate); *Eisenstadt*, 405 U.S. at 453 (discussing the ways in which a woman can carry out her reproductive decision); Vicki G. Norton, Comment, *Unnatural Selection:*

In *Margaret S. v. Treen*, the court, in discussing cryopreservation, indicated that the fundamental right surrounding procreation should encompass the entire process of procreation as well.[98] Thus, "it takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy."[99]

In *Lifchez v. Hartigan*, the district court addressed the constitutional implications regarding the procedure of preimplantation screening.[100] The court extended the right of privacy beyond the scope of contraception, holding that it included fertility procedures for the same reason stated by the *Margaret S.* court.[101] Moreover, the *Lifchez* court stated, "Constitutional choices that include the right to abort a fetus within the first trimester must also include the right to submit to a procedure designed to give information about that fetus which can then lead to a decision to abort."[102] If parents can use this diagnostic testing to determine whether the child should be born, this diagnostic testing may also allow parents to decide if they want the child to be born with his or her genetic defect, or whether the child should undergo gene therapy to correct the defect. An alteration of the fetus is arguably no more extreme than an abortion of the fetus.[103] Although the Supreme Court in *Planned Parenthood of Southeastern Pennsylvania v. Casey* abandoned the trimester system of Roe, *Casey* did not disturb the holding in *Roe* that a

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Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation, 41 UCLA L. REV. 1581, 1594–96 (1994).

98. *See* Margaret S. v. Treen, 597 F. Supp. 636, 671 (E.D. La. 1984), *aff'd sub nom.* Margaret S. II, 794 F.2d 994, 997 (5th Cir. 1986); Coleman, *supra* note 85, at 1337 n.31 (arguing that there exists a positive right of procreation and citing Jean M. Eggen, *The "Orwellian Nightmare" Reconsidered: A Proposed Regulatory Framework for the Advanced Reproductive Technologies*, 25 GA. L. REV. 625, 655 (1991)).

99. Lifchez v. Hartigan, 735 F. Supp. 1361, 1377 (N.D. Ill. 1990); *see also* Roe v. Wade, 410 U.S. 113, 152 (1973) (right to privacy implications have "some extension to activities relating to marriage, . . . procreation, . . . [and] contraception") (citations omitted).

100. 735 F. Supp. 1361, 1377 (N.D. Ill. 1990).

101. *See id.*

102. *Id. But see* John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 939, 965 n.79 (1986) (discussing whether the procedures enabling the selection of certain characteristics in a child may be outside the interests of privacy regarding the right to procreate).

103. John B. Attanasio, *The Constitutionality of Regulating Human Genetic Engineering: Where Procreative Liberty and Equal Opportunity Collide*, 53 U. CHI. L. REV. 1274, 1300 (1986) ("The right to abortion bestowed in [*Roe*] in practice allows people to engage in a form of genetic engineering. A fortiori, it must confer the right to engage in genetic engineering without using abortion. If the prospect of genetic manipulation through abortion is permitted under the trimester system in [*Roe*], then surely genetic manipulation that takes place by improving rather than destroying the fetus must be permissible"); *Cf.* Lifchez v. Hartigan, 735 F. Supp. 1361, 1377 (N.D. Ill.1990) (stating that constitutional choices include the right to undergo procedures that will provide information about the fetus, which can in turn lead to a decision to abort. The Court further applied the right of privacy to fertility procedures, which bring about pregnancy.).

woman's decision to abort constitutes a constitutionally protected privacy interest.[104]

A court could feasibly apply the right of privacy analysis to the reproductive technology of gene therapy because, like other reproductive technologies, the goal of gene therapy is to benefit the embryo.[105] Gene therapy corrects genetic defects by replacing the faulty gene.[106] Just as courts have asserted a privacy right inherent in child rearing, there may also be a privacy right regarding the use of gene therapy to benefit an embryo.[107] Courts have upheld the notion that parents, as primary caregivers, have a duty to care for and nurture the child.[108] Additionally, in *Bowen v. American Hospital Association*, the Supreme Court stated that there is a strong presumption that parents are appropriate decision-makers regarding their infant's interests.[109] The Court declared the state an improper decision-maker by invalidating as unconstitutional a state statute mandating treatment for handicapped newborns.[110] Thus, gene therapy, used to benefit the fetus, would constitute a parent's duty to make care-giving decisions for the child.[111]

Moreover, a parent's ability to make decisions for the child is further demonstrated in the context of abortion cases, in which the mother, prior to

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104. 505 U.S. at 837–38 (stating that the state's requirement regarding information "relating to the consequences to the fetus do not interfere with a constitutional right of privacy between a pregnant woman and her physician" and that such a state regulation "does not underlie or override the abortion right. . . .").

105. *See* Lori B. Andrews, *Regulation of Experimentation on the Unborn*, 4 J. LEGAL MED. 25, 27 (1993).

