

# NOTES

## The Outer Limits of Human Genetic Engineering: A Constitutional Examination of Parents' Procreative Liberty to Genetically Enhance Their Offspring

By THOMAS STUART PATTERSON

*[I]f any one age really attains by eugenics and scientific manipulation, the power to make the descendants what it pleases, all men who live after it are patients of that power. They are weaker not stronger.*

—C.S. Lewis, 1962<sup>1</sup>

### I. Introduction

Imagine a world where parents have the ability to genetically determine the characteristics of their children. Before the conception of their child, they sit down with a genetic specialist and discuss the height, strength, and physique they desire for their child. They then decide what color eyes, hair, and skin the child will have. Depending upon the financial resources of the prospective parents, they may consider the amount of raw musical talent or academic potential they desire for their child, or even decide on particular personality traits. Once these and other preliminary decisions are made, the specialist goes to work by combining sperm and eggs donated by the parents to create a selection of desirable embryos. Finally, after selecting the embryo that proves the closest match to the parents' desires, the specialist performs genetic surgery on the developing embryo to guarantee that the couple's child will be born with the exact characteristics that they chose.

Does this sound too much like science fiction to be true? Actu-

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1. CLIVE S. LEWIS, *THE ABOLITION OF MAN; OR REFLECTIONS ON EDUCATION WITH SPECIAL REFERENCE TO THE TEACHING OF ENGLISH IN THE UPPER FORMS OF SCHOOL* 44 (1962).

ally, such a scenario may occur in the not too distant future.<sup>2</sup> “This is the kind of world that might exist when our grandchildren are grown,” according to sixty-year-old gene therapy pioneer W. French Anderson.<sup>3</sup> He says, “[t]he basic science is already here . . . .”<sup>4</sup> Though he explains that “we will not have the efficiency and safety to *ethically* perform the gene transfers for another ten to fifteen years,”<sup>5</sup> many scientists are convinced “that modest genetic makeovers could become a reality within the next few years.”<sup>6</sup> The rapid identification of genes affecting physical and behavioral traits coupled with improved methods of injecting genes into humans will make genetic makeovers possible.<sup>7</sup> Currently, partial coding exists for over half of all human genes and new discoveries are made almost daily.<sup>8</sup> “And while essentially all complex traits such as intelligence and behavior involve multiple genes, they eventually will be discovered and perhaps one day be available from genetic counselors like entrees on a menu.”<sup>9</sup>

Such possibilities present a host of ethical, religious, and legal considerations. Although convincing arguments suggest that “playing God” with the genes of unborn children is fundamentally wrong, we should not simply brand all genetic engineering as needless meddling with nature. Genetic engineering has the potential to provide us with much needed cures for genetic diseases, such as cancer and immune deficiency disorders.<sup>10</sup> As James M. Gustafson, a medical ethicist and ordained minister at Emory University explains, “[w]e have to avoid the twin extremes, . . . a frightening ‘apocalyptic’ view of genetic engineering and a ‘utopian’ expectation that gene therapy can eliminate all of life’s pain and disappointments.”<sup>11</sup>

This note will discuss some of the implications of the rapidly advancing genetic revolution, as well as the constitutionality of regulations on genetic engineering of unborn children. While a ban on genetic engineering may prevent harm to the gene pool,<sup>12</sup> parents who

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2. See Tim Friend, *Designer Genes Not Farfetched*, CHICAGO SUN-TIMES, Nov. 2, 1997, at 40.

3. *Id.*

4. *Id.*

5. *Id.* (emphasis added).

6. Rick Weiss, *Gene Enhancement’s Thorny Ethical Traits; Rapid-Fire Discoveries Force Examination of Consequences*, WASH. POST, Oct. 12, 1997, at A1.

7. See *id.* The purpose of these genetic makeovers may be for anything—from curing disease-causing defects to enhancements of “favorable” characteristics. See *infra* Part II.

8. See Friend, *supra* note 2, at 40.

9. *Id.*

10. See Robin Herman, *Tinkering with the Essence of Humanity; Scientists and Theologians Debate the Morality of Genetic Engineering*, WASH. POST, Oct. 8, 1991, at Z6.

11. *Id.*

12. See *infra* at II.B.

desire to genetically alter their children may have a constitutional right to do so based upon their procreative liberties and fundamental parental rights.

Before these issues are addressed, however, it is important to have a basic understanding of both the capabilities and potential negative effects of the different forms of genetic engineering. The following discussion divides the types of genetic engineering into three categories, with each category posing its own thought-provoking issues.<sup>13</sup>

## II. The Three Categories of Genetic Engineering

### A. Somatic Gene Therapy

Somatic gene therapy does not affect reproductive cells.<sup>14</sup> Genetic changes attributable to somatic therapy are, therefore, not passed on to subsequent generations.<sup>15</sup> In use today, somatic engineering is employed to cure adverse medical conditions.<sup>16</sup> The therapy, however, could theoretically be used for other purposes, such as trait enhancements.<sup>17</sup> An example of how somatic gene therapy works will be helpful in understanding the issues involved.

One beneficial use of somatic therapy is to ease the suffering of cystic fibrosis patients.<sup>18</sup> Patients with cystic fibrosis have severe breathing problems, poor digestion, and abnormally salty sweat.<sup>19</sup> These patients also have the potential to develop serious lung infections and diabetes. Cystic fibrosis symptoms can be traced to a faulty gene that causes "excessive production of abnormally thick and sticky mucus."<sup>20</sup> While the problems caused in the digestive system can be treated with drugs, the damage caused to the lungs eventually proves fatal.<sup>21</sup> Somatic gene therapy, however, can slow the lung damage through the following steps:

1. Obtain a healthy copy of the CF (cystic fibrosis) gene.
2. Insert it into the genetic material of a convenient bacterium.
3. Allow the bacteria to reproduce many times.

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13. *See id.*

14. *See* MICHAEL J. REISS & ROGER STRAUGHAN, IMPROVING NATURE? THE SCIENCE AND ETHICS OF GENETIC ENGINEERING 202 (1996).

