

## **II.E.2 THE NEW HUMAN GENETIC TECHNOLOGIES**

### ***Introduction***

The new human genetic and reproductive technologies represent, arguably, the single most portentous technological development in all of human history. While many applications are benign and to be welcomed, others could profoundly and perniciously transform the nature of human life and human society.

These technologies are being developed and actively promoted by an influential network of scientists, academics and others who see themselves ushering in a new techno-eugenic human future. This vision celebrates the instrumentalization of human reproduction and the wholesale design of human lives. It dismisses long-established commitments to social justice and human rights as anachronisms ill-suited for the new techno-eugenic era. It celebrates nothing less than the end of our common humanity, as we segregate into separate genetic castes and eventually into separate species.

If these technologies cannot be effectively controlled it is difficult to imagine how the vision of the human future embodied in Scenario 3 and social democratic internationalist values could be sustained. By the same token, it is difficult to imagine how these technologies might be controlled *other* than under a social democratic internationalist regime of global governance.

In this Section we explore the challenges presented by the new human genetic technologies. Section II.E.2.a provides an overview, with special attention given to inheritable genetic modification. Section II.E.2.b documents the larger social and political vision of the human future held by advocates of the new techno-eugenics. Section II.E.2.c reviews policy options for bringing the new technologies under societal control, and assesses the chances of their success under our several narrative scenarios.

### **II.E.2.a. Overview of the New Human Genetic and Reproductive Technologies**

The new genetic and reproductive technologies can usefully be separated into two groups: those that involve intervention in human reproductive processes but which do not manipulate particular genes, and those that do directly manipulate particular genes. The new techno-eugenics achieves its particular power from combinations of these sets of technologies. **BOX IIE-17** displays technologies within these two groups, which we now review.

#### NEW REPRODUCTIVE TECHNOLOGIES

This section describes new human reproductive technologies that do not involve direct manipulation of particular genetic sequences. These technologies allow for the selection and manipulation of gametes, embryos and fetuses, and tissues derived from these. **IIE-18** notes recent developments in this rapidly developing field.

##### **a. Expanded pre-natal, pre-implantation, and pre-conception screening and selection**

i. pre-natal: At present a fetus can be routinely tested for about 450 genetic conditions; some of the more common of these are listed in **IIE-19**. A dramatic increase in the number of disease and non-disease traits for which genetic components are known is expected within a very few years.

ii. pre-implantation: Parents at risk of transmitting certain defective genes to their children can consider the option of pre-implantation genetic diagnosis (PGD). In this procedure several embryos are created using *in-vitro* fertilization (IVF), and each is checked for the presence or absence of the defective gene. Only the healthy embryos are implanted. Between 1991 and 2000 about 150 babies have been born after PGD. The cost is high--about \$10,000-\$60,000 per healthy birth--and success rates are low, although these factors could change. As with pre-natal testing, it should eventually be possible to screen for genes that contribute to tens of thousands of human traits. Conditions for which PGD is available are marked with an asterisk in **IIE-19**.

**BOX IIE-17. NEW HUMAN GENETIC AND REPRODUCTIVE TECHNOLOGIES**

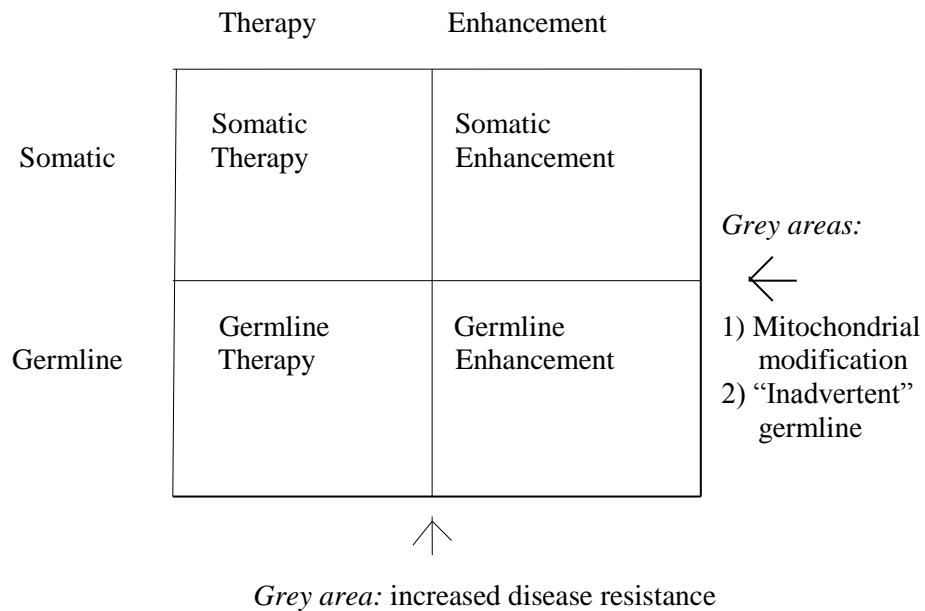
**I. New Human Reproductive Technologies**

(manipulating gametes and embryos but not individual genes)

- Prenatal, Preimplantation and Preconception Genetic Screening
- Somatic Cell Nuclear Transfer (human cloning)
- In-Vitro* Ovum Nuclear Transplant (IVONT); Cytoplasmic Transfer
- Embryonic Stem Cell Technologies
- Mouse Maturation of Human Sperm
- In vitro* Egg Maturation
- Surrogacy; Egg and Sperm Donation
- Human/Animal Hybrids; Human Chimeras

**I. New Human Genetic Technologies**

(manipulating individual genes)



**BOX IIE-18. CURRENT TECHNOLOGIES INVOLVING THE NEW HUMAN GENETIC TECHNOLOGIES**

1. Pre-implantation screening: Researchers at Hammersmith Hospital in London recently implanted an in vitro-fertilized embryo that had been screened for a late-onset form of bowel cancer. The pregnancy failed, as do 80% of IVF attempts, but there is no reason to suspect that future efforts should not succeed. This would be the first PGS for a late onset disorder.<sup>1</sup> In 1998 the Affymetrix Corporation in Santa Clara, CA announced that it is marketing a DNA “chip” that can identify hundreds of different genes simultaneously. As such technologies are perfected the number of traits that PGS can screen for can be expected to grow dramatically.<sup>2</sup>

2. Pre-conception screening: In September 1998 the IVF and Genetics Institute of Arlington, VA, announced that they are offering a new and effective technique to determine the sex of sperm prior to fertilization. The procedure adds \$2,500 to the \$6,000-\$10,000 cost of a typical IVF cycle.<sup>3</sup>

3. In-vitro ovum nuclear transplant: Dr. James Grifo, director of the division of reproductive endocrinology at NYU Medical Center, hopes to achieve the live birth of a baby conceived after nuclear transplant before the end of 1999. St Barnabas Hospital in London has attempted the transfer of mitochondria between eggs from different women, and hopes to have a live baby shortly.<sup>4</sup>

4. Human cloning: Dr. Donald Wolf of the Oregon Primate Research Center hopes to produce rhesus monkey clones by Spring of 1999. Texas A&M University is attempting to clone a millionaire donor’s pet dog. Dr. Severino Antinori of Chieti University in Rome—a leading Italian embryologist—“is considering leaving Italy, where cloning experiments are banned, to begin work that may allow infertile men to have children.” Lee Silver has admitted to knowledge of “quiet” efforts underway at two US IVF clinics to prepare for human cloning. In December 1998 the British Human Genetics Advisory Committee recommended that “therapeutic cloning” be allowed to begin<sup>5</sup>

5. Embryonic stem cells: Scientists at Britain’s Roslin Institute, working with others at the University of Wisconsin--Madison, have applied for permission to begin experiments that would combine cloning and embryonic stem cell technologies. They propose that upon birth a child would have one or more therapeutic clones created. From these, embryonic stem cells would be generated and chemically “frozen”. If, in later life, the child needed a new organ or tissue implant, the appropriate stem cells would be “unfrozen” and used to generate the needed items. This procedure is roughly equivalent to selecting one of two identical twin embryos at a very early age and channeling it into a sort of arrested, modified state, to serve as a tissue bank for the twin that is allowed to come to term.<sup>6</sup>

6. Human Artificial Chromosomes: Several groups of scientists, including Willard et al at Case Western Reserve, are developing HAC’s and hope to have a practicable one by 2007.<sup>7</sup>

<sup>1</sup> San Francisco Examiner, 11/8/98, A-3.