106. *See* Martin L. Lagod & Patricia A. Martin, *The Human Preembryo, the Progenitors, and the State: Toward a Dynamic Theory of Status, Rights, and Research Policy*, 5 HIGH TECH. L.J. 257, 305–06 (1990).

107. Attanasio, *supra* note 103, at 1300–01.

108. *See* Stanley v. Illinois, 405 U.S. 645, 651 (1972) (noting that the right to raise children is an essential right "far more precious . . . than property rights"). *Stanley* appears to support the contention that raising and providing care for a child is a fundamental right because society has traditionally recognized it as a fundamental right. *Id.* at 650–53; *see also* Prince v. Massachusetts, 321 U.S. 158, 166 (1944) (stating that "the custody, care and nurture of the child resides first in the parents").

109. *See* Bowen v. Am. Hosp. Ass'n, 476 U.S. 610, 628 n.13 (1986); *see also* United States v. Univ. Hosp. of State Univ. of N.Y. at Stony Brook, 575 F. Supp. 607, 616 (E.D.N.Y. 1983), *aff'd*, 729 F.2d 144 (2d Cir. 1984) (holding that government involvement in choosing between alternative reasonable medical treatments for handicapped children gives way to right of privacy concerns); *In re* Seiferth, 127 N.E. 2d 820, 823 (N.Y. 1955) (holding that parents have discretionary authority regarding medical treatment of their children when there is no emergency); *but see In re* Jamaica Hosp., 491 N.Y.S. 2d 898, 899–900 (1985) (ordering a blood transfusion for a mother, against her will, to benefit her unborn fetus); Jacobson v. Massachusetts, 197 U.S. 11, 37–39 (1905) (upholding compulsory vaccinations to which the parents and children object).

110. *See Bowen*, 476 U.S. at 627 n.13.

111. *See* Attanasio, *supra* note 103, at 1300–01 (Parental control over genetic engineering would be consistent with the "broad discretion" provided to parents in deciding medical matters for their children. "If parents are empowered to decide questions of life and death for their children, they should certainly be allowed to decide whether to use Genos.").

viability, may abort the fetus based on the sex of the fetus.[112] This decision-making right conferred upon parents in *Roe* allows people to participate in a form of genetic engineering or selection. It should also confer the right to engage in genetic selection to bear and beget a normal, healthy child.[113]

IV. FEARED ABUSES ASSOCIATED WITH HUMAN GENE THERAPY AND POTENTIAL LEGISLATIVE MEASURES TO PREVENT ABUSE

Modern biotechnology techniques have resulted in potential treatments for genetic diseases through the use of gene therapy.[114] Given the potential for abuse of this technology, the legal and ethical issues surrounding the use of gene therapy are as significant as its potential benefits.[115]

Gene therapy remains an experimental technology that exposes its subjects to many unknown and unquantifiable risks.[116] Considering the historical context, gene therapy might conjure up images of the racist eugenics and human experiments of Nazi Germany,[117] resulting in public fear of using gene therapy for enhancement rather than mere treatment of serious genetic abnormalities.[118] In the religious and moral contexts, gene therapy may provoke feelings of trepidation regarding the sanctity of life.[119] In view of such fears and concerns regarding the practice of gene therapy, a balance must be obtained between the progress of biotechnology and the assurance against its abuse.[120]

A common fear is that gene therapy will be used for nontherapeutic purposes, i.e., that biotechnology will be used not to assure parents that their children will be born healthy, but will be used to merely enhance desirable characteristics.[121] Parents might desire to alter the genes of their children to

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112. *Id.* at 1299–1300.

113. *See id.* at 1300.

114. *See* Friedmann, *supra* note 13, at 1275 (stating that gene therapy is very promising by directing treatment to the actual mutant gene); David A. Kessler et al., *Regulation of Somatic-Cell Therapy and Gene Therapy by the Food and Drug Administration*, 329 NEW ENG. J. MED. 1169, 1171–72 (1993) (explaining various regimens of therapy).

115. *See* Friedmann, *supra* note 13, at 1286 (stating that gene therapy is both promising and controversial).

116. *See* Charles F. De Jager, Note, *The Development of Regulatory Standards for Gene Therapy in the European Union*, 18 FORDHAM INT'L L.J. 1303, 1311–12 (1995) (citation omitted).

117. DANIEL KEVLES, IN THE NAME OF EUGENICS: GENETICS AND THE USES OF HUMAN HEREDITY 89 (Alfred A. Knopf ed., 1985).

118. *See* Louis J. Elsas II, *A Clinical Approach to Legal and Ethical Problems in Human Genetics*, 39 EMORY L.J. 811, 830 (1990).

119. *See id.* at 832.

120. *See* Judith Areen, *Regulating Human Gene Therapy*, 88 W. VA. L. REV. 153, 170 (1985).