15. *See id.*

16. *See, e.g., infra* notes 18-22 and accompanying text.

17. *See, e.g., infra* notes 36-38 and accompanying text.

18. *See* REISS & STRAUGHAN, *supra* note 14, at 202-06.

19. *See id.* at 202.

20. *Id.* at 203.

21. *See id.* at 204.

4. Remove the healthy copies of the CF gene from the bacteria.

5. Put these healthy CF genes into a vector (such as a harmless virus), which carries the healthy CF genes to the cells that line the lungs. Here the CF genes insert themselves into the DNA in these cells.

6. The missing protein then moves to the membrane that surrounds the cell. Here it regulates the passage of chloride ions, allowing the mucus produced by the cell to be its normal runny consistency.<sup>22</sup>

Medical ethicist James M. Gustafson explains that since the genetic changes will not be passed on to subsequent generations, there is general agreement that the ethical question posed by somatic therapies is fairly simple: do the potential benefits to the patient outweigh the risks of the therapy?<sup>23</sup> There are some patient risks in this type of therapy, including an increased risk of cancer.<sup>24</sup> These risks, however, do not affect the patient's offspring.<sup>25</sup> If the patient gives informed consent to the procedure, it is difficult to argue that there is a great enough risk to outweigh the benefit of using somatic therapy to cure a devastating disease like cystic fibrosis.

## B. Germ-Line Therapy

Unlike somatic therapy, germ-line therapy—inserting genes into either reproductive cells or an existing embryo—does affect subsequent generations.<sup>26</sup> Some critics of this approach, such as Jeremy Rifkin, the president of the Foundation for Economic Trends, accept somatic therapy but object to germ-line therapy, which “forever alter[s] future generations.”<sup>27</sup> One reason for rejecting germ-line therapy is the potential risk to existing genes.<sup>28</sup> Presently, researchers cannot control exactly where new genes are inserted, raising the “danger that an inserted gene [may] cause damage to an existing gene . . . .”<sup>29</sup> Yet with the rapid advances in genetic technology, it is likely that scientists will develop processes to precisely target the insertion of new genes.<sup>30</sup>

Although other risks of germ-line engineering cannot be determined precisely, our current knowledge of human DNA gives us some

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22. *Id.* at 204-05.

23. *See* Herman, *supra* note 10.

24. *See* REISS & STRAUGHAN, *supra* note 14, at 205.

25. *See id.*

26. *See* Herman, *supra* note 10.

27. Larry Thompson, *Poll Finds Support for Use of Gene Therapy*, WASH. POST, Sept. 25, 1990, at Z9.

28. *See* REISS & STRAUGHAN, *supra* note 14, at 217-18.

29. *Id.* at 217.

30. *See id.*

idea of the gravity involved. For example, we know that minute variations within some sequences of human DNA can result in devastating diseases, such as sickle cell anemia.<sup>31</sup> Further, we know that many human diseases are at least partially caused by defects within genes and that often the diseases are caused by interaction among several or many genes.<sup>32</sup>

It is possible that once the technology is refined, if something were to go wrong with germ-line therapy, the same techniques could be used to reverse the negative effect.<sup>33</sup> However, if the altering of genetic code created devastating diseases that did not show up until late in life, multiple generations may be subjected to the disease due to the initial patients (and possibly their children) having already reproduced.

Still other risks of germ-line engineering are illustrated by our experience with genetic alteration of plants and animals. With both plants and animals, scientists performing genetic alterations have sometimes inserted a desired gene to bring about a certain effect, only to receive unexpected problems. In a case involving plants, corn was engineered to alter a gene that controlled male sterility in corn.<sup>34</sup> However, an unknown effect was that the alteration made the corn highly susceptible to southern corn blight.<sup>35</sup> Unfortunately, because the corn was widely used, in one year the corn crop was severely destroyed.<sup>36</sup> A similar result occurred with the genetic alteration of wheat.<sup>37</sup>

Unexpected and unfortunate results have also occurred in the genetic alteration of animals. For example, in an attempt to find a treatment for the AIDS virus, researchers inserted a gene into the DNA of mice that was meant to have the effect of producing an antiviral substance.<sup>38</sup> The unexpected result was that the inserted gene "knocked out" something else in the middle of a gene that controls the "flight or fight" responses to stress.<sup>39</sup> This caused some of the mice to be unusually aggressive toward each other.<sup>40</sup> Although normal mice do not usually fight, the genetically altered male mice had bite wounds all

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31. See SUSAN ALDRIDGE, *THE THREAD OF LIFE* 138 (1996).

32. See Carl F. Cranor, *Genetic Causation, in ARE GENES US?* 125, 125-34 (Carl F. Cranor ed., 1994).

33. See REISS & STRAUGHAN, *supra* note 14, at 218.

34. See BERNARD E. ROLIN, *THE FRANKENSTEIN SYNDROME: ETHICAL AND SOCIAL ISSUES IN THE GENETIC ENGINEERING OF ANIMALS* 110 (1995).

35. See *id.*

36. See *id.*

37. See *id.*

38. See LOIS WINGERSON, *UNNATURAL SELECTION* 293 (1998).

39. See *id.* at 291, 293.

40. See *id.* at 293.

over their bodies.<sup>41</sup> The insight we should gain from such experiments is that not only may genetic engineering have negative physical consequences, such as unforeseen diseases, but it may also cause unanticipated and devastating behavioral and emotional problems.

Although there are significant risks to germ-line therapy, there are also potential benefits of great magnitude. First, some diseases may only be treatable by using germ-line therapy.<sup>42</sup> Arguably, if such a therapy is devised, it should be regulated much more closely than somatic therapy.<sup>43</sup> Second, it is inefficient to perform somatic therapy generation after generation for an inheritable medical condition if one germ-line therapy could potentially cure the disease for all future generations.<sup>44</sup> Even with these benefits, however, extreme caution should be used before pursuing germ-line engineering. Even though there may be enormous benefits, the risks may still outweigh them. We cannot be sure of what devastating and unknown "monster" we may unleash for the future by attempting to cure diseases of today.