<sup>2</sup> New York Times, 4/8/97; Affymetrix press release: [www.affymetrix.com/press](http://www.affymetrix.com/press).

<sup>3</sup> Time, 9/21/98. “Boy? Girl? Up to You!” p. 82.

<sup>4</sup> New York Times, 10/10/98, A-28.

<sup>5</sup> Wolf: personal communication; Texas A&M: [www.missyplcity.com](http://www.missyplcity.com); Severino: New Scientist, 10/31/98; Silver: NY Times, 12/9/98 p. 1; Seed: San Francisco Examiner, 12/2/98 p. A-16; GTAC: [news.bbc.co.uk](http://news.bbc.co.uk), 12/8

<sup>6</sup> San Francisco Examiner Nov. 8, 1998 p. A-3.

<sup>7</sup> Nature Biotechnology, 16 May 1998, p. 415-416.

**BOX IIE-19. Prenatal Testing and Pre-Implantation Genetic Diagnosis**

**I. Monogenic conditions**

[main source: T. Gelehrter, F. Collins, D. Ginsburg, Principles of Medical Genetics, 1998]

Prenatal testing for about 450 chromosomal and monogenic conditions is offered by many clinics. Some of the most commonly tested for are listed below. Conditions with an asterisk are among those for which pre-implantation genetic screening is also offered. Monogenic conditions are often mentioned as candidates for germline genetic therapy; however, in all but a very small number of instances they can be prevented by prenatal and pre-implantation screening.

Chromosomal Aneuploidies: \*

Down, Turner, and Klinefelter syndromes, and other aneuploidies

Autosomal dominant conditions:

Myotonic dystrophy      Adult polycystic kidney disease  
 Huntington disease \*      Neurofibromatosis 1  
 Familial breast cancer

Autosomal recessive conditions:

sickle cell anemia \*      B-thalassemia      a-thalassemia      Cystic fibrosis \*  
 Phenylketonuria      Tay-Sachs disease \*      a1-Antitrypsin deficiency

X-linked recessive conditions:

Hemophilia A and B      Duchenne and Becker muscular dystrophy \*  
 Fragile X syndrome \*      Ornithine transcarbamylase deficiency

Selected centers also offer testing for:

Rhesus (Rh D) \*      Lesch Nyhan Syndrome \*      Alport Disease  
 Retinitis Pigmentosa      Familial Edematous Polyposis Coli \*  
 Marfan syndrome \*      Spinal muscular atrophy \*

**Polygenic conditions**

main source: Anders Sandburg, [www.aleph.se/Trans/Individual/Body/gene\\_page](http://www.aleph.se/Trans/Individual/Body/gene_page).

Predispositions towards these conditions are thought by many scientists to have polygenic components that should be identifiable and thus available for prenatal and pre-implantation screening. These conditions are also mentioned as candidates for germline genetic intervention, but the caveat noted for monogenic conditions applies here as well. It is likely that genetic components of many thousands of conditions can be identified.

alcoholism	alzheimer's	susceptibility to environmental toxins
schizophrenia	congenital deafness	risk-taking
cancer	obesity	hypertension      drug abuse
diabetes	male sexual orientation	aggression      shyness
manic-depression	breast cancer	

iii. pre-conception: Some couples who desire PGD are troubled by the prospect of destroying surplus embryos that are not implanted. If the genetic contents of eggs and sperm could be determined prior to fertilization, the number of unwanted surplus embryos could be greatly reduced. Such analysis is presently available only for the single trait of sex, but research on testing for other traits is underway.

**b. oocyte cytoplasm transfer (OCT) and *in vitro* ovum nuclear transplant (IVONT)**

Changes in the cytoplasm of an egg often make it more difficult for older women to conceive. Fertility clinics have begun transferring cytoplasm from the eggs of younger women into those of older women in an attempt to remedy this situation. Alternatively they have tried to transplant the nucleus of an egg of an older woman into the enucleated egg of a younger woman. The cytoplasmic mitochondria, which help regulate cellular energy production, have a set of genes independent of those in the cell nucleus. As a consequence, an embryo conceived from an egg that has received cytoplasm from another egg has three genetic parents: a nuclear father, a nuclear mother, and a mitochondrial mother.

**c. somatic cell nuclear transfer (SCNT) / human cloning**

Somatic cell nuclear transfer is the act of taking the diploid nucleus of a somatic cell and transferring it into a female egg from which the haploid nucleus has been removed. Under proper conditions the new construct will begin behaving as a viable zygote and undergo cell division and differentiation. If implanted in a female uterus the expectation is that this clonal zygote would develop and come to term as a clonal infant. The infant would be the genetic twin of the person from whom the somatic cell nucleus was taken. Some researchers propose that SCNT be used not to create a duplicate human being, but to create stem cells that could be used to treat diseases without being rejected by a person's immune system.

**d. embryonic stem cells**

The very early embryonic cells are totipotent, that is, they can each develop into any cell in the human body. As they divide they become successively more committed to specialized developmental paths. In 1998 scientists were able to isolate and grow embryonic stem cells *in vitro*. It is anticipated that stem cells could be used to grow tissues and organs suitable for transplantation. Further, they could be genetically modified to produce novel characteristics. Finally, embryonic stem cells could be used to facilitate human germline engineering. A culture of these cells would be dosed with vectors carrying a desired gene, the nuclei of those that successfully incorporated the new gene would be transplanted into eggs, and these clonal eggs would be implanted into a uterus and grown to term.<sup>8</sup>

**e. *in vitro* egg maturation and “fetal motherhood” technologies**

One drawback of pre-implantation genetic screening as a powerful eugenic technology is that only about 8-15 eggs can typically be obtained from a woman at one time. This limits the number of traits that can be successfully screened for in any single zygote. The following procedure has been suggested as a way to increase the number of screenable zygotes. A woman would conceive a female fetus by pre-conception selection, gestate the fetus until four months, abort it, harvest the 200,000 or so immature eggs that have by then developed within the fetus, cultivate several hundred or thousand of these to maturity *in vitro*, and fertilize them. The fertilized eggs could then be screened and the most desirable ones implanted and brought to term. The mother would in effect be giving birth to her genetic grandchild; the child’s genetic mother would be the aborted fetus. If desired, the eggs could be modified by germline genetic manipulation after fertilization.<sup>9</sup>

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<sup>8</sup> See Zimmerman (1991) for a full description of the important relation between stem cell technologies and germline modification.

<sup>9</sup> See Cha et al. (1991) and Bonnicksen (1997) for a full description and advocacy of such “fetal motherhood” procedures.

**f. mouse maturation of human sperm**

Germline manipulation could be facilitated by removing sperm precursor cells from a man, adding new genes by retroviral transfection, implanting the engineered sperm precursors into mouse testes to mature, extracting mature sperm, testing these for the presence of the desired gene, and using for insemination those sperm found to have the desired gene.<sup>10</sup>

**g. human/animal chimeras, hybrids, and clones**

A chimera is a creature that possesses cells with different genotypes, e.g., those of two different individuals or species. In 1983 Steen Willadsen produced the first sheep-goat chimeras simply by taking cells from very early embryos of each and mixing them together. Sheep and goats are phylogenetically more distant than are humans and chimpanzees, so it appears that human-chimp chimeras would be possible. Alternatively, human/chimp hybrids could be created by implanting human genes into the early embryo of a chimpanzee, or vice-versa. Finally, nuclei from adult human cells have recently been transplanted into enucleated cow eggs cells to create a possibly viable cow-human embryo. The human nucleus would ensure that as the embryo developed it would become increasingly more “human” and less “cow.” But all the cells of the resulting creature would contain cow mitochondria. This procedure was developed as a way to obtain an inexpensive source of embryos that could be used to develop stem cell cultures.<sup>11</sup>

DIRECT GENETIC MODIFICATION

The defining technique of the new technologies of human genetic modification is our ability to add, delete or modify specific genes within a cell. For example, a desired gene (the “transgene”) can be spliced into a retrovirus or other simple organism (the “vector”) capable of

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<sup>10</sup> See Weiss (1998)

<sup>11</sup> See Fehilly et al. (1984) and *New York Times* (1998) for details on human chimera technologies.

penetrating a cell membrane and releasing the transgene into the cell cytoplasm. The transgene integrates into a chromosome and begins producing the desired protein.<sup>12</sup>

Figure 1 of IIE-17 displays two important distinctions that help classify the new genetic technologies.