121. John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 436 (1996).

enhance intelligence, beauty, height, and other desirable traits, not because their given genome is defective, but because this will enhance chances in life.[122]

Enhancement genetic engineering is similar, in many respects, to gene therapy.[123] It operates based on the same technology, and like gene therapy, it could be used on both somatic and germ-line cells.[124] Currently, only somatic gene therapy techniques are considered ethical, and such techniques are being targeted only for the treatment or prevention of serious diseases.[125] However, as knowledge expands in the area of enhancement genetics, regulations must be in place to prevent a divergence from legitimate gene therapies.[126]

A. Gene Therapy Regulation

Existing statutes, regulations and guidelines may provide some insight as to how the practice of gene therapy can be adequately regulated.[127] If the existing regulations for drugs, devices, and biological sciences apply to gene therapy in protecting human research subjects, then the present regulatory scheme should be adequate.[128]

The Food and Drug Administration (FDA) regulates products aimed at treating, preventing and curing diseases under the authority of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA) and the Public Health Service Act of 1944 (PHSA).[129] The relevant question in determining the extent of the FDA's authority to regulate gene therapy is whether "therapy" constitutes medical practice, which the FDA generally does not regulate,[130] or whether it constitutes the use of "articles,"[131] which require FDA investigation before being sold in

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122. *See id.*

123. *See* W. French Anderson, *Human Gene Therapy*, 256 SCI. 808, 812 (1992) (describing as an example of enhancement genetic engineering the transfer of a gene into cells for the purpose of improving characteristics such as height).

124. *See id.*

125. *See* W. French Anderson, *Human Gene Therapy: Why Draw a Line?*, 14 J. MED. & PHIL. 681, 687–88 (1989) (defining serious diseases as diseases that cause significant suffering and premature death).

126. *See* LeRoy Walters, *The Ethics of Human Gene Therapy*, 320 NATURE 225, 225–26 (1986).

127. *See* Wilder J. Leavitt, *Regulating Human Gene Therapy: Legislative Overreaction to Human Subject Protection Failures*, 53 ADMIN. L. REV. 315, 322 (2001).

128. *See id.*

129. *See id.* at 323 (citing Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248 (Oct. 14, 1993), which extends the FDA authority to somatic cell and gene therapy products).

130. *See* Maxwell J. Mehlman, *How Will We Regulate Genetic Enhancement?*, 34 WAKE FOREST L. REV. 671, 702 (1999) (arguing that FDA jurisdiction over medical practices would be considered by doctors as an unreasonable intrusion into their discretionary practices).

131. *See* Elizabeth C. Price, *Does the FDA Have Authority to Regulate Human Cloning?*, 11 HARV. J.L. & TECH. 619, 630 (1998) (stating that gene therapy is more than the practice of medicine because it involves "articles" that may be either drugs or devices aimed at assisting the body to function or to treat a disease).

interstate commerce.[132] The second is a clear means of FDA supervision since the FDA must provide pre-approval review of such applications, and it must receive continuing reports, especially pertaining to adverse consequences.[133]

While there are no particular statutes authorizing the FDA to regulate gene therapy, the FDA can assert jurisdiction over gene therapy if the gene therapy involves articles classified as drugs,[134] medical devices,[135] or biological products.[136] The FDA has declared that the current statutory authorities are broad enough to cover somatic cell and gene therapy technologies.[137]

Current laws and regulations should be sufficient to oversee somatic gene therapy.[138] Also, federal agencies have the authority to integrate protections.[139]

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132. *See id.* at 620. There are three bases for FDA jurisdiction over cloning, which include the following: (1) classification as a "drug" under section 201(g) of the Federal Food, Drug, and Cosmetic Act (FDCA); (2) classification as a medical "device" under Section 201(h) of the FDCA; or, (3) classification as a "biological product" under Section 351(a) of the Public Health Service Act (PHSA). Such "articles" are subject to FDA investigation only through the means provided for experimental new drugs and/or device and require FDA pre-clinical clearance. *Id.*

133. *See* Leavitt, *supra* note 127, at 323 (citing to 21 C.F.R. pts. 50, 56 (2000)).

134. The FDCA defines "drug" as "[an] article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . ." Federal Food, Drug, and Cosmetic Act § 201(g)(1)(B)-(C), *as codified in* 21 U.S.C. § 321(g)(1)(B)–(C) (1994).

135. The FDCA defines "device" as:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals . . . which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Federal Food, Drug, and Cosmetic Act § 201(h), *as codified in* 21 U.S.C. § 321(h) (1994).

136. The PHSA defines "biological product" as any "virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivatives of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings . . . ." Public Health Service Act § 351(a), *as codified in* 42 U.S.C. § 262(i) (1994).

