THE BASICS

STEM CELLS AND PUBLIC POLICY

A CENTURY FOUNDATION GUIDE TO THE ISSUES

The Century Foundation Press ◆ New York City

Stem Cells and Public Policy was authored by Richard Hayes of the Center for Genetics and Society in collaboration with Pete Shanks and Marcy Darnovsky, under the direction of Leif Wellington Haase of The Century Foundation.

The Basics Series

America is engaged in difficult and complex policy debates over critical issues. There are conflicting claims and disagreements over the meaning of the facts and figures relating to the significance of the social safety net, the way our political system works, and the economic issues facing our nation. The Century Foundation hopes to help clarify these issues by collecting the best available information and presenting it in a series of pamphlets called The Basics.

The intent of this series is in keeping with the Foundation's mandate. Since 1919, The Century Foundation, formerly the Twentieth Century Fund, has sponsored and supervised research on economic, social, and political issues. As a nonpartisan but not neutral organization, our underlying philosophy regards government as an instrument, not an enemy, of the people, and therefore we strive, in the words of our bylaws, for the "improvement of economic, industrial, civic, cultural, and educational conditions."

The Century Foundation also believes in the power of well-reasoned, well-researched ideas. These pamphlets are presented in that spirit. They are our contribution to increased citizen understanding and wiser governmental decisions.

Other titles in the series:

Public Policy in an Aging America
USA PATRIOT Act
Immigration Reform
Tax Reform
Balancing the Budget
Social Security Reform
Medicare Reform
Medicaid Reform

To order additional copies of this pamphlet or other Basics pamphlets, please contact the Foundation (see page 88).

Contents

Introduction

Proposals to use human embryonic stem cells for medical research have provoked perhaps the most intense social and political debate over the proper application of technical knowledge since the controversies over nuclear weapons and nuclear power in the 1960s and 1970s. Stem cells first became a topic of widespread public attention in 2001, when President George W. Bush authorized the use of federal funds for research on existing embryonic stem cell lines, but prohibited the derivation of new ones. Since that time, struggles over the types of stem cell research that should be allowed, and the levels of funding committed to such research, have continued unabated.

The issues raised by stem cell research go far beyond the acceptability of research using human embryos, although public debate has focused largely on this ongoing disagreement. Stem cell research requires us to address critical questions about medical research priorities, the treatment of intellectual property rights, the role of religious and scientific institutions in society, the tension between privately and publicly funded health care and medical research, the well-being of research subjects including women who provide eggs for stem cell investigations, the revival of eugenic practices and ideologies, and the effective national and international governance of the burgeoning field of biotechnology.

If stem cell technologies—and the new human biotechnologies more generally—are to promote rather than compromise human well-being, an informed public must fully engage the debate over their proper development and use. The publication of *Stem Cells and Public Policy* is intended to help inform this debate.

I. What Are Stem Cells?

Stem cells are unspecialized cells that develop into the specialized cells that make up the different types of tissue in the human body. They are vital to the development, growth, maintenance, and repair of our brains, bones, muscles, nerves, blood, skin, and other organs. In the laboratory, researchers are learning how to coax stem cells to differentiate into specialized kinds of cells, and to create the conditions under which stem cells will replicate themselves for extended periods of time. If these unique properties can be understood and harnessed, stem cells hold great potential as tools for medical research and as therapeutic agents.[1]

There are two main types of stem cells:

- ***Embryonic stem cells*** are found in embryos at a very early stage of development. They have the ability to differentiate into any of the over two hundred types of cells that make up the human body.

- ***Adult stem cells*** have the ability to differentiate into varieties of a particular type of cell, determined by the type of tissue in which they are found. For example, blood stem cells found in the bone marrow give rise to red blood cells, white blood cells, and platelets. The term *adult* is used to indicate that these stem cells are further along the path of differentiation than are embryonic stem cells. Adult stem cells are found in tissues at all but the very earliest stage of human development: in fetal tissues, in children, and in adults. Scientists have thus far been able to isolate adult stem cells from tissues in the eye, skeletal muscle, liver, skin, fat, dental pulp, pancreas, umbilical cord, and the lining of the gastrointestinal tract.

Some technical terms and concepts useful for understanding stem cells are defined and described in Box 1, page 7. The differentiation of embryonic stem cells is shown in Figure A, page 8.

Scientists are using stem cells to study basic processes of embryological development, including the processes that lead to genetic disease and abnormalities. They also are conducting research to see if stem cells might be used directly for therapeutic purposes.

Given appropriate nutrients, stem cells can replicate in the laboratory without differentiating, and thus create stem cell lines. Such cell lines are valuable because they allow researchers to work with quantities of genetically identical material at different times and places.

Adult stem cells are more difficult to maintain in culture than are embryonic stem cells. It is also difficult to identify and isolate many types of adult stem cells, as they are buried among the many non-stem cells of a given tissue.

It was formerly thought that embryonic stem cell lines could self-replicate indefinitely, but recent research suggests that mutations as well as possible contamination from the nutrient medium may limit the "shelf life" of an embryonic stem cell line.[2]

Embryonic stem cells, while easier to isolate and maintain than adult stem cells, currently are more difficult to control. When put into an organism, they have a tendency to form benign tumors called teratomas. In fact, scientists often verify that they have established an embryonic stem cell line by injecting some of the cells into immunosuppressed mice to see if they develop into teratomas, which contain cells from all three of the most basic embryonic tissue types.

Box I. Stem Cell Terms and Concepts

All human beings develop from the union of an egg and a sperm. The result is a fertilized egg, or *zygote*, a single cell that divides into other cells, which together constitute the early embryo.

The first few of the early embryonic cells are *totipotent*, meaning that they are each capable of giving rise to an entire organism, including all the cell types that make up the embryo and the body, and all the cell types that make up the extra-embryonic supporting tissues, such as the placenta.

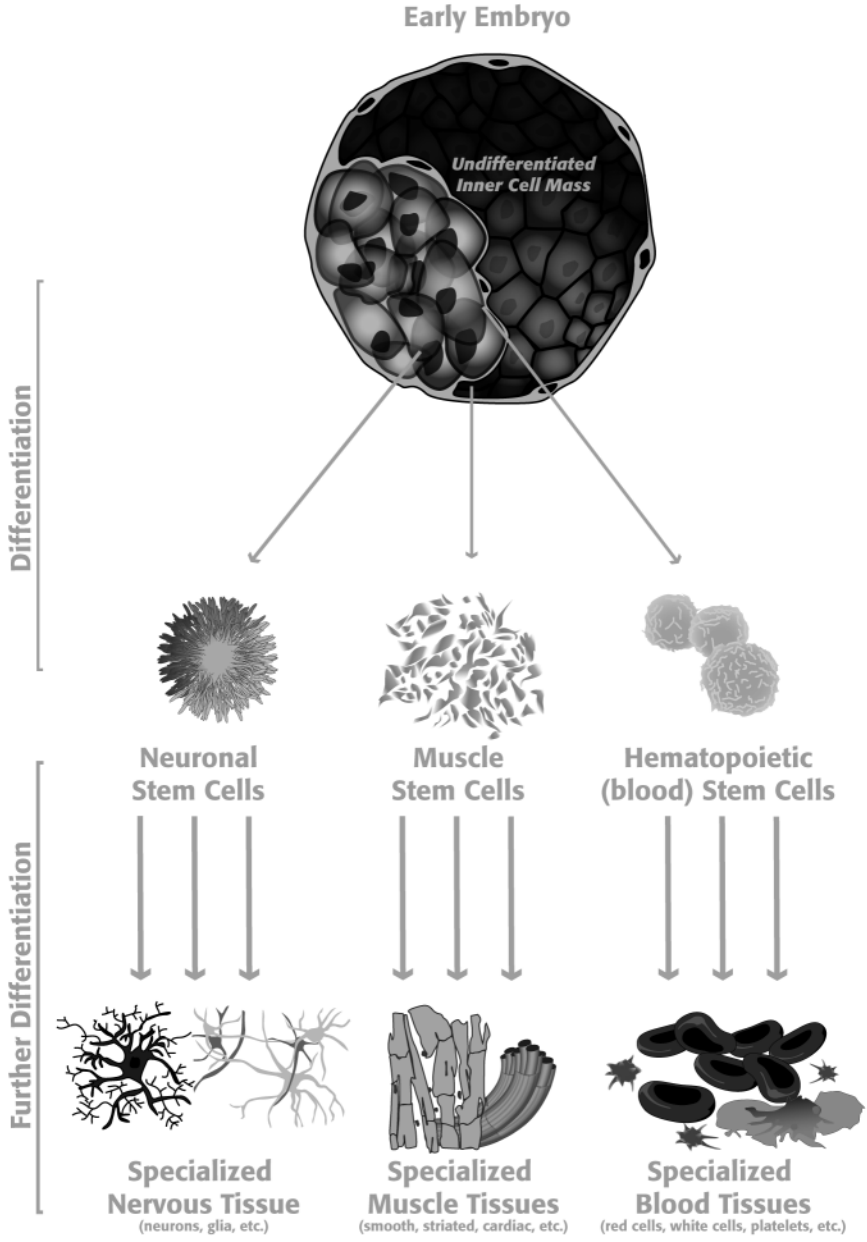
About five to seven days after conception, a zygote will have divided into about one hundred to one hundred and fifty cells. These take the form of a hollow ball called a *blastocyst*, with a mass of undifferentiated cells inside it. These undifferentiated cells are used to generate *embryonic stem cell lines.*

These embryonic stem cells are no longer totipotent, but they are still *pluripotent*, that is, they are capable of differentiating into all the types of cells that comprise a human being. They cannot form extra-embryonic tissues (such as the placenta), and thus cannot give rise to a fetus.

After the embryonic stem cells have differentiated into the many types of cells that make up a fetus, a child, or an adult, most lose their ability to differentiate further. However, a small number, the *adult stem cells,* retain some ability to differentiate. These *multipotent* cells replenish and repair many of the cells of the body.