One distinction is between gene modifications intended to treat a medical condition (“therapy”), and those intended to “enhance” some aspect of appearance or performance. The other distinction is between gene modifications that have an impact solely on a single person, and those that have an impact on a person’s children and subsequent descendants. This is the distinction between “somatic” and “germline” genetic manipulation. Somatic genetic manipulation seeks to change the genetic makeup of particular body (“somatic”) cells that comprise the functioning organs of a person—lungs, brain, bones, etc. Changes in somatic genes are not passed on to the one’s children. Germline genetic manipulation changes the sex cells (i.e., the sperm and egg, or “germ,” cells) whose sole function is to pass a set of genes to the next generation.

These distinctions define four modes of genetic manipulation. *Somatic therapy* seeks to treat a medical condition without changing a person’s germ cells. *Somatic enhancement* seeks to modify the appearance or performance of a healthy person, again without affecting germ cells. *Germ-line therapy* seeks to prevent a medical condition from being passed on to future generations. Finally, *germ-line enhancement* seeks to change the appearance or performance of a child, who is otherwise expected to be healthy, in a way that allows this change to persist over future generations.

Somatic gene therapy trials were begun in 1990. **IIE-20** shows the status of these efforts as of 1998. In general, the results have not been encouraging.

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<sup>12</sup> There are several variations of this process. See any recent human genetics textbook for a fuller account, e.g., Gelehrter et al. (1998).

**BOX IIE-20. SOMATIC GENE THERAPY**

**I. World Wide**

Patients enrolled in somatic gene therapy protocols as of June 1996:

**A. By Disease:**

Cancer:	848	leukemia/myeloma	89
AIDS	372	arterial diseases	16
cystic fibrosis	152	<u>ADA deficiency</u>	<u>12</u>
		<b>TOTAL</b>	<b>1489 (+ ~ 48 others = 1537)</b>

**B. By Country:**

USA	1229	Germany	47	Switzerland	19
UK	61	France	44	Egypt	15
Netherlands	55	Canada	22	Italy	14

(+ < 10 each: Spain, Austria, Sweden, China, Finland, Japan)

**II. United States**

**Totals, as of June 1995:**

Human gene transfer clinical trials:	107
number of subjects:	597
number of institutions:	37

**By disease category:**

	<u>number of patients</u>
I. Gene Therapy	501
A. Monogenic inherited	64
A1-antitrypsin deficiency	0
Chronic granulomatous disease	0
cystic fibrosis	53
familial hypercholesterolemia	5
Fanconi anemia	0
Gaucher disease	0
Hunter syndrome	0
SCID-ADA deficiency	6
B. Carcinomas, multiple types	214
C. HIV	219
D. other	4
Peripheral artery disease	4
rheumatoid arthritis	0
II. Gene Marking Techniques	96
A. Cancer	81
B. Infectious diseases	15
C. other	0

note: "0" means the protocol has been approved but no patients have yet been given gene transfers.

[Sources: T. Marcel and J. D. Grausz, "The TMC Worldwide Gene Therapy Enrollment Report." *Human Gene Therapy*, 10/20/96, p. 2025. Gail Ross et al., "Gene Therapy in the United States: A Five-Year Status Report" *Human Gene Therapy*, 9/10/96, p. 1781.]

Germline therapy has not been attempted, and is explicitly banned in many countries, but its development and use is being advocated by noted scientists, as we discuss in Section IIE.2.b. The conditions listed in Box IIE-19 are suggested as possible early candidates for the germline therapy. **IIE-21** lists proposals for genetic enhancement that have appeared in the literature.

The distinctions between therapy and enhancement, and between somatic and germline gene modifications, are not always clear. Gene manipulation that cures cystic fibrosis would be considered by most people to be therapeutic. Gene manipulation that enables a child of average height potential to reach an adult height of seven feet would clearly be an enhancement. But what about gene manipulation that confers resistance to lung cancer? Prevention of illness has long been considered a proper medical imperative. Yet the example given is clearly an enhancement of the normal human condition.

The distinction between somatic and germline genetic modification is more easily drawn, because germline genetic changes can be detected empirically. However, at least one ambiguous instance exists. As noted above, the cytoplasmic mitochondria possess a set of genes independent of those in the cell nucleus, and in the process of cytoplasmic transfer as a fertility treatment, some mitochondria get transferred as well. Although particular genes have not been engineered, the total genetic complement of the new zygote has been modified, and these modifications would be passed to successive generations.

A difficulty with many applications of germline genetic engineering is the necessity of inserting the correct new gene in precisely the correct location along a human chromosome, a process known as homologous replacement. An alternative is to develop a human artificial chromosome (HAC) which can carry new genes into a cell nucleus, enable these to function effectively, and be transmitted intact through many generations. A person carrying an extra, artificial chromosome in their germs cells would be able to mate only with a partner who also

## **BOX IIE-21. Examples of Proposed Genetic Enhancements**

### **A. LeRoy Walters and Julie Gage Palmer (1997)**

“Five potential types of enhancements...are particularly compelling examples of the prospects for enhancement genetic engineering:

1. Size: “the germline insertion of a growth hormone gene could enhance the stature of a child who is otherwise destined to be short, or even average in size.”
2. Sleep: “a gene for an agent that could reset the circadian clock or reduce the need for sleep would be transferred to cells that could be implanted in the hypothalamus. There they would cooperate with the brain cells controlling sleep.”
3. Aging: “genetic manipulation involving the insertion of hyperactive human superoxide dismutase genes into bone marrow stem cells might provide an anti-aging “therapy.”
4. Memory: “The ability to remember words names, facts and experiences is one thing many people might like to improve for themselves and their offspring. ...The enhancement would be carried out by inserting NMDA (N-methyl-D-aspartate) genes into human cells... to increase the number of NMDA receptors...”
5. Aggression: “Aggression is often cited as an example of a prime candidate for genetic manipulation, although it is not clear whether the desired change would be an increase or decrease in aggressive tendencies.”

### **B. Anders Sandberg (1998)** [source: [www.aleph.se/Trans/Individual/Body/gene\\_page](http://www.aleph.se/Trans/Individual/Body/gene_page)]

1. Artificial symptoms: Since many potentially life-threatening diseases lack easily noticed symptoms, we could “...add genes coding for enzymes producing a strongly coloured compound, which colors the urine. These genes are normally repressed by a repressor which is inactivated by the presence of certain disease-indicative chemicals” (several repressors could be linked, so that only certain highly selective combinations would cause the color shift.)
2. Sight: humans use four slightly different types of rhodopsin for colour vision. Other varieties are known among animals, and could perhaps conceivably be added to expand human perceptive range ...from the near ultraviolet (based on insect rhodopsin) to the near infrared.

### **C. Assorted Others:**

1. Genes implanted to generate growth hormone in short, but normal range, youth.
2. Genes implanted to produce natural vaccines against many diseases.
3. Genes implanted that produce appetite-surpressent hormones to control weight gain.
4. Cosmetic applications: baldness, hair color and type, secondary sex characteristics
5. Genes for resistance to industrial toxins for someone who works with hazardous chemicals
6. Therapeutic enhancement: “insertion of an additional LDL receptor gene in ‘normal’ individuals could significantly decrease the morbidity and mortality caused by atherosclerosis.” (Eisenberg 1997, quoting W.F. Anderson.)

### **D. The Economist; editorial (1992)**

“What of genes that might make a good body better, rather than make a bad one good? Should people be able to retrofit themselves with extra neurotransmitters to enhance various mental powers? Or to change the colour of their skin? Or to help them run faster, or lift heavier weights? Yes, they should. Within some limits, people have a right to make what they want of their lives.”

carried the additional chromosome. In effect, the two persons would become members of a new species of human being.

### DRAWING LINES

The new genetic technologies present humankind with the arguably the most important question we have ever had to answer: where do we draw the lines? There are few persons or constituencies that strongly oppose somatic gene therapy on principle, assuming it is shown to be safe and effective. Somatic gene enhancement raises many concerns. Some somatic enhancements may be no more controversial than dying ones' hair, while others may be profoundly dangerous or otherwise unacceptable. But the effects of somatic enhancements are limited to a single person, and thus potential risks are constrained.