137. *See* Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53,248 (Oct. 14, 1993) (finding that biological products regulated under section 351 of PHSA are also drugs under section 201(g)(1) of the FDCA). Therefore, manufacturers cannot introduce products into interstate commerce until they are licensed by the Center for Biologics Evaluation and Research (CBER), a division of the FDA. *Id.*

138. *See* Peter Barton Hutt, *Research on Recombinant DNA Molecules: The Regulatory Issues*, 51 S. CAL. L. REV. 1435, 1443 (1978) (citing 42 U.S.C. § 264 (1970) (stating that PHSA authorizes DHHS "to take whatever action is necessary 'to prevent the introduction, transmission, or spread of communicable diseases'").

139. *See id.*

Both the PHSA and FDCA authorize preclinical oversight[140] and stipulate safety rules during commercialization.[141]

B. Regulatory Framework Enhancements

The Working Group on National Institutes of Health (NIH) Oversight of Clinical Gene Transfer Research (Working Group) serves as the Advisory Committee to the Director of the NIH. Working Group has developed common recommendations to change gene therapy protocols.[142] The Working Group indicated that improved supervision may be achieved by:

> [I]nfusing the review and oversight system with more requirements for accountability; simplifying, streamlining, and harmonizing the requirements to report serious adverse events to NIH and FDA to ensure that reports are timely and accurate; and assuring that by using an expert body, NIH receives all relevant information regarding adverse events, interprets the data, and makes public what it learns.[143]

The appropriate reaction to gene therapy fears might not be the enactment of more laws and regulations.[144] Although entrusted to two regulatory agencies, it appears that regulatory components for gene therapy sufficiently exist.[145] However, the functions of the NIH and FDA should become more coordinated with one another.[146] Perhaps NIH Guidelines should be united with the confidential oversight of the FDA,[147] and further, perhaps researchers should view

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140. *See id.* at 1444 (concluding NIH is the preferable regulatory agency for rDNA research).

141. *See* Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. at 53,248 (summarizing the FDA's statutory authority under the PHSA and FDCA).

142. *See* ADVISORY COMM. TO THE DIR., WORKING GROUP ON NIH OVERSIGHT OF CLINICAL GENE TRANSFER RESEARCH: ENHANCING THE PROTECTION OF HUMAN SUBJECTS IN GENE THERAPY RESEARCH AT THE NATIONAL INSTITUTES OF HEALTH 2 (evaluating NIH's role in overseeing clinical gene transfer research), *available at* http://www.nih.gov/about/director/07122000.htm (last visited February 4, 2000).

143. *Id.* at 7.

144. *See* Leavitt, *supra* note 127, at 337.

145. *See* David A. Kessler et al., *supra* note 114, at 1171–72 (RAC "ensures broad public discussion of the scientific evaluation of [gene therapy], particularly with regard to social and ethical concerns. The FDA focuses on the development of safe and effective biologic products . . . .").

146. *See* AM. SOC'Y OF GENE THERAPY, REPORTING OF PATIENT ADVERSE EVENTS IN GENE THERAPY TRIALS: STATEMENT FROM THE AMERICAN SOCIETY OF GENE THERAPY (acknowledging industries' wishes for NIH and FDA to create unified regulations), *at* http://www.asgt.org/position_statement/adverse_events.html (visited Jan. 29, 2002); *see also* Recombinant DNA Research: Actions Under the Guidelines, 60 Fed. Reg. 20,726 (Apr. 27, 1995) (proposing closer relationship between FDA Division of Cellular and Gene Therapies and the NIH ORDA).

147. *See* Leavitt, *supra* note 127, at 337 (citing Germ-line Modification Oversight Body Advocated by AAAS, *The Blue Sheet*, (Feb. 23, 2000) (reporting that the American

the FDA and the NIH as one comprehensive agency that handles gene therapy issues.[148]

V. LEVEL OF REVIEW

A. Strict Scrutiny Standard

If gene therapy is considered to be a fundamental procreative liberty interest, then courts must apply strict scrutiny.[149] In order to pass strict scrutiny review, the state may regulate gene therapy only if it asserts a compelling state interest, the regulation is narrowly tailored so that there is a substantial relation between the means and the end, and the challenged regulation is the least restrictive means of attaining the compelling government interest.[150]

There is probably a compelling state interest in preserving genetic diversity given the Court's prior decisions indicating that a state interest in the unborn can be compelling and given authoritative statements that a decrease in the gene pool may interfere with human adaptability to the environment.[151]

Academy for the Advancement of Science is calling for a single regulatory body to oversee inherited gene modification technology).

148. *See id.* (citing Letter from Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluations and Research, to Gene Therapy IND Sponsor/Principle Investigator (Nov. 5, 1999), which is on file with the FDA, Center for Biologics Research and Evaluation, and states that "FDA and NIH each make unique and complementary contributions to the scientific evaluation of safety and potential efficacy of human gene therapy trials").

