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Gene Therapy: Legal, Financial and Ethical Issues

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Paula Campbell:[*]

1. Welcome to the third session of the Biotechnology Law Symposium. Today, a distinguished panel of speakers will address the various complex and legal issues surrounding genetic engineering in general and gene therapy in particular. The keynote speaker is Gina Maranto. Gina has authored several papers in the biotechnology field and has recently published a book, *Quest for Perfection*,[1] discussing how humans have tried to control their genetic destiny. Gina will be followed by three speakers who will give short presentations on various technical, legal, and public health issues related to gene therapy. The first speaker will be Professor Charles Cantor, the Director of the Center for Advanced Biotechnology at Boston University, who will discuss various technology issues and their consequences. The next speaker will be Professor Leonard Glantz, from Boston University School of Public Health, who will discuss public health and ethical issues associated with genetic engineering. Professor Glantz will be followed by Professor Frances Miller, from Boston University School of Law, who will discuss legal and health insurance coverage issues related to genetic engineering. Once the speakers have completed their presentations, the panel will be available to take questions from the audience.

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[1] GINA MARANTO, QUEST FOR PERFECTION (1996).

Gina Maranto:

2. I am neither a lawyer nor a scientist. What I hope to do today is to place the incredible advances now underway in genetic research in historical perspective and to caution everyone involved in this enterprise not to confuse knowledge and the ability to manipulate nature with wisdom. In fact, if history teaches us one thing it is that if technology exists it will be used for both good and ill.

3. While thinking about what I might say today, I kept recalling an image from a bizarre novel written in 1765 by Horace Walpole,[2] the youngest, eccentric son of British Prime Minister Robert Walpole. The novel, the first of the gothic genre, begins with a rather remarkable event: the crashing of a visored helmet from a gargantuan suit of armor into the central courtyard of the Castle of Otranto.[3] This gigantic helmet happens to land, Bambi-meets-Godzilla-style, upon Conrad, the castle lord's son,[4] whom Walpole describes as "homely," "sickly" and "of no promising disposition."[5] Apparently Conrad's untimely demise represents no great loss to the gene pool.

4. Recently we experienced a similar event, the giant helmet in question being, of course, the cloning work of Ian Wilmut of the Roslin Institute, Midlothian.[6] With it sitting in our midst, it is a bit difficult to focus our collective gaze upon anything else. I would like to suggest that gene therapy and Wilmut's helmet are part of the same narrative line.

5. Aside from the obvious fiduciary reasons having to do with agribusiness, why did Wilmut's work capture our imagination? In part, it is because we have been primed to respond to the dramatic possibilities of cloning through at least 60 years worth of speculative essays, novels, movies, cartoons, and comics. There is truly an astonishing array of material in this area. An excellent overview of it was recently provided in *The DNA Mystique*[7] by Dorothy Nelkin and Susan Lindee.

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[2] HORACE WALPOLE, THE CASTLE OF OTRANTO, *reprinted in* THREE GOTHIC NOVELS, 27-106 (E.F. Bleiler ed., Dover Publications 1966).

[3] *See id.* at 28.

[4] *See id.* at 27.

[5] *Id.*

[6] *See* I. Wilmut et al., *Viable Offspring Derived From Fetal and Adult Mammalian Cells*, 385 NATURE 810 (1997); *see also* Michael Specter & Gina Kolata, *After Decades and Many Missteps, How Cloning Succeeds*, N.Y. TIMES, Mar. 3, 1997, at A1 (discussing the history of cloning and how Dr. Wilmut cloned an adult sheep in Scotland).

[7] DOROTHY NELKIN & SUSAN LINDEE, THE DNA MYSTIQUE (1995).

6. Over the years, the media has taught us to view the type of cloning that yielded Dolly the sheep[8] as the ultimate transgression, the crossing of the line that should never be crossed. Like those other legendary oversteppers, Eve, Adam, Prometheus, Icarus, Faust, and Dr. Frankenstein, we will face retribution, if not from heavenly precincts, then from Mother Nature. It is a terrifying prospect that reminds us of our mortality and of our smallness in the face of the mighty cosmos; and as every eighteenth-century esthetician and twentieth-century horror-film producer can tell you, we love to be terrified. Just like the Ebola virus,[9] human cloning serves a kind of perverse need. At some level, it matters very little whether it is a genuine possibility. It gives us a frisson, until we move on to the next item of millennial fervor.

7. But, there is a more profound reason for this fascination, which has deep historical roots: right now, three separate research curves have converged. With the confluence of cloning by nuclear transplantation,[10] genetic engineering,[11] and reproductive medicine,[12] we appear to have achieved what physicians and scientists in the West have been trying to reach for a couple of thousand years.

8. From here on, we will have the power to exercise a far greater degree of control upon reproductive outcomes than ever before. Wilmut has provided what appears to be the last of the techniques needed to dictate the genetic make-up of humans. This goal was elucidated early in this century by German physician and Aryanist, Alfred Ploetz,[13] and embraced by many other eugenicists around the

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[8] Dolly is the name that the researchers gave to the sheep that they cloned at the Roslin Institute. *See* Specter & Kolata, *supra* note 6, at A36 (discussing the science involved in the cloning of Dolly).

[9] *See, e.g.*, Michael Cooper, *Ebola Scare at Hospital Proves False*, N.Y. TIMES, Aug. 6, 1996, at B3 (reporting on a false Ebola virus scare at a Bronx, New York hospital and the standard procedure of treating all possible infections with the "most conservative steps"); Richard Presson, *Crisis in the Hot Zone*, THE NEW YORKER, Oct. 26, 1992, at 58-81.

[10] Dolly the sheep was cloned using nuclear transplantation. *See generally* Specter & Kolata, *supra* note 6, at A1 (discussing the history of cloning by nuclear transplantation).

[11] *See Hearings Before the Subcomm. on Investigations and Oversight of the Comm. on Science and Tech.*, 97th Cong. 285-89 (1982) [hereinafter *Hearings*] (statement of Dr. French Anderson, a physician, explaining how genetic engineering works and describing its potential uses).

[12] *See, e.g.*, R.G. Edwards & Ruth E. Fowler, *Human Embryos in the Laboratory*, 45 SCI. AM. 223 (1970) (discussing reproductive medicine and cloning).

[13] Alfred Ploetz wrote the highly influential GRUNDLINIEN EIHER RASSENHYGIENE (BASIC DETAILS OF RACE HYGIENE) in 1895. *See* MARANTO, *supra* note 1, at 140-42. He also founded the ARCHIV-FÜR RASSEN-UND GESELLSCHAFTSBIOLOGIE (JOURNAL OF RACIAL AND SOCIAL BIOLOGY) in 1904 and the GESELLSCHAFT FÜR RASSENHYGIENE (SOCIETY OF RACE HYGIENE), which, by 1930, had over twenty branches. *See id.* He was the mentor of the medical geneticist, Fritz Lenz. *See id.*

world.[14] It is, I suspect, as the British biologist, J.B.S. Haldane predicted in a famous 1923 talk to the Heretics Club in Cambridge, England: "Developments in the practical applications of biology are going to prove as disquieting in the coming centuries as those of applied physics."[15] Our power to manipulate genes and to create and alter life may, paradoxically, prove as troublesome and destructive as our ability to obliterate life in thermonuclear warfare.

9. The other techniques necessary to engineer human beings are already accepted. There are the molecular biology techniques employed since 1953, when Crick, Watson, and Wilkins elucidated the structure of DNA.[16] These techniques enable researchers to isolate, copy, slice-up, splice, and insert genes into cells in a manner that allows them to be expressed.[17] Genes are expressed when they are switched on within the cellular machinery and trigger a desired event or the manufacture of a protein.[18]

10. Another key set of techniques are being refined in infertility clinics around the world. These techniques are the result of at least 2000 years worth of investigation. They allow reproductive specialists to control the female ovulatory cycle with drugs; to obtain sperm and eggs and keep them alive outside the body; to bring about fertilization in petri dishes; to carry out pre-implantation diagnosis, which is the analysis of the genetic makeup of embryos and the determination of whether they bear certain defective genes or chromosomes; and, finally, to transfer embryos into the womb.[19] One day, scientists envision that the era of natural reproduction will be over. R.G. Edwards, who with Patrick Steptoe and Lesley Brown created the first in vitro fertilization ("IVF") baby in 1978,[20] remarked that in the future, "we will not have reproductive cycles as we know them now. We are still

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[14] *See generally* Paul A. Lombardo, *Medicine, Eugenics, and the Supreme Court: From Coercive Sterilization to Reproductive Freedom*, 13 J. CONTEMP. HEALTH L. & POL'Y 1 (1996) (discussing the legal impact of Eugenicists beginning in the early twentieth century and several United States Supreme Court decisions).

[15] Haldane's talk was published that same year in book form under the title, DAEDALUS, or SCIENCE AND THE FUTURE. *See* J.B.S. HALDANE, DAEDALUS 52-55 (1930).

[16] *See* Gunther Stent, *DNA's Stroke of Genius*, NEW SCIENTIST, Apr. 24, 1993, at 21, 21-22.

[17] A gene is "expressed" once its coded information is translated into a functional product. *See generally* JOEL DAVIS, MAPPING THE CODE: THE HUMAN GENOME PROJECT AND THE CHOICES OF MODERN SCIENCE 40-50 (1990).

[18] *See id.*

[19] *See* ROBERT BLANK & JANNA C. MERRICK, HUMAN REPRODUCTION, EMERGING TECHNOLOGIES, AND CONFLICTING RIGHTS 87-92 (1995) (discussing the in vitro fertilization process).

[20] Louise Brown was the first baby conceived by means of IVF. *See generally* Gail Vines, *Whose Baby is it Anyway?*, NEW SCIENTIST, July 3, 1986, at 27.

trapped in ancient reproductive cycles and we cannot remain in that condition much longer".[21] I am reminded of a 1974 *New York Times* article entitled, *The Embryo Sweepstakes,*[22] which contained a quote from Joseph Fletcher, then with the University of Virginia School of Medicine. Fletcher, admittedly a bit on the extreme side, said:

> It seems to me that laboratory reproduction is radically human compared to conception by ordinary heterosexual intercourse. It is willed, chosen, purposed and controlled, and surely these are among the traits that distinguished homo sapiens from others in the animal genus. . . . With our separation of baby-making from love-making, both become more human because they are matters of choice not chance. . . . I cannot see how either humanity or morality are served by genetic roulette.[23]

11. Cloning, genetic alterations, and reproductive medicine may provide a method to radically overhaul the human species. We are, as Aldous Huxley stated in *Brave New World*, at a point where "the principle of mass production [can] at last be applied to biology."[24]

12. W. French Anderson, the NIH gene therapy pioneer now based at USC, announced the beginning of this new era in a 1990 editorial in *Human Gene Therapy*, the journal he founded.[25] He wrote, with a notable lack of fanfare, that "[h]uman gene therapy, i.e., the genetic engineering of human cells, has become reality."[26] By that time, Anderson had been spearheading the drive to undertake human genetic engineering for more than a decade. At hearings held in 1982, by then Congressman Albert Gore, Anderson drew distinctions that are now conventions.[27] Anderson observed that there is a difference between manipulating the genes of somatic cells–the cells making up the tissues of the body–and manipulating the genes of germ

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[21] *See id.*

[22] David Rorvik, *The Embryo Sweepstakes*, N.Y. TIMES, Sept. 15, 1974, (Magazine) at 16, 17.

[23] *Id.* (first omission in original).

[24] ALDOUS HUXLEY, BRAVE NEW WORLD 6 (Perennial Library 1989) (1932).

[25] *See* W. French Anderson, *Editorial*, HUM. GENE THERAPY, Sept. 14, 1990, at 1.

[26] *See id.*

[27] *See Hearings*, *supra* note 11, at 285-89.

cells–that is, of sperm and eggs.[28] Somatic cell changes affect only one person, but germ-line manipulations are fixed for the generations. They will be passed on to future offspring.[29]

13. Moreover, added Anderson, there is a difference between making alterations in the name of medicine and making them in the name of "bettering" the basic human blueprint.[30] We can justify genetic engineering to correct diseases on humanitarian grounds, argued Anderson.[31] We can, however, offer no equally compelling justification for tampering with genes in the hope of "enhancing" a specific characteristic, for example, height, or of improving "complex . . . traits that depend on a large number of genes as well as extensive interactions with the environment, such as intelligence, personality, [or] character."[32] Anderson stated that our understanding is far too limited, even with current developments, to undertake such projects.[33]

14. To date, the semantic framework laid out by Anderson has effectively dictated the ethical response to human genetic engineering. The framework can be summarized as follows: somatic cell–good; germ line–bad; therapy–good; enhancement–bad. Now, however, thanks to Ian Wilmut, we have a problem. The distinctions that those in the field have been at such pains to draw, between somatic cell and germ-line applications, are, post-Dolly, distinctions without difference. If Wilmut's method works on humans, and there is no immediate reason to assume it will not,[34] then the firewall gene therapists have labored to build has been vaporized. In the future, it would be possible to add genes to a person's somatic cells, use those cells to produce a clone, and achieve the same effect as if one had introduced genes into the germ cells. There would be no more somatic cell–germ cell divide.

