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Will Directed Evolution Destroy Humanity, and If So, What Can We Do About It?

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WILL DIRECTED EVOLUTION DESTROY HUMANITY, AND IF SO, WHAT CAN WE DO ABOUT IT?

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In contemplating the technologies emerging from the Human Genome Project, nothing scares people more than the prospect that we will attempt to use genetic engineering to control the human evolutionary process. Of course, humans, like other species that reproduce sexually,[1] have always engaged in a variety of reproductive behaviors that shape their evolution, such as mating along hierarchical lines, courtship rituals, and the abandonment of defective offspring. But advances in medicine and human genetics have expanded these reproductive behaviors through the introduction of powerful new tools, including computerized dating services; assisted reproductive techniques that use gametes (eggs and/or sperm) from donors chosen for their desirable genetic characteristics or other traits; in vitro fertilization and preimplantation genetic diagnosis to weed out embryos with undesirable genetic characteristics; abortion following prenatal genetic testing; and health care and social support for persons with disabilities that help them survive and reproduce.[2] In all of these cases, specific sets of

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1. Some organisms use a different form of reproduction called parthenogenesis, which does not require fertilization by a male. *See* Michael Lynch & Wilfried Gabriel, *Phenotypic Evolution and Parthenogenesis*, 122 AM. NATURALIST 745 (1983); JOHN MAYNARD SMITH, THE EVOLUTION OF SEX 42 (1978); Demian D. Chapman et al., *Virgin Birth in a Hammerhead Shark*, 3 BIOLOGY LETTERS 425, 425 (2007).

2. "An increasing number of . . . women with moderate [to] severe disabilities are choosing to [have children]." Ann Hallum, *Disability and the Transition to Adulthood: Issues for the Disabled Child, the Family, and the Pediatrician*, 25 CURRENT PROBS. IN PEDIATRICS 12, 38 (1995). For example, more children are born to mothers with cystic fibrosis each year as management of the condition has improved. Frank P. Edenborough, *Women with Cystic*

genes are allowed or encouraged to reproduce. These reproductive behaviors are forms of germline genetic engineering because they influence the genes that will be passed on to future generations, and they collectively have a gradual impact on the evolutionary make-up of the human species.

New technologies affecting human evolution are proliferating in the aftermath of the Human Genome Project. Researchers are searching for genes that are not only associated with disease, but also with traits such as eye color, freckling, baldness, memory, longevity, height, hair thickness, hair color, measures of intelligence, avoidance of errors, and muscle performance.[3] As tests for more of these traits are developed, parents will be able to incorporate the tests into preimplantation genetic diagnoses and implant the embryos that have the best available genomes.[4] Similar genetic testing could be performed *in utero* and lead to the abortion of fetuses with undesirable non-disease genetic characteristics. Somatic interventions made possible by our growing understanding of human genetics, that is, interventions that do not directly affect eggs or sperm, will improve reproductive fitness by decreasing the scourge of illness and, in the case of changes in non-disease characteristics, enable those persons with access to the interventions to improve their socioeconomic environments.

But by far the greatest impact on human evolution may result from germline genetic engineering—the insertion and deletion of genes into DNA in not only somatic cells, but in reproductive cells where the genes can be transmitted to succeeding generations. The results of these technologies are likely to be of a different order than previous genetic interventions. As Emily Marden and Dorothy Nelkin explain, germline genetic engineering is

> far more radical and controversial than earlier gene therapy protocols. Somatic cell gene therapy, the prevailing technique to date, aims to replace flawed genes in already developed individuals and is targeted to particular classes of cells. Under this technology there is negligible risk that germ cells will be affected and that the trait will be passed on to progeny. However, in the case of germline genetic manipulation, it is expected that the procedure will affect the foetus' germ cells. Scientists could therefore potentially "correct" a genetic deficiency in every embryo, thereby permanently eliminating the undesirable trait from future generations. At the same time

Fibrosis and Their Potential for Reproduction, 56 THORAX 649, 649 (2001). Further, until recently, the number of adults in the population with congenital heart disease had been negligible. Now, eighty-five percent of all persons born in the U.S. with congenital heart disease survive into adulthood. Murray G. Baron & Wendy M. Book, *Congenital Heart Disease in the Adult: 2004*, 42 RADIOLOGIC CLINICS N. AM. 675, 675 (2004).

3. 23andMe, Health and Traits: Complete List, http://www.23andme.com/health/all/ (last visited Nov. 14, 2009).

4. Stuart A. Newman, *Averting the Clone Age: Prospects and Perils of Human Developmental Manipulation*, 19 J. CONTEMP. HEALTH L. & POL'Y 431, 435 (2003).

> though, the transferred genes could cause deleterious mutations that could also be passed on to progeny.[5]

Moreover, there are fewer biological boundaries when it comes to germline manipulations. As Stuart Newman observes,

> modification of the early embryo, referred to in what follows as "developmental" modification or manipulation, is unlike manipulations of the fully formed individual, including provision of artificial limbs, heart valve and joint replacements, cosmetic surgery, and even "somatic" (differentiated body cell) gene therapy. Developmental modification changes the generative trajectory of the individual and turns it into something *intrinsically* different from what it would have become without the manipulation. With these procedures there is no guarantee that even the original species-character will be maintained. Although one objective in applying such methods to our own species may be to fabricate improved humans, in some cases, by accident or by intent, the outcomes will be quasi-human or less than human.[6]

As far as it is known, no one has yet set out *intentionally* to perform germline genetic engineering in humans.[7] However, germline changes have been produced inadvertently. In 2001, an experiment in which hemophiliacs were treated through the insertion of corrected genes into their bloodstreams was halted after the altered genes were discovered in one subject's semen, raising the possibility that the changed genes could show up in sperm.[8] Another example is oocyte transfer, an infertility treatment in which ooplasm from a donor egg is injected into the ooplasm of the mother's egg, thus creating a child with DNA from three rather than two individuals: nuclear DNA from the father and mother, and mitochondrial DNA from the egg donor.[9]

Deliberate germline gene therapy is highly controversial; germline manipulation for purposes other than to prevent or treat disease is even more so.[10] Many practical obstacles remain as well, such as the difficulty of

5. Emily Marden & Dorothy Nelkin, *Displaced Agendas: Current Regulatory Strategies for Germline Gene Therapy*, 45 MCGILL L.J. 461, 463-64 (2000) (citation omitted).

6. Newman, *supra* note 4, at 431-32 (citation omitted).

7. Scientists recently announced the first creation of monkeys who passed germline genetic modifications to their offspring, marking the first successful germline engineering in a species closely related to humans. Rob Stein, *Glowing Green Monkeys Illustrate Important but Controversial Advance*, WASH. POST, May 28, 2009, at A1.

8. Eliot Marshall, *News Focus: Viral Vectors Still Pack Surprises*, 294 SCIENCE 1640 (2001).

9. Jason A. Barritt et al., *Mitochondria in Human Offspring Derived from Ooplasmic Transplantation*, 16 HUM. REPROD. 513, 513 (2001).

10. *See* W. French Anderson, *Human Gene Therapy: Why Draw a Line?*, 14 J. MED. & PHIL. 681 (1989) (arguing that in order to prevent unintentional damage to human nature,

altering characteristics that result from the interaction of multiple genes.[11] At the present time, even somatic gene therapy experiments have been met with only mixed success.[12] On the one hand, researchers report successfully using it to treat Leber's congenital amaurosis[13] and metastatic melanoma.[14] However, not forgotten is the 1998 death of Jesse Gelsinger, a subject in an experiment seeking to use gene therapy to treat ornithine transcarbamylase deficiency syndrome,[15] and the unforeseen emergence of leukemia in French newborns treated for an immune-deficiency disorder.[16] Perfecting these techniques will take time, but there is no reason to believe that it cannot be done eventually. Once this happens, we will gain much more rapid and effective means of manipulating the genes of our offspring. If this practice becomes sufficiently widespread, humanity would indeed be directing its own evolutionary process.

For transhumanists,[17] directed evolution is likened to the Holy Grail. Oxford philosopher Julian Savulescu exults that while "[h]umanity until this

gene transfer technology should only be available to treat serious disease). *See also* MARK S. FRANKEL & AUDREY R. CHAPMAN, AM. ASS'N FOR THE ADVANCEMENT OF SCI., HUMAN INHERITABLE GENETIC MODIFICATIONS: ASSESSING SCIENTIFIC, ETHICAL, RELIGIOUS AND POLICY ISSUES, 7-10, 40-42 (2000) (recommending that genetic modification only be used for therapeutic purposes because the use of genetic modification for enhancement may lead to a form of eugenics), *available at* http://www.aaas.org/spp/dspp/sfrl/projects/germline/report.pdf; Rebecca Dresser, *Designing Babies: Human Research Issues*, 26 IRB: ETHICS & HUM. RES., Sept.-Oct. 2004, at 1, 2 (opining that the potential benefits of genetic modification may be outweighed by the ethical and practical problems tied to the technology); Marden & Nelkin, *supra* note 5, at 464, 470 (arguing that serious ethical considerations surrounding germline therapy are being reduced by the excitement over the therapy's technical capabilities); Nancy Pham, Note, *Choice v. Chance: The Constitutional Case for Regulating Human Germline Genetic Modification*, 34 HASTINGS CONST. L.Q. 133, 158 (2006) (concluding that the regulation of genetic modification requires serious analysis of ethical, legal, and social considerations in order to prevent irreversible damage to the human race).

11. *See* FRANKEL & CHAPMAN, *supra* note 10, at 4.

12. Marden & Nelkin, *supra* note 5, at 465.

13. *See* James W.B. Bainbridge et al., *Effect of Gene Therapy on Visual Function in Leber's Congenital Amaurosis*, 358 N. ENG. J. MED. 2231, 2237 (2008).

14. *See* Richard A. Morgan et al., *Cancer Regression in Patients After Transfer of Genetically Engineered Lymphocytes*, 314 SCIENCE 126, 129 (2006).