See the Glossary (page 69) for additional definitions.

Figure A


Early Embryo
Undifferentiated Inner Cell Mass
Differentiation
Neuronal Stem Cells
Muscle Stem Cells
Hematopoietic (blood) Stem Cells
Further Differentiation
Specialized Nervous Tissue
(neurons, glia, etc.)
Specialized Muscle Tissues
(smooth, striated, cardiac, etc.)
Specialized Blood Tissues
(red cells, white cells, platelets, etc.)

Sources of Embryonic Stem Cells

Most embryonic stem cells currently used in research are derived from embryos that were created in the course of infertility treatments by means of *in vitro* fertilization (IVF) procedures. Many IVF embryos are not used to establish a pregnancy, and some of these "spare" IVF embryos are donated for medical research. (See Figure B, page 10.) Embryonic stem cells also can be derived from IVF embryos created specifically for research purposes. Some scientists are investigating a third source of embryonic stem cells, involving the production of embryos by means of a technique variously known as *somatic cell nuclear transfer* (SCNT), *research cloning*, or *therapeutic cloning*. (See Figure C, page 11.)

The phrase "stem cell research" can refer to research using adult stem cells, embryonic stem cells obtained from IVF embryos, or embryonic stem cells derived from clonal embryos. The derivation of stem cells from IVF or clonal embryos involves the destruction of those embryos.

What Is the Relationship between Stem Cell Research and Cloning?

To understand better the controversy over stem cells it is necessary to understand the set of technologies referred to as *cloning*. Cloning is the process of creating a genetically identical copy of an existing organism. To create a clone of an animal (including a human), the first step would be creation of a clonal embryo. This is done using SCNT.

SCNT involves several steps. First, a woman's egg is obtained and the nucleus is removed, creating an enucleated egg. Then the nucleus of a somatic cell from a nuclear donor—typically, an adult—is removed and inserted into the enucleated egg. A somatic cell is any cell in the body other than eggs or sperm; eggs or sperm cells are often called reproductive cells, gametes, or germ cells.

Figure B

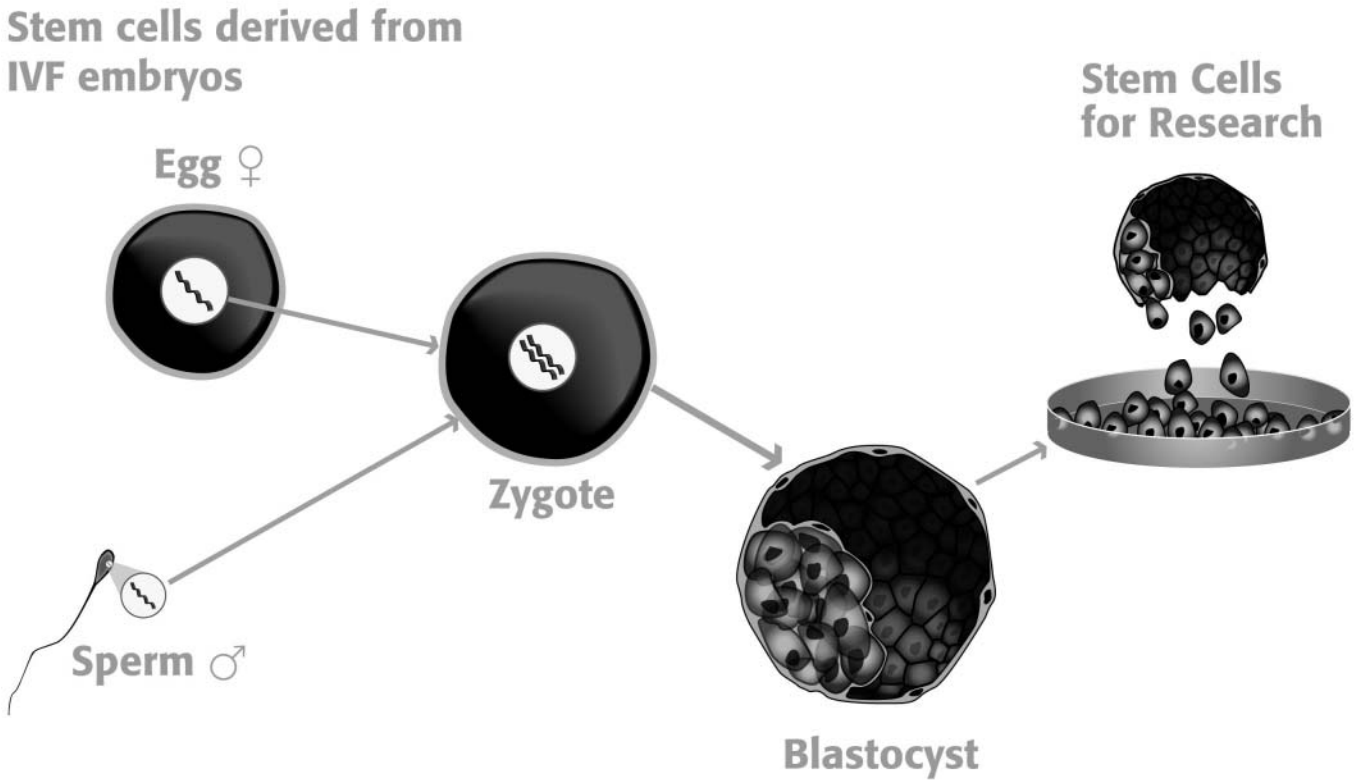
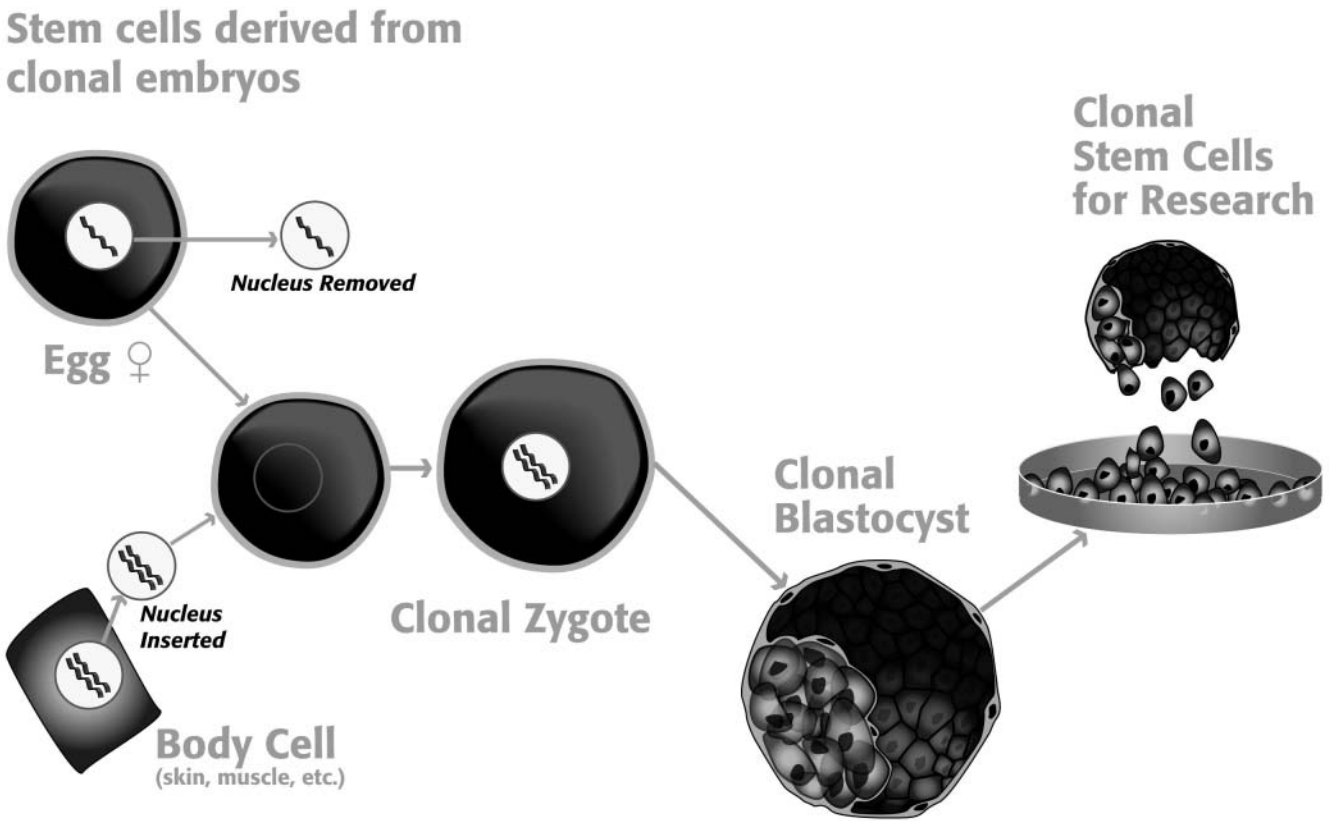

Stem cells derived from
IVF embryos
Egg ♀
Sperm ♂
Zygote
Blastocyst
Stem Cells
for Research

Figure C


Stem cells derived from clonal embryos
Clonal Stem Cells for Research
Nucleus Removed
Egg ♀
Clonal Blastocyst
Nucleus Inserted
Clonal Zygote
Body Cell
(skin, muscle, etc.)

The result of SCNT is a clonal zygote. If treated with chemicals and electricity, the zygote can begin to divide, and become a clonal embryo.

SCNT can be used for either research or reproductive purposes. If the clonal embryo that SCNT creates were implanted in a woman's uterus, successfully gestated, and brought to term, the baby would be a clone of the nuclear donor. It would be genetically identical to the donor. This process is called *reproductive cloning*. (See Figure D, page 13.)