The critical dividing line is between somatic and germline applications, whether for therapy or enhancement. Many people oppose all germline engineering. Others support germline therapy but oppose enhancement, and believe the distinction can be made and enforced. Others are similarly inclined to support therapy and oppose enhancement, but doubt that the distinction can be made or enforced. People of this mind need to decide whether they believe that the benefits of germline therapy warrant accepting the likely spread of germline enhancement, or if the unacceptability of enhancement requires that the benefits of therapy be foregone.

**BOXES IIE-22, IIE-23, IIE-24 and IIE-25** show arguments in favor of and opposing germline gene therapy, and rebuttals to these. **IIE-26** addresses the central question of whether in fact germline modification is necessary as a therapeutic technique. We see that other reproductive and genetic techniques, notably PGD, are at least as good, and in fact preferable, to germline modification as a means of allowing parents at risk of passing on disease-causing genes, in all but a very small number of instances. **IIE-27** summarizes the attitudinal and normative differences that typically underlie opinions as to whether or not germline therapy should be allowed.

**BOX IIE-22. ARGUMENTS IN FAVOR OF GERMLINE GENE THERAPY**

1. Some genetic diseases affect the fetus as it develops. Only early fetal gene therapy can counter these. In the process the germline will be modified, but this is a benefit, not a risk.
2. Parents may wish to spare their children and descendants from having to either:
  - a) undergo somatic gene therapy if they are born afflicted with a defect; or
  - b) face difficult decisions regarding possibly transmitting a disease-related gene to their own children or descendants.
3. Germline therapy is more efficient than somatic therapy, in that it permanently removes defective genes from the gene pool
4. Physicians have a responsibility to offer their patients the fullest possible range of options for medical treatment.
5. Researchers deserve to have the freedom to explore new modes of treating and preventing disease.
6. Humans evolved to compete for advantage, and germline engineering is motivated, ultimately, by the desire of people to out-compete others. Efforts to stop germline engineering will fail because cunning people will do it anyway. Therefore we should support it, and make sure its development and use proceed in a safe and effective manner.

**BOX IIE-23. REBUTTALS TO ARGUMENTS IN FAVOR OF GERMLINE GENE THERAPY**

Each numbered statement below is a rebuttal to the argument with the same number in Box IIE-22.

1. Fetal somatic gene therapy can employ techniques that are specific to cells that need to be treated, and thus avoid the threat of germline modification.
2. Prenatal testing with the possibility of abortion, and pre-implantation screening, can allow parents to accomplish these same ends, while avoiding the risks that germline modification entails, for all but a very small number of couples. [See Box IIE-26 for details]
3. Prenatal and preimplantation procedures also permanently remove defective genes, as do other options for parenthood such as adoption and gamete donation.
- 4, 5. These responsibilities and freedoms are not absolute. Democratic societies have the right and responsibility to proscribe procedures that they believe are unsafe or otherwise undesirable.
6. Humans evolved the ability to work cooperatively in society. If sufficient numbers of people decide that germline engineering is a technology the risks of which outweigh its benefits, or is otherwise undesirable, we can agree to forego its development and use.

**BOX IIE-24. ARGUMENTS AGAINST GERMLINE GENE THERAPY**

1. Unanticipated negative effects of germline manipulation will be passed on to all future generations.
2. Informed consent of the affected subjects is not possible.
3. The research on embryos necessary to develop germline gene therapy is ethically unacceptable.
4. Germline gene therapy will likely always be an expensive procedure available only to the affluent professional classes, thus exacerbating social and economic inequality.
5. Germline gene therapy will open the door to germline enhancement, which
  - a) entails medical risks even greater than those that germline therapy entails;
  - b) if “successful”, would likely greatly exacerbate social and economic inequality;
  - c) could generate cascades of genomic change beyond our ability to understand, assess, or control;
  - d) could give malevolent dictators dangerous powers.
6. Human beings have a moral right to receive a genetic patrimony that has not been subjected to artificial tampering.
7. Germline technologies would contribute strongly to the cultural construction of human beings as biologically perfectible artifacts. This would encourage widespread negative feelings of self-worth, change the nature of the parent-child relationship, and likely have other profound and destabilizing socio-cultural impacts. Further, the standards of “perfection” would reflect current social biases, and children engineered to meet these standards might find themselves genetically “out of fashion” in the world in which they live as adults.

**BOX IIE-25. REBUTALS TO ARGUMENTS AGAINST GERMLINE GENE THERAPY**

Each statement below is a rebuttal to the argument of the same number in Box IIE-24.

1. All innovative efforts at technical progress entail some risk. Society can pledge to compensate anyone who suffers. Also, particular genetic problems created as a result of germline modification could very likely be corrected by using the same techniques that caused them.
2. In most societies parents give informed consent for medical treatment of children of theirs who are unable to. Alternatively, informed consent can be engineered into many germline manipulations by including genetic “on-off” switches that can be activated by patients after they have reached the age of consent.
3. Research on embryos is ethically acceptable if the benefits outweigh the costs, and if the embryos are treated with respect. These conditions can be met in a way that allows germline techniques to be developed.
4. The costs of germline procedures may come down. If they don’t come down far enough to be equitable, public sector assistance could be provided. Even if only the more affluent benefit from the new technologies, this is better for society than if the new technologies were not developed at all.
5. In general, most germline genetic enhancements will turn out to be more desirable than not. If necessary, society can pass laws to prevent enhancements it believes are undesirable. The use of genetic technologies by malevolent dictators needs to be constrained by international commitment and cooperation.
6. This “moral right” has not been universally acknowledged. Future generations could also be said have a moral right to a healthy genome.
7. Human nature, not cultural construction, motivates people to want to improve themselves and endow their children with advantages. Feelings of self-worth, and parent-child relationships, will improve, not suffer, when germline engineering becomes an option. Most important standards of improvement are constant across cultures and historical time.

**BOX IIE-26. IS GERMLINE GENE THERAPY NECESSARY?**

Germline gene therapy is often mentioned as a way of ensuring that a couple can have children free of serious genetic disease. However, there are alternatives to germline engineering that accomplish this: adoption, embryo donation, gamete donation, pre-natal testing with the possibility of pregnancy termination, and pre-implantation screening.

Prenatal and preimplantation procedures enable most couples to have a child that is fully genetically related to them and free of genetic disease. In only two instances is this not possible:

1. Both partners are homozygous for the same genetic disease.
2. A couple, both members of which are heterozygous for a genetic disease, are willing to use pre-implantation genetic screening, but are unwilling to discard defective embryos or donate or discard healthy embryos not implanted.

In both instances the number of couples who fit these descriptions is so small that statistics are not available; cases are cited anecdotally.

Proponents of germline therapy argue that even if there were only a single couple in the world who would not be able to have a healthy child of their own without using germline techniques or violating their conscience, this would be sufficient grounds to justify development of germline technology.

Opponents of germline therapy argue that individuals homologous for a genetic disease can have healthy children of their own by partnering with any one of the 99.96% of people who are *not* similarly homologous, or by adoption or gamete or embryo donation. In any event implications of launching humankind into a new evolutionary epoch are not outweighed by the benefits that might be realized by the number of couples that would fall into the two categories listed above, no matter how individually compelling these might be.

## WHAT IT'S ALL ABOUT

In 1989 biologists David Suzuki and Peter Knudtson issued a warning about the connection between the new genetic and the new reproductive technologies:

“Newspaper headlines trumpeting medical breakthroughs with test-tube babies, surrogate mothers, sperm banks and frozen embryos remind us that this art of external, or in vitro, fertilization is already a reality. Remarkably, even as society becomes increasingly concerned about the potential social and ethical effects of these and other human reproductive technologies, we hear little public discussion about the role these same techniques may play in future human germ-line therapy procedures. The fact is that almost any scientific advance that grants greater access to human reproductive cells and embryos hastens the day when the genetic manipulation of human germ cells will become medically feasible.” (p 204)

A decade later, advocates of the new techno-eugenics were extolling the connection between these sets of technologies. Here is Lee Silver of Princeton, one of the leading techno-eugenic enthusiasts:

“IVF...will now serve as a stepping stone to many reprogenetic possibilities that go far beyond its original purpose... the development of IVF marks the point in history when human beings gained the power to seize control of their own evolutionary destiny...By bringing the embryo out of the darkness of the womb and into the light of day, IVF provides access to the genetic material within.” (1998 pp 74-75)

Ian Wilmut (1998) of the Roslin Institute in Scotland, where the first adult mammalian cloning techniques were devised, makes clear how cloning, stem cell technologies and germ-line engineering are envisioned as components of a single, far-reaching techno-eugenic procedure, in just one sentence:

“If a couple was willing to produce an embryo that could be treated by advanced forms of gene therapy, nuclei from modified embryonic cells could be transferred to eggs to create children who would be entirely free of a given disease.” (pp 58-63)

Although the great majority of genetic researchers justify their work as motivated by a compassionate desire to prevent genetic diseases, they are fully aware that the techniques they are developing could be used for other purposes. Further, many, perhaps most, of these researchers tend to oppose significant societal restrictions on their research. Meanwhile, as we'll see in the next section, a minority of these researchers quite willingly acknowledge that their driving intent is to produce genetically engineered post-human beings.