15. Paul Gelsinger, Jesse's Intent, http://www.jesse-gelsinger.com/jesses-intent.html (last visited Nov. 14, 2009).

16. Jocelyn Kaiser, *News of the Week: Seeking the Cause of Induced Leukemias in X-SCID Trial*, 299 SCIENCE 495, 495 (2003).

17. The term "transhumanism" was invented in 1957 by Julian Huxley. "The human species can, if it wishes, transcend itself—not just sporadically, an individual here in one way, an individual there in another way, but in its entirety, as humanity. We need a name for this new belief. Perhaps *transhumanism* will serve: man remaining man, but transcending himself, by realizing new possibilities of and for his human nature." JULIAN HUXLEY, *Transhumanism*, *in* NEW BOTTLES FOR NEW WINE 13, 17 (1957).

point has been a story of evolution for the survival genes—survival and reproduction. . . we are entering a new phase of human evolution—evolution under reason—where human beings are masters of their destiny. Power has been transferred from nature to science."[18] UCLA biophysicist Gregory Stock proclaims that "[h]umanity is leaving its childhood and moving into its adolescence as its powers infuse into realms hitherto beyond our reach."[19]

Yet to others, directed evolution is a death sentence for the human species. Their fears stem from their conviction that geneticists who seek to reengineer the human genetic code will lack sufficient knowledge and skill to avoid making disastrous mistakes. "Inserting new segments of DNA into the germ line [sic]," warns the Council for Responsible Genetics, "could have major, unpredictable consequences for both the individual and the future of the species . . . ."[20] Longtime biotechnology critic Jeremy Rifkin puts it more bluntly: "[W]e risk undermining our own species' biological integrity in the name of human progress."[21]

The destruction of humanity as a result of ill-informed, overzealous, genetic manipulation would undeniably be a dreadful calamity. If the threat is serious, it certainly must be averted if possible. Determining just how dire

18. Julian Savulescu, *Human-Animal Transgenesis and Chimeras Might Be an Expression of Our Humanity*, 3 AM. J. BIOETHICS 22, 24 (2003).

19. Gregory Stock, *Germinal Choice Technology and the Human Future*, 10 ETHICS L. & MORAL PHIL. REPROD. BIOMEDICINE, Mar. 2005, at 27, 34.

20. Council for Responsible Genetics, Human Genetics Committee, *Position Paper on Human Germ Line Manipulation*, 4 HUM. GENE THERAPY 35, 37 (1993). The Council for Responsible Genetics is a non-profit, non-governmental organization consisting of scientists, public and occupational health activists, and reproductive rights supporters. Their mission is to spark public dialogue on the ethical, social and environmental impacts of genetic technologies. Among the Council's worries is that we inadvertently would introduce "susceptibilities to cancer and other diseases into the human gene pool." *Id.*

21. Jeremy Rifkin, *Human-Animal Hybrids Cross an Ethical Line*, ST. PETERSBURG TIMES, Mar. 30, 2005, at 13A, *available at* http://www.foet.org/global/BC/St.%20Petersburg%20Times-%20March%2030%202005.pdf. In addition, there are many philosophical and political objections to directed evolution, ranging from complaints that it would be hubris to interfere with God's natural plan, to the fear that evolutionarily advanced humans would enslave the rest of the species. *See, e.g.*, BILL MCKIBBEN, ENOUGH: STAYING HUMAN IN AN ENGINEERED AGE 209 (2003) ("In the Western tradition, the idea of limits goes right back to the start, to a God who made heaven and earth, beast and man, and then decided that it was all enough, and *stopped*."); George J. Annas, *The Man on the Moon, Immortality, and Other Millennial Myths: The Prospects and Perils of Human Genetic Engineering*, 49 EMORY L.J. 753, 773 (2000) ("Ultimately, it almost seems inevitable that genetic engineering would move *homo sapiens* to develop into two separable species: the standard-issue human beings would become like the 'savages' of the pre-Columbian Americas, and be seen by the new, genetically-enhanced neo-humans, as heathens who can properly be slaughtered and subjugated.").

this threat is exceeds the scope of this article.[22] The question addressed here is a more preliminary, but nonetheless critical inquiry: how should the threat be assessed? More specifically, what methodological framework should be employed? As will be seen, the answers to these questions are not merely rhetorical; they dictate the starting point for establishing the means by which humanity might be saved from destruction.

A. The Catastrophists

Averting the destruction of humanity has become somewhat of a cottage industry for legal scholars. Harvard law professor and now Administrator of White House Office of Information and Regulatory Affairs Cass Sunstein has written two books on the subject: *Laws of Fear: Beyond the Precautionary Principle* in 2005,[23] and *Worst-Case Scenarios* in 2007.[24] Richard Posner, formerly a law professor at the University of Chicago and now a judge on the U.S. Court of Appeals for the 7th Circuit, wrote *Catastrophe: Risk and Response* in 2004.[25] Both authors pay considerable attention to environmental disasters, especially global warming, but Posner in particular contemplates threats posed by science gone wild, and offers an interesting approach in deciding if we are trying hard enough to prevent them.

The difficulty, according to Posner, is the uncertainty surrounding the probability that a dire risk will materialize.[26] If we knew how likely it is that the Earth will be destroyed by an asteroid, for example, we could calculate the cost if this were to occur and then generate a figure for how much we should be spending to avert it by, say, monitoring the heavens and preparing space weapons to knock the object off course. The problem is that we don't know for sure how likely it is that a large asteroid will strike us. In the face of this uncertainty, one option is to make a guess. But as Sunstein emphasizes, there are all sorts of methods that can be used to guess about risks, and they can lead to very different results.[27] Estimates of a cataclysmic asteroid collision with Earth, according to Posner, for example, range from once in every 50 million to 100 million years.[28] Posner's solution is what he calls "inverse cost-benefit analysis."[29] First, we

22. The author is completing a book on the subject.

23. CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE (2005).

24. CASS R. SUNSTEIN, WORST-CASE SCENARIOS (2007).

25. RICHARD A. POSNER, CATASTROPHE: RISK AND RESPONSE (2004).

26. *See id.* at 175-76.

27. Sunstein is particularly critical of the "Precautionary Principle," which he attacks as being too cautious: "The real problem is that the [Precautionary] principle offers no guidance – not that it is wrong, but that it forbids all courses of action, including regulation." SUNSTEIN, *supra* note 23, at 26.

28. POSNER, *supra* note 25, at 25-26.

29. *Id.* at 176.

must figure out how much the government is spending to prevent the disaster and divide it by the social cost if the disaster were to come about, and this generates "an approximation to the implied probability of the catastrophe."[30] Then we must see how comfortable we are with this probability. For example, we can compare it to the range of risk estimates put forward by experts. If the experts' estimates are much greater, we should take greater precautions; if the estimates are lower, we are overreacting and should cut back on prevention. Posner calculates that we are spending about $3.9 million a year to detect potentially dangerous asteroids, and that this is only commensurate with the mean risk of a collision estimated by experts (1.70 in 100 million per year) if we value a person's life as worth only $50,000, which Posner believes is much too low.[31] Therefore, he concludes, we are not spending enough to avert an asteroid collision.[32]

Using Posner's approach, are enough precautions being taken to prevent the destruction of the human species by the harmful effects of directed evolution? It is extremely difficult to calculate how much spending exists, but for purposes of this discussion it is assumed that the National Institutes of Health is spending about 10 percent of its $18 million annual budget for its Ethical, Legal, and Social Implications (ELSI) program[33] on directed evolution; that 10 percent of the FDA's $245 million annual budget for its Center for Biologics Evaluation and Research,[34] which regulates genetic products, is spent on genetic engineering; and that the annual cost to run the NIH's Recombinant DNA Advisory Committee, which advises the NIH and the FDA on genetic engineering research, is about $3 million.[35] This yields an annual expenditure of around $29.3 million. Posner estimates the value of the human race at $600 trillion.[36] The amount being spent divided by the cost of extinction reveals an implied annual risk of 1 in 4.7 million that directed evolution will destroy the species. No one knows

30. *Id.* at 177.

31. *Id.* at 179-80.

32. *Id.*

33. National Institutes of Health, National Human Genome Research Institute, *ELSI Planning and Evaluation History*, http://www.genome.gov/10001754 (last visited Oct. 25, 2009).

34. JUDITH A. JOHNSON ET AL., CONGRESSIONAL RESEARCH SERVICE, CRS REPORT FOR CONGRESS: THE FDA FY2009 BUDGET REQUEST 4 (2008), *available at* http://digital.library.unt.edu/govdocs/crs/permalink/meta-crs-10745:1.

35. DEP'T OF HEALTH & HUM. SERVICES, CHARTER: RECOMBINANT DNA ADVISORY COMMITTEE 2 (2009).

36. POSNER, *supra* note 25, at 180. Posner himself admits that this figure is highly controversial. *Id.*

the true risk, so we can only ask whether we think the real odds are larger or smaller, and then adjust government spending accordingly.

B. Lessons from History

There have been three major scientific research undertakings that scientists feared could destroy humanity. The first was the Manhattan Project, when one of the researchers, Edward Teller, who would become known as "the father of the hydrogen bomb," warned that an atomic detonation might ignite the nitrogen in the Earth's atmosphere or the hydrogen in its oceans and incinerate the planet.[37] Other scientists on the project examined Teller's concern and concluded that it was groundless because "no matter how high the temperature, energy loss would exceed energy production by a reasonable factor."[38]

Particle acceleration is another scientific effort that has triggered alarm. When the Lawrence Berkeley Laboratory placed the Bevalac accelerator into operation in 1975,[39] there was some speculation that it could create a massive, abnormal state of matter that could destroy the Earth. Joseph Kapusta, who was a physics graduate student at the University of California at Berkeley at the time, describes this speculation as "tongue-in-cheek,"[40] but admits that "no one really knew what to expect when nuclear matter was compressed to three-to-four times the density of atomic nuclei."[41]

Apocalyptic fears surfaced once again when a more powerful accelerator, the Relativistic Heavy Ion Collider (RHIC), was built at Brookhaven National Laboratory in 1999.[42] The RHIC was designed to create "quark-gluon plasma, a new state of matter representative of the state of the universe when it was less than one microsecond old and temperatures were greater than two trillion Kelvin."[43] One concern was that

37. RICHARD RHODES, THE MAKING OF THE ATOMIC BOMB 418-19 (1986).

38. *Id.* at 419 (quoting David Hawkins, *Toward Trinity*, *in* THE HISTORY OF MODERN PHYSICS: 1800-1950 15 (1983)). According to Rhodes, Adolph Hitler joked with Albert Speer about the possibility that the Nazi atomic program could produce the same catastrophic result. *Id.* at 405.

