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# CREATING CLONES, KIDS & CHIMERA: LIBERAL DEMOCRATIC COMPROMISE AT THE CROSSROADS

NATHAN A. ADAMS, IV\*

I am thy creature, and I will be even mild and docile to my natural lord and king if thou wilt also perform thy part, that which thou owest me.<sup>1</sup>

Most agree that biotechnology is leading to a revolution in medicine. Less appreciated is the challenge biotechnology poses to the prevailing liberal democratic consensus pertaining to health and welfare. Biotechnology necessarily impinges upon key health and welfare doctrines at the core of our collective understanding of what it means to advance personal autonomy, self-determination, liberty, and equality within a market economy.

Supporters are confident that the biotechnological industry will affirm these values and channel potentially life-saving biotechnological innovations in directions harmless to all but the human embryo.<sup>2</sup> They favor essentially a self-regulated industry, where medical professionals decide whether and when to create or modify human clones, kids, and chimera.<sup>3</sup> In contrast, opponents of biotechnology fear the natural inclination of the market

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1. MARY SHELLEY, *FRANKENSTEIN*, in *THREE GOTHIC NOVELS* 364 (Peter Fairclough ed., 1968).

2. See, e.g., John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 TEX. L. REV. 1371, 1430-31 (1998) [hereinafter Robertson on Cloning].

3. In ancient Greek mythology, the chimera was a fire-breathing monster with a lion's head, a goat's body, and a serpent's tail. Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 443 (1999). As used in this article, the "human chimera" or, for our purposes, simply "chimera" is a being with some cells from a non-human species and some from a human species. In this respect, chimera differ from "hybrids," because every cell of the latter contains one set of chromosomes from one species and one set from another. *Id.* at 445. Not every cell of the chimera includes cells of both species; rather, the chimera incorporates whole cells of one species and whole cells of another species. *Id.*

is to lead us toward "the dehumanized hell of *Brave New World*."<sup>4</sup> They assert a fundamental, deontological right to ban or strictly limit nearly all forms of biotechnological research.

The modest objective of this Article is to find middle ground between these camps by perpetuating the existing legal compromise pertaining to the complete range of health and welfare doctrines relevant to the biotechnological industry. This Article aspires neither to add to nor detract from this liberal democratic consensus, but to preserve its constitutive balance between positivism and natural law and over-regulation and under-regulation in the hopes of stabilizing new political fault lines developing around the few biotechnological innovations already grabbing headlines.<sup>5</sup>

Part I explores human cloning and two other key biotechnologies that will frame the political debate, including genetic screening and genetic engineering. To provide an historical political economic perspective, we compare their development with a standard model of technological change embracing invention, innovation, and diffusion. This section concludes that biotechnology is leading to a more radical transformation of the political economy than any previous cluster of innovations, because it will impact not merely our tools, but our species.

Part II identifies the primary international and national legal regimes that genetic screening, human cloning, and genetic engineering will either radically alter or which will regulate them, including equal protection, reproductive rights, the First Amendment, human subject experimentation rules, patent law, and parental rights. From the constitutional and other legal principles underpinning these regimes we illuminate the contours of the existing liberal democratic consensus.

Part III wrestles with how to extend this consensus to the biotechnological industry without modifying the existing legal regimes. It explores a variety of policy recommendations, which

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4. *The Ethics of Cloning: Testimony Before the House Comm. on the Judiciary, Subcomm. on Crime*, 107th Cong. (June 7, 2001) (statement of Leon R. Kass) (referencing ALDOUS HUXLEY, *BRAVE NEW WORLD* (1932), available at [http://www.house.gov/judiciary/kass\\_060701.htm](http://www.house.gov/judiciary/kass_060701.htm) (on file with the Notre Dame Journal of Law, Ethics & Public Policy)).

5. Some traditional "pro-life" legislators have found common cause with "pro-choice" legislators favoring human cloning, while other conservative legislators have allied with progressives and feminists against it. See, e.g., Sen. Orrin G. Hatch, *Pro-Life Means Helping the Living: The Case for Regenerative Medicine*, SALT LAKE TRIB., Apr. 30, 2002 (pro-life conservative Sen. Orrin Hatch favors research cloning); Janelle Carter, *Senate Debates Human Cloning*, ASSOCIATED PRESS, Feb. 5, 2002 (pro-choice liberal Sen. Mary Landrieu co-sponsors bill to ban human cloning).

become tougher as the legal issues become less familiar and jurisprudential philosophies are counterposed. Biotechnology uniquely raises questions like what rights should be accorded *ex vivo* living human embryos. Applying the special respect paradigm, I conclude human embryos merit some substantive rights the unregulated biotechnological industry would not accord them.

In *Frankenstein*, Mary Shelley reminds us of the consequences of failing to temper technology.<sup>6</sup> Victor Frankenstein created a monster that when released into the world without direction or moral guidance was left to create a community on its own violent terms that proved less humanitarian than the society from which the creature emerged.<sup>7</sup> In the last scene, the monster destroys its creator.<sup>8</sup> This Article offers one strategy for avoiding a similar mistake: merely extending the prevailing legal regime to govern biotechnology.

## I. FRANKENSTEIN INNOVATES

This section explores the radical implications of genetic screening, human cloning, and genetic engineering for the political economy. It compares the path that biotechnology is taking with a standard model of radical technological change, and concludes that biotechnology will lead to an even more radical transformation of the political economy than other technologies have caused.

### A. *Standard Model*

Scholars have developed a standard model for technological change incorporating three phases: invention, innovation, and diffusion.<sup>9</sup> Invention is the process of arriving at an idea for a product or process and demonstrating its feasibility.<sup>10</sup> Innovation is the process by which the invention is first brought into use through improvements and refinements of the invention.<sup>11</sup> Diffusion involves the spread of the innovation into general use,

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6. SHELLEY, *supra* note 1.

7. *See generally id.*

8. *Id.*

9. *See* LOUIS A. GIRIFALCO, DYNAMICS OF TECHNOLOGICAL CHANGE 3 (1991); JOSEPH A. SCHUMPETER, CAPITALISM, SOCIALISM AND DEMOCRACY (1966).

10. GIRIFALCO, *supra* note 9, at 3.

11. *Id.*

thereby impacting the political economy.<sup>12</sup> Ordinarily, this process follows what is termed an S-curve.<sup>13</sup>

At the bottom of the S-curve, the slope is relatively flat. This is because in the initial phase after invention, an innovation spreads slowly due to its high price, novelty, and inefficiency.<sup>14</sup> As the innovation improves, more consumers adopt it, providing experience, feedback, and funds for additional advances attracting more consumers.<sup>15</sup> The curve steepens as diffusion increases rapidly. However, the rate of diffusion ultimately slows again as further improvements are impossible, economies of scale are maximized, and most of the public has purchased the innovation.<sup>16</sup> The S-curve flattens again at this point.

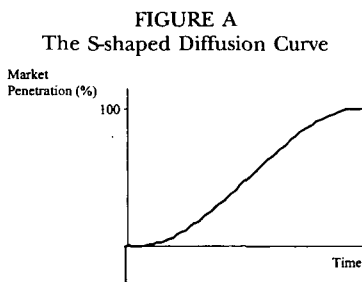
Innovations usually cluster together, reinforcing one another and diffusing together along the S-curve or slowing one another down.<sup>17</sup> Bottlenecks involving one innovation in a cluster can hinder diffusion of others, whereas advances with one may accelerate the diffusion of others.<sup>18</sup> The invention of the Watt engine with a separate condenser is an example of the latter, because it led to a chain of innovations improving steam engine performance, including rotary motion, the governor, the compound engine, and the high-pressure engines.<sup>19</sup> Improvements in metallurgy, especially iron and steel, also improved the efficiency of the steam engine.<sup>20</sup>

Bottlenecks or advances in technological diffusion are caused not only by technology, but also the legal, institutional,

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12. *Id.*

13. *Id.* at 43. An example of an S-curve is set forth below:



PAUL STONEMAN, *THE ECONOMICS OF TECHNOLOGICAL DIFFUSION* 13 (2002).

14. GIRIFALCO, *supra* note 9, at 35.

15. *Id.* at 35, 43.

16. *Id.* at 33, 35, 40, 43–45.

17. *Id.* at 31, 40, 43. The clustering phenomenon also means that innovations do not take place at a constant rate, but in spurts.

18. *Id.* at 40, 43.

19. *Id.* at 44–45.

20. *Id.* at 45.

and managerial environment.<sup>21</sup> The most radical innovations often arise as pure scientific discoveries, but their diffusion ultimately requires or triggers not merely ancillary technologies, but also socio-technical and legal adaptation.<sup>22</sup> The doctrine of negligence, for example, emerged around 1825, as a separate basis for tort liability “probably stimulated a good deal by the enormous increase of industrial machinery in general and by the invention of railways in particular.”<sup>23</sup>

As an innovation interacts with its environment by requiring or triggering ancillary technologies, socio-technical, and legal changes, it eventually becomes cheap, reliable, and safe enough to create significant consumer demand and, thus, to round the lower S-curve. After introduction of the Watt steam engine and related improvements together with a new liability system, for example, steam technology diffused rapidly from rail to water pumps, sea transport, agriculture, electricity generation, assembly lines, and other areas until the range of possible uses for the Watt engine was exhausted and further improvement of the engine was impossible.<sup>24</sup>

On the upswing of the S-curve, rapid diffusion of an innovation can lead to serious political, social, and economic dislocations. For example, the steam engine and a few other technologies led to the Industrial Revolution,<sup>25</sup> including its radical new patterns of organization, management, and labor, as well as its social externalities.<sup>26</sup>

21. Harvey Brooks, *Social and Technological Innovation*, in *MANAGING INNOVATION: THE SOCIAL DIMENSIONS OF CREATIVITY, INVENTION AND TECHNOLOGY* 12–14 (Sven B. Lundstedt & E. William Colglazier, Jr. eds., 1992).

22. *Id.*

23. P.H. WINFIELD, *LAW OF TORT* 404 (5th ed. 1950) (“At that time railway trains were notable neither for speed nor for safety. They killed any object from a Minster of State to a wandering cow, and this naturally reacted upon the law.”). New ways of organizing work and new institutions to market, deliver, and service a new technology may also be essential to take full advantage of it. Brooks, *supra* note 21, at 14.

24. GIRIFALCO, *supra* note 9, at 45.

25. *Id.* at 307–09, 310–12; see also BROOKE HINDLE & STEVEN LUBAR, *ENGINES OF CHANGE: THE AMERICAN INDUSTRIAL REVOLUTION 1790–1860* 15, 21 (1986); G.N. VON TUNZELMANN, *STEAM POWER AND BRITISH INDUSTRIALIZATION TO 1860* (1978); SIMON KUZNETS, *MODERN ECONOMIC GROWTH: RATE, STRUCTURE, AND SPREAD* 10 (1966) (“[O]ne could argue that of the three major technological inventions associated with the Industrial Revolution—in the fields of cotton textiles, iron, and the steam engine—the last was by far the most important and fundamental to subsequent [economic] growth . . .”).

26. The steam engine increased the feasibility of factory production and mechanization away from water; inspired large corporate organization, occupational specialization, and urbanization; attracted workers from agrarian employment and craft guilds; and is associated with the establishment of a modern

Structuralists have tried to generalize about the cyclical impact of radical clusters of innovations on the international political economy.<sup>27</sup> At the micro level, product business cycles are well accepted, suggesting that as a technology ages, social displacements occur as manufacturing moves to less developed countries where factors of production are cheaper.<sup>28</sup> At the macro level, Kuznets, Schumpeter, and Mensch drew a causal connection between the so-called Kondratieff long wave and the most radical technology clusters to date.<sup>29</sup> Other scholars have tried to draw linkages between these long cycles and international conflict and changes in world leadership.<sup>30</sup>

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system of exchange, cost accounting, communication, transportation networks, social stratification, pollution, and political centralization. TUNZELMANN, *supra* note 25, at 6; Wilbert E. Moore, *Industrialization and Social Change*, in *INDUSTRIALIZATION AND SOCIETY* 301 et seq. (Bert F. Hoselitz & Wilbert E. Moore eds., 1970).

27. Oswald Spengler developed a cultural life cycle model around the notion that society is held together by a set of implicit assumptions that later generations challenge and either replace or destroy causing cultural renewal or decline. See OSWALD SPENGLER, *THE DECLINE OF THE WEST* (Charles Atkinson trans., 1926). Pitirim Sorokin argued that social change is inevitable and must be compensated for to avoid overwhelming culture. See PITIRIM SOROKIN, *SOCIAL AND CULTURAL DYNAMICS* (abr. 1957). Arnold Toynbee developed the concept of challenge and response as an organizing principle for understanding human history. See ARNOLD J. TOYNBEE, *A STUDY OF HISTORY* (abridgement by D.C. Somervell 1946). Karl Marx understood dialectic materialism to involve innovation leading to tension, contradiction, and revolution. See KARL MARX, *DAS CAPITAL* (1867); KARL MARX & FRIEDRICH ENGELS, *THE COMMUNIST MANIFESTO* (1848); see also *Marx's View of Technology*, in NATHAN ROSENBERG, *INSIDE THE BLACK BOX: TECHNOLOGY AND ECONOMICS* (1982). Nikolai Kondratieff associated innovation with 50-year long cycles bringing prosperity, then recession, depression, and recovery. William R. Thompson, *Long Waves, Technological Innovation, and Relative Decline*, 44 INT'L ORG. 201, 216-17 (1990).

28. Brooks, *supra* note 21, at 7.

29. GERHARD MENSCH, *STALEMATE IN TECHNOLOGY* (1979); JOSEPH A. SCHUMPETER, *THE THEORY OF ECONOMIC DEVELOPMENT* (1934); SIMON KUZNETS, *SECULAR MOVEMENTS IN PRODUCTION AND PRICES* (1930). According to these authors, the political economy benefits from a cluster of innovations introduced during a rising business cycle that is exhausted when the innovations have fully diffused and competition results in lower profits and automation in fewer jobs. GIRIFALCO, *supra* note 9, at 17-18. Recession, then depression, stimulates exploration of new opportunities leading to new innovations, restarting the business cycle. *Id.* at 18.

30. Richard Rosecrance, *Long Cycle Theory and International Relations*, 41 INT'L ORG. 283, 286 (1987) (citing NIKOLAI KONDRATIEFF, *THE LONG WAVE CYCLE* 62 (G. Daniels & J. Snyder eds., 1984) ("The greatest number of social upheavals (wars and revolutions) occur during the periods of the rising wave of each long cycle.")). Skeptics reviewing this research have difficulty empirically demonstrating the regularity of the long cycles and their nexus with international conflict in the modern era, but admit a strong relationship between innovation and economic growth. See GIRIFALCO, *supra* note 9, at 18. Some believe

Whether or not these macro linkages exist, the standard model of technological change clearly suggests it triggers social, economic, and legal change. This is not to imply a crude technological determinism diminishing the importance of other influences.<sup>31</sup> Rather, it is merely to emphasize that technological and social and legal inventions are associated and, further, that the most radical innovation clusters have been associated with the most serious dislocations.<sup>32</sup>

Biotechnology is among the most radical innovation clusters ever introduced, because it alone portends modification of the human species, not merely our tools. It would enable us to identify and correct genetic "abnormalities," replicate ourselves, and in the near future modify ourselves and create chimera. The ability to correct "abnormalities" raises intractable questions like who and how will we decide which genetic conditions are "abnormal?"<sup>33</sup> We disagree about the standard for health and welfare; therefore, the distinction between "therapy" and "enhancement" is illusive.<sup>34</sup> If therapy loosely conveys treatment aimed at bringing an unhealthy person to health, whereas enhancement con-

long cycles ceased in modern history and others are skeptical altogether of their correlation with political events; the most charitable analysis reveals the following association:

Innovation	Period	Conflict	Hegemon	Challenger
Cotton, textiles & iron	1780–1817		Britain	France
Railroads, steam & steel	1840–1875	American Civil War	Britain	France
Electricity, industrial chemistry & internal combustion engine	1875–1920	World War I	Britain	Germany
Automobiles, plastics & electronics (including the semiconductor)	1940–1972	World War II, Korean War, Vietnam War	United States	USSR
Biotechnology	1973–		United States	China?

31. Accord Moore, *supra* note 26, at 301.

32. Accord Brooks, *supra* note 21, at 2–3. Interestingly, most of the great technological innovators of the early-twentieth century, such as Henry Ford and Thomas Edison, also considered themselves social reformers. *Id.* at 2.

33. *Id.*; Robertson Parkman, *Gene Therapy in the 1990s*, 65 S. CAL. L. REV. 411, 420 (1991); Gerald Coleman, *Genetic Engineering: Should Parents Be Allowed to Design Their Children?*, 34 How. L.J. 153, 165 (1991).

34. President's Council on Bioethics, *Staff Working Paper 7: Distinguishing Therapy and Enhancement*, available at <http://www.bioethics.gov/workpaper7.html> (last modified Aug. 20, 2002) (on file with the Notre Dame Journal of Law, Ethics & Public Policy) [hereinafter *Staff Working Paper 7*] (noting that some argue "health" is, to quote the World Health Organization, "a state of complete physical, mental, and social well-being," rendering virtually every enhancement also therapeutic, whereas Normal Daniels argues that "disease and disability are . . . departures from species-typical normal functional organization or functioning.").



veys extending some characteristic, capacity, or activity,<sup>35</sup> it is tempting to think that we can adopt a bright line rule permitting the former, but never the latter. In truth, this would still require us to define "normality," because therapies always constitute enhancements, but not vice-versa.<sup>36</sup>

Most human capacities express themselves along a bell curve.<sup>37</sup> The "normal range" within this curve can be defined only with respect to standard deviations from the mean. The number of standard deviations from the mean that count as normal is arbitrary, as is the cut-off point denying therapy to those -3 standard deviations from the mean, but not -2.99.<sup>38</sup> Often-times, even those falling on the mean argue they are "disadvantaged" relative to those above them.<sup>39</sup> Theirs is an argument for choosing something above the mean as the starting point for assessing "normality." The act of enhancing also generally increases the pressure to seek enhancements, thus, contributing to "norm creep."<sup>40</sup>

In a world where biotechnology has fully diffused, certain genetic traits most would consider not as good as others, like cystic fibrosis (CF), could be eliminated and others improved until, according to some, excellence itself would become less a function of human achievement, behavioral modification, and experience than biological determinism.<sup>41</sup> Outlandish, but possible in the distant future, would be entire new quasi-human species with diminished civil rights created for specific tasks, for example, chimera without legs to serve on assembly lines.<sup>42</sup> Some non-liberal states might quickly adopt these innovations with radical implications for the international political economy.

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35. *Id.*

36. *Id.* As an example, the drug Ritalin is used to treat so-called Attention Deficit Disorder (ADD), thought to be related to a pituitary deficiency, but is also taken by Ivy League test-takers to improve concentration. *Id.* Recombinant human growth hormone (rhGH) is administered to children of short stature to assist them to attain "normal" height, but may also be administered to children within the "95% envelope" on the height-age curve in an attempt to make them taller.

37. FRANCIS FUKUYAMA, OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION 130-39 (2002); *Staff Working Paper 7, supra* note 34.

38. *Accord* Parkman, *supra* note 33, at 420.

39. *Staff Working Paper 7, supra* note 34.

40. Coleman, *supra* note 33, at 165.

41. *Staff Working Paper 7, supra* note 34.

42. David A. Prentice, *Brave New World of Genetic Engineering*, 1 NAT'L CATH. BIOETHICS Q. 529, 534 (2001).

### B. *Biotechnological Model*

Biotechnology has been defined as the use of biological organisms for commercial ends.<sup>43</sup> The field embraces a cluster of innovations at different stages of development, including, for example, recombinant DNA technology, antisense technology, DNA amplification, genomics, bioinformatics, proteomics, and transcriptomics.<sup>44</sup> "Recombinant" means "new combination."<sup>45</sup> "Recombinant DNA technology" (rDNA), also known as "genetic engineering,"<sup>46</sup> refers to a method of inserting genetic material from one organism into another of either the same or different species or the process of changing the genetic complement of a cell or an organism.<sup>47</sup>

None of these biotechnologies has advanced in isolation. For example, advances with DNA amplification procedures, including Polymerase Chain Reaction (PCR) and ligase chain reaction (LCR), made rDNA viable;<sup>48</sup> progress with bioinformatics (information technology) required to record, catalog, search, and analyze human DNA facilitated early sequencing of the human genome by June 2000;<sup>49</sup> and this stunning achievement

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43. Martin Fransman, *Biotechnology: Generation, Diffusion and Policy*, in TECHNOLOGY AND INNOVATION IN THE INTERNATIONAL ECONOMY 41, 42 (Charles Cooper ed., 1994).

44. "Bioinformatics is the term coined for the new field that merges biology, computer science, and information technology to manage and analyze [biotechnological] data, with the ultimate goal of understanding and modeling living systems." U.S. DEPT. OF ENERGY HUMAN GENOME PROGRAM, GENOMICS AND ITS IMPACT ON MEDICINE AND SOCIETY: A 2001 PRIMER 3 (2001), at <http://www.ornl.gov/hgmis> [hereinafter GENOMICS AND ITS IMPACT]. Proteomics is "the study of protein expression and function." *Id.* at 6. "Transcriptomics involves large-scale analysis of messenger RNAs (molecules that are transcribed from active genes) to determine when, where, and under what conditions genes are expressed." *Id.* The genome is an organism's complete set of DNA. *Id.* at 1. The study of the genome or genomics may be structural or comparative. *Id.* at 6. The former involves three-dimensional modeling of proteins to uncover clues to their functions and provide biological targets for drug design. *Id.* Comparative genomics compares DNA sequence patterns of humans with well-studied model organisms to identify and interpret gene functions. *Id.*

45. HARRY LEVINE III, GENETIC ENGINEERING: A REFERENCE HANDBOOK 11 (1999).

46. *Id.* at 14; Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 Hous. L. Rev. 1597, 1606 (1993).

47. LEVINE, *supra* note 45, at 11, 14. Antisense technology is in many respects the converse of rDNA, because its object is to suppress or "knock out" a gene that a cell normally expresses. Burk, *supra* note 46, at 1607-09.

48. PCR and LCR make rDNA feasible by amplifying otherwise unusable samples of DNA. *Id.* at 1609-10.

49. FUKUYAMA, *supra* note 37, at 73-74.

five years in advance of the predicted deadline accelerated identification of disease-causing genes.<sup>50</sup>

The first biotechnological inventions date from the 1970s, when the first gene was cloned (1973), the first rDNA experiment was performed on an animal (1974), the first cell fused (hybridoma) (1975), and Sanger and Gilbert independently developed DNA sequencing methods (1977).<sup>51</sup> It was not until 1974 that the public awakened to biotechnology when researchers proposed to insert in bacteria a sequence of DNA from a virus known to cause cancer in monkeys.<sup>52</sup> In response to the public outcry that followed, the scientific community volunteered a 16-month moratorium on rDNA experiments on animals (except humans)<sup>53</sup> and the Department of Health, Education, and Welfare (DHEW) established the first biotechnological regulatory body, the Recombinant DNA Advisory Committee (RAC).<sup>54</sup>

Diffusion of biotechnology could not begin until 1980, when the U.S. Supreme Court held that microorganisms are patentable.<sup>55</sup> The same year, the U.S. Patent and Trademark Office (PTO) issued the Cohen-Bayer patent to Stanford University for the technique related to construction of recombinant DNA (rDNA).<sup>56</sup> In addition, Genentech made its first public offering, setting a record for the fastest stock price increase in the shortest time.<sup>57</sup> Genentech was the first biotechnological firm, founded as a spin-off of university-based research in 1976. By the end of 1981, more than 80 biotechnology firms existed in the United States with close ties to research universities.<sup>58</sup>

50. Francis S. Collins & Victor A. McKusick, *Implications of the Human Genome Project for Medical Science*, 285 J. AM. MED. ASS'N 541 (2001).

51. LEVINE, *supra* note 45, at 1; Fransman, *supra* note 43, at 45; Collins & McKusick, *supra* note 50, at 540. Essential precursors to the inventions were Mendel's laws, Garrod's recognition of their application to inborn errors of metabolism, J.D. Watson and Francis Crick's discovery of the double helical structure of DNA in 1954, and elaboration of the role of RNA as a messenger over the next fifteen years. Collins & McKusick, *supra* note 50, at 540.

52. Joseph M. Rainsbury, *Biotechnology on the RAC-FDA/NIH Regulation of Human Gene Therapy*, 55 FOOD & DRUG L.J. 575, 575-76 (2000).

53. LEVINE, *supra* note 45, at 2-3. Human genetic engineering was excluded from the moratorium, because it was considered too emotionally charged and too far from realization. *Id.* at 3. The moratorium was approved until NIH Guidelines became available. *Id.*

54. Rainsbury, *supra* note 52, at 578-85.

55. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

56. Fransman, *supra* note 43, at 45, 55.

57. *Id.* at 46. Genentech shares surged from \$35 to \$89 per share in twenty minutes. *Id.*

58. *Id.* at 46, 75-77 (Monsanto-Washington Univ.), 78 (Genentech-Stanford Univ.; Celltech-Cambridge Univ.).

