AVERTING THE CLONE AGE: PROSPECTS AND PERILS OF HUMAN DEVELOPMENTAL MANIPULATION

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INTRODUCTION

New biotechnologies developed over the past three decades, together with changes in the public discourse around reproductive and reparative medicine, have led to an accelerated deconstruction of the notion of the human. Whereas biological, anthropological, philosophical and sociolegal definitions of human identity before this period were hardly consonant with each other, they were all constrained and unified by the inherent grounding of human identity and individuality in human biology. Members of the human species have a common, and coherent, evolutionary history and therefore a shared genome, which up to now has been subject to random shuffling, but not purposeful replication or manipulation.[1] The *uniqueness* of human individuals is also due in part to genetics, specifically genetic variation. Correspondingly, the legacy of all persons having resulted from a genetic "roll of the dice," and being therefore biologically unprecedented, has also contributed to the shared human condition. Finally, while there have been ambiguities and disagreements over whether certain naturally-occurring human organisms, such as embryos or the "brain-dead," are part of the human community, it has previously not been possible to fabricate quasi-human entities for particular uses.

This is all changing. The capacity afforded by biotechnology to manipulate the human embryo at its early stages, including its genetic material (DNA), has placed the notion of a common humanity up for grabs. Modification of the early embryo, referred to in what follows as "developmental" modification or manipulation, is unlike

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1. *See* RICHARD LEWONTIN, HUMAN DIVERSITY, (Scientific American Books 1982), *and* L. LUCA CAVALLI-SFORZA *et al*., THE HISTORY AND GEOGRAPHY OF HUMAN GENES (Princeton University Press 1994).

manipulations of the fully formed individual, including provision of artificial limbs, heart valve and joint replacements, cosmetic surgery, and even "somatic" (differentiated body cell) gene therapy. Developmental modification changes the generative trajectory of the individual and turns it into something *intrinsically* different from what it would have become without the manipulation.[2] With these procedures there is no guarantee that even the original species-character will be maintained.[3] Although one objective in applying such methods to our own species may be to fabricate improved humans, in some cases, by accident or by intent, the outcomes will be quasi-human or less than human.

Apprehensions concerning such prospects were raised by a number of speculative writers of acute technological and social foresight at the dawn of the Industrial Revolution.[4] Hints of these concerns can be found even earlier.[5] In our own period, these prospects have been the subject both of warnings[6] and enthusiasm.[7] This paper will outline the

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2. See Stuart A. Newman, *The Hazards of Human Developmental Gene Modification*, 13 GENE WATCH 10, (2000). The earlier during development a change is made, the more thoroughgoing is the alteration of the organism. Very early developmental manipulations, such as those involved with cloning and germline modification, inevitably alter the development of the brain.

3. For biological aspects of species identity and alteration *see* Stuart A. Newman, *Carnal Boundaries: The Commingling of Flesh in Theory and Practice* in LYNDA BURKE AND RUTH HUBBARD, REINVENTING BIOLOGY: RESPECT FOR LIFE AND THE CREATION OF KNOWLEDGE 191-227 (Indiana University Press 1995). For legal aspects *see* George L. Annas *et al*., *Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations,* 28 AM. J. LAW MED. 145, 151 (2002).

4. *See* Mary Wollstonecraft Shelley, Frankenstein (Modern Library 1984); H.G. Wells, The Island of Doctor Moreau (William Heinemann 1896); Aldous Huxley, Brave New World (Doubleday 1932).

5. *See* CHAYIM BLOCH, THE GOLEM (John Vennay 1925) which describes the medieval Jewish legend of a fabricated man.

6. *See* Lori B. Andrews, The Clone Age: Adventures in the New World of Reproductive Technology (Henry Holt & Co. 1999). *See also* Francis Fukuyama, Our Posthuman Future: Consequences of the Biotechnology Revolution (Farrar Straus & Giroux 2003) *and* Bill McKibben, Enough: Staying Human in an Engineered Age (Henry Holt & Co. 2003).

7. *See* Lee M. Silver, Remaking Eden: Cloning and Beyond in a Brave New World (Avon Books 1997); Allen Buchanan *et al*., From Chance to Choice: Genetics and Justice (Cambridge University Press 2002); *and* Gregory Stock, Redesigning Humans: Our Inevitable Genetic Future (Houghton Mifflin 2002).

scientific background to these new capabilities and provide a realistic assessment of how quickly we are approaching the "clone age."[8] In addition, it will consider what measures may be taken to avert its most negative aspects. To this end, changes in the relevant science over the last thirty years will be reviewed, both in its technological achievements and in the socioeconomic dimensions of its conduct. The paper will conclude with specific recommendations on how ill-considered manipulation of human biology may be prevented.

II. RAMPING UP TO THE CLONE AGE: TECHNOLOGICAL ASPECTS

Beginning in the late 1970s, the field of human reproductive medicine began to utilize methods of *in vitro* fertilization (IVF) and embryo implantation that up until then had been the exclusive province of animal breeders.[9] The success of these techniques in livestock production were grounded in mid 20th century scientific progress in endocrinology and reproductive physiology. However, calls, and eventually demands, for their use in management of human fertility coincided with wider acceptance of women's autonomy consequent on the women's liberation movement of the late 1960s and 1970s, and with economic realities that both demanded women's participation in the job market and created incentives for the rationalization of family planning.[10]

As they were being introduced, scientifically informed concerns were voiced that such procedures could induce developmental abnormalities and therefore constituted unwarranted experimentation

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8. *See* ANDREWS, *supra* note 6. Like Andrews, I use "clone age" to describe societal changes produced by implementation of new and anticipated reproductive technologies including, but not restricted to, cloning.

9. NEW YORK ACADEMY OF SCIENCES, IN VITRO FERTILIZATION AND OTHER ASSISTED REPRODUCTION (Howard W. Jones, Jr. and Charlotte Schrader, eds., New York Academy of Sciences 1988). This volume is a collection of papers on the scientific basis of human assisted reproduction, but the interplay with studies on farm animal reproductive science and dependence of the human applications on earlier studies on non-human species is evident throughout.

10. *See* ANDREWS, *supra* note 6. Legal landmarks in the acquisition of reproductive autonomy by women during this period were the Supreme Court decisions in Griswold v. Connecticut, 381 U.S. 479 (1965) which affirmed the right to use and be counseled in the use of contraceptives, and in Roe v. Wade, 410 U.S. 113 (1973) which affirmed the right to abortion.

on individuals intended to be brought to term.[11] There were also concerns about the implications of separating the production of humans from the traditional nexus of social relations.[12] In addition, more practical considerations inevitably arose about the assignment of medical liability if, and when, this manipulation led to adverse outcomes.[13]

Despite these concerns, the growing market for these procedures, mainly among people in affluent nations, ensured the quick expansion of fertility services. For many hopeful parents, obtaining "genetically related" children,[14] regardless of what would previously have been insurmountable biological obstacles, came to be considered a right.[15] Louise Brown, the first "test tube baby," arrived without evident problems in 1977, and thousands of children whose existence is dependent on IVF are now born each year.[16] Society has largely accommodated itself to the burdens of the technology, although all the original concerns have proved valid to one extent or another.[17]

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11. Leon R. Kass, Babies By Means of In Vitro Fertilization: Unethical Experiments on the Unborn?, 285 N. ENGL. J. MED. 1174, 1175 (1971).

12. Martin M. Quigley & Lori B. Andrews, *Human In Vitro Fertilization and the Law*, 42 FERTIL. & STERIL. 348 (1984).

13. See, e.g., Mark E. Cohen, The "Brave New Baby" and the Law: Fashioning Remedies for the Victims of In Vitro Fertilization, 4 AM. J. L. & MED. 319, 328-336 (1978); Dennis M. Flannery et al., Test Tube Babies: Legal Issues Raised by In Vitro Fertilization, 67 GEO. L. J. 1295, 1333 (1979); G. Craig Hubble, Liability of the Physician for the Defects of a Child Caused by In Vitro Fertilization, 2 J. LEG. MED. 501, 509-521 (1981).

14. *See generally* B. S. Shastry, *SNP Alleles in Human Disease and Evolution*, 47 J. HUM. GENET. 561 (2002). In any two randomly selected human genomes, 99.9% of the DNA sequence is identical, so everyone is "genetically related." A parent and child have half their gene variants in common, making them slightly more similar than two randomly chosen individuals. To many, this distinction clearly makes a big difference, but it is useful to consider it in perspective.

15. See Suzanne Uniacke, In Vitro Fertilization and the Right to Reproduce, 1 BIOETHICS 241, 241 (1987); see also ANDREWS, supra note 6.

16. Patricia Katz et al., *The Economic Impact of the Assisted Reproductive Technologies*, 4 SUPPL. NAT. CELL BIOL. S29, S29 (2002).

17. On adverse developmental outcomes, *see* Robert M. Winston & Kate Hardy, *Are We Ignoring Potential Dangers of In Vitro Fertilization and Related Treatments?* 4 SUPPL. NAT. CELL BIOL. S14, S14 (2002); on legal questions *see* Goran Samsioe & Anders Abreg, *Ethical Issues in Obstetrics,* 41 INT. J. FERT. MENOPAUSAL STUD. 284, 284-285 (1996); on familial and psychological problems,

(Footnote continued…)

Whatever social barriers previously stood in the way of using IVF for humans, they gave way precisely at the time modern molecular genetics began to take off. The paper that established the possibility of recombining, amplifying, and propagating isolated segments of DNA was published in 1973.[18] By 1977, methods had been found to determine the sequence of subunits in DNA molecules,[19] a step that was indispensable to realizing the potential of the recombinant DNA techniques. For human reproductive biology, this translated into the determination of the sequence aberrations in such genetically related conditions as cystic fibrosis and Duchenne muscular dystrophy,[20] and to the possibility of using this information for preimplantation genetic diagnosis. The claimed right to have a genetically related child now evolved into the right to have such a child free from potentially disabling genetic variants carried by the biological parents.