39. Bevalac was formed by mating two less powerful machines, SuperHILAC and Bevatron. Joseph I. Kapusta, *Accelerator Disaster Scenarios, the Unabomber, and Scientific Risks*, 10 PHYSICS IN PERSP. 163, 166-69 (2008).

40. *Id.* at 169. One argument for dismissing the concern was that, if such an event could occur in an accelerator experiment, it also should take place when cosmic rays bombarded objects in space, including the Moon, and the Moon was still there. *See id.* at 176, 180.

41. *Id.* at 168. In his own tongue-in-cheek manner, Kapusta observes that if this dire prediction came true, "no physicist would be around to be blamed for it! Moreover, it guaranteed that no physicist would ever win a Nobel Prize for the discovery . . . ." *Id.* at 169.

42. *See id.* at 173-74.

43. *Id.* at 173.

the RHIC could create dense objects called "strangelets." These are "objects that comprise approximately equal numbers of up, down, and strange quarks, as opposed to protons and neutrons, which comprise up and down quarks only."[44] Most theorists believed that if strangelets were formed, they would convert to ordinary matter within a thousand-millionth of a second.[45] But if by some chance they were stable, and also negatively charged, they could "infect" the matter around them, and "transform the entire planet Earth into an inert hyperdense sphere about one hundred meters across."[46] The RHIC, it was feared, also could produce a microscopic black hole that would swallow the planet.[47] The Brookhaven National Laboratory commissioned an investigation, which dismissed these concerns.[48] Any strange quarks that were created would have a positive rather than a negative charge, and therefore not bond with nearby matter, and the collider could not concentrate matter into a small enough volume to create sufficient density to form a black hole.[49]

Then came the Large Hadron Collider (LHC) project at CERN (the French initials for the European Council for Nuclear Research).[50] This is a seventeen mile long ring of superconducting magnets straddling the Franco-Swiss border[51] that is so powerful that it is expected to produce fundamental particles under the conditions obtained when the universe was less than one picosecond (one-trillionth of a second) old.[52] One newspaper article described the LHC with such superlatives as "world's largest machine," "fastest race track on [the] planet," "emptiest space in [the] solar system," "hottest spot in the galaxy," and "world's most powerful supercomputer."[53]

44. Kapusta, *supra* note 39, at 175.

45. European Organization for Nuclear Research, The Safety of the LHC, http://public.web.cern.ch/public/en/LHc/Safety-en.html (last visited Nov. 14, 2009).

46. POSNER, *supra* note 25, at 30 (quoting MARTIN REES, OUR FINAL HOUR: A SCIENTIST'S WARNING: HOW TERROR, ERROR, AND ENVIRONMENTAL DISASTER THREATEN HUMANKIND'S FUTURE IN THIS CENTURY – ON EARTH AND BEYOND 120-21 (2003)). Rees is a professor of physics and Master of Trinity College at Cambridge University, and the United Kingdom's Astronomer Royal.

47. Kapusta, *supra* note 39, at 175.

48. *See* Robert L. Jaffe et al., *Review of Speculative "Disaster Scenarios" at RHIC*, 72 REVIEWS MOD. PHYSICS 1125, 1125 (2000).

49. *See* Kapusta, *supra* note 39, at 176.

50. CERN stands for Conseil Européen pour la Recherche Nucléaire (European Organization for Nuclear Research). European Organization for Nuclear Research, Facts and Figures, http://public.web.cern.ch/Public/en/LHC/Facts-en.html (last visited Nov. 14, 2009).

51. Kevin Mayhood, *What Do You Get When You Give $8 Billion to 8,000 Physicists? . . . A Science Project That May Rock the Universe*, COLUMBUS DISPATCH, Sept. 23, 2008, at B4.

52. *See* Frank Close, *Ions in the Fire*, GUARDIAN (UK), Apr. 29, 1999, at 10.

53. Mayhood, *supra* note 51, at B5 (citing European Organization for Nuclear Research, *supra* note 50).

As might be expected, doomsayers once again raised concerns about black holes, strangelets, and similar catastrophic events.[54] Two alarmists even filed a lawsuit in Federal Court in Hawaii.[55] Finding that the U.S. Government's funding of less than ten percent of the $5.84 billion cost of the LHC did not represent a "major Federal action" under the National Environmental Policy Act, the judge dismissed the suit for lack of jurisdiction.[56] Nevertheless, the judge opined that "[i]t is clear that Plaintiffs' action reflects disagreement *among scientists* about the possible ramifications of the operation of the Large Hadron Collider."[57] It is uncertain who these scientists are; the plaintiffs in the lawsuit do not appear to qualify.[58] In any event, CERN commissioned a study to show that the fears were unfounded.[59] Ironically, less than two weeks after the machine was turned on for the first time, it was shut down for two months for repairs.[60] According to the *New York Times*, this occurred when

54. *See, e.g.*, The Misunderstood Universe, France Builds Doomsday Machine, http://www.misunderstooduniverse.com/France_Builds_Doomsday_Machine.htm (last visited Nov. 16, 2009); *see generally* LHC Defense.org (providing various theories and opinions regarding how the Large Hadron Collider may destroy Earth and the Universe), Stop the LHC–Until We Know It's Safe, http://www.lhcdefense.org/ (last visited Nov. 16, 2009).

55. Sancho v. U.S. Dep't of Energy, 578 F. Supp. 2d 1258, 1259 (D. Haw. 2008). The plaintiffs, who were represented pro se, were Walter L. Wagner and Luis Sancho. According to Fox News, Wagner has been indicted for identity theft in connection with a legal battle in Hawaii. Paul Wagenseil, Lawsuit: Huge Atom Smasher Could Destroy World, (Mar. 31, 2008) http://www.foxnews.com/story/0,2933,342854,00.html.

56. *Sancho*, 578 F. Supp.2d at 1267, 1269.

57. *Id.* at 1269 (emphasis added).

58. The New York Times describes Sancho as a science writer and professor in Barcelona. Dennis Overbye, *Suit to Halt Big Collider in Europe Is Dismissed*, N. Y. TIMES, Sept. 30, 2008, at A21. Fox News says he is a Spanish citizen living in Hawaii. Wagenseil, *supra* note 55. According to Fox News, Wagner "claims to have minored in physics at U.C. Berkeley, gone to law school, taught elementary-school science and worked in nuclear medicine at health facilities—but he doesn't appear to have an advanced degree in science." *Id.* The *Times* describes him as "a retired radiation safety officer who lives in Hawaii." Overbye, *supra*.

59. *See* J.-P. BLAIZOT ET AL., EUR. ORG. FOR NUCLEAR RES., STUDY OF POTENTIALLY DANGEROUS EVENTS DURING HEAVY-ION COLLISIONS AT THE LHC: REPORT OF THE LHC SAFETY STUDY GROUP 1 (2003) (demonstrating how many popular theories proposing that the LHC may create dangerous black hole chain reactions are scientifically unfounded), *available at* http://doc.cern.ch/yellowrep/2003/2003-001/p1.pdf. *See generally* Benjamin Koch, Marcus Bleicher & Horst Stöcker, *Exclusion of Black Hole Disaster Scenarios at the LHC*, 672 PHYSICS LETTERS B 71, 71 (2009); Marco Cavaglià, Saurya Das & Roy Maartens, *Will We Observe Black Holes at the LHC?*, 20 CLASSICAL & QUANTUM GRAVITY L205, L211 (2003) (concluding that the LHC would fail to produce the necessary energy to create black holes).

60. Dennis Overbye, *Ah Spring! Swallows, Baseball, Colliding Protons*, N.Y. TIMES, Sept. 24, 2008, at A7.

> an electrical connection between two of the superconducting electromagnets that steer the protons suffered a so-called quench, heating up, melting and leaking helium into the collider tunnel. Liquid helium is used to cool the magnets to superconducting temperatures of only about 3.5 degrees Fahrenheit above absolute zero. Stray heat can cause the magnets to lose their superconductivity with *potentially disastrous consequences*.[61]

Like directed evolution, the third doomsday science project—recombinant DNA technology—actually involves genetic engineering. In 1972, Paul Berg, the Stanford biochemist who would later win a Nobel prize for his work on nucleic acids, published the results of experiments in which he combined DNA from two different organisms: simian virus 40 (SV40); and *E. coli*, a bacterium that lives in the human intestinal tract where it aids in digestion.[62] SV40 was found in monkey kidney cells that had been used to produce the Salk and Sabin polio vaccines in the 1950s,[63] and Berg chose it for his experiment because it was easy to work with.[64] In 1961 however, researchers discovered that SV40 produced cancers in hamsters.[65] Nevertheless, Berg spliced segments of *E. coli* DNA into SV40.[66] A cancer researcher at the genetics research laboratory at Cold Spring Harbor, Robert Pollack, heard of Berg's work and warned him that he could inadvertently introduce a new cancer-causing organism into the human digestive system, possibly infecting himself and his lab workers.[67] Berg suspended his research, raised Pollack's concern with a group of colleagues at the annual meeting of the Gordon Research Conference on Nucleic

61. *Id.* (emphasis added). The LHC also was featured in the film *Angels and Demons*, based on the book by Dan Brown, which is part of the same series as the *The Da Vinci Code*. In *Angels and Demons*, a secret society steals a canister of antimatter from CERN in order to destroy the Vatican. *See* ANGELS & DEMONS (Sony Pictures 2009); DAN BROWN, ANGELS & DEMONS 70 (2000); European Organization for Nuclear Research, Angels and Demons, http://public.web.cern.ch/Public/en/Spotlight/SpotlightAandD-en.html (last visited Nov. 16, 2009).