### C. Enhancement of Physical and Mental Characteristics

The possible future use of genetic engineering to enhance physical and mental characteristics for non-medical reasons engenders much controversy. For example, should people be able to use genetic engineering to enhance their intelligence, change their skin color,<sup>45</sup> add muscle mass,<sup>46</sup> or cure baldness?<sup>47</sup> While many see ethical

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41. *See id.*

42. *See Changing Your Genes*, *ECONOMIST*, Apr. 25, 1992, at 11.

43. *See id.*

44. *See* Ruth Sorelle, *The Gene Doctors*, *HOUSTON CHRON.*, Apr. 2, 1995, at 12.

45. Scott McIvor, a medical researcher who oversees the University of Minnesota's program in gene therapy tells of an e-mail message from a doctor who wanted McIvor to help him change a patient's skin color. *See* Weiss, *supra* note 6. The doctor was aware that the genes affecting skin pigmentation had already been identified and his patient wanted to change his racial appearance. *See id.* McIvor refused to even reply to the request. *See id.*

46. Christopher Evans, who is working at the University of Pittsburgh to devise a genetic therapy for muscle diseases such as muscular dystrophy, has been asked by a sports doctor whether he could get access to the treatment to help athletes grow bigger muscles. *See* Weiss, *supra* note 6. Evans explains that it would be difficult to justify the possibility of harm for such a cosmetic procedure. *See id.* Further, there may be some ethical problems. To some, such as Case Western Reserve University ethicist Eric Juengst, using genetic engineering for uses like this seems like a kind of cheating. *See id.* Gene enhancement would undercut the athletic "spirit of earning rewards through hard work and training." *Id.*

47. Curing baldness, the first example of gene enhancement, is close at hand. *See* Friend, *supra* note 2, at 40. Anticancer Inc. of San Diego will apply soon to the Food and Drug Administration for approval of a salve containing genes to promote hair growth. *See id.* Although Anticancer Inc. will apply for approval to treat hair loss associated with chemotherapy, if approval is granted, the salve can be prescribed for any reason. *See id.* Gene therapy pioneer W. French Anderson refers to this as the "backdoor approach" to getting treatments approved for arguably non-medical purposes. *See id.*

problems with this type of genetic alteration, others argue that “[w]ithin some limits, people have a right to make what they want of their lives.”<sup>48</sup> There is certainly merit to each viewpoint. People should be allowed to do what they want with their own lives. However, when what individuals do adversely affects other individuals or society as a whole, we perceive a basis for regulating behavior. Therefore, regulations on genetic engineering, which are necessary to protect the essential well being of society, should be permitted. Limits should be established so individuals are not allowed to make changes that might bring harm to other people.<sup>49</sup> For example, “people should not be allowed to become psychopaths at will, or to alter their metabolism so that they are permanently enraged.”<sup>50</sup>

Further, the argument that people should be permitted to do as they please to their own bodies would only apply to somatic therapies, not germ-line enhancements. With germ-line engineering, we are no longer dealing only with an adult who has consented to changes within his own body. Rather, we are faced with a child and future generations who cannot possibly give consent to potentially imperfect alterations of their genetic codes.

In his book *Children of Choice*, James A. Robertson notes some of the possible harms that could occur in children altered by germ-line enhancement.<sup>51</sup> For one, “[t]he genetic manipulation could go awry and lead to embryo or fetal demise or cause physical effects that make the manipulated child worse off.”<sup>52</sup> Second, “parents might have unrealistic expectations of children who have been subject to efforts to make them superior. This could create an unhealthy psychological environment, engender disappointment if the child is merely normal, or affect the child’s self-esteem and self-concept in unforeseen, harmful ways.”<sup>53</sup>

Another problem might be the social disparities that genetic enhancements might cause.<sup>54</sup> Those with the wealth and ability to give their children enhanced physical and intellectual characteristics would give their children advantages that other children would not have.<sup>55</sup> This could exacerbate class differences,<sup>56</sup> creating more unfairness

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48. *Changing Your Genes*, *supra* note 42, at 11.

49. *See id.*

50. *Id.*

51. *See* JOHN A. ROBERTSON, *CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES* 165-66 (1994).

52. *Id.* at 165.

53. *Id.* at 165-66.

54. *See id.* at 166.

55. *See id.*

56. Michael S. Langan, Vice President of the National Organization for Rare Disorders says:

than exists under the natural lottery.<sup>57</sup> Other possible social problems that Robertson notes are increased discrimination against women and the disabled,<sup>58</sup> as well as the perception of children as commodities, which undermines children's "inherent worth and dignity."<sup>59</sup>

Because of the unique problems posed by germ-line enhancement, much of the debate over genetic engineering will undoubtedly focus on this type of genetic technology. While genetic treatments of disease seem easily justified and somatic enhancement of adults seems permissible under certain circumstances, full endorsement of germ-line enhancements is much harder to elicit. For these reasons, the remainder of this Note will concentrate on the following controversy: should germ-line enhancements be allowed and, if there are legitimate reasons not to allow the technology, are there constitutional preclusions to statutes prohibiting germ-line enhancements?

### III. How Powerful is Germ-Line Engineering? Can It Determine Our Destiny or Affect Our "Humanness?"

Whether we are concerned enough as a society over the effects of germ-line enhancements depends at least partially on its potential power. One concern regarding the danger of germ-line engineering is that it may affect much more than its subject's physical characteristics. Rather, it may, in fact, alter one's emotional, psychological, and spiritual being. If, however, we are more a product of our nurturing rather than our genetic makeup, we should not be overly concerned about permitting germ-line engineering. On the other hand, if our genes significantly determine who we are emotionally, psychologically, and spiritually, we should think soberly before opting to change genes which may alter the very nature of our "humanness."

