

# SPILLAGE FROM THE FOUNTAIN OF YOUTH: THE REGULATION OF PROSPECTIVE ANTI-AGING MOLECULAR AND GENETIC THERAPIES

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## I. INTRODUCTION

Medical science stands on the verge of developing molecular and genetic therapies capable of slowing, if not reversing, the process of aging. While this will likely not result in an actual anti-aging drug for at least another decade, policy-makers must now begin to consider the myriad complicating effects that such a development will have on our society.

Part II of this Note presents background information on: (1) historical perspectives on anti-aging; (2) the science of anti-aging; (3) the Food and Drug Administration; (4) government administered health insurance programs; and (5) American constitutional law. To provide an analysis of possible solutions, Part III of this Note considers: (1) negative externalities arising from the possible introduction of an effective anti-aging therapy; (2) issues involved in the FDA approval process; (3) legal arguments enabling and supporting a government ban on anti-aging; (4) means by which the government can regulate anti-aging; (5) remedial measures the government may implement if anti-aging is instituted; (6) legal arguments that may be used to challenge a governmental ban or restriction; and (7) legal arguments that may be used to advocate for democratized access to anti-aging. Finally, Part IV reaches the conclusion that our legal tradition enables us to aggressively support an anti-aging therapy in an intelligent and responsive manner. The unique aspects of anti-aging that merit special treatment include the great tradition of anti-aging efforts, the nexus to personal health, the potential for reductions in the long-term cost of health care, and the fact that anti-aging does not alter our identity or peak level of merit. Challenges to a governmental failure to provide access likely will not succeed. Furthermore, in the absence of a government ban, private insurers and Medicare may be required to cover anti-aging under current charters,

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and over the long-term, Medicaid may decide to voluntarily cover it. Consequences stem from anti-aging, but it is essential to remember how technology integrates into society and that there will be opportunities for remedial legislation to address harmful consequences that arise or threaten to arise.

## II. BACKGROUND

### A. *Anti-Aging: Modern and Historical Perspectives*

The idea that old age is a disease that science can eliminate is not a novel idea, but has a recognizable history.<sup>1</sup> In 1550, Italian nobleman Luigi Cornaro wrote the seminal work on prolongevity, *The Art of Living Long*, the English version of which had been through more than fifty editions by 1800.<sup>2</sup> Cornaro argued that individuals were not destined to die at sixty to seventy years of age, but could extend life much longer with proper care.<sup>3</sup> This optimism subsided a bit throughout the nineteenth and early twentieth centuries, as scientists identified specific sobering cellular and tissue pathologies that have a correlation with old age.<sup>4</sup> Few physicians chose to study diseases of the elderly because of the belief that such diseases were impossible to separate from old age due to medicine's inability to stem a downward health spiral associated with old age.<sup>5</sup> Charles A. Stephens was a lonely voice, advocating in the early twentieth century that by perfecting cell nutrition, "[i]mmortal life will be achieved by the aid of applied science . . . . It is what the whole scheme of evolution moves forward to."<sup>6</sup> Soon other physicians joined, proposing other potentially eradicable mechanisms of aging, and engaging in experiments to restore and preserve vitality.<sup>7</sup> This correlated with societal trends favoring novelty and progress, resulting in a declining status for the elderly.<sup>8</sup> This decline reversed with the advent of Social Security, which rescued the elderly from dependence and restored respectability.<sup>9</sup>

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1. Carole Haber, *Anti-Aging: Why Now? A Historical Framework for Understanding the Contemporary Enthusiasm*, GENERATIONS, Winter 2001–02, at 9, 9.

2. *Id.* at 9–10.

3. *Id.* at 10.

4. *Id.*

5. *Id.* “‘From the beginning to the end’, explained Charles Mercier, ‘the process is a continuous, gradually progressive loss. Conduct, intelligence, feeling, and self-consciousness gradually diminish, and at last cease to exist . . . . The decadence of old age is, in fact, a *dementia*, a deprivation of the mind.’” *Id.*

6. *Id.* (quoting THOMAS R. COLE, *THE JOURNEY OF LIFE: A CULTURAL HISTORY OF AGING IN AMERICA* 178 (1992)).

7. Haber, *supra* note 1, at 10–11.

8. *Id.* at 11.

9. *Id.* at 12.

But the fervor for anti-aging returned in modern times, due to a variety of factors. Baby boomers grew up with the notion that the elderly were untrustworthy and unworthy of their authority, and entitlement programs for the elderly are increasingly viewed as economically burdensome.<sup>10</sup> Medical advances have increased longevity, lending credibility to the ability of the profession to slow aging.<sup>11</sup> While human life expectancy to this point has been boosted mainly by improved hygiene, antibiotics, and (non anti-aging) vaccines, the basic ability to materially affect our longevity has inspired the anti-aging movement.<sup>12</sup>

Americans are enthusiastic about countering the physical effects of aging.<sup>13</sup> A preoccupation with exercise and nutrition has come from the desire to sustain the vigor of youth.<sup>14</sup> Cosmetic products are now a billion dollar industry.<sup>15</sup> Many view even the most experimental techniques for radical self-enhancement in a favorable light. According to public opinion polls in 1986 and 1992, forty to forty-five percent of Americans approved of the “concept of using genes to bolster physical and intellectual traits.”<sup>16</sup> The culture of modern medicine views the body as the source of ultimate wellness, and much emphasis is placed on bodily integrity.<sup>17</sup> Daily regimens of multivitamins and anti-oxidant pills aimed at staving off life-ending disease are now commonplace.<sup>18</sup> However, there is a concern that this trend of anti-aging interventions exists as a further step in devaluing old age and can only exacerbate disturbing cultural attitudes.<sup>19</sup>

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10. *Id.* at 13.

11. *Id.* “‘Aging,’ which cannot be divested of the taint of decay, is an offense to the reign of biotechnology and to postmodern dreams of a timeless, placeless, instantaneous now.” Thomas R. Cole & Barbara Thompson, *Anti-Aging: Are You for It or Against It?*, GENERATIONS, Winter 2001–02, at 6, 6.

12. Leonard Hayflick, *Anti-Aging Medicine: Hype, Hope, and Reality*, GENERATIONS, Winter 2001–02, at 20, 23.

13. “[G]rowing old has never been fashionable in the country of the young. Old age is an unwelcome reminder of the limits of our cherished values of self-reliance, health, and productivity.” Cole & Thompson, *supra* note 11, at 6. The catch-line for a popular cosmetic product is, “[b]ecause you’re worth it.” *L’Oréal*, WIKIPEDIA: THE FREE ENCYCLOPEDIA (Sept. 30, 2006), <http://en.wikipedia.org/wiki/L’Or%C3%A9al>. This reflects the view that one’s value derives from something independent of youth. Youth is portrayed as an important superficial reward, and not a fundamental change.

14. See Barbara Hooks, *Holding Back the Years*, BUS. REV. WKLY., Sept. 28, 1998, at 94 (documenting and discussing American enthusiasm with staying youthful).

15. In 1999, the top 100 of the world’s largest cosmetics companies had a combined total beauty sales netting just above \$89 billion. Cosmetics On-Line: An Industry Survey, [http://web.archive.org/web/20040407131149/http://fox.rollins.edu/~slackman/cosmetics\\_online.htm](http://web.archive.org/web/20040407131149/http://fox.rollins.edu/~slackman/cosmetics_online.htm) (last visited Oct. 4, 2006).

16. Rick Weiss, *Cosmetic Gene Therapy’s Thorny Traits*, WASH. POST, Oct. 12, 1997, at A01, available at <http://washingtonpost.com/wp-srv/national/science/ethical/cosmetic.htm>.

17. Martha B. Holstein, *A Feminist Perspective on Anti-Aging Medicine*, GENERATIONS, Winter 2001–02, at 38, 41.

18. H.R. Moody, *Who’s Afraid of Life Extension?*, GENERATIONS, Winter 2001–02, at 33, 36.

19. Holstein, *supra* note 17, at 42.

### B. Anti-Aging Science

Medicine challenges the assumption of the inevitability of normal aging.<sup>20</sup> The American Academy of Anti-Aging Medicine was founded in 1993 with a stated goal to promote “innovative science and research to prolong the healthy lifespan in humans,” and has enjoyed a steadily rising membership.<sup>21</sup> With respect to molecular biology, scientists have noted that no cellular or genetic switch or process exists that specifically demands termination at an appointed time. Thus, cells appear to be able to live as long as certain “death-providing” processes are avoided.<sup>22</sup> Actually, in the cases of stem cells and cancerous cells, chromosomes obtain properties that result in an indefinite postponement of the cellular processes that cause cell death.<sup>23</sup> The process of aging may be at the nexus of the development of the disease processes associated with aging: heart disease, cancer, and so forth.<sup>24</sup> Scientists have identified genes that can vastly expand lifespan in lower organisms.<sup>25</sup> As the scientific community learns more about the connections between aging and the development of common diseases of the elderly, conditions like cancer and arteriosclerosis may no longer be viewed as diseases, but rather as symptoms of a larger process.<sup>26</sup> Given the strong incentives for drug companies to keep advances secret,<sup>27</sup> seemingly far-fetched pharmaceutical innovations may be close to fruition.

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20. Many espouse the view that superlongevity is not possible. Leonard Hayflick is the proponent of this view and discovered the Hayflick Limit—the maximum number of cell divisions that empirically correlates with biological aging. Moody, *supra* note 18, at 36.

21. Ronald Klatz, *Anti-Aging Medicine: Resounding, Independent Support for Expansion of an Innovative Medical Specialty*, GENERATIONS, Winter 2001–02, at 59, 59–60. Five key areas of anti-aging medicine have been identified: genetic engineering, cloning, nanotechnology, artificial organs, and nerve-impulse continuity. *Id.* at 60. While this Note focuses on the potential of genetic engineering and molecular therapies, it is important to recognize there are other ways to achieve strong gains in longevity. See Chris Hackler, *Troubling Implications of Doubling the Human Lifespan*, GENERATIONS, Winter 2001–02, at 15, 15–16.

22. Catherine Arnst, *Aging Is Becoming So Yesterday; Tantalizing New Discoveries Suggest the Possibility of Reengineering the Body*, BUS. WK., Oct. 11, 2004, at 148, 150.

23. Dr. George Johnson, *Why We Grow Old and Cancer Cells Don't*, ON SCIENCE, July 15, 1999, <http://www.txtwriter.com/OnScience/Articles/agingcancer.html>.

24. See Andrew Pollack, *Forget Botox. Anti-Aging Pills May Be Next*, N.Y. TIMES, Sept. 21, 2003, § 3, at 1. Iraj Beheshti, CEO of a Montreal-based company focused on investigating aging, stated that “[w]e really don’t want to go after anti-aging drugs. We want to use aging discoveries to reach diseases of aging.” *Id.*

25. Hackler, *supra* note 21, at 16; Pollack, *supra* note 24, § 3, at 1. According to Michael R. Rose, an evolutionary biologist who bred fruit flies with average lives twice as long as ordinary fruit flies, “[n]o one can doubt that you can postpone aging . . . Thirty years ago, it was thought immutable.” Pollack, *supra* note 24, § 3, at 1.

26. Pollack, *supra* note 24, § 3, at 1 (“[T]o the extent that they follow this strategy, though, the companies become nearly indistinguishable from many other companies developing drugs for cancer, heart disease or the memory loss that precedes Alzheimer’s. The difference, the companies say, is that they are coming at these diseases by understanding aging, rather than the more specific mechanisms of each disease.”).

27. See, e.g., Keith Schneider, *Release of a Gene-Altered Agent Violated Policy, E.P.A. Charges*, N.Y. TIMES, Feb. 27, 1986, at B28 (discussing the release of genetically engineered organisms into the atmosphere, performed without public or governmental knowledge).

One important distinction in genetic therapies lies in the difference between somatic cell alteration and germ line alteration.<sup>28</sup> In somatic cell gene therapy, genes of normal cells in one individual's tissues are affected, whereas in germ line therapy, an individual's reproductive cells are fertilized or used to fertilize.<sup>29</sup> As a result, genetic alteration in somatic gene therapy affects only the individual, whereas in germ line gene therapy, it also affects an individual's descendants.<sup>30</sup>

### C. *The Food and Drug Administration ("FDA")*

As a potential "new drug," the first step for the development of anti-aging technology is approval by the FDA.<sup>31</sup> This federal entity certifies the safety and effectiveness of a drug.<sup>32</sup> With respect to safety, the FDA determines whether the drug's potential for death or injury outweighs the potential for therapeutic benefit to the consumer.<sup>33</sup> The effectiveness requirement assures that the drug performs correctly.<sup>34</sup>

### D. *Medicare, Government Insurance, and Private Insurance*

Medicare<sup>35</sup> does not currently have the ability to deny to its participants access to an FDA-approved drug that has clear utility.<sup>36</sup> In contrast, government insurance programs, such as Medicaid,<sup>37</sup> have no obligation to pay for all FDA-approved drugs; they may discriminate among them.<sup>38</sup> Although states are free not to participate in Medicaid, every state, as well as the District of Columbia, has elected to do so.<sup>39</sup> The states bear from fifty to eighty percent of Medicaid's costs, leaving a substantial contribution from the federal government.<sup>40</sup> If Congress

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28. See Thomas Stuart Patterson, *The Outer Limits of Human Genetic Engineering: A Constitutional Examination of Parents' Procreative Liberty to Genetically Enhance Their Offspring*, 26 HASTINGS CONST. L.Q. 913, 915-16 (1999).

29. *Id.* at 915.

30. *Id.* at 916.

31. 25 AM. JUR. 2D *Drugs and Controlled Substances* § 112 (2004).

32. *Id.*

33. *United States v. Rutherford*, 442 U.S. 544, 555 (1979).

34. *Id.*

35. Medicare is a health insurance program covering Americans over the age of sixty-five. Medicare.gov, Medicare Eligibility Tool, <http://www.medicare.gov/MedicareEligibility/home.asp?version=default&browser=IE%7C6%7CWinXP&language=English> (last visited Nov. 24, 2006).

36. 42 U.S.C. § 1395y(a)(1)(A) (2000).