15. Some have questioned whether making such a fuss over the distinction was more of a shrewd public relations move than an effort at clarity. In much the same way, experimentation on human embryos in the attempt to perfect IVF was

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[28] *See id.* at 287.

[29] *See id.* at 287.

[30] *See id.*

[31] *See id.* at 286-87, 289.

[32] *See* W. French Anderson, *Editorial: Uses and Abuses of Human Gene Transfer*, 3 HUM. GENE THERAPY 1, 1 (1992).

[33] *See* W. French Anderson, *Genetics and Human Malleability*, HASTINGS CENTER REP., Jan.–Feb. 1990, at 21, 23.

[34] *But see* Specter & Kolata, *supra* note 6, at B6 (reporting on the difficulties of cloning humans).

justified by claiming that its sole purpose was to help infertile women,[35] for whom medicine had never before shown such exquisite concern.

16. In any case, it has always been likely that the techniques developed for therapeutic purposes could also be marshaled for purposes of "enhancement." John Robertson is a constitutional law scholar at the University of Texas at Austin and has long been a champion of the "reproductive rights" argument for a hands-off policy regarding the infertility business. In his 1994 book, *Children of Choice*,[36] he mulled over the possibilities and had this to say about enhancements: "If special tutors and camps, training programs, even the administration of growth hormone to add a few inches to height are within parental rearing discretion, why should genetic interventions to enhance normal offspring traits be any less legitimate?"[37]

17. Robertson is hardly alone in saying such things. The quest to breed "better" people dates back at least to the ancient Greeks, though the Greeks had no idea of the existence of hereditary material. In the modern era, we can trace the idea of breeding "better" people by altering hereditary material back to August Weismann, the German zoologist who wrote on evolution and thought deeply about the mechanics of heredity.[38]

18. Weismann's central notion was that of the continuity of the germ-plasm.[39] By his definition, the germ-plasm was the material that parents passed on to their children through the germ cells.[40] Weismann argued that this material governed the development of the embryo and guided differentiation of cells.[41] Rejecting the Lamarckian idea, Weissman stated that the germ-plasm was not subject to environmental forces and that the characteristics that parents developed during their lifetimes could not be passed on to offspring.[42] Rather, the germ-plasm had an inviolability that accounted for the fact that traits could be passed down through the

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[35] *See* JOSE VAN DYCK, MANUFACTURING BABIES AND PUBLIC CONSENT 24, 70 (1995) (noting the correlation between an increased emphasis on infertility as a problem and the initial growth of the in vitro fertilization industry).

[36] JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES (1994).

[37] *Id.* at 167.

[38] *See* AUGUST WEISMANN, THE GERM-PLASM: A THEORY OF HEREDITY (W. Newton Parker & Harriet Rönnfeldt trans., London, Walter Scott, Ltd. 1893).

[39] *See id.* at 183-84.

[40] *See id.* at 9, 184.

[41] *See id.* at 34-35.

[42] *See id.* at 35.

generations.[43] Weissman, however, did not mean that the germ-plasm overrode any influence of the environment, although many biologists misinterpreted him and argued that germ-plasm was destiny and factors such as prenatal nourishment and education could not counteract a degraded germ-plasm.[44]

19. Francis Galton, the polymath who spawned the international eugenics movement, elaborated upon this mistaken notion by emphasizing the biological underpinnings of socioeconomic problems.[45] Eugenicists offered a program that purportedly provided a simple solution for the widely perceived decline, or "degeneration" of civilization. That simple solution was the baby of "quality," upon which the very existence of our species was said to hinge. Although eugenics took many forms and attracted adherents of all political stripes, two key dictums developed: breed "superior" human stock by encouraging childbearing by "superior" couples and eliminate "inferior" stock by discouraging the same by "inferior" couples. In other words, one goal was to stop inferior couples from breeding. Population geneticists, by the heyday of the eugenics movement, revealed how fruitless such a goal was, but had little success.

20. Even Nazi atrocities in the name of eugenics were insufficient to eradicate some people's ardor for the idea. Eugenics was revived in a number of quarters after World War II,[46] but with an element of hard-line biological determinism. Prominent scientists, such as Nobel laureate Hermann Muller, spoke frequently of the need to combat the buildup of negative genes in the population.[47] Muller argued that medicine, by keeping people alive who would have otherwise died in earlier days, allowed deleterious mutations to accumulate in the gene pool.[48] He proposed a eugenical artifical insemination scheme to address this problem.[49] He thought that a woman should have one child with her spouse and then use sperm from "superior"

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[43] *See id.* at 34-35, 183-84.

[44] *See* KENNETH M. LUDMERER, GENETICS AND AMERICAN SOCIETY: A HISTORIC APPRAISAL 39 (1972).

[45] *See* SIR FRANCIS GALTON, INQUIRIES INTO HUMAN FACULTY AND ITS DEVELOPMENT 16-17 (1934).

[46] *See* MARK H. HALLER, EUGENICS: HEREDITARIAN ATTITUDES IN AMERICAN THOUGHT 183-84 (1963).

[47] *See* H.J. MULLER, MAN'S FUTURE BIRTHRIGHT 125 (Elof Axel Carlson ed., 1973).

[48] *See id.* at 127.

[49] *See id.* at 134, 138.

males to conceive all subsequent children.[50] He believed that this would improve the overall genetic pool.[51]

21. Meanwhile, Joshua Lederberg, another Nobelist, touted the hypothetical advantages of vegetative cloning.[52] In 1966, Lederberg wrote, "If a superior individual (and presumably then genotype) is identified, why not copy it directly, rather than suffer all the risks of recombinational disruption, including those of sex."[53] Moreover, he argued, if you are a known carrier of genetic disease, "why not be sure of an exact copy of yourself rather than risk" an overtly diseased offspring.[54] Galton's legacy persists. In 1993, Bentley Glass, a former president of the American Association for the Advancement of Science, wrote in *The Quarterly Review of Biology* that:

> Idealism among scientists is not dead, and so long as the genetic load is a danger to the well-being of the population of any country, or of the whole world, and so long as there is a prospect that the human genome and its environment can be improved beyond their present state, eugenics in its broadest sense will continue to attract the ideals of geneticists, physicians, environmentalists, and in fact everybody else.[55]

22. Mutations are continually occurring and some do not represent improvements to the genetic blueprint. The process has continued for millions of years and does not seem to pose a tremendous impediment to the viability of our species. In fact, the huge upswing in global population since the mid-1700s has shown that environmental factors play as much–or more–of a role in health as genetics. Demographers generally agree that improved hygiene, vaccines, and antibiotics, rather than some fundamental betterment of the genome, have brought about the increase in the average life span, which is responsible for the six-fold or greater growth in population over the last 250 years.

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[50] *See id.*

[51] *See id.* at 134-35.

[52] *See* Joshua Lederberg, *Experimental Genetics and Human Evolution*, 100 AM. NATURALIST 519, 526-27 (1966).

[53] *Id.* at 527.

[54] *Id.*

[55] Bentley Glass, Commentary, *Racism and Eugenics in International Context*, 68 Q. REV. BIOLOGY 61, 67 (1993).

23. Why the emphasis, or one might say overemphasis, on the genetics of disease? The initial rhetoric in favor of somatic cell therapy argued that it would enable physicians to treat many of the roughly 4,000 diseases that are known to be caused by a single defective or missing gene.[56] Such monogenic ailments are passed on in Mendelian fashion and can be tracked in family pedigrees.[57] These ailments were the earliest discovered by geneticists and constitute about seventeen percent of all anomalies that appear at birth.[58] Coupled with genetic ailments that appear by age twenty-five, they make up about 0.36% of all births.[59] Multifactorial ailments, which are attributable to the interaction of genes and environment, occur at a rate almost thirteen times that.[60] Some single gene diseases involve the insufficient production of a certain enzyme or protein and appear treatable by gene therapy.[61] There is one faulty gene and one missing gene product. Supply the cells in question with the correct gene and they should churn out that product and correct the disease.

24. The reality of addressing even these simple genetic diseases has proved daunting. Developing a treatment for even one monogenic ailment is a formidable task requiring several different steps, none of which has yet been perfected. First, the faulty gene must be located, which is often a multi-year endeavor.[62] The Human Genome Project, which will probably wrap up around the year 2000, is likely to speed up this process.[63] The Human Genome Project, however, is not producing the

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[56] It is estimated that there is between 3000 and 4000 inherited disorders caused by defects in a single gene. *See* Richard Saltus, *Latecomer Boston Labs Eyeing Gene Therapy*, BOSTON GLOBE, Feb. 22, 1994, at A1.

[57] *See* Neil Risch, *Genetic Linkage: Interpreting Lod Scores*, 255 SCI. 803, 803 (1992).

[58] *See* 2 ROYAL COMMISSION ON NEW REPROD. TECHS., PROCEED WITH CARE: FINAL REPORT OF THE ROYAL COMMISSION ON NEW REPRODUCTIVE TECHNOLOGIES 748 tbl.26.1 (1993).

[59] *See id.* tbl.26.2.

[60] *See id.*

[61] Even though this is the simplest application of somatic gene therapy, however, there are several practical difficulties. *See* Stuart H. Orkin & Arno G. Motulsky, *Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy* (visited Jan. 28, 1998) <http://www.nih.gov/news/panelrep.html>.

[62] *See* Laura Van Dam, *Putting a Rush on Identifying Genes*, TECH. REV., Jan. 1997, at 10, 10 (stating that it typically takes two years to locate a gene).

[63] "The Human Genome Project is an international research program designed to construct detailed genetic and physical maps of the human genome, to determine the complete nucleotide sequence of human DNA, to localize the estimated 50,000-100,000 genes within the human genome, and to perform similar analyses on the genomes of several other organisms used extensively in research laboratories as model systems." *See National Human Genome Research Institute, The Human Genome Project* (visited Nov. 18, 1997) <http://www.nhgri.nih.gov/HGP/> (stating that the Project began in the mid-1980s and that the goal is to finish the gene map by 2005).

informational equivalent of, say, a British Ordinance Survey map, which shows every dip, trail, remote farmhouse, and neolithic monument. Rather, it is more akin to the maps you get from the car rental counter: enough to get you roughly to where you want to go, if you are lucky. This means that for every genetic ailment, we can, for many years to come, expect a major investment of time and money simply to pinpoint the genetic culprit.

25. There are further technical problems to be solved before somatic cell therapy can become the medical norm.[64] Scientists have not come up with an all purpose method for smuggling new genes into cells. There are currently several methods being explored. Researchers are working with several different vectors, or vehicles, that are capable of introducing new genetic material into the body.[65] The gene can be introduced indirectly by being inserted into a certain type of cell and then infused into the body.[66] Or, the gene may be piggybacked to a substance that will be readily taken up by a cell, such as a liposome–a kind of artificial fat molecule.[67] Researchers have also experimented with injecting DNA into cells with microsurgical tools,[68] using electrical shocks to get cells to pick up DNA that is sitting outside the cell membrane,[69] or injecting altered cells into muscle tissue.[70]

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[64] *See* Orkin & Motulsky, *supra* note 61 (discussing ways to combat the major obstacles to successful somatic gene therapy).

[65] Of the vector systems studied to date, retroviruses appear to be the best suited for delivering genes into host cells due to their efficient integration of retrovirally transduced genes. *See id.* Efficacy, however, has not be established for any gene protocol. *See id.* (discussing several different systems that are in use or under consideration for somatic gene transfer).

[66] "Gene delivery can be achieved either by direct administration of genes containing viruses or DNA to blood or tissues, or indirectly through the introduction of cells manipulated in the laboratory to harbor foreign DNA." *See id.*

[67] *See id.*

[68] *See, e.g.*, Rick Weiss, *Artificial Human Chromosomes that Replicate Developed in Lab: Scientists Aim to Ferry Creative Genes to Cells*, WASH. POST, Apr. 1, 1997, at A1 (discussing how a gene therapy team strung nucleotides, the chemical sub-units of DNA, and then used them to replicate certain chromosomal components, which were injected into cells growing in laboratory dishes).

[69] *See, e.g.*, Peter Gorner, *Breakthrough Made in Gene Transplants*, CHIC. TRIB., Nov. 24, 1988, at 5 (discussing how one leading gene therapy researcher uses electric shock or electroporation to open small holes in a cell's membrane, allowing DNA to enter).

[70] *See, e.g.*, *Muscle Cells Pack the Punch Needed for Successful Gene Therapy*, BUS. WIRE, Dec. 5, 1991, *available in* LEXIS, News Library, Arcnws file (discussing a study with mice that injected genetically altered immature muscle cells, called myoblasts, into normal muscle tissue, which accepted the immature cells as normal muscle cells).