In the case of animal embryology, a branch of the now burgeoning field of developmental biology, the application of the new methods had dramatic consequences. By 1982, "transgenic" mice, which utilized the information in, and transmitted to their offspring, foreign genes that had been introduced at early embryonic stages, had been produced.[21] This opened the way for proposals to enable people to have genetically related offspring who not only were free of the "bad" gene variants carried by the parents, but who also could have gene variants not carried by either parent.[22]

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see Alexina McWhinnie, *Families From Assisted Conceptions: Ethical and Psychological Issues*, 3 HUM. FERTIL. 13, 13 (2000).

18. S.N. Chang, et al., Construction of Biologically Functional Bacterial Plasmids In Vitro, 70 PROC. NATL. ACAD. SCI. U.S.A. 3240 (1973).

19. Allan M. Maxam & Walter Gilbert, *A New Method for Sequencing DNA* , 74 PROC. NATL. ACAD. SCI. U.S.A. 560, 560 (1977); F. Sanger *et al.*, *DNA Sequencing with Chain Terminating Inhibitors,* 74 PROC. NATL. ACAD. SCI. U.S.A. 5463, 5463 (1977).

20. Donald B. Bloch, et al., The Gene for the Alpha il Subunit of Human Guanine Nucleotide Binding Protein Maps Near the Cystic Fibrosis Locus, 42 AM. J. HUM. GENET. 884, 884 (1988). See also A.P. Monaco & L. M. Kunkel, Cloning of the Duchenne/Becker Muscular Dystrophy Locus, 17 ADV. HUM. GENET. 61 (1988).

21. Richard D. Palmiter, et al., Dramatic Growth of Mice that Develop From Eggs Microinjected with Metallothionian–Growth Hormone Fusion Genes, NATURE, Dec. 2, 1982, at 611.

22. *See* Ruth Hubbard & Stuart Newman, *Yuppie Eugenics*, Z MAGAZINE, March 2002, at 36.

The field of developmental biology generated a series of additional findings beginning in the 1970s that initially had only distant connections to any prospect for manipulation of human biology, but which have ultimately proved key to the deconstructive program. Most of these findings depended not so much on advances in DNA technology, but rather on general technical progress in other aspects of embryology and cell biology.

One of these was a demonstration in 1997 (after much preparatory work with amphibians, dating back to the 1950s) that mammals could be genetically cloned using the nucleus of a somatic cell from a fully developed donor and an egg from which the nucleus had been removed.[23] A second was the generation of mammalian (mouse) embryo stem (ES) cells in 1981,[24] and a third was the generation of interspecific mammalian "chimeras"—mammalian embryos and full-term animals originating from embryo cell mixtures—beginning with mice, rats and rabbits in the early 70s, and culminating in the dramatic publication of reports of viable "geeps" (goat-sheep chimeras) in 1984.[25] As we will see, not one of these technological achievements was accomplished with the overt goal of producing modified humans or quasi-humans. Indeed, all this work was initiated during a period when scientific curiosity concerning the nature of genetic and developmental processes were the motivating forces for entering this line of work. As little as thirty years ago, molecular genetics, and particularly developmental biology, the field from which transgenic animals, stem cells, cloning and chimeras originated, had no economic prospects nor obvious medical potential. Moreover, despite enormous technical advances in the ability to analyze and real, but more modest, progress in the ability to manipulate gene expression in embryos, theoretical understanding of the relationships between genes and traits during development remains primitive.[26] Nonetheless, in the context of

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23. Ian Wilmut, et al., Viable Offspring Derived From Fetal and Adult Mammalian Cells, NATURE, Jan. 2, 1997, at 810.

24. See G. R. Martin, Isolation of a Pluripotent Cell Line From Early Mouse Embryos Cultured in Medium Conditioned by Teratocarcinoma Stem Cells, 78 PROC. NATL. ACAD. SCI. U.S.A. 7634 (1981).

25. See Carole B. Fehilly, et al., Interspecific Chimaerism Between Sheep and Goat, NATURE, Jan. 5. 1984, at 634; see also, Sabine Meinecke-Tillman & B. Meinecke, Experimental Chimaeras – Removal of Reproductive Barrier Between Sheep and Goat, NATURE, Jan. 5, 1984, at 637.

26. For deficiencies in the existing paradigm *see* EVELYN F. KELLER, MAKING SENSE OF LIFE: EXPLAINING BIOLOGICAL DEVELOPMENT WITH MODELS,

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externally driven changes in the organization of, and expectations from, biological research during the same period, these experimental techniques are now all components of the emerging deconstructive program in human biology.

III. RAMPING UP TO THE CLONE AGE: SOCIOPOLITICAL ASPECTS

A sea change in the socioeconomic and political environment in which scientific research is conducted accompanied the technological advances described above. As we have seen, developmental biologists, particularly in the United States,[27] currently face societal expectations that the results of their experimental work are presumed applicable to the remaking of human biology. These expectations extend well beyond therapies for existing patients and now include calls for the modification of new individuals from the point of conception.[28]

The social reorganization of biological research occurred in the general post-World War II context of increased government attention to, and funding of, science and engineering.[29] Many of those broader

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METAPHORS AND MACHINES (Harvard University Press 2002) *and* Stuart A. Newman, *Developmental Mechanisms: Putting Genes in their Place,* 27 J. BIOSCI. 97, (2002). For alternative approaches *see* Stuart A. Newman & Wayne D. Comper, *'Generic' Physical Mechanisms of Morphogenesis and Pattern Formation,* 110 DEV. 1 (1990), Scott F. Gilbert & Sahotra Sarkar. (2000). Embracing complexity: organicism for the 21st century. *Dev Dyn, 219*(1), 1-9, and GERD B. MÜLLER & STUART A. NEWMAN (Eds.). ORIGINATION OF ORGANISMAL FORM: BEYOND THE GENE IN DEVELOPMENTAL AND EVOLUTIONARY BIOLOGY. (MIT Press, 2003).

27. *See* Annas, *supra* note 3. There are currently no federal statutes restricting developmental manipulation of human embryos in the United States. Legal bans or moratoria on cloning and certain other manipulations of human embryos have been enacted in several European nations, Japan, Israel and Australia, among others.

28. *See* sources cited *supra* note 7.

29. *See* Vannevar Bush and R.C. Atkinson, Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research (National Science Foundation 1980) (1945). *See also* S.W. Leslie, The Cold War and American Science: The Military –Industrial – Academic Complex at MIT and Stanford (Columbia University Press 1993); *and* J. Wang, American Science in an Age of Anxiety: Scientists, Anticommunism and the Cold War (University of North Carolina Press 1999).

changes spawned by the expanded public economies of the New Deal and its European counterparts, however, were tailored to the physical sciences in their critical roles in large-scale industrial and military development.[30] The modern biology of gene and embryo manipulation, in contrast, came of age in the Reagan-Thatcher period of aggressive private appropriation of the fruits of prior public spending, a climate that still prevails.

Three key changes in the socio-legal and political environment beginning in 1980 profoundly altered the culture of biological research in the United States:

(i) The passage of the Bayh-Dole Act[31] by the U.S. Congress: This occurred in response to industry's reluctance to invest in new technologies that had been developed in universities using federal funding.[32] Since the patent rights to these technologies traditionally and legally resided with the government on behalf of the public, companies could rarely obtain exclusive licenses.[33] The Bayh-Dole Act was predicated on the theory that the public would eventually benefit if patent rights to inventions paid for by federal grants were assigned to the grantees (universities and their investigator-employees), who would in turn be freed to seek venture capital and exclusive corporate licensees.[34] With the resulting financial incentives, the engines of creativity and commerce would be fired up, it was held, and all would gain.

The Bayh-Dole Act indeed initiated an era of academic entrepreneurship and reoriented the attention of major universities on their intellectual property portfolios and financial bottom lines.[35] Although it was not directed in any specific way at the biological sciences and was meant to encompass all federally funded science and engineering-based technologies, the coincidence of the enactment of this legislation with the DNA revolution of the 1980s and 1990s impressed a commercial stamp on much of the new biology. In

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30. *See* LESLIE, *supra* note 29. *See also,* WANG, *supra* note 29.

31. *See* Government Patent Policy Act of 1980, Pub. L. No. 96-517, 94 Stat. 3019.

32. *See* The Bayh-Dole Act: A Guide to the Law and Implementing Regulations (1999), *at* www.ucop.edu/ott/bayh.html (last visited May 19, 2003).