149. *See* Washington v. Glucksberg, 521 U.S. 702, 721–22 (1997) (stating that the Due Process Clause of the Fourteenth Amendment prohibits the government from interfering with "'fundamental' liberty interests at all," unless the state regulation is "narrowly tailored to serve a compelling state interest") (citation omitted); Griswold v. Connecticut, 381 U.S. 479, 503–04 (1965) (stating that statutes regulating liberty must pass "strict scrutiny," which includes the requirement that the regulation be the least restrictive means of attaining the compelling state interest) (citations omitted); Roe v. Wade, 410 U.S. 113, 155 (1973) (stating that the government must have a compelling state interest and that the chosen interference with a fundamental right must be the least restrictive means of attaining the state interest); Mary Patricia Treuthart, *Adopting a More Realistic Definition of 'Family'*, 26 GONZ. L. REV. 91, 108–09 (1991–91) (Under due process or equal protection analysis, state interference with a "fundamental" right cannot be justified by a mere showing of rational basis. Courts must use the "strict scrutiny" level of review, which means that the challenged state regulation must be shown to be necessary to a "compelling state interest" to be upheld.).

150. *See Glucksberg*, 521 U.S. at 721 (stating that government infringement on fundamental liberty interests must be narrowly tailored to serve a compelling state interest) (citations omitted); *Griswold*, 381 U.S. at 504 (defining strict scrutiny as requiring that the regulation is the least restrictive means for achieving a state's compelling interest) (citations omitted).

151. *See Roe*, 410 U.S. at 154 (recognizing that the state has a compelling interest in protecting the public's health, including the health of an unborn child); Superintendent of Belchertown State Sch. v. Saikewicz, 370 N.E. 2d 417, 425 (Mass. 1977) (recognizing that the state has a compelling interest in the preservation of life and the protection of innocent

This compelling state interest could be accomplished by banning the practice of gene therapy. However, banning the practice of gene therapy may not be the least restrictive means.[152] If the state's compelling interest lies in preserving the diversity of the gene pool, legislation could be passed to restrict the use of gene therapy to therapeutic cases, in which gene therapy is the only available treatment to cure a genetic defect. Likewise, if the state's compelling interest lies in preserving the life of the unborn fetus, then legislation could be passed to limit the use of gene therapy to cases in which the fetus' chance of surviving the gene therapy is sufficiently high.

As legislation is passed regulating the use of human gene therapy technology, and if the strict scrutiny standard of judicial review is used, courts will need to balance the competing interests of the government with the individual.[153] If the gene pool diminishes due to use of gene therapy, the resulting gene pool may not be adaptable to our changing environment.[154] Also, the state interest in preventing the screening of embryos with certain genes that may be linked to beneficial genes are similarly compelling.[155]

The compelling state interest appears to prevail over the parent's interest in the case of nontherapeutic genetic screening, such as screening for certain sex or hair color traits.[156] The compelling state interest in preserving genetic diversity and promoting public health may not override the parents' interest when gene therapy is used for therapeutic purposes, such as when it is used to aid in a decision whether to undergo gene therapy or to bear and raise a child with a genetic abnormality.[157] This balancing test should include the emotional, physical, and financial hardships associated with an individual giving birth to a child with a genetic defect.[158] Therefore, the state may be able to ban nontherapeutic genetic screening, as opposed to therapeutic genetic screening, because mere genetic enhancement of a child arguably will not influence an individual's decision to procreate.[159] On the other hand, preventing individuals from utilizing gene therapy for the correction of serious genetic abnormalities may deter individuals from exercising their reproductive freedom. The compelling state interests in protecting the embryo would not outweigh the parent's interest in having a healthy child.[160]

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third parties); Norton, *supra* note 97, at 1642–44 (1994) (noting that a decrease in the gene pool may interfere with the human race's ability to adapt to a changing environment).

152. *See Griswold*, 381 U.S. at 504 (citing Shelton v. Tucker, 364 U.S. 479, 488 (1960), for the proposition that the restriction "must be viewed in the light of less drastic means for achieving the same basic purpose").

153. *See supra* notes 149–50 and accompanying text (regarding cases setting forth the requirements of strict scrutiny).

154. *See* Norton, *supra* note 97, 1642–44 (1994).

155. *See id.* at 1613 (explaining that selections could result in an increase of disease or defects).

156. *See id.* at 1641–42 (discussing the impact that bans on nontherapeutic preimplantation genetic screening would have on the individual's decision to procreate).

157. *See id.* at 1625.

158. *See id.*

159. *See id.* at 1627.

160. *See* Coleman, *supra* note 85, at 1381–82.