Sheep, mice, cattle, horses, pigs, cats, dogs, and several other mammalian species have been cloned. Despite repeated claims, there is no evidence that humans have been cloned. Human reproductive cloning raises a set of issues that are separate from stem cell research.

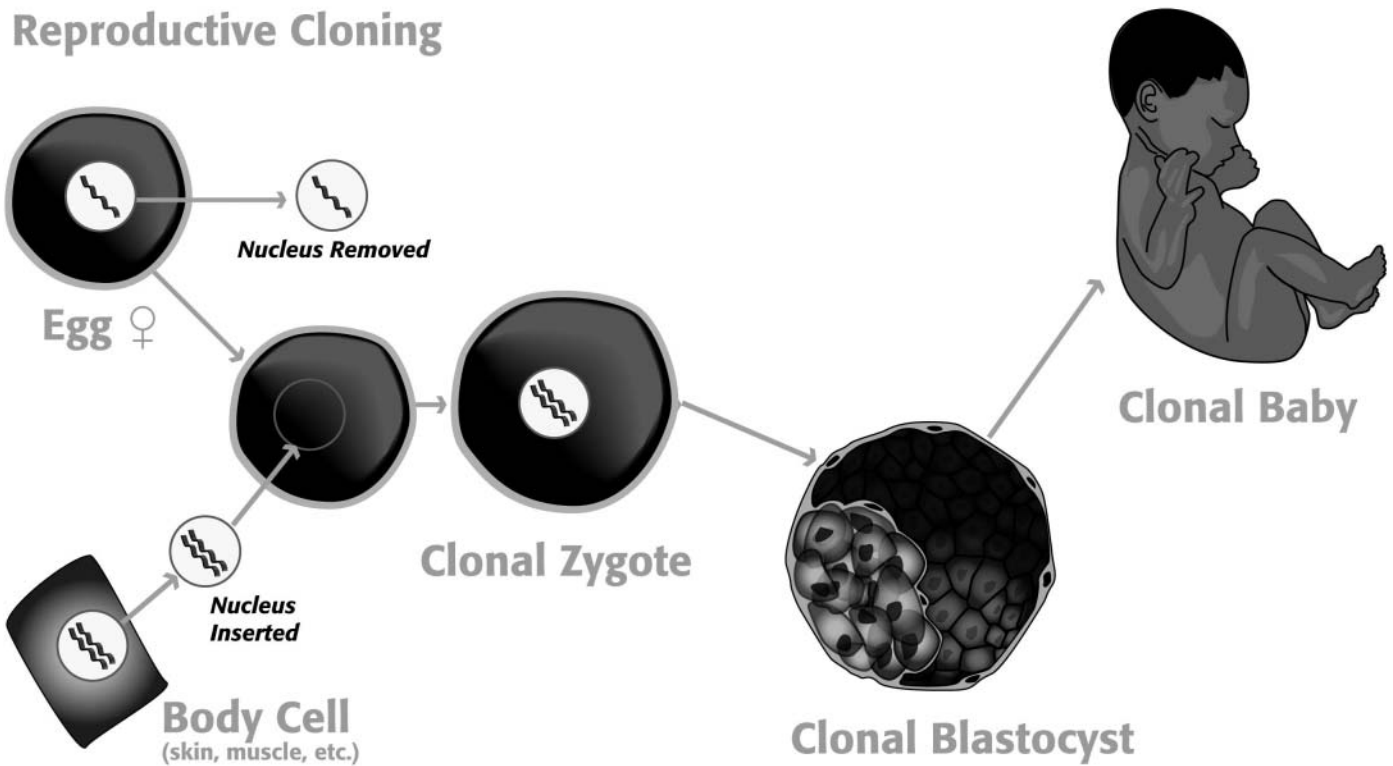
If a clonal embryo is used for research purposes rather than reproductive purposes, the process is often called *research cloning*. If the embryo is used to derive tissues to be used in therapeutic applications, the initial cloning process might be called *therapeutic cloning*.[3]

Research cloning has been proposed as a way to create stem cells with particular known genetic characteristics. By taking the somatic cell from patients with particular conditions and applying research cloning techniques, scientists hope to gain a better understanding of the etiology and very early development of those conditions.

The hope for therapeutic cloning, if it becomes clinically and practically feasible, is for the creation of stem cells for transplantation that are genetically matched to a recipient and therefore less likely to cause immune rejection problems.

Efforts to produce embryonic stem cells from cloned human embryos are ongoing but have not yet succeeded.[4] Widely publicized claims by a team of South Korean and U.S. scientists to have successfully created clonal human embryos in 2004 and 2005 were found later to be fraudulent.

Figure D


Reproductive Cloning
Nucleus Removed
Egg ♀
Nucleus Inserted
Body Cell
(skin, muscle, etc.)
Clonal Zygote
Clonal Blastocyst
Clonal Baby

II. Applications of Stem Cell Technologies

Stem cell technologies have, or are anticipated to have, applications for basic science, medical research, and therapies.

Basic science applications. Stem cells are ideally suited to allow for the study of complex processes that direct early unspecialized cells to differentiate and develop into the more than two hundred cell types in the human body.

Medical research applications. Stem cell studies may allow researchers to follow the processes by which diseases and impairments caused by genetic abnormalities first manifest themselves biochemically or structurally in cells and tissues. Using stem cells to produce large numbers of genetically uniform cultures of organ tissues—for example, liver, muscle, or neural—would allow controlled comparison of the effects of drugs or chemicals on these tissues.[5] Alternatively, testing drugs against stem cell tissues of varying genetic makeup could allow development of pharmaceuticals tailored to provide greater benefits, and with fewer side effects, for patients with specific gene-related characteristics. In addition, the use of human stem cell cultures might reduce the need to use animals for research and testing purposes.[6]

Therapeutic applications. The prospect of using stem cells to repair or replace damaged or diseased tissues has generated enormous interest. In the courses of their lives, the great majority of people suffer from one degenerative condition or another. The conditions that stem cell technologies might conceivably address include Parkinson's disease, spinal cord injury, stroke, type 1 diabetes, heart disease, rheumatoid arthritis, osteoarthritis, kidney disease, blood diseases (including sickle cell anemia), blindness, muscular dystrophy, liver disease, loss of teeth, and baldness. Some researchers have speculated that stem cell technologies might allow entire organs—stomachs, hearts, livers, kidneys, and others—to be grown and used for transplantation. Stem cells also might be used in conjunction with other

therapies. For example, they might be used to replenish immune cells destroyed during chemotherapy for cancer. Box 2 and Box 3, pages 16 and 17, describe ways that stem cells might be used to treat spinal cord injury and type 1 diabetes.

Current Use of Stem Cells for Therapeutic Purposes

One form of therapy involving stem cells has been employed for nearly forty years: the use of adult blood stem cells (hematopoietic cells) taken from bone marrow to treat leukemia, lymphoma, and other blood disorders. Since 1987, more than twenty thousand patients have received hematopoietic transplants using unrelated donors through the National Marrow Donor Program, and many thousands more have received such transplants from relatives.[7]

Preclinical Experimentation and Clinical Trials

Aside from blood stem cell bone marrow transfers, no stem cell–based therapies currently are in use. However, preclinical experimentation using both adult and embryonic stem cells is under way, and adult stem cells are being used in several hundred human clinical trials. Among the conditions for which therapeutic applications of adult stem cells are being tested are damage to the muscles of the heart, diabetes, kidney cancer, liver disease, and lupus.[8]

Two high-profile biotechnology companies—Geron and Advanced Cell Technologies (ACT)—have indicated that they hope to initiate the first clinical trials using embryonic stem cells soon. Geron has suggested that clinical trials might begin in mid-2007, while ACT claimed in early 2005 that it would be in "a couple of years."[9] Many stem cell researchers, however, suggest that serious clinical trials involving human embryonic stem cells will not be ready to begin that soon.

Box 2. Case Study—Spinal Cord Regeneration

An estimated eleven thousand people suffer disabling spinal cord injuries in the United States each year.[10] A completely severed spinal cord causes paralysis and a lack of sensation in muscles and other tissues served by nerves below the point of severance. Scientists are studying several strategies aimed at regrowing the broken connection. Many of these strategies involve stem cells, both adult and embryonic.

- Investigators at the University of California at Irvine used human embryonic stem cells on rats whose spinal cords had been severed. Some improvement was reported with recent injuries, although not with injuries for which scar tissue had built up.[11]

- Other research at the University of California at Irvine showed some improvement in mice with severe spinal cord injuries after they were injected with human fetal stem cells taken from the brains of aborted sixteen- to eighteen-week-old human fetuses. The researchers cautioned that the results were "a first step in what has to be a long series of steps to get to anything clinical."[12]

- In 2004, researchers in Seoul, South Korea, claimed to have demonstrated improvement in feeling and movement for a paralyzed woman who had been treated with adult stem cells from umbilical cord blood, and later published their study in a peer-reviewed journal.[13] In March 2006, however, the patient said that the treatment "had only fleeting benefits that wore off after a few weeks" and complained of feeling "like an animal they used for testing."[14]

At best, the effects observed in these investigations have not been major. Moreover, there are concerns that the hopes of patients have been unjustifiably raised by premature publicity.

Box 3. Case Study—Type 1 Diabetes

Type 1 diabetes—previously known as juvenile diabetes—affects about two million people in the United States, or between 5 percent and 10 percent of all who suffer from diabetes.[15] Diabetes is an autoimmune disorder in which the body's immune system attacks cells within the pancreas that ordinarily produce insulin. Diabetes patients must receive regular doses of insulin daily in order to survive.