37. Medicaid provides health insurance for the poor and disabled. Centers for Medicare and Medicaid Services, Medicaid Overview, <http://www.cms.hhs.gov/MedicaidGenInfo/> (last visited Nov. 24, 2006).

38. Anita Bernstein & Joseph Bernstein, *The Information Prescription for Safe and Effective Drugs* 74 (Feb. 25, 2006) (unpublished article, on file with the University of Illinois Journal of Law, Technology and Policy).

39. LAWRENCE A. FROLIK & RICHARD L. KAPLAN, *ELDER LAW IN A NUTSHELL* 103 (3d ed. 1999).

40. *Id.* at 104.

places conditions on Medicaid funding relating to anti-aging, states may be forced to comply.

A drug that retards the aging process would improve the physical condition of the patient, and thus Medicare coverage would apply.<sup>41</sup> Under Medicaid, anti-aging drugs may or may not be approved. However, in both cases, intense political pressure will manifest itself as anti-aging drugs become more of a reality.

### *E. Constitutional Law*

Congress has “plenary authority” under the Commerce Clause to regulate interstate commerce or intrastate activities that substantially affect interstate commerce.<sup>42</sup> Congress has used the Commerce Clause to address a range of concerns beyond trade, including crime, safety, discrimination, and the environment.<sup>43</sup> The Court reigned in the Commerce Clause power a decade ago in *United States v. Lopez*, striking down regulation of non-commercial intrastate activities,<sup>44</sup> only to very recently sustain expansive application in *Gonzales v. Raich*, which involved a federal statute criminalizing the in-state possession, cultivation, and use of marijuana for medical purposes.<sup>45</sup>

Congress and state governments may use other powers as well to control issues. For example, Congress has the ability to place conditions upon the receipt of federal money,<sup>46</sup> and Congress may raise funds through taxation.<sup>47</sup> Direct legislation related to public health and general interest are typically reserved for individual state governments, barring some need for national uniformity.<sup>48</sup> States can regulate commerce, but they can neither enact laws that discriminate against out-of-state residents or interstate commerce under the Dormant Commerce Clause,<sup>49</sup> nor excessively burden interstate commerce without articulating

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41. See *supra* Part II.B. Of course, Congress can always modify the charter for Medicare.

42. *United States v. Lopez*, 514 U.S. 549, 549 (1995). See U.S. CONST. art. I, § 8, cl. 3.

43. NORMAN REDLICH ET AL., UNDERSTANDING CONSTITUTIONAL LAW 97 (2d ed., Matthew Bender & Co. 1999).

44. 514 U.S. at 549 (disallowing the use of commerce power to restrict proximity of gun possession from schools since activity regulated is non-commercial in nature).

45. 545 U.S. 1 (2005).

46. See REDLICH ET AL., *supra* note 43, at 80–81. The condition placed on receipt of funds must be related to the purpose of the funds. *Id.* at 81.

47. Congress has a broad power to tax for the common defense and general welfare, so long as specific constitutional rights are not violated. *Id.* at 77–79. Courts have consistently refused to look into the reasonableness of a tax. See *Pittsburgh v. Alco Parking Corp.*, 417 U.S. 368, 373 (1974).

48. See REDLICH ET AL., *supra* note 43, at 50–52. “The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.” U.S. CONST. amend. X.

49. REDLICH ET AL., *supra* note 43, at 123. See *e.g.*, *Dean Milk Co. v. Madison*, 340 U.S. 349 (1951) (holding impermissible a city ordinance requiring milk to be pasteurized and bottled within five miles from the town center).

a legitimate state interest.<sup>50</sup> In addition, states cannot violate the Privileges and Immunities Clause of Article IV<sup>51</sup> by restricting the basic rights of out-of-state citizens versus their own citizens.<sup>52</sup> Finally, congressional legislation related to commerce preempts state legislation in the same area.<sup>53</sup>

Government regulation of use and distribution of materials must be tested against claims of violating implied fundamental liberty interests contained in the Due Process Clauses of the Fifth<sup>54</sup> and Fourteenth Amendments.<sup>55</sup> Tradition and history, among other factors, are important and perhaps decisive criteria for determining explicit and implicit liberty interests.<sup>56</sup> Liberties protected include freedom of thought, belief, and expression; freedom from arbitrary search, seizure, confinement, or punishment; and freedom in childbearing,<sup>57</sup> childrearing,<sup>58</sup> and certain other familial matters.<sup>59</sup> The weight assigned to these liberty interests determines the burden of justification for governmental intrusion,<sup>60</sup> and recent Supreme Court decisions indicate that recognized liberty interests draw an intermediate level of scrutiny.<sup>61</sup> There is a recognized fundamental right to procreate,<sup>62</sup> which may specifically affect the right to germ-line engineering or fetal manipulation.<sup>63</sup> There is also a limited right to privacy associated with certain medical procedures.<sup>64</sup> Therefore, one's longevity may fall under the right to privacy within the concept of ordered liberty. Furthermore, the right to enhance the longevity of one's offspring may also fall under fundamental procreative liberties.

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50. *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970) (holding a statute valid because of trivial burdens on commerce compared to the state's interest in conservation and curing waste problems).

51. U.S. CONST. art. IV, § 2, cl. 1.

52. See REDLICH ET AL., *supra* note 43, at 136–37. Such laws are subject to strict scrutiny, which calls for a substantial reason for the differential treatment, and a substantial relationship to a legitimate state objective. *S. Ct. of N.H. v. Piper*, 470 U.S. 274, 284 (1985).

53. REDLICH ET AL., *supra* note 43, at 134. See *Ray v. Atl. Richfield Co.*, 435 U.S. 151, 158 (1978). The state law is preempted if: (1) there is a conflict between the state and federal legislation; (2) Congress has preempted states from the entire field of regulation; or (3) the federal and state laws are incompatible with one another. REDLICH ET AL., *supra* note 43, at 134.

54. U.S. CONST. amend. V.

55. U.S. CONST. amend. XIV; Michael H. Shapiro, *Does Technological Enhancement of Human Traits Threaten Human Equality and Democracy?*, 39 SAN DIEGO L. REV. 769, 832 (2002).

56. Shapiro, *supra* note 55, at 836.

57. See, e.g., *Roe v. Wade*, 410 U.S. 113, 152–56 (1973) (declaring childbearing an activity implicit in the concept of ordered liberty, thereby protecting abortion under right to privacy); *id.* at 168–70 (Stewart, J., concurring).

58. See, e.g., *Pierce v. Soc'y of Sisters*, 268 U.S. 510, 534–35 (1925) (discussing the right of parents to send children to private schools).

59. See, e.g., *Moore v. City of E. Cleveland*, 431 U.S. 494, 499 (1977) (striking down a zoning ordinance prohibiting extended family from living together in single dwelling unit).

60. Shapiro, *supra* note 55, at 834.

61. See *id.* at 835 n.133.

62. *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942) (finding that an Oklahoma law authorizing sterilization of certain habitual offenders was unconstitutional).

63. Shapiro, *supra* note 55, at 833.

64. See generally *Roe v. Wade*, 410 U.S. 113 (1973).

Balanced against these liberty interests are constitutional standards of equality. These include the Equal Protection Clause of the Fourteenth Amendment<sup>65</sup> and the Fifth Amendment's implied parallel protection.<sup>66</sup> These measures aim to prevent state-imposed discrimination and exploitation of discrete, identifiable groups.<sup>67</sup> The Supreme Court has held that Congress can use its power under Section Five of the Fourteenth Amendment to proscribe both private<sup>68</sup> and non-purposeful<sup>69</sup> discrimination. In *Katzenbach v. Morgan*, the Supreme Court treated with great deference congressional specification of conduct as violating Equal Protection, even if courts had not previously recognized the conduct as a violation.<sup>70</sup> The presence of users of anti-aging drugs may create a sufficiently discriminatory environment for non-users.

In addition, there are constitutional proscriptions against slavery and state conferrals of nobility in the Thirteenth Amendment<sup>71</sup> and the Nobility Clause,<sup>72</sup> respectively. Based on constitutional history and Court commentary, state action represents an unauthorized conferral of nobility if it:

- 1) Confers an actual title of nobility; or
- 2) Confers all or many of the following indices of nobility:
  - a) significant and enduring advantages of wealth and political influence;
  - b) significant and enduring advantages with respect to the exercise of basic human faculties, especially those concerned with speech and thought;
  - c) perception by others as special or superior;

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65. U.S. CONST. amend. XIV, § 1.

66. U.S. CONST. amend. V; Shapiro, *supra* note 55, at 838–39.

67. See Shapiro, *supra* note 55, at 838.

68. See *District of Columbia v. Carter*, 409 U.S. 418, 424 n.8 (1973); *United States v. Guest*, 383 U.S. 745, 754–57 (1966); *id.* at 762 (Clark, J., concurring); *id.* at 782–84 (Brennan, J., concurring in part and dissenting in part); Archibald Cox, *The Supreme Court, 1965 Term—Foreword: Constitutional Adjudication and the Promotion of Human Rights*, 80 HARV. L. REV. 91, 114 (1966) (arguing that this power must be exercised for Congress to affirmatively advance welfare and human rights).

69. *City of Rome v. United States*, 446 U.S. 156, 176–77 (1980).

70. 384 U.S. 641, 652–56 (1966). “We perceive a basis upon which Congress might predicate a judgment that the application of New York’s English literacy requirement . . . constituted an invidious discrimination in violation of the Equal Protection Clause.” *Id.* at 656. See also John B. Attanasio, *The Constitutionality of Regulating Human Genetic Engineering: Where Procreative Liberty and Equal Opportunity Collide*, 53 U. CHI. L. REV. 1274, 1320 (1986). Observing this ruling, scholar Archibald Cox remarked, “Congress may decide, within broad limits, how the general principle of equal protection applies to actual conditions.” Cox, *supra* note 68, at 106.

71. U.S. CONST. amend. XIII.

72. U.S. CONST. art. I, § 9, cl. 8.

d) membership in a “closed” class, i.e., one that will resist entry by outsiders regardless of merit.<sup>73</sup>

Governmental approval of age-enhancement (especially where it affects an entire line of descendants) arguably creates the equivalent of a caste system, thus potentially violating the Nobility Clause. One may extrapolate this argument to claim that the non-enhanced will inevitably be made subservient to the enhanced, thus instituting a badge of slavery in violation of the Thirteenth Amendment.

### III. ANALYSIS

#### A. *Consequences of Introduction of Anti-Aging Therapy*

##### 1. *Productivity Gains*

From a utilitarian perspective, there are strong arguments in favor of encouraging access to anti-aging therapies to the greatest extent possible. An anti-aging pill would theoretically retard the process of aging and delay the onset of debilitating and atrophying illnesses. This would extend the number of productive years of the average age-enhanced individual.<sup>74</sup> If this therapy is a germ-line genetic alteration, benefits would accrue to subsequent generations as well. The primary liability of an individual to society occurs in childhood and during the final period before death,<sup>75</sup> and any method that marginalizes those costs relative to productive years contributing to society represents a utilitarian benefit. The net contribution of an individual to society (“NC”) is roughly the product of his average annual productivity (“P”) during productive years multiplied by the number of productive years available (“Y”) minus the fixed cost of the childhood (“C”) and the final months of life (“D”).<sup>76</sup> An anti-aging pill would increase Y and possibly

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73. Richard Delgado, *Inequality “From The Top”: Applying an Ancient Prohibition to an Emerging Problem of Distributive Justice*, 32 UCLA L. REV. 100, 115 (1984).

74. Experts like physician Elie Metchnikoff in 1908 envisioned that:

[t]he prolongation of life would be associated with the preservation of intelligence and the power to work . . . . When we have reduced or abolished such causes of precocious senility as intemperance and disease, it will no longer be [sic] necessary to give pensions at the age of sixty or seventy years. The cost of supporting of [sic] old, instead of increasing, will diminish progressively.

Haber, *supra* note 1, at 13.

75. For example, one study estimated that “the total health care expenditures during the last six months of life for the 2.1 million people who died in 1987 (approximately 0.9 percent of the population) amounted to \$44.9 billion in 1992 dollars (approximately 7.5 percent of total personal health care expenditures).” EZEKIAL EMANUEL & LINDA EMANUEL, *THE ECONOMICS OF DYING* (1997), available at <http://www.nap.edu/readingroom/books/approaching/6.html#what> (last visited Oct. 4, 2006).

76. The equation reads:  $NC = P*Y - (C + D)$ .

P without affecting any of the other factors, resulting in an overall increase in NC.

Extra production from an enhanced person should result in innovations and creative contributions that would improve society in general.<sup>77</sup> With a longer time to earn and save, people could assemble more resources and experience. At the very least, it would result in innovations that improve society's productivity. Aside from economic gains, age-enhanced individuals may build up a wealth of experience, wisdom, and benevolence, discover transcendent truths, or found institutions that expand intellectual horizons and inspire others.<sup>78</sup> Therefore, the individual calculus for even the non-enhanced is made more favorable, as the enhanced may further increase the welfare of all.<sup>79</sup>

However, this calculation could fail to produce gains if, as a result of pre-existing policies, an anti-aging pill does not increase P or Y. That is, people may fail to capitalize on health improvements due to structural disincentives in our current system. For example, a failure of the federal government to revise the minimum age for social security upwards would hold Y constant and would decrease P. If people remain healthy and able well past the age of eighty years, but nevertheless retire and draw from society's resources starting at age sixty-five, a class of individuals will fail to produce despite being in "prime" condition. In addition, the risks of exposing a large portion of the population to a long-term genetic enhancement must be considered.<sup>80</sup> Even if no harmful side effects immediately manifest themselves, there remains the possibility of long-term health risks.<sup>81</sup> This would cast doubt upon estimates of a dramatically enhanced personal career span and productivity.

## 2. *Cost of Health Care*

From a more urgent utilitarian perspective, there is the current problem of the rising costs of health care. This includes the potentially crippling effects of financing the health care of aging baby-boomers.<sup>82</sup> In the short-term, administration of an anti-aging pill in addition to existing drugs could cause costs to balloon. Over the long-term, however, one hopes this therapy will prevent, or at least defer, age-associated illnesses.<sup>83</sup> Heart diseases (31.4%), cancer (23.3%), and strokes (6.9%) are the biggest killers in America.<sup>84</sup> Not surprisingly, these diseases, collectively known as the "degenerative diseases of aging," consume half

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77. See FRIEDRICH A. HAYEK, *THE CONSTITUTION OF LIBERTY* 42–44 (1960).