62. ALAN LIGHTMAN, THE DISCOVERIES: GREAT BREAKTHROUGHS IN 20TH CENTURY SCIENCE, 485-86 (2005); David A. Jackson, Robert H. Symons & Paul Berg, *Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40: Circular SV40 DNA Molecules Containing Lambda Phage Genes and the Galactose Operon of* Escherichia coli, 69 PROC. NAT'L ACAD. SCI. U.S. 2904, 2904 (1972); Nobelprize.org, The Nobel Prize in Chemistry 1980, http://nobelprize.org/nobel_prizes/chemistry/laureates/1980/ (last visited Nov. 16, 2009).

63. NAT'L CANCER INST., SIMIAN VIRUS 40 AND HUMAN CANCER 1 (2003), http://www.cancer.gov/cancertopics/factsheet/risk/sv40.

64. *See* LIGHTMAN, *supra* note 62, at 485.

65. NAT'L CANCER INST., *supra* note 63 (noting that the US government had to screen stocks of polio vaccine to make sure they had not been contaminated with SV40).

66. LIGHTMAN, *supra* note 62, at 486-88.

67. *Id.* at 490.

Acids in 1973, and then collaborated with a number of other prominent scientists to write a letter to the journal *Science* calling for a voluntary, worldwide moratorium on further recombinant DNA experiments[68] "until the potential hazards of such recombinant DNA molecules have been better evaluated or until adequate methods are developed for preventing their spread . . . ."[69] The moratorium appears to have worked, with researchers resuming experimentation only after an international interdisciplinary group assembled at the Asilomar Conference Center in California in February 1975 and recommended that the National Institutes of Health establish safety guidelines to govern recombinant DNA research.[70]

The Berg moratorium is a signal event in the regulation of science—an instance in which researchers policed themselves to avert a potential catastrophe. But Richard Posner doesn't trust scientists to regulate themselves. "Few scientists," he argues, "have the time, the background, or the inclination to master the alien methods of public policy."[71] Moreover, scientists are seekers after knowledge, and "[t]o seekers after knowledge, measures of protection against dangerous knowledge, such as knowledge of how to use gene splicing to create a more lethal pathogen, are simply an impediment . . . ."[72] Instead, the regulation of science must be delegated to lawyers. "Policing the intersection between law and science," he says, "is a more natural role for lawyers than for scientists to play . . . ."[73] But Posner readily acknowledges that most lawyers are scientifically illiterate, and in the end, this forces them to rely on the very scientists they are attempting to regulate to supply the necessary expertise.[74] Posner's solution is for law schools to require that "a substantial fraction of law students be able to demonstrate by the time they graduated . . . a basic competence in college-level math and statistics plus one science such as physics, chemistry, biology, computer science, medicine, public health, or geophysics."[75]

History tends to vindicate Posner's distrust of scientists: the Berg moratorium is the only occasion on which a scientific endeavor has halted itself to avert disaster. But is Posner's solution realistic? Consider the CERN report on the safety of the LHC mentioned earlier.[76] The discussion of the

68. *Id.* at 491.

69. Paul Berg et al., *Potential Biohazards of Recombinant DNA Molecules*, 185 SCIENCE 303, 303 (1974).

70. LIGHTMAN, *supra* note 62, at 491-92.

71. POSNER, *supra* note 25, at 208.

72. *Id.* at 202.

73. *Id.* at 208.

74. *See id.* at 207-08.

75. *Id.* at 203.

76. *See* BLAIZOT ET AL., *supra* note 59.

risk that a black hole would be formed runs a little more than four pages and contains eighteen mathematical formulas, including for example:[77]

$$\begin{aligned}\Gamma_{\rm D} &\approx T_{\rm BH}^{4+d} R_{\rm S}^{2+d} \\ &= M_*^2 \left(\frac{M_*}{M}\right)^{\frac{2}{2+d}} .\end{aligned}$$

According to the chair of the Physics Department at Case Western Reserve University: "At a minimum, it would take an advanced graduate student in theoretical physics to understand and judge these papers."[78] So lawyers and regulators probably are going to have to continue to rely on scientific experts to help police scientific research, and where the science is especially advanced, it may be comprehensible only to the researchers themselves.

C. Engineers vs. Bioethicists

A technology that bears some resemblance to germline genetic engineering in terms of its technicality and the fears that it has evoked is nanotechnology.[79] In 2006, the American Association for the Advancement of Science conducted an invitational workshop on human enhancement.[80] One of the speakers, Mihail Roco, Senior Advisor for Nanotechnology at the National Science Foundation, outlined his recommendations for managing nanotech risks.[81] Following the other speakers, who discussed enhancement technologies in terms of "health, freedom, equity, diversity,

77. *Id.* at 12.

78. Interview with Daniel S. Akerib, Chairman, Department of Physics, Case Western Reserve University (Feb. 17, 2009).

79. *See generally* ROYAL COMM'N ON ENVTL. POLLUTION, NOVEL MATERIALS IN THE ENVIRONMENT: THE CASE OF NANOTECHNOLOGY 5 (2008) (discussing how the lack of knowledge surrounding the health and environmental impacts of certain nanomaterials is of significant concern), *available at* http://www.rcep.org.uk/reports/27-novelmaterials/documents/NovelMaterialsreport_rcep.pdf; MICHAEL CRICHTON, PREY x (2002) (warning that unrestrained nanotechnology development may result in disastrous consequences to humanity); Howard Wolinsky, *Nanoregulation: A Recent Scare Involving Nanotech Products Reveals That the Technology Is Not Yet Properly Regulated*, 7 EMBO REP. 858, 859 (2006) (discussing how regulations specific to nanotechnology are necessary to protect the public and the environment).

80. *See* ENITA A. WILLIAMS, AM. ASS'N FOR THE ADVANCEMENT OF SCI., GOOD, BETTER, BEST: THE HUMAN QUEST FOR ENHANCEMENT: SUMMARY REPORT OF AN INVITATIONAL WORKSHOP CONVENED BY THE SCIENTIFIC FREEDOM, RESPONSIBILITY AND LAW PROGRAM (2006), *available at* http://www.aaas.org/spp/sfrl/projects/human_enhancement/pdfs/HESummaryReport.pdf.

81. AM. ASS'N FOR THE ADVANCEMENT OF SCI., WORKSHOP ON HUMAN ENHANCEMENT ATTENDEES (2006), http://www.aaas.org/spp/sfrl/projects/human_enhancement/pdfs/HEWorkshopAttendees_060107.pdf.

solidarity/community, regulation/access/distribution as they relates [sic] to social justice, shared concern over the commodification of children and the body, and the search for both the meaning of life and a meaningful life,"[82] Roco's words, which spoke of "risk appraisal," "hazard, exposure," "tolerability and acceptability judgment," and "risk management," seemed strangely abstract and impersonal, and his methodological approach, which consisted of "identifying the scientific[ ] and values-based evidence about a risk, and evaluating it by balancing the levels of tolerability or acceptability within societal norms,"[83] sounded like an alien language.

What explains this dissonance? Roco is not oblivious to the potential of nanotech to alter humanity; he notes that this is a cause of much apprehension, particularly in regard to the use of nanotech in genetic modification and in devices that control biological functions.[84] But as an engineer, Roco approaches the safety of nanotech from the viewpoint of engineering,[85] not bioethics. His language is that of environmental, not health care, risk regulation.[86]

An engineering approach to catastrophic science has several implications. First, the scientific endeavor in question tends to be pictured as a single, big project, like building a dam, which creates the impression that it can be easily controlled or, if necessary, stopped altogether. The association of catastrophic risk with "big science" fits the historical examples of the Manhattan Project and huge particle colliders. It even can apply to the development of recombinant DNA technology as laboratories essentially used the same technology despite the geographic dispersion of the laboratories themselves. But it is not appropriate for directed evolution, which, as described at the outset, comprises a wide variety of biomedical interventions occurring at many points in the human reproductive process, and which therefore will be much more difficult to regulate.

82. WILLIAMS, *supra* note 80, at 18.

83. INT'L RISK GOVERNANCE COUNCIL, NANOTECHNOLOGY RISK GOVERNANCE, 26-27 (2007) [hereinafter IRGC] (providing a written description of Roco's approach), *available at* http://www.irgc.org/IMG/pdf/PB_nanoFINAL2_2_.pdf.

84. *Id.* at 11.

85. *See* Nat'l Sci. Found. Directorate for Engineering, Staff Biography, Dr. Mihail C. Roco, http://www.nsf.gov/eng/staff/mroco.jsp (last visited Nov. 16, 2009).

86. *See* IRGC, *supra* note 83, at 13. *See generally* MICHAEL R. TAYLOR, WOODROW WILSON INT'L CENTER FOR SCHOLARS, REGULATING THE PRODUCTS OF NANOTECHNOLOGY: DOES FDA HAVE THE TOOLS IT NEEDS? 1 (2006) (describing the FDA's ability to assess the safety of nanotech drugs as well as medical devices, cosmetics, foods, and biologics), *available at* http://www.nanotechproject.org/process/assets/files/2705/110_pen5_fda.pdf; *and* U.S. ENVTL. PROTECTION AGENCY, NANOTECHNOLOGY WHITE PAPER 58 (2007) (identifying the need to assess the effects of nanotech on human health), *available at* http://www.epa.gov/OSA/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.

The engineer's risk assessment perspective also tends to be relatively detached and impersonal. Roco, for example, worries about the effect of nanotech on "biosystems" rather than on individuals, and victims of harm are characterized as abstract statistical lives, rather than as actual persons.[87] The fears triggered by directed evolution also extend to abstractions like "future generations" or "the human species," as reflected, admittedly, in the title of this article ("Will Directed Evolution Destroy *Humanity*"). But the techniques of directed evolution have a direct effect on actual individuals: those whose genomes are intentionally selected or modified. Directed evolution might well endanger the human species, but foremost, it creates risks for specific human beings.