The Juvenile Diabetes Research Foundation (JDRF), one of the most influential forces in diabetes research, has identified several "therapeutic targets" for research efforts over the next five years. One possibility includes using stem cells to generate either "universal donor" insulin-secreting cells or the tissues in the pancreas that contain insulin-secreting cells.[16]

A recent controversy suggests that high hopes about embryonic stem cells may have worked to the detriment of an alternative therapy that does not depend on stem cells. Working with severely diabetic mice, Harvard Medical School researcher Denise Faustman found a way to reverse the immune system attack that causes the disease, which then allowed the pancreas and its insulin-secreting cells to regenerate on their own. But Faustman was initially unable to obtain funding for her work, which some observers attributed to the political dynamics of the stem cell debate. Her work was eventually funded by the Lee Iacocca Foundation, and her findings have now been confirmed in mice by three other research teams.[17]

The Relative Technical Merits of Embryonic and Adult Stem Cells

Adult and embryonic stem cells have different characteristics, and any therapeutic applications developed from them would have different strengths and weaknesses.

- Embryonic stem cells are capable of generating all the cell types of the body. Adult stem cells may be limited to differentiating into the different cell types that exist in the tissue from which they were obtained, though there is some evidence that adult stem cells may be less limited than previously believed.

- Adult stem cells are difficult to isolate, multiply, and maintain in culture. Embryonic stem cells are more easily isolated, multiplied, and maintained in culture.

- Embryonic stem cells are prone to trigger the development of tumors, usually benign, known as teratomas.[18]

- Adult stem cells derived from a patient's own body can be used for therapeutic purposes without fear of immune rejection. Therapeutic use of embryonic stem cells may require the use of SCNT or the development of other new techniques to avoid immune rejection.

These and other comparisons between adult and embryonic stem cells are displayed in Table 1.

TABLE 1
TECHNICAL ADVANTAGES AND DISADVANTAGES OF ADULT AND EMBRYONIC STEM CELLS FOR THERAPEUTIC PURPOSES

	ADVANTAGES	DISADVANTAGES
ADULT STEM CELLS	• Partially differentiated, so perhaps more easily programmed to serve as therapeutic tissue • Less risk of developing teratomas • If the patient's own, no immune rejection	• Difficult to obtain in quantity and to maintain in culture • Each type less able to develop into as many different cell types as embryonic stem cells • May not be available for all types of cells
EMBRYONIC STEM CELLS	• Can theoretically differentiate into any type of human cell • Can be isolated and maintained in culture more easily than adult stem cells	• Prone to generate teratomas • May be more difficult to control their differentiation
EMBRYONIC STEM CELLS derived from IVF embryos	• Many thousands already available for research use	• Risk of immune rejection if injected into patients
EMBRYONIC STEM CELLS derived from SCNT embryos	• Can likely be transplanted without causing immune rejection • Can be created in ways that facilitate particular experimental uses	• Requires large quantities of women's eggs • Any successfully developed treatments are likely to be more costly than those using IVF embryos • Creation of clonal embryos opens the door to reproductive cloning

Challenges Facing Therapeutic Stem Cell Applications

Experiments with mice and rats, as well as preliminary work with humans, have raised hopes about the eventual development of therapies using stem cells.[19] An honest appraisal, however, suggests that many questions need to be answered before it becomes clear if stem cell–based therapies will be possible, let alone clinically practicable and affordable for average patients.

Regarding the prospects for embryonic stem cell therapies, Lord Robert Winston, President of the British Association for the Advancement of Science and a strong supporter of stem cell research, noted the long list of problems that will need to be addressed before it is clear that therapeutic applications will be possible:

> There are many basic problems—their low cell cycle time leading to slow replication in culture and the fact there may be selective pressure for the faster growing, but possibly abnormal cells, to dominate a culture system; the instability of embryonic cells in general and their remarkable propensity to produce abnormal numbers of chromosomes; the difficulty in weeding out all rogue cells that might proliferate; the risk that stem cells after forced differentiation in culture may undergo de-differentiation, or abnormalities of gene expression, after transfer to the patient with potential for huge harm.[20]

Even if these problems are solved, new problems may be encountered when therapeutic cells are inserted in a living person. As noted in an analysis by the Stem Cell Research Foundation:

> The cells must be integrated into the patient's own tissues and organs and "learn" to function in concert with the body's natural cells. Cardiac cells that beat in a cell culture, for example, may not beat in rhythm with a patient's

> own heart cells. And neurons injected into a damaged brain must become "wired into" the brain's intricate network of cells and their connections in order to work properly.[21]

According to the National Institutes for Health (NIH), in order for embryonic stem cells to be used for therapies, scientists will have to learn how to reliably make them proliferate extensively, differentiate into the desired cell types, survive in the recipient after transplant, integrate into the surrounding tissue, function appropriately for the rest of the recipient's life, and avoid harming the recipient in any way.

A major hurdle to the therapeutic use of embryonic stem cells extracted from IVF embryos is the expected immune rejection problem. Cells or tissues obtained from IVF embryos would likely be identified by a patient's immune system as foreign and thus rejected. Several proposals have been advanced to solve or avoid this problem:

- Whenever possible, use adult stem cells taken from a patient's own body.

- Use stem cell lines that are roughly compatible with a patient's immune system, supplemented with rejection-suppressant drugs. Such lines could be maintained in carefully supervised stem cell "banks."

- Chemically or genetically modify the stem cell surfaces to avoid activating the rejection response.

- Use stem cells derived from clonal embryos created using SCNT, with the patient as the nuclear donor.

Each of these proposals has technical advantages and disadvantages. As noted, adult stem cells may have a limited range of applicability. The use of immune-compatible cell lines and immune-suppressant

drugs may work for some but not all patients. Modification of stem cell surfaces and use of SCNT-derived stem cells are both speculative proposals. Among the uncertainties about the use of clonally derived tissues is the possibility that factors in the cytoplasm of the egg used to generate them might cause rejection.

A number of stem cell scientists and business leaders have expressed doubt that using SCNT to create individually tailored therapeutic tissues could ever be made affordable. According to Lutz Giebel, CEO of CyThera, a San Diego stem cell company, "It is not commercially viable. . . . Quality control is difficult; the FDA can't regulate it, [and] no one can afford the treatment." Geron CEO Thomas Okarma has said that "the process is a nonstarter, commercially." And Alan Robins, chief scientific officer of BresaGen Ltd., which holds several embryonic stem cell patents, says that SCNT is "not something we want to get involved in."[22]

Many scientists are optimistic that the challenges facing the advent of stem cell–based therapies can be overcome. But it is important to remember that for all their promise, we cannot yet be certain whether stem cells will prove to be of real therapeutic value; or, even if the technical obstacles are overcome, whether they will be available at a cost that would allow them to be used by most people.

III. The Ethical, Social, and Political Debate

The major ethical, social, and political questions posed by stem cell research and related topics are easily stated but are by no means easily answered. What should be allowed and what should be prohibited? For activities that are allowed, how tightly or loosely should they be regulated, and through what mechanisms? How should research be funded, and at what levels? What international agreements will be needed to ensure that domestic policies are not compromised by people traveling abroad to take advantage of looser regulations elsewhere?

Most commentators in the popular press and elsewhere have treated the conflict over stem cells as an extension of the conflict over abortion, or of the more generally perceived conflict between conservative religious values and secular liberal values. The reality is more complex and nuanced. Some abortion opponents have come to support at least some forms of embryonic stem cell research, under certain conditions. At the same time, some pro-choice leaders and organizations have voiced concerns about stem cell and cloning research for reasons unrelated to the moral status of the human embryo.

Ethical Principles

The stem cell debate involves both the ongoing and divisive controversy about the moral status of human embryos and an array of other fundamental values and beliefs. These include the healing imperative; the role of science in democratic societies; and the appropriate balance among commitments to individual autonomy, social justice, and the common good.

- ***The moral status of human embryos.*** Beliefs about the moral status of human embryos, and about the obligations that these beliefs entail, differ widely in the United States and elsewhere. Opinion polls show that most people in the United States believe

that human embryos have a greater moral status than, say, an equivalent number of non-embryonic cells clumped together in a petri dish, and that most also believe that abortion should be legal and available, although not necessarily on demand. Most people can imagine a range of situations in which it is acceptable for human embryos to be used for scientific research, although most also recognize the necessity of establishing limits on such use.[23]

- ***The healing imperative.*** Throughout history most societies have put a strong moral and ethical value on coming to the aid of those suffering from disease and impairment and on preventing disease in the first place. To the extent that stem cell research is directed toward these ends, it commands presumptive support. But like most moral and ethical values, the healing imperative is neither absolute nor simple to apply.

  Necessary limits on the healing imperative can be seen in the fact that all countries ban commercial markets in human organs, because of concern that the commercial incentive could produce exploitation. Similarly, the Nuremberg Code of 1947 established ethical constraints on medical experimentation using human subjects, even though the knowledge that could be obtained without these constraints might prove to be lifesaving for some.

  The question of how best to realize the healing imperative is also complex. Deciding how to prioritize different approaches to healing inevitably raises ethical as well as practical questions: How should funds, talent, and other resources be divided among medical research, public health efforts, basic health care, and expensive medical interventions? How do we provide health care for vulnerable populations? Who benefits from biomedical research and health care arrangements, who is left out, and who bears the risks?

Technologies of healing need to be assessed with full attention to their benefits, their costs, and their risks for individuals, communities, and society as a whole.

- ***The role of science in society.*** The quest for knowledge was a core project of the Enlightenment and, together with values of individualism and enterprise, strongly shaped the development of modern liberal democracy. Some people would argue that the freedom to pursue scientific research is so central to human well-being that it should be understood as a foundational right, akin to the right to free speech.[24] Others would reply that no right is absolute, that knowledge has consequences, and that scientific research proceeds within rather than apart from a wider set of social values and interests, especially when the means used affects the lives or welfare of other beings.[25] On this view, democratic societies have an obligation to monitor and, when necessary, regulate the course of scientific research. These concerns have heightened in recent years as the lines between scientific research and commercial enterprise have become increasingly indistinct.