78. See ROBERT NOZICK, *PHILOSOPHICAL EXPLANATIONS* 410, 436–40, 618 (1981).

79. See HAYEK, *supra* note 77, at 42–44.

80. See Shapiro, *supra* note 55, at 798.

81. See *id.*

82. The baby boom consists of those Americans born between the years 1946 and 1964. See, e.g., Darnell Little, *Who Will Drive Future Demand?*, *J. PROP. MGMT.*, Jan. 1, 1998, at S1.

83. Klatz, *supra* note 21, at 61.

84. *Id.*

of the U.S. healthcare budget.<sup>85</sup> One hundred million Americans currently receive treatment for at least one of these problems at a cost of over \$700 billion annually.<sup>86</sup> An anti-aging therapy could forestall these conditions, spreading out over decades their onset across the baby-boomer generation. In the short term, this would help avert an immediate financing problem. Over the long term, fewer people would suffer from the conditions of aging, resulting in a decline in the costs associated with treatment. Certain people may live such healthy lives that they eventually choose to die by their own methods when they feel their goals have been achieved.<sup>87</sup> While this raises legal and ethical issues, it also would decrease health care costs for our society.

### 3. *Value of the Individual*

From a deontological perspective,<sup>88</sup> it is difficult to determine which path (using anti-aging therapies or not) values humanity the most. Subjugating wealthy people's dreams of self-actualization based on natural free will to egalitarian concerns of inequality<sup>89</sup> degrades people by treating them as a means rather than a legitimate end—a violation of the Kantian categorical imperative.<sup>90</sup> Yet from the same deontological perspective, one could also argue that the existence of age-enhanced people will suddenly destroy any sense of self-actualization of those without access.<sup>91</sup> A critical response may be that such inequality of mortality already exists, given disparate access and assorted environmental advantages.<sup>92</sup>

A deontological humanist would also challenge the utilitarian concept of welfare. The non-enhanced will likely see positive results, but not as much as the enhanced, leading to a widening gap in advantages between the two groups.<sup>93</sup> If the therapy is unsubsidized, it may simply amplify the gap between the rich and the poor. This results in a socially

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85. *Id.*

86. *Id.*

87. See Hackler, *supra* note 21, at 16.

88. The deontological perspective involves observing a moral rule, rather than the most utilitarian approach.

89. ROBERT NOZICK, ANARCHY, STATE, AND UTOPIA 235 (1974) [hereinafter ANARCHY]. “Whenever ‘anti-aging’ encourages evasion, denial, or avoidance of painful constraints, it points in anti-human or dehumanizing directions.” Cole & Thompson, *supra* note 11, at 7.

90. NOZICK, *supra* note 78, at 452–59.

91. “‘Men are, in great measure, what they feel themselves to be.’” ANARCHY, *supra* note 89, at 348 n.7 (quoting R.H. TAWNEY, EQUALITY 171 (1964)). Self-respect has increased with softening inequalities in modern history. *Id.*

92. As of 1998, 17% of Americans under age sixty-five possessed no health care coverage, and 13% of Americans had no ongoing source of primary care. See Leading Health Indicators, Healthy People 2010, [http://www.healthypeople.gov/Document/html/uih/uih\\_bw/uih\\_4.htm](http://www.healthypeople.gov/Document/html/uih/uih_bw/uih_4.htm) (last visited Oct. 4, 2006).

93. See Shapiro, *supra* note 55, at 819. See generally Richard A. Posner, *Equality, Wealth, and Political Stability*, 13 J.L. ECON & ORG. 344 (1977) (discussing the impact of variations in equality and wealth on political stability).

unstable situation, and represents a problem even if everyone technically achieves a much higher state of welfare.<sup>94</sup> Individuals base their sense of poverty largely on relative welfare, rather than absolute welfare, indicating that widening gaps in health and welfare would cause more social tension.<sup>95</sup>

Contrast this with a drug that artificially makes someone more intelligent or hardworking.<sup>96</sup> Such a drug would clearly conflict with our conceptions of identity as evidenced by the evocation of specific dilemmas, such as whether to attribute a person's accomplishments to his or her intrinsic merit or to artificial assistance.<sup>97</sup> Philosopher Robert Nozick contends, "[w]ithout free will, we seem diminished, merely the playthings of external forces. How then can we maintain an exalted view of ourselves? Determinism seems to undercut human dignity . . . [and] undermine our value."<sup>98</sup>

There is no analogous dilemma with an anti-aging pill. It does not implicate our individual identities, and is therefore distinguishable from other perhaps unfair or unnatural enhancements.<sup>99</sup> The concern about normalization typically associated with genetic engineering dissipates because anti-aging does not materially implicate personality.<sup>100</sup> Anti-aging technology helps an individual remain mentally and physically sharp, resulting in a longer career.<sup>101</sup> Therefore, while there is a competitive advantage, an individual's peak performance potential either remains unaffected or will grow only as fast as the individual gains additional experience from an extended career. Given the preservation of effort as an institution, an anti-aging treatment involves a unique case of an enhancement that does not directly alter merit attributes but instead preserves them.<sup>102</sup> While youth may be admired in certain circumstances, it is distinguishable from discrete and indisputably meretricious traits such as intelligence, motivation, and character.

94. Shapiro, *supra* note 55, at 819.

95. *Id.* "Our notions of poverty seem to involve ordinal rankings as well as the cardinal value of one's holdings." *Id.*

96. See generally Attanasio, *supra* note 70.

97. Shapiro, *supra* note 55, at 781–83.

98. NOZICK, *supra* note 78, at 291.

99. See Shapiro, *supra* note 55, at 780–81.

If a pathological condition is successfully treated, we are unlikely to describe the restorative process or its result as enhancement unless the intervention appears to go beyond canceling out the disorder and induces a non-natural condition that masks or displaces the impairment rather than restores the patient's *ex ante* personal baseline.

*Id.* at 780. An example of an enhancement that affects peak merit and identity is the use of steroids in baseball to improve hitting prowess. This expansion of peak performance affects the merit attributed to the player in the minds of observers. It can turn a good player into an All-Star, an All-Star into a Hall-of-Famer, etc.

100. See *id.* at 781.

101. See Hackler, *supra* note 21, at 16.

102. See Shapiro, *supra* note 55, at 782. "Enhancement almost inevitably targets merit attributes, which are generally wealth-attracting resources." *Id.* at 814.

#### 4. *Wealth Disparity and Social Stratification*

Even if the short-term calculus of an anti-aging drug yields positive results, long-term societal changes might be unfavorable. An anti-aging pill priced at market rates could easily cause a widened longevity gap between the rich and the poor.<sup>103</sup> If germ-line enhancements become the popular mode of alteration, then age-defiance may directly tie to lineage.<sup>104</sup> Even if the enhancements are somatic and impermanent, the advantage will still lie with the wealthy. Either way, “noble” lineages will consistently be enhanced, potentially diminishing the efforts of the non-enhanced.<sup>105</sup> Current discrepancies in health care access do not create differences so universally visible as a clan of youthful-looking people of advanced age.<sup>106</sup> Yet if anti-aging technology makes differences physically obvious, then an individual’s membership in such a lineage would become apparent by a certain age, possibly resulting in isolation or discrimination of the non-enhanced. Based on such identification, opportunities for marriage and employment may accrue disproportionately to those of the higher caste of semi-mortals.<sup>107</sup>

#### 5. *Instability and Institutional Change*

In response to the aforementioned situations, individuals that cannot afford to enhance themselves or have a moral objection to the practice would feel considerable consternation.<sup>108</sup> As noted previously, a widening gap between the wealthy and poor may create an unstable situation.<sup>109</sup> With a price-inelastic mindset, certain individuals from less advantaged backgrounds may strain themselves to spend whatever they have to achieve anti-aging. People may expend risk capital (committing crimes with a risk of punishment),<sup>110</sup> engage in gambling to raise money (accepting a low probability opportunity to gain additional capital), or expend moral capital (selling illegal goods). However, over time, mass production and demand may yield economies of scale and nearly universal low cost treatments.<sup>111</sup> This may eliminate equality concerns

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103. Hackler, *supra* note 21, at 16–17.

104. See Attanasio, *supra* note 70, at 1315–16.

105. See *id.*

106. Anecdotally, one can observe that wealthy elderly individuals will generally look as old as middle-class elderly individuals, with only some pecuniary differences attributable to cosmetic enhancement or surgery.

107. See Shapiro, *supra* note 55, at 779.

108. See JOHN RAWLS, A THEORY OF JUSTICE 62–63 (1971). Rawls excuses envy engendered by an imbalance in distribution of “primary goods.” *Id.* at 92, 546. Resentment is likely to result if people think that superiority is ill-gotten. *Id.* at 533.

109. See Shapiro, *supra* note 55, at 819.

110. See *id.* at 801. If the prize is big enough, motivated people will accept great risks. A 1981 poll reported that over half of Olympic athletes at the 1984 games said they would take a drug that would kill them five years later if it enabled them to win a gold medal. Michael H. Shapiro, *Technology of Perfection*, 65 S. CAL. L. REV. 11, 82 n.229 (1991).

111. See Shapiro, *supra* note 55, at 820.

for those most desperate for access.<sup>112</sup> Restricted access, in contrast, could cause a lucrative black market to develop.<sup>113</sup>

There may be further effects on social stability. Moral objectors may take extraordinary means to prevent the perpetuation of enhancements by harassing physicians and lobbying governments.<sup>114</sup> Globally, social effects may include prolonged survival of oppressive dictators.<sup>115</sup> Overpopulation could become a greater concern if access to this drug becomes widespread and is unaccompanied by a decrease in fertility rates.<sup>116</sup> Other global developments could also result, including an upsurge in concern about environmental stability, health promotion, and accident prevention as people can look over a hundred years into their future.<sup>117</sup>

An anti-aging pill could also dramatically alter family structure.<sup>118</sup> Marriage may no longer remain a life-long contract given such an extended maximum duration.<sup>119</sup> Children would know members from several older generations in the family.<sup>120</sup> Where family members choose not to take a somatic-based treatment, different generations in a family may find themselves of similar biological age.<sup>121</sup> Interpersonal relationships across generations may undergo dramatic shifts.<sup>122</sup> On an individual level, virtually eternal life may result in newfound boredom, although new institutions may develop to assuage this problem.<sup>123</sup> In the workplace, younger employees may find it more difficult to obtain promotions, given the continued efficiency of older, more experienced workers.<sup>124</sup> The list of potential consequences continues ad infinitum. Society must decide whether to incur such changes, and society must also properly address such changes, in the event that widespread use of anti-aging takes hold.

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112. *See id.*

113. Due to the difficulty of receiving a prescription or lack of government approval, black market prices for Viagra in Ho Chi Minh City, Vietnam, and Latin America were reported to be as high as \$175 per pill when the drug was introduced. Russell Watson, *The Globe Is Gaga for Viagra*, NEWSWEEK, June 22, 1998, at 44–45. Viagra is an erectile dysfunction drug manufactured by Pfizer. Kim H. Finley, *Life, Liberty, and the Pursuit of Viagra? Demand for “Lifestyle” Drugs Raises Legal and Policy Issues*, 28 CAP. U. L. REV. 837, 837 n.4 (2000).

114. This is akin to anti-abortion activists' efforts to disrupt the sale of abortion services. *See Abortion Clinic*, WIKIPEDIA: THE FREE ENCYCLOPEDIA (Aug. 29, 2006), [http://en.wikipedia.org/wiki/Abortion\\_clinic](http://en.wikipedia.org/wiki/Abortion_clinic).

115. Hackler, *supra* note 21, at 17–18.

116. *Id.* at 18.

117. Moody, *supra* note 18, at 34.

118. *Id.*

119. *Id.*

120. *Id.*

121. Haylick, *supra* note 12, at 25.

122. *Id.* An example of a dramatic shift might be if a child has grandparents who are as ambitious and vigorous as her parents. This would alter the traditional comforting role of the elderly grandparent.

123. Moody, *supra* note 18, at 35.

124. Hackler, *supra* note 21, at 18.

### B. FDA Approval Process

In the United States, the FDA regulates pharmaceuticals based on the Constitution's authorization for congressional control of interstate commerce.<sup>125</sup> The purpose of the FDA,<sup>126</sup> sometimes called its overriding purpose,<sup>127</sup> as well as its primary objective,<sup>128</sup> is the protection of public health; the FDA, as a whole, is designed primarily to protect consumers from dangerous products.<sup>129</sup> Any safety considerations used to fight the drug approval must fully outweigh the potential for therapeutic benefit.<sup>130</sup> Public health concerns do not by themselves enable the FDA to reject a new drug application.<sup>131</sup> However, in order for a recognizable therapeutic benefit to exist, there must be some disease or disorder,<sup>132</sup> without which the FDA may not grant approval, or even allow a clinical trial of a drug to slow aging.<sup>133</sup> Finally, a state may have the exclusive ability to regulate a drug or treatment if the company with rights to the drug can keep all phases, including manufacture, distribution, and consumption within the state's borders.<sup>134</sup>

With the FDA limitations in mind, aging must be classified as a disorder before the FDA will approve drugs to combat it.<sup>135</sup> The process of aging occurs in every individual, and unless abnormal, a strict interpretation would place aging outside the realm of disease.<sup>136</sup> Additionally, the process is diffuse, unlike other common disorders, such as male impotence, which result in an identifiable malfunction of a body part. Thus, the FDA may conclude that an anti-aging drug falls outside its domain of regulating the treatment of disorders.

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125. JAMES ROBERT NIELSON, HANDBOOK OF FEDERAL DRUG LAW 4 (2d ed. 1992).

126. Bristol-Myers Co. v. FTC, 738 F.2d 554, 559 (2d Cir. 1984).

127. Nutritional Health Alliance v. FDA, 318 F.3d 92, 97–98 (2d Cir. 2003); United States v. Lee, 131 F.2d 464, 466 (7th Cir. 1942).