In deciding whether who we are as persons is derived from either nature or nurture, "a wealth of new research has tipped the scales

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There will be many wealthy people willing and eager to pay the price of making their child taller and more beautiful . . . . Eventually there will be discrimination against those who look "different" because their genes were not altered. The absence of ethical restraints means crooked noses and teeth, or acne, or baldness, will become the mark of Cain in a century from now.

Weiss, *supra* note 6, at A1.

57. See ROBERTSON, *supra* note 51, at 166.

58. See John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U.L. REV. 421, 453-63 (1996). Robertson explains that because it is likely that couples will choose to have sons more than daughters and that they will engineer their children to be free of disabilities, that women and the disabled could be hurt in the political process. See *id.* Furthermore, "[p]ersons or families with disabled children have claimed that a policy that encourages prebirth genetic deselection of persons with disabilities is a public statement that the lives of the disabled are worth less than those of the able-bodied." *Id.* at 453.

59. *Id.* at 423.



overwhelmingly toward nature."<sup>60</sup> Studies of twins and advances in molecular biology have shown that personality is determined much more by genetic makeup than was previously known.<sup>61</sup>

The following example demonstrates the extent of genetic influences on personality. In 1979, two identical twins that were separated five weeks after birth, named Jim Lewis and Jim Springer, were reunited.<sup>62</sup> The twins were raised by different families and lived eighty miles apart in Ohio.<sup>63</sup> Reunited thirty-nine years later, the similarities in their lives were amazing.<sup>64</sup> Both had dark hair, were six feet tall, and weighed 180 pounds.<sup>65</sup> "[T]hey spoke with the same inflections, moved with the same gait, and made the same gestures."<sup>66</sup> Each had the same sports interests: they loved stock car racing and hated baseball.<sup>67</sup> Each of them married a woman named Linda, got divorced, and remarried a woman named Betty.<sup>68</sup> Each of them drove Chevrolets, drank Miller Lite beer, chain-smoked Salems, chewed their nails, and vacationed within a half-mile of each other on a Florida beach.<sup>69</sup> Even their medical conditions were similar: each had elevated blood pressure, nearly identical heart rates and brain waves, suffered from severe migraines, and both had undergone vasectomies.<sup>70</sup> Finally, their IQs were almost identical and their scores on a personality test were so close that they could have been from the same person taking the test twice.<sup>71</sup>

The evidence of nature over nurture is not confined to isolated or anecdotal occurrences. Statistical studies of twins have shown that many behaviors are due at least fifty percent to nature, rather than nurture.<sup>72</sup> These behaviors include "alienation, extroversion, traditionalism, leadership, career choice, risk aversion, attention deficit disorder, religious conviction and vulnerability to stress."<sup>73</sup> One study even shows that happiness is rarely dependent on wealth, achievement, or marital status; rather, happiness is an attribute that is 80 percent inheritable.<sup>74</sup>

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60. George Howe Colt, *Were you Born That Way?*, LIFE, Apr. 1, 1998, at 40.

61. *See id.*

62. *See id.*

63. *See id.*

64. *See id.*

65. *See id.*

66. *Id.*

67. *See id.*

68. *See id.*

69. *See id.*

70. *See id.*

71. *See id.*

72. *See id.*

73. *Id.*

74. *See id.*

Given the potent evidence regarding the genetic source of human personalities, we should approach the possibility of manipulating our children's genes with the gravest of caution. Still, there are some, such as biologist Clifford Grobstein, who posit that "humanity is on the verge of a revolutionary transition . . . ." <sup>75</sup> He further states, "we are moving from chance to purpose, from genetic roulette to genetic determinism." <sup>76</sup> According to Grobstein and eugenists before him, we must no longer "shift responsibility to Divinity, Chance, or Unkind Fate." <sup>77</sup> Rather, we must become the creators of ourselves. <sup>78</sup> We might, however, be wiser to ask ourselves "[h]ow far can scientists go in altering the genetic makeup of individuals before they risk changing the very nature of a person—the basic characteristic of 'humanness?'" <sup>79</sup>

## IV. Regulation

### A. Current Regulation

Currently, there is limited regulation of genetic engineering in place. The federal government requires that scientists who receive federal funding secure approval from the National Institutes of Health (NIH) and from the Food and Drug Administration (FDA). <sup>80</sup> The scientists must convince the NIH and the FDA that the potential benefits of the proposed genetic engineering outweigh the risks. <sup>81</sup> Generally, privately funded researchers also submit proposals for approval, although federal law does not require approval. <sup>82</sup> The NIH officials examine the "ethics of the experiment, the completeness of the informed-consent document that each patient must sign, the rationale for exposing patients to the procedure and its potential for harm or benefit." <sup>83</sup> The NIH process of approval is very open, with experimental data made available to the public before the meetings where applicants defend their potential treatment plans. <sup>84</sup> FDA approval is quite different, however, in that its approval process takes place en-

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75. GINA MARANTO, QUEST FOR PERFECTION 274 (1996).

76. *Id.*

77. *Id.*

78. *See id.*

79. Herman, *supra* note 10, at Z6.

80. *See* Weiss, *supra* note 6, at A1. *See also* National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules, 59 Fed. Reg. 34496 (1994) (discussing the procedures for NIH approval); Recombant DNA Research: Actions Under the Guidelines, 60 Fed. Reg. 20726 (1995) (discussing the procedures for facilitating approval from both agencies).

81. *See id.*

82. *See id.*

83. Sorelle, *supra* note 44, at 12.

84. *See id.*

tirely behind closed doors.<sup>85</sup>

Those seeking to market their genetic therapies, however, whether privately or federally funded, are required under current law to obtain approval from the FDA.<sup>86</sup> Although the advent of genetic therapies followed the statutory delegation of regulatory power to the FDA, the agency has taken the position that the statutes "are sufficiently broad in scope to encompass these new products and require that areas such as quality control, safety, potency, and efficacy be thoroughly addressed prior to marketing."<sup>87</sup> Some argue that the traditional drug approval process is inappropriate for such a rapidly advancing area of medicine and may prevent potential patients from receiving beneficial treatments.<sup>88</sup> Yet, in light of the risks previously discussed, an alternative approach encouraging more, not less, stringent regulation may be warranted.