33. Id.

34. Id.

35. Eyal Press and Jennifer Washburn, *The Kept University,* THE ATLANTIC MONTHLY ONLINE, March 2000, *at* http://www.theatlantic.com/issues/2000/03/press.htm.

particular, informal scientific give-and-take that had characterized biological research in earlier periods was curtailed[36] and conflict of interest concerns that were previously unknown to fields such as cell and developmental biology became prominent.[37] Whether or not the public has actually benefited in any net fashion from this new scientific culture is unclear.[38] Importantly for the issues discussed here, the biotechnology industry set in motion by the privatization of biological science, and its representative organizations, have been major driving forces behind acclimatizing the public to instrumental uses and commercialization of genetically modified human embryos.[39]

(ii) The Supreme Court's decision in *Diamond v. Chakrabarty*:[40] This case opened the way to the patenting of living organisms and, although it did not address itself specifically to these issues, contributed to a climate of acceptance of privatization of naturally occurring cell types and DNA sequences. Although the United States Patent and Trademark Office (PTO) opposed the granting of a patent to Dr. Ananda M. Chakrabarty and his employer, the General Electric Corporation, for an oil-eating bacterium,[41] it was overruled by the Court of Customs and Patent Appeals. That court held, absurdly, that bacteria are "more akin to inanimate chemical compositions…[than] to

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36. Id.

37. *See generally* Sheldon Krimsky, Biotechnics & Society: The Rise of Industrial Genetics (Praeger 1991).

38. The development of digital computers, and of monoclonal antibodies, which have become essential biomedical research tools, progressed rapidly despite lack of patent protection of key early technological advances. *See* JOHN PALFREMAN & DORON SWADE, THE DREAM MACHINE: EXPLORING THE COMPUTER AGE (BBC Books,1991) 106, 183 ; *see also* ALBERTO CAMBROSIO & PETER KEATING, EXQUISITE SPECIFICITY: THE MONOCLONAL ANTIBODY REVOLUTION forward (Oxford University Press 1995). In fact, it has been suggested that biotechnology patents can actually impede scientific progress and technological innovations. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research,* 280 SCIENCE 698, 698-699 (1998).

39. *See, e.g.,* the June 2001 testimony of Thomas Okarma, President of Geron Corporation, on behalf of the Biotechnology Industry Organization, before the Committee on Energy and Commerce of the U.S. House of Representatives, *at* http:
//energycommerce.house.gov/107/hearings/06202001Hearing291/Okarma450.htm.

40. 447 U.S. 303 (1980).

41. *Id.* at 303-309.

horses and honeybees and raspberries and roses."[42] Notwithstanding the stated distinction, the Supreme Court's upholding of this decision in *Chakrabarty* enabled the issuance of patents on mice, pigs and cows, some containing introduced human genes,[43] as well as naturally occurring human cells[44] and nonhuman mammals containing such cells.[45] In April 1987, the U.S. Patent Commissioner issued a rule stating that "[t]he PTO now considers nonnaturally occurring, nonhuman, multicellular living organisms, including animals, to be patentable subject matter."[46] A year later, the PTO granted the first patent for a mammal and its progeny to Harvard University.[47] The new "composition of matter" was the Oncomouse—a strain of genetically modified mice that developed cancer at a rate of 40-fold that of the unmodified strain.[48]

(iii) The election of Ronald Reagan: This President's agenda included the rollback of the right to abortion affirmed by the Supreme Court in its 1972 decision in *Roe v. Wade*.[49] From the 1950s, when the chemical nature of the genetic material as DNA had first been delineated, through 1980, a major utility of identifying sequence aberrations in disease-related genes was acknowledged to be in the potential afforded to inform decisions about elective termination. This potential was not fully realized until DNA mapping and sequencing methods were developed in the 1970s.[50] But changes in personnel in

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42. *In re* Bergy, Coats, and Malik, 195 USPQ 344, 350 (1977); *aff'd sub nom*. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

43. *See* U.S. Patent No. 6,030,833, Transgenic swine and swine cells having human HLA genes (issued Feb. 29, 2000).

44. *See* U.S. Patent No. 5,972,703, Bone precursor cells: compositions and methods (issued Oct. 26, 1999).

45. U.S. Patent No. 6,353,150, Chimeric mammals with human hematopoietic cells (issued Mar. 5, 2002).

46. Notice by the Patent and Trademark Office, Patent and Trademark office Notice*: Animals-Patentability*, 1077 Official Gazette U.S. Pat. and Trademark Off. 8 (Apr. 21, 1987).

47. U.S. Patent No. 4,736,866, Transgenic non-human mammals (issued Apr. 12, 1988).

48. See Aya Leder et al., Consequences of Widespread Deregulation of the C-MYC Gene in Transgenic Mice: Multiple Neoplasms and Normal Development, 45 CELL 485, (1986).

49. 410 U.S. 113 (1973).

50. D.M. Kurmit & H. Hoehn, *Prenatal Diagnosis of Human Genome Variation,* 13 ANN. REV. GENET. 235 (1979).

federal agencies involved in policy making and funding of the biomedical sciences, most particularly the National Institutes of Health (NIH), shifted the discourse on acceptable rationales for genetic research away from prenatal diagnosis and selection, toward eventual intervention—genetic modification and the like.[51] The effect of this in making developmental manipulation "politically correct" has been largely overlooked, but it has left a permanent mark on the culture and ideology of biological research.

These late 20th century changes in the biomedical research environment occurred in parallel with a shift in the post-World War II U.S. academic culture that brought renewed respectability to the search for genetic explanations and remedies for human characteristics. After the assimilation of the gene concept into the mainstream of biological thought in the early 20th century, scientists and other commentators across the political spectrum began to attribute human group differences, including differences in intelligence, moral perception and other valued qualities, to genetic differences between the groups.[52] Anti-miscegenation laws in the U.S., sterilization laws in the U.S. and countries such as Sweden, and ultimately the policies that led to the Nazi death camps, were bolstered by the eugenic writings of some of the most prestigious genetic scientists of this country and England.[53]

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51. President Reagan's Secretary of Health and Human Services, Margaret Heckler, was outspokenly anti-abortion. The director of the NIH, a political appointee, was her subordinate. Deliberations on biomedical science policy relating to embryo and fetal research increasingly made use of opponents of abortion as panelists and consultants (*see, e.g.* , *Report of the human fetal tissue transplantation panel*, U.S. National Institutes of Health, December, 1988). During this period and the Bush presidency that followed, articles by NIH officers and favorite consultants began to appear that suggested that germ line intervention, once technically perfected, would be a reasonable alternative to prenatal diagnosis and selective abortion for those whose religious beliefs led them to reject the latter. *See* W.F. Anderson, *Prospects for Human Gene Therapy in the Born and Unborn Patient.* 29 CLIN. OBSTET. GYNECOL. 586 (1986); R.M. Cook-Deegan, *Human Gene Therapy and Congress*,1 HUMAN GENE THERAPY 163 (1990); Nelson A. Wivel & Leroy Walters, *Germ-line Gene Modification and Disease Prevention: Some Medical and Ethical Perspectives,* 262 SCIENCE 533 (1993).

52. Daniel J. Kevles, In the Name of Eugenics: Gentics and the Uses of Human Heredity, *passim* (Knopf 1985).

53. *See* J. B. S. Haldane, a Paper Read to the Heretics, Cambridge, on Feb. 4, 1923, Daedalus; or Science and the Future (E.P. Dutton & Co. 1924); R. Fisher, The Genetical Theory of Natural Selection (Clarendon Press 1930); Hermann J.

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After World War II, due to revulsion from Nazi actions and in response to an increasing acceptance of the legitimacy of calls to redress the legacy of racism in the U.S., this mode of discourse temporarily went into eclipse in academia.[54] By the late 1960s, however, the pursuit of biological, evolutionary, and thus genetic, explanations for human biological differences, and for some of the more negative aspects of human commonality, was well underway again. Traits asserted to have a genetic basis included performance on standardized intelligence tests, the propensity to be violent, to cheat on one's mate, to become addicted to alcohol and drugs and to enslave others. Landmarks along the way to the re-legitimization of genetic accounts of human behavior and inclinations include Robert Ardrey's *Territorial Imperative* (1966),[55] Desmond Morris's *The Naked Ape* (1967)[56] and Arthur Jensen's 1969 article, "How Much Can We Boost IQ and Scholastic Achievement?"[57] However, none of these had the impact among biological scientists and the intellectual culture as a whole as did the 1975 publication of *Sociobiology* by the Harvard evolutionary biologist, Edward O. Wilson.[58]

Although Wilson's research focused on ant societies, and many of his examples were drawn from this area, his last chapter on the purported genetic bases of aspects of human culture and behavior struck a chord that continues to resonate among many academics and other writers.[59] However, it is one thing to suggest, as Wilson did, that

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Muller, Out of the Night: A Biologist's View of the Future (Vanguard Press 1935). These three scientists were among the most important geneticists of the 20th century. Haldane (British) and Muller (American) were identified with the Marxist Left, Fisher (British) with the Christian Right.

54. D.B. Paul & H. G. Spencer, *The Hidden Science of Eugenics*, NATURE, March 23, 1995, at 302.

55. Robert Ardrey, The territorial imperative; a personal inquiry into the animal origins of property and nations (Atheneum 1966).