- ***Balancing individual autonomy and the common good.*** In the United States, most people place a high value on individual autonomy and rights. But most also recognize that individual choices are shaped by social forces and that these choices often have social consequences.

Discussions about stem cells, cloning, and related technologies have invoked a wide range of ethical principles, some of which are often in tension or conflict. Negotiating such conflicts—within and among individuals and groups—is central to what it means to be a person and a citizen. Ethical principles that have played a role in the stem cell debate include:

- ***Non-malfeasance ("Do no harm").*** The obligation to ensure that the development and use of stem cell technologies, whether or not they provide benefits, at least does no harm to individuals or society.

- ***Beneficence ("Do good").*** The obligation to use stem cell technologies to improve the health and well-being of individuals and society as a whole.

- ***Justice ("Be fair").*** The duty to ensure equitable distribution of any benefits (or harms) occasioned by stem cell technologies.

- ***Autonomy.*** The right of individuals to make choices regarding stem cell research or treatment that directly affects them.

- ***Democracy.*** The recognition that decisions about stem cell technologies that may affect community welfare and shape the life chances of individuals and groups must reflect the collective interest.

- ***Precaution.*** The wisdom of approaching powerful new technologies with care and caution, and of evaluating the likely consequences of their development in the early stages of societal commitments to them.

- ***Humanity.*** The recognition that the use of stem cell and related technologies could affect the welfare and security of humankind and what it means to be a human being.

Social and Political Concerns about Stem Cell Research

Though much of the public debate over embryonic stem cell research has focused on differences about the acceptability of destroying human embryos in the course of research, many concerns unrelated to beliefs about the moral status of human embryos have been voiced. Such issues are often raised by people who support embryonic stem cell research but are concerned about particular aspects of the research process and about potential social and political consequences. Some of these concerns apply to research using both IVF and SCNT embryos; others apply only to research using SCNT. These concerns include:

Accessible and affordable health care. Therapeutic applications of SCNT are likely to be very expensive: it has been estimated that such individualized stem cell treatments could cost at least $100,000 per patient.[26] Egg retrieval alone is estimated by institutions that perform it to cost over $20,000 per procedure.[27] Observers worry that the development of such individualized therapies, especially during a period in which funding for public health is being cut, could exacerbate existing inequities in the provision of health care, and question whether public funds should be devoted to this approach to stem cell–based treatments. Other health policy experts have raised concerns about whether the billions now being committed to stem cell research represent the best use of scarce health research funds.[28]

Patent and ownership issues. Over the past twenty-five years, the courts have interpreted intellectual property laws to allow a wide range of patents on basic biotechnologies. The commercialization of scientific research also has been encouraged by the 1980 Bayh-Dole Act, which allows universities and other research centers to patent and license to businesses the discoveries they have made using federal grants.[29] The act's intent was to foster technology by providing patent protection to firms willing to turn researchers' scientific findings into useful products such as new drugs and medical devices. However, as *Fortune* magazine has observed, this practice has had an "unintended consequence—a legal frenzy that's diverting scientists from doing science."[30] Many researchers and even some venture capitalists now suggest that the proliferation of patents is interfering with basic research in fields such as stem cell therapies.[31] The Patent Office has issued more than 750 patents that mention stem cells in their abstracts, and has over a thousand more applications pending; thousands more mention stem cells in their text.[32]

Consumerist eugenics and other abuses. In the absence of strong systems of regulation and oversight, stem cell and cloning technologies could be misapplied for socially unacceptable purposes.[33] The creation of clonal embryos is the necessary first step toward the creation of clonal human beings and paves the way for the creation of "designer babies," that is, children who have been genetically modified to suit parental preferences.[34] According to the Genetics and

Public Policy Center at Johns Hopkins University, "rapid advances in stem cell research and other genetic technologies make the possibility of successful permanent modification of the human genome . . . much more likely . . . and as a society, we are running out of time to plan sensible policies."[35]

Women as egg providers. Women's eggs are the critical "raw materials" for creating embryos using SNCT. If individualized stem cell therapies are developed for common degenerative conditions such as heart disease, arthritis, and Parkinson's, millions of women's eggs would be needed to meet the therapeutic demand. The potential for the development of a market for eggs and the exploitation of economically vulnerable women is a cause for concern. The assisted reproduction industry, which is likely to serve as the major supplier of eggs for stem cell research, has been widely criticized for lax standards. (See Box 4, pages 30–31.)

Over-promising results. A disturbing number of scientists and other supporters of stem cell and cloning research have made highly exaggerated claims about the likelihood and imminence of treatments and cures. Even before the cloning scandal centered in South Korea was revealed in November 2005, responsible scientists were warning about the prospect of a public backlash if unrealistic hopes for early results are raised, and then dashed. In November 2004, Princeton University president and geneticist Shirley Tilghman said, "Some of the public pronouncements in the field of stem-cell research come close to overpromising at best and delusional fantasizing at worst."[36] Leading Australian stem cell researcher Alan Trounson said in May 2005,

"[T]he so-called therapeutic cloning to my mind is a non-event . . . it's just not realistic [as a source of cures]."[37] In September 2005, Lord Robert Winston, current president of the British Association for the Advancement of Science, said that the notion that a host of cures for serious, degenerative disorders are just around the corner is fanciful. "The study of stem cells is one of the most exciting areas in biology," he said, "but I think it is unlikely that embryonic stem cells are likely to be useful in healthcare for a long time."[38]

Integrity in science. Concerns have been raised that stem cell research is proceeding in a manner and in an environment highly conducive to undermining the research's integrity, and that of biomedical research in general: prospects of immense financial gain; the lure of celebrity and renown; exaggerated claims of treatments and cures; competition among cities, states, and countries to develop research centers; researchers' desires to show and publish quick results; and the lack of a strong framework of regulatory oversight and control. The South Korean cloning scandal is a recent and notable instance of the manner in which scientific integrity can be compromised under such conditions. (See Box 5, pages 32–33.) As the scandal unfolded, stem cell scientists, science journalists, bioethicists, and others began asking if they had helped to create a climate that encouraged and condoned irresponsible behaviors. (See Box 6, page 34).

Box 4. Women's Eggs and Stem Cell Research

If stem cell researchers create embryos using SCNT or IVF techniques, rather than using "surplus" embryos donated from fertility clinics, they will need a supply of women's eggs. To procure such eggs, women undergo injections of hormones that first shut down and then hyperstimulate their ovaries, followed by surgical extraction of multiple eggs.[39]

The drug most often used to shut down the ovaries, Lupron, can cause side effects such as severe joint pain, difficulty breathing, chest pain, depression, amnesia, hypertension, and asthma. The drugs used to hyperstimulate the ovaries can lead to Ovarian Hyperstimulation Syndrome. The syndrome can range from mild to severe; on rare occasions, it has caused deaths.[40] There has been little sustained research on the frequency of these conditions, and estimates vary widely.

The United States has no federal regulations on the procurement and use of women's eggs for research.[41] In states such as California, Massachusetts, and New Jersey, where SCNT has been approved, regulation of egg extraction from women is inadequate, or only now being put in place. The importance of careful regulation was highlighted by the South Korean cloning scandals of late 2005, in which women's eggs were illicitly purchased, and at least two women working in the research laboratory were coerced into donating their eggs.[42]

Some women's health advocates, health law experts, public interest organizations, and others recognized the potential problems as researchers began to discuss using SCNT. They have proposed a set of "best practices" that would minimize risks to women who provide eggs and prevent the emergence of a commercial market for human eggs for research:

continued

continued from previous page

- Women who provide eggs for research should be classified as research subjects, so that they are entitled to federal and state protections and so that researchers follow effective informed consent rules.

- Egg extraction procedures should be conducted by physicians who are independent of the research.

- Women who provide eggs should receive compensation only for direct out-of-pocket expenses, in order to avoid undue inducement of economically vulnerable women.

- Researchers or their funding agencies should cover the medical costs of any adverse reactions associated with egg extraction procedures.

- A registry should be established to monitor the health of women who undergo egg extraction.[43]

George Annas, Chair of the Health Law Department at Boston University, notes that given the small but real possibility of harm to a donor, "Whether a physician should even perform the procedure purely to help produce eggs for research is a medical ethics issue that has not been sufficiently addressed." At a minimum, "each potential donor should have her own personal physician, whose job, of course, is to protect her health and welfare."[44]

Box 5. The Cloning Scandals of 2005, Part I

In 2004, South Korean veterinary scientist Hwang Woo Suk and a team of twenty-five researchers at Seoul National University announced that they had successfully created the first clonal human embryo, using 242 eggs from eighteen women.[45] In May 2005, Hwang and his team announced that they had created eleven stem cell lines from clonal embryos, using only 185 eggs, a fourteen-fold increase in efficiency. The following August, Hwang announced the cloning of the first dog, and in October, he and a U.S. collaborator, Gerald Schatten of the University of Pittsburgh, announced the formation of the "World Stem Cell Hub," a multinational consortium established to create and distribute clonal embryos and stem cell lines worldwide.

Hwang became a national hero of rock-star proportions, was feted at international scientific conclaves, and was mentioned as a strong candidate for a Nobel prize.

While doubts had been raised about aspects of his work from the beginning, they were largely ignored. In fall 2005, however, repeated charges of irregularities led to serious scrutiny, and by the end of that year Hwang's so-called achievements were found to have constituted one of the biggest deceptions in the history of biomedical science. It was found that Hwang:

- had never created even a single embryonic stem cell line from clonal embryos,
- had used eggs coerced from junior researchers working in his laboratory,
- had used other eggs illicitly purchased by a colleague from sixteen women for nearly $1,500 each,

continued

continued from previous page

- had used more than 2,200 eggs in total (about five times the number he had originally claimed) and that about 20 percent of the women providing them suffered side effects, and[46]

- had directed a researcher to prepare doctored photographs to submit to *Science* magazine.