Until recently, the infant state of genetic technology did not necessitate governmental regulations regarding the use of genetic therapies for non-medical treatment.<sup>89</sup> In March 1997, however, NIH officials—in an effort to find a cure for cystic fibrosis—approved a gene therapy experiment involving people who are not sick.<sup>90</sup> Some scientists and ethicists have expressed concern that the approval might serve as a precedent for other gene manipulations in healthy people.<sup>91</sup> Indeed, a salve containing genes to promote hair growth is now before the FDA for approval.<sup>92</sup> Although the genetic salve was submitted to help chemotherapy patients, once the technology is approved, the salve can be prescribed for any purpose.<sup>93</sup> It is important to note, however, that a current governmental ban on federal funding for some human gene tampering implicitly prohibits such funding for germ-line intervention.<sup>94</sup>

The FDA and the NIH met for the first time in September 1997 to discuss regulations that may be appropriate for cosmetic gene therapy.<sup>95</sup> In an effort to adequately prepare for the widespread use of genetic technology, FDA and NIH officials purposely organized the

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85. *See id.*

86. *See* Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53, 248 (1993).

87. *Id.*

88. *See, e.g.,* Martha J. Carter, *The Ability of Current Biologics Law to Accommodate Emerging Technologies*, 51 FOOD & DRUG L.J. 375, 378-79 (1996).

89. *See* Weiss, *supra* note 6, at A1.

90. *See id.*

91. *See id.*

92. *See* Friend, *supra* note 2, at 40.

93. *See id.*

94. *See* Elizabeth Manning, *Panel of Leading Geneticists Call Germ Line Interventions Inevitable*, BIOTECHNOLOGY NEWSWATCH, Oct. 6, 1997, at 1, 6.

95. *See* Weiss, *supra* note 6, at A1.

meeting before the technology became widely available.<sup>96</sup> This prospective approach is a partial result of the retrospective and hasty action taken in response to the unexpected February 1997 cloning of an adult mammal.<sup>97</sup>

In regard to non-governmental regulation, the American Medical Association (AMA) has not taken a solid stand on the matter of genetic enhancements.<sup>98</sup> The AMA states that genetic enhancement of traits should only be an option when there is “no trade off with other characteristics or traits.”<sup>99</sup> The AMA statement on genetic engineering, however, represents only a subjective and non-binding guideline.<sup>100</sup> Furthermore, with our limited and imperfect knowledge of the human genome, it is arguably difficult, if not impossible, to ever say with complete confidence that a certain gene therapy will not negatively affect other traits.

### **B. Is There a Need for Further Regulation?**

To some commentators, the current restraints on germ-line enhancement offer sufficient protections because so much of the research is federally funded and so many of the private scientists voluntarily submit to the federal guidelines.<sup>101</sup> As the technology becomes more readily available to perform germ-line enhancements, however, the federal government might reduce funding and the private scientists may no longer voluntarily submit to federal guidelines. According to public opinion polls in 1986 and 1992, the demand for genetic enhancements may be substantial.<sup>102</sup> Those polls show that forty to forty-five percent of Americans approved of the “concept of using genes to bolster physical and intellectual traits.”<sup>103</sup> Yet these same polls also suggest that the public did not understand the risks inherent in genetic engineering.<sup>104</sup> These surveys may suggest that further restraints on the ability of parents to genetically enhance their children are needed. Though there are federal impediments that would prevent federal funding to go to these procedures, such a significant portion of the population (40% to 45%) could create enough of a demand to boost the private market in genetic engineering. With the prospect of financial gain, some less scrupulous physicians may

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96. *See id.*

97. *See id.*

98. *See id.*

99. *Id.*

100. *See id.*

101. *See id.*

102. *See id.*

103. *Id.*

104. *See id.*

jump at the prospect of performing procedures that might adversely affect their patients, as well as future society.

Because germ-line therapy and engineering, coupled with our limited knowledge in the genetic arena, pose a significant risk to the gene pool, it is likely that federal or state governments may attempt to place at least temporary bans on germ-line engineering. Some prominent genetic scientists advocate these bans.<sup>105</sup> Reiss and Straughan argue that "at present, germ-line therapy is unsafe."<sup>106</sup> Reiss and Straughan, however, realize that time may bring improved safety in the field of genetic technology.<sup>107</sup> They therefore posit that ethical arguments in favor of an unconditional and permanent ban on germ-line therapy are flawed.<sup>108</sup> Reiss and Straughan argue that germ-line therapy may prove beneficial for alleviating certain diseases.<sup>109</sup> Still, they explain, it may be best for the present to ban the use of both somatic and germ-line therapies to enhance human traits.<sup>110</sup> Apprehension about our current knowledge and our ability to manipulate human DNA motivates Reiss and Straughan's suggestions. Taking significant risks to merely enhance genetic traits seems too much of a gamble. If such regulations were imposed, an interesting constitutional issue is posed: would parents have constitutional safeguards that would invalidate the regulations based upon the parents' possible "right" to genetically alter their children's DNA?

## V. Constitutional Analysis

### A. Procreative Liberty

The constitutional doctrine concerning procreative liberty is found in the abortion cases. Because the technology for germ-line enhancement has not completely materialized, the Court has not had the opportunity to decide whether there is a constitutional right to genetically engineer one's children. Still, as discussed here, the cases regarding procreative liberty do provide some guidance on how the Court may rule on the constitutionality of possible future genetic regulation.

While the abortion cases attempt to outline procreative rights of parents created by the Constitution, it is almost certain that the Court did not consider current genetic issues. Nonetheless, some proponents of germ-line engineering propose that the fundamental right to procreative liberty, as currently defined by the Court, includes the

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105. See REISS & STRAUGHAN, *supra* note 14, at 223.