128. United States v. Bacto-Unidisk, 394 U.S. 784, 786–87 (1969); United States v. Undetermined No. of Unlabeled Cases, 21 F.3d 1026, 1028 (10th Cir. 1994); United States v. Rx Depot, Inc., 290 F. Supp. 2d 1238, 1246 (N.D. Okla. 2003).

129. Gen. Med. Co. v. FDA, 770 F.2d 214, 217–18 (D.C. Cir. 1985); Pharm. Mfrs. Ass'n v. FDA, 484 F. Supp. 1179, 1183 (D. Del. 1980).

130. See *supra* Part II.C.

131. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 134 (2000).

132. “‘Disorder’ is meant to embrace a family of ideas, including disease, sickness, illness, injury, trauma, lesion, and defect.” Shapiro, *supra* note 55, at 780 n.14.

133. See Pollack, *supra* note 24.

134. In 1977, a pharmaceutical company obtained permission from the Nevada legislature to sell a proposed anti-aging drug without FDA approval. Larry Kramer, *Gambling with the FDA in Nevada: State Approves Drug that Claims to Help the Elderly*, WASH. POST, Nov. 13, 1977, at F1.

135. *Id.*

136. See Hayflick, *supra* note 12, at 20–21. “Biological aging is an expression of the Second Law of Thermodynamics, or increasing entropy, or disorder, in a system. Aging is not a disease, so the concept of seeking a cure for it is tantamount to seeking a cure for embryogenesis or child or adult development.” *Id.* A rare disease involving premature aging is an example of abnormal aging, for which anti-aging therapies stand a greater chance of approval.

On the other hand, “scientific curiosity has a way of turning up discoveries that unexpectedly change the way we look at the world.”<sup>137</sup> If a drug exists that effectively retards the aging process, informed individuals may begin to take the non-FDA approved treatment and live past normal age, avoiding cellular degeneration.<sup>138</sup> Knowledge of individuals living youthfully and well past normal age may then erode the perception that overwhelming cellular demise at an appointed time is inherently natural. In addition, the values of affected consumer groups should be considered, and policymakers should not limit themselves to abstract ethical principles.<sup>139</sup> Baby boomers, the primary beneficiaries of this drug, consider themselves youthful and vibrant, committed to maintaining themselves, learning new things, and fulfilling their needs and wants.<sup>140</sup> The well-publicized proliferation of effective anti-allergens and erectile dysfunction treatments reinforces this attitude with respect to health.<sup>141</sup> The baby boomer generation will likely view an anti-aging pill more favorably than perhaps any generation in the past.

On the scientific side, an anti-aging drug may require us to revise our implied assumptions of disorder as involving failure of a single organ system or body member.<sup>142</sup> Discoveries may unveil the pathological process of aging as the underlying problem responsible for more localized disorders.<sup>143</sup> As such discoveries become common knowledge, conditions that are currently viewed as disorders (heart disease, cancer, diabetes) may soon become viewed as symptoms of the more general aging process.

The subtle determination of whether aging is a true disorder has recently become important to FDA regulation in an indirect manner. Recent developments indicate that the FDA no longer views safety and effectiveness as distinct issues; instead, the two considerations have merged into a general consumer welfare inquiry.<sup>144</sup> In 1997, the *Restatement of Torts: Product Liability* declared that a drug is defectively designed if a reasonably informed provider would prescribe it for no class of patients.<sup>145</sup> The question of whether a drug adds value in a clinical setting is now part of the FDA’s regulatory doctrine because the FDA reduces its safety requirements for a drug that scores high on

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137. Moody, *supra* note 18, at 37.

138. The FDA probably cannot regulate the drug if the drug is used within a state and does not move in interstate commerce. *United States v. Vital Health Prod., Ltd.*, 786 F. Supp. 761, 767 (E.D. Wis. 1992), *aff’d* 985 F.2d 563 (7th Cir. 1993).

139. See Bernstein & Bernstein, *supra* note 38, at 16–18.

140. *Id.* at 16. “The rule of thumb has been that the Boomers have doubled the demand for all goods and services that have come within their reach—prenatal products, elementary schools, high schools, colleges, starter homes.” Little, *supra* note 82.

141. Bernstein & Bernstein, *supra* note 38, at 17.

142. See *supra* Part II.B.

143. *Id.*

144. Bernstein & Bernstein, *supra* note 38, at 79.

145. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY, § 6(c) (1997).

effectiveness.<sup>146</sup> By contrast, the FDA holds idle or superfluous drugs with little therapeutic benefit to a higher safety standard in regulatory and product liability contexts.<sup>147</sup> The value judgments in the FDA evaluation process govern whether the FDA will judge anti-aging drugs through the prism of superfluity. If believers in the value of anti-aging medicine control the FDA, the FDA may view such drugs as extremely beneficial, and apply a less rigorous safety standard. Subjective considerations are important, as the FDA increasingly asks whether a drug is “good enough” to sell.<sup>148</sup> Whether a drug is directed at a legitimate disorder, disease, or injury may depend upon society’s cultural habits and the existing environmental conditions.<sup>149</sup> Based on Western culture’s long history of seeking youth, as well as modern trends, aging has recently been looked at with dismay by a significant segment of the population.<sup>150</sup> The current conditions would therefore advocate in favor of approval of an anti-aging drug.

Even if the drug fails approval for anti-aging purposes, it may be approved for treatment of a traditional medical disorder like diabetes, chronic hypertension, or heart disease.<sup>151</sup> An anti-aging pill will likely alleviate age-associated disorders to some degree, although the mechanism by which the pill works may not function as a specific therapy.<sup>152</sup> However, the FDA considers a drug’s effectiveness without comparison to other drugs.<sup>153</sup> This would create a gateway for anti-aging drugs to enter the marketplace, and would avoid the problem of verifying total longevity claims.<sup>154</sup> If the FDA perceives the drug as reasonably safe and effective, many physicians may respond to market demands and prescribe it off-label,<sup>155</sup> or at the very least preferentially prescribe an alternative with anti-aging benefits over a traditional treatment.<sup>156</sup> A

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146. Bernstein & Bernstein, *supra* note 38, at 7.

147. *Id.*

148. *See id.* at 29–35.

149. Shapiro, *supra* note 55, at 781. Shapiro asks, for example, for the socially acceptable emotional states, the prevailing attitudes towards persons of a given condition, and the societal perception of the symptoms. *Id.*

150. *See supra* Part II.A.

151. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 141–42 (2000).

152. *See supra* notes 24, 26. An example of a mechanism targeted as a specific therapy may be a drug that alters expression of membrane receptors to increase uptake of LDL (bad cholesterol), in order to prevent heart disease.

153. Paul Wallace, *Using Evidence to Understand New Approaches*, THE PERMANENTE JOURNAL, Fall 2002, <http://xnet.kp.org/permanentejournal/fall02/approaches.html>.

154. Pollack, *supra* note 24. “You would have to start treating people in their 50’s and possibly follow them up to the next 50 years. . . . Your patent would expire,” said one CEO of a Massachusetts anti-aging compound developer. *Id.*

155. *See* Daniel B. Klein & Alexander Tabarrok, *Who Certifies Off-Label?*, REGULATION, Summer 2004, at 60. For example, thalidomide’s on-label purpose is to treat leprosy, but it is prescribed mainly off-label for cancer and AIDS. *Id.*

156. For instance, a salve containing genes to promote hair growth is now before the FDA for approval. Tim Friend, *Designer Genes Not Farfetched*, CHI. SUN-TIMES, Nov. 2, 1997, at 40. Although the genetic salve was submitted to help chemotherapy patients, once the technology is approved, the salve can be prescribed for any purpose. *Id.*

drug company that manufactures this anti-aging pill masked as a traditional drug would certainly attempt to market its associated benefits.<sup>157</sup> Courts have permitted off-label promotion when the information provided is not false or misleading and comes from a “bona fide peer reviewed professional journal,” a “bona fide independent publisher,” or an “independent program provider.”<sup>158</sup> Prominent economists claim that these post-marketing experiments “generate important new knowledge,” as clinical practice unveils new possible avenues.<sup>159</sup> After some time on the market and further observation and testing, the FDA may then approve the drug explicitly to combat aging.<sup>160</sup> If this occurs, or even if customers only anecdotally hear of such benefits, they will place enormous pressure on physicians to prescribe the drug for this alternative purpose.

Lack of appropriate FDA oversight could have dire consequences, because it may detract from the treatment’s legitimacy. Obviously, government obstruction would function to chill innovation in this field. In addition, in the case of a truly effective anti-aging therapy, government obstruction may not be enough to stop scientists with the ability to manufacture the drug, and a booming black market may develop.<sup>161</sup> Alternatively, if FDA approval appears too onerous, enterprising companies will tap into the market for nutritional supplements, which can reach the market faster.<sup>162</sup> In such cases, prohibitions or severe restrictions and the associated lack of FDA safety oversight may inhibit safety controls, such as physician guidance.<sup>163</sup> An anti-aging treatment may accompany contemporary developments in pharmacogenomics,<sup>164</sup> which permit individualized tailoring of drugs to minimize side effects.<sup>165</sup> Its application to a future anti-aging pill can only occur if legitimate medical institutions administer the therapy, as

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157. According to Ed Canon, chief executive of Elixir (based in Cambridge, Mass.), extending healthy life “is the reason Elixir exists. But along the way there is a toll stop, and we have to pay our toll by showing we can intervene in conventional disease indications.” Pollack, *supra* note 24.

158. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 74–75 (D.D.C. 1998). *See also* *Pearson v. Shalala*, 164 F.3d 650, 660–61 (D.C. Cir. 1998) (striking down certain FDA regulations on the promotion of dietary supplements on the ground they excessively suppress speech).

159. Klein & Tabarrok, *supra* note 155, at 60–61.

160. This would be similar to the way the FDA has successfully proceeded in the past with controversial therapies. For example, in 1957, the FDA approved the first birth control pill as a means of inducing temporary sterility for countering gynecological disorders, and, in 1960, the FDA approved it for use as a contraceptive. BERNARD ASBELL, *THE PILL* 159, 163, 167 (1995).

161. *See* Shapiro, *supra* note 55, at 797.

162. *See* Pollack, *supra* note 24. “Still, citing the daunting prospects for getting FDA approval, some companies like GeroTech and LifeGen say they are aiming for nutritional supplements, which can reach the market faster than drugs.” *Id.* Juvenon, co-founded by a professor of molecular biology at UC-Berkeley, is already selling its Juvenon Energy Formula. *Id.*

163. *See* Shapiro, *supra* note 55, at 797.

164. Pharmacogenomics is the study of how variations in the human genome affect the response to medications. MedicineNet.com, Pharmacogenomics Definition, <http://www.medterms.com/script/main/art.asp?articlekey=15313> (last visited Oct. 4, 2006).

165. *See* Antonio Regalado, *Inventing the Pharmacogenetics Business*, 56 AM. J. HEALTH-SYS. PHARMACY 40 (1999).

opposed to clandestine or off-label channels.<sup>166</sup> Finally, if the FDA chooses to ignore anti-aging, development in this field may still occur but with the research and concomitant riches shifting to Europe and Asia. It may be noted that these arguments can also be used in the context of contesting a governmental ban on the therapy. In consideration of these myriad complexities of anti-aging, there is a strong argument for maximal oversight.

### *C. Arguments Permitting Governmental Restriction of Anti-Aging*

#### *1. Legal Grounds for an Outright Ban*

In order to avoid any of the negative consequences, including changes in family character and risk of social ills, governments may ban anti-aging procedures at the national or state level.<sup>167</sup> Given the fact that many citizens negatively affected will object to any distribution scheme financed by taxes, and the fact that any distribution scheme can break down through black markets,<sup>168</sup> Congress may reasonably believe that a ban is the only option.<sup>169</sup> Congress has an independent duty to enforce the Constitution, and can make laws in accordance with this objective.<sup>170</sup> Specifically, under Section Five of the Fourteenth Amendment, Congress has an uncertain range of powers to promote constitutional rights.<sup>171</sup>

##### *a. Legitimate State Interests*

Our legal tradition allows state governments to represent state interests while trumping potentially legitimate liberty or privacy claims.<sup>172</sup> Courts have upheld foundational egalitarian constraints, including regulation of economic enterprise.<sup>173</sup> Within the family unit, the Court has supported compulsory education laws in the face of parental opposition, and upheld laws against polygamy despite religious

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166. See Shapiro, *supra* note 55, at 797.

167. The current administration may strike an abruptly conservative approach to anti-aging. “Leon R. Kass, a professor at the University of Chicago and chief bioethics advisor to President Bush [in September 2003], has said society should ‘resist the siren song of the conquest of aging and death.’” Pollack, *supra* note 24.

168. See GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 122 (1978).

169. See Attanasio, *supra* note 70, at 1328.

170. See GEOFFREY R. STONE ET AL., CONSTITUTIONAL LAW 50–52 (2001).

171. U.S. CONST. amend. XIV, § 5; Shapiro, *supra* note 55, at 839.

172. *Roe v. Wade*, 410 U.S. 113, 154 (1973); Attanasio, *supra* note 70, at 1303.

173. There have been many decisions upholding economically redistributive statutes establishing minimum wages, maximum hours, and collective bargaining. See generally *United States v. Darby*, 312 U.S. 100 (1941); *Labor Bd. v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 33–34 (1937). But see *Pollock v. Farmers’ Loan & Trust Co.*, 157 U.S. 429 (1895) (declaring income tax unconstitutional as an impermissible restraint on liberty).

convictions.<sup>174</sup> With respect to health care in particular, the Court in *Jacobson v. Massachusetts* endorsed compulsory child vaccination statutes.<sup>175</sup> The Court maintained with respect to individual objectors to vaccinations,

[w]e are unwilling to hold it to be an element in the liberty secured by the Constitution of the United States that one person, or a minority of persons, residing in any community and enjoying the benefits of its local government, should have the power thus to dominate the majority when supported in their action by the authority of the state.<sup>176</sup>

The Court argued that subjugating the welfare of the population to the notions of a single individual is a “spectacle.”<sup>177</sup> However, restrictions on germ-line genetic enhancement will likely face a more lenient standard.<sup>178</sup> When evaluated in the tradition of ordered liberty, it is difficult to find a place for the chemical manipulation of genetic structure in our history and traditions.<sup>179</sup> The government may successfully argue that a legitimate state interest exists for making age-enhancement a decision for each individual to make for themselves, and that it is inappropriate for parents to make age-enhancement determinations for the unborn.<sup>180</sup>

#### b. Equal Protection Clause of the Fourteenth Amendment

Congress may find that anti-aging therapies violate the spirit of the Fourteenth Amendment’s Equal Protection Clause if Congress anticipates that discrimination will result.<sup>181</sup> Congress can exercise its powers under Section Five of the Fourteenth Amendment to enact laws in furtherance of the Amendment.<sup>182</sup> Congress may reason that pressure

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174. *Cleveland v. United States*, 329 U.S. 14 (1946); *Jacobson v. Massachusetts*, 197 U.S. 11, 29 (1905); *Reynolds v. United States*, 98 U.S. 145 (1878).