From 1993 to 1999, the biotechnology industry doubled in size, producing direct revenues in 1999 totaling \$20 billion and indirect revenues totaling \$27 billion.<sup>59</sup> In the last decade, biotechnological firms have allied and merged with international drug companies to acquire manufacturing, marketing, and distribution channels, rendering effective regulation of biotechnological innovations an international concern and the notion of an "American" biotechnological industry misleading.<sup>60</sup> Most companies now expect that the majority of future drug development will come from biotechnology.<sup>61</sup>

The impact of biotechnology on plants and animals is just taking shape. The first plant engineered with rDNA technology made its commercial debut in 1996: corn that incorporated DNA from bacteria that is toxic to insects.<sup>62</sup> Now, 25% of the corn and 40% of the soybeans that are grown in the U.S. are genetically modified.<sup>63</sup> Overall, ag-biotech plant researchers promise higher yields of allegedly better tasting produce, grown with less water, in inferior soil, and less dependent on fertilizer and pesticides.<sup>64</sup>

On April 13, 1988, the PTO issued the first patent on a higher life form, the so-called Harvard onco-mouse, genetically engineered to express a cancer-causing gene in its mammary tissue for purposes of cancer research.<sup>65</sup> Since this date, the annual U.S. market for animal disease models has reached \$1

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59. GENOMICS AND ITS IMPACT, *supra* note 44, at 9 (citing ERNST & YOUNG, ECONOMIC CONTRIBUTIONS OF THE BIOTECHNOLOGY INDUSTRY TO THE U.S. ECONOMY (2000)).

60. See generally Fransman, *supra* note 43, at 79–81 (Genentech-Eli Lilly and KabiVitrum (Sweden), Kyowa Hakko and Mitsubishi Chemical (East Asia), merged in 1990 with Hoffman-LaRoche (Switzerland) and Celltech-The Boots Co. Sumitomo Corp. and Sankyo (East Asia)); Cheryl D. Hardy, *Patent Protection and Raw Materials: The Convention on Biological Diversity and Its Implications for U.S. Policy on the Development and Commercialization of Biotechnology*, 15 U. PA. J. INT'L BUS. L. 299, nn.49–52 (1994).

61. Collins & McKusick, *supra* note 50, at 543.

62. Fukuyama, *supra* note 37, at 76 (developed by Ciba Seeds (now Novartis Seeds) and Mycogen Seeds).

63. Melinda Kimble, Press Briefing of the U.S. Delegation to the Sixth Meeting of the Working Group on Biosafety Convention on Biological Diversity (1999), at <http://www.usinfo.state.gov> (on file with the Notre Dame Journal of Law, Ethics & Public Policy), cited in Jasmine Chambers, Note, *Patent Eligibility of Biotechnological Inventions in the United States, Europe, and Japan: How Much Patent Policy is Public Policy?*, 34 GEO. WASH. INT'L L. REV. 223, 237 n.4 (2002).

64. David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 FORDHAM INT'L L.J. 990, 994–95 (1992–1993).

65. SHELDON KRIMSKY, *BIOTECHNICS & SOCIETY: THE RISE OF INDUSTRIAL GENETICS* 44–45 (1991).

billion.<sup>66</sup> In addition, bioindustry has introduced transgenic farm animals into the market expressing hormones like the bovine growth hormone (BGH) or other chemicals that animals do not ordinarily produce in nature.<sup>67</sup>

In contrast, biotechnology's impact on humans remains largely theoretical. The next three sections explore two innovations that have begun diffusing (*i.e.*, genetic screening and human cloning) and one pure invention (*i.e.*, human genetic engineering) incorporating two approaches: gene transfer research and germline manipulation.

### 1. Genetic Screening (GS)

Genetic screening (GS) or DNA-based testing was among the first commercial medical applications of biotechnology. It is designed to identify so-called genetic "defects" or "abnormalities," signaled by a mutation in a gene preventing manufacture of a protein or altering a protein's activity and, thus, the function of cells and organs.<sup>68</sup> Something like GS has been used in a rudimentary form for about two decades in prenatal fetal blood sampling, chorionic villi sampling, amniocentesis, and maternal serum alphafetoprotein screening.<sup>69</sup> All involve some risk of fetal death and of infection to the woman.<sup>70</sup>

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66. Neil Munro, *The New Patent Puzzle*, 34 NAT'L J. 628 (2002).

67. Ryan M.T. Iwasaka, Note, *Chakrabarty to Chimeras: The Growing Need for Evolutionary Biology in Patent Law*, 109 YALE L.J. 1505, 1532 (2000). "Transgenic animals" are those that carry and express a gene of another species. By 1999, the PTO had received over 1,900 patent applications for genetically altered animals. *Id.* at 1507; see also Linda Maher, *The Environment and the Domestic Regulatory Framework for Biotechnology*, 8 J. ENVTL. L. & LITIG. 133, 149 (1993) (BGH is a bio-engineered protein hormone that significantly increases milk production in cows); Nicholas D. Kristof, *Part Cow, Part Man, All Business: Bioengineering is a Growth Industry*, PITTSBURGH POST-GAZETTE, Aug. 7, 2002, at A15.

68. Charles F. De Jager, Note, *The Development of Regulatory Standards for Gene Therapy in the European Union*, 18 FORDHAM INT'L L.J. 1303, 1307 (1995).

69. LEVINE, *supra* note 45, at 19; Natalie Smith, Note, *The Right to Genetic Privacy? Are We Unlocking the Secrets of the Human Genome Only to Risk Insurance and Employment Discrimination?*, 2000 UTAH L. REV. 705, 707-08, 716; Lori B. Andrews, *Prenatal Screening and the Culture of Motherhood*, 47 HASTINGS L.J. 967, 968 (1996) [hereinafter Andrews on Prenatal Screening].

70. Andrews on Prenatal Screening, *supra* note 69, at 968.

Fetoscopy, in which blood is sampled from the fetus while it is in utero, is associated with a 3% to 6% risk of fetal death. Chorionic villi sampling, in which tissue surrounding the fetus is sampled and analyzed between eight and twelve weeks of gestation, is associated with a 2% to 3% spontaneous abortion rate. Amniocentesis, in which fluid from the amniotic sac is withdrawn and analyzed, causes spontaneous abortion in approximately one or two per thousand pregnancies.

*Id.*

Carrier screening, a more recent form of GS, involves identifying unaffected individuals who carry one copy of a gene for a disease that requires two copies for the disease to be expressed.<sup>71</sup> As an example, potential carriers are commonly tested today for Tay-Sachs or sickle cell anemia.<sup>72</sup> The least utilized form of GS is pre-symptomatic GS, which may be utilized to confirm diagnoses of a symptomatic individual and for forensic testing.<sup>73</sup>

Altogether, there are currently several hundred genetic tests in clinical use and many more in development, including so-called "multi-plex testing" in which numerous genetic tests are performed on a single tissue sample.<sup>74</sup> Currently, most genetic tests reveal only a probability for developing a disorder.<sup>75</sup> Genes do not entirely determine most diseases; environmental and other factors like age, exercise, and diet play an important role.<sup>76</sup> Studies of identical twins reveal that individuals with the same genetic makeup do not develop the same diseases and disorders. Furthermore, some diseases are not inherited at all, but acquired after birth as a result of an alteration of the genetic code.<sup>77</sup> Various forms of cancer are acquired diseases.<sup>78</sup>

GS is not useful for determining whether an individual will develop an acquired disease; however, between acquired and inherited diseases are "complex gene-influenced conditions that have a predisposition to the development of a disease."<sup>79</sup> An example of this is breast cancer for which there is now a genetic test of limited reliability.<sup>80</sup> Technological refinements in GS may improve their predictive value and, some believe, reveal disputed

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71. *Id.* at 761.

72. *Id.* at 970.

73. The most sophisticated GS techniques involve direct examination of the deoxyribonucleic acid (DNA) molecule. *Human Genome Project Information: Gene Testing*, [www.ornl.gov/hgmis/medicine/genetest.html](http://www.ornl.gov/hgmis/medicine/genetest.html) (last modified Feb. 18, 2002) (on file with the Notre Dame Journal of Law, Ethics & Public Policy). Dated GS methods include biochemical testing for such gene products as enzymes and other proteins and microscopic examination of stained or fluorescent chromosomes. For some types of genetic tests, researchers design short pieces of DNA called probes, which bind to and flag mutations. Other procedures involve comparing a patient's DNA with a "normal" sequence. *Id.*

74. LEVINE, *supra* note 45, at 18; Andrews on Prenatal Screening, *supra* note 69, at 968, 970.

75. Smith, *supra* note 69, at 746.

76. *Id.* at 713; Jill Gauding, Note, *Race, Sex, and Genetic Discrimination in Insurance: What's Fair?*, 80 CORNELL L. REV. 1646, 1666 (1995).

77. Smith, *supra* note 69, at 714.

78. *Id.*

79. *Id.* at 715 (citations omitted).

80. GENOMICS AND ITS IMPACT, *supra* note 44, at 7; Smith, *supra* note 69, at 715.

genetic linkages to conditions and behaviors like aggression, sexuality, and intelligence.<sup>81</sup>

## 2. Human Cloning (HC)

Human cloning (HC) may be performed in two ways: (1) somatic nuclear transfer (SCNT), or (2) parthenogenesis.<sup>82</sup> The latter procedure remains largely theoretical and involves chemically inducing egg cells to divide without fertilization.<sup>83</sup> Researchers employing the experimental SCNT procedure insert DNA drawn from an adult into an egg stripped of its nucleus (enucleated),<sup>84</sup> then stimulate the genetically modified egg to commence embryonic development.<sup>85</sup> The result is a living human embryo nearly genetically identical to the DNA donor.<sup>86</sup> Alternatively, the simplest chimera could arise from HC if researchers inserted human DNA into an animal egg or vice-versa.

SCNT is rarely successful when performed on complex life forms. As an example, only about 20% of cow clones survive to the blastocyst stage of embryonic development.<sup>87</sup> Once created, the clone's fate depends upon the purpose of the experiment. Researchers distinguish between so-called "reproductive cloning" and so-called "therapeutic cloning."<sup>88</sup> The former would lead to

81. Smith, *supra* note 69, at 715.

82. See, e.g., Joannie Fischer, *The First Clone*, U.S. NEWS & WORLD REP., Dec. 3, 2001, at 50; Gina Kolata & Andrew Pollack, *A Breakthrough on Cloning? Perhaps or Perhaps Not Yet*, N.Y. TIMES, Nov. 27, 2001, at A1; Joyce Price, *Human Embryo Cloned for First Time*, WASH. TIMES, Nov. 26, 2001, at A1; Jose Cibelli et al., *The First Human Cloned Embryo*, SCI. AM., Jan. 2002, at 44 [hereinafter Cibelli I].

83. See Sylvia Westphal, *Stem Cells from Embryo Created Without Sperm*, NEW SCIENTIST, Feb. 12, 2002, at 8; Raja Mishra, *Eggs Produce Stem Cells and Widen Debate on Life*, B. GLOBE, Feb. 1, 2002, at A1 [hereinafter Mishra I].

84. Jose Cibelli et al., *Somatic Cell Nuclear Transfer in Humans: Pronuclear and Early Embryonic Development*, 2 E-BIOMED: J. REGENERATIVE MED. 25 (2001) [hereinafter Cibelli II].

85. *Id.*

86. Human clones created through SCNT would not be exactly like their DNA donors, because human DNA is located in the mitochondria of the enucleated ovum. Therefore, unless the same woman who acts as the genetic donor donates the ovum, clones will not possess identical mitochondrial DNA. Duane Nash, *Recommended Response for Human Cloning Patent Applications*, 42 IDEA 279, 285 (2002).

87. Kolata & Pollack, *supra* note 82, at A12.

88. The biotechnology industry increasingly refers to "therapeutic cloning" as simply "nuclear transplantation" to avoid any association with cloning. See Bert Vogelstein et al., *Please Don't Call It Cloning!*, 295 SCI. 1237 (2002); Jacqueline Stenson, *Change Name of Therapeutic Cloning: Scientists*, REUTERS, Feb. 14, 2002.

a born clone, whereas the latter would lead to killing and cannibalizing the clone for its constituent parts.

Today, about 97% of the simplest cloned animals die prior to birth in cloning trials.<sup>89</sup> Dolly is the extraordinary exception. Dr. Ian Wilmut, Dolly's creator, began with 277 enucleated sheep eggs, and wound-up with a single sheep; twenty-nine became embryos that were implanted in thirteen sheep; twelve out of thirteen of the sheep miscarried.<sup>90</sup> In a lesser-known experiment to replicate transgenic animals, Dr. Wilmut began with 425 enucleated sheep eggs, and wound up with fourteen embryos.<sup>91</sup> Six lambs born alive after artificial inducement were nearly twice the average weight and died within days of birth.<sup>92</sup>

In general, born clones suffer from serious—some say “gross”—genetic abnormalities and, therefore, live short lives. This is likely due to dormant genetic abnormalities that blossom with age, bypassing the protective mechanisms present in germ cells that correct DNA errors,<sup>93</sup> as well as the chronological age of the DNA inserted into the egg (which is that of an adult, not an infant). Dolly, for example, is aging prematurely and will have to be put down.<sup>94</sup>

Dr. Wilmut and most scientists favor a ban on cloning to produce children for these and utilitarian and psychological reasons, including the pressures parents might place upon a cloned child to be similar to a lost one or the possibility that genetic twins would come into the world years apart.<sup>95</sup> These preconceived expectations are totally absent with respect to naturally occurring twins and, according to a few commentators, could give rise to a form of “genetic bondage.”<sup>96</sup> Introducing clones

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89. Kolata & Pollack, *supra* note 82, at A12.

90. GINA KOLATA, CLONING: THE ROAD TO DOLLY AND THE PATH AHEAD 239 (1998); Lawrence Wu, Note, *Family Planning Through Human Cloning: Is There a Fundamental Right?*, 98 COLUM. L. REV. 1461, 1467 (1998).

91. Lori B. Andrews, *Is There A Right to Clone? Constitutional Challenges to Bans on Human Cloning*, 11 HARV. J.L. & TECH. 643, 651–52 (1998) [hereinafter Andrews on Cloning] (referencing 425 enucleated eggs, rather than 277).

92. *Id.*

93. Nash, *supra* note 86, at 288.

94. Camillo Fracassini, *Dolly the Sheep's Creator Admits She May Have to be Put Down*, SCOT. ON SUNDAY, Jan. 6, 2002, at 1; *Cloned Sheep Dolly Develops Arthritis*, REUTERS, Jan. 4, 2002. Likewise, of ten pigs recently born through cloning, researchers destroyed five due to defects including heart failure, lameness, and anemia. *Cloned Animals Suffer Death, Deformities According to Leading Journal Articles*, U.S. NEWSWIRE, Aug. 13, 2002, available at <http://www.usnewswire.com> (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

95. KOLATA, *supra* note 90, at 239, 243; *Cloned Animals Suffer Death, Deformities According to Leading Journal Articles*, *supra* note 94.

96. Andrews on Cloning, *supra* note 91, at 655, 668.



who are replicas of family members including elder children, dead persons, and parents would have unknown implications for family stability. They could also lead to unsafe reproduction patterns and kinship and lineage confusion.<sup>97</sup> Cloning for the purpose of replication may also obviously give rise to new species.

Presently, the biotechnology industry is interested not in cloning to produce children, or what we shall refer to as "reproductive cloning," but in cloning for the purpose of biomedical research, or what we shall refer to as "research cloning." The industry would permit cloned embryos to develop for five to seven days to the point where they are marked by a peripheral cellular layer called the trophoblast or feeding layer (which becomes the embryonic placenta) surrounding an inner central cavity called the blastocyst (which gives rise to the embryo), then terminate them, derive their stem cells, and coax or differentiate the stem cells into a tissue type needed for research.<sup>98</sup>

### 3. Human Genetic Engineering (GE)

Human genetic engineering (GE) would modify the genetic makeup of persons either by modifying body (somatic) cells that comprise the organs and tissues of a person or the germ cells (gametes, zygotes, and early-embryos) that pass on parental genes to the next generation.<sup>99</sup> GE performed on somatic cells never results in an inheritable trait, may be administered either *ex vivo* or *in vivo*, and is called "gene transfer research" or, less appropriately "gene therapy."<sup>100</sup> GE on germ cells permanently

97. Without statutory assistance, human clones could be subject to multiple kinship claims; for example, by the egg donor, DNA donor, and gestational mother; and could mistakenly reproduce with persons sharing familial DNA.

98. Some refer to five to seven day old human embryos as "pre-embryos," "activated cells," or "cleaving cells"; however, there is no scientific basis for this distinction. See, e.g., RONAN O'RAHILLY & FABIOLA MULLER, *HUMAN EMBRYOLOGY & TERATOLOGY* (3d ed. 2001).

99. LEVINE, *supra* note 45, at 23; *Human Genome Project Information: Gene Therapy*, [www.ornl.gov/hgmis/medicine/genetherapy.html](http://www.ornl.gov/hgmis/medicine/genetherapy.html) (last modified Nov. 21, 2002) (on file with the Notre Dame Journal of Law, Ethics & Public Policy) [hereinafter *Gene Therapy*].

100. LEVINE, *supra* note 45, at 23; STUART H. ORKIN & ARNO G. MOTULSKY, NAT'L INSTS. OF HEALTH, REPORT AND RECOMMENDATIONS OF THE PANEL TO ASSESS THE NIH INVESTMENT IN RESEARCH ON GENE THERAPY (1995), available at [www.nih.gov/news/panelrep.html](http://www.nih.gov/news/panelrep.html) (on file with the Notre Dame Journal of Law, Ethics & Public Policy) [hereinafter REPORT ON RESEARCH ON GENE THERAPY]; Eugene H. Kaji & Jeffrey M. Leiden, *Gene and Stem Cell Therapies*, 285 J. AM. MED. ASS'N 545, 545 (2001) (the *ex vivo* approach involves carrying out genetic modifications on cultured cells that are subsequently administered to the patient, whereas the *in vivo* approach involves inserting a healthy gene in a vector for delivery to a diseased area of the body).

modifies a population's genetic endowment and is called "germline manipulation."<sup>101</sup>

*a. Gene Transfer Research*

Gene transfer research comprises a variety of approaches including: (1) introducing a gene that supplements the function of a mutated gene, adds a missing function, or regulates the expression of another gene; (2) directly repairing a mutated gene; or (3) suppressing a gene.<sup>102</sup> The goal of gene transfer research is to treat diseases in an individual patient by administering genetic material (DNA) rather than a drug.<sup>103</sup> The success of the strategy hinges both on the delivery of genetic material into the target cells and the expression of the gene once it reaches its target site.<sup>104</sup>

Most gene transfer research procedures involve three components: (1) a gene or other nucleic acid; (2) a vector that allows delivery of the gene or nucleic acid to the appropriate cell; and (3) a device to deliver the gene-vector combination to the appropriate tissue *in vivo*.<sup>105</sup> The most common vectors are human or animal viruses, which mix with progenitor cells from the patient's bone marrow.<sup>106</sup> When the virus splices its genes into those of the bone marrow cells, it simultaneously inserts the gene for the missing enzyme.<sup>107</sup> Special bacterial enzymes "cut and

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101. Christine Willgoos, Note, *FDA Regulation: An Answer to the Questions of Human Cloning and Germline Gene Therapy*, 27 AM. J.L. & MED. 101, 105 (2001); De Jager, *supra* note 68, at 1308–09; Burk, *supra* note 46, at 1613.

102. Advisory Comm. to the Dir., Nat'l Insts. of Health, *Enhancing the Protection of Human Subjects in Gene Transfer Research at the National Institutes of Health* 5, (July 12, 2000), available at <http://www.nih.gov/about/director/07122000.htm> (on file with the Notre Dame Journal of Law, Ethics & Public Policy) [hereinafter *Enhancing the Protection of Human Subjects*] (gene therapy comprises three approaches including: (1) altering or supplementing the function of a mutated gene by providing a copy of a normal gene; (2) directly altering or repairing a mutated gene; or (3) providing a gene that adds missing functions or regulates the expression of another gene); Burk, *supra* note 46, at 1611 (gene therapy may be used to suppress genes).

103. *Enhancing the Protection of Human Subjects*, *supra* note 102, at 5.

104. *Id.*; see also Burk, *supra* note 46, at 1611–13.

105. Kaji & Leiden, *supra* note 100, at 546.

106. SUNIL MAULIK & SALIL D. PATEL, *MOLECULAR BIOTECHNOLOGY: THERAPEUTIC APPLICATIONS AND STRATEGIES* 39, 41–50 (1997).

107. LEVINE, *supra* note 45, at 12.

paste" DNA into new sequences.<sup>108</sup> Then, as the infected cell replicates, the new gene multiplies.<sup>109</sup>

In 1980, UCLA physician Martin Cline unsuccessfully conducted the first gene transfer research on human subjects overseas (some believe to avoid U.S. law).<sup>110</sup> Dr. Cline was criticized and demoted for what others deemed premature research.<sup>111</sup> It took ten more years before the research community heralded the first gene research success, which critics contend is at best inconclusive since it imposed a gene research protocol over non-genetic treatment.<sup>112</sup> The trial has enabled one child afflicted with Severe Combined Immunodeficiency (SCID) to live a relatively normal life years later.<sup>113</sup>

In the interim between Cline's unmitigated failure and French's disputed success, the RAC and the FDA, which first asserted jurisdiction over rDNA products in 1984, elaborated regulatory guidelines for gene transfer trials.<sup>114</sup> Initially, the approval process was a laborious case-by-case process, requiring the approval of seven gatekeepers.<sup>115</sup> However, in response to patient advocacy groups, NIH Director Harold Varmus led a suc-

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108. *Id.*; MAULIK & PATEL, *supra* note 106, at 39, 41–50; Burk, *supra* note 46, at 1606–07. DNA may be inserted into tissues through direct injection, but this is ordinarily considered a crude approach and is not suitable for many tissues. *Id.* at 53.

109. LEVINE, *supra* note 45, at 12; MAULIK & PATEL, *supra* note 106, at 39.

110. Rainsbury, *supra* note 52, at 578.

111. *Id.*

112. Angela Liang, *Gene Therapy: Legal and Ethical Issues for Pregnant Women*, 47 CLEV. ST. L. REV. 61, 65 (1999); Larry R. Churchill et al., *Genetic Research as Therapy: Implications of "Gene Therapy" for Informed Consent*, 26 J.L. MED. & ETHICS 38, 44 (1998).

113. Churchill et al., *supra* note 112, at 44 ("Blood tests indicated that over 50 percent of [one child's] circulating T cells contained the new, corrected gene after three years, compared to only 0.1 to 1 percent in the second patient-subject."). Less than 100 persons worldwide have SCID, a single-cell hereditary disease and, thus, are unable to produce the ADA enzyme. These children (also known as "bubble kids") experience chronic and repeated infection. LEVINE, *supra* note 45, at 12; NAT'L HUMAN GENOME RESEARCH INST., RESULTS FROM FIRST HUMAN GENE THERAPY CLINICAL TRIAL, at <http://www.nhgri.nih.gov> (Oct. 19, 1995) (on file with the Notre Dame Journal of Law, Ethics & Public Policy) [hereinafter RESULTS FROM GENE THERAPY TRIAL]; Churchill et al., *supra* note 112, at 44.

114. Rainsbury, *supra* note 52, at 578–85.

115. These included the following: (1) the full body of RAC; (2) a sub-committee of RAC dealing exclusively with human gene engineering, now called the Human Gene Therapy Sub-committee (HGTS); (3) the FDA; (4) the institutional review board (IRB) at the National Cancer Institute; (5) the IRB at the National Heart, Lung, and Blood Institute; (6) a hospital safety committee; and (7) the NIH's Institutional Biohazard Committee (formed to oversee rDNA research locally). *Id.* at 583.

cessful effort in the mid-1990s to expedite and consolidate this process.<sup>116</sup> Gene research trials on humans multiplied. Between 1989 and May 2000, 280 new gene transfer drug applications for trials on humans were submitted to the FDA, with 206 still active in May 2000.<sup>117</sup> By 1995, NIH reported its researchers had filed eighty-one gene research-related patent applications and that a total of 597 subjects had undergone gene transfer experiments.<sup>118</sup> These applications dealt with single-cell hereditary genetic abnormalities and a few more complex diseases like cancer and AIDS.<sup>119</sup>

In September 1999, just as NIH seemed to be routinizing gene transfer research, healthy 18-year-old Jesse Gelsinger died from a severe immunological response to the administration of a gene transfer product in an adenoviral vector gene transfer clinical trial.<sup>120</sup> Congressional hearings followed, leading to slightly modified NIH research protocols, calling for additional adverse-event reporting to the RAC and fuller disclosure of potential conflicts of interest on the part of an investigator and institution.<sup>121</sup>

The incident underscored problems with existing vectors and, specifically, the industry's underdeveloped understanding of the biological interaction of vectors with their host (including toxicity, immune and inflammatory responses).<sup>122</sup> The development of gene delivery devices and research on multiple-gene caused diseases lags even further behind.<sup>123</sup> Where multiple genes are involved, they interact with each other and the environment in complex ways, "rendering their identification orders of magnitude more difficult than for single gene defects."<sup>124</sup> Nevertheless, as of June 2001, more than 500 clinical gene trans-

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116. Varmus eliminated the HGTS, rendered the RAC solely an advisory body, and shifted most authority to the FDA. *Id.* at 585-92.