56. Desmond Morris, The naked ape; a zoologist's study of the human animal (McGraw-Hill 1967).

57. Arthur Jensen, *How Much Can We Boost IQ and Scholastic Achievement*? 39 HARVARD EDUCATIONAL REVIEW 1 (1969).

58. Edward O. Wilson, Sociobiology: the new synthesis (Belknap Press 1975).

59. *See* Richard J. Hernstein & Charles A. Murray, The bell curve: intelligence and class structure in American life (Free Press, 1994). The field known as "evolutionary psychology" also stems from sociobiology. *See also* Robert Wright, The moral animal: evolutionary psychology and everyday life (Vintage Books 1995). *See* David Buss Evolutionary psychology: the new science of the mind

(Footnote continued…)

one or another trait was molded by natural selection. This may be disputable in any given case,[60] but it is not scientifically naive. It is quite another thing, however, to assert that such gene-trait relationships are modular and transferable across genetic backgrounds. Recent writers advocating the use of genetic technologies to acquire biologically improved offspring, however, convey little uncertainty that desirable human qualities will eventually be susceptible to being engineered into an arbitrary genetic setting (i.e., a couple's own fertilized egg) by plugging in a new gene or two.[61]

IV. BLURRING THE BOUNDARY: CURRENT ACTIVITIES IN HUMAN DEVELOPMENTAL BIOLOGY

As a result of the scientific achievements and socio-political developments outlined above, and notwithstanding the enduringly enigmatic nature of the developmental process, by the 1990s a significant segment of the public in the U.S. were ready to contemplate intervening in the development of their offspring. At the present time, four distinct, but partially related, technologies have come to be applied, or seriously proposed to be applied, to human biology. These are cloning, stem cell research, embryo gene modification and chimerism.

This paper does not intend to lump these methodologies together and to assert, for example, that all techniques that employ human embryonic cells or tissues are morally or ethically questionable. The production of stem cells from stored "excess" embryos in IVF clinics, while of deep concern to those for whom the embryo has the same moral status as full-term humans, can plainly be conducted without reconfiguring the material nature of the human organism. This paper will focus, rather, on the potential of these methodologies to effect developmental transformation and their capacity, when employed in particular combinations, to transgress any provisional definition of the biologically human, regardless of the belief system that stipulates it.

(Allyn & Bacon 1999) *and* Stephen Pinker, The blank slate: the modern denial of human nature (Viking 2002).

60. *See generally* examples and discussion in MICHAEL RUSE, SOCIOBIOLOGY, SENSE OR NONSENSE? (D. Reidel Pub. Co 1979); Richard C. Lewontin, THE TRIPLE HELIX: GENE, ORGANISM, AND ENVIRONMENT (Harvard University Press 2000); *and* ULLICA SEGERSTRÅLE, DEFENDERS OF THE TRUTH: THE BATTLE FOR SCIENCE IN THE SOCIOBIOLOGY DEBATE AND BEYOND (Oxford University Press 2000).

61. *See generally* sources cited *supra* note 7.

(i) *Cloning*—The cloning of a sheep by a Scottish agricultural research group, reported in February 1997,[62] provoked a spectrum of responses from philosophers, ethicists and other observers of science. Opinions ranged from the assertion that cloning technologies should never be applied to humans, to enthusiasm for the prospects of doing just that.[63] In interviews, and in testimony before the U.S. Senate, Ian Wilmut, the leader of the scientific group that accomplished the cloning feat, expressed his hope that no one would attempt to clone a human.[64] Although the patents that he and his colleagues were awarded specifically covered human cloning, Wilmut stated that this provision was intended to foreclose others from attempting it.[65] Two years later, after the report of the generation of ES cells from human embryos (see infra), Roslin Bio-Med, the company Wilmut and his colleagues formed to exploit the cloning technique for animal breeding, merged with Geron, Inc., a U.S. company with patent rights on the ES cell technology. The stated business model of the new company was to generate ES cells of defined genetic constitution from clonal human embryos.[66]

Cloning to produce full-term human individuals currently has little support in the United States or in other countries. One reason is the accumulation of data from scientific studies during the five years following the announcement of the first mammalian clone showing that the procedure is highly hazardous. Clonal mice, for example, exhibit perturbed patterns of expression in hundreds of genes,[67] and

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62. Wilmut, *supra* note 23.

63. For early reactions, *see, e.g.,* citations in Stuart A. Newman, *Human Cloning and the Law,* 1 J. BIOLAW AND BUSINESS 59 (1998). For additional views, *see also* GREGORY E. PENCE, FLESH OF MY FLESH: THE ETHICS OF CLONING HUMANS: A READER (Rowman & Littlefield 1998*), and* MARTHA NUSSBAUM & CASS SUNSTEIN, CLONES AND CLONES: FACTS AND FANTASIES ABOUT HUMAN CLONING (Norton 1998).

64. Statement before the Subcommittee on Public Health and Safety of the Senate Committee on Labor and Human Resources, Mar. 12, 1997, *at* http://www.cnn.com/HEALTH/9703/12/nfm/cloning/index.html.

65. American Association for the Advancement of Science, *Forum on Cloning, available at* http://www.aaas.org/spp/sfrl/projects/cloning.htm (June 25, 1997) (discussing comments made by Ian Wilmut).

66. M. Wadman, US Stem-Cell Pioneers Buy 'Dolly' Cloning Company, NATURE , May 6, 1999, at 92.

67. David Humpherys et al., Epigenetic instability in ES Cells and Cloned Mice, 293 SCIENCE 95, 95 (2001); David Humpherys et al., Abnormal Gene

(Footnote continued…)

cloned animals of all species in which it has been attempted have high rates of unexplained postnatal deaths, as well as anomalies such as enlarged hearts and grossly abnormal lungs and signs of premature aging.[68] It stands to reason that a technique that brings together the remnants of two damaged cells, an egg from which the nucleus has been removed and the extirpated nucleus of a somatic cell, will have difficulty cooperating to produce a presentable member of the originating species. Moreover, whereas many biological processes are protected by error-correcting mechanisms that have evolved over vast periods of time (for example, errors in the replication of DNA are repaired by numerous sophisticated enzyme systems), evolution has not confronted, nor arrived at correctives for, the errors introduced into the developmental process resulting from this atypical combination of cell parts.

On the other hand, the prospect of full-term human cloning was enthusiastically received by some opinion makers, including a U.S. Senator[69] and the chief technology officer of Microsoft, when Dolly the sheep was first announced.[70] More recently, a specialist in bioethics and the law has opined that the Supreme Court has grounds to affirm the right to clone oneself.[71] Claims by Clonaid, an affiliate of the Raelian religious cult, that they had produced several full-term human clones were met with skepticism and condemnation by the mainstream media,[72] but the pioneering spirit of "early adopters" of such technologies has also been praised in some recent books.[73] If a few

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Expression in Cloned Mice Derived from Embryonic Stem Cell and Cumulus Cell Nuclei, 99 PROC. NATL. ACAD. SCI. U.S.A., 12889, 12889 (2002).

68. John F. Allen & Carol A. Allen, A Mitochondrial Model for Premature Aging of Somatically Cloned Mammals, 48 IUBMB LIFE, 369, 369 (1999). See also P. Chavatte-Palmer et al., Cloning and Associated Physiopathology of Gestation, 28 GYNECOL. OBSTET. FERTIL. 633 (2000); Rudolf Jaenisch & Ian Wilmut, Developmental Biology: Don't Clone Humans! 291 SCIENCE 2552 (2001).

69. Jeff Levine, *Scientist Who Cloned Sheep: Cloning Humans Would Be 'Inhuman,'* March 12, 1997, *at* http://www.cnn.com/HEALTH/9703/12/nfm/cloning/index.html.

70. Nathan Myhrvold, *Human Clones: Why Not*?, SLATE, March 13, 1997.

71. Rick Weiss, Legal Barriers to Human Cloning May Not Hold Up, WASH. POST. May 23, 2001, at A01.

72. D. Grady & R. Pear, *Claim of Human Cloning Provokes Harsh Criticism,* N.Y. TIMES*,* Dec. 29, 2002 at A18; G. Kolata, & K. Chang, *For Clonaid, a Trail of Unproven Claims,* N.Y.TIMES,(Jan. 1, 2003), at A13; Gerald Schatten *et al., Cloning Claim is Science Fiction, Not Science*, 299 SCIENCE 344 (2003).

73. *See* SILVER; and STOCK. *supra* note 7.

confirmed human clones relatively free of obvious health problems were to be presented, it is reasonable to expect that opposition to cloning would diminish, despite the biological uncertainties. These uncertainties include the complete lack of knowledge of how the gene disregulation that seems inevitably to accompany cloning would affect the "wiring" of the human brain that occurs during development.[74]

The motivations for producing full-term clones from a known prototype have been widely discussed.[75] Common experience with natural human clones—identical twins, triplets, etc.—show that biologically related traits such as personality, tastes and the occurrence of diseases, such as diabetes and cancer, are not fully determined by one's genes. Most people now understand that producing genetically identical organisms, as effected by cloning, is not the same thing as producing organisms that are identical in every important respect. This has quelled some of the impulse toward full-term cloning, but not all of it. As we will see, the merging of cloning with stem cell research and germline manipulation is creating even greater incentives to produce full-term, or near full-term clones.

(ii) *Embryo stem (ES) cells*—Embryo stem cells entered the world in 1981 and have since become a source of promised health benefits, secular-religious controversy, political realignments and new business models. Gail Martin, a researcher at the University of California, San Francisco, found that cells isolated from early mouse embryos (at a stage corresponding to about a week of human gestation) could, if exposed to appropriate growth factors[76] and a "feeder layer,"[77] continue to divide in culture.[78] Like certain cancer cells, ES cells would give rise to a variety of differentiated cell types if removed from the feeder layer. ES cells have the potential to form neuron-like cells, cartilage, cells resembling the endodermal lining of the gut and so

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74. Known developmental disorders of the brain are associated with widespread gene dysregulation in brain tissue; *see e.g.*, M. Freidl et al*., Deterioration of the Transcriptional, Splicing and Elongation Machinery in Brain of Fetal Down Syndrome*, 61 J. NEURAL. TRANSM. SUPPL. 47 (2001). It is reasonable to expect that the global gene dysregulation induced by cloning (see *supra*, note 67) would be associated with defects in the wiring of the neural circuits of the brain, although direct evidence is not available.