26. There are also direct methods that employ viruses.[71] It makes sense to use viruses, which have long since perfected the art of cellular "breaking and entering" for the purposes of availing themselves of the genetic machinery therein. The viruses that scientists have singled out belong to: (i) the adenovirus family,[72] which includes at least forty types of viruses that cause upper respiratory ailments, conjunctivitis, and other infections in humans; (ii) the retrovirus family, of which HIV is the most infamous member;[73] and (iii) the herpesvirus family, which includes, among others, herpes simplex, cytomegalovirus, and Epstein-Barr viruses.[74] The idea is to modify these viruses so that they lose the ability to cause disease, but retain the ability to shoehorn new genes into cells' DNA. None of the methods for transferring new genes into cells have been terribly efficient or foolproof.[75] Red flags have been raised about retroviruses, in particular, because of their association with cancer.[76] Many scientists, including French Anderson, believe that the development of feasible vectors is the most important and intractable problem facing the field today.[77] Finally, once a gene has been introduced into a cell, there is the problem of getting it to turn on and off as needed and to churn out enough protein or enzyme to reverse the disease.[78] In some cases, it may require only a small blip in the output of a particular protein to do this; however, this is unlikely to be true across the board.

27. If you look at NIH spending on gene therapy research–the most recent figures at the NIH website are for 1995–you can see that the NIH awarded $40.2 million in grants for gene therapy research.[79] Approximately thirty-nine percent, or $15.7 million, went to study five monogenic ailments: cystic fibrosis, sickle cell

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[71] *See* Orkin & Motulsky, *supra* note 61 (discussing the virus vector systems in use or under consideration today).

[72] *See id.*

[73] There is more extensive research with the retroviral vectors than with other viruses or nonviral DNA. *See id.*

[74] *See id.*

[75] *See id.* (explaining the advantages and disadvantages of the vector systems in use or under consideration for gene therapy).

[76] *See id.* (noting that "multiple integration events resulting from repeated administration of large doses of retroviruses theoretically poses a risk for leukemic transformation").

[77] This statement is based on personal communication with W. French Anderson by Gina Maranto.

[78] *See* Orkin & Motulsky, *supra* note 61 (discussing how gene therapy is dependent on the expression of transferred genes).

[79] *See NIH Office of Extramural Research Grants* (visited May 1, 1998) <www.nih.gov/grants/oer.htm>.

anemia, hemophilias A and B, and Duchenne muscular dystrophy.[80] Of the $40.2 million total, $100,000 went to one ethical study.[81] There was one grant to explore the issues surrounding informed consent and $7.4 million was awarded for research on possible gene therapies for cancer, only about $100,000 less than what was spent on cystic fibrosis.[82] The other key expenditures were for other diseases that are not strictly genetic: $2.4 million for liver disease, $2.3 million for AIDS, $1.1 million for cardiovascular disease, and $444,000 for retinal degeneration.[83]

28. Researchers have modified their initial aims and started to apply the technology to multi-gene and multifactorial diseases. This may or may not be attributable to a paradigm shift. Certainly, the proponents of the Human Genome Project would like to foster a new view that all disease, perhaps even all behavior, is genetic.[84] Recall James Watson's oft-quoted statement to *Time*, "We used to think our fate was in the stars. Now we know, in large part, that our fate is in our genes."[85] Jonathan Marks, a molecular anthropologist and the author of *Human Biodiversity*, observed that Watson's statement is, in one sense, nothing but a grant proposal.[86] At the same time, it is a statement of scientific faith, which, if taken literally, suggests that the trajectory of a person's life is attributable to his or her genes. This is no different than suggesting, as Italian psychiatrist and physical anthropologist Cesare Lombroso did late last century, that a person's character may be read from his physiognomy.[87] It is no different, finally, from palmistry, phrenology, and the rest of the enterprises that journalist Walter Lippman once called the "Babu sciences."[88]

29. What is disquieting is the way the ballyhoo over genetic medicine once more shifts the focus onto biology and gives support for the age old-shibbeloth that social problems are in the "blood" or in the "germ-plasm" or in the genes, all of which we know to be untrue. And even if it were true, we who believe in democratic ideals

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[80] *See id.*

[81] *See id.*

[82] *See id.*

[83] *See id.*

[84] For more information on the Human Genome Project, see *Human Genome Organisation* (visited May 1, 1998) <http://hugo.gdb.org>.

[85] Leon Jaroff, *Happy Birthday Double Helix*, TIME, Mar. 15, 1993, at 56, 57.

[86] This statement is based on personal communication with Jonathan Marks by Gina Maranto.

[87] *See* GINA LOMBROSO-FERRERO, CRIMINAL MAN: ACCORDING TO THE CLASSIFICATION OF CESARE LOMBROSO 5-15 (1971).

[88] *See* Walter Lippmann, *A Future for the Tests*, NEW REPUBLIC, Nov. 29, 1922, at 10.

would want to behave as if they were not true. It is either that, or go back to the old Chain of Being, the class-based society, and neo-Darwinism.

30. At this point, it is quite unlikely that human genetic engineering for the treatment of disease will be stopped. Between 1980 and 1990, at least twenty international bodies carried out assessments of gene therapy.[89] A survey by Georgetown ethics professor LeRoy Walters found that all twenty accepted "the moral legitimacy of somatic cell gene therapy for the cure of disease."[90] Most ethicists have concluded that providing a person with a gene that would enable him to produce a substance vital to metabolism is not very different from giving a diabetic insulin. Public polls have generally revealed that a large majority feel gene therapy research should continue.[91] Indeed, a 1992 Harris poll revealed that ninety percent of the people surveyed advocated continuing gene therapy research.[92]

31. What some critics have questioned is whether spending money on genetic medicine represents the best use of scarce public health dollars, especially when the preponderance of health problems among infants and children, the main victims of genetic diseases, are attributable to poor prenatal care, poor early childhood nutrition, and other environmental factors.[93] Many people have made this case in some detail, including Harvard biologists Richard Lewontin and Ruth Hubbard.[94] Unfortunately, they are largely ignored, in part because preventive health is far less sexy than big research campaigns, just as water conservation is far less sexy than building big dams. We live in times when social welfare programs are disfavored. Moreover, no one wants to discuss prenatal care when they can talk about the El Dorado of huge profits for the patent holders on the techniques and genes involved in gene therapy.

32. If medical applications are a foregone conclusion, what about genetic engineering and germ-line experimentation? The same twenty international bodies that considered somatic therapy acceptable, opposed attempts to enhance "human capabilities by genetic means."[95] The Canadian Royal Commission on New Reproductive Technologies examined the issues surrounding gene therapy and heard

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[89] *See* 2 ROYAL COMMISSION ON NEW REPROD. TECHS., *supra* note 58, at 925.

[90] *See id.*

[91] *See Gene Therapy's Future*, CQ RESEARCHER, Dec. 8, 1995, at 1098, 1101.

[92] *See id.*

[93] *See* George G. Graham, *Poverty, Hunger, Malnutrition, Prematurity, and Infant Mortality in the United States*, 75 PEDIATRICS 117-25 (1985) (discussing how various non-genetic factors affect health problems among children).

[94] *See* Richard Saltus, *Sounding the Alarm*, BOSTON GLOBE, May 26, 1996, (Magazine) at 14, 31-35.

[95] *See* 2 ROYAL COMMISSION ON NEW REPROD. TECHS., *supra* note 58, at 925.

testimony from dozens of religious, women's, and medical groups who strongly recommended against using genetic engineering "as a means of seeking to reinvent human beings."[96] The Commission recommended that, as a policy, Canada should fund "no research involving the alteration of DNA for enhancement purposes," and none "involving alteration of the DNA of human zygotes."[97] Furthermore, Germany bans all embryo research[98] and Britain requires labs handling embryos to be licensed.[99]

33. The pressure is going to be toward doing both of these things. Science has its own internal momentum and manipulating the genetics of embryos represents the next logical step in a 2000-year continuum. Scientists *want* to use these technologies; they are the ones who thought them up! Moreover, there is substantial support among scientists and science apologists for ending what has been called "reproductive roulette."

34. I could cite you chapter and verse from dozens of researchers who have spoken positively during the last several decades about germ-line manipulations because this is not a goal that science in general reprehends. Many share the view articulated by J.B.S. Haldane in *Daedalus*, or *Science and the Future*.[100] Haldane said, "We must learn not to take traditional morals too seriously. And it is just because even the least dogmatic of religions tend to associate itself with some kind of unalterable moral tradition, that there can be no truce between science and religion."[101]

35. Science is "a-ethical." By this, I do not mean that scientists are unethical. Scientists operate under a system of professional ethics. Contraventions of the codes against fudging or massaging data, or fabricating results, cause great consternation within the scientific community and, in recent years, have received a good deal of attention by the media. But as an epistemological method, science does not intersect with ethics. Nowhere in the outlining of its basic precepts of how to observe the material universe, of how to test the veracity of facts, of how to construct deductions and inductions; nowhere in the methodological ponderings of Bacon, Locke, Descartes, or Buckley do ethical axioms figure.

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[96] *See id.* (quoting P. Marshall).

[97] *See id.* at 942, 945.

[98] *See* Michele Grygotis, *Seed's Announced Intention to Open Commercial Cloning Clinic in Chicago Creates Uproar*, TRANSPLANT NEWS, Jan. 16, 1998, *available in* 1998 WL 9525427.

[99] *See* Human Fertilisation and Embryology Act, 1990, ch. 37, § 3 (Eng.).

[100] *See* HALDANE, *supra* note 15.

[101] *See id.* at 90.

36. This means that if we want an ethical science, we as a society must impose values on it from the outside. Science takes as its right the pursuit of knowledge for knowledge's sake, wherever it leads. But society, not necessarily granting the same absolute permission to scientists as scientists grant themselves, may feel less convinced of the probity of certain types of investigations, especially when knowledge is translated into technology.

37. There is no inevitability to the course of scientific research. For at least the last 50 years, the direction that science has moved in the U.S. has been shaped by peer review in the federal granting process.[102] What was studied depended upon the personal biases or interests of those in granting agencies and the government.[103] Also, the work of younger scientists has been dictated largely by those higher up in the scientific community.

38. Today, the direction science takes is extremely sensitive to money, as the government has encouraged business to increase its investment in research.[104] The chance for a winning number in the patent and licensing sweepstakes lures investors, who put enormous pressure on researchers for results that will pay off. Now more than ever, science's vaunted commitment to free inquiry comes fully into play only where there is sufficient grant money or venture capital to be deployed.[105] We need only consider how little money is spent on developing a vaccine against malaria[106] to realize the power of the bottom line. Malaria afflicts few in the developed world and, thus, is of little market value for drug companies.[107]

39. Like biotechnology in general, gene therapy, narrowly defined as genetic engineering for medical purposes, has been oversold. This is the fault of scientists, biotech firms, public relations agencies, stock analysts, and the press–some members of whom, it must be admitted, know little or nothing about genetics. This results in the ubiquitous gene-of-the-week stories in which scientist are proclaimed

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[102] *See generally* Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and Sciences*, 9 High Tech. L.J. 1, 3-4 (1994) (discussing the peer review process).

[103] *See id.* at 4-7.

[104] *See, e.g.*, Symposium, *Financing the Biotech Industry: Can the Risks Be Reduced?*, 4 B.U. J. SCI. & TECH. L. 1 (1998).

[105] *See generally id.*

[106] Eighty-five million dollars a year is spent globally on malaria research. *See* Nicholas D. Kristof, *Malaria Makes A Comeback, And Is More Deadly Than Ever*, N.Y. TIMES, Jan. 8, 1997, at A1.

[107] Because the disease primarily affects poor people, pharmaceutical companies doubt whether those suffering from the disease could pay for a vaccine, even if it was developed. *See id.*

to have "discovered" the gene "for" alcoholism, aggression, maternal instincts, or what have you.[108]

40. For all that, genetic medicine will probably end up like the war on cancer. Some advances will be made, but there will be no panacea. I suppose it is all right if we need to propagandize ourselves to get the work done. Grails, after all, are great motivators, even if you never get to hold them in your hands. If scientists want to hype what they are doing and venture capitalists want to respond, it is a folie à deux one would be hard-pressed to dispel.

41. We have to understand that the enthusiasm for human genetic engineering, in whatever form, does not constitute scientific fact. Rather, it is a manifestation of personal interests, marketplace forces, and cultural values. Technology is not inevitable. We need to stop believing that we have a social obligation to accept whatever technologies science turns out. In fact, we are far beyond the days in which science can proclaim itself as our only defense against the dark forces of superstition. To limit a line of scientific exploration or to reject a technology is not to abandon the underlying intellectual foundations of science or rationalism, or even to reject the notion that some technologies can provide unalloyed benefits. Science is not the framework by which we in a pluralistic democratic society must formulate our choices, any more than market capitalism, Marxism, Christianity, or any other world view is.

42. Germ-line tinkering is the end to which these three lines of research that I mentioned earlier are headed.[109] In 1983, when the first artificial twinning of horses was performed in this country using another type of cloning known as blastomere separation,[110] ethicists insisted that no one would ever attempt the procedure on humans because there was too much opposition within ethical review boards and other institutional oversight bodies to permit it. They were wrong. In 1993, Jerry Hall at George Washington University Medical Center performed blastomere

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[108] *See, e.g.*, Nicholas Wade, *Discovery of Gene Offers Clues on Deafness*, N.Y. TIMES, Nov. 14, 1997, at A28 (discussing the discovery of a gene that "helps operate the delicate hair cells in the ear that respond to sound vibrations"); Anita Manning, *Found: A Gene That Controls Place Memory*, USA TODAY, Dec. 27, 1996, at D1 (discussing the discovery of a gene in mice that helps control memory); Natalie Angier, *People Long On Neuroticism Appear to be Short a Gene*, BALTIMORE SUN, Dec. 10, 1996, at E4 (discussing a link between anxiety-related behavior and the gene that controls seratonin).