Hwang had lied, blatantly and repeatedly, about these and other activities to the press, the public, and his government.

Some analysts attributed the scandal to the actions of "one bad apple." But competition for fame, fortune, and national prestige, combined with the absence of effective national and international regulatory oversight and control, were major contributing factors.

Box 6. The Cloning Scandals of 2005, Part II

In the wake of the cloning scandals centered in South Korea, scientists and others in the United States and around the world acknowledged that many stem cell supporters frequently have overstated the prospects of this research, at least in the near term.

As science journalist Peter Aldhous noted in *New Scientist,* "stem cell science is no stranger to claims that don't stack up, results that can't be replicated and doctors willing to rush into the clinic."[47] Harvard Stem Cell Institute researcher David Shaywitz said, "It is common knowledge that the bar for publication in this field often has appeared remarkably low. . . . The result of this frenzy has been an entire body of literature that is viewed with extreme skepticism."[48] And the editors of *Scientific American* acknowledged that "Hwang is guilty of raising false expectations, but too many of us held the ladder for him."[49]

Others remarked on the impact of the allure of fortune and fame among researchers. University of Maryland bioethicist Adil Shamoo said, "There is tremendous pressure today to be first. If you do something first, all the money and fame will come to you."[50]

A case in point is stem cell scientist Gerald Schatten, who used his renown as Hwang Woo Suk's lead U.S. collaborator, and as a holder of patent claims to the stem cell techniques they developed, to help win a $16.1 million federal stem cell research grant.[51] An investigation by his university found Schatten innocent of fraud but chastised him for "research misbehavior" associated with his financial dealings.[52]

Following these revelations, the Center for Science in the Public Interest proposed that scientific journals require authors to declare "all financial conflicts of interest, including patents and patent applications, whose values may be affected by publication; to tell authors they will publish those conflicts; and to impose a three-year ban on authors who fail to disclose any financial conflicts."[53]

Human Embryos for Stem Cell Research

Perspectives on the morality of embryonic stem cell research are tied to beliefs about the moral status of the human embryo. The variety of viewpoints about this issue fall along a spectrum.

1. Some people believe that early-stage human embryos are in no way morally equivalent to human infants, children, or adults, and that the rights or protections that are due human beings do not apply to these embryos. For people who hold this view, the use of early-stage embryos for medical research generally does not raise serious moral or ethical problems.

2. Others do not regard early-stage embryos as full human beings, yet believe that these embryos are due some level of respect. People holding this view may support the use of early-stage embryos for medical research if careful procedures are in place to ensure that the research is justified and conducted in a responsible manner. Some may support the use for research of "spare" IVF embryos that were created but not used for fertility purposes.

3. Others believe that an embryo implanted in a woman's uterus deserves absolute protection, but that embryos outside a woman's body are not capable of becoming human beings, and may be used for medical research. This is the view of some who oppose abortion but support embryonic stem cell research.

4. Others believe that personhood exists upon conception and that embryos at any stage of development deserve the full respect and protection due any other living human being. Given this view, the destructive use of embryos for medical research is tantamount to murder.

Religious Views about Stem Cell Research

Ethical, moral, and theological perspectives on stem cell research differ widely among religious faiths, denominations, and individuals.[54] In general, there is little opposition to adult stem cell research. Opposition to embryonic stem cell research is strongest among Catholics, Evangelicals, and Mormons.[55] Protestant denominations that allow abortion tend to be supportive of embryonic stem cell research, although some, such as the United Methodist Church and most Orthodox Protestant churches, oppose SCNT. Leaders of major Reform, Conservative, and Orthodox Jewish religious bodies have tended to be supportive of embryonic stem cell research. Sunni Muslim theologians typically date the arrival of the soul in an embryo somewhat later than do Shi'ites, and tend to be more accepting of research that involves embryonic stem cells.[56]

At its November 2005 General Assembly, the U.S. National Council of Churches of Christ, representing many of the socially liberal Protestant and Orthodox denominations, adopted a policy addressing the new human biotechnologies. They acknowledged both the deep moral injunction to heal the sick and the many ways in which genetic technologies, if misused, could generate individual harm and social injustice. They declared that individuals and denominations could differ in good faith on the specific topic of embryonic stem cell research and did not take a formal position either in support or in opposition.[57]

A number of U.S. senators and representatives who oppose abortion on religious grounds have endorsed embryonic stem cell research. Many argue that so long as an embryo is not implanted in a womb, it is incapable of developing into a human person and thus its use in important medical research is morally acceptable. Most, including Senate Majority Leader Bill Frist (R-TN), support stem cell research using embryos from IVF clinics while remaining opposed to SCNT. Some, including Senator Orrin Hatch (R-UT), support research using both IVF and SCNT embryos.

Technical Fixes for Theological Concerns?

Theological concerns about destroying human embryos in the course of stem cell research have led to proposals to develop procedures that would circumvent the need to do so. Possibilities include:

- Stem cells from reprogrammed adult cells. In the cloning process, the egg cell modifies the genetic material of the donated adult nucleus so that the resulting zygote can differentiate into all the types of cells in the human body. If scientists can figure out how this happens, they may be able to reprogram adult cells by putting their nuclei directly into stem cells without having to use women's eggs. No embryo of any sort would be created, and women would not have to put themselves at risk to donate eggs.[58]

- Altered nuclear transfer. Stanford University medical ethicist William Hurlbut, a member of the President's Council on Bioethics, has proposed that cell nuclei used in the process of SCNT be modified by removing or otherwise inactivating certain genes necessary for the creation of placental and related tissues, to prevent the zygote from developing into a viable embryo. Hurlbut, who is candid about his opposition to abortion, argues that the altered entity would not be an embryo, but "biologically (and morally) more akin to the partial organic potential of a tissue or cell culture."[59] This procedure would not address the risks to women who provide eggs for stem cell research.

- Other proposals include generating embryonic stem cells from zygotes created using nonhuman eggs, using zygotes that have been rejected by IVF centers because they had stopped dividing, extracting stem cell precursors from five-day-old IVF embryos that subsequently are implanted and brought to term, generating stem cells from sperm cell precursor cells, and using parthenotes (zygotes created from unfertilized eggs).[60]

These proposals have been met with mixed reactions. Some supporters of embryonic stem cell research welcome them, while others believe that attempts to develop them could delay research efforts on, or compromise support for, procedures that currently appear more straightforward. Some who oppose stem cell research welcome them as ways to break the deadlock, while others believe they are as morally unacceptable as current technologies, and that some proposals—notably those to create defective embryos in order to claim that they are therefore not embryos—are even more morally suspect.

Whether or not the proposed techniques can resolve the concerns voiced by religious conservatives, they would also need to be evaluated in the light of the social and political concerns about health equity, commercialization, and eugenic applications that some approaches to stem cell research raise.

Tips of Icebergs, Slippery Slopes, and Dispositions

The technological and social dynamics that have developed around stem cell and cloning research are germane to concerns about a number of other controversial genetic and reproductive procedures. Some of these currently are in use or in early stages of development; others now are used in animals and are being considered for use in human beings. Many share the characteristic of being generally acceptable for certain applications but problematic or generally unacceptable for others. To the extent that stem cell, cloning, or other human biotechnologies enable desirable applications, they generate support. For those that also pave the way for unacceptable applications, the need for caution, regulation, and effective oversight is heightened.

Controversial new genetic and reproductive applications include:

- ***Preimplantation genetic diagnosis (PGD).*** Couples at risk of passing on certain genetic conditions can conceive using *in vitro* fertilization techniques, have the resulting embryos tested for the presence or absence of the gene of concern, and use only

nonaffected embryos to create a fetus. This procedure is currently available for several hundred single-gene conditions. What kind of conditions, if any, are appropriately chosen or eliminated using PGD? Should it also be developed for genes that appear to have a bearing on traits such as height, cognitive abilities, or skin color?

- ***Human/animal chimeras.*** Scientists have inserted human neural stem cells into embryonic mouse brains to produce mice whose brains contain small portions of working human brain tissue, for the purpose of modeling treatment for brain disorders. Even if a mouse whose brain was composed entirely of human brain tissue were created, it would probably not be conscious in the manner that a human is. But what if this technology were used on chimpanzees? Should experiments intended to explore this question be allowed?

- ***Gene therapy and "enhancement."*** Efforts to perfect gene therapy have been under way for over two decades. The most commonly used procedures, which involve using altered viruses to insert "healthy" genes into cells containing "unhealthy" genes, have proven disappointing and unreliable. But techniques involving stem cells may allow some forms of gene therapy to succeed. The use of such techniques to treat diseases is generally accepted, but should their use to enhance musculature, respiratory capacity, appearance, or other nondisease traits also be allowed?

- ***Inheritable genetic modification (IGM).*** Inheritable genetic modification would involve modifying the genes in eggs, sperm, or zygotes in such a manner that these modifications would be transmitted to succeeding generations. Currently, human IGM experiments are widely viewed as unacceptable on safety grounds alone, but procedures using stem cells and cloning might allow the risks to be reduced. PGD techniques already can prevent genes that cause serious diseases from being inherited. Should IGM techniques be developed to allow "enhancements" to be inherited?

Political and policy responses to these and other proposed new human biotechnologies vary greatly. A spectrum of general dispositions that characterize most responses might be identified as follows:

- Opposition, with a preference that some or most of the technologies be restricted or prohibited, even if other benefits, including medical treatments or reproductive options, might be forfeited as a result.

- Precaution and strong concern, with support for technologies that provide the clearest medical benefits and raise the fewest social and ethical issues, as long as there are effective oversight and regulatory structures in place to prevent misuse, and prohibitions against clearly unacceptable applications.

- Minimal concern, with a preference for letting individuals and markets decide what is developed and used, and for voluntary professional regulation rather than government regulation; sometimes coupled with recognition that some technologies might need to be restricted for safety reasons.