106. *Id.*

107. *See id.*

108. *See id.*

109. *See id.*

110. *See id.*

right to bear children whose characteristics have been altered by genetic engineering.<sup>111</sup>

One of the less sophisticated arguments in support of this proposition is that because the Supreme Court has been protective of a woman's right to procreate, the Court is therefore likely, when presented with the opportunity, to include germ-line engineering as one of the seemingly broad set of procreative liberties. Although it is true that the Court has been considerably protective of procreative liberty over the past three decades,<sup>112</sup> proponents of this argument fail to account for the enormous difference between the effects of currently protected reproductive liberties and the effects of protecting the right to genetically engineer human babies. Although the current protected rights have potent and irreversible effects,<sup>113</sup> they do not present great risk to the human gene pool. The exercise of current rights, therefore, arguably does not affect future generations of human society as profoundly.

In addition, the argument can also be countered by the fact that the Supreme Court, when given recent opportunities, has not consistently expanded procreative rights, but rather restricted abortion and other procreative rights.<sup>114</sup> Thus, this argument by no means offers

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111. See John B. Attanasio, *The Constitutionality of Regulating Human Genetic Engineering: Where Procreative Liberty and Equal Opportunity Collide*, 53 U. CHI. L. REV. 1274, 1285 (1986).

112. The Court began its jurisprudence in this area by granting married couples the right to make decisions regarding contraception, see *Griswold v. Connecticut*, 381 U.S. 479, 485 (1965), and later extended that right to non-married couples, see *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

The Court has also been protective of the right of minors to obtain non-prescription contraceptives. For example, it has held that state laws prohibiting the non-prescription sale of contraceptives to persons under the age of sixteen are invalid. See *Carey v. Population Servs. Int'l*, 431 U.S. 678 (1977).

The Court took a giant step in its procreative rights jurisprudence when it established the unchecked right to an abortion during the first trimester in *Roe v. Wade*. See 410 U.S. 113 (1973). The Court held that only after viability (twenty-four to twenty-eight weeks) could a state have a compelling interest in potential human life, which would provide a basis for a state to restrict or prohibit an abortion. See *id.*

The Court, however, did not stop with *Roe*, but went on to expand abortion rights. It declared that spousal consent laws were invalid, see *Planned Parenthood v. Danforth*, 428 U.S. 52 (1976), and provided a judicial bypass procedure for minors to get abortions without their parents' consent, see *Bellotti v. Baird*, 443 U.S. 622 (1979). In addition, the Court has strengthened the right to an abortion by eliminating the possibility of criminal liability for doctors who perform an erroneous determination of viability based on good faith. See *Colautti v. Franklin*, 439 U.S. 379, 394-95 (1979).

113. Note, for example, the termination of human life in the case of abortion.

114. The Court has upheld state laws that refuse to fund welfare abortions. See *Harris v. McRae*, 448 U.S. 297 (1980); *Maher v. Roe*, 432 U.S. 464 (1977). It has also upheld state laws that prohibit the use of public facilities or employees to perform abortions. See *Webster v. Reprod. Health Servs.*, 492 U.S. 490 (1989).

conclusive support to opponents of germ-line regulations.

John A. Robertson advances a much stronger argument in favor of germ-line engineering. Robertson argues procreative liberty, as defined by the Court, protects — with some exceptions — a woman's choice to have or not to have a child through both the right to contraceptives and the right to abort.<sup>115</sup> This procreative liberty guarantees the right to accept or refuse to have a child on any grounds, including situations where pre-viability screening determines an “unacceptable” or undesirable genetic makeup of the child.<sup>116</sup> This selective right to reproduce children with only certain genetic characteristics “may thus be articulated as a prebirth right to select or control offspring characteristics.”<sup>117</sup> Thus, if a woman decided to abort a potential child because restrictions prohibited genetic enhancement of the fetus, she could argue a potential infringement of her procreative liberties. The enhancement is central to procreative liberty because it determines whether she will produce at all.<sup>118</sup> As long as no harm would come to the child, she could argue that the enhancement should be protected as part of her procreative rights.

Although Robertson's argument seems fairly convincing, the abortion cases offer a firm counter-argument. First, in *Roe v. Wade*, “the Court itself admits that the protected sphere of liberty does not include all childbearing activity.”<sup>119</sup> The Court held:

[O]nly personal rights that can be deemed ‘fundamental’ or ‘implicit in the concept of ordered liberty,’ . . . are included in [the] guarantee of personal privacy. [Earlier decisions] also make it

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The Court has refused to strike down laws requiring a forty-eight hour waiting period and parental notification for minors (as long as there is a judicial bypass available), see *Hodgson v. Minnesota*, 497 U.S. 417 (1990), and has held that Congress may deny funds to family planning clinics that mention abortion as a method of family planning, see *Rust v. Sullivan*, 111 S.Ct. 1759 (1991).

One of the Court's most significant limitations came with *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992). In *Casey*, the Court, while purporting to uphold the essential holding of *Roe*, restructured the right to abortion. The Court divided pregnancy into pre-viability and a post-viability stages, defining viability as the “time at which there is a realistic possibility of maintaining and nourishing a life outside the womb.” *Id.* at 870. During pre-viability, a state may regulate abortion as long as it does not place an “undue burden” on the woman's decision to abort. See *id.* at 877. During post-viability, states may, except where necessary to preserve the life or health of the mother, regulate to the extent of proscribing abortion. See *id.* at 878. Under this standard, the Court upheld Pennsylvania's informed consent provisions, a twenty-four hour waiting period, a one-parent consent requirement (with a judicial bypass provision), certain record-keeping requirements, and struck down a spousal notification requirement. See *id.* at 881-901.