[109] Nuclear transplantation, genetic engineering, and reproductive medicine. *See supra* text accompanying notes 10-12.

[110] In relation to cloning, blastomere separation "splits the cells or blastomeres of an early multicelled embryo before the cells have begun to differentiate. Because each blastomere at this stage is in theory totipotent (that is, capable of producing an entire organism itself), separated cells can become new embryos, all of which have the same genome." John A. Robertson, *The Question of Human Cloning*, HASTINGS CENTER REP., Mar. 1, 1994, at 6. For a response to Robertson's view of human cloning using blastomere separation, see Richard A. McCormick, *Blastomere Separation: Some Concerns*, HASTINGS CENTER REP., Mar. 1, 1994, at 14.

separation using "genetically abnormal" human embryos.[111] He told *Science* that he did it intentionally to "get the ethical discussion moving."[112]

43. The discussion did not "move," however, just as it did not move in the late 1960s, when scientists issued the same assurance that cloning of anything was impossible and unthinkable. We should have known better, but too often in our society, we react only to what exists. Now, we have the unthinkable and we must scramble to catch up. Even while the public and politicians do that, drug companies and researchers are proceeding apace with the patenting of genes, often without the fully informed consent of the people involved. I am referring to the Human Genome Diversity Project[113] (the "HGDP"), implemented to expand the Human Genome Project so that it would include genetic material from various aboriginal peoples, ostensibly "to record human ethnic and geographic diversity before this possibility is irretrievably lost."[114] The HGDP is now under fire for ignoring the basic medical tenet of informed consent and for exploiting the tissues of aboriginal people for profit.[115] Moreover, some critics have challenged the scientific rationale for the HGDP, which assumes that the human gene pole contains pockets of "purity," an assumption that modern genetical evidence does not support.[116]

44. Recently, responsibility for overseeing gene therapy protocols shifted almost entirely to the Food and Drug Administration, which has a statutory right to evaluate gene therapy proposals on a case-by-case basis.[117] There was also a move last fall to disband the National Institute of Health's Recombinant DNA Advisory Committee ("RAC") on the grounds that it was duplicating the effort of institutional review boards and the FDA.[118] The RAC presides over genetic engineering research, ensures public scrutiny, and evaluates social, ethical, and scientific issues regarding

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[111] *See* Rebecca Kolberg, *Human Embryo Cloning Reported*, 262 SCIENCE 652, 652 (1993).

[112] *Id.*

[113] The goal of the HGDP is to sample the DNA of certain human populations, preserve their cell lines, and allow future generations of geneticists to study it. *See* Jonathan Marks, *The Human Genome Diversity Project: Good for if Not Good as Anthropology?*, ANTHROPOLOGY NEWSL., Apr. 1995, at 72, 72.

[114] L.L. Cavalli-Sforza et al., *Call for a Worldwide Survey of Human Genetic Diversity: A Vanishing Opportunity for the Human Genome Project*, 11 GENOMICS 490, 490 (1991).

[115] *See* Marks, *supra* note 113.

[116] *See, e.g.*, *id.* at 72; JONATHAN MARKS, HUMAN BIODIVERSITY: GENES, RACE, AND HISTORY 175-80 (1995). *See also* Symposium, *Probing the Human Genome: Who Owns Genetic Information?*, 4 B.U. J. SCI. & TECH. L. 2 para. 47 (1998) (comments of Wendy McGoodwin).

[117] *See* Recombinant DNA Research: Actions Under Guidelines, 60 Fed. Reg. 20,726, 20,728 (1995).

[118] *See* Recombinant DNA Research (NIH Guidelines) Regarding Enhanced Mechanisms for NIH Oversight of Recombinant Actions, 61 Fed. Reg. 35,774, 35,775 (1996).

genetic engineering.[119] There was such outcry over the proposal to dissolve it that the NIH backed off the plan, but the committee has been reduced to fifteen members and its future role is still uncertain.[120]

45. Also, the United States has equivocated on reproductive technologies, and one does not feel very confidant that society has the will to superintend technology. The government has refused to take a stand on the many issues raised by IVF, largely because of the political terror of anti-abortion fanatics. There has been a de facto moratorium on federally funded embryo research,[121] although there have been no constraints placed on privately-funded research. Unless some firm policy is drafted based on the National Bioethics Advisory Commission report to President Clinton,[122] or unless legislation is passed, we will see the next "advances" in human genetic engineering in the infertility clinics, which have already produced innumerable other "advances" of dubious benefit. Thank you.

Charles R. Cantor:

46. I am going to agree with much of what Gina Maranto said, but disagree with some as well. To put my remarks into perspective: I am a scientist. I first began to think about these issues in the early 1980s when I was chairman of the human genetics department at Columbia University. A film that we used to show our medical students about a well educated family from nearby with thirteen children, almost all of whom were institutionalized, caught my attention and affected me. The parents had an unbalanced chromosome situation, making it impossible for them to have a normal child. They understood this, and the film presented the science behind their medical problem. The parents understood what the problem was, but they went on having child after child. They said they loved their children as much as if they were normal. Fortunately, the family had enough money so that the children were not a burden to society, but only a burden to the parents. I am still horrified by this because it seems to me that at some point, society has to step in and say, "Wait a minute, the rights of individuals only go so far; you cannot do this."

47. Gene manipulation raises profound issues, and I think what makes this exciting to talk about is that there are no simple answers. The basic issues

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[119] *See id.* at 35,775-35,776.

[120] *See* Recombinant DNA Research: Action Under the Guidelines, 62 Fed. Reg. 4782, 4782 (1997).

[121] In January, 1997, on his second day in office, President Clinton lifted the moratorium on federally funded fetal research. *See* Susan Brink et al., *Top 10 Health Stories to Watch*, U.S. NEWS & WORLD REP., May 10, 1993, at 81, 89.

[122] *See* NAT'L BIOETHICS ADVISORY COMM'N, CLONING HUMAN BEINGS: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 109 (1997) (recommending, among other points, continuation of the moratorium on federal funding "of any attempt to create a child by somatic cell nuclear transfer).

underlying gene manipulation concern the rights of individuals versus the rights of society. These are issues which will be with us as long as there are societies. My position on some of these issues slowly changed over the years, which I find interesting. I am going to talk very briefly about technical issues and applications. Then, I will discuss what I consider to be a few of the really tough issues.

48. I do not think that there are overwhelming technical barriers to somatic therapy, germ-line therapy, and cloning. It may take a few more years or decades, but if people are motivated, they will be able to do it. Thus, one cannot finesse the difficult legal and ethical issues under the facade that "it is not possible now," because it will be possible soon. My first reaction is that the cloning of a sheep, earlier this year, does not really change things very much. Identical twins raise much of the same issues that clones raise. In fact, identical twins are more identical than clones because they share a much more common environment than clones share.[123] However, cloning is a little more problematic.

49. Things start getting sticky when one talks about germ-line gene therapy and the use of gene therapy. There are two types of uses: therapeutic uses and what I would call frivolous-cosmetic uses. The therapeutic uses sound great on paper because they seem to fix that which is broken, which makes sense. The cosmetic uses do not fix that which is broken. How much and what types of gene therapy society uses are issues of cost and propriety, among other things. Today, germ-line gene therapy is already practiced in a specialized, low-tech form. Thus, if one has qualms about it, they need to be aired now. Selective abortion for sex-selection of offspring is practical and in some cultures it may even be widespread;[124] it is not discussed, but we do it. By using such germ-line gene therapy, one affects the gene pool that is passed on to its progeny because the progeny is chosen based on sex. It is difficult to make a delicate argument about other kinds of germ-line therapy mostly on principle alone.

50. Germ-line therapy is potentially serious because our diversity as a species is one form of evolutionary protection. For instance, we are resistant to malaria because we carry genes such as sickle cell hemoglobin and thalasemia.[125] A

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[123] *See, e.g.*, Wray Herbert et al., *The World After Cloning: A Reader's Guide to What Dolly Hath Wrought*, U.S. NEWS & WORLD REP., Mar. 10, 1997, *available in* LEXIS, News Library, MAGSPLUS File.

[124] *See* Mark J. Evans et al., *Attitudes on the Ethics of Abortion, Sex Selection, and Selective Pregnancy Termination Among Health Professionals, Ethicists, and Clergy Likely to Encounter Such Situations*, 164 AM. J. OBSTETRICS & GYNECOLOGY 1092, 1098 (1991) (stating that no one knows the actual extent of sex selection abortions in the U.S.); *cf.* Nora Frenkiel, *'Family Planning': Baby Boy or Girl*, N.Y. TIMES, Nov. 11, 1993, at C1 (noting that doctors interviewed around the country believed that sex-selection abortions are extremely rare in the United States).

[125] *See* Geoffrey Pasvol, *Malaria and Resistance Genes: They Work in Wondrous Ways*, 348 LANCET 1532, 1533 (1996) (stating that thalasaemia and sickle cell are types of genes that may modify the host's response to malaria).

gene that is potentially harmful in Boston is helpful in Africa. If we were to cure the so-called "defective genes," we would run the risk of ignorantly making people vulnerable to diseases that we cannot anticipate. This, however, is a very long term, slow process. It is the paradox of eugenics: to have a significant impact on the gene pool, one would have to continue gene therapy for hundreds of generations, at which point people will get bored with it by the time the changes actually occur. I do not think that that is going to be a major problem for us.

51. It is very hard today, however, to be convinced that any specific germ-line therapy designed to prevent the birth of individuals with certain inherited diseases will be cost-effective. On the surface, it does not sound like good medical practice. In almost any case that one can imagine, with the rarest exception of the Columbia University family mentioned earlier, there is the cheap alternative of abortion. Imposing germ-line therapy will be extremely expensive and probably somewhat risky. Abortion, moral qualms aside, is functionally very effective,[126] and it is going to be extremely hard to justify complex procedures when simple alternatives work.

52. This leads me to the two serious issues. One, I think I know how to deal with, and the other, I am not so sure. Suppose I had a medical procedure that would make the quality of life perfect. What would that mean? It would mean that one would have no medical problems until, suddenly, one day the individual dropped dead. This is an Aldous Huxley solution, as described in *Brave New World*. One could take a pill and it does it all. How long would one live? The better our developments in medicine, the longer people live. But if one wants to increase the life span as part of increasing the quality of life, one is also going to increase the population. With finite resources, one cannot do that blindly; one has to make a decision. How are the resources allocated? I personally would prefer living happier and breathing cleaner air in a lower population than living in a larger population. This is a choice society can make, and it does not have to be made the same way in each sub-segment of the community.

53. This last issue is the one that really troubles me. I would like someone to discredit this argument, which I find deeply disturbing, because *I* do not know how to discredit it. Perhaps directed germ-line manipulation is merely the next natural stage in our evolution as a species. Those members of the population who persevere will be those who use it wisely. I think this a terrifying argument, but I have not been able find a way to dispel it. If one accepts that we now know how to direct germ-line manipulation, then we must use it for the best purpose. The good news is that I do not think we have to confront this issue today, as an actual decision in practice. Our 100,000 genes are comparable to a computer program containing 100,000 statements. If one changes one of those at random in an attempt to do good, one will almost certaintly do harm. We do not know enough today to manipulate

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[126] RU-486 treatments are over 96% effective at terminating pregnancies, "almost as effective as a surgical abortion." Gwendolyn Prothro, *RU 486 Examined: Impact of a New Technology on an Old Controversy*, 30 U. MICH. J.L. REFORM 715, 725-26 (1997).

genes in an effective manner to improve our species. Yet this argument will weaken with time, and we will eventually have to confront this difficult problem. Are we doing this because it is our natural next step? I hope someone can prove that it is not. Thank you.

Leonard H. Glantz:

54. I want to make a couple of comments before I get into my prepared comments. One has to do with whether or not gene therapy is hyped and is promising to deliver more than it can. I certainly would agree that it is, but let me tell you something that happened recently. The Federal Trade Commission ordered Ciba-Geigy and Sandoz to license more than 20 patents covering gene therapy technology as a condition of their merger.[127] The Commission believes that gene therapy could be a $45 billion market by the year 2010.[128] So if you want to talk about optimistic, that is optimistic.

55. My other comment concerns the statement made by Professor Cantor that sex-selection abortion seems to be accepted. I do not think that is true,[129] and I would like to discuss that more. Last week, I was at a local hospital that received a call from an OB/GYN clinic. They said that they had a woman who wanted an ultrasound to verify the sex of the fetus. If the fetus was female, she wanted to abort it. The OB/GYN clinic refused to do the ultrasound, and they wanted to know whether or not that was acceptable. These were all very pro-choice people making the decision. I do not believe that it would be fair to say that sex-selected abortion is an accepted practice.