For these reasons, the better conceptual framework for grappling with the threats posed by directed evolution is the approach of bioethics, which requires us to focus on the welfare of discreet individuals. This does not mean that an individual's well-being trumps the welfare of the group. Bioethicists disagree, for example, over whether deontology, which holds that individuals must be treated as ends in themselves rather than as means to the benefit of others, or utilitarianism, which seeks to maximize the greatest good for the greatest number, rather than the good of any single person, is ethically correct, and virtually all bioethicists would agree that there are limits to an individual's freedom of action. Nor does a bioethics approach mean that we should ignore risks to future persons or the human gene pool. As we contemplate directed evolution, bioethics merely forces us to keep in the forefront of our minds what happens to our children. Posner and Sunstein, who decidedly take an engineer's perspective on catastrophic risks, implicitly seem to recognize this. Although they include genetic modification of plants among the risks they consider,[88] they omit a discussion of the risks of human genetic engineering. Interestingly, they also do not discuss genetically modified animals, not even food animals.[89] They do not explain why, but one reason may be that they sense that, when it comes to manipulating animals to benefit humans, it is necessary to consider the welfare of individual animals rather than just the fate of animal populations or species.[90]

87. *See* IRGC, *supra* note 83, at 11.

88. *See* POSNER, *supra* note 25, at 38, and SUNSTEIN, *supra* note 24, at 127-28.

89. Sunstein mentions genetically modified "food" though, and he recognizes the distinction between the loss of an animal species and the loss of a member of that species. SUNSTEIN, *supra* note 23, at 20, 64, 116 ("The point is not that the death of individual animals is reversible; it is not. The point is that on a widely held view, extinction counts as a catastrophic loss, whereas the death of species members does not.").

90. *See, e.g.*, Animal Welfare Act, 7 U.S.C. § 2143 (2006) (requiring the Secretary of Agriculture to promulgate regulations which ensure the humane treatment of animals for research and other uses).

D. Directed Evolution from a Bioethics Perspective

From the perspective of bioethics, the central question raised by directed evolution is whether intentional changes to the genes of our children, whether they occur directly, such as through germline manipulation, or indirectly, such as through mating decisions or the selection of desirable embryos during assisted reproduction, comport with the basic principles of bioethical behavior. These principles were most clearly articulated in the 1979 report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, known as The Belmont Report: "respect for persons, beneficence, and justice."[91]

1. Respect for Persons

As the Belmont Report points out, respect for persons differs depending on whether or not the individual is capable of making autonomous decisions, that is, whether the individual is "capable of deliberation about personal goals and of acting under the direction of such deliberation."[92] If so, then respect for persons requires that that individual be allowed to do so. If not, the individual must be protected from harm.

Clearly, future generations that will be affected by directed evolution are incapable of making autonomous decisions about the actions of their ancestors. This requires us to be careful about what changes we introduce into the human germline, but it does not preclude us from making any changes whatsoever. As bioethicist Ray Moseley points out, the argument that we cannot shape the human genome of the future because future humans cannot give their consent, "[t]aken at face value . . . would imply that it is unethical to do anything affecting future generations, including produce them, since one cannot acquire their permission nor predict their wishes."[93] Moseley proposes instead that a "more reasonable and ethically sound guiding principle in regard to decisions effecting [sic] future generations should be that whatever is done must . . . not lead to *predictably* bad consequences for future persons."[94]

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91. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RES., THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 4 (1979) [hereinafter BELMONT REPORT]. Although the Belmont Report focuses on the ethics of human subjects research, its overarching principles have come to be generally accepted as the foundational principles of bioethics. *See, e.g.*, TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 12-13 (6th ed. 2009).

92. BELMONT REPORT, *supra* note 91, at 5.

93. Ray Moseley, *Commentary: Maintaining the Somatic/Germ-Line Distinction: Some Ethical Drawbacks*, 16 J. MED & PHIL. 641, 643 (1991).

94. *Id.*

In the context of directed evolution, the individuals most immediately affected are the children whose genomes have been changed or chosen. Like more remote future generations, they too are incapable of making autonomous decisions. This has led some commentators to claim that it may be unethical to modify the germline of one's children.[95] Similar objections have been lodged against parents using biomedicine to enhance their children's mental and physical abilities. Joel Feinberg, for example, argues that children have a right to an "open future."[96] "It is a duty of parents," he states, "to keep as many as possible of a child's central life-options open until the child becomes an autonomous adult himself, and can decide on his own how to exercise them."[97] Tom Murray, the bioethicist in charge of the prestigious Hastings Center, would deny parents the right to use genetic testing to select their children's gender on the basis that it would mean "giving in to a parental whim where that whim is not particularly significant, and when there's not a compelling reason for having more choice and control in children . . . ."[98]

But parents routinely choose or change their children's futures, from deciding with whom to have a child, to purchasing donor gametes, to agreeing to proceed to term despite fetal tests that reveal abnormalities, to picking their children's schools and selecting their extra-curricular activities. From the standpoint of autonomy, the fact that parents do so through the use of safe and effective genetic technology does not seem to justify any greater limitations on their freedom than if they employ more traditional techniques, such as education accompanied by punishment or rewards. Although Julian Savulescu and Bennett Foddy acknowledge that genetic testing could allow parents to identify their children's talents much earlier than has been possible in the past, they point out that "[w]e already look to identify a person's particular talents when they [sic] are very young. Children with nimble fingers and perfect pitch are encouraged to play the violin, and children who grow tall at a young age are encouraged to play basketball."[99] Even firm opponents of genetic engineering like Mark Frankel and Audrey Chapman, authors of the report of the American Association for the Advancement of Science that concluded that germline genetic

95. *See, e.g.*, Council for Responsible Genetics, Human Genetics Committee, *Position Paper on Human Germline Manipulation*, HUM. GENE THERAPY Feb. 1993, at 37; John C. Fletcher, *Moral Problems and Ethical Issues in Prospective Human Gene Therapy*, 69 VA. L. REV. 515, 542 (1983); Marden & Nelkin, *supra* note 5, at 471.

96. Joel Feinberg, *Autonomy, Sovereignty, and Privacy: Moral Ideals in the Constitution?*, 58 NOTRE DAME L. REV. 445, 465 (1983).

97. *Id.*

98. Kevin B. O'Reilly, *Testing Embryos & Ethics*, AM. MED. NEWS, Feb. 26, 2007, at 10.

99. Julian Savulescu & Bennett Foddy, *Comment: Genetic Test Available for Sports Performance*, 39 BRIT. J. SPORTS MED. 472, 472 (2005).

modification currently would be unethical, concede that "[i]f we do have responsibilities to our descendants, our obligations undoubtedly encompass efforts to make life better for our children . . . ."[100] Consequently, Nicholas Agar, a proponent of using technology to enhance human capabilities, argues that we should regard an intervention as reducing a child's freedom to an unacceptable degree only if it would prevent the child from leading a successful life based on values opposed to those of the parents.[101]

As will be seen in the next section, however, although the fact that children cannot give their consent does not bar parents from playing an active role in designing their genetic makeup, the principle of respect for persons requires children to be protected from resulting harm.

2. Beneficence

Beneficence has both a negative and a positive component: "do no harm," and "maximize possible benefits and minimize possible harms."[102] This opens up the question of what efforts to direct evolution should be deemed to cause harm to children, which in turns leads to an inquiry about how much latitude the parents themselves should have to provide an answer.

Parents enjoy wide latitude to raise their children as they choose. The Supreme Court in 1923 acknowledged that parents have a right to "bring up children."[103] In 1925, the Court reaffirmed that parents are entitled "to direct the upbringing and education of children under their control."[104] Even though in 1944, the Court ruled that parents could not force their children to work in violation of a state child labor law, the Court again recognized the fundamental nature of the parental right of control: "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."[105] As recently as 2000, the Court proclaimed that "the interest of parents in the care, custody, and control of their children—is perhaps the oldest of the fundamental liberty interests recognized by this Court."[106]

100. FRANKEL & CHAPMAN, *supra* note 10, at 35.

101. NICHOLAS AGAR, LIBERAL EUGENICS: IN DEFENCE OF HUMAN ENHANCEMENT 124 (2004).

102. BELMONT REPORT, *supra* note 91, at 6.

103. Meyer v. State of Nebraska, 262 U.S. 390, 399 (1923) (striking down a state law prohibiting teaching languages other than English in public schools).

104. Pierce v. Soc'y of Sisters, 268 U.S. 510, 534-35 (1925) (holding unconstitutional an Oregon statute requiring all children to attend public schools).

105. Prince v. Massachusetts, 321 U.S. 158, 166 (1943).

106. Troxel v. Granville, 530 U.S. 57, 65 (2000).

Parental rights include the right to impose health risks on children. The Court points out that "[s]imply because the decision of a parent . . . involves risks does not automatically transfer the power to make that decision from the parents to some agency or officer of the state."[107] Parents have been allowed to withhold consent to corrective surgery for a child's heart defect;[108] refuse to consent to chemotherapy;[109] deny permission for their children to be given psychotropic drugs even though the parents no longer had custody;[110] and donate a child's kidney to a sibling.[111] Parents also place their children at risk when they permit them to play dangerous sports.

Parental authority is not unlimited, however. The Supreme Court points out that "a state is not without constitutional control over parental discretion in dealing with children when their physical or mental health is jeopardized."[112] The courts have intervened when parents failed to obtain treatment for a five-week-old infant with two broken arms;[113] when a mother exposed a child to secondhand cigarette smoke during visitations;[114] when a mother tried treating her seriously-burned daughter at home with "wheat germ oil, Golden Seal, comfrey, myrrh and cold water," [115] rather than taking her to a hospital; and when a six week-old baby born to a vegan couple died of malnutrition after being fed a diet of soy milk and apple juice.[116] In a recent case, a mother who fled Minnesota with her son to avoid chemotherapy was threatened with contempt unless she returned and allowed him to obtain treatment.[117]

An interesting question is what leads courts to uphold the parents when they refuse chemotherapy for their children, such as in the Delaware case referenced above, but then order treatment in other cases, such as the one in Minnesota. One possibility is that judges will defer to parents when parents object to chemotherapy on the grounds that, despite its potential effectiveness, it would subject their child to excessive pain and suffering (the

107. Parham v. J.R., 442 U.S. 584, 603 (1979).

108. *In re* Phillip B., 92 Cal. App. 3d 796, 803 (Cal. Ct. App. 1979).