115. See Robertson, *supra* note 58, at 426.

116. See *id.* at 427.

117. *Id.*

118. See ROBERTSON, *supra* note 51, at 166.

119. Attanasio, *supra* note 111, at 1287.

clear that the right has some extension to activities relating to marriage, . . . procreation, . . . contraception, . . . family relationships, . . . and child rearing and education.<sup>120</sup>

Thus, the mere fact that genetic engineering of offspring may possibly be characterized as “childbearing activity” or even as central to a particular parent’s choice to bear children, does not necessitate that it be classified as a “fundamental right,” one that is implicit in the concept of ordered liberty. While Fourteenth Amendment liberty is not something that is precisely defined, the Court has explained it as “a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints.”<sup>121</sup> In light of the risks discussed, regulations on genetic engineering cannot be seen as “arbitrary impositions” or “purposeless restraints” under this definition. The “fundamental right” standard seems to be one that would require a more significant showing than “central to a particular parent’s choice.”

Another counter to Robertson’s argument is that he fails to realize that *Roe* and *Casey* are not based solely upon procreative liberty but also upon rules of personal autonomy and bodily integrity.<sup>122</sup> In the genetic engineering scenario, bodily integrity plays absolutely no role. The personal autonomy of the woman will not be affected by inability to genetically engineer her children. Thus, much of the rationale behind the decisions in *Roe* and *Casey* fails to support Robertson’s assertion.

While it is true that the “fundamental rights” declared by the Court tend to be malleable,<sup>123</sup> malleability is not necessarily an argument in favor of those promoting germ-line engineering. In recent years, the Court has actually used this malleability as a basis to restrict procreative rights. The Supreme Court’s post-*Roe* restrictions demonstrate the malleability of procreative rights.<sup>124</sup> In *Planned Parenthood of Southeastern Pennsylvania v. Casey*,<sup>125</sup> the Court significantly modified the right during the pre-viability stage by allowing abortion regulations, so long as the regulations do not create “undue burdens” for women who wish to obtain abortions.<sup>126</sup> As shown above, *Roe* and the transition from *Roe* to *Casey* illustrate that the zone of privacy surrounding procreative rights is not protected from all congressional

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120. *Roe v. Wade*, 410 U.S. 113, 152-53 (1973) (citation omitted).

121. *Poe v. Ullman*, 367 U.S. 497, 543 (1961) (Harlan, J., dissenting on jurisdictional grounds) (quoted in *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 848-49 (1992)).

122. *See Casey*, 505 U.S. at 857.

123. *See Attanasio*, *supra* note 111, at 1290.

124. *See id.*

125. 505 U.S. 833 (1992).

126. *See id.* at 877; *see also supra* text accompanying note 108.



intrusion.<sup>127</sup> Rather, the right is quite malleable and may allow Congress to ban germ-line enhancements without infringing on parents' substantive due process.<sup>128</sup> Realistically speaking, the Court may come to the conclusion that there is neither a "fundamental" right nor a right "implicit in the concept of ordered liberty" to genetically enhance one's children.

There is another counter to Robertson's argument. *Casey* established that the states have an interest in the life of the fetus (and the ability to interfere with the mother's procreative liberty on behalf of its interest) at both the pre-viability and post-viability stages.<sup>129</sup> By defining viability as "the time at which there is a realistic possibility of maintaining and nourishing a life outside the womb,"<sup>130</sup> *Casey* made the ability to regulate procreative liberty dependent upon the sophistication of current reproductive technology. As technology increases, and doctors gain the ability to "maintain and nourish life outside the womb" at earlier stages of embryonic development, states will gain the ability, according to *Casey*, to more strictly regulate parents' actions for the purpose of protecting the fetus' life.

In the end, *Casey* articulates the strongest counter to Robertson's argument: "that the state has legitimate interests from the outset of the pregnancy in protecting . . . the life of the fetus that may become a child."<sup>131</sup> Robertson correctly states that, pursuant to certain regulations, a woman may legally choose to abort her pre-viable fetus for any reason, including the fact that the child does not have certain characteristics. This, however, does not necessitate the conclusion that she may genetically enhance the child to have certain characteristics. According to *Casey*, the state has a legitimate interest in the health of a viable fetus. Because the health of the potential child may be adversely affected by germ-line engineering, the state would arguably have a legitimate interest in preventing the alteration of the potential child's DNA.

## B. Parental Control

The proposed right to genetically engineer one's children may also be argued as a more specific right of parental control. Proponents of genetic therapy (as opposed to enhancement) argue that the issues

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127. See Attanasio, *supra* note 111, at 1290-91 (discussing the implications of *Roe* on the issue).

128. See *id.* at 1291.

129. See *Casey*, 505 U.S. at 870.

130. *Id.*

131. *Id.*

here are analogous to the privacy right inherent in child rearing.<sup>132</sup> Courts have held that parents have a duty to care and nurture their children.<sup>133</sup> In addition, the Court has noted a strong presumption that parents are appropriate decision-makers.<sup>134</sup> The same analogy could be used as an argument for the right to genetically enhance one's children.

The Court has given parents the right to safeguard their children's education.<sup>135</sup> It has held that parents have a right to choose the school that their child will attend<sup>136</sup> and to influence their education in the public school system.<sup>137</sup> Furthermore, the Court has held that parents have a right to direct their children's religious upbringing.<sup>138</sup> The rights to mold a child through education are analogous to the right to genetically enhance children.<sup>139</sup> As Robertson argues:

If special tutors and camps, training programs, even the administration of growth hormone to add a few inches to height are within parental rearing discretion, why should genetic interventions to enhance normal offspring traits be any less legitimate? As long as they are safe, effective, and likely to benefit offspring, they would no more impermissibly objectify or commodify offspring than postnatal enhancement efforts do.<sup>140</sup>

W. French Anderson, a pioneer in genetic science, sees logic in Robertson's argument but "has repeatedly cautioned against germline enhancements."<sup>141</sup> He understands how parents might be tempted to improve their children's memory so the children would have an "extra edge" in school.<sup>142</sup> However, Anderson argues that such enhancements do not fall in the same class as "postnatal enhancement efforts."<sup>143</sup> He explains that medicine is very inexact and though there is a wealth of knowledge of the genetic makeup of humans, it is only a rough knowledge.<sup>144</sup> He says:

Even though we do not understand how a thinking, loving interacting organism can be derived from its molecules, we are approaching the time when we can change some of those

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132. See June Coleman, Comment, *Playing God or Playing Scientist: A Constitutional Analysis of State Laws Banning Embryological Procedures*, 27 PAC. L.J. 1331, 1366 (1996) (arguing in regard to the right to use gene therapy, not enhancements).