56. What I want to do is discuss the social and the ethical context of the discussion. If genes are the building blocks of life, then talking about genes requires us to go back to the building blocks of ethics, law, and social policy. We start with the proposition that fooling with genes is presumptively suspect as opposed to fooling with larger pieces of people's bodies, such as organs. When transplantation of organs was being developed, we did not to think of that activity in terms of grand philosophical schemes. We asked, "can science do that successfully?" Can it really put organs in people and not kill them? When it comes to gene therapy, we are more inclined to ask if science can really do this. If the answer is yes, I think we tend to find that answer disturbing. In dealing with genetics we seem to intuitively feel that we are playing with the very elements of nature, of human nature.

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[127] *See* In re Ciba-Geigy Ltd., F.T.C. File No. 961-0055 (Dec. 5, 1996).

[128] *See id.*

[129] *See* Frenkiel, *supra* note 124, at C6.

57. In 1981, Clifford Grobstein wrote a book entitled, *From Chance to Purpose: An Appraisal of External Human Fertilization*.[130] I find the distinction between "chance" and "purpose" important. In this era of science and rationality, we feel better about chance than purpose when it comes to reproducing human beings. Joseph Fletcher, however, said that it is more human to use artificial forms of reproduction because it is more purposeful and attentive;[131] Fletcher believes that to be human is to be efficient and to make choices.[132] What is notably absent from Fletcher's belief about being human is pleasure and contact with other human beings, which, I would argue, is human purpose.

58. When we undertake gene therapy or gene manipulation, we are fooling with mother nature. How angry will she be when she finds out? The reason this question is not as stark in the realm of non-genetic therapy is that other therapies are perceived as simple mechanical fixes, such as patching a flat tire. After all, as dramatic as a heart transplant might seem, it is only a sophisticated plumbing job that substitutes one pre-existing body part for another. Tinkering with genes, at least for now, is perceived as more of an intrusion on a natural order than tinkering with organs. It is interesting that a discussion of these elemental matters causes us to go back to our legal, ethical, and policy roots and to search for analogies as guidance. In fact, there is a project going on now, funded by ELSI, that is actually a search for analogies to gene manipulation.[133]

59. Somatic gene therapy is less controversial than germ-line gene therapy.[134] Somatic gene therapy can be analogized to organ transplantation. In somatic gene therapy, very tiny parts called genes are taken and implanted into the body to replace other very tiny body parts that are not working. It looks like heart transplantation. If it is legitimate to give insulin to a diabetic or even to implant a highly sophisticated reservoir into a diabetic so that insulin is released over time, then what is wrong with changing a somatic gene so that insulin is released into the person? How is that really different than implanting a reservoir? It seems to be okay. Somatic gene therapy seems acceptable when it is used to treat sick people

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[130] CLIFFORD GROBSTEIN, FROM CHANCE TO PURPOSE: AN APPRAISAL OF EXTERNAL HUMAN FERTILIZATION (1981).

[131] *See supra* notes 22-23 and accompanying text.

[132] *See* Rorvik, *supra* note 23, at 17.

[133] ELSI is a part of the Human Genome Project involving the study of "ethical, legal and social implications" of genetics research. Eliot Marshall, *The Genome Program's Conscience*, 274 SCI. 488, 488 (1996).

[134] *See supra* notes 30-34 and accompanying text.

who have diseases and disabilities, as long as there is no risk to others and the person is well informed.[135]

60. Germ-line therapy, however, not only cures the disease or disability of an existing individual, but creates a somewhat "made-to-order individual," who, if all goes right, will create others who will also inherit the "made-to-order" characteristics.[136] We substitute purpose for chance, which causes us to have some concern. There is a consensus, as has been discussed, that we should not be practicing germ-line gene therapy.

61. Even the American Medical Association ("AMA"), which is a fairly laissez faire organization, has said that germ-line gene therapy should not be performed.[137] The AMA believes it is "appropriate to limit genetic intervention to somatic cells" because of the implications of germ-line gene therapy.[138] It should be noted that the AMA's concern is not based on a lack of technical knowledge, but on the fear of the far-reaching implications of germ-line gene therapy. Let me read you some material from the AMA on this. It says, "[e]fforts to enhance 'desirable' characteristics through the insertion of a modified or additional gene, or efforts to 'improve' complex human traits–the eugenic development of offspring–are contrary not only to the ethical traditions of medicine, but also to the egalitarian values of our society."[139] The AMA states that genetic manipulation used on "non-disease traits may never be acceptable and perhaps should never be pursued" due to the "potential for abuse."[140] But if we decide to pursue germ-line therapy, the AMA has some requirements, and one of them is that "all citizens should have equal access to the genetic technology."[141] The AMA demonstrates a deep suspicion of germ-line gene therapy. Germ-line gene therapy is a technology that becomes more dangerous as we learn more about it and perform it better. The AMA policy also causes us to consider why we should conduct germ-line gene therapy for disease traits. Professor

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[135] *See* Anderson, *supra* note 33, at 2.

[136] *See* Toby E. Huff, *The Fourth Scientific Revolution*, SOCIETY, May-June 1996, at 9, 11 (discussing how germ-line therapy changes the gene pool of future generations, regardless of whether it is done to eliminate disease or to achieve certain physical traits).

[137] COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, AMERICAN MED. ASS'N, CODE OF MEDICAL ETHICS, Op. 2.11, at 21 (1996-97 ed. 1996).

[138] *Id.*

[139] *Id.*

[140] *Id.*

[141] *Id.*

Cantor observes that one could accomplish the same thing by screening embryos for undesirable genetic conditions and only implant the unaffected embryos.[142]

62. If the line is to be drawn at non-disease traits, we need to determine what a disease trait is. The question is how to classify diseases or non-diseases? Is aging a disease? We talked about people living longer. Is that something that would be a disease trait or non-disease trait? Trish Engleheart argues that if we could find the gene for presbyopia,[143] the need for reading glasses at middle age, it would provide us with a societal good. Is presbyopia a disease or is it just part of the normal aging process? Do those of us who wear eyeglasses care about whether or not presbyopia is a disease or part of normal aging? Why is the AMA so concerned about equitable access to this technology with respect to income? We as a society make medical care available to those who either have money or are so poor they qualify for Medicaid. I would not begin my plan to make access to health care equitable with germ-line gene therapy. What is it about this technology that makes the AMA the advocate of egalitarism?

63. What about trying to increase the intelligence of offspring that we have every reason to believe would be of normal intelligence? These are issues of parental authority and discretion to improve the functioning of one's children. Certainly, improving a child's intellectual capacity and performance is an activity and an outcome that we urge parents to undertake in a variety of ways. Private schools, tutors, and complex mobiles suspended over the cribs of infants are all things that parents are encouraged to do so that their children will attain their intellectual potential. A couple of weeks ago it was theoretically discovered that children who take music lessons do better intellectually than those who do not.[144] At that moment, you should have run out and bought stock in clarinet companies because parents would certainly see this as another reason for torturing their children with music lessons.

64. Why should parents be discouraged from using a new technology to help their children achieve this goal? This assumes, of course, that the technology has advanced to a point where the risks are well-known and accepted. Under such circumstances, parents' efforts to improve the intelligence of their offspring is in the children's or the ensuing grandchildren's best interest. Parents should not be

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[142] *See supra* note 124 and accompanying text.

[143] Presbyopia is a refractive error of the eye from which the lens and cornea do not focus images correctly on the retina and is characterized by "the loss of reading ability or accomodation as the visual system ages." Thomas A. Deutsch, *Opthalmic Surgery*, 186 J. AM. C. SURGEONS 189, 189 (1998). *See also* Ira A. Abrahamson, Jr., *Eye Changes After Forty*, 29 AM. FAM. PHYSICIANS 171, 171 (1984) (stating that "[s]ooner or later, presbyopia will affect nearly every individual over 40").

[144] *See* Judy Foreman, *How Music Tunes Our Mental Strings*, BOSTON GLOBE, Apr. 14, 1997, at C1 (describing research by psychologist Carol Krumhansl that shows that music lessons improve temporal-spatial reasoning and reporting the "virtuoso" test scores of children who studied music in school).

prohibited from making this decision. A state's attempt to interfere with parents' ability or right to make this decision would raise constitutional issues. Would you feel bad if you learned that your parents acted prior to your birth to make you smarter, or make you be able to remember things better? Would you feel that your parents had injured you or helped you in that way?

65. That genetic enhancement raises concern about eugenics is both real and understandable. We have seen what governments are capable of when they try to improve their population through genetic fixes. I include the United States in this statement and not just Nazi Germany.[145] In *Buck v. Bell*,[146] the Supreme Court upheld the involuntary sterilization of an "imbecile."[147] The case is fifty years old and still has not been either directly or indirectly repudiated by the Supreme Court.[148] This issue, along with the increased willingness of governments to use coercive measures–like the mandatory testing of newborns in New York for HIV[149] and the increased use of random drug testing[150]–should keep us alert for governmental misuses of technology. Before we can think about doing serious germ-line enhancement, we need to be sure that the proper laws exist to outlaw coercive governmental eugenics programs. I think we should limit governmental authority in this area and consider passing a constitutional amendment if necessary.

66. It is clear that if private genetic manipulation could be shown to bring harm to society, it should be outlawed. The most serious concern about germ-line gene therapy, apart from governmental misuse and the fact that we do not have the ability to do it, is that when it does go wrong, it goes wrong for generations. This assumes, however, that if it goes wrong, we will not be able to fix it in future generations and that people who have been negatively affected will continue to reproduce this new genetic flaw. The question of injuring future generations is a serious one from both an ethical and a legal prospective. Due to our limited

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[145] *See* Lombardo, *supra* note 14, at 1.

[146] 274 U.S. 200 (1927).

[147] *See id.* at 207.

[148] *But see* Skinner v. Oklahoma, 316 U.S. 535, 541-42 (1942) (finding that procreation was a fundamental right and rejecting an Oklahoma statute that authorized involuntary sterilization upon a third conviction for a felony involving "moral turpitude"). The Court distinguished *Buck* by noting that in *Buck*, sterilization enabled people who would otherwise be kept confined to return to the world, while in *Skinner*, the statute punished people whose crimes were inequitably categorized as felonies. *See id.* Furthermore, the state, in *Skinner*, did not even attempt to demonstrate a connection between criminalization and genetics. *See id.*

[149] *See* N.Y. PUB. HEALTH LAW § 2500-f (McKinney 1996).

[150] *See, e.g.*, Skinner v. Railway Labor Executives' Ass'n, 489 U.S. 602, 620 (1989) (upholding the drug testing of employees involved in major train accidents because the government's interest in maintaining public safety outweighs employee privacy concerns).

understanding of gene interactions, we may find out, for example, that fixing the presbyopia gene[151] interfered with some other complex set of genetic interactions. Because humans, unlike fruit flies, take a long time to reproduce, cross-generational problems may not become apparent for a long time. Establishing cause and effect will be a tough task. Those that wish to conduct such interventions have the burden of demonstrating how they will determine the safety of their techniques not just in the first generation, but also in future generations.

Frances H. Miller:

67. My function here is to bring everyone thudding down to earth and take a pragmatic approach to what is going on in this conference and what people are worrying about. Genetic diagnosis, therapy, and germ-line manipulation will not be done on a large scale without money. Any kind of genetic intervention in this area is going to cost a great deal, at least with our current state of technology. At the moment, we are a long way away from the widespread use of genetic technology because of its cost. Ciba-Geigy and others may put a lot of resources into genetic therapy research,[152] and they may continue to do it to see where it leads, but they certainly will not fund the therapy for everyone. This means someone else must pay for it. Anyone who can afford to pay for the therapy out-of-pocket can receive it, if we do not ban it as unethical. If we reduce the cost, genetic therapy may enter into popular use.

68. Today, investigational and experimental therapies are excluded from insurance coverage because traditional medical and health insurance contracts will only pay for medically necessary care.[153] In the old days, doctors decided what was medically necessary and insurers accepted their word for it. Under managed care, insurers do not leave it up to the physicians. They purport to do so, but they have very interesting ways of constraining physicians' discretion.

69. Patients are not passive actors in this play. Insured patients will not receive more than they pay for, and they pay for the actuarially determined reasonable costs, medically necessary diagnoses, and therapies for a given patient

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[151] *See supra* note 143 and accompanying text.

[152] Ciba-Geigy merged with Sandoz to form Novartis, which is now the "world's largest agrochemical company, the second-largest seed company, the second-largest pharmaceutical company and the fourth-largest veterinary-medicine company." Jeremy Rifkin, *Genesis II; Commercial Prospects of Genetic Engineering and Biotechnology*, ACROSS BOARD, June 1998, at 29, *available in* LEXIS, Busfin library, Bus file. *See also* Adam Katz-Stone, *Big-Company Money Backs Gene Therapy Research*, WASH. BUS. J., Mar. 20, 1998, at 38, *available in* 1998 WL 7692579 (reporting that small research companies look for large pharamceutical company backing to help fund the development of gene therapy treatments, which can cost "upwards of $300 million").

[153] *See* Wendy K. Mariner, *Patients' Rights After Health Care Reform: Who Decides What is Medically Necessary?*, 84 AM. J. PUB. HEALTH 1515, 1516 (1994).

population.[154] They should not receive more than they contracted for. When someone other than the patient buys the insurance, the master contract with the insurer may contain clauses about which the employee/subscriber/patient is not even aware.