**BOX IIE-27. CORE DIFFERENCES BETWEEN PRO- AND ANTI-GERMLINE ADVOCATES**

These lists summarize attitudinal and normative differences between pro - and anti- germline advocates based on the sets of arguments and rebuttals shown in Boxes IIE-22 through IIE-25.

FAVOR Germline

1. More confident that serious harm can be avoided; more willing to accept harm that might happen.
2. More protective of individual than of societal prerogatives. Libertarian tendencies.
3. Less willing to constrain researchers.
4. Less concerned about equity impacts.

OPPOSE Germline

1. Less confident that serious harm can be avoided; less willing to accept harm that might happen.
2. Seek to balance individual and societal prerogatives. Social democratic tendencies.
3. More willing to constrain researchers.
4. More concerned about equity impacts.

## **II.E.2.b THE NEW TECHNO-EUGENIC VISION OF THE HUMAN FUTURE**

A core set of philosophical, normative and political commitments are held by many proponents of the new techno-eugenics. These include commitments to:

- \* materialism, reductionism and determinism
- \* science and technology as autonomous endeavors properly exempt from social control
- \* laissez-faire economics, de-regulation, and the presumed priority of market outcomes
- \* a libertarian political philosophy grounded in social Darwinist views of human nature and society

Together these core commitments represent a unique ideological stance. It differs from conservative ideologies in its antipathy towards religion and traditional social values, from left-progressive ideologies in its rejection of egalitarian values and social welfare as a public purpose, and from Green ideologies in its celebration of the technological transformation of the natural world – plants, animals, humans and ecosystems. It might be thought of as a sort of utopian libertarian scientism. It is shared by a small but influential number of scientists, persons associated with high-tech private enterprise, and technologically literate academics and journalists.

A further common thread in the statements of many of these scientists and others is the repeated assertion that the advent of the new techno-eugenic human era is “inevitable,” and, for good measure, that this is so “whether we like it or not.”

This section highlights statements by a variety of scientists and others who espouse one aspect or another of the new techno-eugenics, or of libertarian scientism more generally. The authors cited are hardly of one mind on all matters, but they show a strong commonality of perspective and normative commitment. Their statements also suggest that they may share many perspectives with supporters of the Extraordinary Future cited in Section II.E.1.

### **Lead Speakers at the March 1998 UCLA Symposium**

In March 1998 a major symposium was held at the University of California, Los Angeles, titled “Engineering the Human Germline.” Nearly 1000 participants heard a roster of noted scientists speak in favor of the new human genetic engineering technologies. The lead organizer, Gregory Stock, described the symposium as the kick-off of a campaign “to make it [germline engineering] acceptable” to the American people.<sup>13</sup> Statements and texts prepared by scientists who spoke at the UCLA Symposium are excerpted below.

#### 1. Gregory Stock

Stock serves as Director of the Science, Medicine and Society Program at UCLA’s Center for the Study of Evolution and the Origin of Life. He received a Ph.D. from Johns Hopkins University and an MBA from Harvard. In his 1993 book, *Metaman: The Merging of Humans and Machines into a Global Superorganism*, Stock offers this vision of the human future:

“By applying biological techniques to embryos and then to the reproductive process itself, Metaman will take control of human evolution.. Once people begin to reshape themselves through biological manipulation,.. the definition of “human” begins to drift. Altering even a small number of the key genes regulating human growth might change human beings into something quite different.. Competitive pressures within Metaman will ensure the spread of any useful ways of significantly enhancing human capabilities. Populations that adopt such techniques will generally outdistance those that do not, just as has been the case with other technologies. The computer has become a necessity for modern society, and if a process were developed to triple human intelligence or to enable people to get along with no sleep, these too would soon become ‘necessities’. Such changes will not be painless. Like all major developments, they will cause great stresses within society. But asking whether such changes are ‘wise’ or ‘desirable’ misses the essential point that they are largely not a matter of choice; they are the unavoidable product of the technological advance intrinsic to Metaman.” (pp 168-169)

#### 2. Lee Silver

Silver is a Princeton University scientist conducting research in mammalian genetics, evolution, reproduction and developmental biology. He received his doctorate from Harvard University. In his 1998 book, *Re-Making Eden*, Silver celebrates the coming future of “repro-

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<sup>13</sup> The official Symposium report can be found at [www.css.ucla.edu:80/huge/report.html](http://www.css.ucla.edu:80/huge/report.html).

genetic” human enhancement, in which the health, appearance, personality, cognitive ability, sensory capacity and life-span of our children become artifacts of genetic manipulation, traits literally selected from a catalog. Silver acknowledges that cost and other factors will limit their full use to only a small portion of Americans, so that over time society will segregate into the “GenRich” and the “Naturals:”

“The GenRich—who account for 10 percent of the American population—all carry synthetic genes... that were created in the laboratory ...All aspects of the economy, the media, the entertainment industry, and the knowledge industry are controlled by members of the GenRich class...Naturals work as low-paid service providers or as laborers, and their children go to public schools... If the accumulation of genetic knowledge and advances in genetic enhancement technology continue ... the GenRich class and the Natural class will become...entirely separate species with no ability to cross-breed, and with as much romantic interest in each other as a current humans would have for a chimpanzee.” (pp 4-7)

Silver continues:

“Many think that it is inherently unfair for some people to have access to technologies that can provide advantages while others, less well-off, are forced to depend on chance alone... (But) American society adheres to the principle that personal liberty and personal fortune are the primary determinants of what individuals are allowed and able to do. Anyone who accepts the right of affluent parents to provide their children with an expensive private school education cannot use “unfairness” as a reason for rejecting the use of reprobogenetic technologies. Indeed, in a society that values individual freedom above all else, it is hard to find any legitimate basis for restricting the use of reprobogenetics... I will argue (that) the use of reprobogenetic technologies is inevitable. It will not be controlled by governments or societies or even the scientists who create it. There is no doubt about it...whether we like it or not, the global marketplace will reign supreme.” (pp 9-11)

### 3. James Watson

Watson shared the Nobel Prize for Chemistry in 1962 for the discovery of the structure of DNA, served as Director of the National Center for Human Genome Research and was responsible for establishing the Human Genome Project. In 1973 he offered this suggestion regarding pediatric care:

“If a child were not declared alive until three days after birth, then all parents could be allowed the choice that only a few are given under the present system. The doctor could allow the child to die if the parents so chose and save a lot of misery and suffering.”  
(*Time*, May 28)

An interviewer asked Watson how he felt about eugenics; he replied, “We do it right now...I wouldn’t marry a stupid woman.”<sup>14</sup> On another occasion Watson was asked if he feared that genetic engineering could be used for “enhancement” eugenic ends; he replied, “It’s not much fun being around dumb people.”<sup>15</sup> In a major address to molecular biologists held in Berlin in 1997, Watson urged Germans to overcome their hostility to genetics research. He said that the time has come “to put Hitler behind us.”<sup>16</sup>

#### 4. Daniel Koshland, Jr.

Koshland served as editor of the most prestigious peer-reviewed scientific journal in America, *Science*, for ten years. Since 1965 he has been a professor (now emeritus) of Molecular and Cell Biology at the University of California at Berkeley. He has a building named after him—Koshland Hall—on the U.C. Berkeley campus.