B. The Undue Burden Standard

Thus far, gene therapy has been discussed in the context of privacy rights and procreative freedom. However, a court may compare the practice of gene therapy to cases dealing with the right to an abortion.[161] In *Roe v. Wade*, Justice Stewart's concurrence stated that the prior *Griswold* decision "can be rationally understood only as a holding that the Connecticut statute substantively invaded the 'liberty' that is protected by the Due Process Clause of the Fourteenth Amendment."[162] A woman's right to privacy is a "fundamental right" under the Fourteenth Amendment.[163] Therefore, the legislature has only a limited right to regulate, and may not completely proscribe, abortions.[164] "Liberty" under the Fourteenth Amendment is "broad enough to encompass a woman's decision whether or not to terminate her pregnancy."[165]

In *Casey*, the plurality emphasized that in the context of abortion, a woman's liberty is at risk due to the woman's unique condition, and this, in turn, presents courts with unique questions of law.[166] The *Casey* plurality stated, "The mother who carries a child to full term is subject to anxieties, to physical constraints, to pain that only she must bear . . . . Her suffering is too intimate and personal for the State to insist, without more, upon its own vision of the woman's role. . . ."[167] Given the unique risk presented to pregnant women through state regulations of reproductive choices, the judiciary should proceed cautiously.[168]

The *Casey* Court rejected *Roe*'s trimester approach by stating that abortion simply may not be "unduly burdened."[169] *Casey* also rejected the *Roe* contention that abortion is a fundamental right.[170] Instead, under *Casey*, a woman has the right to have an abortion before viability without undue interference from the state.[171] State regulation will constitute an undue burden if the regulation's "purpose or effect is to place substantial obstacles in the path of a woman seeking an abortion before the fetus attains viability."[172] Since the right to an abortion was not deemed to be a "fundamental right" by the *Casey* Court, strict scrutiny was not applied.[173] Instead, the Court applied the new "undue burden" standard.[174]

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161. *See* Attanasio, *supra* note 103, at 1300 (discussing abortion as one form of genetic engineering).
162. Roe v. Wade, 410 U.S. 113, 168 (1973) (Stewart, J., concurring).
163. *Id.* at 114.
164. *See id.*
165. *Id.* at 153.
166. *See* Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 852 (1992).
167. *Id.*
168. *Id.*
169. *Id.* at 837.
170. *See id.*
171. *See id.*
172. *Id.*
173. *Id.*
174. *Id.*

Both the contraception and the abortion contexts concern private decisions regarding not only the significance of procreation, but also respect for individual responsibility.[175] The Supreme Court, in *Casey*, stated:

> Our law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education . . . . These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment. At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.[176]

While strict scrutiny was not applied in *Casey*, the "essential holding" of *Roe* was reaffirmed.[177] The plurality in *Casey* stated, "the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood."[178]

Banning the practice of prenatal gene therapy would infringe on the individual's "liberty" to procreate. Therefore, a ban on gene therapy could be reviewed under the undue burden standard set forth in the context of abortion in *Casey*.[179] In *Casey*, Justice O'Connor stated, "A finding of an undue burden is a shorthand for the conclusion that a state regulation has the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus."[180] Liberties that also involve the state interest in potential life may therefore be regulated if the regulations do not unduly burden the individual's liberty interest. Any government-imposed restriction that applies an undue burden on a liberty is unconstitutional under substantive due process analysis, no matter how valid the state interest.[181]

According to the *Casey* plurality, "[a] burden may be 'undue' either because the burden is too severe or because it lacks a legitimate, rational

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175. *Id.* at 853 (The Court applied the "undue burden" standard of review to infringements on the liberty to choose abortion. This is a third standard of review in addition to the strict scrutiny standard of review applied to laws infringing on "fundamental rights" and the rational basis standard of review applied to laws infringing on mere "liberty interests").

176. *Id.* at 851.

177. *Id.* at 849.

178. *Id.*

179. *Id.* at 874–75. Although the decision in *Casey* was a plurality, it is likely that the "undue burden" standard supported by the plurality will become a common standard of review, since it represents the narrowest grounds for the Court's holding.

180. *Id.*

181. *See id.* at 877 ("[A] statute which, while furthering the interest in potential life or some other valid state interest, has the effect of placing a substantial obstacle in the path of a woman's choice cannot be considered a permissible means of serving its legitimate ends.").

justification."[182] It follows that in order for a ban on embryonic gene therapy to survive a challenge under the undue burden standard, a ban must: (1) not be a substantial obstacle to the right to procreate; and (2) must be rationally related the state's legitimate interest, such as preserving genetic diversity.

1. Prohibition of Enhancement Embryonic Gene Therapy Does Not Pose a Substantial Obstacle, While a Prohibition on Therapeutic Gene Therapy Does Pose a Substantial Obstacle to the Right to Procreate

Prohibition of nontherapeutic embryonic gene therapy likely does not pose a substantial obstacle to the liberty to procreate. While those parents seeking to use embryonic gene therapy for purely genetic enhancement reasons might be discouraged from choosing to have a child, such discouragement would not constitute a substantial obstacle on the decision to procreate. After all, in *Casey*, the Court upheld regulations that might discourage women from getting an abortion.[183] Furthermore, a ban on nontherapeutic gene therapy differs from the one restriction on abortion that the *Casey* plurality determined to be an undue burden. The *Casey* plurality determined that it must strike down the spousal notification requirement as an undue burden because the requirement provided the husband with an inordinate amount of authority and control over the wife.[184] A ban on nontherapeutic gene therapy, on the other hand, would not render an individual's interests subject to the dominion of another.