133. See *id.* at 1365-66.

134. See *id.* (citing *Bowen v. Am. Hosp. Assoc.*, 476 U.S. 610, 637-38, n.13 (1986)).

135. See Attanasio, *supra* note 111, at 1291.

136. See *Pierce v. Soc'y of Sisters*, 268 U.S. 510, 534 (1925).

137. See *Meyer v. Nebraska*, 262 U.S. 390, 400 (1923).

138. See *Wisconsin v. Yoder*, 406 U.S. 205, 213-14 (1972).

139. See Attanasio, *supra* note 111, at 1291.

140. ROBERTSON, *supra* note 51, at 167.

141. MARANTO, *supra* note 75, at 273.

142. *Id.*

143. *Id.*

144. See *id.* at 273-74.

molecules. Might there be genes that influence the brain's organization or structure or metabolism or circuitry in some way so as to allow abstract thinking, contemplation of good and evil, fear of death, awe of "God"?<sup>145</sup>

This argument demonstrates that the proposed parental ability to genetically enhance children may be far beyond any constitutional parental right. It is certainly not clear that the Supreme Court meant parents to have such broad control over their children's genetic futures. Anderson continues:

What if in our innocent attempts to improve our genetic make-up we alter one or more of those genes? Could we test for the alteration? Certainly not at present. If we caused a problem that would affect the individual or his or her offspring, could we repair the damage? Certainly not at present. Every parent who has several children knows that some babies accept and give more affection than others, in the same environment. Do genes control this? What if these genes were accidentally altered? How would we even know if such a gene were altered?<sup>146</sup>

Even if parental rights include the right to genetically engineer children, the dangers involved may provide the government with a compelling and legitimate interest in strictly regulating, or even banning, the use of such technology.

### C. The Rights of the Child

Finally, after examining the possible constitutional rights of parents, we shall look at the potential rights of the fetus. "While the Supreme Court has rejected the notion that fetuses should be considered human at conception, it has not rejected all claims of fetal rights."<sup>147</sup> "Although *Roe* rhetorically denies fetal rights, the decision postulates a sliding scale that allows the state to recognize substantial fetal rights that, at viability, trump even maternal rights."<sup>148</sup> In addition, as discussed above, *Casey* established the states' interest in protecting — from the very advent of fetal life — the health of a fetus that may become a child. Because the states have an interest in the health of future children, there must be a basis for regulating genetic engineering, which has a tremendous capability of adversely affecting their health.

Moreover, the Court has also demonstrated governmental interest in the life of fetuses outside of the abortion context. For example, the Court has recognized a duty to protect the fetus from prenatal

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145. *Id.* at 274.

146. *Id.*

147. Attanasio, *supra* note 111, at 1294.

148. *Id.* (footnotes omitted).

injuries.<sup>149</sup> The Court has even allowed recovery if the fetus is born alive, even where the injury occurred before the fetus was viable.<sup>150</sup> In fact, both criminal and inheritance laws recognize the rights of a pre-viable fetus.<sup>151</sup> If such laws may be established to protect the fetus from injuries and even to protect its economic interests, certainly there is a basis for enacting laws that would protect the health and physical well-being of the child to be born.

## VI. Conclusion

In sum, it seems possible that the Supreme Court could go either way in deciding the constitutionality of parental decision-making in the context of genetic engineering. Yet, the argument supporting the constitutionality of banning genetic tampering, at least temporarily, holds more weight. The Court must balance the dangers inherent in germ-line therapy against possible parental rights. Although parents have specific fundamental rights in the context of abortion and child-rearing, the dangers of genetic engineering outweigh the potential right of parents to genetically determine the futures of their children.

It is imperative that the consequences of genetic engineering be thoroughly explored. "Like quantum physicists, reproductive endocrinologists and geneticists and embryologists have taken it upon themselves to fiddle with some pretty fundamental stuff. The stuff of life."<sup>152</sup> By "fiddling" with genetic technology, geneticists have entered an area that concerns all of humankind.<sup>153</sup> As Gina Maranto argues, genetic manipulation is a process that can be likened to stealing fire from heaven.<sup>154</sup> It is impossible to argue that we would be better off without fire.<sup>155</sup> However, the "fire of Trinity, with Siva's mushroom cloud over the white sands — certainly, we did not need that."<sup>156</sup>

Like fire, the knowledge of what is locked within our genetic code can afford much benefit to humankind. By using genetic technology properly, many diseases may be eliminated. Yet just as the knowledge of how to make fire has evolved into the ability to make mushroom clouds, our ability to alter genetic codes could present grave risks to humankind. Not only may we cause more physical

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149. *See id.*

150. *See id.*

151. *See id.*

152. MARANTO, *supra* note 75, at 276-77.

153. *See id.*

154. *See id.*

155. *See id.*

156. *Id.*

problems than we can cure, we may also unwittingly alter the unknowable components that make us human.

In the end, we must seek a balanced approach. We must choose to place at least temporary legal bounds on the ability to genetically engineer children. In light of the inherent danger and the constitutional standards discussed above, limitations prove a wise and warranted step.

This is not a question of obliterating technology. It is a matter of recognizing the dark impulses which have guided our species vis-a-vis reproduction, of recognizing the unsavory fantasies adults have regarding children. Upon the unborn, and then upon the born, we impose images of perfection — whatever those may be for us, whether physical, moral, intellectual, or social. We want our children to be what we cannot: above the mundane world, immortal, ourselves incarnate.<sup>157</sup>

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157. *See id.*