175. *Jacobson*, 197 U.S. at 29.

176. *Id.* at 38.

177. *Id.* However, this logic would dictate that if access somehow posed no problem, and relatively few citizens did not pursue anti-aging therapy, the Court would not sustain an outright ban.

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

179. See Attanasio, *supra* note 70, at 1288.

180. See NOZICK, *supra* note 78, at 78. Robert Nozick contends that self-knowledge is integral to the existence of a self. *Id.* at 78–82. A fetus has the self-contained capacity to develop moral personality or self-reference—whereas a sperm cell or an egg does not—and is thus a separate genetic entity. See Attanasio, *supra* note 70, at 1294 (explaining a pro-enhancement point of view).

181. *Fullilove v. Klutznick*, 448 U.S. 448 (1980) (allowing Congress to act based on speculation and projection about a drug in development with respect to Equal Protection); Attanasio, *supra* note 70, at 1320.

182. U.S. CONST. amend. XIV, § 5. “The Congress shall have power to enforce, by appropriate legislation, the provisions of this article.” *Id.*

to take anti-aging drugs will be so coercive<sup>183</sup> on individuals that there will effectively be a “taking” of their liberty interest in refraining from their use, subjecting them to further oppression and manipulation.<sup>184</sup> Even if an anti-aging drug were made freely available, the government may argue that the problem remains; the few that either decline therapy or still cannot afford it will find themselves further isolated.<sup>185</sup> In all these situations, however, the non-enhanced would have to retain sufficient political power to influence Congress to enact these measures, perhaps in opposition to the enhanced, who may be more powerful politically.<sup>186</sup>

### c. The Thirteenth Amendment

The Thirteenth Amendment prohibits slavery and involuntary servitude.<sup>187</sup> Congress is empowered to pass all laws necessary and proper for abolishing badges and incidents of slavery and “to translate that determination into effective legislation.”<sup>188</sup> Congress may conclude that anti-aging therapy will inevitably subject people to extreme inferiority, violating the minimum equality condition of this Amendment.<sup>189</sup> For example, if Congress determines that the introduction of anti-aging medication would inevitably prevent the non-enhanced from obtaining quality job prospects, it may ban anti-aging on the basis that it subjects the non-enhanced to a permanent position of inferiority.

### d. Nobility Clause

Congress could reference the constitutional prohibitions against conferring titles of nobility, as indicative of the Framers’ intent to limit strong social stratifications.<sup>190</sup> The case of germ-line genetic enhancement via anti-aging technology deserves special attention.<sup>191</sup>

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183. People often do things under adverse circumstances that they would rather avoid for fear others will gain advantages over them. Shapiro, *supra* note 55, at 797. This may disputably be called coercion. *Id.*

184. *See id.* at 784.

185. *See* Attanasio, *supra* note 70, at 1328 n.272.

186. *See id.* at 1314; Shapiro, *supra* note 55, at 779.

187. U.S. CONST. amend. XIII, § 1.

188. *Jones v. Alfred H. Mayer Co.*, 392 U.S. 409, 439–40. The Supreme Court has held that the concept extends a certain distance, and comprehends education and employment. Attanasio, *supra* note 70, at 1309 n.184.

189. *See* Attanasio, *supra* note 70, at 1309. This can be refuted on a technical basis by strictly interpreting the Thirteenth Amendment to proscribe slavery and rigid aristocracy. *See id.* The goal would then be to assure equal opportunity to participate in the majoritarian political process, not a generalized equality of condition. *Id.* at 1310.

190. U.S. CONST. art I, § 9, cl. 8; *id.* § 10, cl. 1. The prohibitions against titles of nobility are somewhat indeterminate. *See also* Note, *Eugenic Artificial Insemination: A Cure for Mediocrity?*, 94 HARV. L. REV. 1850, 1858–61 (1981).

191. *See supra* Part II.A. *See also* *Diamond v. Chakrabarty*, 447 U.S. 303 (1983) (allowing patenting of genetically engineered bacteria and rejecting arguments about “depreciating the value of life”).

Given that this would create an enhanced lineage, instead of an enhanced person, the Congress may effectively invoke the spirit behind the prohibitions against nobility in the Constitution<sup>192</sup> in support of a ban. The government may point out that risks of social stratification increase when the enhancement is permanent and does not depend upon repeated renewal.<sup>193</sup> Constitutional grounds for a challenge to such government action are provided *infra* in Part III.D.

## 2. Avenues for Regulation

States may regulate areas protected by liberty and privacy rights.<sup>194</sup> *Roe v. Wade* specifically mentions that states “may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life.”<sup>195</sup>

Congress can substantially regulate the anti-aging business under the Commerce Clause.<sup>196</sup> This would allow Congress to potentially ban interstate transport of an anti-aging drug, or impose myriad regulations on its use.<sup>197</sup> The Commerce Clause could also permit restrictions on the very manufacture of the product, but only if Congress can show that its manufacture substantially affects interstate commerce.<sup>198</sup> Medical technology is generally not an area of regulation restricted to the states, so there would likely be no federalism<sup>199</sup> issues.<sup>200</sup> Congress’ taxing and spending powers could also be used to persuade states to adopt certain policies in promotion of constitutional rights.<sup>201</sup> Conditions on the application of these powers exist, however, as taxes must be reasonably

192. U.S. CONST. art. I, § 9, cl. 8; *id.* § 10, cl. 1. The Nobility Clause, however, is not literally violated unless Congress or a state actually confers noble status. Attanasio, *supra* note 192, 1308 n.178.

193. See Shapiro, *supra* note 55, at 779. Michael C. Langan, President of the National Organization for Rare Disorders, warns with respect to germ line enhancements generally, “[e]ventually 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.” Rick Weiss, *Gene Enhancement’s Thorny Ethical Traits; Rapid-Fire Discoveries Force Examination of Consequences*, WASH. POST, Oct. 12, 1997, at A1.

194. *Roe v. Wade*, 410 U.S. 113, 154 (1973).

195. *Id.*

196. See U.S. CONST. art. I, § 8, cl. 3. See e.g., REDLICH ET AL., *supra* note 43, at 97–116.

197. An anti-aging drug that does not move in interstate commerce may be outside the Commerce Clause’s reach. See Kramer, *supra* note 134.

198. See *United States v. Lopez*, 514 U.S. 549, 559 (1995).

199. REDLICH ET AL., *supra* note 43, at 47 (“American federalism is composed of the following elements: (1) a union of autonomous states; (2) the division of powers between the federal government and the states; (3) the direct operation of each government, within its assigned sphere, on all within its territorial limits; (4) the provision of each government with the complete apparatus of law enforcement; and (5) federal supremacy over any conflicting assertion of state power.”) (citing E. CORWIN, *THE CONSTITUTION OF THE UNITED STATES OF AMERICA: ANALYSIS AND INTERPRETATION* xi (1952)).

200. Attanasio, *supra* note 70, at 1324.

201. Shapiro, *supra* note 55, at 839.

calculated to provide for the general welfare.<sup>202</sup> The conditions attached to the receipt of federal funds under the Spending Clause must be related to the purpose of the grant.<sup>203</sup> Furthermore, Congress can withhold funding to the National Institute of Health to research anti-aging generally or other specific types of research that it finds troublesome.<sup>204</sup>

### 3. Remedial Measures

Congress and state governments can also take remedial steps to address any harmful consequences stemming from the approval of an anti-aging drug.<sup>205</sup> One such step concerns the widening gap between the enhanced and the non-enhanced, possibly leading to the creation of a caste-system.<sup>206</sup> Congress and state legislatures could also promote equal opportunity in employment by enacting laws that prohibit discrimination against the enhanced (due to personal disapproval) or the non-enhanced (on the assumption that they will be less talented).<sup>207</sup> Presuming that the Supreme Court continues its policy of not shielding people from distributive standards based on ability,<sup>208</sup> federal and state governments may redress superior ability (in the form of increased longevity) that results in superior wealth by taxing income and inheritance progressively.<sup>209</sup> Governments may also institute affirmative action to help those without a legacy of germ-line enhancement or personal somatic enhancement.<sup>210</sup> However, a new schematic for affirmative action will cause tremendous controversy, and the costs of enforcement and determination of disadvantage may be insurmountable.

Congress may have to enact a host of administrative changes to deal with the consequences of a class of age-enhanced individuals. Most notably, to avoid a long-term fiscal crisis, Congress may find it necessary to revamp the simple age requirement for Social Security.<sup>211</sup> Given the variations in extent and duration of anti-aging therapies that might be taken by Americans, Congress will find it difficult to set one fair age at which Social Security benefits begin. Formulas might be employed on an

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202. See REDLICH ET AL., *supra* note 43, at 77–78 (explaining that the taxing power is related to generating revenue but may have other purposes, including welfare and the power to destroy unfavorable things). Justice John Marshall once wrote that “[t]he power to tax involves the power to destroy.” *McCulloch v. Maryland*, 17 U.S. (4 Wheat.) 316, 431 (1819).

203. See *South Dakota v. Dole*, 483 U.S. 203, 208–09 n.2 (1987).

204. See *Patterson*, *supra* note 28, at 922.

205. See *Shapiro*, *supra* note 55, at 839.

206. See *supra* Part III.A.4.

207. This may be akin to Title VII of the Civil Rights Act of 1964 § 703, 42 U.S.C. § 2000e-2(a) (2000), which enforced the right of equal access to employment.

208. See generally James V. Dick, Note, *Equal Protection and Intelligence Classifications*, 26 STAN. L. REV. 647 (1974).

209. 26 U.S.C. §§ 1–1564, 2001–09 (2000); Attanasio, *supra* note 70, at 1276 n.10.

210. See Attanasio, *supra* note 70, at 1307–08; Shapiro, *supra* note 55, at 839.

211. United States citizens are universally entitled to Social Security at age 65. 42 U.S.C. § 1395c (2000).

individual basis, or Congress might overhaul the entire system. As for structural changes, a constitutional amendment may be required to re-evaluate the life terms given to Supreme Court justices, in order to ensure that the judiciary evolves with the population and that a few individuals do not dominate it for decades.<sup>212</sup>

#### *D. Legal Challenges to a Governmental Ban on Anti-Aging*

##### *1. Constitutional Concerns*

###### *a. General Liberty Interest*

If government severely restricts use of a safe, FDA-approved anti-aging therapy, it may run afoul of important legal principles. Libertarians may argue that the right to extended life is a *property* right that government may not regulate.<sup>213</sup> *Lochner v. New York* and its progeny gave constitutional protection to labor, recognizing ability as a worthy property interest.<sup>214</sup> If ability is a property interest protected under the Constitution, then one can claim that prolonged life should be similarly protected.

If the ban is imposed for egalitarian reasons, the challengers can respond by pointing out an inconsistency. The Constitution routinely underwrites the economic value of disparities in potential by protecting private property, even when acquired as a result of differential ability or circumstances.<sup>215</sup> The government routinely distributes jobs based on the natural mental ability of individuals.<sup>216</sup> It has been shown that beneficial mental traits, such as conscientiousness, are genetic,<sup>217</sup> so opponents of an egalitarian-justified ban on anti-aging drugs may correctly question why advantage based on ancestry is fair and advantage that one purchases is unfair.<sup>218</sup> The libertarians will further argue that traditional equal protection theory does not protect majorities, as they can help themselves through the political process.<sup>219</sup> In addition, libertarians will argue that the wealthy few generally have a rational self-interest in

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212. This assumes many Supreme Court justices will serve as long as their health allows.

213. Attanasio, *supra* note 70, at 1276.

214. *Id.* See, e.g., *Lochner v. New York*, 198 U.S. 45 (1905).

215. Attanasio, *supra* note 70, at 1276 n.11.

216. *Id.* at 1276.

217. STEPHANIE CEMAN, MEDICAL GENETICS 300, CURRICULUM 305 (2004).

218. In other words, why is benefit by design less fair than benefit by nature?

219. Attanasio, *supra* note 70, at 1312. The state action in the case of an anti-aging drug would be its approval by the FDA. However, absent a discriminatory purpose, it is unlikely that a successful challenge to government approval would result on grounds of Equal Protection. See, e.g., *Washington v. Davis*, 426 U.S. 229 (1976).

alleviating inequality by redistributing the increased resources they generate.<sup>220</sup>

b. Application of the Equal Protection Clause

Opponents of an anti-aging ban can challenge the reasoning of Congress through use of the Equal Protection Clause, given that courts ultimately interpret that Clause.<sup>221</sup> Courts have repeatedly refused to view the poor as a suspect class,<sup>222</sup> although challengers of a ban will argue that Congress holds the poor in such a light. Wealth disparities count for little in constitutional jurisprudence,<sup>223</sup> and the Court historically has rejected claims based on economic inequality when faced with competing liberty claims.<sup>224</sup> Therefore, even if Congress proposes an egalitarian reason for the ban, it will not easily overcome the Fourteenth Amendment liberty interest in taking the drug.<sup>225</sup> Courts will decide this on the merits because Congress cannot make laws that oppose the Court's interpretation of the Constitution.<sup>226</sup> Recent Supreme Court decisions have indicated that congressional powers under Section Five of the Fourteenth Amendment are not as expansive as previously thought.<sup>227</sup> Under intermediate scrutiny, the government must show the importance of its identified interests and that the means selected to further those interests are reasonably narrowed so as to promote them without an undue impingement on the liberty interest.<sup>228</sup> A challenger to a government ban can legitimately bring up possible regulatory schemes and policies that Congress could alternatively enact to achieve its Equal Protection objective without an outright ban. Given the fact that the Court has used various and vague standards of review when dealing with

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220. RICHARD A. POSNER, *THE ECONOMICS OF JUSTICE* 89–90 (1981).