70. The *Globe* ran a story a few weeks ago about a Rhode Island boy who needed a heart transplant.[155] The point of the story was that Blue Cross/Blue Shield would not pay for his heart transplant,[156] but Blue Cross/Blue Shield should not have to pay for it, because there was a specific policy exclusion for heart transplantation.[157] The parents were given the option to purchase a rider that would have "topped up" the insurance to include a heart transplant but chose to not do so.[158] Why should Blue Cross/Blue Shield have to bear the financial burden of paying for a transplant that no one was willing to pay for on an actuarial basis? Are they the guardians of morality for society? Now, that is a hard-line approach to take, but insurers are not the core problem. It is not the insurer's obligation to pay for things that are not insured against. When you see stories about big bad Blue Cross/Blue Shield or big bad managed care, ask if the condition at issue was factored into the actuarial risk? When people claim that their insurance company will not pay for certain kinds of gene therapy that they want or need, ask yourself whether their insurance contract actually covered or excluded the particular type of procedure.

71. Most insurance companies insure only for "medically necessary care."[159] In most cases that means generally accepted or proven therapeutic procedures.[160]

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[154] *See, e.g., A Little Knowledge: Ethics of Genetic Screening*, ECONOMIST, Feb. 25, 1995, at 13, 15, *available in* 1995 WL 9568424 (discussing insurance companies' desire to know their insureds' predisposition to cancer so that "people [could] be sorted into different classes of risk, [and] those in the lower risk categories should pay lower premiums for the same cover").

[155] *See* Richard Morin, *R.I. Boy, 14, Dies Without New Heart*, BOSTON GLOBE, Feb. 15, 1997, at A6.

[156] *See id.*

[157] *See id.*

[158] *See id.*

[159] *See* Mariner, *supra* note 153, at 1516; *see also* Sarchett v. Blue Shield, 729 P.2d 267, 270-73 (Cal. 1987) (discussing typical "medical necessity" language in health insurance contracts).

[160] *See* Mariner, *supra* note 153, at 1516; *see also* Hendricks v. Central Reserve Life Ins. Co., 39 F.3d 507, 511 (4th Cir. 1994) (noting that the insurance policy at issue denied coverage for treatment or services which were not generally accepted medical practices); Healthcare Am. Plans, Inc. v. Bossemeyer, 953 F. Supp. 1176, 1186 (D. Kan. 1996) (quoting the policy at issue, which denied coverage for experimental, unproven or obsolete, investigational or educational procedures or treatments that were not generally accepted by the medical community). *See generally* Mark A. Hall & Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1644-48 (1992) (discussing the historical development of the "medical necessity" standard in health insurance policies).

Gene therapy, however, is not yet in that category. It is getting there and at some point will cross over the line and become medically accepted, but it is not right now. Gene therapy is in a transition phase, and it should surprise no one that insurance companies are denying reimbursement for treatment. How do insurers determine what is medically accepted, or therapeutic, and what is experimental? It is determined by expert medical opinion, and when experts differ interesting solutions develop.[161]

72. One example is autologous bone marrow transplantation ("HDC-ABMT") in women who have stage-four breast cancer.[162] Health insurers initially won most of the early cases challenging their refusal to cover HDC-ABMT, and did not have to pay for the procedure.[163] Then they started to lose cases because medical opinion shifted as the therapy became somewhat more accepted and efficacious.[164] The costs of this litigation and the public pressure associated with it were so high that Blue Cross and Blue Shield made a deal with its insureds. Blue Cross/Blue Shield pays for the treatment so long as the women receiving the therapy enter clinical trials to determine its efficacy.[165] This solution is interesting because a combination of public pressure and the costs of defending repeated litigation ended up shifting the insurer's opinion about whether it should pay for the therapy. At the end of a

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[161] *See, e.g.*, CLARK C. HAVIGHURST, HEALTH CARE CHOICES: PRIVATE CONTRACTS AS INSTRUMENTS OF HEALTH REFORM 125-35 (1995) (discussing various ways the insurance companies decide what procedures are medically acceptable and covered by policies or experimental and not covered).

[162] *See generally* Jody C. Collins, Comment, *Experimental Medical Treatments: Who Should Decide Coverage?*, 20 SEATTLE U. L. REV. 451 (1997) (examining case law and resulting legislation pertaining to HDC-ABMT as a treatment for breast cancer).

[163] *See, e.g.*, McLeroy v. Blue Cross/Blue Shield, 825 F. Supp. 1064, 1067 (N.D. Ga. 1993) (holding that the treatment was "experimental" or "investigational" and excluded by the plan); Boland v. King County Med. Blue Shield, 798 F. Supp. 638, 645-46 (W.D. Wash. 1992) (holding that coverage could properly be denied for beneficiary's cancer treatment because it was "experimental or investigational service"); Schnitker v. Blue Cross/Blue Shield, 787 F. Supp. 903, 906 (D. Neb. 1991) (holding that the insurer properly exercised its discretion in denying the insured's claim for high dose chemotherapy because the policy excluded investigative or unproven treatments).

[164] *See* Whitney v. Empire Blue Cross/Blue Shield, 920 F. Supp. 477, 487 (S.D.N.Y. 1996) (holding that HDC-ABMT was not experimental and, therefore, was covered); Bucci v. Blue Cross/Blue Shield, 764 F. Supp. 728, 733 (D. Conn. 1991) (holding that denial of benefits for high dose chemotherapy with autologous bone marrow transplant was arbitrary and capricious); Adams v. Blue Cross/Blue Shield, 757 F. Supp. 661, 672 (D. Md. 1991) (holding that high dose chemotherapy with autologous bone marrow transplant was not experimental and was covered by plan); Taylor v. Blue Cross/Blue Shield, 517 N.W.2d 864, 869 (Mich. Ct. App. 1994) (holding that in light of medical testimony indicating HDC-ABMT is an effective treatment for breast cancer and that breast cancer patients who are treated with HDC-ABMT have a better prognoses than those who receive only conventional treatment, the treatment is not experimental in nature).

[165] *See* Curt Suplee, *Blue Cross Agrees to Fund Breast Cancer Experiment: Women to Undergo Bone Marrow Transplants*, WASH. POST, Nov. 13, 1990, at A1.

reasonable period of time, this outcome data will help to answer the question of therapeutic effectiveness. That is not a bad solution, but it takes time. Women who want the treatment nonetheless have a chance to receive it while the whole question of whether the procedure is therapeutic or efficacious is being worked out. A lot of anxiety and uncertainty on the part of both sides surrounds these issues, but resolution of coverage questions will come as science determines the effective scope of gene therapy.

73. At the same time, insurance companies are weary of getting into "battles of the experts" over the medical acceptability of particular therapies. In response, they typically insist on covering only medically necessary procedures and usually specifically exclude experimental or investigational therapy.[166] The same controversies will come up again and again unless insurers more clearly define what they mean by experimental or investigational. Now they define these terms by some specific experimental exclusions, leaving the larger question of what constitutes experimental therapy unresolved. They may specifically pay for HDC-ABMT, but not for heart transplants, the issue in that Rhode Island story.[167] If you want coverage for heart surgery, then you must pay a higher premium because the financial risk is higher.[168] That is not unreasonable. I think Blue Cross/Blue Shield is still not-for-profit in Rhode Island. Other insurance companies are beginning to define medically acceptable procedures by deferring to some other group of payors or to an expert body.[169] They want to stop having to litigate over cutting-edge therapies. Those interested in gene therapy should be thinking about getting it covered by insurance. This could involve designating an appropriate regulatory body to decide the issue and convincing insurers that avoiding reimbursement controversies will enhance their bottom lines.

74. What is the role of the industry standard of care? By that, I mean the malpractice standard of care that a physician must meet by treating similar patients similarly. What if a professional is routinely administering a drug that the FDA still defines as investigational, but which has become the de facto standard of

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[166] *See, e.g.*, Caudill v. Blue Cross & Blue Shield, 999 F.2d 74, 80 (4th Cir. 1993) (upholding the insurers' decision to deny coverage, given the policies' exclusionary provisions); HAVIGHURST, *supra* note 161, at 125-32. *But see* Ponder v. Blue Cross, 193 Cal. Rptr. 632, 635-36 (Cal. Ct. App. 1983) (rejecting the insurer's coverage denial because the policy's specific exclusion of the disease, temporomandibular joint syndrome, was not worded in layperson terms). *See generally* Frank P. James, *The Experimental Treatment Exclusion Clause*, 12 J. LEGAL MED. 359, 365 (1991) (arguing that insurers' practices of clearly listing specific exclusions in insurance policies are completely defensible under contract law).

[167] *See* Morin, *supra* note 155, at A6.

[168] *See id.*

[169] *See* HAVIGHURST, *supra* note 161, at 130-32.

care for a particular disease? Much of current cancer therapy takes place with investigational drugs.[170] Insurers can be vulnerable to the claim that experimental drugs are actually therapeutic. If all oncologists are administering an investigational drug to their cancer patients, it has become the industry standard of care regardless of its technical label. There is a powerful argument against an insurance company denying coverage for the drug only because the therapy is technically still labeled investigational when in fact it is the state-of-the-art standard.

75. The first step in determining who will pay for genetic therapy is to analyze an insurance contract and figure out whether the particular genetic procedure is covered. The second step is to determine whether a legislative or public policy overrides the basic contract principles that would otherwise govern. For example, many states mandate certain insurance benefits.[171] In Massachusetts, insurers must offer, among other things, a certain level of outpatient mental health benefits and infertility treatments.[172] Many infertility clinics relocated to the Massachusetts area simply because the treatments are statutorily required to be covered here. This makes them more widely available and, as a direct result, increases health insurance premiums in the Commonwealth.[173] A negative effect of the extraordinarily rich array of mandated benefits in Massachusetts is that more and more employers simply stop offering health insurance coverage altogether because it becomes too expensive[174] or they self insure so they can take advantage of the federal ERISA override of state health insurance regulation.[175]

76. More than half of the insured patients in this country are insured under ERISA qualifying plans and are, therefore, not covered by state-mandated

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[170] *Cf.* Hilary Stout & Laurie McGinley, *Cancer Drugs To Get Speedier FDA Review*, WALL ST. J., Mar. 29, 1996, at B1 (discussing FDA efforts to speed up federal approvals and increase the availability of experimental therapies to cancer patients).

[171] All fifty states have mandated benefits statutes. *See* Maria O'Brien Hylton, *Insurance Risk Classifications After McGann: Managing Risk Efficiently in the Shadow of the ADA*, 47 BAYLOR L. REV. 59, 75 (1995) (discussing various statutes and the benefits mandated).

[172] *See* MASS. GEN. LAWS ch. 175, § 47B (1987) (requiring certain minimum mental health benefits); MASS. GEN. LAWS ch. 176B, § 4J (Supp. 1990) (requiring coverage for expenses incurred from the diagnosis and treatment of infertility).

[173] *See* Diane E. Hoffmann, *Emergency Care and Managed Care: A Dangerous Combination*, 72 WASH. L. REV. 315, 395 (1997) (noting insurers' criticism of the costs imposed by state mandated health insurance benefits).

[174] *See* Hylton, *supra* note 171, at 75-77 (noting that mandates are an attractive device because they do not require a tax increase, but arguing that they interfere with insurance markets and ultimately encourage employers to stop offering insurance altogether).

[175] *See id.* at 77-79.

benefits.[176] The ERISA override excludes insurance plans from state tort liability for plan negligence as well.[177] It is a win-win proposition for health insurance companies and, perhaps, a lose-lose proposition for patients. The predictable result of mandating benefits is driving more employers to drop health insurance or to self-insure to avoid the mandate.[178] This means that in the end, fewer people actually get access to that mandated benefit.[179] At the federal level, ERISA basically nullifies state legislation for ERISA-qualifying plans. There is at least one mandated benefit on the federal level, however, that reaches all female insureds: the forty-eight hour maternity stay.[180] The private health insurance industry deserves a large share of the blame or praise, depending on your point of view, for defeating universal health insurance coverage.[181] It does not just fall over and play dead with respect to mandated benefits or universal coverage, but fought back to defeat the Clinton reforms of health insurance.

77. The final area to look at, and one within the federal arsenal of legislation, is the Americans with Disabilities Act ("ADA").[182] There has been much discussion here and elsewhere about applying the ADA to genetic therapy.[183] Many people

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[176] *See* Anne Marie O'Keefe, *Will ERISA's Wall Come Tumbling Down?*, BUS. & HEALTH, Feb. 1, 1995, at 35 (noting roughly half of all privately insured employees in the U.S. are covered under self-funded, ERISA-qualifying plans).

[177] *See* Metropolitan Life Ins. v. Taylor, 481 U.S. 58, 62-63 (1987) (holding that ERISA preempted common law tort claims).

[178] *See* Hylton, *supra* note 171, at 77-79 (predicting that the added costs of mandated coverage to employee insurance would drive more employers to switch to self-insurance schemes to avoid the mandates).

[179] *See id.* at 75.

[180] *See* 29 U.S.C. § 1185 (1996) (requiring insurance companies to cover forty-eight hours of care following a vaginal birth and ninety-six hours following a cesarean birth).