117. *Enhancing the Protection of Human Subjects*, *supra* note 102, at 19.

118. REPORT ON RESEARCH ON GENE THERAPY, *supra* note 100, at 4, 27.

119. *Gene Therapy*, *supra* note 99, at 38-39; Rainsbury, *supra* note 52, at 585.

120. Rainsbury, *supra* note 52, at 593; *Enhancing the Protection of Human Subjects*, *supra* note 102, at 2.

121. Rainsbury, *supra* note 52, at 594-95; *Enhancing the Protection of Human Subjects*, *supra* note 102, at 5, 15-17.

122. See REPORT ON RESEARCH ON GENE THERAPY, *supra* note 100, at 1-2; MAULIK & PATEL, *supra* note 106, at 42; *Gene Therapy*, *supra* note 99; Kaji & Leiden, *supra* note 100, at 546 (discussing alternative vectors and their present shortcomings).

123. Kaji & Leiden, *supra* note 100, at 547.

124. Collins & McKusick, *supra* note 50, at 542.

fer research trials involving 3,500 patients worldwide had been conducted, including roughly 78% in the United States.<sup>125</sup>

### b. *Germline Manipulation*

Germline manipulation hinges upon many of the technologies discussed in the last section, in addition to fairly routine IVF egg recovery, artificial fertilization, cyropreservation, and thawing techniques.<sup>126</sup> All the cells derived from the first altered germ cell, including the gametes that will engender the embryo's offspring, will carry the new genetic alteration.<sup>127</sup> Germline manipulation has been practiced on animals for roughly twenty years, primarily mice (*e.g.*, the Harvard onco mouse);<sup>128</sup> however, there are no reports of researchers knowingly attempting germline manipulation on humans.<sup>129</sup> In fact, it is contrary to current federal policy to review research proposals for germline manipulation on human beings, whether or not born.<sup>130</sup> It is likely to be at least two decades before clinical trials are feasible.<sup>131</sup>

## II. THE MONSTER CONFRONTS LIBERAL DEMOCRACY

The cluster of biotechnologies we covered in the last section will shortly emerge at the crossroads of a variety of international and national legal regimes that biotechnology will either radically alter or which will regulate biotechnology. We review below equal protection, reproductive rights, First Amendment, human subject experimentation, patent, and parental rights law.

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125. GENOMICS AND ITS IMPACT, *supra* note 44, at 8. Most protocols aim at establishing the safety of gene delivery procedures, rather than their effectiveness. *Id.*

126. Burk, *supra* note 46, at 1613–14.

127. *Id.* at 1614.

128. Prentice, *supra* note 42, at 534; Burk, *supra* note 46, at 1614–15.

129. Prentice, *supra* note 42, at 536–37. Nevertheless, one published report indicates that an ART clinic inadvertently engaged in germline manipulation by transferring cytoplasm from a donor human oocyte to an older oocyte to “rejuvenate” it prior to fertilization. *Id.*

130. NAT’L INSTS. OF HEALTH, NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES APP. M (2002), available at <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> (Apr. 2002) (on file with the Notre Dame Journal of Law, Ethics & Public Policy); RECOMBINANT DNA ADVISORY COMMITTEE, NAT’L INSTITUTES OF HEALTH, RAC STATEMENT, at <http://www4.od.nih.gov/oba/rac/racinutero.htm> (Mar. 11, 1999) (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

131. Willgoos, *supra* note 101, at 105; *Germ-line Gene Therapy Enters the Foreseeable Future*, GENELETTER, Aug. 1, 1998, at <http://www.geneletter.com/archives/foresfuture.html> (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

### A. Legal Regimes GS Implicates

GS raises simpler legal questions than more sophisticated biotechnologies. This is fortunate because GS is now poised to diffuse rapidly. Prenatal testing for selected inheritable diseases like alpha-fetoprotein (AFP) is already part of the accepted national standard of care.<sup>132</sup> Multiplex genetic screening will shortly become cheaper and more reliable.<sup>133</sup> Now, we must decide what to do with this information.

#### 1. Equal Protection

The United Nations General Assembly ("General Assembly") and European Council (EC) have declared illegal discrimination on the basis of genetic heritage and declared genetic information confidential.<sup>134</sup> Roughly half the American states have done likewise and a minority has outlawed employment discrimination relating to genetics.<sup>135</sup> Comprehensive federal legislation is pending.<sup>136</sup> Meanwhile, a variety of federal laws provide some protection, including the Americans with Disability Act (ADA) and Health Insurance Portability and Accountability Act

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132. See Lois Shepherd, *Protecting Parents' Freedom to Have Children with Genetic Differences*, 1995 U. ILL. L. REV. 761, 775.

133. FUKUYAMA, *supra* note 37, at 75 (concerning introduction of the so-called DNA chip offered by Affymetrix that automatically screens a DNA sample for various markers of cancer and other disorders).

134. U.N. ESCO, Universal Declaration on the Human Genome and on Human Rights, arts. 6–9, Nov. 11, 1997, *available at* <http://www.unesco.org/ibc/en/genome/projet/index.htm> (on file with the Notre Dame Journal of Law, Ethics & Public Policy); Convention on Human Rights and Biomedicine, Council of Europe, art. 11, ETS 164, Apr. 4, 1997, *available at* <http://www.fuente.de/bioethik/conven6e.htm> (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

135. See Smith, *supra* note 69, at 732–33, 742 (at least twenty-three states have enacted anti-discrimination legislation pertaining to genetics, whereas only about nine states have enacted anti-discrimination legislation pertaining to employment).

136. See, e.g., Genetic Nondiscrimination in Health Insurance and Employment Act, S. 318, 107th Cong. (2001).

(HIPA).<sup>137</sup> An executive order also prohibits genetic discrimination against federal employees.<sup>138</sup>

Without regulation, genetic discrimination would occur naturally because employers prefer to reduce their medical costs and minimize employee leave,<sup>139</sup> and insurers seek to match the highest premiums to those posing the most medical risks.<sup>140</sup> Employers and insurers have already sought to use genetic information in this manner.<sup>141</sup> Not incidentally, the persons disproportionately affected by this genetic discrimination were minorities.<sup>142</sup>

As demonstrated by the quick reaction outlawing this,<sup>143</sup> most believe that discriminating on the basis of genes like "the color of a person's skin and the country of his origin are immutable facts that bear no relation to ability, disadvantage, moral culpability, or any other characteristics of constitutionally permissible interest to government[;]"<sup>144</sup> and, thus, violates the Equal Protection Clause of the Fourteenth Amendment. According to the U.S. Supreme Court, "Distinctions between citizens

137. See Americans with Disabilities Act of 1990, 42 U.S.C. §§ 12101-12213 (1995); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 29 U.S.C.A. and 42 U.S.C.A.). For a discussion of the applicability of both to genetic discrimination, see Smith, *supra* note 69. In 1995, the EEOC issued a guideline interpreting the ADA to apply to pre-symptomatic individuals with a genetic predisposition for a disabling condition. See 2 EEOC Compl. Man. (BNA) § 902.0045 (Mar. 1995).

138. See GARY S. MARX & GARY G. GOLDBERGER, DISABILITY LAW COMPLIANCE MANUAL app. B14 (2d ed. 1998).

139. Smith, *supra* note 69, at 720.

140. *Id.*

141. In the 1970s, employers discriminated against African-Americans who were carriers of sickle cell anemia, although their carrier status had no relation to their health or ability to perform work. Andrews on Prenatal Screening, *supra* note 69, at 986-87; see also LORI B. ANDREWS, MEDICAL GENETICS: A LEGAL FRONTIER (1987). Likewise, shortly after scientists discovered the genes linked to Tay-Sachs disease and sickle cell anemia, insurers discriminated against those possessing the genes. Smith, *supra* note 69, at 707-08; Carol Lee, Comment, *Creating a Genetic Underclass: The Potential For Genetic Discrimination by the Health Insurance Industry*, 13 PACE L. REV. 189, 216 (1993).

142. Ashkenazi Jews and African-Americans disproportionately carry, respectively, Tay-Sachs disease and sickle cell anemia. John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 441 (1996) [hereinafter Robertson on Genetic Selection]; Andrews on Prenatal Screening, *supra* note 69, at 970.

143. Smith, *supra* note 69, at 708 (citing ALA. CODE § 27-5-13 (1996); FLA. STAT. ANN. § 626.9706 (West 1984); LA. REV. STAT. ANN. § 22:652.1 (West 1995); TENN. CODE ANN. § 56-7-207 (1994)).

144. *Minnick v. Cal. Dept. of Corrections*, 452 U.S. 105, 128-29 (1981) (Stewart, J., dissenting).

solely because of their ancestry are by their very nature odious to a free people whose institutions are founded upon the doctrine of equality."<sup>145</sup>

On the other hand, those who would permit genetic discrimination contend there is yet no history of invidious discrimination on the basis of genes.<sup>146</sup> The closest analogy is discrimination against the disabled, but the Supreme Court has not treated the disabled as a quasi-suspect class.<sup>147</sup> Even the ADA does not entirely prohibit discrimination against them. After extending a conditional job offer, employers may require GS test results through a pre-placement medical exam and general medical record release or family history,<sup>148</sup> and decide whether they can "reasonably accommodate" a disability.<sup>149</sup>

Insurers may also restrict underwriting based on family medical history, a variable closely connected with genes. Last, insurers and employers commonly discriminate on the basis of intelligence, self-control, and similar factors that may have genetic links, suggesting that society does not reject all forms of discrimination on the basis of immutable factors.<sup>150</sup> Indeed, we prefer employees to reveal medical information that threatens third parties, for example, airline pilots predisposed to heart attack.<sup>151</sup>

Professor Epstein and others add that preventing discrimination on the basis of genetics could actually increase discrimination through proxies and prove far more costly to society than overtly subsidizing the costs associated with hiring or insuring individuals with defects.<sup>152</sup> He would bring the costs the healthy will pay through, for example, increased insurance premiums into view "so that honest choices may be made."<sup>153</sup> These costs would necessarily increase as GS improves.<sup>154</sup> In fact, some

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145. *Loving v. Virginia*, 388 U.S. 1, 11 (1967) (quoting *Hirabayashi v. United States*, 320 U.S. 81, 100 (1943)).

146. Colin S. Diver & Jane M. Cohen, *Genophobia: What is Wrong with Genetic Discrimination?*, 149 U. PA. L. REV. 1439, 1476-78 (2001).

147. *Bd. of Trustees of the Univ. of Alabama v. Garrett*, 531 U.S. 356, 366 (2001) (citing *Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432 (1985)).

148. 42 U.S.C. § 12112(d).

149. Diver & Cohen, *supra* note 146, at 1479-80.

150. *Id.* at 1451.

151. *Id.* at 1454, 1460-62.

152. Richard A. Epstein, *The Legal Regulation of Genetic Discrimination: Old Responses to New Technology*, 74 B.U. L. REV. 1, 21-22 (1994).

153. *Id.* at 21.

154. Diver & Cohen, *supra* note 146, at 1457-58 (indicating that the resulting market equilibrium would make meaningful health insurance unaffordable).



scholars believe that if left unregulated, GS would eventually undermine the rationale for insurance, because persons could know their future medical expenses.<sup>155</sup>

On the other hand, if the state permits employers and insurance companies to discriminate based on genetic test results, they will inevitably penalize minorities linked to inheritable diseases and those born of or possessing moral or religious convictions opposed to interfering with natural childbirth. Plaintiffs' sole recourse would be under HIPA, the ADA, Title VII, and state law. Some have argued that Title VII provides an adequate remedy for prospective religious and racial employment discrimination, but this does not necessarily follow.

A plaintiff alleging racial discrimination related to his genetic endowment might state a claim for relief,<sup>156</sup> but not necessarily a plaintiff averring religious discrimination.<sup>157</sup> For example, a plaintiff born gen-natural because her parents felt strongly about the matter may not state a claim that a job designed solely for those with or without a particular genetic complement violates the employee's religious faith. Even a rule denying insurance coverage to employees who chose to have gen-natural children may not violate an employee's religious faith. Employees may request a religious accommodation, but employers must incur no more than "*de minimis* cost" to satisfy it.<sup>158</sup> Furthermore, if an employee states a *prima facie* case of racial or religious discrimination, an employer may state a non-pretextual reason for adverse employment action by contending it was due to genetics.<sup>159</sup>

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155. *Id.*

156. To establish a *prima facie* case of racial discrimination under Title VII, the complainant must allege the following: (1) that the plaintiff belongs to a class protected by Title VII; (2) that the plaintiff was qualified for the position at issue; (3) that the defendant made an adverse employment decision despite the plaintiff's qualifications; and (4) that the plaintiff was replaced with a person not a member of the protected class. *McDonnell Douglas Corp. v. Green*, 411 U.S. 792 (1973).

157. To establish a *prima facie* case of religious discrimination under Title VII, the complainant must allege the following: (1) a sincerely held religious belief that prohibits compliance with an employment requirement; (2) the employee informed his employer of this religious belief putting the employer on notice; and (3) the employee was subject to discharge, discrimination, discipline, or other adverse treatment as a result of noncompliance. *See Heller v. EBB Auto Co.*, 8 F.3d 1433, 1438 (9th Cir. 1993); *Smith v. Pyro Mining*, 827 F.2d 1081, 1085 (6th Cir. 1987); *Philbrook v. Ansonia Bd. of Educ.*, 757 F.2d 476, 481 (2d Cir. 1985) (quoting *Turpen v. Mo.-Kan.-Tex. R.R. Co.*, 736 F.2d 1022, 1026 (5th Cir. 1984)).

158. *Heller*, 8 F.3d at 1440.

159. *McDonnell Douglas Corp.*, 411 U.S. at 802-04.

## 2. Reproductive Rights

### a. Abortion Rights

The information GS will unveil is, in Professor Andrews' words, "powerful information," capable of dramatically impacting the behavior of parents, their children, extended family, and, as we have seen, employers and insurers. Genetic test results may affect one's personal relationships, leading some to withdraw from family, society, and long-term commitments. According to surveys, both genders (although primarily men) would alter their marriage plans if they learned their fiancé carried a recessive genetic disorder.<sup>160</sup> Other couples would decide on ARTs, HC, or adoption.<sup>161</sup>

In general, at least a ten-year "therapeutic gap" exists between the discovery of genes linked to inherited disease and the prospect of treating them genetically.<sup>162</sup> Only a few conditions like phenylketonuria are treatable.<sup>163</sup> Accordingly, for now, most parents who learn that their embryo or fetus may have an inheritable disease have the option of bearing the child or aborting. Likewise, children and adults who learn that they have an inheritable disease may not have any recourse.

Consequently, scholars worry that women may delay fetal-mother bonding until they learn of GS test results, potentially damaging child development.<sup>164</sup> Likewise, children and adults who learn of untreatable genetic disorders may suffer severe depression, dramatically modify their lifestyles and educational and vocational choices, or harm themselves.<sup>165</sup> The suicide rate is four times higher among persons with Huntington's Disease than among the general population.<sup>166</sup>

For this reason, many advisory boards have begun recommending against pre-symptomatic testing for certain diseases until therapies exist.<sup>167</sup> Likewise, the EC permits GS "only for health purposes or for scientific research linked to health pur-

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160. Andrews, *supra* note 69, at 979.

161. See, e.g., *Couple Wants to Have Baby Using Human Cloning; Interview with Erin Runnion* (CNN television broadcast Aug. 12, 2002), available at <http://www.cnn.com/Transcripts/0208/12/cct.00.html> (on file with the Notre Dame Journal of Law, Ethics & Public Policy) [hereinafter *Couple Wants Clone*].

162. Smith, *supra* note 69, at 726.

163. Andrews, *supra* note 69, at 972.

164. *Id.* at 980-81.

165. *Id.* at 980; Shepherd, *supra* note 132, at 800-02.

166. Andrews, *supra* note 69, at 976.

167. *Id.* at 984, 991 n.121 (the Institute of Medicine Committee on Assessing Genetic Risks); Mary Z. Peltas & Susan H. Blanton, *Genetic Testing in Children and Adolescents: Parental Authority, The Rights of Children, and Duties of Geneticists*, 3

poses, and subject to appropriate genetic counselling."<sup>168</sup> Some would import this idea by, for example, placing a moratorium on pre-symptomatic testing for conditions lacking any therapy, but one U.S. district court has held that parents have a reproductive right to genetic test results as a corollary of the right to abort.<sup>169</sup>

An even more controversial proposal that some, besides those generally opposed to abortion favor, would limit the ability of women to abort children for adult-onset disorders, discriminatory reasons, and so-called "trivial" reasons like hair and eye color.<sup>170</sup> In general, positive test results from GS indicate merely an increased probability that a child will develop a disease; therefore, parents open to abortion on the basis of test results will inevitably have to wrestle with uncertainty about whether a disease will in fact be manifested and the extent of its manifestation.<sup>171</sup> Some parents will also have to take into account the interests of their children in living normal lives until well into their adulthood, because GS will occasionally reveal inheritable diseases that are adult-onset in character like Huntington's or Alzheimer's Disease.<sup>172</sup> Some would outlaw abortion in these circumstances, as they would disapprove of its use as a gender selection tool in China and India.<sup>173</sup> This would require a modification of prevailing reproductive rights law.<sup>174</sup>

Another controversial proposal some recommend is publicly mandating GS to detect particular genetic abnormalities. Five states already require examination of the blood of newborns for treatable genetic disorders like phenylketonuria and congenital hypothyroidism.<sup>175</sup> Forty other states require medical providers

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U. CHI. L. SCH. ROUNDTABLE 525, 527-28 (1996) (Huntington Disease researchers).

168. Convention on Human Rights and Biomedicine, *supra* note 134, art. 12.

169. *Lifchez v. Hartigan*, 735 F. Supp. 1361, 1377 (N.D. Ill. 1990).

170. Robertson, *supra* note 142, at 444-45 (discussing, but rejecting this proposal).

171. Smith, *supra* note 69, at 746; *see, e.g.*, Wood v. Univ. of Utah Med. Ctr., 2002 WL 31895671 (Utah 2002) (parents informed of 85% chance their would-be child would be born with Down Syndrome but advised that the tests often result in false positives and, thus, not to worry). Lee Silver predicts women in the future will produce multiple embryos, then screen and abort or modify those they consider disadvantageous. LEE M. SILVER, REMAKING EDEN: CLONING AND BEYOND IN A BRAVE NEW WORLD 233-47 (1997).

172. Andrews, *supra* note 69, at 976 (on Huntington's Disease).

173. *See* Erik Eckholm, *Desire for Sons Drives Use of Prenatal Scans in China*, N.Y. TIMES, June 21, 2002, at A3.

174. *See* *Roe v. Wade*, 410 U.S. 113 (1973); *Planned Parenthood of South-eastern Pa. v. Casey*, 505 U.S. 833 (1992).

175. ANDREWS, *supra* note 141, at 238.

to offer newborn screening to parents, which they may decline in writing.<sup>176</sup> These tests are for treatable and untreatable conditions like Duchenne muscular dystrophy.<sup>177</sup>

As GS improves and treatment becomes possible, legislators will be tempted to mandate prenatal GS in more circumstances without opt-outs. Professor Robertson contends there may be no reproductive right to oppose this.<sup>178</sup> Professor Andrews disagrees and would also assert a Fourth Amendment right against unreasonable searches and seizures.<sup>179</sup> Consistent with this, one lower federal court has held that the state may not mandate GS without a compelling interest pursued in the least restrictive manner.<sup>180</sup>

Although a state may claim that it has a compelling interest in furthering the birth of healthy children or saving money by discouraging the birth of children with genetic disorders, Professor Andrews argues that saving money has never been deemed a sufficient policy basis to override fundamental rights and prenatal GS does not further the birth of healthy children because treatment for most genetic disorders is not available.<sup>181</sup> Instead, mandatory GS encourages abortion and spurs social condemnation of those who would continue pregnancies of fetuses with inherited diseases.<sup>182</sup> In this respect, it is similar to the so-called "negative eugenics" policies liberal democracies have now uniformly rejected.

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176. *Id.*; see also Shepherd, *supra* note 132, at 775. In reality, few health-care providers advise parents of their waiver right, so testing is *de facto* mandatory in most jurisdictions. Andrews, *supra* note 69, at 972, 1003.

177. Andrews, *supra* note 69, at 972.

178. Robertson, *supra* note 142, at 471.

179. Andrews, *supra* note 69, at 997–98. Recent cases involving Cesarean sections have recognized a woman's right to refuse medical procedures during pregnancy, but distinguished in dicta less substantial invasions of the body like drawing blood. *Id.* at 998–1001. Ordinarily, mandatory blood testing is considered a search and seizure subject to the Fourth Amendment balancing test weighing the nature and quality of the intrusion against the strength of the state's interest. Accordingly, mandatory HIV testing of incarcerated individuals without a warrant is unconstitutional, see *Schmerber v. California*, 384 U.S. 757, 771–72 (1966), as is mandatory HIV testing of state employees working with developmentally disabled clients, see *Glover v. E. Neb. Cmty. Office of Retardation*, 867 F.2d 461, 464 (8th Cir. 1989).

180. *Lifchez v. Hartigan*, 735 F. Supp. 1361, 1376 (N.D. Ill. 1990).

181. Andrews, *supra* note 69, at 1002.

182. *Id.* at 981–82, 1002 (noting that women have already been criticized for continuing pregnancies, for instance, when a radio talk show host learned that a television anchorwoman affected with ectrodactyly, a mild genetic condition which fused the bones in her hand, decided to continue a pregnancy of a fetus diagnosed with the same condition).

*b. Negative Eugenics*

Mendel's work in the late 1860s and social Darwinism led Sir Francis Galton to coin the word "eugenics" from its Greek roots meaning "good in birth."<sup>183</sup> He hoped to improve the human hereditary endowment by encouraging the ablest and healthiest people to have more children, so-called "positive eugenics," but preventing breeding, or "negative eugenics," proved easier.

During the 1920s, agencies like the American Eugenics Records Office (ERO) sprouted across the industrialized world to share the eugenic message.<sup>184</sup> At least twenty-eight states, besides Nazi Germany, borrowed liberally from the ERO's Model Eugenical Sterilization Law (Model Law), which authorized sterilization of those maintained at public expense, particularly the "feeble-minded, insane, criminalistic, epileptic, inebriate, diseased, blind, deaf, deformed, and dependent," including "orphans, ne'er-do-wells, tramps, the homeless and paupers."<sup>185</sup> States also passed antimiscegenation statutes prohibiting inter-ethnic marriage and restrictive immigration laws discouraging immigration from genetically less desirable regions.<sup>186</sup>

The political and scientific proponents of Virginia's Model Law allegedly conspired with defense counsel before passage to ensure it would survive a test case against Carrie Buck, a 17-year-

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183. Mary Kay Pelias & Nathan J. Markward, *The Human Genome in the Public View: Genetics, Geneticists, and Eugenics*, 13 ST. THOMAS L. REV. 827, 844 (2001).

184. See Stephanie Hyatt, *A Shared History of Shame: Sweden's Four-Decade Policy of Forced Sterilization and the Eugenics Movement in the United States*, 8 IND. INT'L & COMP. L. REV. 475, 481 (1998).

185. In 1907, Indiana passed the first eugenic sterilization law to prevent "defective" individuals from reproducing amongst themselves and reduce the social burden. Connecticut was next. The ERO developed the Model Law to address the infirmities courts used to strike this early legislation. See HARRY LAUGHLIN, *EUGENICAL STERILIZATION IN THE UNITED STATES* 446-51 (1922); Pelias & Markward, *supra* note 183, at 845-46; Hyatt, *supra* note 184, at 490 (twenty-seven states). Nazi Germany adapted and passed the Model Law in 1933. See Paul A. Lombardo, *Three Generations, No Imbeciles: New Light on Buck v. Bell*, 60 N.Y.U. L. REV. 30, 31 n.6 (1985) [hereinafter Lombardo I] (Hitler's sterilization law was based on the Model Law); Paul Lombardo, *Eugenic Sterilization Laws*, at <http://www.eugenicsarchive.org/html/eugenics/essay8text.html> (last accessed Nov. 17, 2002) (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

186. Pelias & Markward, *supra* note 183, at 846. The Immigration Restriction Act of 1924 was a conscious effort to prevent the immigration of southern and eastern Europeans.

old unwed mother and daughter of an asylum resident.<sup>187</sup> Expert witnesses testified that Carrie had "a record during life of immorality, prostitution, and untruthfulness," that the Buck family belonged to a "shiftless, ignorant, and worthless class of anti-social whites," and that Carrie's seven-month-old child had below-average intelligence and was "not quite normal."<sup>188</sup> Sadly, the U.S. Supreme Court agreed:

Carrie Buck 'is the probable potential parent of socially inadequate offspring, likewise afflicted, that she may be sexually sterilized without detriment to her general health and that her welfare and that of society will be promoted by her sterilization . . . .' It is better for all the world, if instead of waiting to execute degenerate offspring for crime, or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. . . . Three generations of imbeciles are enough.<sup>189</sup>

Twelve years later (December 31, 1939), the ERO closed its doors for good as the extent of Nazi atrocities became evident. Although never expressly overturning *Buck*, the U.S. Supreme Court struck a mandatory sterilization policy in 1942, finding no basis for inferring the inheritability of a criminal trait,<sup>190</sup> and overturned Virginia's antimiscegenation statute in 1967.<sup>191</sup> In a few more decades the U.S. government ceased sterilizing persons confined to mental institutions.<sup>192</sup> Mandating prenatal GS would reverse this policy consensus by once again coercing vulnerable populations to forego reproduction and to abort when no therapy for an inheritable disease exists or none is affordable.