“If a child destined to have permanently low IQ could be cured by replacing a gene, would anyone really argue with that? ...It is a short step from that decision to improving a normal IQ. Is there an argument against making superior individuals? Not superior morally, and superior philosophically, just superior in certain skills; better at computers, better musicians, better physically. As society gets more complex, perhaps it must select for individuals more capable of coping with its complex problems.” (p 88)<sup>17</sup>

Koshland received widespread notice in 1989 when he defended the \$3 billion Human Genome Project as “a great new technology to aid the poor, the infirm, and the underprivileged.”<sup>18</sup> At the 1998 UCLA Symposium, Koshland said, “The demand for gene enhancement therapy will probably be very large, to give your children a better chance of success in the world.”<sup>19</sup>

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<sup>14</sup> Quoted in Appleyard, 1998 (p 82)

<sup>15</sup> Quoted in Eubank, 1998

<sup>16</sup> *Science*, 6 May 1997

<sup>17</sup> Quoted in Appleyard, 1998

<sup>18</sup> *Science*, 13 October 1989. Editorial (p 189)

<sup>19</sup> “Engineering the Human Germline,” [www.ess.ucla.edu:80/huge/report.html](http://www.ess.ucla.edu:80/huge/report.html). (p 10)

## 5. LeRoy Hood

LeRoy Hood holds an M.D. from Johns Hopkins and a Ph.D. from Cal Tech. In 1982 he developed the first procedure for germline genetic engineering, using mice. He is currently William Gates Professor of Biomedical Sciences and founding chair of the Department of Molecular Biotechnology at the University of Washington. The department was established with a \$12 million endowment from Bill Gates of Microsoft.

“We could probably engineer people to be totally resistant to AIDS, or to certain kinds of cancers. We might engineer people to live much longer. I would say all these are good qualities....There will come a time when we will understand enough to manipulate even complex genetic systems.. For example, we will be able to dramatically affect intelligence. That, I think, will be pretty irresistible.” (p 129)<sup>20</sup>

## **Others**

### 1. Joseph Fletcher

Fletcher has been lauded as “America’s patriarch of medical ethics.” He has been praised as offering “an insightful and commonsense approach to ethical evaluation of the new genetic and reproductive technologies.” Nobel Laureate Joshua Lederberg applauded Fletcher’s “wise counsel,” and suggested that Fletcher’s outlook “will inspire many demoralized and confused people, especially parents...” Here are excerpts from Fletcher’s 1988 book, “The Ethics of Genetic Control: Ending Reproductive Roulette”<sup>21</sup>:

“Chimeras or parahumans might legitimately be fashioned to do dangerous or demeaning jobs. As it is now, low grade work is shoved off on moronic and retarded individuals, the victims of uncontrolled reproduction. Should we not “program” such workers thoughtfully instead of accidentally, by means of hybridization? Hybrids could also be designed by sexual reproduction, as between apes and humans. If interspecific coitus is too distasteful, then laboratory fertilization and implant could do it. If women are unwilling to gestate hybrids animal females could. Contrived in order to protect human beings from danger or disease, chimeras and cyborgs would be morally justified.” (p 173)

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<sup>20</sup> New Scientist 3 October 1998 (p 29)

<sup>21</sup> Lederberg’s quotes are from the Introduction. Other quotes are from the back cover.

“Good reasons in general for cloning are that it avoids genetic diseases, bypasses sterility, predetermines an individual’s gender, and preserves family likeness. It wastes time to argue over whether we should do it or not; the real moral question is when and why.” (p 154)

“...there is nothing inherently or absolutely wrong [about incest], yet the greatest good for the greatest number might best be served by disapproving it. Having said as much, however, we may then hold that in particular cases it could be right to practice incest. It would depend on the situation, presumably an odd and highly unusual situation.” (p 174)

## 2. James Hughes

Hughes has served on the faculty of the University of Connecticut and acts as a bioethics consultant to individuals and businesses. In his 1995 article, “Embracing Change with All Four Arms,” he writes,

“People desire different attributes and abilities, for themselves and their children; for every Aryan parent that chooses a blond, blue-eyed Barbie phenotype, I expect there would be a Chinese parent choosing a classic Chinese ideal of beauty. True, this might lead to the convergence toward few physical and mental ideals, though I suspect that phenotypic fashions will change quickly. But I see no ethical difference between permitting people to change their genes in conformity with social fashions, and permitting them to change their clothes, makeup and beliefs to do so.”

“Parents will probably be less gene-obsessed when they can either have a child with all their parent’s genetic flaws, or one that shares their facial features, but has been tweaked with someone else’s good teeth, arched feet, height, and intelligence. It will be considered obsessive and dumb to give your kids only parental genes, and parenting will be the definition of parental ties, not parentage.... (f)ertility treatments, surrogacy and genetic technology do not reify the genetic bond, but cause its slow deconstruction... genetic intervention will force us to clarify the relationship of social ties and genetic ties. If you’ve picked most of your child’s genes from a catalog, it’s likely to reinforce the importance of your social parenting ties to your child.”

“The right to a custom made child is merely the natural extension of our current discourse of reproductive rights. I see no virtue in the role of chance in conception, and great virtue in expanding choice... If women are to be allowed the “reproductive right” or “choice” to choose the father of their child, with his attendant characteristics, then they should be allowed the right to choose the characteristics from a catalog.”

## 3. Rachel Fishman

Fishman is a legal scholar whose 1993 article, “Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?,” appeared in the highly-regarded *American Journal of Law and Medicine*:

“To prevent the loss of legal rights of an altered human being who may no longer be found to be a member of the human species, it is imperative that the definition of “human being” be expanded. It is preferable that the definition be broad rather than narrow, as it is better to err on the side of generosity rather than parsimony when depriving a being of his or her legal rights.”

Fishman proposed that the following clause be inserted at the end of section 100 of Title 35 of the United States Code:

- “(e) The term “human being” means:
- (i) any genetically altered animal possessing one or more higher faculties such as: the ability to reason...; the ability to evaluate principles and observations to arrive at reasoned decisions; the ability to formulate speech and communicate; the ability to write; the ability to develop meaningful personal relationships with other human beings on the basis of equality; the demonstration of awareness of self as a unique and separate being; the ability to feel concern for others; or any other higher faculty.”
  - (ii) any creature born of the ovum and sperm of parents who are human beings...”

Fishman explains,

“If a researcher transfers human characteristics to his or her animal subjects so that the animal possesses significant human characteristics, section (i) ensures this newly altered creature has legal status as a “human being” with attendant rights. .. If half-human creatures are created, courts will have to define the scope of this section on a case-by-case basis.” (pp 461-482).

#### 4. Gregory Pence

Pence is professor of philosophy in the Schools of Medicine and Arts/Humanities at the University of Alabama. In his 1998 book, *Who’s Afraid of Human Cloning?*, he writes:

“...many people love their retrievers and their sunny dispositions around children and adults. Could people be chosen in the same way? Would it be so terrible to allow parents to at least aim for a certain type, in the same way that great breeders... try to match a breed of dog to the needs of a family?” (p 168)

“As for what is best for “society” or “the community,” these questions imply too much control over the family or creation of the child to be good questions. Besides, if it’s good for the child and good for the family, society will be fine.” (p 166).

#### 5. Stephen Hawking

In May of 1998 the distinguished physicist Stephen Hawking spoke at a gala event held at the White House, attended by President and Mrs. Clinton and several hundred of our country’s

political and scientific elite. To a “rapt audience,” Hawking shared his vision of the human future:

“...the human race needs to improve its mental and physical qualities if it is to deal with the increasingly complex world around it and meet new challenges like space travel. And it also needs to increase its complexity if biological systems are to keep ahead of electronic ones...” To do this we will have to “completely redesign” the human DNA. “Of course, many people will say that genetic engineering on humans should be banned. But I rather doubt if they will be able to prevent it. Genetic engineering on plants and animals will be allowed for economic reasons, and someone is bound to use it to change human DNA unless we have a totalitarian order. Clearly, developing improved humans will create great social and political problems...I’m not advocating human genetic engineering as a good thing. I’m just saying that it is likely to happen in the next millennium, whether we want it or not.” (San Francisco Chronicle, 3/20/98, p 1)

## 6. Steen Willadsen

Willadsen developed the somatic nuclear cell transfer technology that Ian Wilmut later modified to produce cloned sheep. He became wealthy as a result of a stock-option arrangement with an early employer, Alta Genetics, that hoped to use his techniques to clone prize cattle.<sup>22</sup> Willadsen is currently involved in private research concerning oocyte cytoplasm transfer and other reproductive technologies.