75. *See generally* Newman; PENCE; and NUSSBAUM & SUNSTEIN, *supra* note 63.

76. *I.e.*, nutritive and stimulatory molecules different from those these cells normally encounter.

77. *I.e.*, a population of nonembryonic cells.

78. Martin, *supra* note 24.

forth. These cells continue to reproduce themselves as a tumorigenic stem cell population, as demonstrated by their propensity to form carcinomas when injected subcutaneously into adult mice.[79] The potential of these cells to generate *any* cell of the juvenile or adult body was demonstrated by the ability of an ES cell to contribute to all tissues and organs of a developing embryo into which it had been incorporated at an early stage.[80] It did so without inducing any tumors in the resulting individual— in effect, the microenvironment provided by the normal embryo could "tame" this abnormal cell type.[81]

Between the time that Martin described mouse ES cells in 1981 and when James Thomson, a reproductive biologist at the University of Wisconsin, described human ES cells in 1998,[82] there had been little discussion of the reparative potential of ES cells. First, human cancer cells ("teratocarcinomas") with properties similar to ES cells had been available for more than thirty years[83] and no plausible therapeutic modalities had emerged from the numerous studies devoted to them. Second, even in the mouse system itself, where both authentic ES cells and virtually unlimited genetically compatible subjects had been available since 1981, there had been essentially no progress in curing or even palliating diseases or disabling conditions for which mouse "models" existed, such as diabetes, spinal cord injury, Parkinsonism and so forth.[84]

However, the intervening seventeen years had been precisely the period in which the Bayh-Dole act and the *Chakrabarty* decision had impressed their stamp on biomedical science. A comparison of the last

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79. Id.

80. See Sakura Saburi et al., Developmental Fate of Single Embryonic Stem Cells Microinjected Into 8-cell-stage Mouse Embryos, 62 DIFFERENTIATION 1 (1997).

81. Id.

82. James A. Thomson, et al., Embryonic Stem Cell Lines Derived From Human Blastocysts, 282 SCIENCE 1145-7 (1998).

83. *See* Virginia E. Papaioannou, *Ontogeny, Pathology, Oncology,* 37. INT. J. DEV. BIOL. 33, 33-37 (1993). Although any single cell line derived from a teratocarcinoma is not as versatile as an ES cell no individual candidate for reparative therapy requires a fully totipotent cell population.

84. *See*, *e.g.,* Huda Y. Zoghbi & Juan Botas, *Mouse and Fly Models of Neurodegeneration*, 18 TRENDS GENET, 463, 463-471 (2002); F. Susan Wong & Charles A. Janeway, Jr., *Insulin-Dependent Diabetes Mellitus and its Animal Models*. 11 CURR OPIN IMMUNOL 643, 643-647 (1999); *See also*, Michael S. Beattie, *et al., Cell Death in Models of Spinal Cord Injury.* 137 PROG BRAIN RES. 37 (2002).

sentences of the summary paragraphs in the papers of Martin, Thomson and coworkers is revealing. Martin's seems almost quaint now in its pure science orientation: "The availability of such cell lines should make possible new approaches to the study of early mammalian development."[85] The corresponding sentence in the Thomson paper had a more 1990s flavor: "These cell lines should be useful in human developmental biology, drug discovery, and transplantation medicine."[86] CNN's web report of the announcement ran with the headline: "Researchers isolate human stem cells in the lab: Breakthrough could lead to treatments for paralysis, diabetes."[87]

As of mid-2003, there remain few studies using the mouse as an experimental system that point to therapeutic efficacy for ES cells. Mouse ES cells or "pluripotent" subpopulations derived from them can sometimes repopulate damaged tissues in mice, but they usually also give rise to malignant tumors as well.[88] Human ES cells, when injected into immunocompromised mice incapable of rejecting them, usually form benign tumors in addition to various differentiated cells.[89] It is not clear whether human ES cells grafted into human patients would behave as they do in mice, or rather behave like mouse ES cells grafted into mice, forming malignant tumors.

A different kind of stem cell, the so-called embryo germ (EG) cell, is prepared by growing tissue isolated from five-to-nine-week fetuses rather than very early stage embryos.[90] These cells have the advantage of not forming tumors when injected into immunocompromised mice.[91] However, it is not clear how they would behave in human patients. EG cells appear to be capable of generating the full spectrum of cell

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85. Martin, *supra* note 24, at 7634.

86. Thomson et al., *supra* note 82, at 1145.

87. *See Researchers Isolate Human Stem Cells in the Lab*, CNN.COM, Nov. 5, 1998, *at* http://www.cnn.com/HEALTH/9811/05/stem.cell.discovery/index.html.

88. *See* Martin, *supra* note 24.

89. Benjamin E. Reubinoff, et al., Embryonic Stem Cell Lines From Human Blastocysts: Somatic Differentiation In Vitro, 18 NATURE BIOTECHNOLOGY 399, 399 (2000).

90. Michael J. Shamblott, et al., Derivation of Pluripotent Stem Cells From Cultured Human Primordial Germ Cells, 95 PROC. NATL. ACAD. SCI. U.S.A., 13726, 13726 (1998).

91. Michael J. Shamblott, et al., Human Embryonic Germ Cell Derivatives Express a Broad Range of Developmentally Distinct Markers and Proliferate Extensively In Vitro. 98 PROC. NATL. ACAD. SCI. U.S.A. 113, 113 (2001).

and tissue types seen with ES cells[92] and, therefore, would have equal therapeutic potential.

As noted, the reparative and tumor-forming potential of both mouse and human stem cells can be tested in immunocompromised mice. For human testing, or therapy, the transplanted cells would in most cases be rejected by the human host since they are of a different genotype and would provoke an immune reaction that could destroy the graft, or worse, prove fatal to the patient. The human ES cell lines that existed as of the summer of 2001, and were approved for further study using federal funds by President George W. Bush,[93] would, in general, not be immunologically tolerated by an arbitrary patient.

It is for this reason that proposals have been made and have been strongly advocated by the spinal cord-injured actor and activist Christopher Reeve,[94] among other patient and industry representatives,[95] to permit federal funding of the production of clonal embryos—embryos made by nuclear transfer that would have the same genotype as the patient—and to resist any legal restriction on these embryos being produced with private funds.[96] This prospect, termed "therapeutic" cloning, although "experimental" cloning is a more accurate term for it, has gained the support of pro-choice legislators across party lines, in both houses of Congress[97] and even some opponents of abortion such as Senator Orrin Hatch, who has reformulated his opposition to abortion as only pertaining to embryos that have been implanted in a woman's uterus, and which the woman

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92. Id.

93. President George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001) (transcript available at www.whitehouse.gov/news/releases/2001/08/20010809-2.html).

94. Christopher Reeve, Statement on Cloning Debate, *available at* http://www.genemediaorg (last visited April 11, 2003).

95. See supra note 39.

96. *See* President Bush's remarks, *supra* note 93. Current administrative policy pertains to research done with federal funds. The various pending Congressional bills call for legal bans on all forms of cloning or only full-term ("reproductive") cloning. Any research not banned by Congress but subject to an Administrative funding restriction could still be supported from private sources.

97. S. 2439, 107th Cong. (2002). This bill, introduced by Sens. Arlen Specter (R-PA), Edward Kennedy (D-MA) and Dianne Feinstein (D-CA), had the intention of permitting experimental cloning, as did a substitute amendment to a more restrictive bill (H.R. 2505) introduced in the House of Representatives the previous year. (*See* H.R. 2505, 107th Cong. (2001)).

seeks to eliminate.[98] The drive to get Congress and the public to accommodate itself to experimental cloning has occurred with little acknowledgement that alternative strategies exist for altering existing ES cell lines so as to prevent their immune-mediated rejection.[99]

Some research groups are working on culture methods to extend the viability of human embryos *in vitro*,[100] and this could afford the possibility of harvesting EG cells from two-month fetuses (currently legal, though not approved for federal funding).[101] However, patient advocacy groups, biotech industry representatives and legislators have yet specifically to advocate the generation of clonal fetuses for the production of EG cells genetically matched to the patient.

Such reluctance could easily give way as better products of these technologies emerge. After Dolly the sheep was cloned, a British researcher speculated that inactivation of brain-inducing genes could be used to produce headless full-term human clones for organ harvesting.[102] A second British biologist, a prominent public spokesperson on scientific issues, opined that this proposal raised no ethical issues.[103]

(iii) *Embryo gene modification*—The hazards of genetic modifications to humans are usually discussed in terms of *somatic* (body cell) modification, in which only nonreproductive tissues are

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98. Dawn House, *Hatch Stand Stirs Debate on Cloning,* SALT LAKE TRIB., April 30, 2002, at http://www.sltrib.com/2002/apr/04302002/utah/732910.htm). *See also* Eugene Russo, *Clone Hearings Continue*, THE SCIENTIST, Jan. 30, 2002. This line of argument gives credibility to the charge that, for some, opposition to abortion is more about curtailing women's autonomy than the welfare of the embryo.