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187. Lombardo I, *supra* note 185, at 33, 48–55 (citing *Buck v. Bell*, 274 U.S. 200 (1927)). Carrie's foster parents cooperated because they said they could not afford her. *Id.* at 54.

188. Hyatt, *supra* note 184, at 491–92; Lombardo I, *supra* note 185, at 51–52. In reality, Carrie's daughter who lived barely eight years did well in school, once earning a spot on her school Honor Roll. *Id.* at 61.

189. *Buck v. Bell*, 274 U.S. 200, 207 (1927).

190. *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

191. *Loving v. Virginia*, 388 U.S. at 1 (1967) (overturning the Virginia Racial Integrity Act).

192. In the interim, an estimated 60,000 Americans were sterilized without their consent or the consent of a family member. Hyatt, *supra* note 184, at 488; Lombardo I, *supra* note 185, at 31. Sterilization campaigns aimed at poor women continue in some parts of the world. See *Mass Sterilization Scandal Shocks Peru*, BBC NEWS, July 24, 2002, available at <http://news.bbc.co.uk/2/hi/americas/2148793.stm> (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

## B. *Legal Regimes HC Implicates*

The next biotechnological innovation behind GS on the innovation curve is HC. The issues it raises depend on the type and purpose of HC: (1) parthenogenesis or SCNT and (2) reproductive cloning or research cloning. A developing consensus suggests that HC through parthenogenesis is acceptable,<sup>193</sup> reproductive cloning is never acceptable, but research cloning may be acceptable. Rarely has this consensus confronted key legal obstacles discussed below.

### 1. Reproductive Rights

#### a. *Reproductive Cloning*

A number of commentators argue that HC is a reproductive liberty.<sup>194</sup> The predominant international response is to the contrary. The General Conference has declared human reproductive cloning contrary to human dignity.<sup>195</sup> The Council of Europe has precluded "[t]he creation of human embryos for research purposes."<sup>196</sup> Its Protocol on Cloning Human Beings adds, "[a]ny intervention seeking to create a human being genetically identical to another human being, whether living or dead, is prohibited."<sup>197</sup> The definition of "human being" is unstated, but widely interpreted to be a born person.<sup>198</sup>

193. No pending federal bill proposes to ban cloning through parthenogenesis, not even the most restrictive anti-cloning bill. See Human Cloning Prohibition Act of 2001, S. 1899, 107th Cong. (2001) (formerly Human Cloning Prohibition Act of 2001, S. 790, 107th Cong. (2001)); Human Cloning Prohibition Act of 2001, H.R. 2505, 107th Cong. (2001).

194. Robertson on Cloning, *supra* note 2, at 1430, 1442–46; Wu, *supra* note 90, at 1509.

195. U.N. ESCO, *supra* note 134, art. 11.

196. Convention on Human Rights and Biomedicine, *supra* note 134, art. 18(2).

197. Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine on the Prohibition of Cloning Human Beings, Council of Europe, art. 1(1), available at <http://conventions.coe.int/treaty/en/Treaties/Htm1/168.htm> (last visited Jan. 12, 1998) (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

198. *Explanatory Report on the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings* ¶ 6 ("In conformity with the approach followed in the preparation of the Convention on Human Rights and Biomedicine, it was decided to leave it to domestic law to define the scope of the expression 'human being' for the purposes of the application of the present Protocol."), available at <http://conventions.coe.int/Treaty/en/Reports/Htm1/168.htm> (last visited Nov. 16, 2002) (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

Nevertheless, American scholars who consider HC and GE reproductive rights rely in the former instance upon the notion that reproduction by any means is constitutionally protected and, in the latter instance, upon the close connection between the expected characteristics of offspring and the decision whether or not to reproduce.<sup>199</sup> The first argument stems from cases with holdings far removed from the sweeping, non-binding dicta they cite for the proposition that the rights to conceive and to raise one's children are "essential,"<sup>200</sup> "fundamental,"<sup>201</sup> "basic civil rights of man,"<sup>202</sup> "[r]ights far more precious . . . than property rights,"<sup>203</sup> and "among the most private and sensitive" rights.<sup>204</sup>

To constitute a fundamental right, reproductive cloning must be deemed "implicit in the concept of ordered liberty" such that "neither liberty nor justice would exist if [they] were sacrificed" and, objectively speaking, "deeply rooted in this nation's history and tradition."<sup>205</sup> The Supreme Court has struggled to articulate how to spot such a tradition.<sup>206</sup> The "originalist" perspective advocated by Justices Rehnquist, Scalia, and Thomas, examines "the most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified."<sup>207</sup> If this standard was applied to a ban on implanting clones, the ban would survive, because no American tradition of HC exists. Indeed, a minority of states has outlawed it.<sup>208</sup>

199. Robertson on Cloning, *supra* note 2, at 1425–29; Samuel A. Gunsburg, Note, *Frozen Life's Dominion: Extending Reproductive Autonomy Rights to In Vitro Fertilization*, 65 *FORDHAM L. REV.* 2205 (1997). Professor Robertson argues cloning is only procreative "if the genome that is cloned is that of the person herself or of an embryo, fetus, or child that has been created from her gametes." Robertson, *supra* note 2, at 1438.

200. *Meyer v. Nebraska*, 262 U.S. 390 (1923) (The rights to conceive and to raise one's children have been deemed "essential.").

201. *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972) ("If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.").

202. *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942) ("basic civil rights of man").

203. *May v. Anderson*, 345 U.S. 528, 533 (1953) ("[r]ights far more precious . . . than property rights").

204. *Carey v. Population Services Int'l*, 431 U.S. 678, 685 (1977) (decision whether or not to bear or beget a child is fundamental to individual autonomy); *Stanley v. Illinois*, 405 U.S. 645, 651 (1972).

205. *Washington v. Glucksberg*, 521 U.S. 702, 720–21 (1997).

206. See Gunsburg, *supra* note 199, at 2222–23.

207. *Michael H. v. Gerald D.*, 491 U.S. 110, 127–28 n.6 (1989) (plurality opinion).

208. See CAL. HEALTH & SAFETY CODE §§ 24,185–89 (Deering 2000) (moratorium on reproductive cloning sunsets on Jan. 1, 2003); Human Cloning Pro-



However, the majority of the U.S. Supreme Court has thus far rejected the originalist perspective on fundamental rights and indicated a willingness to examine whether a specific liberty interest is "close enough" to any interest previously deemed protected by the Fourteenth Amendment.<sup>209</sup> Courts held abortion and receipt of contraception a fundamental right, despite a widespread and longstanding American tradition restricting both.<sup>210</sup> Reproductive rights scholars contend assisted reproductive tech-

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hibition Act, Iowa Senate File 2118 (to be codified at IOWA CODE §§ 707B.1-4) (enacted Apr. 26, 2002) (ban on research and reproductive cloning); LA. REV. STAT. ANN. §§ 1299.36-.36.6 (West 1999) (ban on human cloning for the purpose of or to implant the clone to initiate a pregnancy); MICH. COMP. LAWS § 333.16,274 (2000) (prohibiting a health care licensee from engaging in research cloning); R.I. GEN. LAWS §§ 23-16.4-2 to -4 (2000) (moratorium on reproductive cloning); VA. CODE ANN. §§ 32.1-162.21 to -22 (Michie 2001) (ban on research and reproductive cloning); *see also* S.D. CODIFIED LAWS §§ 34-14-16 to -20 (Michie 2002) (ban on non-therapeutic research on human embryos).

209. *See* *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 847 (1992) (expressly rejecting Justice Scalia's originalist formula in note 6 of *Michael H.*). The views of Justice O'Connor are particularly important, because, to a significant extent, she has shaped substantive due process law since *Bowers v. Hardwick*, 478 U.S. 186, 209 n.4 (1986). *See Michael H.*, 491 U.S. at 132 (O'Connor and Kennedy, JJ., concurring in part) (refusing to join note 6 on the grounds it is inconsistent with, among other cases, *Griswold v. Connecticut*, 381 U.S. 479 (1965), and *Eisenstadt v. Baird*, 405 U.S. 438 (1972) ("On occasion the Court has characterized relevant traditions protecting asserted rights at levels of generality that might not be 'the most specific level' available."); *id.* at 133 (Stevens, J., concurring in judgment) (assuming a fundamental right for purposes of the case); *id.* at 139-40 (Brennan, Marshall, Blackmun, JJ., dissenting) (applying a looser standard to identify a deeply rooted tradition: "If we had looked to tradition with such specificity in past cases, many a decision would have reached a different result.") (citing, *inter alia*, *Eisenstadt*, 405 U.S. 438, *Griswold*, 381 U.S. 479, and *Stanley v. Illinois*, 405 U.S. 645 (1972)); *see also* *Washington v. Glucksberg*, 521 U.S. at 721 (1997) ("[W]e have required in substantive-due-process cases a 'careful description' of the asserted fundamental liberty interest."); *id.* at 736, 741, 750 (O'Connor, J., concurring) (implying the Justice might have found a right to assisted suicide where a person was experiencing great suffering).

210. *See* Paul B. Linton, *Planned Parenthood v. Casey: The Flight from Reason in the Supreme Court*, 13 ST. LOUIS U. PUB. L. REV. 15 (1993).

At the time *Roe* was decided, thirty States allowed abortion only to save the life of the mother; two States and the District of Columbia allowed abortion to save the life or preserve the health of the mother; one State allowed abortion to save the mother's life or to terminate a pregnancy resulting from rape; thirteen States had adopted Section 230.3 of the American Law Institute's Model Penal Code or some variant thereof allowing abortion under specified circumstances; and four States allowed abortion on demand, but set limits in terms of the age of the fetus. No State allowed unrestricted abortion throughout pregnancy, as *Roe* effectively does.

*Id.* at 26-27.

nology (ART) and HC using one's own DNA is "close enough" to coital reproduction to be treated similarly.<sup>211</sup> Although no court has reviewed a woman's right to clone, one lower federal court has found and other courts have stated in dicta that a couple has a right to reproduce under federal and state law through ART,<sup>212</sup> which has been widely practiced in the United States for roughly two decades.

Of course, HC is distinguishable from ART, because (1) HC does not involve the joining of gametes, (2) the medical and psychological risks to the embryo of the two procedures are very different, and (3) the consequences for the traditional family structure are not the same. Reproductive rights scholars contend all of these risks can be addressed with narrower means than a ban on HC (*e.g.*, through oversight by hospital Institutional Review Boards (IRBs)) and by preventing the implantation of clones a couple does not intend to rear or banning the implantation of the clone of a parent or oneself.<sup>213</sup>

Opponents of a ban on implanting human clones probably could not mount a successful facial challenge to the ban on this basis,<sup>214</sup> but a woman who could not produce coitally, cloned

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211. See generally Robertson on Cloning, *supra* note 2; Wu, *supra* note 90.

212. *Lifchez v. Hartigan*, 735 F. Supp. 1361 (N.D. Ill. 1990) (overturning Illinois provision banning non-therapeutic research on fetuses interpreted by the court to include embryos because it was impermissibly vague and infringed upon a woman's fundamental right to privacy); *J.B. v. M.B.*, 783 A.2d 707 (N.J. 2001); *Davis v. Davis*, 842 S.W.2d 588, 600-02 (Tenn. 1992) (stating in the context of a contest over the disposition of embryos created with ART, "the right of procreational autonomy is composed of two rights of equal significance—the right to procreate and the right to avoid procreation."); see also *Goodwin v. Turner*, 908 F.2d 1395 (8th Cir. 1990) (affirming denial of prisoner's writ of habeas corpus asserting that the Bureau of Prison's refusal to allow him to provide semen to his wife for the purpose of artificially inseminating her violated his constitutional right of procreation; court said the regulation was "reasonably related to legitimate penological interests" while assuming without deciding that he had an alleged fundamental procreation right); *Cameron v. Board of Educ. of Hillsboro, Ohio*, 795 F. Supp. 228 (S.D. Ohio 1991) (denying employer's motion for summary judgment on teacher's complaint for sexual discrimination on the grounds that her contract was not renewed because she conceived a child using artificial insemination. "A woman has a constitutional privacy right to control her reproductive functions. Consequently, a woman possesses the right to become pregnant by artificial insemination."); *In re Baby M*, 537 A.2d 1227 (N.J. 1988) (fundamental right of procreating, while including the right to use artificial insemination, did not extend to include a right of custody of the biologically related child).

213. Robertson on Cloning, *supra* note 2, at 1411, 1430, 1439, 1442-46, 1451; Wu, *supra* note 90, at 1509.

214. A successful facial challenge would require the plaintiff to establish "no set of circumstances . . . under which the Act would be valid." *Washington v. Glucksberg*, 521 U.S. 702, 739-40 (1997) (O'Connor, J., concurring) (quot-

herself, and sought to implant and rear the human clone could challenge it on an as-applied basis.<sup>215</sup> Her claim could draw sympathy from not only the pro-choice community, but also those in the pro-life community interested in "rescuing" human clones from the primary alternative left by a ban on implanting them: terminating them.

In contrast to a ban on implanting human clones, a ban on creating them is similar to laws precluding certain types of sexual acts like incest, adultery, and sodomy,<sup>216</sup> as well as illicit relationships precedent to reproduction like bigamy, polygamy, and prostitution.<sup>217</sup> Although government may not prohibit the birth

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ing *United States v. Salerno*, 481 U.S. 739 (1987)). No significant reproductive rights victory has been achieved on the basis of a facial attack.

215. See, e.g., *Couple Wants Clone*, *supra* note 161.

216. See, e.g., *State v. Benson*, 612 N.E.2d 337 (Ohio Ct. App. 1992) (statute prohibiting incest constitutional); *State v. Buck*, 757 P.2d 861 (Or. App. 1988); *Bowers v. Hardwick*, 478 U.S. 186, 186 n.4 (1986) (laws against sodomy constitutional); *State v. Kaiser*, 663 P.2d 839 (Wash. Ct. App. 1983). "Various justices have . . . expressed the view that other extra-marital sexual crimes are valid and enforceable." *Roe v. Butterworth*, 958 F. Supp. 1569, 1578 (S.D. Fla. 1997) (citing, *inter alia*, *Carey v. Population Services, Int'l*, 431 U.S. 678 (1977) (White, J., concurring) ("I do not regard the opinion, however, as declaring unconstitutional any state law forbidding extramarital sexual relations."), *Griswold v. Connecticut*, 381 U.S. 479, 498 (1965) (Goldberg, J., concurring) ("The State of Connecticut does have statutes, the constitutionality of which is beyond doubt, which prohibit adultery and fornication."); *id.* at 505 (White, J., concurring) ("the State's policy against all forms of promiscuous or illicit sexual relationships . . . [is] concededly a permissible and legitimate legislative goal."); *Poe v. Ullman*, 367 U.S. 497, 552 (1961) (Harlan, J., dissenting) ("I would not suggest that adultery, homosexuality, fornication and incest are immune from criminal enquiry, however privately practiced.")); see also *Andrews*, *supra* note 91, at 669.

217. See *Barnes v. Glen Theatre, Inc.*, 501 U.S. 560 (1991) (White, J., dissenting) ("[T]he State clearly has the authority to criminalize prostitution and obscene behavior."); *id.* at 575 (Scalia, J., concurring); *id.* at 584 (Souter, J., concurring); *Paris Adult Theatre I v. Slaton*, 413 U.S. 49, 68 n.15 (1973) ("Statutes making bigamy a crime surely cut into an individual's freedom to associate, but few today seriously claim such statutes violate the First Amendment or any other constitutional provision."); *Hoke v. United States*, 227 U.S. 308 (1913) ("There is unquestionably a control in the states over the morals of their citizens, and, it may be admitted, it extends to making prostitution a crime."); *Roe II v. Butterworth*, 958 F. Supp. at 1578 (finding prostitution not a fundamental reproductive right); see also *Cleveland v. United States*, 329 U.S. 14 (1946) (upholding conviction of Mormon under the Mann Act for transporting one of plural wives across state lines for immoral purposes); *Late Corp. of the Church of Jesus Christ of Latter-Day Saints v. United States*, 136 U.S. 1 (1890) (upholding the Edmonds Act and describing polygamy as "a crime against the laws, and abhorrent to the sentiments and feelings of the civilized world"); *Davis v. Beason*, 133 U.S. 333, 341-42 (1890) (bigamy and polygamy "tend to destroy the purity of the marriage relation . . . . Few crimes are more pernicious to the

of babies created despite these laws, courts have not found any fundamental right to engage in these reproductive acts or to enter into these relationships. Likewise, whether or not a fundamental right to implant a clone exists, it is safe to assume the Fourteenth Amendment does not preclude the government from prohibiting altogether creation of human clones. A ban on creating clones would be far less invasive of privacy than a ban on implanting them, and target researchers' activities, rather than women and clones.<sup>218</sup>

Furthermore, the state has many more compelling interests in a ban on creating clones, such as (1) upholding standard human subject experimentation rules; (2) preventing the creation of life solely to cannibalize it; (3) preserving human genetic patrimony and diversity; (4) prohibiting eugenics; and (5) preventing the exploitation of women's reproductive capacity. Concerning the latter point, one estimate indicates that it will take 800 million eggs to experimentally treat 16 million diabetics in the United States, never mind the multitude of other diseases

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best interests of society and receive more general or more deserved punishment."); *Murphy v. Ramsey*, 114 U.S. 15 (1885) (assuming the constitutionality of the Edmonds Act denying voting rights and the right to hold office to practicing polygamists and denying the right to sit on juries to both practitioners and believers in polygamy); *Reynolds v. United States*, 98 U.S. 145 (1878) (upholding conviction of polygamist despite striking of polygamist jurors and of defense that his religion required polygamy).

218. Indeed, pending legislation, read literally, would authorize the state to require a woman to abort a human clone implanted in violation of the bill. The Human Cloning Ban and Stem Cell Research Protection Act of 2002, S. 1893, 107th Cong. § 301(d)(3) (2002), requires forfeiture of any "property" derived from or used to commit a violation or attempted violation of § 301(b). Section 301(b) renders illegal implanting or attempting to implant the "product of nuclear transplantation" into a uterus or the functional equivalent of a uterus. The product of nuclear transplantation, as defined in § 301(a)(3), is a cloned human embryo. To the extent the cloned embryo is not a human being, it must be "property" used to commit a violation of § 301(b) and, therefore, subject to forfeiture under § 301(d)(3). *Accord Statement of Daniel J. Bryant, Assist. Attorney Gen., Office of Legislative Affairs, Before the U.S. House of Representatives Committee on Government Reform, Subcommittee on Criminal Justice, Drug Policy and Human Resources*, 107th Cong. (2002) [hereinafter *DOJ Statement*]. The only way for the state forcibly to take a cloned embryo actually implanted in a woman is to compel her to abort it, contrary to reproductive liberty, which implies the right to carry a fetus to term. *See Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 859 (1992) (opinion of O'Connor, Kennedy, and Souter, JJ.) (citing *Arnold v. Bd. of Educ. of Escambia County, Ala.*, 880 F.2d 305, 311 (11th Cir. 1989) (relying upon *Roe* and concluding that government officials violate the U.S. Constitution by coercing a minor to have an abortion)); *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (invalidating a criminal statute that provided for the mandatory sterilization of those who committed certain types of felonies).

advocates of cloning hope to cure.<sup>219</sup> The only potential alternative is to implant human DNA in cow or pig eggs and, thus, create chimera.

Professor Leon Kass has argued persuasively that only a total ban on cloning is enforceable, because, once human clones exist in laboratories and ART clinics, it will be virtually impossible to control what is done with them.<sup>220</sup> The Department of Justice (DOJ) recently testified that it would have to begin scrutinizing ART clinics, laboratories and, it should be added, uteruses to attempt to distinguish cloned human embryos that are or may be implanted from identical non-cloned embryos.<sup>221</sup> DOJ insists that even an officer standing next to a researcher violating an implantation ban would not detect it.<sup>222</sup> Establishing *mens rea* to engage in reproductive cloning would also prove problematic.<sup>223</sup> Therefore, a ban solely on reproductive cloning would probably not achieve any asserted compelling state interest.<sup>224</sup>

#### *b. Research Cloning*

Unlike reproductive cloning, research cloning arguably has nothing to do with reproductive liberty for the simple reason that it never leads to implantation and birth. On the other hand, most abortion rights law suggests that the state possesses a sufficient interest in the *ex vivo* living human embryo to justify prohibiting persons from maltreating it. For example, *Roe* acknowledged that the State of Texas possessed an important and legitimate interest in protecting potential life, "separate and distinct" from the interest in protecting the health of the mother.<sup>225</sup> The interest *Roe* recognized commenced at viability, whereas the interest the *Casey* plurality recognized arose at conception.<sup>226</sup>

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219. Council for Biotechnology Policy, *Human Cloning and the "Egg Dearth": Where Will They Get the Eggs?*, BIOTECH BULL. #10 (Mar. 14, 2002) (on file with author).

220. Statement of Leon R. Kass, *supra* note 4.

221. DOJ Statement, *supra* note 218.

222. *Id.*

223. *Id.* ("In the absence of a confession, it would be exceedingly difficult for law enforcement authorities to establish that those performing a clonal implantation did so with the requisite *mens rea* at the time the procedure was performed, even if the ultimate result is the birth of a cloned human being.")

224. In contrast, DOJ has testified and Professor Kass agreed that a ban on creating clones is enforceable and capable of achieving its objective. *Id.*; Statement of Leon R. Kass, *supra* note 4.

225. *Roe v. Wade*, 410 U.S. 113, 163 (1973).

226. *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 876 (1992) ("[T]here is a substantial state interest in potential life throughout preg-

Accordingly, federal law prohibits the use of federal funds for "research in which embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero*."<sup>227</sup> Likewise, states have adopted legislation banning or regulating embryonic research.<sup>228</sup> Additionally, courts have upheld fetal manslaughter statutes even for lack of evidence the fetus was viable.<sup>229</sup> Responding to one convict's plea to overturn his conviction under such a law, the Sixth Circuit stated that petitioner "misconceives the nature of the right established in *Roe*"; it vindicated a

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nancy."). *But see* Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992) (preceding *Casey* and finding the state's interest in living human embryos created through ART too slight—even slighter than the state's interest in prohibiting abortion during the first trimester—to justify infringing the alleged reproductive right of gamete providers to decide the fate of the embryos).

227. This language has been included in every HHS appropriations bill since 1995. *See* Omnibus Consolidated Appropriations Act of 2001, Pub. L. No. 106-554, § 510 (2000); Omnibus Bill, Pub. L. No. 106-113, § 510 (1999); Omnibus Bill, Pub. L. No. 105-277, § 511, 112 Stat. 2681-386 (1998); Labor/HHS/Education Appropriations Act, Pub. L. No. 105-78, § 513, 111 Stat. 1517 (1997); Omnibus Bill, Pub. L. No. 104-208, § 512, 110 Stat. 3009-270 (1996); Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 34 (1996). In 2001, Congress deemed this provision consistent with President Bush's policy of permitting the federal funding of research on allegedly roughly 70 lines of stem cells already derived from living human embryos. *See* H.R. REP. NO. 107-229, § 510 (2001).

228. *See, e.g.*, FLA. STAT. ANN. § 390.0111(6) (West 1998) (banning the use of any live fetus "for any type of scientific, research, laboratory, or other kind of experimentation"); LA. REV. STAT. ANN. § 9:129 (West 2000) (prohibiting the destruction of any *in vitro* fertilized human ovum); ME. REV. STAT. ANN. tit. 22, § 1598 (West 1992) (stating that the use of intrauterine and extra-uterine human fetuses or products of conception cannot be used for scientific or any form of experimentation); MICH. COMP. LAWS ANN. § 333.2685 (West 2001) (prohibiting research on embryos if the research will substantially jeopardize the life or health of the embryo); MINN. STAT. § 145.422 (1998) (stating that anyone who uses a living human conceptus for experimentation that is not harmless to the embryo is guilty of a gross misdemeanor); N.M. STAT. ANN. § 24-9A-3 (Michie 2000) (stating "[n]o fetus shall be involved as a subject in any clinical research activity unless the purpose of the activity is to meet the health needs of the particular fetus" and that "the fetus will be placed at risk only to the minimum extent necessary to meet such needs or no significant risk to the fetus is imposed by the research activity"); 18 PA. CONS. STAT. § 3216 (2000) (stating that "any person who knowingly performs any type of non-therapeutic experimentation or non-therapeutic medical procedure" upon an unborn child is guilty of a third degree felony, and defining "non-therapeutic" as "that which is not intended to preserve the life or health of the child upon whom it is performed").