In her 1998 book, *Clone: the road to Dolly and the path ahead*, New York Times reporter Gina Kolata says that the “near mythical” Steen Willadsen “did not accept the notion that there should be insurmountable obstacles to cloning adults... throughout his scientific life, he had scoffed at the very idea that hypothetical biological or technical barriers might stymie him.” She quotes Willadsen: “‘The role of the scientist is to break the laws of nature, rather than to establish, let alone accept them’.” She says that Willadsen “tosses off judgmental statements and tends to outbursts that he immediately confesses sound brash, or arrogant...” His life goal is “to engage in great, absorbing endeavors while maintaining a high degree of freedom, and avoiding tedium and coercion.” In graduate school, Kolata says, “he thought that just two subjects were [in his words] ‘worth wasting time on’ - the brain and reproductive physiology.”

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<sup>22</sup> Willadsen cashed out before the plan was abandoned and the stock crashed.

Willadsen “lives in a huge pink-stucco house...with thirteen foot ceilings and a swimming pool on an enclosed porch. He denied that his house was large or terribly luxurious, although, he noted in one of his inadvertently brash asides, ‘it’s not for the underprivileged.’” Willadsen “spends his days tending his lawn, writing, and working part-time at two in vitro fertilization centers...In between helping infertile women have babies, Willadsen experiments with mice and with human eggs that would otherwise have been discarded.” (*passim.*)

***Comments***

Many of the statements by the authors noted above might strike some readers as so preposterous that the first reaction is that they need not be taken seriously. This is incorrect--- Watson, Silver, Stock, and the others are indeed serious. They are by-and-large gifted, productive, and influential scientists who share a common social and political world-view and agenda, and are working very hard to make it happen.

### **II.E.2.c POLICY REGIMES**

How do we credibly counter the vision of the human future promoted by the scientists and others just quoted? In particular, how do we counter the claim that the “post-human” future is “inevitable, whether we like it or not”? We need to do at least two things. One is to give credible examples of the sorts of policies that would prevent such a future from happening. A second is to show that large numbers of people support or could come to support such policies. In this section we briefly note proposed and existing policies that address human genetic technologies. In the section after this we review public opinion about these technologies.

**BOXES IIE-28** and **IIE-29** display sets of policy recommendations by Jedediah Purdy and Andrew Kimbrell, respectively, addressing a wide range of concerns raised by the new human genetic and reproductive technologies. Purdy is a writer for *The American Prospect*, a centrist/social democratic political journal. Kimbrell is director of the International Center for Technology Assessment, an activist NGO. Their recommendations cover much the same ground, although Purdy’s is somewhat more permissive and Kimbrell’s a bit more restrictive. Both lists touch on many important concerns not addressed explicitly in these notes, including privacy, discrimination and access issues, that would likely figure prominently in a full public engagement over human genetics policy. The global ban on “super enhancements” that Purdy proposes still leaves enormous latitude for germline manipulation.

The two countries that have gone the furthest in adopting policies of the sort recommended by Purdy and Kimbrell are the United Kingdom and Germany. In 1991 the British Parliament passed a bill establishing the Human Fertilization and Embryology Authority (HFEA). The HFEA has 21 members, directly appointed by the several health ministers of the UK. It is charged with making and enforcing rules concerning the responsible use of human genetic materials. Relatively few forms of human genetic modification are legislatively banned. Rather,

**BOX IIE-28. JEDEDIAH PURDY'S PLATFORM**

[“Dolly and Madison”, *The American Prospect*, June 1998]

1. Bar insurers from treating genetic illnesses as “pre-existing conditions.”
2. Bar insurers from refusing general coverage to victims of genetic disorders.
3. Ban the use of tests that identify predilections to homosexuality or other stigmatized but harmless qualities.
4. Rule out, absolutely and in advance, the assignment of any institutional position on the basis of genetic profiles.
5. Ensure the absolute privacy of genetic profiles.
6. Ban the development of human organ farms.
7. Basic genetic therapeutic procedures should be incorporated into Medicaid and other programs for the poor.
8. Coverage of basic genetic therapeutic procedures should be mandated coverage by HMO's.
9. Develop global accords to ban “super-enhancements,” such as:
  - \* the proposed extra chromosomes that would create new species of human beings.
  - \* any enhancement that adds capacities that are not now part of the human lot.
  - \* any deliberate reduction in human capabilities.
  - \* the engineering of specialized excellences focused on a particular function.

**BOX IIE-29. ANDREW KIMBRELL'S PLATFORM**

*[The Human Body Shop, 1993]*

1. A moratorium on the use of induced-abortion fetuses for transplantation and research until the profound ethical and legal problems surrounding this practice are fully discussed and resolved.
2. No eugenic use of "superior" sperm or eggs.
3. No experimentation on embryos, and maximum attempts to see that frozen embryos are given a chance at life.
4. Limits on the use of genetic screening of the unborn (amniocentesis, CVS, or preimplantation genetic screening of embryos) to ensure that screening is used only for detecting life-threatening disease.
5. No genetic screening or monitoring of workers, and no discrimination against individuals in questions of employment or insurance or health coverage based on their genetic readout.
6. No use of genetically engineering drugs to alter or treat human traits that are the object of discrimination (height, pigmentation, and so on.)
7. Limitation of gene therapy to the treatment of life-threatening disease. No use of gene engineering of humans for cosmetic or enhancement purposes.
8. A moratorium on the germline alteration and cloning of animals, including the engineering of human genes into animals, until there has been a full public debate on the issue and the ethical and environmental consequences of the genetic engineering of animals are better understood.
9. A ban on germline genetic therapy for the foreseeable future. We do not have the wisdom to know which genes are "good" and which genes are "bad."
10. A complete ban on the cloning of human beings.

the HFEA is given broad latitude to set policies. This has the advantage of giving flexibility concerning a new and rapidly changing set of issues, but gives a relatively small, appointive body the final say over matters of far-ranging consequence. The most important structural feature of the HFEA is its authority to license and monitor all public and private institutions whose work involves the use of human gametes or embryos. This allows real public accountability and control, as distinguished from many proposals, notably by researchers and the fertility industry, for self-regulation, or for adoption of statements of principles and guidelines that have no enforcement mechanisms. See more about the HFEA in **II E-30**.

The German *Embryonenschutzgesetz* (Embryo Protection Law) was also adopted in 1991 and is among the strictest sets of restrictions on human genetic and reproductive research and services world-wide. It bans all uses of human embryos for research purposes and pre-implantation genetic screening, and allows *in-vitro* fertilization and other assisted reproductive technologies only under tightly constrained conditions. Because these activities are banned outright rather than regulated, there is no need in Germany to establish a regulatory structure such as the HFEA. For more on the *Embryonenschutzgesetz* see **II E-31**.

Legislation brought before the Canadian parliament in 1996 strikes a middle ground between that adopted by the British and the Germans. It bans outright more technologies than is the case in the UK British but less than in Germany, and establishes a regulatory body to oversee the remainder. The proposed Canadian legislation is interesting in having been developed after an extensive five year consultation with thousands of Canadian civil society organizations, experts and the general public, under the auspices of a Canadian Royal Commission. Provisions of the Canadian legislation are shown in **II E-32**.

The single most significant human genetics policy instrument agreed upon in recent years is the *Convention on Biomedicine and Human Rights*, adopted by the Council of Europe in 1997. The Council itself was established after World War II as a body for coordinating European-wide policies on a large number of social, cultural and political matters, and currently has 44 members.

**BOX IIE-30. The Human Fertilization and Embryological Authority (HFEA)**

[main source: [www.doh.gov.uk/embryo.htm](http://www.doh.gov.uk/embryo.htm)]

The Human Fertilization and Embryology Authority (HFEA) was established in the United Kingdom in 1991 following extensive national consultation and debate. It remains one of the few statutory bodies of its kind in the world, and is often pointed to as a model for regulating reproductive and genetic technologies.

The main functions of the HFEA are:

1. To license and monitor all UK treatment clinics offering: in vitro fertilization (IVF) donor insemination (DI) storage of eggs, sperm or embryos;
2. To license and monitor all research involving human embryos.

The HFEA also produces a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities, and keeps a formal register of information about donors, treatments and children born from those treatments.