99. See D.S. Kaufman & J.A. Thomson, Human ES Cells Haematopoiesis and Transplantation Strategies, 200 J. ANATOMY 243 (2002); F. Fandrich et al., Embryonic Stem Cells Share Immune-Priviliged Features Relevant for Tolerance Induction, 80 J. MOL. MED. 343 (2002).

100. Robin McKie, *Men Redundant? Now We Don't Need Women Either. Scientists Have Developed an Artificial Womb that Allows Embryos to Grow Outside the Body,* OBSERVER INTL, Feb. 10, 2002, *available at* www.observer.co.uk/international/story/0,6903,648024,00.html.

101. *See* Fact Sheet, The White House, President George W. Bush, Embryonic Stem Cell Research (Aug. 9, 2001) (available at www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html).

102. J. Slack*, quoted in* S. Connor & D.Cadbury, *Headless Frog Opens Way for Human Organ Factory,* LONDON SUNDAY TIMES*,* Oct. 19, 1997, *available at www.organicconsumers.org/Patent/headless.html.*

103. *Id*. at 2 (referring to British biologist L. Wolpert).

affected, and *germline* (egg or sperm cell) modification, in which changes to an individual's DNA can be passed down to future generations.[104] However, genetic modification of early embryos, similarly to cloning, is hazardous to developing individuals even when there is no germline transmission to future generations.

The hazards of germline transmission of DNA modification are clear. For example, "germline introduction in mice of an improperly regulated normal gene resulted in progeny with unaffected development, but high tumor incidence during adult life."[105] Such effects may not be recognizable for a generation or more.

It is important to recognize, however, that the hazards to the embryo of such alterations are not eliminated even if there is no germline transmission. The biology of the developing individual will still be profoundly altered by the manipulation of his, or her, genes at an early stage, hence the utility of the concept of "developmental manipulation" to cover both cloning and germline procedures. Laboratory experience shows that insertion of foreign DNA into inopportune sites in an embryo's chromosomes can lead to extensive perturbation of development. For example, the disruption of a normal gene by insertion of foreign DNA in a mouse caused abnormal circling behavior when present in one copy, lack of eye development, lack of development of the semicircular canals of the inner ear and anomalies of the olfactory epithelium (the tissue that mediates the sense of smell), when the mice were inbred so that the mutation appeared in the homozygous form (i.e., on both copies of the relevant chromosome).[106] Another such "insertional mutagenesis" event led to a strain of mice that exhibited limb, brain and craniofacial malformations, as well as displacement of the heart to the right side of the chest, in the homozygous state.[107] Each of these developmental anomaly syndromes were previously unknown. From current, or even anticipated,[108] models for the relationship between genes and organismal forms and functions, the prediction of complex phenotypes

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104. *See* Paul R. Billings, et al., *Human Germline Gene Modification: A Dissent,* 353 LANCET 1873(1999).

105. *Id.*

106. *See* Andrew J. Griffith, et al., *Optic, Olfactory, and Vestibular Dysmorphogenesis in the Homozygous Mouse Insertional Mutant Tg9257*, 19 J. CRANIOFAC. GENET. DEV. BIOL. 157 (1999).

107. *See* Gurparkash Singh, et al., *Legless Insertional Mutation: Morphological, Molecular, and Genetic Characterization,* 5 GENES DEV. 2245, 2245 (1991).

108. *See* sources cited *supra* note 26.

on the basis of knowledge of the gene sequence inserted or disrupted is likely to remain elusive.

Unexpected and even fatal outcomes of attempts at somatic cell gene modification have plagued this area of medicine.[109] However, attempts at developmental modification would be susceptible to a distinct category of hazard not shared by the somatic procedures. The tissues of a developed organism are in some sense modular—if blood, skin, a heart or a liver is diseased or damaged, it can be replaced by a substitute without changing the "nature" of the individual. Similarly, with gene alteration in a developed individual, in reasonable candidate cases for somatic therapy, the gene is playing a defined role in a particular tissue or organ,[110] and the goal of the modification is to replace, or correct, the poorly functioning gene in one or a very limited set of tissues.[111]

During development, the situation is much more complicated. Tissues and organs are taking form during this period and genes function in anything but a modular fashion. In development many, if not most, gene products can have multiple effects on the architecture of organs and the wiring of the nervous system, including the brain.[112] Individuals produced by developmental intervention (particularly as it

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109. Nikunj Somia & Inder Verma, *Gene therapy: Trials and Tribulations,* NAT. REV. GENET. 1, 91-99 (2000).

110. Even in cases where the gene's protein product is confined to one or a few tissue types its function may depend in a complex and elusive fashion on other gene products or cell properties. This has proved to be the case for the ß-globin protein compromised in sickle cell disease; *see* A. Mozzarelli, J. Hofrichter, J., and W.A. Eaton, *Delay time of hemoglobin S polymerization prevents most cells from sickling in vivo*., 237 SCIENCE 500, 500-6 (1987); and the transmembrane conductance regulator protein compromised in cystic fibrosis; *see* The Cystic Fibrosis Genotype-Phenotype Consortium, *Correlation between genotype and phenotype in patients with cystic fibrosis*, 329 N. ENGL J MED. 1308, 1308-13 (1993). This can affect the success of somatic gene replacement or repair, and therefore the health of the patient. The inherent identity of the individual is not at issue in such manipulations the way it is with germline modification.

111. W. French Anderson, *Prospects For Human Gene Therapy,* 226 SCIENCE 401, 402 (1984); Theodore Friedmann, *Progress Toward Human Gene Therapy,* 244 SCIENCE 1275, 1275 (1989).

112. *See* I. Salazar-Ciudad, *et al., Mechanisms Of Pattern Formation In Development And Evolution*. 130 DEVELOPMENT 2027, 2037 (2003); G. Streidter, *Epigenesis and evolution of brains,* ORIGINATION OF ORGANISMAL FORM: BEYOND THE GENE IN DEVELOPMENTAL AND EVOLUTIONARY BIOLOGY (G. B. Müller & S. A. Newman, eds., MIT Press 2003).

comes to extend beyond the single gene, to chromosomes or groups of chromosomes[113]) could begin to approach the status of "experimental artifacts," in the sense that their bodies and mentalities could be quite different from those of anyone generated by processes using the standard starting materials generated by evolution (including IVF).

The prospect of linking the techniques of cloning and germline modification will create incentives that could cause some desperate parents to put aside these concerns. Some parents have already chosen to produce a second child in order to provide bone marrow or umbilical cord stem cells for an existing child with a treatable disease, such as Fanconi's anemia.[114] This is an uncertain procedure. In general, many attempts will be needed and potentially scores of embryos will be produced and discarded, before an appropriate "match" in tissue type is achieved, the implanted embryo is brought to term, and the grafted tissue accepted by the patient. Even then, success is not guaranteed.[115]

In order to improve chances for success, it could be considered logical to *clone* the sick child. In this case, all the embryos generated would be a perfect match and there would be no likelihood of rejection of tissue grafted from the second child into the first. If the original child's condition was due to a gene variant, genetic manipulation of the clonal embryo could be performed to ensure that the grafted tissue (which would remain immunologically compatible) could effect the cure. It must also be noted that even if the fetus dies prematurely *in utero*, as is often the case with clonal animals,[116] it might still be possible to harvest therapeutically useful tissues.[117] The uncertainties of the cloning process, therefore, might not be an important disincentive in such cases.

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113. Tokuyuki Shinohara, *et al., Stability of Transferred Human Chromosome Fragments in Cultured Cells and in Mice,* 8 CHROMOSOME RES. 713, 723 (2000).

114. Lisa Belkin, *The Made-To-Order Savior. Producing a Perfect Baby Sibling*. N.Y. TIMES MAG., July 1, 2001, at 36.

115. *Id.*

116. Jaenisch & Wilmut, *supra* note 68, at 2552.

117. Transplantation of human fetal tissues has proved effective in treating several conditions. *See e.g.,* Timothy M. Crombleholme, *et al., Transplantation of Fetal Cells,* 164 AM. J. OBSTET. GYNECOL. 218, 227 (1991); A. Bjorklund, *Cell Replacement Strategies for Neurodegenerative Disorders,* 231 NOVARTIS FOUND. SYMP.7, 16-20 (2000). *See also,* T. Freeman, e*t al., Neural Transplantation in Parkinson's Disease,* 86 ADV. NEUROL. 435 (2001).

A recent study with genetically-impaired mice has demonstrated that cures, or at least palliation, of an immune deficiency can be achieved using bone marrow from their cloned, genetically-engineered siblings.[118] As would need to be the case with any human applications of this methodology, multiple clonal embryos were generated by first producing ES cells from an original clone. The gene modification was performed on the ES cells, which were then used to form viable embryos. Thus, all three techniques discussed so far, cloning, ES cells, and embryo gene alteration, were brought together in this experimental prototype for constructing a medically useful sibling for a sick child.