Prohibition of therapeutic gene therapy, with the purpose of correcting a serious genetic abnormality as opposed to mere "enhancement" of desired characteristics, would likely be upheld even under the undue burden standard, which is lower than the strict scrutiny standard discussed above. Individuals possess "[t]he right to procreate," which includes "the right to have natural children, whether through sexual intercourse or artificial insemination."[185] A total ban on therapeutic gene therapy would likely constitute an undue burden on reproductive liberties because it would result in the government dictating to individual's that if they are to have children, they must bear an afflicted child with all of the accompanying the emotional, physical, and financial hardships associated with a special needs child.[186] Therefore, a ban on gene therapy would probably constitute a substantial obstacle to individual liberty and would fail under the "undue burden" level of review.

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182. *Id.* at 920 (quoting Justice Stevens in his dissenting opinion, which describes the plurality's judgment). This analysis of the plurality judgment is supported by the plurality's words that "the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child." *Id.* The plurality further explained that its undue burden standard was not inconsistent with the rational basis standard. *Id.* at 846–47.

183. *See id.* at 881–85 (upholding a provision requiring informed consent); *id.* at 885–86 (upholding a twenty-four hour waiting period provision); *id.* at 899 (upholding a parental consent provision).

184. *See id.* at 897.

185. *In re* Baby M, 537 A.2d 1227, 1253 (N.J. 1988).

186. Norton, *supra* note 97, 1625.

2. A Ban on Embryonic Gene Therapy Is Rationally Related to the State's Legitimate Interest

Even if the ban on nontherapeutic gene therapy does not constitute an undue burden on the individual's decision to procreate, there must also be a rational relationship between the ban and a legitimate state interest, such as the interest in preserving genetic diversity.[187]

The more genetically diverse a species, the greater the likelihood that the species can adapt to a changing environment because some individuals will probably possess the necessary genes to thrive in new conditions.[188] Therefore, courts should recognize the state interest in genetic diversity as important and legitimate. The question is whether there is a rational relationship between the ban and the state's legitimate interest in promoting genetic diversity. There is certainly a rational relationship between a ban on nontherapeutic gene therapy and the state interest in promoting genetic diversity.[189] The state interest in genetic diversity is independent of any moral or ethical debate regarding the practice of enhancement gene therapy. If a large percentage of individuals use enhancement therapy to bring about desired characteristics, the gene pool could become composed of a detrimental number of homozygous traits.[190]

However, a complete ban on therapeutic gene therapy would probably lack a rational relationship to the state's interest in promoting gene therapy. If the practice of gene therapy is reserved for the correction of genetic abnormalities, then gene therapy would only serve to eliminate genetically defective traits that are harmful to the adaptability of the species. The only genetic diversity to be eliminated would be defective traits that are actually detrimental to the human species.

VI. WHEN PRENATAL GENE THERAPY TECHNOLOGY BECOMES AVAILABLE, MAY THE COURT ORDER PRENATAL INTERVENTIONS?

Courts typically consider four state interests when they decide whether to supersede competent medical decisions. These four interests include preserving

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187. *See Casey*, 505 U.S. at 846–47 (plurality stating that "the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman and the life of the fetus that may become a child"). The plurality further explained that its undue burden standard was not inconsistent with the rational basis standard. *Id.*

188. *See* CHARLES DARWIN, THE ORIGIN OF SPECIES 124 (J.M. Dent & Sons 1951) (1928). Darwin writes:

> [I]f variations useful to any organic being ever do occur, assuredly individuals thus characterized will have the best chance of being preserved in the struggle for life; and from the strong principle of inheritance, these will tend to produce offspring similarly characterized. This principle of preservation, or the survival of the fittest, I have called Natural Selection.

Id.

189. *See* Norton, *supra* note 97, at 1647.