229. *See, e.g.*, Coleman v. DeWitt, 282 F.3d 908 (6th Cir. 2002), *cert. den'd.*, 122 S.Ct. 2379 (2002) (rejecting petitioner's plea to overturn his conviction for manslaughter for causing his baby to miscarry after kicking his girlfriend in the abdomen for lack of evidence it was viable).

woman's interest in self-determination while recognizing "that the state had important interests in protecting fetal life."<sup>230</sup>

Likewise, Tennessee's Supreme Court found that even frozen human embryos deserve "special respect" and, therefore, some interim level of protection between persons and property.<sup>231</sup> The metaphors of "person" or "property" may be inadequate for the purpose of biotechnological regulation where the *ex vivo* subject is not mere tissue, but living; not another species, but human; not self-conscious, but possessing the entire genetic code of an adult person. "[A]lthough fetuses and embryos may not be persons in the full sense, they are still entitled to certain kinds of respect and moral regard" more important than "mere things."<sup>232</sup> Pursuant to the special respect paradigm, the state has the authority to preclude or regulate research cloning without impacting a woman's right to choose.

## 2. First Amendment

The First Amendment is another legal regime relevant to biotechnology. Proponents of HC contend that scientists have a free speech and Fourteenth Amendment right to engage in scientific inquiry and cloners have a Free Speech and Free Exercise right to express themselves.<sup>233</sup> They argue that research is an essential precondition to dissemination of scientific ideas; therefore, "it should have the same constitutional status as dissemination of scientific information"; otherwise, "government could control access to ideas by locating restraints at the point where the information sought to be disseminated is developed or obtained."<sup>234</sup>

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230. *Id.* at 912-14.

231. *Davis*, 842 S.W.2d at 597. Concerning *Davis*, Professor John Robertson remarked, "[O]ne may reject the right-to-life position that early embryos are themselves persons . . . and still agree that early embryos deserve 'special respect'. . . ." John A. Robertson, *In the Beginning: The Legal Status of Early Embryos*, 76 VA. L. REV. 437, 446-47 (1990) [hereinafter Robertson on Early Embryos]; see also John A. Robertson, *Embryos, Families, and Procreative Liberty: The Legal Structure of the New Reproduction*, 59 S. CAL. L. REV. 939, 972-75 (1986) [hereinafter Robertson on New Reproduction].

232. Kayhan Parsi, *Metaphorical Imagination: The Moral and Legal Status of Fetuses and Embryos*, 4 DEPAUL J. HEALTH CARE L. 703, 784-85 (1999).

233. See, e.g., Elizabeth Price Foley, *The Constitutional Implications of Human Cloning*, 42 ARIZ. L. REV. 647, 696 (2000); John A. Robertson, *The Law of Institutional Review Boards*, 26 UCLA L. REV. 484 (1979) [hereinafter Robertson on IRBs]; John A. Robertson, *The Scientist's Right to Research: A Constitutional Analysis*, 51 S. CAL. L. REV. 1203 (1977) [hereinafter Robertson on Right to Research].

234. Robertson on IRBs, *supra* note 233, at 503.

Expressive conduct warrants First Amendment protection only if (1) the conduct is intended to convey a particularized message and (2) there is a "great" likelihood that "the message will be understood by those who view[ ] it."<sup>235</sup> Cases establishing this proposition in the 1960s and 1970s involved flag burning, registration card burning, and black armbands.<sup>236</sup> Biotechnological research may not meet this standard. Nevertheless, one commentator declares that "[t]hrough experimentation, scientists express their creativity and intellectuality in much the same way that musicians express themselves through music or artists express themselves through art."<sup>237</sup> Banning this research, according to the scholar, would interfere with the conveyance of a message "in the same way as would a law which banned impressionistic painting or rap music."<sup>238</sup>

One of the first American couples pursuing cloning says it wants to "tell the world" cloning is safe and acceptable.<sup>239</sup> The couple adds, "God really wants us to do [it]."<sup>240</sup> Cults organizing around this theme include the church of Prometheus, church of conscious evolution, and Raelians.<sup>241</sup> Therefore, American courts will likely decide arguments for human cloning premised

235. *Spence v. Washington*, 418 U.S. 405 (1974) (displaying American flag with peace symbol superimposed was protected by First Amendment because it was essentially a form of expression).

236. See *United States v. Eichman*, 496 U.S. 310 (1990) (invalidating Flag Protection Act of 1989, which made it a crime for any person knowingly to mutilate, deface, physically defile, burn, maintain on the floor or ground, or trample upon any flag of the United States); *Texas v. Johnson*, 491 U.S. 397 (1989) (overturning conviction of person under Texas flag desecration statute who burned an American flag as part of a political demonstration protesting the policies of the Reagan Administration); *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503 (1969) (invalidating suspensions of three public school students who wore black armbands to school to protest the government's policy in Vietnam); *United States v. O'Brien*, 391 U.S. 367 (1968) (upholding indictment of defendant on basis he "willfully and knowingly did mutilate [sic], destroy, and change by burning [his] Registration Certificate . . .").

237. *Foley*, *supra* note 233, at 683 (adding that permitting creation of a human clone, but not its implantation, according to this commentator, would prevent the scientists from "performing a play one has written or singing a song one has composed").

238. *Id.*

239. See *Couple Wants Clone*, *supra* note 161.

240. *Id.*

241. See *The First Sovereign Transhuman and Neo-Eugenic Libertarian Religious State*, (declaring it is the church of Prometheus' "aim to create a [genetically] enhanced race that will . . . become a new, superior species . . .") And stating, "We seek to bring ourselves closer to Godhood. Through [eugenics] and other forms of . . . self-improvement, [we will] bring about higher civilization, higher creativity, higher consciousness to the Universe."), at <http://www.prometheism.net> (last visited Nov. 17, 2002) (on file with the Notre Dame Journal of Law,



on free speech; free exercise; and so-called "hybrid rights" claims,<sup>242</sup> incorporating free speech, free exercise, and parental rights.<sup>243</sup>

Generally applicable, viewpoint-neutral regulation of religious expression is permissible.<sup>244</sup> Regulation of expressive conduct that is not viewpoint neutral or, in other words, subject merely to neutral time, place and manner restrictions, must satisfy strict scrutiny.<sup>245</sup> In this event, a law proscribing cloning would have to serve a compelling interest unrelated to the suppression of free expression in the least restrictive manner.<sup>246</sup> One commentator urges that a ban on HC would not be content neutral, because it would necessarily "emanate from fears concerning the expressive content of cloning activity," and would not be narrowly tailored because a ban merely on reproductive cloning would do.<sup>247</sup> If carried to its logical conclusion, this position would treat as viewpoint discrimination any regulation serving the health and safety of human subjects, yet liberal democracies have always both encouraged liberal scientific inquiry and regulated a wide variety of medical research, including, for example, human subject experimentation,<sup>248</sup> gene transfer research,<sup>249</sup> and fetal tissue research.<sup>250</sup>

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Ethics & Public Policy); Aaron Zitner, *Clones, Free Love, and UFOs*, L.A. TIMES, Mar. 5, 2002, at A1 (concerning Raelians).

242. *Employment Div., Dept. of Human Res. of Or. v. Smith*, 494 U.S. 872, 881 (1990) (holding that incidental infringements on religious expression caused by neutral, generally applicable laws are subject merely to rational review, unless the infringements impact "hybrid rights"—such as hybrid free exercise-free speech rights—or are part of a generalized system of exceptions).

243. Andrews on Cloning, *supra* note 91, at 648; Liza Mundy, *A World of Their Own; In the Eyes of His Parents, If Gauvin Hughes McCullough Turns Out to be Deaf, That will be Just Perfect*, WASH. POST, Mar. 31, 2002, at W22; *see also* Coleman, *supra* note 33, at 160 ("Another argument for a parental right to genetically design their children focuses on First Amendment considerations: The very essence of a free society lies in the liberty of each individual citizen to develop in the direction that she pleases. [GE] advances the prospects for self actualization of its recipients.").

244. *Smith*, 494 U.S. at 881.

245. *United States v. O'Brien*, 391 U.S. 367, 376–77 (1968); *see also* *Rosenberger v. Rector & Visitors of the Univ. of Va.*, 515 U.S. 819, 829 (1995) (citing *R.A.V. v. St. Paul*, 505 U.S. 377, 391 (1992)) ("When government targets not subject matter, but particular views taken by speakers on a subject, the violation of the First Amendment is all the more blatant.").

246. *O'Brien*, 391 U.S. at 377; *see also* *Capitol Square Review and Advisory Bd. v. Pinette*, 515 U.S. 753, 761 (1995).

247. Foley, *supra* note 233, at 683–85.

248. *See infra* Part II(B)(3)(b).

249. *See supra* Part I(B)(3)(a).

Professor Robertson would distinguish these regulations concerning research methods from limitations on a scientist's ability to select a research topic. He would allow the former, but protect absolutely the latter and, thus, disallow any ban on acquiring scientific knowledge concerning HC.<sup>251</sup> Case law does not necessarily support this distinction. To be sure, the U.S. Supreme Court stated in dicta in *Meyer v. Nebraska*, that Fourteenth Amendment liberty "denotes not merely freedom from bodily restraint but also the right . . . to acquire useful knowledge . . . ."<sup>252</sup> Although it is conceivable a court could use this as a basis to expand Fourteenth Amendment jurisprudence, no court has yet identified a deeply rooted liberty interest in scientific inquiry, never mind HC or GE. On the other hand, courts have held that there is no fundamental right of scientific inquiry to experiment on human fetuses.<sup>253</sup>

Once more, to the extent biotechnological research is symbolic speech, it could be characterized solely as commercial speech subject to intermediate scrutiny.<sup>254</sup> Whereas the Supreme Court has implied that the conduct of science is generally not commercial,<sup>255</sup> some of the initial efforts to engage in

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250. See National Institutes of Health Revitalization Act of 1993 § 112, 42 U.S.C. § 289g-2(a) (1994) ("It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."); 42 U.S.C. § 289g (Research on nonviable human fetuses is banned, unless it poses "no added risk of suffering, injury or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge that cannot be obtained by other means."); 42 U.S.C. § 289g-1(b)(2)(A)(ii) (Human fetal tissue may not be used if obtaining it alters the timing, method, or procedure used to terminate pregnancy.).

251. Robertson on Cloning, *supra* note 2, at 1436-39; Robertson on IRBs, *supra* note 233, at 506; Robertson on Right to Research, *supra* note 233, at 1204-09. He would also concede the government's ability to condition federal funding for medical research as it chooses; for example, by precluding funding for the purpose of destroying living human embryos. Robertson on IRBs, *supra* note 233, at 507; Robertson on Right to Research, *supra* note 233, at 1208.

252. 262 U.S. 390, 399 (1923) (emphasis added).

253. Andrews, *supra* note 91, at 663; see, e.g., Wynn v. Scott, 449 F. Supp. 1302 (N.D. Ill. 1978).

254. A four-part test exists for determining the validity of restrictions on commercial speech: (1) the content of the speech must concern lawful activities and not be misleading; (2) the asserted governmental interest in regulating the speech must be substantial; (3) the regulation must directly advance the asserted governmental interest; and (4) the regulation must be no more extensive than necessary to serve the asserted governmental interest. *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980).

255. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748, 762 (1976) (Commercial speech is "speech which does no more than propose a commercial transaction" such that it "is so removed from any experi-

reproductive cloning appear primarily for-profit.<sup>256</sup> Even with respect to research cloning, we shall see that biotechnological inquiry is dominated by a close relationship between business and the academy.<sup>257</sup> It is so close that in many instances the demands of Wall Street appear to govern biotechnological research more than time-honored academic principles.<sup>258</sup>

### 3. Human Subject Experimentation Rules

Human subject medical experimentation was not widely practiced or legally authorized prior to 1935.<sup>259</sup> Therefore, liberal democracies did not begin regulating it until after the Nuremberg Trials. This section explores the legal regime that resulted, which proponents of HC consider inapplicable to genetically altered living human embryos.

#### a. *International Codes*

The atrocities that Nazis committed in World War II were the genesis of human subject experimentation law. The Doctors'

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tion of ideas and from truth, science, morality, and arts in general . . . that it lacks all protection.").

256. See Bob LaMendola, *Cloning Claims Spawn Skepticism and Outrage; Scientists Question Company's Assertions, Credibility*, SUN-SENTINEL (Ft. Lauderdale Fla.), Jan. 1, 2003, at 1A (referencing Clonaid's cloning services including human reproductive cloning for \$200,000, preserving cells for future cloning for \$200 per year, and cloning pets for an undisclosed fee; those services are advertised at Clonaid.com, <http://www.clonaid.com/english/pages/services.html> (last visited Jan. 14, 2003) (on file with the Notre Dame Journal of Law, Ethics & Public Policy)).

257. See *infra* Part II(B)(3)(b) at 40–41.

258. For example, Advanced Cell Technology, Inc. (ACT) announced in November 2001 that it had cloned human beings, but the scientific community concluded the claim was a spurious attempt to raise capital. See, e.g., Gina Kolata & Andrew Pollack, *A Breakthrough in Cloning? Perhaps, or Perhaps Not Yet*, N.Y. TIMES, Nov. 27, 2001, at A1.

259. Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157 (1998).

We recognize the fact that if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him, and must not vary too radically from the accepted method of procedure.

*Id.* at 169 (citing *Fortner v. Koch*, 261 N.W.2d 762 (1955)). Only one case preceding the Nuremberg Code dealt with non-therapeutic human subject experimentation and held that a fifteen-year-old minor, together with his parent, could consent to a non-therapeutic skin graft benefiting the minor's cousin. George J. Annas, *Mengele's Birthmark: The Nuremberg Code in United States Courts*, 7 J. CONTEMP. HEALTH L. & POL'Y 17, 22 (1991) (citing *Bonner v. Moran*, 126 F.2d 121, 121 (D.C. Cir. 1941)).

Trials after the War led to the Nuremberg Code, which prohibited altogether human subject experimentation where (1) the researcher knew the experiment could lead to death or disabling injury; (2) the research was not based on sufficient animal studies; (3) the human subject had not given voluntary informed consent; (4) the researcher could obtain the results another way; and (5) the experiment allowed unnecessary suffering and injury.<sup>260</sup>

Research cloning violates each of these criteria, some inevitably. For example, it necessarily leads to the death of the human subject (the embryo) and the subject cannot consent to the procedure. Additionally, only a handful of generally unsuccessful animal studies presently reveal that embryonic stem cells can treat disease, whereas a number of studies involving adult

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260. The Nuremberg Code states,

1. The voluntary consent of the human subject is absolutely essential, [and the human subject] should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.

. . . .

2. The experiment should be . . . unprocurable by other methods or means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease . . . .
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

. . . .

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end . . . .
10. [T]he scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him that a continuation of the experiment is likely to result in injury, disability or death to the experimental subject.

NUREMBERG CODE (1949), available at <http://ohsr.od.nih.gov/nuremberg.php3> (on file with the Notre Dame Journal of Law, Ethics & Public Policy); see also *United States v. Carl Brandt, II TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10* 181–82 (1946–49).

stem cells suggest they have the potential to achieve all of the objectives of embryonic stem cell research.<sup>261</sup>

The Code remains the "most complete and authoritative statement of the law of informed consent to human experimentation."<sup>262</sup> It is "part of international common law and may be applied, in both civil and criminal cases, by state, federal and municipal courts in the United States."<sup>263</sup> Although federal courts have not found that it creates an implied right of action in circumstances where adequate domestic remedies exist,<sup>264</sup> they have found, contrary to claims of qualified immunity, a "clearly established right" to bodily integrity in § 1983 litigation.<sup>265</sup>

However, a successor code of medical ethics exists. The 1964 Helsinki Declaration was promulgated in response to the demand by researchers for a more "flexible" ethical standard to facilitate *bona fide* (in contrast to Nazi) experimentation on incompetent humans.<sup>266</sup> In 1954, the World Medical Association (WMA) proposed approving experimentation on incompetent human subjects with the consent of a person legally responsible for the individual.<sup>267</sup> Since amended, the Declaration now more closely resembles the Code than ever.

Most importantly, the Declaration now expressly prohibits proxy consent to human subject research if (1) the research is not necessary to promote the health of the subject; (2) the research can be performed on legally competent individuals; and

261. See *Opportunities and Advancements in Stem Cell Research: Hearing Before the Gov't Reform Subcomm. on Criminal Justice, Drug Policy & Human Res.*, 107th Cong. n.16 (2001) (statement of David Prentice and supplemental statement of David Prentice).

262. GEORGE ANNAS ET AL., INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA 21 (1977).

263. *Id.* at 21; accord *Heinrich v. Sweet*, 49 F. Supp. 2d 27, 42 (D. Mass. 1999) (citing *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 821 (S.D. Ohio 1995)).

264. *Heinrich*, 49 F. Supp. 2d at 42 (citing *White v. Paulsen*, 997 F. Supp. 1380, 1383–84 (E.D. Wash. 1998)).

265. *Id.* at 320–21 (referencing 42 U.S.C. § 1983 and citing *Stadt v. Univ. of Rochester*, 921 F. Supp. 1023 (W.D.N.Y. 1996)).

266. WORLD MED. ORG., DECLARATION OF HELSINKI, 313 BRIT. MED. J. 1448–49 (1996), available at <http://www.cirp.org/library/ethics/helsinki> (on file with the Notre Dame Journal of Law, Ethics & Public Policy); Annas, *supra* note 259, at 24.

267. Annas, *supra* note 259, at 24–25 (citing WORLD MED. ASS'N, HUMAN EXPERIMENTATION, 2 WORLD MED. J. 14, 14–15 (1955)). The British drafter reasoned, "So long as the research worker is imbued with the Hippocratic ideal, this and his conscience should be a sufficient guide." *Id.* at 25.

(3) the research is not based on sufficient animal studies.<sup>268</sup> This is also in accord with independent declarations of the General Assembly and EC.<sup>269</sup> Research cloning violates each of these principles.

The human clone also appears to lack a relationship with any person qualified to subject it to experimentation. Parents and legal guardians have a fiduciary-like responsibility to their wards, rendering their proxy consent to experimentation on progeny meaningful.<sup>270</sup> DNA and egg donors do not necessarily have a similar responsibility to human clones. To the contrary, as a condition of providing DNA or eggs, donors may disavow any responsibility, financial or otherwise, for the human clone.<sup>271</sup> Regardless, fiduciaries may not expose their wards to more than minimal risk.

The single American court to discuss intentionally exposing a child to non-therapeutic experimentation (lead poisoning) stated, "[I]n our view, parents whether improperly enticed by trinkets, food stamps, money or other items, have no more right to intentionally and unnecessarily place children in potentially hazardous non-therapeutic research surroundings than do researchers. In such cases, parental consent, no matter how informed, is insufficient."<sup>272</sup>

Proponents of HC object that human embryos are not juridical persons; therefore, the same rules of human experimentation

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268. Initially, the Declaration of Helsinki expressly allowed proxy consent "in accordance with national legislation" for therapeutic human experimentation, but not necessarily non-therapeutic experimentation. The Declaration otherwise preserved the Code's emphasis on uncoerced, informed, and competent consent and, regardless of consent, left the responsibility for the human subject on the researcher. The Declaration also firmly stated, "Concern for the interests of the subject must always prevail over the interests of science and society." The Declaration has been amended five times since, including as recently as October 2000, so that now proxy consent for legally incompetent persons is expressly prohibited unless "the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons." The amended Declaration adds that vulnerable research populations merit special protection and that human experimentation should not proceed until there is "adequate laboratory and, where appropriate, animal experimentation." WORLD MED. ORG., *supra* note 268, at 1448-49.

269. U.N. ESCO, *supra* note 134, art. 5; Convention on Human Rights and Biomedicine, *supra* note 134, arts. 5-6.

270. *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807, 856-58 (Md. 2001).

271. Clones replicated from the DNA and eggs of those who would create it are the closest to possessing a quasi-fiduciary relationship with the resulting embryo, but these donors are still not exactly birth parents.

272. *Grimes*, 782 A.2d at 814.

should not apply. Contrary to this view is a widely accepted definition of human subject experimentation: "any manipulation, observation, or other study of a *human being*—or of anything related to that human being that might subsequently result in manipulation of that human being—done with the intent of developing new knowledge and which differs in any form from customary medical (or other professional) practice."<sup>273</sup>

International human subject experimentation law exists in general to vindicate the rights of vulnerable incompetent human subjects.<sup>274</sup> Its primary purpose is to preserve the autonomy, self-determination, liberty, and equality of living human subjects,<sup>275</sup> and to compensate for the imbalance in power between the researcher and subject and for their divergent interests nurtured by the public-private cooperation undergirding biotechnology. Accordingly, the burden of proof is upon those who would entirely exempt living human embryos from this framework, not upon those who would apply it.

#### *b. U.S. Human Subjects Policy*

The first systematic American effort to develop a policy to protect the human subjects of experimentation incorporated the Code.<sup>276</sup> However, the U.S. Human Subjects Policy was elaborated through three waves of activism. In the 1960s, deformities and other terrible side effects of the experimental drug

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273. Robert LeVine, *The Boundaries Between Biomedical or Behavioral Research and the Accepted and Routine Practice of Medicine*, in 1 NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS, THE BELMONT REPORT, app. (1979).

274. Note that HHS' Advisory Committee on Human Research Protections now advises on the responsible conduct of research involving human embryos. See Rick Weiss, *New Status for Embryos in Research*, WASH. POST, Oct. 30, 2002, at A01 (referencing HHS Charter, Secretary's Advisory Committee on Human Research Protections, which is available at <http://ohrp.osophs.dhhs.gov/sachrp/charter.pdf> (last visited Jan. 14, 2003) (on file with the Notre Dame Journal of Law, Ethics & Public Policy)).

275. Morin, *supra* note 259, at 159 ("[T]he doctrine of informed consent is rooted in some of the most fundamental values of Anglo-Saxon legal philosophy—individuality, autonomy, and bodily integrity."); This is a reflection of the common law that holds no right more sacred "than the right of every individual to the possession and control of [the human being's] own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Union Pacific Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

276. See *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 821 (S.D. Ohio 1995) (citing Memorandum for the Secretary of the Army, Navy, Air Force (Feb. 26, 1953)); Morin, *supra* note 259, at 169 ("[B]y 1952, the Armed Forces Medical Policy Council adopted a resolution whereby principles found in the Nuremberg Code were to become the guidelines of research related to atomic, biologic, and chemical warfare.").

Thalidomide became known (along with unrelated monopoly and pricing concerns), leading Congress to hold its first hearing to discuss the need for informed consent in human subject experimentation trials.<sup>277</sup> This led to amendments to the Food, Drug and Cosmetic Act, granting the FDA authority to screen drugs for their efficacy and safety.<sup>278</sup>

In 1966, continued reports of abuses of informed consent even at America's finest hospitals<sup>279</sup> stimulated the Surgeon General and FDA to announce new policies governing the use of experimental drugs, which adopted language from the Code and Declaration (particularly their consent provisions).<sup>280</sup> Compliance with the FDA's policy became a condition of experimental drug trials,<sup>281</sup> whereas compliance with the Surgeon General's

277. Morin, *supra* note 259, at 170–71.

278. *Id.* at 171 (citing Drug Industry Act of 1962, 108 CONG. REC. 17395–99 (1962)). The Declaration was announced in 1964 on the eve of the FDA's proposal to standardize research on experimental drugs. Annas, *supra* note 259, at 25.

279. Richard Delgado & Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67, 71 n.12 (1986) (citing, *inter alia*, Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966)). Two experiments attracted the most attention: one involving the experimental injection of cancer cells into elderly patients who could not consent at a Jewish Chronic Disease Hospital and the unsuccessful transplant of a chimpanzee's kidney into a human being. Morin, *supra* note 259, at 173.

280. Concerning the FDA's Statement of Policy Concerning Consent for Use of Investigational New Drugs on Humans, *see* Morin, *supra* note 259, at 171 (citing 31 Fed. Reg. 11,415 (1966)). Subsection (h) stated,

"Consent" or "informed consent" means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of all material information concerning the administration of the investigational drug, or his possible use as a control, as to enable him to make an understanding decision as to his willingness to receive said investigational drug. This latter element requires that before the acceptance of an affirmative decision by such person the investigator should make known to him . . . that the person may be used as a control; the existence of alternative forms of therapy, if any; and the effects upon his health or person that may possibly come from the administration of the investigational drug.

31 Fed. Reg. 11,415(h). For the Surgeon General's Policy Statement on Clinical Investigations Using Human Subjects, *see* Morin, *supra* note 261, at 174; Robertson on IRBs, *supra* note 233, at 487–88 (citing Memorandum from Surgeon General to Heads of Institution Conducting Research with Public Health Service Grants (Feb. 8, 1966), *quoted in* W. CURRAN & E. SHAPIRO, *LAW, MEDICINE, AND FORENSIC SCIENCE* 898 (2d ed. 1970)).