(iv) *Chimerism*—In November of 2002, a meeting took place at the New York Academy of Sciences to discuss the proposal, by a Rockefeller University scientist, to inject human embryo stem cells into mouse embryos in order to explore the developmental fate, and therapeutic potential, of the ES cells.[119] The meeting was called because of brewing opposition among some scientists in the developmental biology research community. One leading stem cell researcher in attendance stated, "I am completely opposed to putting human embryonic stem cells into any condition that will cause moral affront,"[120] while others suggested alternatives to making such human-animal chimeras that could provide the same information.[121] Some participants from the New York Academy meeting were excluded from a closed session held by investigators interested in pursuing the chimera protocol. Among those excluded was a researcher from the National Institute of Neurological Disorders and Stroke (NINDS), who was also chair of the National Institute of Health Stem Cell Task Force, and who later criticized the chimera advocates for "excessive secrecy."[122]

As it happens, five years previously, with the help of the social critic Jeremy Rifkin, president of the Foundation on Economic Trends in Washington, D.C., this writer applied for a patent on chimeric embryos and animals containing both human and nonhuman, cells. Among the patent application's claims was precisely what was being proposed at

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118. William Rideout, *Correction of a Genetic Defect by Nuclear Transplantation and Combined Cell and Gene Therapy,*109 CELL 17, 23 (2002).

119. Natalie DeWitt, *Biologists Divided Over Proposal to Create Human–Mouse Embryos*, NATURE, November 21, 2002, at 255.

120. *Id.*

121. *Id.*

122. *Id.*

the New York Academy forum.[123] I had no intention of producing such creatures, nor does U.S. patent law require that an actual prototype for an invention be supplied, only that feasibility, novelty and utility be demonstrated.[124] Moreover, as noted above, ever since the 1980 *Chakrabarty* decision, it has been legal in the United States to obtain a patent on living organisms and their descendants. Congress has drawn no clear line that would preclude a pre-term human embryo, if appropriately modified, from being patented. Further, Congress has not indicated how many human genes or cells a non-human animal would have to contain before it could *not* be patented by virtue of the Constitutional protections pertaining to members of the human community.[125] While a decision regarding patentability of human-animal chimeras by the PTO would not control whether it would be legal to produce such entities, or other types of biologically manipulated humans, Rifkin and I considered that applying for a chimera patent would raise these issues before the public and the legal system in a particularly dramatic fashion.[126]

The proposed human-animal chimera, whose production would depend on techniques developed in the 1970s and 1980s that led to the generation of "geeps,"[127] could contain anywhere from a minuscule proportion to a majority of human cells. Goats and sheep, whose embryo cells cooperate completely in forming a composite animal having features of both originating species, have followed separate

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123. U.S. PATENT AND TRADEMARK OFFICE, 1997 CHIMERIC EMBRYOS AND ANIMALS CONTAINING HUMAN CELLS. UTILITY PATENT APPLICATION SUBMITTED. S*ee also* David Dickson, *Legal Fight Looms Over Patent Bid on Human/Animal Chimaeras,* NATURE, April 2, 1998, at 423 (1998).

124. 35 U.S.C. §§101-103 (2000).

125. See, e.g., Thomas A. Magnani, The Patentability of Human-Animal Chimeras,14 BERKELEY TECH L. J.443 (1999); James P. Daniel, Of Mice And 'Manimal': The Patent & Trademark Office's Latest Stance Against Patent Protection For Human-Based Inventions, 7 J. INTELL. PROP. L. 99 (1999); Mark Jagels, Dr. Moreau Has Left the Island: Dealing with Human-Animal Patents in the 21st Century, 23 T. JEFFERSON L. REV. 115 (2000); Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 Stan. L. Rev. 303.

126. *See* Stuart A. Newman, *The Human Chimera Patent Initiative,* 9 MEDICAL ETHICS NEWSLETTER (LAHEY CLINIC) 7 (2002).

127. *See* Wilmut, *supra* note 23.

evolutionary paths for approximately seven million years.[128] While humans and mice diverged perhaps thirty-two million years ago,[129] and their embryo cells would not be expected to cooperate as readily to form a full-term animal, development would likely progress long enough to provide important information to developmental biologists, hence the 2002 New York Academy workshop. Humans and chimpanzees, another pair covered by the patent application, are about as closely related evolutionarily as goats and sheep.[130]

In order for the chimera patent application to be admissible, it had to document utility.[131] the application anticipated the usefulness to developmental biologists of chimeric embryos containing human cells. In addition, it suggested that partly human embryos could be used to test drugs and chemicals for toxicity and as sources of transplantable tissues and organs for human patients. It is clear from such examples (and statements by some scientists at the New York Academy meeting) that biotechnology is capable of producing items that, while legal and eminently useful, would be sufficiently "transgressive" to provoke objections by increasingly broad sectors of the public.

At the time the original patent filing was announced in early 1998, both the PTO and critics in the scientific community (including the researcher who patented the first mammal) accused Rifkin and me of scaremongering—speculating about monstrous quasi-human concoctions that no responsible scientist would contemplate producing or patenting.[132] Since then, however, Advanced Cell Technology, a

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128. *See* E. Randi, *et al., Allozyme Divergence and Phylogenetic Relationships Among Capra, Ovis and Rupicapra Artyodactyla, Bovidae,* 67 HEREDITY 281(1991).

129. *See* Chen Su & Masatoshi Nei, *Evolutionary Dynamics of the T-Cell Receptor VB Gene Family as Inferred from the Human and Mouse Genomic Sequences,* 18 MOL. BIOL. EVOL. 503 (2001).

130. Naoyuki Takahata & Yoko Satta, *Evolution of the Primate Lineage Leading to Modern Humans: Phylogenetic and Demographic Inferences from DNA Sequences,* 94 PROC. NATL. ACAD. SCI. U.S.A. 4811, *passim* (1997).

131. 35 U.S.C. §101 (2000).

132. *See* Meredith Wadman, *U.S. Office Claims Right to Rule on Morality,* 393 NATURE 200 (1998). Professor Philip Leder, Chair of the Genetics Department, Harvard Medical School and developer of the Oncomouse (*see supra,* note 48 and accompanying text) stated on the National Public Radio program All Things Considered "[t]he creation of chimeras is an outlandish undertaking. No one is trying to do it at present, certainly not involving human beings." *See All Things Considered* (NPR Radio Broadcast, April 15, 1998).

(Footnote continued…)

Massachusetts biotechnology company, announced its intention to obtain a patent on a technique for creating cloned embryos produced from human cell nuclei and cow eggs.[133] And as we have seen, some academic scientists have subsequently announced their intention to produce human-mouse embryo chimeras.[134]

As it attempted with the Chakrabarty patent application, the PTO rejected the chimera invention in its initial reviews, claiming, in the first instance, that the human-nonhuman chimera was inappropriate subject matter for a patent since it "embraces a human."[135] One major difference between the *Chakrabarty* case and that of Rifkin and myself is that the PTO no longer opposes patents on organisms as it did in the late 1970s. Instead, it would like to draw a line between obviously disturbing inventions of the sort we propose and other life forms for which they have issued patents, such as human bone-marrow cells and pigs containing human genes.[136]

V. FROM PERSON TO ARTIFACT

The prospect of human developmental manipulation holds out the promise of biologically customized, and eventually "better" people, as well as new modalities of reparative medicine. The first program, already underway, if claims of the self-described extraterrestrially affiliated biotechnology company, Clonaid,[137] can be believed, is being promoted as benign[138] in that it is a eugenics of individual choice rather than state coercion.[139] Cheered on by futurologists unencumbered by

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133. S. Hall, *The Recycled Generation,* N.Y. TIMES MAG., January 30, 2000, at 30.

134. *See* E. Check, *Biotech Critic Tries to Sew Up Research on Chimaeras,* 421 NATURE 4 (2003).

135. D. Dickson, *U.S. Bid to Patent Human-Animal Hybrid Fails,* 399 NATURE 626 (1999).

136. *See generally* sources cited *supra* notes 43 and 44.

137. *See* Clonaid's Website, *at* http://www.clonaid.com (last visited April 11, 2003).

138. *See generally,* BUCHANAN *et al*., *supra* note 7, at 196-202. *See also* STOCK, *supra* note 7.

139. Hubbard & Newman, *supra* note 22.

scientific skepticism,[140] provided with the means by unscrupulous technologists and physicians,[141] and motivated by a consumer ideology of the "new and improved" and the desire to gain competitive advantage, technophilic early adopters will be tempted to subject their future offspring to methods that are inherently uncertain and fraught with potential error to accomplish preemptive "cures" of disease and enhancement of appearance, intelligence and talent.

Although one refrain of the advocates of this vision is that developmental manipulation of a child is just an extension of providing it with social advantages such as piano lessons,[142] a scientifically informed appraisal would have to conclude (to stay with the musical motivation) that cloning, or genetic manipulation, in order to generate talented performers is more akin to the commissioning of castrati by 18th Century kapellmeisters. But in contrast to the products of those earlier experiments in biological improvement, whose culture and social environment may have made it difficult to resist being tracked into the profession their handlers chose for them, modern day children (and their lawyers) are likely to be less compliant.

An increasingly discussed scenario[143] is that if certain goals are actually achieved by the use of such techniques, genetically modified offspring will become the new standard for those who can afford them. This will lead to society eventually separating into genetic "haves" and "have nots," like the world portrayed in the 1997 film *Gattaca*.[144] The experience of the field of developmental biology suggests that this is based on much too optimistic projections concerning the likely success of such attempts. Contrary to popular misconceptions (often abetted by journalists and scientists of a reductionist bent[145]), genes do not

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140. Stock, *supra* note 7, at 104-111; *see also* the web site of the Extropy Institute at http://www.extropy.org/about/index.html (last visited April 11, 2003).

141. BBC News report, Doctors Defiant on Cloning, March 9, 2001 *available at* http://news.bbc.co.uk/1/hi/sci/tech/1209716.stm.