[181] *See* Katherine Eban Finkelstein, *Insuring Children: Health Care Reform Writ Small*, NATION, Mar. 3, 1997, at 18, 19 (stating that private insurance agencies spent $100 million to defeat the national health reform plan).

[182] 42 U.S.C. §§ 12101-12213 (1995).

[183] *See* Larry Gostin, *Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers*, 17 AM. J.L. & MED. 109 (1991) (analyzing the legality of genetic discrimination under the ADA and proposing an amendment to cover genetic discrimination); Frances H. Miller & Philip A. Huvos, *Genetic Blueprints, Employer Cost-Cutting, and the Americans with Disabilities Act*, 46 ADMIN. L. REV. 369 (1994) (discussing restraints which may or may not be imposed by the Americans with Disabilities Act on the acquisition and use of information revealing genetic abnormalities).

theorize that the ADA might have some role here.[184] I am not one hundred percent sure they are correct, but it could be another useful tool to secure wider application of genetic therapy.

78. Gene therapy is basically still technically experimental or investigational. As I have already said, it has not crossed that line into being considered medically acceptable or therapeutic yet. But, when we start crossing that line, we should distinguish among the various issues that have been articulated and discussed today. There is a difference between genetic therapy and genetic screening. The case for genetic screening of population as medically acceptable or reasonable is very, very dubious. The case for genetic testing of individuals is easier, especially with respect to certain familial traits. A story in the *Boston Globe* today about genetic therapy makes the point that without counseling, both screening and testing can be deleterious to patient health.[185] You have to insure genetic counseling as well whenever you do testing and screening. That means someone has to pay for it.

79. Most people believe that cosmetic surgery costs ought to come out-of-pocket for patients, unless there are severe psychiatric ramifications from the cosmetic condition. I would think that most genetic testing and screening at this stage would fall into the category of "do not fix what is not broken." If there is a psychiatric overlay to the situation, then you can justify genetic testing and screening as medically necessary, perhaps, and you might wish to alter the germ line for future generations; but, that is another story. In conclusion, I do not think genetic testing, screening, or therapy will occur on a widespread basis, unless it makes sense on the bottom line. Thanks.

Question and Answer Session

Paula Campbell:

80. Several issues have arisen in this discussion and one of the major ones is the difference between using gene therapy for therapeutic applications and using it for enhancement applications. My first question to the panel is: What should be the regulatory role? Should gene therapy permit therapeutic applications but deny enhancement?

Gina Maranto:

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[184] *See id.*

[185] *See* Lawrence L. Knutson, *Genetic Testing Protections Sought*, BOSTON GLOBE, July 15, 1997, at A3 (noting that genetic testing can be potentially life-saving).

81. Yes. In fact, there is a precedent that has been set: the RAC[186] approved a proposal by doctors at the NYU-Cornell Medical Center to do gene therapy experiments using normal subjects. The people are not ill; they are being asked to test a viral vector.[187] This opens the possibility for future enhancement, and I think there ought to be regulatory steps taken to prevent anything but therapeutic uses, either at the somatic level or at the germ level.[188]

Charles R. Cantor:

82. I think that where you draw the line gets sticky. The question is: Why would one not permit enhancement? I am not sure that the regulatory approach that I see is a prohibition approach. Assuming the technology existed, is there any reason why we would not allow people to become smarter?[189]

Leonard H. Glantz:

83. First of all, I think it is a bogus concept. I do not think that multi-genetic traits are accessible to treatment by genes.[190] That is part of the problem. Yes, we have a genetic predisposition, but environmental factors play an enormous role in virtually all diseases.[191]

Frances H. Miller:

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[186] The Recombinant DNA Advisory Committee ("RAC") is an NIH panel that approves gene therapy trials funded by the government. *See* Robert Lee Holtz & Thomas H. Maugh II, *Biotech: the Revolution is Already Underways*, L.A. TIMES, Apr. 27, 1997, at A1; Michael Unger, *Eyes on the Future: New Drug-Making Labs Give LI a Role in the 21st Century*, NEWSDAY, Nov. 24, 1997, at C8.

[187] *See* Holtz & Maugh, *supra* note 186, at A1.

[188] Robert Wivel, director of the RAC, says that for now, the RAC "will not consider any protocols to attempt germ-line gene therapy or enhancement." Robin Herman, *Tinkering with the Essence of Humanity; Scientists and Theologians Debate the Morality of Genetic Engineering*, WASH. POST, Oct. 8, 1991, at Z6.

[189] *But see id.* Wivel argues that through enhancement engineering, the human race "would lose a firm sense of its own characteristics." *Id.*

[190] W. French Anderson, a leading expert and pioneer in gene therapy, refers to this as eugenic genetic engineering. *See Hearings*, *supra* note 11, at 285. Anderson believes that eugenic genetic engineering will not be feasible in the near future and is so complex, it may never be feasible. *See id.* at 288.

[191] *See* FY98 Labor HHS Appropriations, 105th Cong. 713 (1997) (statement of Kenneth Olden, Dir., Nat'l Inst. of Envtl. Health Sci. ("NIEHS"), stating that because virtually all diseases have both a genetic and environmental impact, the NIEHS was setting up a new Environmental Genome Project to study the connection between the two).

84. If that is true, however, then we do not need regulation because we cannot do it. You only need regulation if genetic intervention works.[192]

Gina Maranto:

85. That is a very different question. The question is: How do you regulate that which is either unknown or used for enhancement purposes? The answer is that we cannot do it. It is a technical issue of what we can and cannot do.

Charles R. Cantor:

86. Suppose that we do not try genetic intervention because we do not quite know what the results will be. There is an ethical reason to at least try genetic intervention. We try experimental therapies for cancer because we do not have any other options. Here is an example. Suppose I want to do gene therapy so that someone who would otherwise be predisposed to skin cancer can get a good suntan without the risk of skin cancer. There is nothing that is being solved, addressed, or treated. What is the social value of spending money on that?

Gina Maranto:

87. We have very scarce medical dollars. Why should we be spending money on someone who wants to get a suntan but has a predisposition to cancer?

Leonard H. Glantz:

88. Do you think that breast implants should be outlawed?

Gina Maranto:

89. No.

Leonard H. Glantz:

90. Why should scarce medical dollars go towards that? It uses up medical resources.

Gina Maranto:

91. I do not think insurance pays for that.[193] Insurers do not even pay for reconstructive surgery after breast cancer anymore.[194]

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[192] Somatic-cell gene therapy and enhancement engineering are now technically feasible. *See* Herman, *supra* note 188, at Z6.

[193] *See* HAVIGHURST, *supra* note 161, at 141 n.19 (stating that most comprehensive insurance contracts exclude "cosmetic surgery undertaken solely for purposes of beautification").

[194] *See generally* Christine Nardi, Comment, *When Health Insurers Deny Coverage for Reconstructive Surgery: Gender Meets Disability*, 1997 WIS. L. REV. 777, 780-83 (1997).

Charles R. Cantor:

92. But that raises a question of reimbursement, not of regulation. I think neither the government nor the insurance companies should pay for genetic enhancement, just as they should not pay for any cosmetic matter. But the question of regulation, I assume, deals with the issue of whether or not scientists, technicians, or physicians can actually do it.

Gina Maranto:

93. You have no problem at all with regulation? You think everything should be unregulated?

Charles R. Cantor:

94. I do not think that I said that. I do not think that everything should be unregulated.

Gina Maranto:

95. So if we can regulate, why not regulate uses of the technology which we feel are socially unacceptable?[195]

Leonard H. Glantz:

96. The question is: How does one determine what is socially unacceptable? I would be willing to regulate germ-line therapies, for example, and prohibit it until a good risk assessment device was devised. There is a risk not only to the individual now, but also to a future individual. I think we have to look at the risks and not just ask about social utility. We should ask about social utility when we make and draw questions about payment and who should pay. Individuals can make their own utility determinations. I want to ask Dr. Cantor: When did sex selection become socially acceptable?[196]

Charles R. Cantor:

97. What I mean by socially acceptable, I do not mean by society-at-large. There is at least a subset of society that is practicing this rather broadly.[197]

Gina Maranto:

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[195] *See generally* Thomas O. McGarity & Karl O. Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 463 (1983) (discussing regulation of genetic engineering).

[196] *See* Evans et al., *supra* note 124, at 1098; Frienkel, *supra* note 124, at C6.

[197] *See* Owen D. Jones, *Sex Selection: Regulating Technology Enabling the Predetermination of a Child's Gender*, 6 HARV. J.L. & TECH. 1, 11-18 (1992) (discussing how sex selection abortions are widely used in China and India, but that no one knows the actual extent sex selection abortions are performed in the U.S.).

98. Charles, I think it is almost impossible to have a doctor perform a sex typing for you and then perform an abortion. I mean reproductive clinics and OB/GYNs simply will not do it.[198]

Charles R. Cantor:

99. I may have accessed a biased sample, but I know a few physicians who admit to doing this regularly.

Leonard H. Glantz:

100. I do not think that makes it acceptable. There are people who do all sorts of things, but it is a big step to go from it being done to the fact that it is acceptable.

Paula Campbell:

101. At this point, we will open up the discussion to questions from the floor.

Audience Member:

102. Since I first heard about Dolly,[199] I was thinking, "why anyone would try to use this technology on humans." The one case in which I could see the government actually condoning the use of gene enhancement is for military use to produce a more efficient fighting machine in the form of human bodies. What does the panel think about the ethical ramifications of that?

Gina Maranto:

103. Actually, it is interesting because when artificial insemination began to be widely used in the 1930s, speculation about making a superior fighting force was rampant. The notion was that you would take superior male sperm and make this army of superior soldiers. I think this technology is going to be used by individuals much more than by governments.

Charles R. Cantor:

104. I think military obsolescence will occur in far less than twenty years. So, I do not think that it will be used.

Leonard H. Glantz:

105. I think this is an efficiency question. It is such an inefficient way of producing anyone or anything. There are better ways of making people into fighters, killers, or whatever you think armies turn people into, and it is hard to imagine what the ultimate benefit would be to use cloning for this. I would be surprised if it

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[198] *See* Frienkel, *supra* note 124, at C6.

[199] *See supra* note 8 and accompanying text.

were ever a problem. Is it unacceptable for armies to use physical fitness plans, like push-ups and running and all that sort of stuff, to make people into better fighters?

Audience Member:

106. I think about this from the standpoint of when cloning is a commercially viable alternative. There is already a precedent for the military acting outside the realm of what we, as a society, might generally condone. So the military and other governmental bodies, such as the Central Intelligence Agency, have set themselves apart from the ethical norms of our country. They have done things that we would never consider appropriate, if it were not for world peace or our national interest. I think there are people in the Pentagon who are currently thinking about how this could be used. They certainly have the money to do it and a great deal of time on their hands.

Gina Maranto:

107. A far more reasonable scenario is using gene therapy to make someone immune to mustard gas. Then, give everyone in the military that gene therapy and start using mustard gas as a weapon. It is similar to what agribusiness is doing now. We can make a plant that will be immune to a particular herbicide.[200] Now we can take this plant, plant it, and dose the fields with the herbicide.[201]

Leonard H. Glantz:

108. But, would that be different or worse than developing a drug that people in the Army could take? The Army would use mustard gas and the soldiers would be immune. The reason I think that is interesting is because there is something about these genes that really bother us. For some reason, if we could do a genetic manipulation that would make us immune to mustard gas, which I assume the Army would use, it seems to have a different effect than if we had a drug that people could take, or substances that people could take, which would make them immune to it. There is something about gene therapy that makes us think of armies in a different way than just physical fitness programs. I am not sure what it is. Is it nature verses interfering with nature? There is something very elemental about that. This requires serious social discussion. For example, before anyone could do enhancement, assuming that enhancement would be legal, I think there would have to be a body of people who determine that it would not offend basic social values.

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[200] *See, e.g.*, Peter Fritsch, *Plastic Products From Peter Piper's Peppers?*, WALL ST. J., Mar. 12, 1997, at B1 (stating that Monsanto labs have developed "transgenic plants that are immune to herbicides and resist insects").

[201] *See, e.g.*, Charles Conner, *Agribusiness: Cotton Weathers Spring Via Herbicide Resistance*, THE COM. APPEAL, June 14, 1997, *available in* 1997 WL 10383365 (discussing the use and success of herbicide resistant plants).

There would be things that would offend social values, such as sex selection abortions, to which we would say, "No, you cannot do that."

Gina Maranto:

109. I think the problem is that we have no mechanism for dealing with thorny biological problems. For instance, there is a great deal of consensus that post-menopausal women should not have children,[202] not because of the age issue, but because it is fundamentally wrong to reverse a woman's natural cycle.[203] Also, there is a great deal of opposition to storing a dead man's sperm and then looking for a surrogate mother to carry the child.[204] Recently, there was a story in the paper about a couple who had their son's sperm and were looking for someone to bear their grandchildren.[205] These issues have been raised by this technology. The same thing is going to happen with gene therapy. How are we going to grapple with these things? Institutionally, we can sit around on panels and discuss them, but how are we, as a society, going to implement any kind of change? That is why I think right now gene therapy should be regulated; then, everyone should sit down and discuss it.