221. See *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

222. See *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 22–23 (1973); *Dandridge v. Williams*, 397 U.S. 471, 484 (1970).

223. Attanasio, *supra* note 70, at 1323 (citing *Maher v. Roe*, 432 U.S. 464, 471–74 (1977); *Dandridge*, 397 U.S. at 485).

224. Claims of liberty have often made economic inequality worse. See *First Nat'l Bank of Boston v. Bellotti*, 435 U.S. 765 (1978) (noting that free speech extended to corporations, superceding individual claims of unequal ability to speak); *Buckley v. Valeo*, 424 U.S. 1 (1976) (per curiam) (striking down a federal campaign act limiting the amount a candidate can spend on his own campaign); ROBERT NOWAK, RONALD ROTUNDA & R.J. NELSON YOUNG, *CONSTITUTIONAL LAW* 731–34 (2d ed. 1983).

225. See *Miss. Univ. for Women v. Hogan*, 458 U.S. 718, 732 (1982); Attanasio, *supra* note 70, at 1322 n.245.

226. *Cooper v. Aaron*, 358 U.S. 1, 18 (1958); *Marbury*, 5 U.S. (1 Cranch) at 177.

227. Shapiro, *supra* note 55, at 839. See also, e.g., *United States v. Morrison*, 529 U.S. 598, 627 (2000) (holding that the Violence Against Women Act exceeded Congress' authority under the Commerce Clause and Section Five); *City of Boerne v. Flores*, 521 U.S. 507, 536 (1997) (holding that the Religious Freedom Restoration Act exceeded Section Five power); *United States v. Lopez*, 514 U.S. 549, 567–68 (1995) (holding that Congress exceeded its power under the Commerce Clause by regulating intrastate non-economic activity).

228. Shapiro, *supra* note 55, at 835 n.133. See generally ERWIN CHEMERINSKY, *CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES* § 6.5 (1997).

Section Five powers, a Court decision on this matter will likely involve some subjectivity and general fairness considerations.<sup>229</sup>

### c. Right to Privacy

The most promising avenue of constitutional protection of consumption of anti-aging therapy involves the right to privacy found in the Fourteenth Amendment.<sup>230</sup> While the Constitution does not explicitly mention any such right, “the Court has recognized that a right of personal privacy, or a guarantee of certain areas or zones of privacy, does exist under the Constitution.”<sup>231</sup> According to the Supreme Court, “only personal rights that can be deemed ‘fundamental’ or ‘implicit in the concept of ordered liberty,’ are included in [the] guarantee of personal privacy.”<sup>232</sup> So in the context of anti-aging technology, a challenger would have to argue that the ability to live longer and fulfill one’s dreams is implicit in ordered liberty. It is a rather strong case, given how the argument echoes the unalienable rights of “life, liberty, and the pursuit of happiness.”<sup>233</sup> If the Constitution protects essential activities, then perhaps the years in which one performs those activities merit fortification. In this realm, fundamental rights decisions often rest on notions of tradition.<sup>234</sup> The Court upheld abortion as a fundamental right based on procreative liberty, and it reasoned that abortion was not historically considered categorically reprehensible.<sup>235</sup> By contrast, the grounds are even stronger for an anti-aging drug, given the storied tradition of a search for the fountain of youth through science and discovery.<sup>236</sup> A legal challenge to a government ban may go even further and link our society’s desire to remain youthful to a First Amendment right to freedom of thought and expression, in that disallowing extended life cuts short one’s ability to increase in intellect and complex expression.

If the Court declares that anti-aging is a fundamental right, then the government must present a “compelling state interest” to justify a ban, and Congress must narrowly draw any legislative measures to satisfy this interest.<sup>237</sup> This would be a difficult standard for Congress to meet with regards to an outright ban of anti-aging therapy, given the wide variety of remedial measures available to address the negative consequences of

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229. See Shapiro, *supra* note 55, at 835 n.133.

230. See generally *Roe v. Wade*, 410 U.S. 113 (1973).

231. *Id.* at 152–53. In *Griswold v. Connecticut*, 381 U.S. 479 (1965), the Court overturned a Connecticut ban on the use of artificial contraceptives by married couples, finding the right to privacy.

232. *Roe*, 410 U.S. at 152.

233. THE DECLARATION OF INDEPENDENCE para. 1 (U.S. 1776).

234. Attanasio, *supra* note 70, at 1288.

235. See generally *Roe*, 410 U.S. 113.

236. See *supra* Part II.A.

237. *Roe*, 410 U.S. at 155–56.

anti-aging therapies.<sup>238</sup> Furthermore, the Court will likely not give much weight to ethical concerns regarding immortality or extended life. With regard to the issues of when life begins, Justice Blackmun in *Roe v. Wade* wrote:

[w]e need not resolve the difficult question of when life begins. When those trained in the respective disciplines of medicine, philosophy, and theology are unable to arrive at any consensus, the judiciary, at this point in the development of man's knowledge, is not in a position to speculate as to the answer.<sup>239</sup>

He further reasoned that “by adopting one theory of life, Texas may override the rights of the pregnant woman that are at stake.”<sup>240</sup> If the Court follows this model, it will not allow any government entity to restrict the liberty or privacy right to anti-aging based upon a single ethical theory with respect to life extension.

## 2. *Unique Legal Challenges to a Ban on Germ-Line Therapy*

Parents insistent on enhancing their offspring with anti-aging properties may invoke the specific principle of procreative liberty in the right to privacy articulated most prominently in *Roe v. Wade*.<sup>241</sup> Under that doctrine, parents may assert a fundamental right to regulate aspects of their procreation, including genetic enhancements.<sup>242</sup> It is established that 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.<sup>243</sup> This selective right to reproduce children with only certain genetic characteristics “may thus be articulated as a pre-birth right to select or control offspring characteristics.”<sup>244</sup> With respect to the argument that this practice would exert excessive control over a child's future, the Court has previously safeguarded a similar parental right to choose a child's religious upbringing.<sup>245</sup> That right is arguably more invasive than pre-determining lifespan as religion implicates the very nature of the child's existence and potentially the child's post-mortem. The Court further extended the procreative liberty framework in *Lawrence v. Texas*, in which the Court struck down laws against sodomy because of their impact on the intimate personal choices of homosexuals.<sup>246</sup> Indeed, the *Lawrence* majority drew on the importance of reproductive rights as the

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238. See *supra* Part III.C.3.

239. *Roe*, 410 U.S. at 159.

240. *Id.* at 162.

241. See Attanasio, *supra* note 70, at 1286–87. See generally *Roe*, 410 U.S. 113.

242. Attanasio, *supra* note 70, at 1286–87.

243. See John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 427 (1996).

244. *Id.*

245. *Wisconsin v. Yoder*, 406 U.S. 205, 213–14 (1972).

246. 539 U.S. 558, 572–78 (2003).

basis for finding an unenumerated right.<sup>247</sup> Thus, the Supreme Court has recognized within the concept of ordered liberty concerning procreation a concept (sodomy) that is actually opposed by tradition.<sup>248</sup> Therefore, the Court could recognize genetic enhancement, which is neither refuted nor advocated by tradition, within procreative ordered liberty due to its close affiliation with the process of modern reproduction.

It is true that liberty considerations do not apply to the unborn, because they are not “persons” as used in the Fourteenth Amendment.<sup>249</sup> However, the Court has upheld governmental regulation to benefit the post-viable fetus based on rational state interests.<sup>250</sup> While the abortion decision is made pre-viability, the decision to give birth to an age-enhanced child involves a post-viable fetus, and therefore will not be automatically immune from regulation.<sup>251</sup> Thus, based on prior Court decisions it appears likely that the Court would uphold a prohibition of germ-line alterations if the government presents a rational state interest.

If no prohibition occurs, parents will likely successfully fend off any wrongful enhancement suit by their children. Courts have treated “wrongful life” suits dismissively, limiting collection strictly to medical expenses for deformities.<sup>252</sup> Damages for wrongful enhancement would be subjective, because while enhanced children might fall behind their classmates developmentally, they would then enjoy better long-term health. Given this tradeoff, courts will likely continue their reluctance to empower themselves to override parental decisions in order to protect fetal interests with respect to anti-aging.<sup>253</sup> If there are mishaps in the genetic manipulation, the outcome may differ because the Court has recognized a duty to protect the fetus from prenatal injuries.<sup>254</sup> The Court has allowed recovery if the fetus is born alive, even where the injury occurred before viability.<sup>255</sup>

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247. *Id.* at 565.

248. *See, e.g., id.* at 559.

249. *Roe v. Wade*, 410 U.S. 113, 158 (1973).

250. *See Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992) (allowing states to proscribe abortions once the fetus can survive outside the womb); Attanasio, *supra* note 70, at 1294 (“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.”).

251. *See Attanasio, supra* note 70, at 1294 (“Although *Roe* rhetorically denies such rights, the decision postulates a sliding scale that allows the state to recognize powerful fetal rights that, at viability, even trump maternal rights.”); Patterson, *supra* note 28, at 929.

252. *Turpin v. Sortini*, 643 P.2d 954 (Cal. 1982); *Siemieniec v. Lutheran General Hospital*, 480 N.E.2d 1227 (Ill. App. Ct. 1985); *Procanik v. Cillo*, 478 A.2d 755 (N.J. 1984); *Azzolino v. Dingfelder*, 322 S.E.2d 567 (N.C. Ct. App. 1984); *Harbeson v. Parke-Davis, Inc.*, 656 P.2d 483 (Wash. 1983) (en banc).

253. CAL. CIV. CODE § 43.6 (West 1982); *Turpin*, 643 P.2d at 959 (asserting that parents, not children, possess authority to make abortion decisions on behalf of their deformed child).

254. Attanasio, *supra* note 70, at 1295.

255. *Id.* at 1295–96.

*E. Egalitarian Objective: Ensuring Access for All?*

If an anti-aging drug enters the market, there will be consumers interested in the treatment that are unable to afford it on their own. Should insurance companies pay for anti-aging medicine, either on their own accord or as a result of a governmental mandate? Should Medicaid and government insurance pay for it? Can Medicare do anything but pay for the treatment? Indeed, having a viable scheme for the problem of access may determine whether the drug clears the hurdle of a potential government ban.<sup>256</sup>

*1. Constitutional Principles and General Policy*

While myriad environmental factors make the ideal of equality of condition impossible,<sup>257</sup> tolerance of a single purchasable factor that elevates selected people in profound ways distances society even more from that ideal. If only a few are able to obtain the therapy, there arises the prospects of a master race of the longevity-enhanced.<sup>258</sup> The enhanced may perceive themselves as having more “intrinsic merit,” having greater use to society, and being more worthy of rewards and power.<sup>259</sup> Can the existence of such a group be challenged on legal grounds?

Yet the Constitution permits great differentiation based on wealth.<sup>260</sup> “The Court repeatedly has refused to hold that the poor are a ‘suspect class’: it has held that poor people do not have any constitutional right to welfare or a particular level of education.”<sup>261</sup> It seems to follow that the poor have no *per se* right to extended life as a subsidized commodity.<sup>262</sup> Individuals will likely appeal a governmental decision not to finance anti-aging pills under Medicaid, on the basis that extending one’s life and enhancing the longevity of offspring implicate fundamental

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256. See *supra* Part III.C for a discussion of legal arguments for a government ban.

257. See Peter Westen, *The Empty Idea of Equality*, 95 HARV. L. REV. 537 (1982). In a representative democracy, representatives have more clout than ordinary citizens. Attanasio, *supra* note 70, at 1310 n.188 and accompanying text. Only if a town-hall meeting were the decision-center could equality of power result. *Id.*

258. John Attanasio predicts this result in the case of humans genetically engineered to be more intelligent or conscientious. See Attanasio, *supra* note 70, at 1306–07 (discussing the point of view that the risk of social stratification is a sufficient egalitarian concern to suppress individual liberty interests associated with a genetic enhancement of intelligence). People with these qualities secure resources disproportionately, and thus permanently tie these qualities to wealth. *Id.*

259. See Shapiro, *supra* note 55, at 809.

260. Attanasio, *supra* note 70, at 1311 (observing that many methods of differentiation based on wealth are permitted by the Supreme Court). See, e.g., *Dandridge v. Williams*, 397 U.S. 471, 486–87 (1970).

261. Attanasio, *supra* note 70, at 1311 (citing *San Antonio Indep. Sch. Dist v. Rodriguez*, 411 U.S. 1, 22–23 (1973); *Dandridge*, 397 U.S. at 485). See also *supra* Part III.D.1.b.

262. See *San Antonio Indep. Sch. Dist.*, 411 U.S. at 23–24. See also *Dandridge*, 397 U.S. at 485. “Fundamental noninterference rights are protected under the United States Constitution. Affirmative (welfare) rights generally are not, even when directed toward increasing or preserving equality in whatever sense.” Shapiro, *supra* note 55, at 790.

rights. However, “judicially declared ‘fundamental rights’ tend to be malleable” and recent Supreme Court decisions have severely limited the reach of these rights.<sup>263</sup> Relevant to this discussion, Supreme Court decisions<sup>264</sup> conclude “that the right to procreative liberty, does not include the right to state financial support of abortions.”<sup>265</sup> In *Harris*, the Court reasoned, “although government may not place obstacles in the path of a woman’s exercise of her freedom of choice, it need not remove these obstacles not of its own creation.”<sup>266</sup> However, the decision in *Harris* has been criticized<sup>267</sup> and rested on a thin majority with four dissents and one concurrence.<sup>268</sup> The gravity of the liberty interest and the consequences of anti-aging therapy may alter the scales. There is the intricate argument that by approving a drug that extends life, the government creates a situation where science has revised the definition of “long life,” presenting an obstacle to achieving the sense of self-actualization that comes with living a long life.