142. *See, e.g.,* Arthur L. Caplan *et al.*, *What is Immoral About Eugenics?* 319 BMJ 1284 (1999).

143. SILVER, *supra* note 7, at 4-11. *See also,* LESTER THUROW, CREATING WEALTH: THE NEW RULES FOR INDIVIDUALS, COMPANIES AND NATIONS IN A KNOWLEDGE-BASED ECONOMY 33 (Harper Collins 1999).

144. GATTACA (Sony Pictures 1997).

145. RICHARD DAWKINS, THE SELFISH GENE (2d ed., Oxford University Press 1989).

constitute an organism's "blueprint," or "program"; the genotype determines or prescribes the phenotype in only an approximate sense.[146] A study that compared outcomes of behavioral tests on inbred, genetically uniform strains of mice conducted in three different laboratories showed systematic differences across environments that the experimenters had designed to be the same. The researchers concluded that effects of a given genetic alteration on behavior could differ markedly despite uniformity of genetic background and setting.[147]

In another study in which mice were actually genetically modified with the intention of inducing a changed behavioral profile, they performed in a superior fashion on several tests of learning and memory,[148] and were featured in the popular media as the "Doogie" mouse, after a fictional child prodigy.[149] Not as widely reported was that these mice also exhibited enhanced sensation of pain when exposed to chronic stimuli.[150]

Humans are much less genetically uniform than inbred strains of mice, and it is to be expected that many, if not most, attempts at genetically engineering children will have unexpected adverse outcomes. One way of controlling such uncertainties (to follow the logic of this questionable enterprise) is to start with ES cells derived from a clonal embryo produced from a known prototype and attempt to correct or improve on the prototype. In that situation, however, the ideology of enhancement would work against accepting the inevitable experimental errors—children with brain damage and other profound disabilities resulting from genetic engineering gone awry— motivating parents in search of perfection to try again, with another of the inexhaustible clonal ES cells, for a better result. In effect, the quality control paradigm appropriate to any design-oriented technology would set in.

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146. *See* Stuart A. Newman, *Idealist Biology,* 31 PERSPECTIVES BIOL. MED 353 (1988). *See also* Müller, *supra* note 26. *See also* L. MOSS, WHAT GENES CAN'T DO (MIT Press 2003).

147. John Crabbe, *et al., Genetics of Mouse Behavior: Interactions with Laboratory Environment,* 284 SCIENCE 1670, 1672 (1999).

148. Ya-Ping Tang et al., *Genetic Enhancement of Learning and Memory in Mice*, 401 NATURE 63 (1999).

149. Michael D. Lemonick, *Smart Genes?,* TIME, Sept. 13, 1999, at 53.

150. Feng Wei, *et al., Genetic enhancement of inflammatory pain by forebrain NR2B over-expression,* 4 NATURE NEUROSCIENCE 164 (2001).

The products of mixing and matching fragments of cells and genes from different sources are not organisms as the concept has been understood till now. They straddle the categories of organism and artifact. At the furthest extreme, few would deny that a concoction of synthetic DNA and off-the-shelf chemical reagents that moved and replicated like a living cell would have an ambiguous ontological status somewhere between life and machine.[151] One can question the Supreme Court's description of Chakrabarty's genetically variant bacteria as an "invention,"[152] but it is clear that we are moving toward an era of lifelike artifacts.[153] And what would be the moral and legal status of such humanoids?

Even with the more circumscribed aim of producing tissues for reparative medicine, human developmental manipulation can bring us to a similar pass. The boundary between the acceptable and unacceptable could easily drift under practical impetus. If ES cells (derived from one-week clonal embryos) fail to live up to their promise in the repair of spinal cord injuries, infarcted hearts, or type 1 diabetes, there will surely be calls to permit harvesting EG cells from five-to-nine-week clonal embryos. Women could be encouraged to act as gestational surrogates for clonal embryos derived from the DNA of a patient. They may even be given the option of terminating the cloned fetus if anomalies are detected prenatally (or even if they are not). In either case, useful tissues could be harvested.[154] Like the indigent woman in the documentary film *Roger and Me*[155] who offered rabbits for sale as "pets or meat," it will become increasingly difficult to distinguish subjects from consumables.

While some advocates of producing clonal, genetically modified, or chimeric embryos for research and therapy are comfortable with

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151. *See* Jeronimo Cello *et al., Chemical synthesis of poliovirus cDNA: generation of infectious virus in the absence of natural template,* 297 SCIENCE 1016 (2002); see also the recent report of plans by human genome mapper Craig Venter to build a partly artificial life form, *available at* http://abc.net.au/news/newsitems/s732339.htm.

152. *Chakrabarty*, 447 U.S. at 305.

153. *See* KEEKOK LEE, THE NATURAL AND THE ARTEFACTUAL (Lexington Books 1999). *See also* BILL MCKIBBEN, ENOUGH. STAYING HUMAN IN AN ENGINEERED AGE (Times Books 2003).

154. *See generally* sources cited *supra* note 118.

155. ROGER & ME (Warner Studios 1989).

growing the embryo for fourteen days,[156] or only as long as it remains microscopic,[157] or up to a defined developmental stage such as gastrulation (when the distinct tissue layers of the embryo are established),[158] or through the first trimester, or to any point so long as it is not implanted in a woman's uterus,[159] there does not appear to be a scientifically or philosophically based inherently defensible stopping point. Once embryo modification technology is underway, the boundary of acceptability is in danger of being dictated by those with the loudest voices or largest financial resources, or greatest profits to reap.

VI. DRAWING A LINE

These projections suggest that in the absence of binding restrictions—which would represent a societal agreement not to cross certain absolute lines—the public could be induced to accommodate itself to fabricated humans and near-humans, organisms that previously existed only in the realm of speculative fiction.

An international consensus to ban full-term human cloning is emerging,[160] and some nations' legislative bodies have enacted or are considering more comprehensive bans, including a ban on embryo cloning for research and potential therapeutic applications.[161] On the

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156. COMMITTEE OF INQUIRY INTO HUMAN FERTILISATION AND EMBRYOLOGY, HMSO, THE 1984 WARNOCK REPORT, CMDR 9314 (recommending a limit of 14 days for research with human embryos). *See also* 1990 Human Fertilisation and Embryology Act of 1990, *at* http://www.hmso.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm (last visited June 3, 2003).

157. Michael Kinsley, *Reason, Faith, and Stem Cells*, SLATE.COM, Aug. 29, 2000, *at* http://slate.msn.com/id/88862/.

158. The President's Council on Bioethics, *Human Cloning and Human Dignity: an Ethical Inquiry, at* www.bioethics.gov/reports/cloningreport/fullreport.html#paragraph137.

159. *See* sources cited *supra* note 98.

160. G.A. Res. 56/93, U.N. GAOR, 56th Sess. (2002) (establishing an Ad Hoc Committee, open to all Member States of the United Nations or members of specialized agencies or of the International Atomic Energy Agency, for the purpose of considering the elaboration of an international convention against the reproductive cloning of human beings).

161. A House bill (H.R. 2505) banning all forms of cloning, sponsored by Rep. Dave Weldon (R-FL) and Bart Stupak (D-MI) passed in the full House by a large bipartisan majority in 2001 and a modified version of this bill, retaining the full

(Footnote continued…)

other hand, some statements by bioethicists individually[162] and organizationally,[163] have affirmed the "right" to genetically engineer one's offspring. The Council for Responsible Genetics (Cambridge, MA), a public interest organization that has been scrutinizing the new biotechnologies for more than twenty years, has proposed that all cellular and genetic manipulations of human embryos be prohibited. The Council argues that drawing this sharp line is the only way to prevent the eventual production of experimentally damaged humans and quasi-humans.[164]

Under this proposed legal framework, there would be no impediment to production of embryos by IVF for implantation, or storage for future implantation. However, the developmental manipulation of IVF embryos by genetic means, or the production of clonal or chimeric embryos, would be prohibited. Establishing this line would not prevent scientists from continuing research on ES cells from nonclonal embryos, including genetically manipulating those ES cells. It would, however, help individuals and societies to resist entering into a series of dubious enterprises by which quasi-humans are produced for their capacity to provide spare parts and other functional utilities. Moreover, it would block a pathway leading to the intentional creation of genetically "improved" humans, where those brought about without the benefit of newest technologies, or those representing failed experiments, would come to be increasingly disdained.

No legal framework can prevent the production of cloned and genetically manipulated humans by those determined to do so, but it can stigmatize such activities and guarantee that scientific "progress" in these areas is not accepted into the mainstream technical literature where it could enable further attempts. Notwithstanding recommendations that society accommodate itself to technological "inevitabilities"[165] in human developmental manipulation, the proposal

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cloning ban (H.R. 534) passed in early 2003. Senators Sam Brownback (R-KS) and Mary Landrieu (D-LA) have recently introduced The Human Cloning Prohibition Act of 2003 (S. 245), essentially identical to H.R. 534. A similar bill ended in a Senate stalemate in the 107th Congress.

162. *See* Weiss, *supra* note 71.

163. *European Scholars Support Development of Germ Line Modification, available at* http://www.eurekalert.org/pub_releases/2002-12/sari-ess121302.php (last visited April 11, 2003).

164. Council for Responsible Genetics, Statement on Embryo Research, June 6, 2001, *at* http://www.gene-watch.org/programs/cloning/embryo-statement.html.

165. STOCK, *supra* note 7.

outlined here affirms the idea that humans must control technology rather than be controlled, and in this case defined, by it.