Leonard H. Glantz:

110. The question is: Should you institute regulations and then discuss it, or discuss it and then institute regulations? I agree with you entirely that there is no locus for it. I think it is a question of where that discussion happens–how one involves society and creates a consensus. Of course, I think that if you told people that they could become smarter without a risk, people would not have a problem with that.

Gina Maranto:

111. What about the access to that technology? That is going to be a huge problem with this, just as there was with in vitro fertilization ("IVF").[206] IVF is

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[202] *See, e.g.*, Margaret Carlson, *The 2000-Year-Old Mom*, TIME, May 5, 1997, at 28 (discussing public reaction to post-menopausal births); Susan Reimer, *Mom's Fair Game, But Don't Kid Dad*, FLA. TODAY, May 11, 1997, at D1.

[203] *See, e.g.*, Carlson, *supra* note 202; Reimer, *supra* note 202.

[204] *See* Kathleen Parker, *The Race is on for Men's Liquid Assets*, FLA. TODAY, June 2, 1997, *available in* 1997 WL 10726972; Mark Sauer, *Never Say Die: Troubling Questions Surround the Technology of Harvesting Sperm*, SAN DIEGO UNION-TRIB., Nov. 9, 1997, *available in* 1997 WL 14533618.

[205] *See* Marilynn Marchione, *New Turn in Couple's Quest for Grandchild: Couple Say They Won't Consider Single Women*, MILWAUKEE J. SENTINEL, June 15, 1997, *available in* 1997 WL 4802887.

[206] *See* BLANK & MERRICK, *supra* note 19, at 87.

covered in Britain and Australia,[207] and if you look at the class and the socio-economic distribution of those individuals who have access to the technology, it is broad. If you look in this country, it is only those people with high incomes who can afford IVF,[208] except for the few states that include it as part of their mandated benefits.[209] IVF technology is usually not covered by insurance; thus, it is an out-of-pocket expense.[210] If you have a technology and you know it is like the AIDS drug, that is alright. But, if you have a gene therapy treatment that can make someone smarter, how much do you think they are going to charge for that? Is it going to be inaccessible to all but the very wealthy? Then we will have an even greater divide between people.

Leonard H. Glantz:

112. I think there are two answers to that. One, is that it will be accessible to the very wealthy at first. Computers were first available to the very wealthy and now they are available to the less wealthy and someday they will be available to the not wealthy because that is how markets work. When capitalists run out of one part of the market, they go to others. The other issue is: Why would we focus on the economic injustice here? We might be able to make an economic injustice argument for IVF, for housing, and for education. Why should we particularly focus on this with gene therapy? We know rich children get a better education and are subject to more educational enhancement than poor children. I do not hear anyone saying that, therefore, rich children should not get that.

Gina Maranto:

113. Yes, but there is a general feeling that books, television, and movies are fairly accessible. There is a general feeling that even the poor, under the right circumstances, could obtain this.

Leonard H. Glantz:

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[207] *See* INTERNATIONAL SURVEY OF LAWS ON ASSISTED PROCREATION 9, 184 (Jan Stepan ed., 1990).

[208] *See* BLANK & MERRICK, *supra* note 19, at 227.

[209] *See, e.g.*, 215 ILL. COMP. STAT. ANN. 5/356m (West 1992); MD. CODE ANN., INS. § 15-810 (1997); MASS. GEN. LAWS ch. 175, § 47J (1989). *But see* CAL. INS. CODE § 10119.6 (West 1990) (exempting in vitro fertilization from coverage).

[210] *See Biofertec Develops New In-Office Infertility Treatment That Costs Roughly 1/3 Less Than In-Vitro Fertilization*, IN VIVO BUS. & MED. REP., June 1, 1996, *available in* 1996 WL 9153300 (reporting that "60% of the couples pay their own fertility bills due to lack of insurance coverage"). *But see* John Dwight Ingram, *Should In Vitro Fertilization Be Covered by Medical Expense Reimbursement Plans?*, 7 AM. J. FAM. L. 103, 104 (1993) (stating that many courts do not consider IVF experimental and, therefore, do not allow medical expense reimbursement plans to exclude it).

114. People may feel that way, but I think that they are not correct. What the poor and the people who go to the library are able to get is fine and good, but it is the basic line under below which we think people should not fall. They are not getting private tutors, if that is what people think of as "good." They are not getting a summer in France. They are not getting various other things that wealthy children get. The Ivy League colleges are not an egalitarian place. I am not opposed to egalitarianism; the question is, why should we focus on this particular technology to draw our egalitarian line? Fran Miller will not give poor kids heart transplants– that is how tough she is.

Audience Member:

115. I have a question for Professor Miller. Transplants can involve long-term mechanical means of maintenance while somatic-gene therapy does not. Why are the insurers not more in favor of paying for the therapy? The therapy removes the disease forever. Ultimately, this would save the cost of the treatment for one of these mono-diseases about which Gina was talking. Get your treatment when you are young and it is over. There is no ongoing payment by insurers. Does the patent system increase the price of that treatment so that if the insurer amortizes it over the healthy life of the individual, the insurer loses money?

Frances H. Miller:

116. No. First, assume that the drug company is willing to price the treatment at a loss to begin with; volume can enable it to get it all back later. In the long run that would be fine, because then it will make economic sense. Do not forget, if you keep the patient healthy with respect to that disease, then that patient is going to keep living with, perhaps, other diseases. Are we saving someone at the age of seventy, in which case we need to be careful because he is going to live longer with some other chronic problems, or are we saving a newborn? As soon as it makes economic sense for insurers to cover it, believe me, they will cover it.

Leonard H. Glantz:

117. Remember, the insurance companies do not set the price. The industry will charge whatever the market will bear, and the market will be based upon what consumers demand. The history of drug development in this country is not a history of cheaper and cheaper drugs. I think that our experience has taught us that technology makes health care more expensive. The thought that technology will make it less expensive is not true. The other thing is that somatic therapy is not a one-time event.[211] If the treatment only requires being done once, it probably would not be developed. This is the reason why the pharmaceutical industry is not

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[211] *See* Andrew Pollack, *Gene Therapy's Focus Shifts from Rare Illnesses*, N.Y. TIMES, Aug. 4, 1998, at F1, F6 (stating that "a one-time cure for a rare disease might offer less chance of profit").

interested in developing vaccines.[212] In terms of marketing, birth control pills are a good thing because they are bought every month; but a drug that you inject only once and then never need again is something that the industry is really not that interested in.

Frances H. Miller:

118. I just want to add one other thing. Look at the cost of drugs in western European countries. They are minuscule compared to what they cost here for the same drug, the same everything.[213] Why? It has to do with who will pay for it, what they will pay, and the bargaining power of nationalized medical delivery systems.[214] The differences are startling.

Audience Member:

119. I have a question for Professor Miller. I want to know the details of the bargain struck between the insurer and the breast cancer patients seeking autologous bone marrow transplants.[215] I want to know if they were all part of the experimental group or if some were sent to a control group?

Frances H. Miller:

120. The nationwide study, directed by the National Cancer Institute and underwritten by the Blue Cross and Blue Shield Association, is sponsoring three large national trials to study whether autologous bone marrow transplants are preferable to and more effective than regular chemotherapy.[216] You cannot get reimbursed for the treatment unless you are in a clinical study so that Blue Cross and Blue Shield can get the outcome data.[217] Researchers are having a hard time enrolling participants in the trials because some of the patients will receive ABMT and some will receive chemotherapy.[218] Many patients want cutting-edge health care and will not settle for anything less.

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[212] *See* DONALD DRAKE & MARIAN UHLMAN, MAKING MEDICINE, MAKING MONEY 82 (1993) (claiming that "[d]rug companies can make more money from drugs that keep alive the terminally ill . . . than from a low-cost vaccine for a child").

[213] *See id.* at 85-101 (discussing how tight government controls keep European drug prices at a minimum compared to prices in the United States).

[214] *See id.*

[215] *See supra* notes 162-65 and accompanying text.

[216] *See* Suplee, *supra* note 165, at A1.

[217] *See id.* at A8.

[218] *See NBC Nightly News: Profile* (NBC television broadcast, June 3, 1996), *available in* 1996 WL 10301877.

Audience Member:

121. Correct me if I am wrong, but I have the impression from several of the panel members that some of the ethical concerns we have are delayed or depressurized because this is an economically inefficient technology. Is that correct? If it is, my question is: If the technology changes and it becomes very efficient, will we see more of it?

Frances H. Miller:

122. I am sure of it. You cannot pick up a newspaper without seeing some breakthrough and that creates pressure on the part of the patients to go to their doctors and say, "What is this?," and it all builds up.

Audience Member:

123. The follow-up question is: Who do you foresee as actually instituting laws or regulations, to the extent that those are deemed necessary?

Charles R. Cantor:

124. I have always felt that the first step here is to educate the public because the public is fairly ignorant in this area, present company, perhaps, excluded. One of the serious factors is that people respond to the word "gene" or "genetic" as an intrinsically bad thing, like "nuclear toxic waste."[219] There is a reason for that: namely, a lack of education. Until we have an informed public, I do not see how you can go forward with it.

Leonard H. Glantz:

125. I think we have to go further than to say that there is no reason for that reaction. There is a reason for that reaction and there is a place where that reaction comes from. It is not because the technology is bad or can only be used for bad things. There is a history of eugenics, a history of trying to create human beings by government.[220] The public has a sense of inequity when it comes to the appropriate allocation of resources. The idea of tinkering with genes and determinism, of discovering what is innate and what is cultural, really does matter. We can learn about it, we can understand it, but until we really understand the social meaning of genetics, I do not know that the public will just say, "Oh, Okay."

Charles R. Cantor:

126. I think it has filtered through so many decades that people cannot intellectualize their feelings on the subject.

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[219] *But see Gene Therapy's Future*, *supra* note 91, at 1101.

[220] *See* Lombardo, *supra* note 14, at 1.

Leonard H. Glantz:

127. But I think that is the question. There is a question of outcomes and there is a question of means, most of which have to be addressed. The question of what people can pass laws for, though, and what is actually constitutionally protected is a really interesting one. Mostly, we find unacceptable and unconstitutional laws that regulate people's reproductive behaviors.[221] States will need a really good social harm argument to outlaw reproductive behaviors and the upbringing of children.

Gina Maranto:

128. But, there is one thing that has always perplexed me about the reproductive rights argument. The right to procreate is not the same thing as the right to access the technology. People have the right to attempt to get pregnant. We have the right to the pursuit of happiness, but everybody does not have the right to a liver transplant.

Leonard H. Glantz:

129. I think it is a good and an important question and one that has not been answered. John Robertson takes a very extreme view that anything that helps people reproduce, or have offspring, or bear children is acceptable.[222] I said to him once, "Well, what about kidnapping? If that is the only way people can get kids, what do you think of that?" He said, "Well, you know, that is not okay because obviously it harms the reproductive rights of others to rear their own children." Thus, he would not say that you could do absolutely anything to help yourself have children. Suppose a woman, however, is infertile because her fallopian tubes are blocked. Can the state say she cannot have her fallopian tubes opened? And the question is: Is that a technology? Right now she cannot have children, but she could with the help of doctors. Then the question is: Why would the state be able to say to a woman, "No, you can't"? What is the state's overriding interest on either a rational basis or some compelling basis that would say to a woman, "You can't do this"? It is hard to think of one, although, in her case, she certainly needs the assistance of technology to bear children.

Gina Maranto:

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[221] *See, e.g.*, Roe v. Wade, 410 U.S. 113, 159 (1972) (establishing the constitutional right of a woman to have an abortion); Griswold v. Connecticut, 381 U.S. 479, 481-86 (1965) (establishing a married couple's right to obtain and use birth control).

[222] *See, e.g.*, ROBERTSON, *supra* note 36.

130. The state does say to people who are on welfare that they have to go on Norplant.[223] The state is intervening in people's reproductive rights.[224]

Leonard H. Glantz:

131. No, the state certainly does not say that they have to go on Norplant.[225] That is not correct. What the state does is condition benefits based on people doing things.[226] That is very different from the state outlawing somebody from being able to undergo a process to open up fallopian tubes.

Gina Maranto:

132. The effect is the same.

Leonard H. Glantz:

133. The idea of conditional spending by states is really a very different issue than the question of mandating or outlawing access to something. It is very clear, for example, that while the state may not prohibit a woman from having an abortion,[227] the state certainly does not have to pay for it.[228] But how is this any different from IVF? That is the Robertson argument.

Michael Baram:

134. I want to thank everybody for joining in the discussion and the panel speakers for doing such a great job in enlightening us. Thank you.

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[223] *See* David S. Coale, *Norplant Bonuses and the Unconstitutional Conditions Doctrine*, 71 TEX. L. REV. 189, 189-90 (1992) (stating that many states provided either reimbursement for the cost of Norplant to women on AFDC or a cash bonus for those women who agreed to be implanted with the device).

[224] *See id.*

[225] *See id.*

[226] To receive welfare benefits, the women had to use Norplant. *See id.*

[227] *See* Roe v. Wade, 410 U.S. 113, 159 (1972).

[228] *See* Harris v. McRae, 448 U.S. 297, 317-18 (1979) (establishing that while the Constitution protects a woman's right to have an abortion, it does not entitle her to the funds necessary to have one).