- Enthusiasm about all or most of the technologies, optimism about their promise, and strong opposition to all or most efforts to restrict their development and use.

Balancing Benefits and Risks

If society accepts the use of human embryonic stem cells for applications likely to offer research or therapeutic benefits, but finds other applications of stem cell techniques unacceptable—such as, say, the creation of live-born human-chimpanzee hybrids—then the question of where to draw the lines, and how tightly or loosely, must be addressed.

In practical terms, the lines will be expressed through laws that encourage, allow, discourage, or prohibit various procedures; the lenience or severity of sanctions that accompany prohibitions; the type and level of funding allowed or made available for acceptable procedures; and the particulars of regulatory and oversight rules.

Many factors need to be weighed in order to come to full and fair judgments about any particular set of policies. A person—or a legislature—may decide, for example, that stronger rules are appropriate if the therapies based on stem cell and cloning techniques would be affordable by only a handful of the most wealthy, but that more permissive policies are preferable if those therapies will be inexpensive enough to relieve the suffering of tens of millions.

IV. Public Opinion

The results of public opinion surveys on stem cell research need to be assessed with caution. Many studies suggest that public understanding of basic technical distinctions and social implications is rudimentary. This makes surveys extraordinarily sensitive to the wording and context of their questions.

Within a month of each other, in May and June 2001, both the United States Conference of Catholic Bishops (USCCB) and the Coalition for the Advancement of Medical Research (CAMR) released the results of surveys on embryonic stem cell research. Pollsters for the USCCB found 70 percent of respondents in opposition to such research, while those working for CAMR found 70 percent in support.[61]

It is not difficult to see how this came about. The USCCB prefatory material noted that "live embryos would be destroyed in their first week of development" and asked about "using your federal tax dollars," while the CAMR survey referred to "excess fertilized eggs," and listed seven "deadly diseases" that the research could help treat.

The public discourse over stem cells and cloning has been conducted almost entirely within the framework established by the ongoing debates over abortion and the moral status of the embryo. Little data exists on opinions about the social, political, and economic implications of stem cell research.

Given these provisos, an assessment of eighteen public opinion surveys conducted in 2005, supported by comparison with fifteen earlier polls, suggests that among the American public there is:[62]

- profound opposition to reproductive cloning, with up to 93 percent against it;

- very strong support for research using embryos left over from fertility procedures that would otherwise be discarded, with about 70 percent in favor;

- strong support for embryonic stem cell research in general, with about 60 percent in favor;

- mixed support for more liberal federal funding of human embryo research in general, with about 50 percent to 56 percent in favor, but with a few polls ranging from 36 percent to 66 percent, showing clear wording and context effects;

- no agreement about the creation of clonal embryos for research (SCNT), with responses ranging from 80 percent to 13 percent against and from 76 percent to 16 percent in favor, depending on the wording and context of questions asked.

The 2002–2005 annual Life Sciences Surveys conducted by Virginia Commonwealth University (VCU) suggest that public opinion on research cloning has been both divided and fairly stable for several years. The exact question asked each time was: "Do you favor or oppose using human cloning technology IF it is used ONLY to help medical research develop new treatments for disease?"[63] (See Table 2, page 44.)

TABLE 2
PUBLIC OPINION ON CLONING TECHNOLOGY, 2002–2005

"Do you favor or oppose using human cloning technology IF it is used ONLY to help medical research develop new treatments for disease?"

	PERCENT OF RESPONDENTS			
	2005	2004	2003	2002
Strongly favor	17	16	21	21
Somewhat favor	26	26	29	24
Somewhat oppose	16	18	16	13
Strongly oppose	35	38	32	38
Don't know/no answer	6	3	3	3
Summary (PRO–CON)	**43–51**	**42–56**	**50–48**	**45–51**

Source: Virginia Commonwealth University Life Sciences, *2005 VCU Life Sciences Survey,* available online at http://www.vcu.edu/uns/Releases/2005/oct/102405a.html.

The 2005 VCU survey, but not those of previous years, also asked: "Do you favor or oppose human cloning technology IF it is used to create human embryos that will provide stem cells for human therapeutic purposes?" The response was "oppose" by 59 percent to 34 percent, with 41 percent strongly opposed.

In an extensive survey conducted in 2004 by the Genetics and Public Policy Center (GPPC) at Johns Hopkins University, respondents were asked, "Do you think that human embryo cloning for research should be allowed at all?" In response, 24 percent said "yes" and fully 76 percent said "no." In the same survey, reproductive cloning was opposed by margins of 88 percent to 12 percent and 93 percent to 7 percent, in response to differently worded questions.[64]

A 2005 GPPC survey showed respondents almost exactly split (49 percent to 48 percent) on the question of creating embryos for research by traditional IVF techniques, using sperm and eggs.[65] The report on this survey stressed that there is "a subtle topography of the public's attitudes with only a small fraction (6 percent at each pole) of the public occupying the extreme positions that so frequently characterize the public and policy debate."[66] For example, almost a quarter of those who do not accord significant moral status to an embryo in a petri dish nonetheless support a ban on embryonic stem cell research, while one-third of those who *do* see such embryos as morally valuable nevertheless support more funding for such research.

The available demographic data on public opinion is limited. According to the GPPC survey, men tend to be more permissive about genetic and reproductive technology issues than women; the young more than the old; the highly educated more than those who never went to college; the affluent more than the poor; and those with no religious affiliation more than the devout.[67] In partisan political terms: "More Democrats (75 percent) than Republicans (55 percent) approve or strongly approve of ESC research with independents falling in between (66 percent)."[68]

These trends are supported by an unusually detailed, though geographically limited, poll conducted by the University of New Hampshire (UNH) Survey Center for the *Boston Globe* in March 2005. However, the GPPC surveys report no significant difference by race or ethnicity, while the UNH poll shows whites consistently more supportive of genetic technologies than African Americans or Hispanics.[69]

The most thorough analysis of polling on stem cell research was conducted by Matthew Nisbet of Ohio State University and published in the spring 2004 issue of *Public Opinion Quarterly.* He found evidence of "strong wording effects," and concluded that "the controversy over human embryonic stem cell research and therapeutic cloning remains unresolved." He suggested further that "the public may be highly susceptible to influence by changes in media attention and media characterization of the issue."[70]

V. The Policy Challenge

Policy on stem cell research and related issues takes many forms on many levels. Countries and states enact legislation. International bodies issue guidelines and negotiate treaties. Government regulatory agencies adopt rules. Courts adjudicate conflicts. In order to appreciate the challenges facing policymakers, it is necessary to understand the history and current status of the stem cell policy debate in the United States, in other countries, and at the international level.

United States

The debate over stem cell and cloning policy in the United States has developed through three phases over the past ten years:

- The period between 1996 and 2001 was marked by the birth of Dolly the cloned sheep in 1996, followed by the less heralded but equally important first culture of human embryonic stem cells in 1998. These developments sparked an intense debate that concluded with President Bush's 2001 decision to allow, but strictly limit, federal funding of embryonic stem cell research.

- Between 2001 and 2004, supporters and opponents of embryonic stem cell research and research cloning attempted unsuccessfully to get the federal government to pass legislation supporting their positions.

- In 2004, the success of California's $3 billion stem cell research ballot initiative encouraged supporters to seek additional public funding in other states.

1996–2000

The cloning technique of somatic cell nuclear transfer was perfected during the early and mid-1990s at the Roslin Institute in Scotland, resulting in the birth of Dolly the sheep in 1996 and the announcement of her birth in 1997. Many world leaders in science, religion, politics, and law quickly agreed that human cloning for reproductive purposes should be banned.

The California-based Geron Corporation began funding experiments by James Thomson at the University of Wisconsin and John Gearhart at Johns Hopkins to create human embryonic stem cell lines. Geron's founder, Michael West, acknowledged that his motivation was to find the secret of immortality.[71]

In November 1998, Thomson announced the creation of the first such lines, using donated embryos. Shortly thereafter, Gearhart announced that he had successfully isolated embryonic germinal cells, with properties similar to those of embryonic stem cells, using tissues from aborted fetuses. Scientists the world over immediately recognized the therapeutic potential of embryonic stem cells, and the possibility that SCNT might provide a way to avoid the immune rejection problem of eventual stem cell transplants.

In 1996, the U.S. Congress approved the Dickey-Wicker Amendment prohibiting the use of federal funds for research involving the creation or destruction of human embryos. With the creation of Thomson's stem cell lines, pressure from scientists to allow federal funding increased. In 1999, the U.S. Health and Human Services Department ruled that although federal funds could not be spent for research on human embryos, they could be spent for research involving stem cells that had been derived from human embryos.

2001–2004

On August 9, 2001, President Bush announced that he would allow embryonic stem cell research to begin, but only using stem cells from lines created prior to that date.[72] While most scientists would have preferred a more liberal policy, others were glad to be able to get under way. And while most religious conservatives were opposed on principle to funding for even the limited number of cell lines, they did not protest greatly. As Reverend Jerry Falwell said at the time, "I can live with it."[73]

In short order, however, controversy revived. Rogue scientists announced plans to begin cloning human beings, and in 2001, bills to outlaw cloning were introduced in the U.S. Congress. Democrats and Republicans alike unanimously supported bans on reproductive cloning. But most Republicans, following their conservative religious base, demanded a simultaneous ban on research cloning. They reasoned that support for a law banning reproductive cloning but not research cloning would in effect be support for a policy requiring the destruction of human embryos, because if an embryo is created by cloning, but cannot be implanted in a woman's uterus, eventually it will die. Some scientists and biotechnology industry figures were enthusiastic about research cloning. Others felt obliged to fight any proposed research cloning bans on principle, despite differing opinions about the importance of research cloning itself. Although the Republican-sponsored legislation passed in the House with a vote of 269 to 103, it was not able to secure sufficient votes in the Senate, and the measure died in 2002. Similar legislation was introduced in 2003, but likewise stalled short of a Senate vote in 2004.