109. Newmark v. Williams, 588 A.2d 1108, 1120 (Del. 1991) (allowing parents in Delaware to stop chemotherapy for their son, who eventually died although they changed their minds 4 months later). *See also Boy Dies of Leukemia 4 Years After Ruling*, AKRON BEACON J., May 23, 2007, at B3.

110. *In re* Lyle A., 830 N.Y.S.2d 486, 492 (N.Y. 2006).

111. Hart v. Brown, 289 A.2d 386, 391 (Conn. Super. Ct. 1972).

112. *Parham*, 442 U.S. at 603.

113. Matter of L.E.J., 465 A.2d 374, 375, 379 (D.C. 1983).

114. DeMatteo v. DeMatteo, 749 N.Y.S.2d 671, 673, 679-80 (N.Y. Sup. Ct. 2002).

115. *In re* Petra B., 265 Cal. Rptr. 342, 343, 346-47 (Cal. Ct. App. 1989).

116. *Vegan Couple Gets Life Over Baby's Death*, MSNBC.COM, May 9, 2007, http://msnbc.msn.com/id/18574603/.

117. *Boy Who Fled Chemo May Be Heading to Mexico*, MSNBC.COM, May 21, 2009, http://msnbc.msn.com/id/30824587/.

argument made by the parents in Delaware).[118] On the other hand, the courts may overrule the parents when they reject chemotherapy for treatment approaches that are not recognized as effective. In the Minnesota case, for example, the mother told a judge that she preferred natural remedies such as herbs and vitamins that she heard about on the Internet.[119] In addition, the mother and son belonged to an American Indian religious group called Nemenhah, which believes in natural healing.[120] The distinction, it might be said, is that parents can be expected to be best able to know whether a particular treatment would be inhumane treatment for their children, but not in a position to second-guess medical experts about the effectiveness of alternative treatment approaches. But in another case from Northern Ohio,[121] as well as in this Minnesota example, the parental motives are not so clearly distinct. The Ohio parents objected to chemotherapy because of its side effects, but they also took their son to a holistic practitioner who attempted to treat their son's cancer by putting him on a special diet.[122] The Minnesota mother's attorney argued that, in addition to preferring a natural alternative treatment approach for her son, the mother felt that the treatment, which the attorney described as "a poison," would kill the boy in the same way the mother believed it had killed her sister.[123]

Indeed, the whole issue of how far parental discretion extends is murky. The case law is highly fact-specific, and seems to reach different conclusions depending on the jurisdiction and the temperament of each particular judge. Therefore, it is not possible to predict with certainty how courts would react to more extreme forms of directed evolution, such as parental decisions to genetically engineer their offspring. It seems likely that parents will be given wide latitude to direct the genetic make-up of their children using more traditional methods of reproduction. The courts may well extend parental autonomy to the use of assisted reproductive technologies such as sperm and egg donation and embryo selection for implantation following

118. *Williams*, 588 A.2d at 1120.

119. MSNBC.COM, *supra* note 117.

120. Maura Lerner, *Mom: Teen Would Defy Court Order*, STAR TRIB. (Minn.), May 9, 2009, at A1.

121. *Boy Dies of Leukemia 4 Years After Ruling*, *supra* note 109, at B3.

122. *Id.*

123. Warren Wolfe, *Judge Keeps Firm Hand in Hauser Case*, STAR TRIB. (Minn.), June 24, 2009, at 1B. Other cases also present a mixed set of parental motives. A Tennessee judge's decision in 1983, for example, forced a twelve year-old girl to undergo chemotherapy for bone cancer over her and her parents' objections that it would make her sick. Her parents also asserted a religious objection to medical treatment in general. Madison Park, *Parents Clash with State, Kids in Medical Decisions*, CNN.COM, May 27, 2009, http://www.cnn.com/2009/HEALTH/05/27/parents.medical.custody/index.html.

IVF.[124] Courts also are likely to respect parental decisions to protect their children from severe suffering, even if this creates risks to the child's health.[125] But the law will likely jump in if the parents appear to be imposing unreasonable harm or suffering on their kids.[126]

When would directed evolution violate this standard? One possibility is intentional diminishment: parental decisions or manipulations that intentionally decreased a child's capacities or attractiveness. This is an extremely controversial topic which has come up in connection with parents with disabilities who wish to deliberately produce a child with the same disability. A salient example concerns deaf parents who wish to select only those embryos for implantation that have the same genetic characteristic for deafness.[127] Some say that reproductive freedom does not extend this far,[128] and that intentional diminishment denies children an open future.[129]

124. There have been only two cases in which the courts have considered the constitutionality of government interference with assisted reproduction. A federal court struck down an Illinois law that made it illegal to experiment upon a fetus in part because the law could be interpreted to prohibit the process by which an embryo fertilized in the laboratory is implanted in the womb. Lifchez v. Hartigan, 735 F. Supp. 1361, 1367, 1377 (N.D. Ill. 1990), *aff'd*, 914 F.2d 260 (7th Cir. 1990), *cert. denied*, 498 U.S. 1069 (1991). The other case involved a teacher who alleged that she had been fired by an Ohio public school board because she was an unwed mother who had become pregnant with the aid of artificial insemination. Cameron v. Bd. of Educ. of Hillsboro, Ohio, City Sch. Dist., 795 F. Supp. 228, 232, 237 (S.D. Ohio 1991) ("A woman has a constitutional privacy right to control her reproductive functions. Consequently, a woman possesses the right to become pregnant by artificial insemination.").

125. *See, e.g.*, *Newmark*, 588 A.2d at 1118.

126. The American Academy of Pediatrics asserts that the state should impose medical treatment over parental objections "only when treatment is likely to prevent substantial harm or suffering or death." Am. Acad. of Pediatrics, Comm. on Bioethics, *Religious Objections to Medical Care*, 99 PEDIATRICS 279, 280 (1997). In sanctioning parents for not providing modern burn treatment for their daughter, a California appellate court stated that "it is only when a child's health is actually and seriously threatened that the state should intervene." *In re Petra B.*, 265 Cal. Rptr. at 343.

127. I. Glenn Cohen, *Intentional Diminishment, the Non-Identity Problem, and Legal Liability*, 60 HASTINGS L.J. 347, 347, 349 (2008).

128. *See* John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 467 (1996); John A. Robertson, *Liberalism and the Limits of Procreative Liberty: A Response to My Critics*, 52 WASH. & LEE L. REV. 233, 233 (1995); John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 480 (2003); Maura A. Ryan, *Cloning, Genetic Engineering, and the Limits of Procreative Liberty*, 32 VAL. U. L. REV. 753, 754-55 (1998).

129. Dena S. Davis, *Genetic Dilemmas and the Child's Right to an Open Future*, 28 RUTGERS L.J. 549, 567, 569-70 (1997).

Others argue that the parents should not be able to shift the costs of caring for these children onto society.[130]

But should parents be prevented from making genetic changes that increase a child's capacities or attractiveness? Fifteen years ago, the American Medical Association's Council on Ethical and Judicial Affairs issued a policy statement on genetically enhancing children that said that "genetic interventions to enhance traits should be considered permissible only in severely restricted situations."[131] In addition to requiring "clear and meaningful benefit to the person," the Council declared that there should be "no trade-off with other characteristics or traits."[132] Taken literally, this would preclude parents from making a substantial improvement in one of a child's capabilities that was accompanied by a minor decrease in another, for example, increasing IQ by thirty points at the expense of a slight reduction in height. It is difficult to find a persuasive reason for such a limitation on parental decision-making, since parents constantly make choices that enhance some characteristic or ability of their children's at the expense of others, by for example, giving a child music lessons or tutoring that interferes with other potential extracurricular activities.

Another possibility is that parents should be prohibited from engaging in active forms of genetic engineering such as adding or deleting genes, and be allowed to engage only in "passive" forms of engineering such as in vitro fertilization followed by genetic testing of the resulting embryos and the selective implantation of those embryos with the most desirable genomes. This would restrict parents to selecting from among a naturally-occurring set of genetic traits, rather than introducing new or fanciful characteristics. This might reduce the chance that a genetic modification would go awry and produce unexpected injury to the child, but if the technique used to produce the genetic modification had been shown to be safe and effective, there is no reason to forbid it on the ground that it is not natural. Clearly "natural" does not equate with "good," since many curses of human existence are natural phenomena, such as tornados and cancer.

130. Eric Rakowski, *Who Should Pay for Bad Genes?*, 90 CAL. L. REV. 1345, 1391-92 (2002).

131. Am. Med. Ass'n, Council on Ethical and Judicial Affairs, *Ethical Issues Related to Prenatal Genetic Testing*, 3 ARCHIVES FAM. MED. 633, 640 (1994). This policy statement also insisted that there be "equal access to genetic technologies, irrespective of income or other socioeconomic characteristics." *Id.* at 641. *See infra* text accompanying notes 135-40. That same year, the Council also came out specifically against germline genetic engineering and the use of gene transfer technology for enhancement purposes. AM. MED ASS'N, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION: CURRENT OPINIONS WITH ANNOTATIONS 48 (2008) [hereinafter AMA CODE OF ETHICS].

132. AMA CODE OF ETHICS, *supra* note 131, at 48.

So in the end, we are left merely with the principle that parents should be allowed to direct their children's genomes to the extent that such direction does not cause their children unreasonable harm or suffering. This is not as lame as it seems, since the unreasonableness standard is a well-known legal mechanism that hinges on community values as represented by the views of jurors. But when it comes to judging parental actions, and especially actions in the course of reproduction, it is important to remember the constitutional deference to parental decisions mentioned earlier.[133] Hence, the standard must be qualified by adding that any interference by the state must be given strict scrutiny by the courts: in addition to serving a compelling state interest in protecting child welfare, the state action must be narrowly tailored and the least restrictive means to achieve that interest.[134] Furthermore, in keeping with the parents' fundamental right of parenting, any doubts about whether the parents' action is or is not reasonable should be resolved in favor of the parents.