Consumers seeking to democratize access to anti-aging treatment may also invoke the constitutional prohibitions against state conferrals of nobility and badges of slavery. One could argue that government approval of anti-aging without a plan for ensuring widespread access amounts to state conferral of indices of nobility. The age-enhanced will likely have political and physical advantages. In addition, many of these advantages will be readily apparent to the naked eye. The class will likely be somewhat closed with respect to those able to secure treatment; one cannot radically slow aging through perseverance or hard work. Concerns about badges of slavery would be relevant if there is a fear that the superior class would exploit this inequality.

Direct application of the Nobility Clause against the government will face challenges, however. It is true that the Nobility Clause itself would only be triggered if the government distributed a commodity so inequitably as to satisfy the aforementioned test for unconstitutional ennoblement.<sup>269</sup> Failure to distribute even-handedly does not necessarily violate the Nobility Clause.<sup>270</sup> The Clause prevents the government “from concentrating power and resources in an elite class.”<sup>271</sup> The government is not compelled to recognize any “right” to health, education, or other commodity: there is no obligation to aid the poor.<sup>272</sup>

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263. Attanasio, *supra* note 70, at 1290.

264. *Harris v. McRae*, 448 U.S. 297, 316 (1980) (upholding denial of federal funding for abortions); *Maier v. Roe*, 432 U.S. 464, 480 (1977) (upholding denial of state funding for abortions).

265. Attanasio, *supra* note 70, at 1290.

266. *Id.* at 1290 n.85 (quoting *Harris*, 448 U.S. at 316).

267. Christopher A. Julka, Note, *A New Sexual Revolution?: Viagra as Pandora’s Box for the Elderly*, 7 *ELDER L.J.* 409, 443 & n.309 (1997).

268. *Harris*, 448 U.S. at 327–57.

269. Delgado, *supra* note 73, at 122.

270. *Id.*

271. *Id.*

272. *Id.*

So a challenge under this clause cannot target government inaction vis-à-vis a failure to distribute anti-aging therapy appropriately. An effective challenge must instead target the specific FDA approval of anti-aging therapy<sup>273</sup> on the grounds that approval of such a drug creates or sanctions indices of nobility. This presents at least a sliver of hope for opponents of anti-aging, which would not be present in a challenge to a minimally regulated consumer item. A legal challenge implicating badges of slavery may be too remote at such an early stage, given the fact that the therapy has not even entered society.

Aside from potential constitutional issues, there will likely be competing public policy perspectives. The question of whether aging is truly a disorder<sup>274</sup> will be prominent, as “characterizing an alteration as enhancement rather than treatment provides at least a loose policy reason for declining to allocate public or private resources to finance it.”<sup>275</sup> Strong pressures will exist to “expand the boundaries of the disorder treatment model in order to secure insurance” or alternative modes of reimbursement.<sup>276</sup> Also, there will be practical concerns over the creation of a black market, if anti-aging is sufficiently mature when the government proposes a ban.<sup>277</sup>

With respect to Equal Protection, there is also the concern that, paradoxically, wider access to anti-aging therapies may actually cause more isolation of a proposed non-enhanced suspect class.<sup>278</sup> If all but a few obtain it, the situation would avoid the problem of a small master race, but instead may create a distinct subservient race of the non-enhanced. The Equal Protection Clause does not protect any majority, but it may defend a sufficiently “discrete and insular,” non-enhanced minority.<sup>279</sup> When everyone has access to a given genetic or molecular therapy, those moral objectors who refuse to enhance themselves run a greater risk of being isolated than if access were restricted to the wealthy.<sup>280</sup> The Court may adjudicate disputes in such a manner as to protect this disadvantaged group, or permit Congress to use its fact-finding ability to craft laws to address violations of the Equal Protection Clause.<sup>281</sup> If Congress believes that this group may become actively oppressed, it may act based on Thirteenth Amendment concerns.

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273. One could argue that FDA approval constitutes government action for the purposes of showing a conferral of nobility.

274. See *supra* note 132.

275. Shapiro, *supra* note 55, at 778.

276. *Id.* at 806.

277. *Supra* Part III.A.5.

278. *Supra* Part III.C.1.b.

279. *United States v. Carolene Prods. Co.*, 304 U.S. 144, 152 n.4 (1938); Attanasio, *supra* note 70, at 1310, 1312.

280. See Attanasio, *supra* note 70, at 1328 n.272.

281. *Supra* Part III.C.1.b.

## 2. Health Insurance Programs

The final judgments about whether egalitarianism is the prescription for anti-aging will be expressed through the statutory framework of Medicare and government insurance programs, including Medicaid and the United States Veterans Affairs Administration (“Veterans Affairs”).<sup>282</sup> The government may decline to fund this treatment, for reasons that correspond to the reasons for banning the drug—namely the cost and the fear of social changes.

### a. Medicare

Under the charter for Medicare, the government may have no choice but to fund an anti-aging therapy. After the additional prescription drug coverage became law in 2003,<sup>283</sup> “29 million older and disabled Americans that the Congressional Budget Office projects to enroll” received access to approved drugs at an estimated “average savings . . . [of] 37 percent in 2006.”<sup>284</sup> In order for a therapy or drug to receive coverage, it must either be “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”<sup>285</sup> Strictly speaking, slowing the process of aging appears to satisfy at least the first requirement. It is reasonable for the goal of forestalling age-related illnesses because it improves the functioning of anyone undergoing microscopic death-inducing processes of cellular degeneration.

In response, the government could argue that the drug is not necessary to prevent age-related diseases, and natural cellular degeneration is not what the legislature envisioned as a malformed member. Both tenuous arguments would have to be successful in order to restrict Medicare coverage. To look for an analogous situation, consider the fate of Viagra under Medicare. On February 1, 2005, Health and Human Services officials announced coverage of Viagra under the Medicare Prescription Benefit.<sup>286</sup> According to Gary Karr, spokesman for the Centers for Medicare and Medicaid Services, “[t]he law says if it’s an [FDA]-approved drug and it is medically necessary, it has to be covered.”<sup>287</sup> The determination was that Viagra, a lifestyle

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282. Veterans Affairs provides medical benefits, as well as other benefits, to those who served in the military. US Department of Veterans Affairs, Health Eligibility Center, <http://www.va.gov/healtheligibility/> (last visited Nov. 24, 2006); US Department of Veterans Affairs, Veterans Benefits Administration, <http://www.vba.va.gov/> (last visited Nov. 24, 2006).

283. Medicare Prescription Drug, Improvement & Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

284. Laurie Kellman, *Medicare Benefit Will Cover Viagra*, ASSOCIATED PRESS, Feb. 1, 2005.

285. 42 U.S.C. § 1395y(a)(1)(A) (2000).

286. Kellman, *supra* note 284.

287. *Id.*

drug, was medically necessary.<sup>288</sup> This bodes well for the argument of medical necessity for a drug that preserves youthful vigor in a more general sense. The possible prevention of age-related diseases would be added atop that justification, further buttressing the case for coverage. The number of Americans on Medicare is a large group, and if they should begin to take treatment en masse, the physical and societal effects of anti-aging will become very prominent.<sup>289</sup>

b. Medicaid and Veterans Affairs

The greatest benefit from anti-aging will accrue when people take anti-aging medicine *before* they reach old age, and thus some citizens may demand this therapy under Medicaid and Veterans' programs, which cover beneficiaries regardless of age. According to Nancy-Ann DeParle, former Administrator of the Health Care Financing Administration, federal law requires Medicaid to cover federally approved drugs prescribed for medically approved uses with few exceptions.<sup>290</sup> Federal officials may exempt certain drugs after determining, based on evidence from the states, that the medications are being abused or improperly used.<sup>291</sup> Therefore, Medicaid may cover an anti-aging treatment. However, first it would have to enter the list of approved drugs. As mentioned *supra*, legitimate medical reasons exist for prescribing anti-aging therapy, and the case for such prescriptions increases if the therapy is officially a traditional treatment with attractive age-defying side benefits.<sup>292</sup>

Policy concerns may determine the eventual result. While, over the long term, agreeing to extended anti-aging coverage may dramatically reduce the cost of age-related diseases to society, it will require large up-front expenditures by the federal government. However, coverage is likely in the best interests of the federal government: the benefits of averting hospitalization due to age-related illnesses are extremely high and will therefore serve to mitigate the cost of therapy.<sup>293</sup> It is reasonable to suspect this possibility, especially once anti-aging enters the realm of generic competition. Given the political difficulties involved, a

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288. *Id.*

289. As of 2003, Medicare insured over 41 million people. U.S. CENSUS BUREAU, MEDICARE—ENROLLMENT BY STATE AND OTHER AREAS: 1995 TO 2003 (2003), *available at* <http://www.census.gov/compendia/statab/tables/06s0131.xlw>.

290. See Laurie McGinley, *Medicaid Programs Are Told to Pay for Viagra but Monitoring Continues*, WALL ST. J., July 2, 1998, at B5.

291. *Id.*

292. See *supra* Part II.B. Some expect an anti-aging drug will first be tested and introduced as a treatment for a traditional ailment like diabetes or heart disease.

293. See *supra* note 75.

presidential directive could compel coverage of an anti-aging treatment under Medicaid.<sup>294</sup>

With respect to federal programs, Congress has the power to amend programs in which states are allowed to participate. In this way, Congress can effect a change in state policy. For instance, Congress used Medicaid amendments to force participating state governments to pay for Viagra.<sup>295</sup>

Federal decisions on funding need not be based on high-minded principles; rather, considerations of pragmatism may dominate. For example, because only one-tenth of Medicaid patients are adult men, the cost of the Viagra mandate appears to be rather inexpensive.<sup>296</sup> Because it does not serve a distinct age group, the demographic interested in aggressive anti-aging therapy may also comprise a small portion of the Medicaid patient roster.<sup>297</sup> It must be remembered that any person over sixty-five years of age will be eligible for Medicare entitlement and will therefore not depend on Medicaid for the entirety of his or her health care costs.<sup>298</sup>

### c. Private Insurance

Health management organizations (“HMOs”) may elect not to cover anti-aging technology, and this will not necessarily harm consumers. A management or agency problem<sup>299</sup> may be behind decisions by the HMOs, because corporate managers worry about the short-term profit shortfalls that result from the coverage of all aging HMO beneficiaries. Unless an HMO can convince investors of the long-term profit benefits, the HMO’s stock price will suffer and the responsible managers could face risks to their careers. However, consumers may suffer in the short run from coverage, given that “the greater the expansion of coverage of various medical conditions and groups of persons, the higher the price of insurance, and the greater the exclusion of lower income groups.”<sup>300</sup> Until long-term cost savings are realized, widespread private sector coverage of anti-aging therapies may

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294. See Associated Press, *States Told to Ignore Viagra Directive*, BATON ROUGE SUNDAY ADVOC., Aug. 9, 1998, at 12A. On July 2, 1998, the Clinton administration directed states to cover Viagra when medically necessary under Medicaid. *Id.* Previously, state Medicaid programs had to cover a list of federally approved drugs that did not include Viagra. See *Medicaid; States Question Feds About Viagra*, DAYTON DAILY NEWS, July 4, 1998, at 4A.

295. Finley, *supra* note 113, at 839.

296. *Id.* at 842 n.39.

297. Medicaid is available only to “certain low-income individuals and families who fit into an eligibility group that is recognized by federal and state law.” Centers for Medicare and Medicaid Services, Medicaid Overview, <http://www.cms.hhs.gov/MedicaidGenInfo> (last visited Oct. 4, 2006).

298. See *supra* note 35.

299. An agency or management problem results when the person or agent entrusted with a responsibility fails to fulfill the overarching mission due to his or her own personal interests.

300. Shapiro, *supra* note 55, at 806.

actually increase the burden on lower income persons.<sup>301</sup> Despite this reality, individuals seem to prefer coverage of lifestyle drugs (arguably the proper category for anti-aging), and may apply pressure to obtain coverage.<sup>302</sup> According to a poll by the Kaiser Family Foundation, forty-nine percent of Americans believe that health plans should cover Viagra.<sup>303</sup>

At any rate, private insurers are not immune from regulation. A handful of state governments imposed a mandate on private insurers to cover Viagra,<sup>304</sup> and a similar story might play out for anti-aging drugs. Aside from direct mandates from the government, individuals may have legal options. Consider the following possibilities.

i. Employee Retirement Income Security Act (“ERISA”)

Employee health plans are subject to special legislation governing drug coverage. In 1998, plaintiffs with diabetes-induced erectile dysfunction sued their employee benefit plans for violating ERISA, 29 U.S.C. § 1001(3), claiming that the plans wrongfully “refused to provide coverage for Viagra which had been prescribed for them as medically necessary, by a physician following FDA approval.”<sup>305</sup> Pursuant to ERISA, 29 U.S.C. § 1104, the plans owed the class “a duty of loyalty and care, and a duty not to act in a discriminatory, arbitrary or capricious manner toward any participant in the plans.”<sup>306</sup> Employee benefit plans would face the same scrutiny in the case of an anti-aging drug.

ii. Enforcing Terms of Policies

Many HMOs provide coverage for all medically necessary procedures and drugs dispensed at participating pharmacies based on prescriptions from participating physicians.<sup>307</sup> Like employee benefit plans, many major HMOs retreated from Viagra coverage when the costs became apparent.<sup>308</sup> Many cited alternate reasons, such as reports of

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301. *See id.*

302. *See* Michael Grunwald, *U.S. Judge Asserts Need for More Viagra Coverage; Huge Sums at Stake over ‘Lifestyle Drug’ Claims*, WASH. POST, Mar. 27, 1999, at A03 (“Pfizer estimates that forty percent of American health plans cover at least some Viagra pills.”).

303. *Id.*

304. Finley, *supra* note 113, at 839.

305. *See Class Action Complaint Filed in N.Y. Federal Court on Behalf of Viagra Users*, MEALEY’S LITIG. REP.: INS., May 19, 1998, at 5 (internal quotations omitted).

306. *Id.*

307. *See* Annotation, *What Services, Equipment, or Supplies Are “Medically Necessary” for Purposes of Coverage Under Medical Insurance*, 75 A.L.R. 4th 763, 768 (1990). Medically necessary drugs and procedures are commonly characterized as directed towards the improvement of the functioning of a body member. *Id.* at 800.