281. *See* Morin, *supra* note 259, at 171–72.



policy became a condition of extramural funding and, eventually, all DHEW grants and contracts.<sup>282</sup>

In 1974, the Willowbrook hepatitis study and Tuskegee trials<sup>283</sup> catalyzed establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, IRBs, and adoption of the Federal Policy for the Protection of Human Subjects (Human Subjects Policy).<sup>284</sup> Underlying the Human Subjects Policy is an emphasis on promoting individual autonomy, protecting the patient-subject's status as a human being worthy of respect, minimizing fraud and duress, and encouraging self-scrutiny by the physician-researcher.<sup>285</sup>

Amended frequently since, the Human Subjects Policy today applies to all "research" involving IVF,<sup>286</sup> "human beings,"<sup>287</sup> and "human subjects."<sup>288</sup> Since 1981, it has also applied to some samples of blood and tissue.<sup>289</sup> Except in certain circumstances,<sup>290</sup> the Policy requires: (1) *legally effective* informed consent of the

282. Morin, *supra* note 259, at 174; Robertson on IRBs, *supra* note 233, at 488. By the 1960s, the National Institutes of Health, which was established in 1953 as the Clinical Center of the National Institutes of Health, had become an important funder of medical research. Morin, *supra* note 259, at 173-74.

283. *The Tuskegee Syphilis Study*, 289 NEW ENG. J. MED. 730 (1973) (researchers studying syphilis failed to inform African-Americans of the availability of penicillin).

284. 39 Fed. Reg. 18,914 (May 30, 1974); Morin, *supra* note 259, at 175; Robertson on IRBs, *supra* note 233, at 488-89.

285. See generally R.R. FADEN ET AL., A HISTORY AND THEORY OF INFORMED CONSENT (1986); D.J. ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING (1991); Morin, *supra* note 259, at 159; A.M. Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 341, 349 (1974).

286. Protection of Human Subjects, Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research, 45 C.F.R. § 46.203(g) (2001). IVF is defined as "any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means." *Id.*

287. *Id.* § 46.116. The Code does not define "human being."

288. *Id.* § 46.101(a). "Human subjects" are defined as "living individuals." *Id.* § 46.102(f).

289. *Id.* § 46.102(f)(2) ("includes . . . physical procedures by which data are gathered (for example, venipuncture) . . . ." *But see id.* § 46.101(b)(5) (exemptions)).

290. The Human Subjects Policy exempts certain types of research including educational research, research involving surveys and interviews, research that consists of observing public behavior, and research that uses existing records or data. *Id.* §§ 46.101(b)(1)-(6). Informed consent may also be modified or waived when research concerns an evaluation of certain government programs or presents only minimal risk to subjects and "could not practicably be carried out without the waiver or alteration." *Id.* §§ 46.101(b)(6), 46.116(d)(1)-(3).

subject or the subject's legally authorized representative;<sup>291</sup> (2) minimization of risks;<sup>292</sup> (3) risks to subjects reasonable in relation to anticipated benefits;<sup>293</sup> and (4) additional safeguards to protect the rights and welfare of subjects when some or all of them are likely to be vulnerable to coercion or undue influence.<sup>294</sup>

The Human Subjects Policy defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."<sup>295</sup> Curiously, it does not define "informed consent," except by way of listing those items researchers must disclose to human subjects.<sup>296</sup> Plainly, the Human Subjects Policy also acknowledges that some proxy consent to research is not legally effective. The Policy clarifies that "minimal risk" exists when "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."<sup>297</sup>

In general, the Human Subjects Policy anticipates that the medical profession will police itself.<sup>298</sup> It includes no remedy for a violation beyond terminating a federal grant or not qualifying for additional ones.<sup>299</sup> Instead, the Policy requires principal investigators of federally-funded studies and studies subject to FDA regulation to certify compliance and answer to IRBs.<sup>300</sup> IRBs are supposed to be composed of a racially and culturally diverse cross-section of the scientific and lay communities and not to have competing interests that prevent unbiased performance of their duties.<sup>301</sup> In practice, medical institutions retain

291. *Id.* § 46.116; *Id.* § 46.111(a)(4).

292. *Id.* § 46.111(a)(1).

293. *Id.* § 46.111(a)(2).

294. *Id.* § 46.111(b).

295. *Id.* § 46.102(d).

296. *Id.* §§ 46.116(a)(1)–(8).

297. 45 C.F.R. § 46.102; *see also id.* §§ 46.401–09 (stating that children may be subject only to a minor increase over minimal risk).

298. *See generally* 45 C.F.R. § 46.123; 48 C.F.R. § 309.4 (1985) (debarment of federal contracts); Morin, *supra* note 259, at 498; Robertson on IRBs, *supra* note 233, at 544.

299. Robertson on IRBs, *supra* note 233, at 498; Morin *supra* note 259, at 175 (NIH had "no enforcement authority beyond refusing to grant funds . . .").

300. 45 C.F.R. § 46.103(a); *see also* Robertson on IRBs, *supra* note 233, at 499 ("To receive funds, a researcher must be affiliated with an institution that has an approved general or special assurance on file."). Accordingly, the Human Subjects Policy is also referred to as the General Assurance. *Id.*

301. 45 C.F.R. §§ 46.107(b), (e).

"broad discretion" over IRB composition, policies, procedures, and transparency.<sup>302</sup> DHEW review of IRB operations is negligible.<sup>303</sup> Once more, until recently, IRBs and medical institutions have been protected altogether from private litigation.<sup>304</sup> "Consequently, institutions and the investigators who comprise the IRBs, rather than the subjects whom IRBs ostensibly aim to protect, largely determine the extent of regulation."<sup>305</sup> Even the researchers IRBs are supposed to control are independent of them, because IRBs rarely interfere in experimentation after approving it except on a perfunctory annual basis.<sup>306</sup>

Many criticize this regulatory structure because of both "conflicts of interest" and "conflicts of value" that arise between subjects and researchers.<sup>307</sup> The former arise when the researcher has a direct economic interest in the outcome of the research.<sup>308</sup> The latter are always present because experimentation impacts a researcher's professional prestige and career advancement.<sup>309</sup> As a result, commentators say researchers treat the requirements of

302. Robertson on IRBs, *supra* note 233, at 493, 537-40.

303. *Id.* at 547-48 ("DHEW control of IRB operations, however, is actually quite limited. In extreme situations, DHEW may find IRB activities and procedures inadequate and refuse to provide funds or demand stricter compliance with its requirements and more closely monitor institutional performance. Nevertheless . . . the IRB is legally subject to the policy choices of institutional authorities, not the DHEW.").

304. *See id.* at 530-45 (discussing immunity provided to medical peer review committee members that potentially include IRB members, and the inapplicability of FOIA and potential inapplicability of state FOIA laws, privileges, confidentiality of peer review committee records, and unregulated IRB record retention policies); *cf.* Morin, *supra* note 259, at 207-10 (indicating that in recent cases involving human experimentation, "the role of hospitals and IRBs has been scrutinized and liability ascribed to hospitals when affiliated investigators have failed to secure informed consent") (citing *Kus v. Sherman Hosp.*, 644 N.E.2d 1214 (Ill. App. Ct. 1995); *Fritter v. IOLAB Corp.*, 607 A.2d 1111 (Pa. Super. Ct. 1992)).

305. Robertson on IRBs, *supra* note 233, at 546. Moreover, the research subjects who are supposed to be selected to prevent over-reliance on certain groups are generally young, poor, and ill. *Compare* 45 C.F.R. § 46.107, with Delgado & Leskovac, *supra* note 279, at 101-02. *See also* Churchill et al., *supra* note 112, at 42.

306. Robertson on IRBs, *supra* note 233, at 547-48.

307. Churchill et al., *supra* note 112, at 38 (conflicts of interest); Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 St. Louis U. L.J. 63, 104 (1993); Delgado & Leskovac, *supra* note 279, at 91-92, 97-101 (conflicts of value); Robertson on IRBs, *supra* note 233, at 548-49 (calling for structural modifications to the IRB system to enhance subject protection without losing the advantages of institutional control).

308. Delgado & Leskovac, *supra* note 279, at 91-92.

309. *Id.* at 97-101, 104.

the Policy as empty formalities—Miranda Rights—and report a paternalistic attitude on the part of researchers that they know best what is good for subjects and society.<sup>310</sup> Furthermore, they note a “persistent failure to distinguish clearly between research and therapy in medical science,” particularly when research subjects are also patients or when research takes place within the clinical environment.<sup>311</sup>

These problems are exacerbated in biotechnological research. The reasons are three-fold: (1) inflammatory rhetoric about the near-miraculous therapeutic potential of biotechnology; (2) the regulatory structure; and (3) the close relationship between the scientific and industrial community. Heightened expectations for biotechnological research exist, because it has the potential not merely to manage disease, but cure it.<sup>312</sup> No other therapeutic modality except vaccines holds this potential.<sup>313</sup> However, proponents of biotechnology fail to distinguish this potential from its present state-of-the-art by, among other things, misappropriating terms like “therapy” (*e.g.*, “gene therapy” and “therapeutic cloning”).<sup>314</sup> Frequently, proponents also engage in a form of genetic determinism, understating the environmental, behavioral, and social causes of disease.<sup>315</sup>

According to the Belmont Report, the practice of accepted therapy denotes “interventions that are designed solely to enhance the well-being of an individual patient . . . and that have a reasonable expectation of success.”<sup>316</sup> In contrast, research is “an activity designed to test a hypothesis . . . and contribute to generalizable knowledge.”<sup>317</sup> Under this definition, cloning and GE constitute research, not therapy. So-called therapeutic cloning is precisely the opposite, because it kills the human subject.

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310. *Id.* at 84; *see also* Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 839 (Md. 2001) (“Researchers, under competitive pressure and also financial pressure from corporate backers, operate under a paternalistic approach to research subjects, asserting professional expertise and arguing experimental necessity while minimizing the right to self-determination—a key aspect of the exercise of autonomy—of their subjects.”).

311. Churchill et al., *supra* note 112, at 38.

312. *Id.* at 43.

313. *Id.*

314. *Id.* (concerning gene “therapy”).

315. *Id.*

316. U.S. DEP’T OF HEALTH, EDUC. & WELFARE, NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMED. & BEHAVIORAL RESEARCH, THE BELMONT REPORT, ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (Apr. 18, 1979), *available at* <http://ohsr.od.nih.gov/mpa/belmont.php3> (on file with the Notre Dame Journal of Law, Ethics & Public Policy) [hereinafter BELMONT REPORT].

317. *Id.*

Even so-called gene therapy has failed to demonstrate a single unambiguous instance of therapy.<sup>318</sup>

Notwithstanding the death of Jesse Gelsinger, the idea that it is discriminatory to exclude individuals from participating in biotechnological trials has great currency. The public appears not to understand that, for the most part, it is pure experimentation unlikely to lead to any direct benefit to the subject, as opposed to some possible attenuated benefit for future generations.<sup>319</sup> The long-standing Western tradition of permitting desperately ill patients to participate in therapeutic trials is miles from this scenario, where the subject stands to gain nothing and lose everything. Yet the regulatory structure for gene therapy is still modeled primarily upon a therapeutic alliance between physician and patient.<sup>320</sup> With the possible exception of the FDA, all of the institutions responsible to regulate the research have a vested interest in promoting it.<sup>321</sup>

The "science push," instead of "market pull" of biotechnology, nurtures close relationships between biotechnological firms and universities, which spills over into public regulation when elites in both sectors cross over to the NIH and FDA. It further influences basic research and scientists' objectivity.<sup>322</sup> Corporate funding and stock valuation hinge upon invention and diffusion, reducing the incentive for basic research and creating pressure to exaggerate success.<sup>323</sup> Scientists performing research cloning have substantial interests generally in promoting biotechnology and specifically in patenting inventions.<sup>324</sup> Research institutions "usually will share the goals and interests of researchers; research

318. See *supra* Part I(B)(3)(a).

319. See Churchill et al., *supra* note 112, at 40.

320. See Rainsbury, *supra* note 52, at 595-600; Churchill et al., *supra* note 112, at 40 (focusing on FDA and NIH "emergency" gene research and drug protocols).

321. The RAC still has minimal authority to monitor clinical trials and industry has reason to avoid disclosing adverse reactions due to proprietary concerns. See Rainsbury, *supra* note 52, at 598-600.

322. See MARTIN KENNEY, *BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX* (1986); ALAN T. BULL ET AL., *BIOTECHNOLOGY: INTERNATIONAL TRENDS AND PERSPECTIVES* (OECD ed., 1982); REPORT ON RESEARCH ON GENE THERAPY, *supra* note 100; Fransman, *supra* note 43, at 77, 92 (scientists have invested their capital in biotechnology leading to the risk of "hi-tech hype").

323. Churchill et al., *supra* note 112, at 42. As an example, consider ACT's claim to have cloned the first human being, which was later disputed by most in the field and deemed merely a ploy to raise funds. See Kolata & Pollack, *supra* note 258.

324. Kaji & Leiden, *supra* note 100, at 549 (concerning investigators' financial interests in companies with which they conduct clinical trials); Churchill et al., *supra* note 112, at 43.

productivity may be as important to the institution as to the well-being of individual researchers.”<sup>325</sup>

The cluster of scientific, economic, and cultural hopes swirling around our genes seems to intensify and sustain the future promise of gene therapy at the same time that it frames this revolutionary concept in traditional garb—as merely the next wave of therapeutic options. The failure to discuss these factors candidly leads regulators, professionals, and the public to perpetuate confusion, misrepresentation, and disappointment in the sometimes appropriate, and occasionally misguided, pursuit of medical advancement.<sup>326</sup>

#### 4. Patent Law

This section explores the patentability under international and U.S. patent law of processes to clone human life and chimera and the clones themselves. The purpose of a patent is to reward an inventor for creative effort by granting an exclusive right to make, use, or sell an invention or assign it for a limited duration. Patents stimulate investment and reward publication of knowledge, thereby precluding duplication of research and permitting successors to build on prior art. We explore below whether applying this regime to all that biotechnology proponents would prefer is appropriate.

##### a. *International Patent Law*

The 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) provides that members of the World Trade Organization may exclude from patentability “inventions, the prevention within their territory of . . . which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.”<sup>327</sup> The TRIPs agreement adds that members may exclude from patentability, “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” and “plants and animals other than micro-organisms, and essential biological processes for the production of plants or ani-

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325. Robertson on IRBs, *supra* note 233, at 547.

326. Churchill et al., *supra* note 112, at 43–44.

327. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, §5, art. 27(2), *available at* [http://www.wto.org/english/docs\\_e/legal\\_e/final\\_e.htm](http://www.wto.org/english/docs_e/legal_e/final_e.htm) (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

mals other than non-biological and microbiological processes."<sup>328</sup>

This exception in TRIPs reflects the content of patent statutes in most of the industrialized world except the United States, precluding the patenting of inventions "contrary to *ordre public* or morality."<sup>329</sup> Regional integration efforts have also adopted the *ordre public* exception, most importantly the European Union (EU).<sup>330</sup> Even America's common law originally embraced the idea.<sup>331</sup>

From the early-nineteenth century until midway through this one, U.S. courts withheld patents on inventions falling chiefly within two classes: (1) inventions used to defraud buyers, particularly medicinal products, and (2) machines used for gambling.<sup>332</sup> Although never overruled, this so-called beneficial utility theory fell out of favor in the 1970s and has since been discussed only in dicta.<sup>333</sup> The United States opposed incorpora-

328. *Id.* art. 27(3).

329. See PATENTS THROUGHOUT THE WORLD (Alan J. Jacobs ed., 4th ed. 1996).

330. See European Patent Convention, Oct. 5, 1973, art. 53, available at <http://www.european-patent-office.org/legal/epc/e/ar53.html> (on file with the Notre Dame Journal of Law, Ethics & Public Policy) ("European patents shall not be granted in respect of: (a) inventions the publication of which would be contrary to 'ordre public' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting States . . ."); Council Directive 98/44, art. 6(1) 1998 O.J. (L 213) 13, 18 [hereinafter Directive] ("Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation."); Japanese Patent Law, Law No. 121 of 1959, art. 32 ("The inventions liable to contravene public order, morality or public health shall not be patented . . ."), available at <http://www.jpo.go.jp/shoukaie/patent.htm> (last accessed Feb. 9, 2003) (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

331. *Lowell v. Lewis*, 15 F.Cas. 1018 (C.C. Mass. 1817) (Story, J.). "The principle derives from an early British patent statute, which excluded otherwise patentable inventions that were 'contrary to the law, . . . mischievous to the State, by raising prices of commodities at home, . . . or generally inconvenient.'" M. Bruce Harper, *TRIPs Article 27.2: An Argument for Caution*, 21 WM. & MARY ENVTL. L. & POL'Y REV. 381, 413 (1997) (quoting 1 STEPHEN P. LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS § 4 (1979)) (ellipses in original).

332. Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1062-65 (1988).

333. ERNEST BAINBRIDGE LIPSCOMB III, WALKER ON PATENTS 538-41 (1984) (citing *Ex Parte Murphy*, 200 U.S.P.Q. 801 (Bd. App. 1977); Application of Anthony, 414 F.2d 1383 (C.C.P.A. 1969)). But see *Tol-O-Matic, Inc. v. Proma Prod.-und Mktg. Gesellschaft M.b.H.*, 945 F.2d 1546, 1552 (Fed. Cir. 1991) (discussing *Lowell* in dicta).

tion of the *ordre public* or morality exception in TRIPs, but it nonetheless survived.<sup>334</sup>

Under the European Patent Convention (EPC), *ordre public* grants Europeans standing to challenge individual patents and thereby shape biotechnology policy.<sup>335</sup> The Technical Board of the European Patent Organization (EPO) has held that the doctrine requires "a careful weighing up of the suffering of animals and possible risks to the environment on one hand, and the invention's usefulness to mankind on the other."<sup>336</sup> In contrast, we shall see that the American public has no general right to intervene in the prosecution of patent applications to prevent their issuance.<sup>337</sup>

Some patent statutes and international treaties specifically enumerate types of biotechnology contrary to *ordre public*. For example, Australia has outlawed patenting human beings.<sup>338</sup> Likewise, the European Parliament's Directive on the Legal Protection of Biotechnological Inventions (Directive) lists as contrary to *ordre public*: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; and (c) uses of human embryos for industrial or commercial purposes.<sup>339</sup>

334. Harper, *supra* note 331, at 415.

335. Scalise & Nugent, *supra* note 64, at 1014. The EPC provides uniform procedures and standards for examining a European patent application, but reserves to members of the European Union the task of interpreting and enforcing a patent thus granted. See Robin Beck Skarstad, Comment, *The European Union's Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning*, 20 U. PA. J. INT'L ECON. L. 353, 363 (1999) (citing Scalise & Nugent, *supra* note 64, at 1013). In contrast, the European Parliament's Directive on the Legal Protection of Biotechnological Inventions (Directive) was adopted to facilitate harmonization of these policies in pursuit of a European competitive advantage. See Chambers, *supra* note 63 (citing Skarstad, *supra*, at 367-68).

On October 20, 1988, the European Commissioners proposed the Directive on the Legal Protections of Biotechnological Inventions to supersede the EPC and harmonize European patent law to protect the biotechnology industry. . . . The Directive became effective with its publication on July 30, 1998, and it ordered Member States to comply with its mandate by July 30, 2000.

Skarstad, *supra*, at 367-68.

336. Decision T 19/90-3.3.2, 1990 O.J. Eur. Pat. Off. 476, 477.

337. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991).

338. Section 18(2) of the Australian 1990 Act provides that "[h]uman beings and the biological processes for their generation[ ] are not patentable inventions." MARTIN J. ADELMAN ET AL., *PATENT LAW* 174 (1998).

339. Directive, *supra* note 330, art. 6. The earliest draft of this provision would have rendered unpatentable "the human body or parts of the human body *per se* . . . processes for modifying the genetic identity of the human body



Although not an exhaustive list, the Directive states that these processes "offend against human dignity," as would processes to produce chimeras from germ cells or totipotent cells of humans and animals."<sup>340</sup> Accordingly, these "are obviously also excluded from patentability,"<sup>341</sup> as is the human body "at the various stages of its formation and development" and its gene sequence, except for an element isolated from the human body including a gene.<sup>342</sup> The EPC adds that "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body"<sup>343</sup> are not patentable. The EPO has interpreted this to prevent patents on gene research.<sup>344</sup>

Developing countries generally altogether resist patenting plants and animals and resent what they term "biopiracy" or "bioprospecting" of their genetic patrimony.<sup>345</sup> They are also generally opposed to intellectual property rights, which leaders believe impede development and are too expensive to enforce.<sup>346</sup> Article 27 was a condition of their support for TRIPs;<sup>347</sup> however, the Convention on Biological Diversity, which

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for a *non-therapeutic purpose* which is contrary to the dignity of man." Scalise & Nugent, *supra* note 64, at 1026–27 (emphasis added). This reveals a connection between human subject experimentation law and patent law.

340. Directive, *supra* note 330, at Preamble 38. Industrialized countries also generally limit the enforceability of a patent against the progeny of commercial transgendered animals. For example, the Directive states that farmers who purchased patented livestock may make them available for agricultural activity, but not for commercial reproduction. *Id.* art. 11(2). Likewise, the propagation of transgendered animals necessarily resulting from the application for which they were marketed is allowed. *Id.* art. 10 (under the EPC, a conflict of authority exists over whether the progeny of transgendered animals and plants are protected).

341. *Id.*

342. *Id.* art. 5.

343. European Patent Convention, *supra* note 330, art. 52(4).

344. BRUKER/Non-Invasive Measurements T 385/8, 6 Eur. Pat. Off. Rep. 357, 359 (1988).

345. See Skarstad, *supra* note 335, at 374; Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279, 279–80, 290–94 (1999) (developing countries view bioprospecting as an "insidious new form of colonialism" and generally reject the patentability of life due to religious convictions); Cheryl D. Hardy, Comment, *Patent Protection and Raw Materials: The Convention on Biological Diversity and Its Implications for U.S. Policy on the Development and Commercialization of Biotechnology*, 15 U. PA. J. INT'L BUS. L. 299 (1994).

346. Kevin W. McCabe, *The January 1999 Review of Article 27 of the TRIPs Agreement: Diverging Views of Developed and Developing Countries Toward the Patentability of Biotechnology*, 6 J. INTELL. PROP. L. 41, 54–55 (1998).

347. *Id.* at 44–45.

calls for, among other things, transfers of patented technology, best reflects their views.<sup>348</sup>

#### b. U.S. Patent Law

The U.S. Constitution provides that "Congress shall have power . . . to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."<sup>349</sup> The Patent Act of 1793, authored by Thomas Jefferson (himself an accomplished architect and inventor), defined patentable subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]."<sup>350</sup> This language remains part of the U.S. Code, apart from the substitution of the word "process" for "art."<sup>351</sup>

Under the Patent Act, "[d]espite the anomalous patent, such as that issued to Louis Pasteur in 1873 for his purified culture of yeast, the courts invariably rejected patents that involved living subject matter."<sup>352</sup> The primary reason was the "products of nature" doctrine, which stands for the proposition that something cannot be "new" if it already exists in nature.<sup>353</sup> One of the

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348. Convention on Biological Diversity, art. 8(j), 15–16 (1992), *available at* <http://www.biodiv.org/convention> (on file with the Notre Dame Journal of Law, Ethics & Public Policy). On reconciling this with TRIPs, see Valentina Tejera, Note, *Tripping Over Property Rights: Is It Possible to Reconcile the Convention on Biological Diversity with Article 27 of the TRIPs Agreement?*, 33 NEW ENG. L. REV. 967, 981 (1999).

349. U.S. CONST. art. I, § 8.

350. Patent Act of 1793, 1 Stat. 319 § 1 (1793).

351. This substitution was made in 1952, when Congress re-codified the patent laws. Pub. L. No. 82-593, 66 Stat. 797 (1952) (codified at 35 U.S.C. § 101). The U.S. Supreme Court has interpreted "manufacture" to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (citing *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931)). "Composition of matter" includes "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powers or solids." *Id.* (citing *Shell Dev. Co. v. Watson*, 149 F.Supp. 279, 280 (D.C. 1957)).

352. Scalise & Nugent, *supra* note 64, at 1003; *see also* KRIMSKY, *supra* note 65, at 46–47 (after Louis Pasteur received the first patent on a living microorganism in 1873 (*e.g.*, purified yeast), nine additional patents issued on single-celled organisms from 1908 to 1925 (*e.g.*, ground vegetable or animal matter inoculated with bacteria, bacteria mixed with cocoa, food product containing lactic acid bacilli, and microorganisms in vegetable oil)); Ryan M.T. Iwasaka, Note, *Chakrabarty to Chimeras: The Growing Need for Evolutionary Biology in Patent Law*, 109 YALE L.J. 1505, 1511 (2000).