As a practical matter, what does it mean to say that parents' ability to genetically engineer their offspring should be restricted in this way? Should parents who genetically harm their children be punished? Although this might deter parents from causing harm, it also would be likely to aggravate the child's condition by either depriving the child of parental care if the parents are jailed, or decreasing the resources available to raise the child if the parents are fined. A better approach would be to focus enforcement efforts on the health care professionals who facilitate the parents' actions, namely, the fertility clinics and physicians who provided the genetic services. At present, there is little regulation of the assisted reproduction industry,[135] but this could be changed by requiring clinics to be certified and threatening withdrawal of certification if they permitted parents to make harmful decisions. Still, keep in mind the constitutional framework; undue

133. *See supra* text accompanying notes 103-111.

134. *See, e.g.*, Carey v. Population Servs. Int'l, 431 U.S. 678, 686 (1976).

135. In 1992, Congress enacted the Fertility Clinic Success Rate and Certification Act of 1992, but all this law requires is that fertility clinics report their pregnancy success rates to the Centers for Disease Control and Prevention (CDC). 42 U.S.C. § 263a-1 (2006). There is also little state regulation of IVF clinics, and virtually no controls on the donor egg and sperm industry or on preimplantation or prenatal genetic testing. Assuming that a new regulatory regime was created, one model would be the Human Fertilization and Embryology Authority established in Great Britain in 1991 under the Human Fertilisation and Embryology Act of 1990. This agency licenses IVF clinics and dictates the preimplantation genetic testing that they can perform. HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, CODE OF PRACTICE § 9 (2009), http://www.hfea.gov.uk/docs/complete_CoP8.pdf. This still leaves open, however, the question of how much government regulation would be consistent with constitutional protections for parental reproductive decision-making.

restrictions on providers could be said to interfere indirectly with the parents' procreative rights.[136]

Another possibility would be to allow the children who were harmed to obtain damages from these providers. (The parents would not be able to recover because they had collaborated in producing the harm, and therefore would be deemed to be contributorily negligent or to have assumed the risk.) This depends on whether the jurisdiction recognizes the tort of wrongful life, and if so, what elements of damages may be awarded.[137]

In keeping with the second part of the beneficence principle, maximizing potential benefits and minimizing possible harms, the government also has an important role to play in making sure that the technologies that parents use to alter their children's genomes are safe and effective.[138] At present, there is little assurance that the government is equipped to fulfill this role. The Food and Drug Administration asserts that it has the authority to regulate gene therapy as either drugs or "biologics."[139] Genetic modifications for non-therapeutic (i.e., enhancement) purposes would not fit within the definition of a biologic.[140] The definition of a "drug" is broader and includes "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[141]

Regarding a genetic modification as a drug or biological product, however, raises the question of whether it is an article—i.e., a product—or a

136. *Cf.,* Griswold v. Connecticut, 381 U.S. 479, 481 (1964) (permitting physician convicted of aiding-and-abetting married couples in violation of a state law prohibiting contraception, to assert constitutional rights of contraceptives users).

137. *See* Judith F. Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERKELEY J. GENDER L. & JUST. 18, 69 (2008) (explaining that courts largely shun the wrongful life cause of action). An even more bizarre approach would be to allow the children to sue their parents. *See* Kirsten Rabe Smolensky, *Creating Children with Disabilities: Parental Tort Liability for Preimplantation Genetic Interventions*, 60 HASTINGS L.J. 299, 299-302 (2008).

138. I will not waste time discussing the absurd notion that the parents themselves, acting as intelligent "consumers," can determine whether or not a genetic intervention is safe and effective.

139. *See* U.S. Food & Drug Admin., Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products, 58 Fed. Reg. 53248 (Oct. 14, 1993) [hereinafter Human Somatic Cell Therapy Products and Gene Therapy Products]; U.S. Food & Drug Admin., Statement of Policy for Regulating Biotechnology Products, 49 Fed. Reg. 50878 (Dec. 31, 1984) [hereinafter Biotechnology Products].

140. The Federal Food, Drug, and Cosmetic Act defines a biologic as a "virus, therapeutic serum, toxin, antitoxin, or analogous product *applicable to the prevention, treatment or cure of diseases or injuries of man*." 21 C.F.R. § 600.3(h) (2009) (emphasis added).

141. 21 U.S.C. § 321(g)(1)(C) (2006).

medical service. The FDA does not regulate the practice of medicine.[142] Nevertheless, the agency has asserted jurisdiction over gene therapy—the introduction of modified genes into the body to prevent, cure or mitigate disease—which the agency regards as falling within the definitions of both drugs and biological products under the Federal Food, Drug, and Cosmetic Act.[143] This sounds defensible insofar as modified genes represent "products." But the FDA also has claimed jurisdiction over both human reproductive cloning[144] (which prompted Richard Merrill, a law professor and former FDA chief counsel, to describe the FDA's rationale as "surprisingly delphic"),[145] and ooplasmic transfer (an assisted reproductive technique used to treat infertility in which a portion of a normal donor egg called the ooplasm is removed and injected into a woman's infertile egg, enabling it to implant itself in the womb).[146] In both of these cases, the FDA seems to be claiming that a human egg is a "product," which may strike some as a stretch.

Assuming the FDA does have jurisdiction over genetic engineering, or Congress confers jurisdiction in future amendments to the FDA's legislative authority, it is not clear how well the agency can fulfill the role of protecting children from unsafe or ineffective genetic interventions. The FDA relies on large-scale clinical trials to establish safety and efficacy, but growing understanding of individual differences in responses to biomedical technologies—the rise of so-called "personalized medicine"—raises doubts about the usefulness of this approach: what works well for one child may be harmful or even deadly for another, based on differences in their genes and environment.[147] Increasingly, regulators are planning to rely on actual

142. David G. Adams, *The Food and Drug Administration's Regulation of Health Care Professionals*, *in* 2 FUNDAMENTALS OF LAW AND REGULATION 423, 423-25 (David G. Adams, Richard M. Cooper & Jonathan S. Kahan eds., 1997) (stating that "the FDA has traditionally taken the position that it does not regulate the practice of medicine or pharmacy and has generally avoided regulatory actions that would directly restrict or interfere with professional service to patients"). *See also* S. REP. NO. 74-361, AT 5 (1935).

143. Human Somatic Cell Therapy Products and Gene Therapy Products, *supra* note 139, at 53248; Biotechnology Products, *supra* note 139, at 50878.

144. Gail H. Javitt & Kathy Hudson, *Regulating (for the Benefit of) Future Persons: A Different Perspective on the FDA's Jurisdiction to Regulate Human Reproductive Cloning*, 2003 UTAH L. REV. 1201, 1202 (2003); Richard A. Merrill, *Human Tissues and Reproductive Cloning: New Technologies Challenge FDA*, 3 HOUS. J. HEALTH L. & POL'Y 1, 54 (2002).

145. Merrill, *supra* note 144, at 57.

146. *See* Erik Parens & Eric Juengst, Editorial, *Inadvertently Crossing the Germ Line*, 292 SCIENCE 397, 397 (2001). In 2001, the FDA sent a letter to the research community asserting that ooplasmic transfer was an investigational use of a new drug that did not have FDA approval. Javitt & Hudson, *supra* note 144, at 1226-28.

147. *See* Maxwell J. Mehlman, *Quackery*, 31 AM. J.L. & MED. 349, 359 (2005) (describing limitations of clinical trials (citing Ruiping Fan, *Modern Western Science as a Standard for*

experience with a technology, assessed after it has entered the marketplace, which is known as "post-marketing surveillance."[148] But this means that numbers of children will be exposed to potentially risky genetic manipulations before the agency obtains the data to determine just how dangerous the manipulations actually are.

To the extent that genetic manipulation is studied in formal clinical trials, the FDA requires these investigations to conform to the human subjects protections embodied in regulations called the "Common Rule."[149] Special sections of these regulations govern research with children and fetuses.[150] But there are numerous unresolved questions concerning how to apply these rules to experiments involving interventions aimed at enhancing human traits rather than addressing disease,[151] which is likely to be a major aspect of parental genetic engineering of offspring. Moreover, although there are special protections for pregnant women, there are none for embryos, and as mentioned earlier, some kinds of genetic engineering are likely to be performed on embryos fertilized in the laboratory.[152] Finally, there is widespread agreement that institutional review boards—the primary mechanism for ensuring that the regulations are followed—do not do an adequate job.[153]

In addition to actual genetic engineering, another tool of directed evolution, as discussed above, is genetic testing, which helps would-be parents decide whether or not to procreate, which embryos to implant in the uterus, and which fetuses to bring to term.[154] Genetic testing is regulated by

Traditional Chinese Medicine: A Critical Appraisal, 31 J.L. MED. & ETHICS 213, 219-20 (2003))).

148. Peter Chang, *Reauthorization of PDUFA: An Exercise in Post-Market Drug Safety Reform*, 36 J.L. MED. & ETHICS 196, 197-98 (2008); Stuart Hogarth et al., *Closing the Gaps—Enhancing the Regulation of Genetic Tests Using Responsive Regulation*, 62 FOOD & DRUG L.J. 831, 844 (2007).

149. 21 C.F.R. §§ 50, 56 (2008). The National Institutes of Health also exerts oversight over genetic research that it funds, again applying the provisions of the Common Rule. 45 C.F.R. § 46 (2008).

150. For a general description of these rules, see Jessica W. Berg et. al., *Making All the Children Above Average: Ethical and Regulatory Concerns for Pediatricians in Pediatric Enhancement Research*, 48 CLINICAL PEDIATRICS 472, 474-78 (2009).

151. *See id.* at 478.

152. *See supra* text accompanying notes 127-32.