308. *See, e.g., Special Report: Viagra or Bust: Is Pharmacy Cost Crisis Unraveling HMO Utilization Strategy?*, MED. UTILIZATION MGMT., Aug. 6, 1998, 1998 WL 10321912, at \*1 [hereinafter *Special Report*].

cardiac complications.<sup>309</sup> Aetna, a major HMO, maintained that Viagra was an optional medication rather than a medical necessity.<sup>310</sup> It estimated that covering Viagra would add \$50 million a year to its costs, providing the impetus for avoiding coverage.<sup>311</sup>

Given the high short-term cost of covering anti-aging drugs, insurance plans may try to characterize the drugs as optional or cosmetic, and not directed towards the improvement of a malformed body part. The spirited debate would likely center on the malformed requirement. Our bodies appear to have inherent maladaptive processes that lead to cell demise, and the issue is whether this amounts to a malformed body member. Plaintiffs have sued HMOs, arguing that it is the physician's, not the insurance company's, decision to prescribe what is medically necessary according to the insurance policy.<sup>312</sup> A court may, upon hearing expert testimony, determine that an anti-aging pill is medically necessary based on improved cellular function. Alternatively, a court could avoid this issue by citing the nexus of anti-aging therapy to the prevention of age-related diseases.

### iii. Americans with Disabilities Act of 1994 ("ADA")

Another legal basis to compel private insurance coverage is the ADA. Section 302 of the ADA<sup>313</sup> provides that "[n]o individual shall be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person who . . . operates a place of public accommodation."<sup>314</sup> "The term 'public accommodation' is defined to include the 'professional office of a health care provider.'"<sup>315</sup>

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Kaiser Permanente, the nation's largest health maintenance organization, announced on June 21, 1998, that it would exclude coverage of the drug, saying that it is costing the company too much money. By early August, numerous other health insurance providers, including Aetna/U.S. Healthcare, Humana Inc., Prudential Insurance Co. of America, and United HealthCare Corp., also had shied away from coverage of the drug. Prudential is not covering Viagra, pending a final decision by its pharmacy and therapeutics committee, while United HealthCare, with six million members, has an interim policy that pays for up to eight pills a month. Kaiser and Aetna say they will provide coverage through a special rider contract but will not make it part of their normal benefit packages.

Julka, *supra* note 267, at 426-27 (footnotes omitted).

309. *Special Report, supra* note 308, at \*2.

310. *Pfizer Blasts Insurers for Lack of Viagra Coverage*, BEST'S INS. NEWS, July 8, 1998, at 1.

311. *Id.* "Likewise, Kaiser said allowing patients ten pills a month would have cost the company more than \$100 million. That figure eclipses the \$59 million which Kaiser spent in 1997 for all antiviral drugs, including protease inhibitors for treatment of HIV, the virus which causes AIDS." Julka, *supra* note 267, at 427 (footnote omitted).

312. *Pennsylvania Man Files Viagra Lawsuit, Targets Prudential in New Jersey Federal Court*, MEALEY'S EMERGING INS. DISP., June 18, 1998, at 22.

313. 42 U.S.C. §§ 12101-12213 (2000).

314. *Bragdon v. Abbott*, 524 U.S. 624, 629 (1998) (citing 42 U.S.C. § 12182(a)).

315. *Id.* (citing 42 U.S.C. § 12181(7)(F)).

Courts are divided on the issue of whether the ADA applies to insurance policies.<sup>316</sup> Even if a patient has a recognized disability, there may still not be a violation of the ADA if a private insurer refuses coverage. In *EEOC v. Staten Island Savings Bank*, “the Court of Appeals, joining the Third, Seventh and Eighth Circuits, held that insurance distinctions that apply equally to all insured employees do not discriminate on the basis of disability.”<sup>317</sup>

However, at least one district court has held that Title III of the ADA applies to the substance of, rather than merely the access to, an insurance policy.<sup>318</sup> The ADA statute defines disability in part as “a physical or mental impairment that substantially limits one or more of the major life activities of [an] individual.”<sup>319</sup> Furthermore, the Court concluded that the ADA “addresses substantial limitations on major life activities, not utter inabilities.”<sup>320</sup> The Court places no limits on the breadth of the term “major life activity” to exclude limitations that are historically normal.<sup>321</sup> Rather, historically natural conditions, like male impotence, might fall under this rubric because they affect major life activities.<sup>322</sup> A detailed analysis of ADA applicability to Viagra reveals that liability for disparate access is a real possibility.<sup>323</sup>

However, courts have limited protection where the disability is sufficiently natural. Courts that have applied the ADA to health insurance plans have taken the position that an infirmity “[resulting] from the natural aging process, rather than from some disease or defect, is not a ‘disability’ within the meaning of the ADA. . . .”<sup>324</sup> The court in

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316. Julka, *supra* note 267, at 434. The First Circuit Court of Appeals in *Carparts Distribution Center, Inc. v. Automotive Wholesalers Ass’n of New England, Inc.*, 37 F.3d 12, 16 (1st Cir. 1994), held that the ADA does apply to insurance policies.

317. *Saks v. Franklin Covey Co.*, 117 F. Supp. 2d 318, 326–27 (S.D.N.Y. 2000) (citing *Staten Island Savings Bank*, 207 F.3d 144, 148–49 (2d Cir. 2000)). “So long as every employee is offered the same plan regardless of that employee’s contemporary or future disability status, then no discrimination has occurred even if the plan offers different coverage for various disabilities.” *Ford v. Schering-Plough Corp.*, 145 F.3d 601, 608 (3d Cir. 1998).

It is fully consistent with an understanding that the ADA protects the individual from discrimination based on his or her disability to read the Act to require no more than that access to an employer’s fringe benefit program not be denied or limited on the basis of his or her particular disability.

*Staten Island Savings Bank*, 207 F.3d at 151. Requiring equal coverage for every type of disability “would destabilize the insurance industry in a manner definitely not intended by Congress . . .” *Ford*, 145 F.3d at 608.

318. *Connors v. Maine Med. Ctr.*, 42 F. Supp. 2d 34, 45–46 (D. Me. 1999).

319. 42 U.S.C. § 12102(2)(A). HIV patients have been ruled in this class, even though there may be no visible abnormality. See *Bragdon*, 524 U.S. at 628.

320. See *Bragdon*, 524 U.S. at 641.

321. See *id.* at 638. The Court specifically rejected the notion that the ADA covers only those aspects of a person’s life that have a “public, economic, or daily character.” *Id.* Thus the fact that a person without age-enhancement is not immediately detectable or economically affected is immaterial.

322. See generally Julka, *supra* note 267.

323. *Id.* at 439.

324. *Saks v. Franklin Covey Co.*, 117 F. Supp. 2d 318, 326 (S.D.N.Y. 2000) (holding that a post-menopausal woman cannot claim disability for her inability to reproduce since her body is functioning

*McGraw v. Sears, Roebuck, & Co.* held that women in, during, or after menopause do not suffer from an ADA disability merely because menopause impairs their ability to have children.<sup>325</sup> Rather, it took “judicial notice of menopause as an entirely normal consequence of human aging.”<sup>326</sup> As a result, the court denied ADA applicability for a reproductive deficiency, even though reproduction is a major life activity. The Court today would likely view cellular aging in the same vein. However, a federal court recognized as a fascinating question whether there would be a disability if the normal arrival of an infirmity had arrived abnormally early—as in premature menopause.<sup>327</sup> If, due to use of an anti-aging drug over time by the privileged, individuals (and perhaps their descendants) age at vastly different rates, then it will become increasingly difficult to characterize a particular rate of aging as “normal.” An individual that lacks age-retarding faculties may be regarded as having a physical impairment that (while not currently debilitating) limits life itself, in addition to all associated life activities that decline with age and perish with death. The argument that no discrimination can occur because everyone ages may be refuted by the counterargument that uniformity in aging is quickly vanishing.

#### IV. RECOMMENDATION

Regardless of whether the government considers aging a true disorder, it cannot afford to use this as a justification to avoid involvement in the development and clinical evaluation process of anti-aging drugs.<sup>328</sup> If it approves a potential anti-aging drug for premature aging or for an age-related disease, it has to recognize that people may try to use the drug solely for anti-aging.<sup>329</sup> If it severely restricts access, the drug may still end up on the black market or in the market for unregulated supplements.<sup>330</sup> The government cannot prefer this outcome, as it subjects individuals to a possibly dangerous, unregulated therapy.<sup>331</sup> If the treatment is demonstrated to be safe and effective with proper medical guidance, the FDA should approve the drug.

With respect to Equal Protection, Thirteenth Amendment prohibitions on slavery, and the Nobility Clause, Congress is free to legislate in the spirit of these rules, but it is a difficult leap to declare that anti-aging will inevitably lead to unacceptable social stratification. It

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normally). “When passing the ADA, Congress was not trying to undo the inevitable effects of aging, like some legislative King Canute commanding in vain that the tide not come in.” *Id.*

325. See *McGraw v. Sears, Roebuck & Co.*, 21 F. Supp. 2d, 1017, 1021 (D. Minn. 1998).

326. *Id.*

327. *Id.* (considering whether premature menopause would be a disability within the context of the ADA).

328. See Shapiro, *supra* note 55, at 797.

329. *Supra* Part III.B.

330. *Id.*

331. *Id.*

must be remembered that Congress, state governments, and the deliberative process can address the harmful consequences through remedial legislation and evolving judicial interpretations. As for the equality of condition issue, the effects of disparate access to anti-aging can also be addressed through remedial legislation.<sup>332</sup> Society accepts inequality in many situations, and it is possible that people will accept extended longevity as a luxury item. For the purposes of Equal Protection, the disadvantaged will not be a suspect class unless they are extremely discrete and insular.<sup>333</sup> It is difficult to predict whether this will occur, so future Equal Protection concerns seem insufficient to justify a Congressional ban on anti-aging. If social stratification becomes a real risk, Congress and state governments can implement egalitarian distribution schemes and take other positive measures to prevent isolation and segregation.

Government attempts to proscribe anti-aging across the board will face considerable legal trouble, and should ultimately fail. Congress has the ability to regulate pharmaceutical sales under the Commerce Clause or through other enumerated powers, but it must not violate an individual's constitutional rights.<sup>334</sup> Given the long and proud history of the pursuit for the fountain of youth, it will be difficult to deny that the desire to extend one's longevity has a strong basis in tradition.<sup>335</sup> Anti-aging does not radically alter a person's identity or peak level of merit, like a drug that increases intelligence.<sup>336</sup> Therefore, it is likely that anti-aging will fit comfortably within our traditions of ordered liberty. It will then merit strong protection under the constitutional right to privacy, just like abortion rights. Given the enormous cost savings possible from anti-aging and the important benefit in preventing age-related diseases,<sup>337</sup> concerns over speculative societal changes are more than balanced by the positive aspects.

Germ-line anti-aging enhancement, however, does not have the sufficient basis in ordered liberty to overcome a governmental ban based on legitimate state interests. Government restriction of such therapy will not face as strong a liberty interest.<sup>338</sup> The freedom to enhance one's own longevity may be recognized in Western and non-Western tradition, but this should not extend to enhancing the longevity of one's descendants—individuals who may not desire such an alteration. Due to the nascent stage of current clinical applications of genetic manipulations, safeguarding an entire line of descendants from a possibly dangerous

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332. Affirmative action for the non-enhanced would be an example of remedial legislation.

333. Attanasio, *supra* note 70, at 1310, 1312.

334. *Supra* Part III.C–D.

335. *Supra* Part II.A.

336. *Supra* Part III.A.3.

337. *Supra* Part III.A.1–2.

338. *Supra* Part III.C.1.a.

therapy constitutes a very strong state interest.<sup>339</sup> This should be strong enough to trump invocations of the right to privacy associated with childrearing.<sup>340</sup>

Given the presence of an approved anti-aging drug on the market, many private insurance plans and government insurance plans will have no choice but to cover anti-aging therapies. HMO plans that cover any “medically necessary” drug will have a difficult time arguing that a drug that prevents a broad range of pervasive age-related diseases is not medically necessary.<sup>341</sup> There are interesting legal arguments to compel private coverage under the ADA, but it seems unlikely that a person that ages normally could be considered “disabled” in the near future.<sup>342</sup> Medicare’s prescription drug benefit must similarly cover FDA approved anti-aging drugs.<sup>343</sup> As for Medicaid, the poor are not a suspect class and are therefore not *per se* entitled to government provision of the anti-aging advantage.<sup>344</sup> However, Congress should strongly consider financing anti-aging therapies under Medicaid. The elderly will not be implicated because they are already entitled to Medicare, reducing the costs of covering the remaining impoverished Americans. Covering this group under Medicaid promises to spread the medical costs from age-related diseases over many decades.<sup>345</sup>

## V. CONCLUSION

Anti-aging may come upon society surreptitiously, but preparations should be made today. By finding the mechanisms that underlie the onset of age-related disease, scientists are slowly opening the door to altering the course of aging itself. The nexus of anti-aging to personal health and self-actualization will rightfully protect revolutionary anti-aging technology as the science matures. If it takes hold, anti-aging may leave few aspects of modern life unchanged. However, this in itself is no reason to stop progress and prevent substantial liberty interests from being realized. Humanity has a remarkable record of adjusting to revolutionary technology. The immediate impact of anti-aging is benevolent, although some will benefit more than others. The challenge is to mold a promising new science to conform to the values and interests

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339. *Id.*

340. *Id.* This echoes the reasoning in *Roe v. Wade*, 410 U.S. 113 (1973), but with a different result. Abortion was not unilaterally approved in that case. Rather, the Court reasoned that Texas had not presented a sufficiently strong state interest to counter the liberty interest associated with child-bearing. *Id.* at 162–66. In the case of germ-line alterations, there appears to be a sufficiently strong state interest.

341. *Supra* Part III.E.2.c.

342. *Supra* Part III.E.2.c.iii.

343. *Supra* Part III.E.2.a.

344. *Supra* Part III.D.1.b.

345. Of course, it must be considered whether policy-makers have the foresight to take on a large debt today in order to realize a benefit a long time in the future after their political careers are finished.

contributed by various segments of society. This is always the challenge with technology: a challenge that our nation can surely overcome.