190. *See id.*

life, preventing suicide, maintaining the ethical integrity of the medical profession, and protecting third parties.[191] All four factors weigh in favor of respecting the pregnant woman's decision whether to undergo gene therapy *in utero* for the sake of her fetus.[192] First, the state interest in preserving life is irrelevant since courts have "traditionally examined the refusal of treatment as it impacts upon the preservation of the life of the [decision-maker]."[193] Second, the state's interest in preventing suicide does not apply to embryonic gene therapy.[194] Third, the state's interest in maintaining the integrity of the medical profession supports the woman's decision because "the medical profession strongly supports upholding the pregnant woman's autonomy in medical decision-making."[195] The state's final interest in protecting third parties is not always appropriate for consideration by courts. For example, some courts consider this interest only when the woman's refusal of medical treatment will result in her own death and orphan her "already-born" children.[196] In addition to the foregoing state interests, courts may also consider the enforceability of a court order. In *Baby Boy Doe*, the court determined that granting and enforcing such a court order compelling a pregnant woman to submit to a cesarean section would be repugnant to the concept of liberty, which is protected by the Due Process Clause.[197] In *In re A.C.*, the court stated:

> Enforcement could be accomplished only through physical force or its equivalent. A.C. would have to be fastened with restraints to the operating table, or perhaps involuntarily rendered unconscious by forcibly injecting her with an anesthetic, and then subjected to unwanted major surgery. Such actions would surely give one pause in a civilized society, especially when A.C. had done no wrong.[198]

In *In re Fetus Brown*, the court declined to grant an order forcing a pregnant woman to undergo a blood transfusion for the sake of her fetus.[199] Similarly, the court in *Baby Boy Doe* stated, "[A] woman is under no duty to

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191. *See In re* Fetus Brown, 689 N.E.2d 397, 405 (Ill. App. Ct. 1997) (The Court held that a mother could not be compelled to undergo blood transfusions for the benefit of her viable fetus. The woman's right to refuse medical treatment on religious grounds was held to outweigh the state's interest in the welfare of the viable fetus.); *In re* Baby Boy Doe, 632 N.E. 2d 326, 334 (Ill. App. Ct. 1994) (holding that none of the four state interests justified overriding the mother's decision not to undergo cesarean section to protect the fetus).

192. *See* Angela Liang, *Gene Therapy: Legal and Ethical Issues For Pregnant Women*, 47 CLEV. ST. L. REV. 61, 65 (1999).

193. *Id.* (quoting language from *Baby Boy Doe*, 632 N.E.2d at 334).

194. *See id.*

195. *Id.* (quoting language from *Baby Boy Doe*, 632 N.E.2d at 334, in the court's discussion of the American Medical Association's recommendation that the physician's duty is limited to ensuring that the woman can make an informed decision, rather than attempting to control the woman's decision).

196. *Id.* (citing *Baby Boy Doe*, 632 N.E.2d at 334 and *In re* Brooks Estate, 205 N.E.2d 435, 438–39 (Ill. 1965)) (additional citations omitted).

197. *See id.* (citing *Baby Boy Doe*, 632 N.E. 2d at 335).

198. *In re* A.C., 573 A.2d 1235, 1244 n.8 (D.C. Cir. 1990).

199. *See In re* Fetus Brown, 689 N.E.2d 397, 405 (Ill. App. Ct. 1997).

guarantee the mental and physical health of her child at birth, and thus cannot be compelled to do or not do anything merely for the benefit of her unborn child."[200]

VII. CONCLUSION

If gene therapy is considered to be a fundamental procreative liberty interest, then courts must apply strict scrutiny, in which the state must assert a compelling state interest, the regulation must be narrowly tailored so that there is a substantial relation between the means and the end, and the challenged regulation must be the least restrictive means of attaining the compelling government interest.

There is probably a compelling state interest in preserving genetic diversity so that the human species will be adaptable to a changing environment. However, if the state's compelling interest lies in preserving the diversity of the gene pool, legislation could be passed to restrict the use of gene therapy to therapeutic cases, in which gene therapy is the only available treatment to cure a genetic defect. Therefore, a ban on nontherapeutic gene therapy would probably pass strict scrutiny review, while a ban on therapeutic gene therapy would likely fail strict scrutiny.

Even if gene therapy is analyzed under the "undue burden" standard of review applied to abortion cases following *Casey*, as opposed to the strict scrutiny standard of review applied to privacy rights in the contexts of contraception, marriage, and family, the practice of gene therapy arguably cannot be completely banned if it is limited to the correction of genetic abnormalities and excludes enhancement therapy. A complete ban on therapeutic gene therapy would probably lack a rational relationship to the state's interest in promoting gene therapy. If the practice of gene therapy is reserved for the correction of genetic abnormalities, then gene therapy would only serve to eliminate genetically defective traits that are harmful to the adaptability of the species. The only genetic diversity to be eliminated would be defective traits that are actually detrimental to the human species.

As the practice of gene therapy becomes more refined and predictable, our society will struggle with the implications of such expansive scientific technology. We should carefully consider the potential abuses that can occur in the absence of state regulation.

As regulations are challenged, the courts will determine which standard of review to use in evaluating the constitutionality of such state action. Regardless of which standard of review is eventually used by the courts, it appears likely that while therapeutic embryonic gene therapy might be regulated, it cannot be banned by the state.

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200. Baby Boy Doe, 632 N.E. 2d at 332 (Ill. App. Ct. 1994).