153. *See, e.g.,* Eric Y. Drogin & Daniel A. Bronstein, *Institutional Review Boards: The Debate Continues*, 4 SCITECH LAW 4, 6 (2008); *see also* David A Hyman, *Institutional Review Boards: Is This the Least Worst We Can Do?*, 101 NW. U. L. REV. 749, 749, 756, 762 (2007); Hazel Glenn Beh, *The Role of Institutional Review Boards in Protecting Human Subjects: Are We Really Ready to Fix a Broken System?*, 26 L. & PSYCHOL. REV. 1, 34 (2002).

154. *See generally* Susannah Baruch et al., *Genetic Testing of Embryos: Practices and Perspectives of U.S.* In Vitro *Fertilization Clinics*, 89 FERTILITY & STERILITY 1053, 1053 (2008) (noting that preimplantation genetic diagnosis was "initially viewed as an alternative to

a mishmash of government entities; the result is a web of oversight that is both overlapping and incomplete.[155] One of the most glaring gaps is that the FDA has reviewed only a small proportion of genetic tests in widespread use, and many of the devices relating to genetic testing have been marketed in reliance on the "substantial equivalence" provisions of the Federal Food, Drug, and Cosmetic Act, which essentially allows a manufacturer to market a product without going through the full approval process for a new device.[156] An area of particular concern is genetic testing that is sold directly to consumers, as opposed to being provided through physicians or other health care professionals. Without their involvement, parents might incorrectly assume that the tests really can do what they claim, when there may not be sufficient evidence to establish their validity, or parents might misinterpret the results.[157] Currently, there is virtually no regulation of at-home tests by the FDA or other branches of the government.

In short, the regulatory system requires significant improvement before parents, and in turn society, can be confident that attempts to direct evolution will avoid undue harm to the children who are the immediate targets of these efforts.

3. Justice

The final ethical principle that should govern directed evolution is justice. The Belmont Report discusses justice primarily in connection with selecting subjects for medical experiments, prohibiting the use of subjects who face undue economic pressures to participate or who lack the resources to benefit from the experimental intervention should it become commercially available.[158] But the principle of justice is much broader. For example, justice concerns would arise if only wealthier parents could

prenatal genetic diagnosis"); John A. Robertson, *Extending Preimplantation Genetic Diagnosis: The Ethical Debate*, 18 HUMAN REPROD. 465, 465-66 (2003) (tracing the demand for preimplantation genetic diagnosis in relation to insurance coverage, access to the services, and sufficient personal motivation); Karen Sermon et al., *Preimplantation Genetic Diagnosis*, 363 LANCET 1633, 1633 (2004) (discussing preimplantation genetic diagnosis as an early form of prenatal diagnosis allowing for analysis of embryonic genetic abnormalities).

155. *See, e.g.,* 21 C.F.R. §§ 50, 56 (2008); 45 C.F.R. § 46 (2008); Human Somatic Cell Therapy Products and Gene Therapy Products, *supra* note 139, at 53248; Biotechnology Products, *supra* note 139, at 50878.

156. *E.g.,* Gail H. Javitt, *In Search of a Coherent Framework: Options for FDA Oversight of Genetic Tests*, 62 FOOD & DRUG L.J. 617, 629-32 (2007); Lauren B. Solberg, NOTE, *Over the Counter But Under the Radar: Direct-to-Consumer Genetic Tests and FDA Regulation of Medical Devices*, 11 VAND. J. ENT. & TECH. L. 711, 714-15, 729 (2009).

157. Am. College of Med. Genetics Bd. of Directors, *ACMG Statement on Direct-to-Consumer Genetic Testing*, 6 GENETICS MED. 60, 60 (2004), *available at* http://www.acmg.net/resources/policies/Direct_Consumer_Testing.pdf.

158. BELMONT REPORT, *supra* note 91, at 9-10.

genetically engineer their offspring.[159] The American Medical Association's Council on Ethical and Judicial Affairs policy on genetically enhancing children thus states that "genetic interventions to enhance traits should be considered permissible only in severely restricted situations," one of which is that there is "equal access . . . irrespective of income or other socioeconomic characteristics."[160]

I have devoted considerable attention to this concern in other work.[161] I worry especially about the danger that lack of equal access could create a "genobility," a term that I coined in the book I co-authored with Jeffrey Botkin in 1998 entitled *Access to the Genome: The Challenge to Equality*.[162] In my 2003 book, *Wondergenes*, I warned that a widening gap between genetically enhanced and unenhanced segments of society could destroy our democratic political system.[163] And in my latest treatment of the topic, *The Price of Perfection: Individualism and Society in the Era of Biomedical Enhancement*, I argue that everyone should be able to access technologies that significantly enhance human capabilities, and that the government should subsidize access if need be for those less well-off.[164] This should apply as well to directed evolutionary techniques that parents employ to give their children significant social advantages.

E. Is Bioethics Up to the Task?

The three main principles of bioethics—autonomy, beneficence, and justice—would go some way toward preventing directed evolution from injuring children who were its immediate targets. Parental discretion to genetically engineer offspring would not be unlimited. Despite the deference that the Constitution gives to parental autonomy in engaging in reproductive practices and in making parenting decisions,[165] the principle of

159. *See generally* BEAUCHAMP & CHILDRESS, *supra* note 91, at 242.

160. Am. Med. Ass'n, *supra* note 131, at 640-41.

161. *See* Maxwell J. Mehlman & Kirsten M. Rabe, *Any DNA to Declare? Regulating Offshore Access to Genetic Enhancement*, 28 AM. J.L. & MED. 179, 181-82 (2002); Maxwell J. Mehlman, *How Will We Regulate Genetic Enhancement?*, 34 WAKE FOREST L. REV. 671, 687-88 (1999); Maxwell J. Mehlman, *The Human Genome Project and the Courts: Gene Therapy and Beyond,* 83 JUDICATURE 124, 129-30 (1999); Maxwell J. Mehlman, *The Law of Above Averages: Leveling the New Genetic Enhancement Playing Field*, 85 IOWA L. REV. 517, 522 (2000).

162. MAXWELL J. MEHLMAN & JEFFREY BOTKIN, ACCESS TO THE GENOME: THE CHALLENGE TO EQUALITY 99 (1998).

163. MAXWELL J. MEHLMAN, WONDERGENES: GENETIC ENHANCEMENT AND THE FUTURE OF SOCIETY 108-20 (2003).

164. MAXWELL J. MEHLMAN, THE PRICE OF PERFECTION: INDIVIDUALISM AND SOCIETY IN THE ERA OF BIOMEDICAL ENHANCEMENT 218-26 (2009).

165. *See, e.g.,* Elaine M. Chiu, *The Culture Differential in Parental Autonomy*, 41 U.C. DAVIS L. REV. 1773, 1784-85 (2008).

beneficence gives the public the right to intervene to protect children from unreasonable risks and from significant harm. The principle of justice extends the scope of societal concern beyond the impact on specific children to the adverse consequences for the polity as a whole of basing access to directed evolutionary technologies on ability to pay.

Acknowledging these principles in the abstract, however, does not ensure that they will be applied effectively. As can be seen from the foregoing discussion, bioethicists themselves disagree about how these principles should be interpreted; for example, bioethicists may disagree how far parents should be allowed to go in controlling their children's futures. Ideological differences preclude consensus on what the role of the market should be in distributing access to scarce evolution-directing technologies. Indeed, a sizeable segment of American society continues to reject the idea of natural evolution in the first place,[166] and many of those who accept it no doubt believe that directed evolution would offend their God. As genetic technology continues to advance, these disputes will have to be resolved in order for bioethics to play its proper role.

Bioethics, I have argued, is the foremost theoretical framework for preventing directed evolution from destroying us. But bioethics is not the only way; the engineering approach also has its place. It forces us to consider whether successfully applying the principles of bioethics, assuming this could protect our children, would in fact stave off species-wide catastrophe. Are there threats to the species that would not register as undue harm to a child? I can think of at least one possibility: parents selecting the gender of their offspring, and opting overwhelmingly for one sex. It is doubtful that sex selection per se could be said to harm the child or be unjust. If parents favored giving birth to boys rather than girls, a widespread preference in parts of Asia,[167] how many people would hold that

166. In a 2005 survey, fifty-one percent of Americans believed that God created humans as is, thirty percent believed humans evolved but God directed the evolution, and fifteen percent believed that humans evolved without help from God. Sean Alfano, *Poll: Majority Reject Evolution: 51 Percent Believe God Created Humans*, CBS NEWS, Oct. 23, 2005, http://www.cbsnews.com/stories/2005/10/22/opinion/polls/main965223.shtml. In a 2006 survey of thirty-two European countries, Japan, and the United States, the United states had the second lowest percentage of people that believe in evolution, with only Turkey having fewer. The survey found that forty percent of Americans accept evolution, thirty-nine percent reject it, and twenty-one percent are unsure. Jon D. Miller et al., *Science Communication: Public Acceptance of Evolution*, 313 SCIENCE 765, 765 (2006).

167. *E.g.,* David T. Courtwright, *Gender Imbalances in History: Causes, Consequences and Social Adjustment*, 16 REPROD. BIOMED. ONLINE 32, 32 (2008); Therese Hesketh & Zhu Wei Xing, *Abnormal Sex Ratios in Human Populations: Causes and Consequences*, 103 PROC. NAT'L ACAD. SCI. U.S. 13271, 13272 (2006); Siu Fai Leung, *Will Sex Selection Reduce Fertility?*, 7 J. POPULATION ECON. 379, 379 (1994); Nandini Oomman & Bela R. Ganatra, *Sex Selection: The Systematic Elimination of Girls*, 10 REPROD. HEALTH MATTERS 184, 184

being born a boy rather than a girl was bad? Yet an extreme gender imbalance could have deleterious effects on human survivability.[168]

How the engineering approach to preventing catastrophe would respond to such a threat is a discussion for another paper. The point here is that it cannot be the sole or even the primary way we protect ourselves.

(2002); The President's Council on Bioethics, *Choosing Sex of Children*, 29 POPULATION DEV. REV. 751, 752, 756 (2003).

168. *See, e.g.,* Hesketh & Xing, *supra* note 167, at 13273-74 (examining potential negative consequences of extreme gender imbalance within a population); Leung, *supra* note 167, at 391(discussing reduced fertility given an imbalanced sex ratio).