353. Scalise & Nugent, *supra* note 64, at 999.

earliest decisions articulating this doctrine found the fiber within pine needles unpatentable:

Even if . . . this were the first time that men had discovered that a fiber existed in the leaves and needles of the trees which could be . . . made useful for mankind, it is doubtful whether the invention would consist of anything more than the process by which the fiber could be taken from the natural leaf. . . . Otherwise it would be possible for an element or a principle to be secured by patent, and the patentee would obtain the right, to the exclusion of all other men, of securing . . . the fiber which nature has produced.<sup>354</sup>

Although the product of nature doctrine is simple, judiciaries have struggled to apply it consistently to distinguish products of nature from patentable processes using these products.<sup>355</sup> Until 1930, the PTO understood the doctrine to preclude the patenting not merely of animals, but also plants.<sup>356</sup> Congress addressed this concern and the inability of inventors to provide an adequate "written description" of plants in 1930 by passing the Plant Patent Act, which expanded patentable matter to certain varieties of asexually reproduced plants (*i.e.*, plants propagated by cuttings, grafting, and budding, but not seeds).<sup>357</sup>

An explosion in plant breeding followed, which, together with the rise of pesticide and herbicide use, led to the Green Revolution. Sexually reproduced plants were not included in the Plant Patent Act of 1930, because, according to the U.S. Supreme Court, "new varieties could not be reproduced true-to-type through seedlings."<sup>358</sup> By 1970, this problem had been resolved; therefore, Congress also extended plant variety protection to novel strains of sexually-reproduced plants (except fungi, bacte-

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354. DONALD S. CHISUM, CHISUM ON PATENTS § 1.02[7][a], 1-30 to 1-34 (citing *Ex parte Latimer*, 1889 Comm'n Dec. 13, 125-27 (1889)) (ellipses in CHISUM, *supra*).

355. Scalise & Nugent, *supra* note 64, at 999-1001; see, e.g., Dennis v. Pitner, 106 F.2d 142, 143 (7th Cir. 1939) ("A discovery in the field of science of a new quality of phenomenon of an old product may be . . . the proper subject of a patent.").

356. *Chakrabarty*, 447 U.S. at 311-12 (PTO granted two patents stating claims for living microorganisms in 1967 and 1968).

357. Plant Patent Act of 1930, 35 U.S.C. § 161 ("Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore . . .").

358. *Chakrabarty*, 447 U.S. at 313.

ria, or first-generation hybrids), rendering patentable major food crops developed through classical hybridization techniques.<sup>359</sup>

This legislation, together with the Patent Act, provided the backdrop for the U.S. Supreme Court's pathbreaking *Chakrabarty* decision in 1980, holding oil-digesting bacterium patentable.<sup>360</sup> Arguing for the opposite result, the government contended (1) bacteria were excluded from the Plant Patent Act of 1930; (2) the Patent Act did not apply to living things (as evidenced by the Plant Patent Acts of 1930 and 1970); and (3) genetic engineering technology was unforeseen when Congress enacted the Patent Act.<sup>361</sup> Four Justices agreed, insisting that at least since 1930, Congress must have intended the PTO not to patent living organisms under the Patent Act; otherwise, plants could have been patented without the Plant Patent Act of 1930 and 1970.<sup>362</sup> They argued that Congress expressly excluded bacteria from protection under the Plant Patent Act of 1970, indicating its affirmative intent not to patent bacteria.<sup>363</sup>

The *Chakrabarty* majority disagreed, arguing that the relevant distinction Congress meant to draw under the Patent Act was not between living and inanimate things, but between products of nature (whether or not living) and human-made inventions.<sup>364</sup> The majority added that patent law inevitably addresses unforeseen technologies, discounting the minority's argument that Congress presumed the product of nature doctrine rendered this type of invention unpatentable.<sup>365</sup>

The PTO and its judicatories took the next steps toward patenting plants and animals. The Board of Patent Appeals and

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359. Plant Variety Protection Act of 1970, Pub. L. No. 91-577, 84 Stat. 1547 (codified at 7 U.S.C. § 2402(a)) ("The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety . . . shall be entitled to plant variety protection therefore . . .").

360. *Chakrabarty*, 447 U.S. at 309 (1980). *Chakrabarty*, who worked for General Electric Company, applied for a patent with three claims: the process of making the microbe, a method of dispersal, and the organism itself. The PTO granted all but the last one. PTO's denial was on the grounds that micro-organisms are products of nature and living things are not patentable subject matter under 35 U.S.C. § 101. *Id.* at 305-06.

361. *Id.* at 310-11, 313-15.

362. *Id.* at 319-20 (Brennan, White, Marshall, and Powell, JJ., dissenting).

363. *Id.* at 321 n.3.

364. *Id.* at 313. The Court distinguished *Funk Bros. Seed v. Kalo Inoculant*, 333 U.S. 127 (1948), where the inventor produced no new bacteria, but merely combined existing species of root-nodule bacteria to inoculate seeds. "Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature . . ." *Chakrabarty*, 447 U.S. at 310.

365. *Compare id.* at 316, *with id.* at 305 n.2.

Interferences was the first to extend *Chakrabarty* by holding that non-naturally occurring, multi-celled plants are patentable under the Patent Act.<sup>366</sup> Then, the same body held patentable multicellular organisms known as polyploid oysters (non-naturally occurring oysters produced by making multiple copies of genes through hydrostatic pressure, not biotechnology).<sup>367</sup> Within days, the PTO announced that it would begin treating all non-naturally occurring, multi-celled organisms (animals) as patentable, except humans.<sup>368</sup> The PTO grounded the exception for humans on an unspecified constitutional objection widely assumed to be the Thirteenth Amendment.<sup>369</sup>

A year after the PTO's policy announcement, animal rights organizations, farmers, and others brought suit challenging it as an improper exercise of agency discretion in violation of the Administrative Procedure Act (APA).<sup>370</sup> They lost on multiple grounds, including that the plaintiffs lacked standing, because the patent statute did not grant members of the public the right to intervene in the prosecution of patent applications and they could not demonstrate injury proximately caused by the mere issuance (as opposed to use) of a patent.<sup>371</sup> The Court reserved the question whether the PTO's exclusion of humans from patentability was substantive.<sup>372</sup>

The PTO issued the first patent on a multi-celled animal on April 12, 1988, the Harvard Onco-mouse.<sup>373</sup> The PTO now regularly grants patents on a barnyard of transgenic animals, including some with spliced human DNA expressing human hormones

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366. *Ex Parte Hibberd*, 227 U.S.P.Q. 443, 447 (Bd. Pat. App. & Interf. 1985).

367. *Ex Parte Allen*, 2 U.S.P.Q.2d 1425 (Bd. Pat. App. & Interf. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988) (holding multicellular animals patentable but rejecting the particular application made in this case for unrelated reasons).

368. See Comm'r of Patents and Trademarks, *Policy Statement on Patentability of Animals*, 1077 OFF. GAZ. PAT. OFFICE 24 (Apr. 7, 1987), reprinted in DONALD S. CHISUM, CHISUM ON PATENTS app. 24-2 to 24-3 (1998). Critics of the expansion of *Chakrabarty* to this extent note the progressively narrower forums in which decisions about patentability have been made from the legislature to the courts to the executive branch. See, e.g., KRIMSKY, *supra* note 65, at 48.

369. *Id.*; see also Magnani, *supra* note 3, at 448.

370. *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991).

371. *Id.* at 929-30. On standing, the Court noted that third parties have no right to intervene in the prosecution of patent applications to prevent their issuance. *Id.* at n.9. And the Court rejected appellants' claims to have suffered injuries traced to the challenged action that could be redressed by a favorable decision. *Id.* at 930.

372. *Id.* at n.9.

373. Magnani, *supra* note 3, at 448.

or other chemicals that animals do not produce in nature.<sup>374</sup> The PTO also regularly allows patents on human cell lines and methods of deriving them, including, as of 2001, 1,000 patents covering gene research, some of which would yield transgenic humans.<sup>375</sup> The PTO has even issued a patent covering the product and a procedure to clone humans through at least parthenogenesis.<sup>376</sup>

Nonetheless, the stated position of the PTO continues to be that it will not grant patents on human life nor even a process to create human life, albeit the agency has publicly abandoned the Thirteenth Amendment as the reason.<sup>377</sup> Instead, in April 1998, the PTO resurrected Justice Story's beneficial utility theory as the rationale why humans and chimera are not patentable:

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374. Iwasaka, *supra* note 352, at 1532. By 1999, the PTO had received over 1,900 patent applications for genetically altered animals. *Id.*

375. Warren D. Woessner, *The Evolution of Patents on Life—Transgenic Animals, Clones, and Stem Cells*, 83 J. PAT. & TRADEMARK OFF. SOC'Y 830, 844 (2001); Magnani, *supra* note 3, at 448; Munro, *supra* note 66.

376. Andrew Pollack, *Debate on Human Cloning Turns to Patents*, N.Y. TIMES, May 17, 2002, at A14; Antonio Regalado, *Patent on Human-Cloning Method is Granted, Despite Current Policy*, WALL ST. J., May 16, 2002, at D3 [hereinafter Regalado I]; see also Press Release, Patent Watch, The U.S. Patent Office (PTO) Has Granted a Patent on Human Reproductive Cloning and the Embryos, Fetuses and Children that Would Be Created Through that Process (May 16, 2002), available at <http://www.patentwatchproject.org> (on file with the Notre Dame Journal of Law, Ethics & Public Policy). At least three additional pending patent applications cover cloned human embryos and fetuses and an additional application would patent a human-mouse chimera, dubbed the humouse, and fuse human cells with those of a monkey, ape, or other animal. *Id.* (applications from Geron Corp., the University of Connecticut, and University of Massachusetts cover cloned human embryos); Aaron Zitner, *Patently Provoking a Debate*, L.A. TIMES, May 12, 2002; Rick Weiss, *Rifkin Files Human-Chimp Chimera Patent*, WASH. POST, Apr. 2, 1998, at A12. The humouse application submitted in 1997 was initially rejected in 1999, because it embraced a human being.

377. Pollack, *supra* note 376. ("Brigid Quinn, a spokeswoman for the patent office, said the agency was not using the 13th Amendment argument anymore but was not granting patents on humans because it had not received any guidance from Congress or the courts saying it should do so."); Regalado I, *supra* note 376 ("Our policy is that we do not issue patents to claims drawn to humans. Our policy has not changed."); Munro, *supra* note 66 ("The U.S. Patent and Trademark Office does not issue patents drawn to human beings."); Antonio Regalado, *Ethical Concerns Block Widespread Patenting of Embryonic Advances*, WALL ST. J., Aug. 20, 2001, at B1 [hereinafter Regalado II] ("A spokesman for the Patent Office says the agency not only forbids patents on human beings but also on any method for making them. The reason is that the owner of a patented "process" can prevent anyone else from importing products made using the technique. With cloning, that could lead to human clones born overseas being legally denied entry into the U.S.).

The PTO will not . . . issue a patent for an invention of incredible or specious utility or for inventions whose utilization is not adequately disclosed in the application. Additionally, the courts have interpreted the utility requirement to exclude inventions deemed to be "injurious to the well being, good policy, or good morals of society." . . . [T]he existence of a patent application directed to human/non-human chimera has recently been discussed in the news media. It is the position of the PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.<sup>378</sup>

Although the beneficial utility doctrine remains valid with a history of applicability to medical inventions, skeptics contend the PTO is poorly suited to make normative judgments about biotechnology.<sup>379</sup> Some would avoid this by statutorily banning the issuance of patents on human life and chimera.<sup>380</sup> Precedent for this exists in the U.S. Code regulating another dangerous technology: atomic energy.

The Department of Defense (DOD) reviews patent applications pertaining to atomic energy to decide whether an invention has weapons-related uses.<sup>381</sup> If the invention has only defense applications, DOD is entitled to all the rights of the invention in exchange for just compensation.<sup>382</sup> Patents may not be issued at all to private parties on inventions useful solely for atomic weapons.<sup>383</sup>

With respect specifically to medicine, U.S. patents are unenforceable in relation to "medical activity" defined as "a medical or surgical procedure on a body."<sup>384</sup> The statute defines "body" (rather unhelpfully) as a "human body, organ or cadaver, or a nonhuman animal used in medical research or instruction

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378. PATENT & TRADEMARK OFFICE, MEDIA ADVISORY: FACTS ON PATENTING LIFE FORMS HAVING A RELATIONSHIP TO HUMANS (1998) (citations omitted), available at <http://www.uspto.gov/web/offices/com/speeches/98-06.htm> (Apr. 1, 1998) (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

379. See, e.g., Nash, *supra* note 86, at 297-98 (citing Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1062 (1988)).

380. Amendment to Prohibit Patentability of Human Life Forms, 107th Cong., 2d Sess. (May 2002).

381. See 35 U.S.C. §§ 181-88 (1982). Under this provision, the PTO must review all patent applications for military application. *Id.* § 181.

382. 42 U.S.C. § 2187 (2000).

383. 42 U.S.C.A. § 2181(a) (1994).

384. 35 U.S.C. § 287(c)(2)(A) (2000).

directly relating to the treatment of humans.”<sup>385</sup> One commentator argues a “human body” should not mean a living human embryo and that HC should not be subject to the statute.<sup>386</sup>

*c. Legal Regimes GE Implicates*

Non-inheritable and inheritable GE remains purely an invention with gene transfer research the more advanced of the two. Both have hardly begun the trip along the S-curve, providing us with a unique opportunity to regulate GE in anticipation of the legal questions it will inspire. Many are similar to HC, because GE also bears upon reproductive rights, the First Amendment, human subject experimentation law, and patent law. Others raise troubling new questions about the limits of parental authority to modify their progeny and equal protection.

*d. Parental Rights*

Procreative liberty and parental rights or the doctrine of “family autonomy,” are sometimes merged;<sup>387</sup> however, they may be understood as independent rights. Those preferring to treat them as unified focus on dicta uniting the right to conceive and the right to raise children.<sup>388</sup> On the other hand, the U.S. Supreme Court recognized parents’ rights construed as the right to the care, custody, education, management, and control of children long before it acknowledged procreative liberty.<sup>389</sup> Most famously, the Court remarked, “The child is not the mere creature of the State; those who nurture him and direct his destiny have the right, coupled with the high duty, to recognize and prepare him for additional obligations.”<sup>390</sup>

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385. *Id.* § 287(c)(2)(E).

386. Nash, *supra* note 86, at 302.

387. Wu, *supra* note 90, at 1481–85; Coleman, *supra* note 33, at 157.

388. Wu notes that, otherwise, we are forced to find islands of protection for procreative capacity, conception, gestation, childbirth, and child rearing. Wu, *supra* note 90, at 1482–83 (quoting *Stanley v. Illinois*, 405 U.S. 645, 651 (1972)).

389. See *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923) (invalidating a state law prohibiting the teaching of any modern language other than English in public school; explaining that the liberty guaranteed by the due process clause of the Fourteenth Amendment “denotes not merely freedom from bodily restraint but also the right of the individual to [engage in the pursuit of happiness]”); see also *In re Baby M*, 537 A.2d 1227, 1253–54 (1988) (stating in the context of a custody battle that parenting rights are not part of procreation rights).

390. *Pierce v. Soc’y of Sisters*, 268 U.S. 510, 535 (1925). As recently as 2000, the Court reaffirmed this precedent, emphasizing the primary role of the parents in the upbringing of their children. *Troxel v. Granville*, 530 U.S. 57, 66 (2000) (citing *Wisconsin v. Yoder*, 406 U.S. 205 (1972)); see also *Washington v.*



Some would find in reproductive liberty<sup>391</sup> and others in parental rights,<sup>392</sup> the right to clone or genetically modify children. In this respect, one commentator argues Aldous Huxley missed the most pressing ethical and legal question posed by GE and cloning: it is not "How do we protect human reproduction against government control?" but "Are there any limits to what individuals or couples may do in their quest for happy, successful offspring, for offspring in their own image and likeness?"<sup>393</sup>

The predominant international response has been affirmative. For example, the Council of Europe permits GE only for preventive, diagnostic, or therapeutic reasons and only where it does not aim to change the genetic make-up of a person's descendants.<sup>394</sup> A U.S. Senate bill would also have outlawed germline manipulation.<sup>395</sup> Professor Robertson has argued that any such regulation would violate reproductive rights, except to the extent it merely prevented parents from creating "offspring who have fewer capacities than they could otherwise have had."<sup>396</sup>

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Glucksberg, 521 U.S. 702, 720 (1997) ("In a long line of cases, we have held that, in addition to the specific freedoms protected by the Bill of Rights, the 'liberty' specially protected by the Due Process Clause includes the right . . . to direct the education and upbringing of one's children."); Santosky v. Kramer, 455 U.S. 745, 753 (1982) (discussing the "fundamental liberty interest of natural parents in the care, custody, and management of their child"); Parham v. J.R., 442 U.S. 584, 602 (1979) ("Our jurisprudence historically has reflected Western civilization concepts of the family as a unit with broad parental authority over minor children."); *Stanley*, 405 U.S. at 651 ("It is plain that the interest of a parent in the companionship, care, custody, and management of his or her children 'come[s] to this Court with a momentum for respect lacking when appeal is made to liberties which derive merely from shifting economic arrangements.'"); *Prince v. Massachusetts*, 321 U.S. 158, 166 (1944) ("It is cardinal with us that the custody, care, and nurture of the child reside first in the parents, whose primary function and freedom include preparation for obligations the state can neither supply nor hinder.").

391. Robertson on Genetic Selection, *supra* note 142, at 465 (GE is a reproductive right, but not necessarily cloning).

392. Coleman, *supra* note 33, at 159 ("[I]f science can give parents the ability to mold their child into a specific makeup or disposition, even before birth, then this ability certainly falls within the realm of the parental right to direct or control the destiny of their child and 'prepare him for additional obligations.'").

393. Maura A. Ryan, *Cloning, Genetic Engineering, and the Limits of Procreative Liberty*, 32 VAL. U. L. REV. 753, 753 (1998).

394. Convention on Human Rights and Biomedicine, *supra* note 134, art. 13.

395. See Human Germline Gene Modification Prohibition Act of 2001, S. 7123, 107th Cong. (2001).

396. JOHN A. ROBERTSON, *CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES* 170 (1994).

Whereas some commentators worry that the state will restrict GE, others are concerned that the state will permit or mandate it. These scholars argue parents have a fundamental right to refuse GS and GE.<sup>397</sup> The Supreme Court has specifically upheld the right of parents to forego treatment that might have prolonged an infant's life, but without improving the infant's overall impairment.<sup>398</sup> GE will lead to much harder test cases when, for example, parents decide against therapy in favor of bearing children subject to inheritable disease or seek to invent new characteristics for their progeny.

Parental rights are obviously not absolute. According to precedent involving adoption and visitation disputes, they may not spring at all or not full-blown until conception.<sup>399</sup> Certainly, the Supreme Court has never held that parental rights (as distinguished from reproductive rights) vest prior to birth. Were strict scrutiny to apply to the medical decisions of parents for their children, the state could regulate them if it had a compelling interest pursued in the least restrictive fashion. Two potential compelling interests the Supreme Court has stated may legitimate restricting parental rights include the health or safety of children and, more controversially, parental decisions imposing substantial social burdens.<sup>400</sup>

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397. See, e.g., Pelias & Blanton, *supra* note 167, at 531–32; Shepherd, *supra* note 132, at 767.

398. *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 627 (1986) (reversing the Department of Health and Human Services' attempt to discontinue federal funding of a hospital that deprived an infant of treatment on the basis of her handicap because the parents would not consent to the treatment).

399. See, e.g., *Michael H. v. Gerald D.*, 491 U.S. 110 (1989) (holding that father's due process liberty interest in maintaining some connection with his child was not sufficiently powerful to overcome a state statutory presumption that the husband of the child's mother was the child's parent; therefore, the biological father could be denied visitation rights); *Lehr v. Robertson*, 463 U.S. 248, 260 (1983) (holding that putative biological father who had never established an actual relationship with his child did not have a constitutional right to notice of his child's adoption by the man who had married the child's mother; a parent's liberty interest "do[es] not spring full-blown from the biological connection between parent and child. They require relationships more enduring.") (quoting *Caban v. Mohammed*, 441 U.S. 380, 397 (1979)).

400. See *Wisconsin v. Yoder*, 406 U.S. 205, 233–34 (1972) (finding that parents' rights may be subject to limitation if it appears that parental decisions will jeopardize the health or safety of the child, or have a potential for significant social burdens); see also *Troxel v. Granville*, 530 U.S. 57, 67–68 (2000).

So long as a parent adequately cares for his or her children (*i.e.*, is fit), there will normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children.

In keeping with this dictum, three primary legal regimes already limit parental rights: child abuse laws, the best interest of the child test, and wrongful life liability.<sup>401</sup> Least controversially, children's rights prevail over parental rights, in the event of child labor, child abuse, and child neglect. Definitions of child abuse and neglect vary among the states, but it is not uncommon for them to cover neglecting or refusing to provide care necessary for a child's health and creating a substantial risk of death, disfigurement, or impairment of bodily or mental functions.<sup>402</sup> Limited immunity exists in some states against child abuse and neglect for parents who insist upon faith healing,<sup>403</sup> but a movement has begun to abandon or interpret this exception narrowly.<sup>404</sup>

Some scholars contend the prevention of genetic disease is so important that parents who decide to give birth to a child with an inheritable disease should be criminally liable for child abuse.<sup>405</sup> Child abuse statutes normally do not protect the unborn, but there are exceptions.<sup>406</sup> Courts have been hesitant to characterize as child abuse or negligence parents' reasonable

*Id.* at 67–68.

401. See generally Shepherd, *supra* note 132.

402. See, e.g., FLA. STAT. ANN. § 827.04(1) (West 1987).

Whoever, willfully or by culpable negligence, deprives a child of, or allows a child to be deprived of . . . medical treatment, or who, knowingly or by culpable negligence, permits physical or mental injury to the child, and in so doing causes great bodily harm, permanent disability, or permanent disfigurement to such child, shall be guilty of a felony of the third degree.

*Id.*

403. See, e.g., CAL. WELF. & INST. CODE § 18950.5 (West 1998) ("For the purposes of this chapter, a child receiving treatment by spiritual means . . . shall not for that reason alone be considered an abused or neglected child.").

404. See, e.g., Walker v. Superior Court, 763 P.2d 852 (Cal. 1989) (en banc) (holding that exemption to misdemeanor child neglect statute for parents who utilized prayer treatment in lieu of medical care did not provide defense to prosecution for involuntary manslaughter and felony child endangerment); Commonwealth v. Foster, 764 A.2d 1076, 1081 (Pa. Super. Ct. 2000) (holding that parents were guilty of endangering the welfare of a child when their religiously-grounded decision not to provide medical care to their son led to his near death from a liver tumor even though they were exempt from prosecution for child abuse), *appeal denied*, 782 A.2d 542 (Pa. 2001); Commonwealth v. Nixon, 718 A.2d 311 (Pa. Super. Ct. 1998) (holding that although parents whose religious beliefs led them to eschew medical treatment for their sick child were exempt from child abuse, their due process rights to notice were not violated when they were prosecuted for involuntary manslaughter), *aff'd*, 761 A.2d 1151 (2000), *cert. denied*, 532 U.S. 1008 (2001).

405. Margery W. Shaw, *Conditional Prospective Rights of the Fetus*, 5 J. LEGAL MED. 63, 98–104 (1984).

406. See, e.g., WIS. STAT. § 48.981(1)(h) (2001).

medical judgment about what is best for their children, but have indicated that the graver the risks to children, the more likely the judgment of medical professionals about the children's best interests will prevail.<sup>407</sup> This model of "reviewable parental discretion" appeals to many geneticists who would at least limit the ability of parents to refuse potential genetic therapies.<sup>408</sup>

Another model vindicating the interests of children over parents some would adapt from the child custody context is the "best interests of the child" test.<sup>409</sup> The drawback of this test is that it is not always obvious what is in the best interests of the child or, more particularly, that judges are better equipped to make this evaluation than parents. Critics argue that the best

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"Subject" means a person or unborn child named in a report or record as any of the following:

1. A child who is the victim or alleged victim of abuse or neglect or who is threatened with abuse or neglect.
- 1m. An unborn child who is the victim or alleged victim of abuse or who is at substantial risk of abuse.

*Id.*

407. See *Kia P. v. McIntyre*, 235 F.3d 749, 757 n.3 (2d Cir. 2000), *cert. denied*, 534 U.S. 820 (2001) (refusing to decide "whether the Constitution prohibits a state-owned hospital from holding a child for medical reasons against a parent's wishes," noting that the Supreme Court had yet to mark "the boundaries of a parent's right to control the medical treatment of his or her child or a medical provider's ability to override a parent's medical decision," and noting that the Court has recognized in dictum "parents' constitutional liberty interest in having 'a significant decision-making role concerning medical procedures sought to be undertaken by state authority upon their children'" (quoting *Van Emrik v. Chemung County Dep't of Soc. Servs.*, 911 F.2d 863, 867 (2d Cir. 1990)); *HCA, Inc. v. Miller*, 36 S.W.3d 187, 193-94 (Tex. Ct. App. 2000) (making a similar statement in dictum); *M.N. v. S. Baptist Hosp. of Fla.*, 648 So.2d 769, 770 (Fla. Dist. Ct. App. 1994) ("[T]he parents' rights are not absolute, as the state has *parens patriae* authority to ensure that children receive reasonable medical treatment which is necessary for the preservation of life. And as between parent and child, the ultimate welfare of the child is the controlling factor.") (citations omitted). By statute in many states, medical professionals may veto the decision of parents voluntarily institutionalizing their children. See *Parham v. J.R.*, 442 U.S. 584, 604 (1979).

[I]n the voluntarily commitment setting . . . the parents . . . retain a substantial, if not the dominant, role in the decision, absent a finding of neglect or abuse. . . . [H]owever . . . the child's rights and the nature of the commitment decision are such that the parents cannot always have absolute and unreviewable discretion to decide whether to have a child institutionalized. They . . . retain plenary authority to seek such care for their children, subject to a physician's independent examination and medical judgment.