The HFEA has 21 members, appointed by UK Health Ministers. The HFE Act requires that the Chair, Deputy Chair and at least half of the HFEA's membership are neither doctors nor scientists involved in human embryo research or providing infertility treatment.

Licensed clinics are inspected annually, by an inspection team consisting of a clinician, a scientist, a person with a background in another field, such as counseling, as well as a member of the HFEA's executive staff. The HFEA employs 65 part-time inspectors.

To grant a research license the HFEA must be satisfied that the use of human embryos is "necessary or desirable" for at least one of the following purposes:

- \* to promote advances in the treatment of infertility
- \* to increase knowledge about the causes of congenital disease
- \* to increase knowledge about the causes of miscarriages
- \* to develop more effective techniques of contraception
- \* to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation

UK law does not permit certain activities involving human embryos. These include:

- \* keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is earlier; placing a human embryo in an animal;
- \* replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo, or subsequent development of an embryo;
- \* altering the genetic structure of any cell while it forms part of an embryo;
- \* using embryos for any other purposes except in pursuance of a license.

In 1998 the HFEA reiterated its opposition to human reproductive cloning, and forbade clinics to engage in activities specific to human cloning. The HFEA also called for national legislation, just to solidify the case against cloning.

**BOX IIE-31. The German Embryonenschutzgesetz (Embryo Protection Act)**

[source: [www.bundesregierung.de/en/News-by-subject/Science-and-Technology-,11165](http://www.bundesregierung.de/en/News-by-subject/Science-and-Technology-,11165)]

The Embryo Protection Act entered into force on January 1, 1991. Key provisions include:

1. a ban on all somatic cell nuclear transfer (human cloning) whether for research or reproduction.
2. a ban on gene transfers in germ cells and embryos (germline manipulation).
3. a ban on gender selection, except in cases of sex-linked genetic diseases.
4. a ban on the creation of chimeras and hybrids.
5. a ban on the implantation of human embryos into animals, and vice-versa.
6. a ban on artificial fertilization of egg cells with the sperm of persons who are dead.
7. strict controls over fertility clinic operations, including strict monitoring and accountability to guard against accidental or intentional misapplications (e.g., trafficking in embryos).
8. strict controls over operations of researchers involved with human genetic materials.

**BOX III- 32. CANADIAN BILL C-47: THE HUMAN REPRODUCTIVE AND GENETIC TECHNOLOGIES ACT**

[Source: [http://www.parl.gc.ca/bills/government/C-47/C-47\\_1/17946bE.html](http://www.parl.gc.ca/bills/government/C-47/C-47_1/17946bE.html)]

Bill C-47 was based on the 1993 Report of the Canadian Royal Commission on New Reproductive Technologies (1993) and considered by the 35<sup>th</sup> Parliament, 1996-97. Parliament adjourned before taking final action but the bill is expected to be re-introduced.

The intent of the bill was to draw boundaries concerning those human genetic and reproductive technologies where the lines were clear and social consensus was evident. Subsequent legislation was intended to establish a commission to oversee licensing and operations of those practices which were to be permitted.

Activities prohibited under Bill C47 included:

1. creating human zygotes by somatic cell nuclear transfer
2. creating human-animal zygotes
3. implanting human zygotes in animals, or vice-versa
4. germline alteration
5. creating zygotes intended for implantation from gametes harvested from cadavers or fetuses
6. sex selection for non-medical reasons
7. maintenance of embryos outside the human body
8. creating human embryos specifically for the purpose of research
9. commercialization of surrogacy
10. purchase and sale of ova, sperm, zygotes, embryos or fetuses
11. use of ova, sperm, zygotes and embryos for any purpose without informed consent of donors

The legislation provided that anyone guilty of violating these proscriptions is liable to fines up to \$250,000-\$500,000 and/or prison terms up to four to ten years.

As noted in **II.E-33**, the *Convention* at once bans all germline engineering, whether therapeutic or “enhancement;” all enhancement applications, whether somatic or germline; sex selection; and the creation of human embryos for research purposes. The Convention explicitly does not prohibit research using human embryos. The Convention comes as close as any document has to date in embodying what might be an international policy consensus. States who sign the Convention commit themselves to seek to incorporate the Convention’s provisions into domestic law. As of late 1999 the Convention had been signed by 30 member countries.

The only existing globally international policy document addressing the new human genetic technologies is the *Universal Declaration on the Human Genome and Human Rights* adopted by the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1997. Unlike the Council of Europe’s *Convention* or national legislation, it is a declaration only, and has no force of law. The hope, however, was that the *Declaration* would encourage and set ground rules for national and regional legislation and treaties, and set the stage for a subsequent round of global negotiations. The UNESCO declaration is comparatively permissive. Most of its provisions are very general exhortations to respect individual and human rights, and the concerns of developing countries, when considering policies regarding human genetic research and applications. Although the document declares that human reproductive cloning is “contrary to human dignity” and should be prohibited, it takes a more equivocal position regarding germline modification, stating only that this practice “may” be contrary to human dignity. Other provisions are summarized in **II.E-34**. The generality and tentativeness of the Declaration is perhaps to be expected for a text agreed upon by representatives from 110 countries. It remains to be seen what steps UNESCO might take towards more explicit language.

The declarations, laws and regulations just reviewed, despite their differences, are existence proofs of the ability of societies to draw lines in just the right places and agree to support benign and beneficent applications of the new human genetic technologies while proscribing pernicious ones. However, the fact that in the instance at hand these laws and

**BOX IIE-33. Council of Europe Convention on Biomedicine and Human Rights  
[1997]**

[Source: Convention for the Protection of Human Rights and The Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. European Treats, ETS No. 164 (1997).]

The several chapters and articles cover a wide range of topics, including equitable access to health care, adherence to professional standards, informed consent, non-discrimination, genetic privacy, patient protection, organ donation and transplantation, and other topics. Articles dealing explicitly with human genetics topics include:

***Article 11 - Non-discrimination***

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

***Article 12 - Predictive genetic tests***

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counseling.

***Article 13 - Interventions on the human genome***

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

***Article 14 - Non-selection of sex***

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

***Article 18 - Research on embryos in vitro***

1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo; 2. The creation of human embryos for research purposes is prohibited.

As of December 1999 the *Convention* had been signed by 28 of the Council's 44 member countries, and ratified by 6 of them.

**BOX IIE-34. UNESCO'S UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS**

[[http://portal.unesco.org/shs/en/ev.php@URL\\_ID=1881&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php@URL_ID=1881&URL_DO=DO_TOPIC&URL_SECTION=201.html)]

In 1997 UNESCO approved a declaration on human genetic technologies and related issues, explicitly grounding its concern within a human rights framework. Key provisions include:

***A. Human Dignity and the Human Genome***

*Article 1.* “The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of all humanity.”

*Article 4.* “The human genome in its natural state shall not give rise to financial gains.”

***B. Rights of the Persons Concerned***

*Article 5* calls for “prior, free and informed consent” for any diagnosis, treatment, research and information sharing concerning genetic matters, and review procedures for genetic research.

*Article 6* stands in opposition to genetic discrimination.

*Article 7* affirms the need for confidentiality in the course of genetic research or other purpose.

***C. Research on the Human Genome***

*Article 10* says no genetic research should prevail over basic human rights, freedoms and dignity.

*Article 11:* “Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted.”

*Article 12* affirms freedom of scientific research, but implies that genetic research should confine itself to “relief from suffering and improving the health of individuals and humankind.”

***D. Conditions for the Exercise of Scientific Activity***

Articles 13 through 15 call on States to support human genome research, to establish comprehensive systems of oversight, and to encourage the establishment of independent review committees regarding human genetic research.

***E. Solidarity and International Cooperation***

Articles 16 through 19 emphasize the need for North-South cooperation concerning human genetics issues, and the need to ensure that research and development meets the needs of the South.

***F. Promotion of the Principles set out in the Declaration***

Articles 20 through 25 contain recommendations to States and other bodies on ways to support the principles stated in this declaration. Article 24 says that UNESCO's International Bioethics Committee should “give advice... regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions.”

regulations need to be universal if they are to be effective at all poses an immense practical challenge. It is reasonable to expect that when people come to realize all that is at stake, they will be motivated to support the needed policies. But this will not happen at the scale and in the time required without a major commitment on the part of social, political and other world leaders, and a popular base, working to make it happen. In the next section we review a range of surveys of general publics and influential leaders concerning the new human genetic technologies.