*Id.*

408. *Pelias & Blanton*, *supra* note 167, at 532.

409. See generally *Joseph Goldstein et al., Beyond the Best Interests of the Child* 3-7 (1973).

interest of the child test is "vague, subjective, and open to excessive judicial discretion."<sup>410</sup>

The most controversial instance when children's rights could prevail over parental rights is when they are "wrongfully born" or born lacking a "sound mind and body." California's Supreme Court first upheld a cause of action for wrongful life in 1982, when a deaf child sought damages for being "deprived of the fundamental right of a child to be born as a whole, functional human being without total deafness."<sup>411</sup> This judgment and others since have been against medical professionals;<sup>412</sup> however, children have also received awards against their parents for allegedly unreasonable decisions; for example, mothers abusing alcohol or drugs during pregnancy.<sup>413</sup>

In dictum, one court stated that parents who decide to proceed with a pregnancy knowing that the fetus is seriously impaired should be liable for the "pain, suffering and misery which they have wrought upon their offspring,"<sup>414</sup> whereas another refused to recognize a child's wrongful life claim against a physician precisely because it feared that women would eventually be found liable for proceeding with a pregnancy with knowl-

410. Ilana Hurwitz, *Collaborative Reproduction: Finding the Child in the Maze of Legal Motherhood*, 33 CONN. L. REV. 127, 178 (2000) (citation omitted).

411. *Turpin v. Sortini*, 643 P.2d 954, 956 (Cal. 1982).

412. See, e.g., *id.* (finding a cause of action for "wrongful life" where a deaf child sought damages for being "deprived of the fundamental right of a child to be born as a whole, functional human being without total deafness."); *Womack v. Buchhorn*, 187 N.W.2d 218, 222 (Mich. 1971) (upholding right of eight-year-old child to sue for injuries suffered in an automobile accident when he was a four-month old fetus, and finding that "a child has a legal right to begin life with a sound mind and body") ("If the wrongful conduct of another interferes with that right, and it can be established by competent proof that there is a causal connection between the wrongful interference and the harm suffered by the child when born, damages for such harm should be recoverable by the child.") (quoting *Smith v. Brennan*, 157 A.2d 497, 503 (1960)).

413. *Grodin v. Grodin*, 301 N.W.2d 869 (Mich. Ct. App. 1980) (mother could be held liable for injury caused to child resulting from use of a prescription drug during pregnancy if the use was an unreasonable exercise of parental discretion); *In re Baby X*, 293 N.W.2d 736, 739 (Mich. Ct. App. 1980) (holding that newborn suffering drug withdrawal symptoms because of prenatal drug addiction may be considered a neglected child; added that "[s]ince a child has a legal right to begin life with a sound mind and body . . . we believe it is within the best interest to examine all prenatal conduct bearing on that right.") (citation omitted). See generally Sam S. Balisy, Note, *Maternal Substance Abuse: The Need to Provide Legal Protection for the Fetus*, 60 S. CAL. L. REV. 1209 (1987).

414. *Curlender v. Bio-Science Labs.*, 165 Cal. Rptr. 477, 488 (Cal. Ct. App. 1980).

edge of probable fetal impairments.<sup>415</sup> Agreeing with the underlying policy concern of the second court, one commentator would clarify the "right to a sound body and mind" as the right to be free from others' noxious conduct, but not to connote an affirmative obligation on the part of parents to modify their genetic endowment.<sup>416</sup>

The difficult judgments that courts and legislators will have to make when deciding whether a parent's decision to refuse therapeutic GE for her progeny constitutes a fundamental right, child abuse, activity not in the best interest of the child, or a wrongful birth are not nearly as substantial when GE is merely "enhancing." Courts do not ordinarily rule that progeny are entitled to more resources than required to meet the minimum threshold established by child abuse, welfare, and similar laws. Thus, although it is not unusual in child support proceedings for courts to award greater support to the children of wealthy spouses than poor ones, courts generally do not require parents to provide greater resources to children than they can afford. By the same token, children should not have an affirmative right to genetic enhancements counterbalancing parental rights.

### B. *Equal Protection*

Of course, not everyone will have the wherewithal to obtain even therapeutic biotechnologies without a vast expansion of the welfare state; therefore, many will only have the option of negative eugenics or to bear gen-natural children. As suggested by the story of Carrie Buck, mandated eugenics programs have historically targeted women and minorities.<sup>417</sup> Even today, "'97% of obstetricians favor sterilizing unmarried welfare mothers.'"<sup>418</sup> A policy subjecting poor women bearing gen-natural children to criminal or civil liability would inevitably follow this bankrupt model.

Even absent liability for gen-natural births, the poor will likely find themselves severely disadvantaged in a society permitting genetic enhancements. First, minorities may become more insular. Because HC and GE enable parents to select their offspring, some fear that "the offspring qualities most likely to be

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415. *Elliott v. Brown*, 361 So. 2d 546, 548 (Ala. 1978). California's legislature apparently agreed with this result and consequently adopted a parents' immunity statute.

416. Shepherd, *supra* note 132, at 770-71.

417. Liang, *supra* note 112, at 77-79; Hyatt, *supra* note 184, at 484.

418. Liang, *supra* note 112, at 79 (quoting Lori B. Andrews, *Past as Prologue: Sobering Thoughts on Genetic Enthusiasm*, 27 SETON HALL L. REV. 893, 898 (1977)); see also *Mass Sterilisation Scandal Shocks Peru*, *supra* note 192.

selected are those that correlate with high social status," including whiteness and maleness.<sup>419</sup> Second, minorities and the poor could find themselves at an increasing competitive disadvantage because of "norm creep."<sup>420</sup> The gap between the abilities of haves and have-nots would widen as parents with resources raise the bar of genetic normality through persistent efforts to gain a genetic advantage over peers.

Although surprisingly few minority scholars have published on this subject, some feminists have subjected interpretations of reproductive rights law justifying GE to a "hermeneutic of suspicion." Christine Overall, for example, has shared her concern that biotechnology could lead to the objectification of children and women's reproductive capacity.<sup>421</sup> This potential is most obvious with respect to research cloning, but GE could also disadvantage women who prefer natural conception. GE is currently possible solely on *ex vivo* human embryos and, therefore, would be easiest in combination with ARTs. However, it is not inconceivable that GE will also eventually be used in combination with artificial wombs such as are currently under development for animals.<sup>422</sup>

Traditionally, unequal treatment of persons is unconstitutional. Strict scrutiny applies to any race-specific law disadvantaging or benefiting racial minorities even if facially neutral.<sup>423</sup> A neutral law with an incidental disproportionate impact on a minority is subject to rational basis review.<sup>424</sup> A gender-specific

419. Ryan, *supra* note 393, at 763.

420. See *supra* Part I(B).

421. CHRISTINE OVERALL, *ETHICS AND HUMAN REPRODUCTION: A FEMINIST ANALYSIS* 170 (1987); see also Michael Lasalandra, *Women's Health Activist Wants Embryo Cloning Halt*, B. HERALD, Mar. 5, 2002, at 24 (concerning Judy Norsigian's opposition to human cloning, because "the technology will depend on thousands, perhaps millions, of women who will have to undergo substantial health risks associated with harvesting of their eggs").

422. See, e.g., Tony Blankley, *Artificial Wombs for Artificial Moms*, WASH. TIMES, Feb. 13, 2002, at A21.

423. *Adarand Constructors, Inc. v. Peña*, 515 U.S. 200 (1995) (finding that even a program with a "benign" purpose intending to benefit minorities with a minimal exclusionary impact is subject to strict scrutiny; however, a public entity may have a compelling interest in responding to and remedying the present effects of past discrimination if an individualized inquiry supports it); *Loving v. Virginia*, 388 U.S. 1 (1967) (invalidating Virginia statute making it a felony for any white person to intermarry with a person of color and vice-versa); *Strauder v. West Virginia*, 100 U.S. 303 (1879) (overturning West Virginia statute limiting jury service to white males who are citizens of the state).

424. *Washington v. Davis*, 426 U.S. 229 (1976) (affirming validity of a qualifying test measuring verbal ability, vocabulary, and reading comprehension for entrance to the D.C. police force).

law disadvantaging one sex compared to another is subject to intermediate scrutiny,<sup>425</sup> whereas a gender-specific law benefiting females has an unknown constitutional status.<sup>426</sup> Any law mandating GE for purposes of therapy or enhancement without subsidizing the poor would necessarily and not incidentally disadvantage minorities and women and, therefore, be subject to strict scrutiny under the Equal Protection Clause. On the other hand, subsidizing GE in a race-neutral, gender-neutral, and potentially even female-biased manner would likely satisfy equal protection.

### III. FRANKENSTEIN MOLLIFIES THE MONSTER

Neither an entirely unregulated nor an over-regulated biotechnological enterprise is consistent with the prevailing liberal democratic compromise discussed in the last section. On the one hand, the free market would inexorably lead to a new political economy allowing genetic discrimination in insurance, employment, and other areas incidental to GS; patents on living human embryos; negative eugenics through increased abortion incidental to GS; the creation of living human embryos solely to destroy and experiment using their parts; born human clones and chimera; and positive eugenics through GE performed on human beings and chimera birthed naturally or from artificial wombs.

On the other hand, in an over-regulated market the state would prevent or remediate genetic "abnormalities" and "inequities" by mandating or subsidizing GS and GE. It would further prohibit employers and insurance companies from utilizing any genetic information even when it benefits the employee or insured or could avoid mass injuries (*e.g.*, caused by a trucker who suffers a predictable coronary attack); implanting living human embryos regardless of how created; and patents on

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425. *Craig v. Boren*, 429 U.S. 190 (1976) (invalidating Oklahoma statute prohibiting sale of non-intoxicating beer to males under the age of 21 and to females under the age of 18, notwithstanding that the objective of the statute was to enhance public safety).

426. A gender-specific law benefiting females has not been before the Court since *Adarand Constructors, Inc.*, 515 U.S. at 200. Previously, the Court approved such laws if they served an important governmental objective. *See, e.g., Califano v. Webster*, 430 U.S. 313 (1977) (upholding a law which sought to remedy past discrimination against women by granting them a slight economic advantage under the Social Security Act); *Schlesinger v. Ballard*, 419 U.S. 498 (1975) (holding gender-based classifications which benefit women may be legitimate where men and women are not similarly situated).



*processes* leading to biotechnological inventions including living human embryos and chimera.

In the first instance, the unregulated market would naturally create disincentives for parents to have gen-natural children due to the competitive disadvantage they would face and the medical costs of children with inherited diseases. The gap between the haves and have-nots, the Caucasians and minorities, males and females, and able and disabled would widen. In addition, previously unknown health and other problems would arise, including anxiety related to untreatable inherited diseases disclosed through GS; repercussions from delayed fetal-maternal bonding; new physical and genetic defects related to flawed HC and GE often resulting in premature death; families incorporating persons who appear like replicas of deceased or older family members or unrelated individuals whose image will be associated with another person's personality and achievements with unknown psychological consequences for the clone and others; anxiety related to choosing the optimal genetic traits for children while remaining true to religious convictions; and a class of new chimera whose civil rights are yet undefined.

In the second instance, the over-regulated market would lead to an unprecedented expansion of the welfare state as it sought to ensure a baseline for genetically healthy humans. Public commissions, legislatures, and courts would become battlegrounds for alternative viewpoints on the illusive minimum standard of "normal" genetic health the state should ensure. Norm creep would also commence as entrepreneurial parents sought to exceed whatever baseline government sets, creating persistent pressure for the government and others also to raise their baseline. Government would further infringe upon the family and religion as the state's equality, economic, and other interests trumped parental and First Amendment rights to direct the upbringing of children including their genetic destiny. The employment and insurance markets would also become overly distorted ultimately to nobody's benefit.

During the last half-century, liberal democracy has generally been the most successful when policymakers have chosen middle ground between the free market and over-regulation, thus seeking balance between the market-friendly utilitarian objectives of legal positivism and immutable human rights associated with natural law. Particularly in the field of medicine, legal positivism has never unequivocally gained the upper hand. Its impact on a woman's right to choose is obvious. On the other hand, the Nuremberg Code and Declaration of Helsinki prohibited ultra-hazardous human subject experimentation. Civil rights laws also

banned invidious discrimination on the basis of race, gender, religion, and national origin. In essence, these prohibitions reflect a liberal democratic consensus that human life and potential has intrinsic value; consequently, we accept certain inefficiencies to protect them.

From the vantage point of two to four decades before the most sophisticated biotechnologies discussed in this article begin to diffuse rapidly, we have a unique opportunity to avoid the displacements normally accompanying revolutionary innovations. Many, if not most of the repercussions are not foreseeable and will have to be accommodated extemporaneously, but deciding now how to confront known problems would provide a foundation for confronting others and prevent us from becoming overwhelmed by the sheer volume of policy decisions that would passively erode our liberal democratic compromise. Experts at negotiation contend that one of the keys to developing consensus around difficult issues is to broaden the options for mutual gain by expanding the menu of issues available for resolution.<sup>427</sup> This is another advantage of confronting the panoply of issues now, rather than deciding them one-by-one. Addressing them democratically instead of through court-imposed mandates and neither adding to nor subtracting from the existing liberal democratic compromise is also important to avoid further fragmenting the *polis*.

The last section carefully outlined the existing legal compromise along the following lines: (1) genetic discrimination disadvantaging persons on the basis of race, religion, and gender is unlawful, but genetic discrimination favoring persons on the basis of gender, intelligence, and other reasons may be permissible; (2) genetic information should generally be confidential; (3) negative eugenics in the form of mandated GS is unconstitutional; (4) the right to implant living human embryos may be fundamental, but not the right to create human clones; (5) the state has a legitimate interest in protecting the *ex vivo* living human embryo; (6) regulating scientific inquiry probably does not infringe symbolic speech rights particularly if the regulation concerns research methods; (7) regulating scientific inquiry may infringe religious expression, but usually without triggering strict scrutiny; (8) lethal human subject experimentation is unlawful, as is human subject experimentation preceding sufficient animal studies, the results of which could be achieved through other research and incorporating neither informed consent nor legally

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427. See, e.g., ROGER FISHER & WILLIAM URY, GETTING TO YES: NEGOTIATING AGREEMENT WITHOUT GIVING IN ch. 4 (2d ed. 1991).

effective proxy consent; (9) patents on human life and certain dangerous technologies are unlawful, but not necessarily processes to produce them; and (10) parental rights to direct the upbringing of progeny including their genetic destiny are fundamental, but parents may not jeopardize the health or safety of children nor impose excessive burdens upon society.

Below we review a variety of policy recommendations that would extend this democratic consensus to biotechnology. Although I seek neither to add to nor subtract from the existing consensus, this becomes more challenging as the legal issues become less familiar and jurisprudential philosophies are counterposed. Relatively unsophisticated biotechnologies like GS raise less compelling legal and moral questions. On the other hand, applications of existing law to novel issues raised by biotechnology, like whether to accord any rights to the *ex vivo* living human embryo, are more difficult and likely to trigger anxiety and suspicion.

#### A. *Consensual Recommendations*

The first set of policy recommendations already enjoy substantial popular support and would: (1) render unlawful any application of biotechnology disadvantaging persons upon the basis of race, gender, or religion; and (2) treat human genetic information as confidential. Therefore, in keeping with authority outlawing invidious discrimination, the insurance industry and employers would not be able indirectly to discriminate against particular racial groups or genders by virtue of inheritable diseases disproportionately affecting them. Generally, they would also not be able to penalize persons for exercising their religious convictions. On the other hand, employers would be able to take account of genetic information when persons pose unique risks to third parties (*e.g.*, airline pilots). Although some would go further and preclude all forms of genetic discrimination, the existing consensus does not require this.

#### B. *Familiar Recommendations*

The next set of policy decisions require balancing state interference with parental, First Amendment, and reproductive rights with the State's interest in preventing child abuse, serving the best interests of children, and minimizing healthcare costs. The application of these legal regimes to HC and GE are new, but follow predictable patterns. When applied in keeping with the common law, they do not offend the objectives of positivism or natural law.

## 1. When Parental Rights Should Be Paramount

Existing authority suggests that parental rights should be paramount in refusing: (1) GS for diseases that are not treatable; (2) biotechnologies like GS and GE when (a) it is not in the best interest of the child according to prevalent social norms, (b) it would not overly burden society, or (c) it would "enhance" the child or the child's progeny; or (3) GE that is inheritable even if therapeutic. State infringement upon any of these freedoms should be subject to strict scrutiny because of parental and personal autonomy rights. Private infringement should be subject to liability under Title VII, the ADA, HIPPA, state law, and new regulations.

Mandating GS for untreatable diseases would have numerous negative psychological and other repercussions without adequate offsetting benefits. Mandating genetic enhancements would be equivalent to public eugenics. It would inevitably lead to inequality between the classes and races and coercive abortion, unless heavily subsidized. The savings from reduced long-term health care costs could theoretically offset the cost of therapeutic GE, but not GE that is enhancing.

With respect to inheritable GE even when therapeutic, many will object to it for deontological reasons that are not necessarily religious, such as avoiding long-term damage to humankind's natural genetic patrimony and the ability of future generations to decide for themselves how to live. Utilitarians also want to ensure freedom of choice. Therefore, even if the welfare state dramatically expanded to subsidize inheritable GE, parents should have an absolute right to refuse it at least until its effect upon generations of human beings is clear.

## 2. When Parental Rights Should Not Be Absolute

Existing authority suggests that the state may trump parental rights in some circumstances when for religious or other reasons parents would deny their progeny therapeutic GE even after it becomes safe and subsidized. Subsidized genetic therapy is key because the State should not be able to overcome a parent's objection to genetic therapy, or even permit a parent to pay for the expense of refusing genetic therapy (through higher insurance premiums or otherwise), if the parent cannot afford it. Otherwise, parents would be penalized for refusing genetic therapy they cannot afford.

Prevailing parental, First Amendment, and equal protection values suggest that the best way to identify situations when parental rights should give way to the State's interest in preserving per-

sonal health and welfare is to subject a parent's exercise of *bona fide* religious or other convictions to judicial reversal upon proof of a compelling state interest pursued in the least restrictive manner.<sup>428</sup> Under this standard, the State should generally succeed over a parent's objection to gene therapy when, for example, a child's inheritable condition was immediately life-threatening (as when parents object to blood transfusions in life-threatening circumstances for their children).<sup>429</sup> On the other hand, when parents refuse GS and gene therapy where there is a substantial risk of an inheritable disease that is disabling, but not life-threatening, or when a disease is adult-onset in character, parental rights should ordinarily prevail if we are to continue to respect the free exercise of religion and parental authority.

In between these scenarios, courts will be left to make hard decisions about what is in the best interest of the child, for example, when medical professionals, state welfare agencies, or one parent, but not the other believes they have a compelling interest in performing GS and GE. As before, courts should generally defer to the objecting party when (1) the reason a healthcare professional wants to perform GS is linked to an inheritable disease for which no treatment exists; (2) the particular biotechnology under consideration is not proven absolutely safe; and (3) the health care professional proposes an inheritable genetic modification.

### 3. When State Interests Should Be Paramount

Courts should generally consider State interests paramount when parents seek to reduce or enhance the genetic endowment of their embryo. The State should be able to regulate either decision, subject to rational review. As discussed above, distinguishing certain enhancements from therapies raises intractable questions centered on how we define "normal" health;<sup>430</sup> however, the alternative to confronting them on a case-by-case basis is to treat as morally or legally equivalent genetic therapy and

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428. In contrast, the state's interests in preventing non-parents like researchers and businesses from undertaking inheritable and non-inheritable GE without parental consent should be subject to mere rational basis review in recognition of the significant countervailing moral and equal protection issues involved and less substantial fundamental rights at stake.

429. See, e.g., *In re Clark*, 185 N.E.2d 128 (Ohio C.P. 1962) (holding that the court could summarily provide under a state statute for emergency medical or surgical treatment for any child pending service of a citation upon the parents even where the parents were Jehovah's Witnesses who believed that blood transfusions were prohibited).

430. See *supra* Part I(A).

enhancements when these are no more similar than experimentation and therapy.<sup>431</sup>

Medicine and particularly the Human Genome Project and politics can facilitate or muddle this line-drawing process by developing a comprehensive list of genetically-linked inheritable diseases constituting the "abnormal."<sup>432</sup> The state's interest in preventing persons from using GE for purposes other than modifying these abnormal conditions (*e.g.*, for the purpose of modifying eye, skin, and hair color due to time-bound predilections about physical traits) should generally be deemed adequate if based on rational concerns.

#### 4. When Women's Rights Should Be Paramount

Women's rights are not ordinarily implicated with respect to *ex vivo* living human embryos, but they should be deemed paramount if a woman's right to implant human embryos is threatened. Although it would be consistent with existing precedent to prohibit altogether the creation of human clones, preventing their implantation is contrary to the goals of both the pro-choice and pro-life community.

#### C. *The Special Respect Paradigm*

The last set of policy recommendations apply existing precedent to novel issues biotechnology raises like whether any restraints should apply to manipulating the *ex vivo* living human embryo to create kids, clones, and chimera. To extend no civil rights to the living human embryo, but treat it as the moral and legal equivalent of a thing to be produced, patented, priced, and purchased would substantially extend utilitarianism beyond its current foothold in medical science.

In contrast, the concept of special respect for the living human embryo admits that human life may have intrinsic value while permitting positivists to help frame the ways government recognizes this by according some rights of persons to human

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431. Statistics will inevitably play an important role in every dispute where the state or one parent seeks to avoid GE. Experts on both sides will opine on the probability that a particular gene will lead to certain "abnormal" conditions and behaviors. Other experts will discuss the extent to which an inheritable disease is likely to express itself in multiple environments. The statistics and science-thick nature of this litigation will make it difficult to follow, but juries are best suited to make these case-by-case factual findings and assess the sincerity of the moral, religious, and other convictions of those involved.

432. Similar attempts to elaborate on abnormal conditions include, for example, the American Psychiatric Association's Diagnostic and Statistical Manual (DSM).

embryos, but not others. Unlike the property rights model, the special respect paradigm need not expand or retract the twin positivist and natural legal foundations of modern law, and, therefore, better preserves the existing liberal democratic compromise.

The special respect paradigm also enables us to adopt an honest, common rhetoric in relation to key terms like "cloning," "therapy," "experimentation," and "living human beings" and use them in their conventional sense, so that we can make hard policy choices. Distorting rhetoric may subvert the truth and ultimately the law but it cannot undermine the reality.<sup>433</sup> By honestly and democratically confronting policy choices impinging on human rights we can decide which substantive rights should be accorded the *ex vivo* living human embryo and which denied without threatening political instability.

Although the list of potential compromises is lengthy, Professor Robertson concedes that efforts to limit the number of cryopreserved embryos,<sup>434</sup> regulate destruction of human embryos,<sup>435</sup> and restrict or ban non-therapeutic research on living human embryos<sup>436</sup> may be constitutional. It is consistent with the Nuremberg Code and Declaration of Helsinki, for example, to require at least the exhaustion of the medical advances possible with adult stem cell research and already or naturally deceased human embryos and fetuses before permitting researchers to terminate more human embryos, much less create new ones through research cloning.

Patents on human life and chimera also have no precedent in Western history, unlike patents on *processes* to create or modify life. Liberal democracies have banned or monopolized the few technologies too dangerous to proliferate in the free market or which threaten fundamental human rights while encouraging the patenting of all other devices. The Nuremberg Code, Declaration of Helsinki, and Human Subjects Policy all ban some types of scientific inquiry, as do federal statutes on fetal tissue

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433. See PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY xiv (2002), available at <http://www.bioethics.gov> (on file with the Notre Dame Journal of Law, Ethics & Public Policy).

434. Robertson on Early Embryos, *supra* note 231, at 499, 504–06.

435. *Id.*

436. *Id.*

research<sup>437</sup> and some state statutes on experimenting with embryos.<sup>438</sup>

The United States monopolized and banned nuclear energy, due partly to its dangerous implications for humanity. Over a much longer period of time, GE also could modify humanity by introducing fundamental, inheritable alterations to the human species and creating new species. Radical repercussions call for bold initiatives like banning or monopolizing inheritable genetic engineering and the creation of human clones or refusing to issue or fully enforce patents relating to them at least until the long-term medical consequences of GE and HC are obvious.

#### IV. CONCLUSION

Frankenstein should not have released his innovation into the world without direction or moral guidance. The responsibility was his alone to ensure the welfare of his monster and ability of his community to co-exist. We have a similar responsibility with respect to creating and modifying clones, kids, and chimera. Leaving biotechnology to regulate itself would shirk this responsibility, whereas over-regulating it would distort the market. Accommodating biotechnology by favoring either legal positivism or natural law would upset an already fragile balance supported by a fragmented *polis*. The most feasible solution is simply to extend the existing liberal democratic compromise with respect to equal protection, reproductive rights, the First Amendment, human subject experimentation rules, patent law, and parental rights. This includes banning or monopolizing certain biotechnologies and extending substantive special respect to the *ex vivo* living human embryo.

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437. See National Institutes of Health Revitalization Act of 1993 § 112, 42 U.S.C. § 289g-2 (1994) ("It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.").

438. See *supra* note 228.