At the same time that scientists were fighting efforts to ban research cloning, they were becoming increasingly frustrated by their experience with the federally approved stem cell lines. It turned out that of the sixty-six lines supposedly available for research, only about twenty-two were in fact usable, due to contamination and other factors. (See Box 7.) These scientists, joining with the powerful biotechnology lobby and disease-specific research advocacy groups, began looking to private companies, universities, and state governments for sources of funding.

Box 7. The Federally Approved Stem Cell Lines

In his August 9, 2001, televised speech, President George W. Bush announced that over sixty embryonic stem cell lines qualified for federal funding and were available for research use. On August 27, 2001, the National Institutes of Health (NIH) identified sixty-six lines, later increased to seventy-eight.[74]

This turned out to be optimistic at best. By January 2006, the NIH stem cell registry listed only twenty-two approved lines as "available for shipping" and forty-three "not yet available," while others were listed as having "failed to expand into undifferentiated cell cultures."[75] Some have been withdrawn by their creators; others are proprietary and expensive. About half of the available lines, and three-quarters of those not yet available, are from foreign sources—Korea, Israel, Sweden, India, and Singapore—which may impose their own conditions of use, as India has done.[76]

In January 2005, a study published in *Nature Medicine* concluded that the available lines had been contaminated with a nonhuman molecule, N-glycolylneuraminic acid, that is targeted for attack by human immune systems.[77] This came from the culture in which the lines were grown and maintained. Although they remain suitable for research purposes, they may be unsuitable for therapeutic purposes.

The awareness that fewer embryonic stem cell lines were available for federally funded research than had originally been pledged contributed to the renewal of demands that the funding policies of the Bush administration be liberalized. The inadequacy of the federally approved lines is compounded by the fact that a number of them, along with basic processes that underlie embryonic stem cell research, are controlled in the United States by a few biotechnology companies and research institutions. The most vocal complaints, about high licensing fees and burdensome licensing conditions, have been levied against the major patent holder in the field, the Wisconsin Alumni Research Foundation.[78]

In 2004, stem cell advocates devised an ambitious plan to address the lack of federal funding. Venture capitalists, biotechnology entrepreneurs, stem cell scientists, patient advocates, and others in California organized to put an initiative creating a publicly funded $3 billion stem cell research program on the November ballot. The coalition spent a total of $36 million to pass Proposition 71, outspending opponents by about forty to one. Most of the opposition to the measure came from conservative taxpayer and religious groups.[79] A number of pro-choice, liberal, and progressive groups also opposed it.[80]

The measure passed by a vote of 59 percent to 41 percent, but the new stem cell program became a source of controversy almost immediately. Conservative groups brought lawsuits seeking to scuttle the program on constitutional grounds. Meanwhile, pro-choice and liberal public interest and consumer advocacy groups, along with a Democratic state senator who had been a longtime champion of stem cell research, raised questions about conflicts of interest, exorbitant salaries, inadequate protections for women who provide eggs for research, the inadequacy of public input and legislative oversight, intellectual property arrangements that favor corporations, and related concerns.[81]

2005 and After

In early 2005, the U.S. House of Representatives approved legislation to expand federal support for embryonic stem cell research, by a vote of 238 to 194. The bill, which would allow federal funding for new stem cell lines derived from embryos that have been created but are not used for fertility treatment, was introduced by Representatives Mike Castle (R-DE) and Diana DeGette (D-CO).[82] The measure would not provide funding to derive stem cells from cloned embryos. The Senate version is also bipartisan, with forty cosponsors joining Senators Arlen Specter (R-PA) and Tom Harkin (D-IA). Its chances for passage in the Senate seems good, but President Bush has vowed to veto it.

During this period, U.S. state legislatures moved aggressively to fill the policy and funding vacuum and to compete with California. By October 2005, over half the states had enacted or were considering

Box 8. State Policies on Stem Cell and Cloning Research

State policies on embryonic stem cell research vary from active encouragement to explicit bans. In many states, the only relevant laws concern embryos or fetuses, with the legal status of stem cells being implied. Several states prohibit all research on embryos or fetuses; in some cases, the extent of the prohibition is not clear. These policies are being contested in all states by all sides of the stem cell debate.

Research cloning is currently banned in:

Arkansas	Iowa	North Dakota
Indiana	Michigan	South Dakota

Arizona prohibits the use of public funds for research cloning. Virginia appears to ban research cloning, but the law is unclear.

Research cloning is specifically legal in:

California	Illinois	New Jersey
Connecticut	Massachusetts	Rhode Island

Bills addressing research cloning—some that ban it, others that allow or encourage it—were introduced in more than twenty states in 2005.[83]

legislation that addressed stem cells and cloning. (See Box 8, above.) From 2003 to 2005, state legislators approved or considered upward of $6 billion in taxpayer funds for stem cell research. (See Box 9, page 53.) Supporters as well as opponents of stem cell research have questioned whether this represents the best use of medical research funds. In January 2005, former Pennsylvania Congressman James Greenwood, now president of the Biotechnology Industry Organization, the nation's top biotechnology lobbying organization, suggested that while his members certainly appreciated the strong show of support for stem cell research, states should perhaps consider diversifying their medical research investments.[84]

In California, the governing body of the stem cell research institute concluded its contentious first year by adopting policies that appeared to meet some, though hardly all, of the objections voiced by liberal critics. Continued controversy appears all but certain.[85]

Other Countries

Policies on stem cell and cloning research differ widely among countries. A few countries have banned all research involving human embryos. Many more allow research using spare IVF embryos but forbid the creation of embryos explicitly for research, whether by SCNT or fertilization. Several countries allow research cloning, but typically under systems of tight regulatory oversight. In the United Kingdom, for example, a high-level agency, the Human Fertilisation and Embryology Authority (HFEA), reviews each research proposal involving SCNT on a case-by-case basis before granting a license to proceed (see "Comprehensive Policy Models," page 59). Other countries that permit SCNT are moving to establish their own oversight programs. (See Box 10, page 55.)

Every country that has adopted legislation on reproductive cloning has banned it, and others have affirmed its unacceptability through executive order or existing regulations. Opposition to reproductive cloning seems to be universal among countries, but in many, disagreements over the acceptability of cloning for stem cell research have impeded adoption of legislation to ban reproductive cloning.

To complicate matters, some scientists and other proponents of stem cell research are establishing multinational collaborations that appear to be designed in part to circumvent national regulations on the procurement of women's eggs and SCNT. The first initiative of this sort occurred in October 2005, when the South Korean scientists at Seoul National University led by Hwang Woo Suk, together with their U.S. collaborators, announced the creation of the World Stem Cell Hub. Their plan called for institutions working through the World Stem Cell Hub to generate embryonic stem cells from SCNT embryos created with eggs obtained by partners around the world,

Box 9. Funding in the States for Embryonic Stem Cell Research

Active funding policies in effect[86]

California: $300 million per year for ten years. Passed by ballot initiative in November 2004, but stalled by legal challenge. Amended state constitution to create "a right to stem cell research." Funded by bonds, managed by new agency. SCNT permitted.[87]

Connecticut: $10 million per year for ten years. Legislature approved in June 2005. Managed by Department of Public Health. Researchers at University of Connecticut preparing to begin SCNT.[88]

Illinois: $10 million for one year. Authorized by executive order in July 2005. SCNT permitted. A proposal for $100 million per year for ten years died in the Senate in May 2005. That proposal would have been funded by bonds, paid with a tax on elective cosmetic surgery.[89]

New Jersey: $5 million for research at a new institute established by executive order in August 2005. SCNT permitted. All grants reviewed by an ethics board. The Senate has approved $250 million in funding for three stem cell research centers, with a vote in the Assembly still pending.[90]

Maryland: $15 million allocated in the first year for the new Maryland Stem Cell Research Fund. It will require further appropriations.[91]

Other proposals and "trial balloons"

Florida: $20 million per year for ten years and a constitutional right to stem cell research were proposed as a ballot initiative for November 2006, but sufficient signatures were not obtained.[92]

New York: $100–200 million per year proposal passed the State Assembly in January 2006 and awaits action in the Senate.[93]

State elected officials have discussed public funding of embryonic stem cell research in several other states, including Wisconsin, Massachusetts, Pennsylvania, Delaware, Texas, and North Carolina.[94]

including a private San Francisco fertility clinic.[95] After the exposure at the end of 2005 of Hwang's wholesale fraud, the World Stem Cell Hub was shut down but then reopened in April 2006 as a gene therapy center.[96] Other transnational stem cell consortia are in development, including one involving scientists in the United Kingdom, the United States, Russia, Cyprus, and Belize.[97]

International Organizations

In 2001, France and Germany introduced a resolution at the United Nations establishing a framework for an international convention banning the reproductive cloning of human beings. Although no countries expressed opposition to such a ban, some were opposed to adopting a treaty that did not ban research cloning as well. Over more than three years of negotiation and debate, no consensus could be reached. In March 2005, the UN General Assembly adopted a nonbinding resolution calling on countries to ban both research and reproductive cloning, by a vote of 84 to 34, with 37 abstentions, and 36 not voting. Although opponents of research cloning claimed victory, countries that support such research made clear their intention to continue.

In 1997, the Council of Europe adopted the Convention on Biomedicine and Human Rights. This treaty allows stem cell research but bans creation of human embryos explicitly for research purposes, reproductive cloning, inheritable genetic modification, and sex selection for nonmedical purposes. By 2006, the convention had been signed by 32 of the Council's 46 members; signatories are obligated to adjust their domestic legislation to the requirements of the convention. A provision in the convention allows countries other than members of the Council of Europe to sign it, and Mexico has done so. It has been suggested that the convention could serve as a vehicle for a universal agreement.

For several years running, the European Union has approved funding for embryonic stem cell research, in countries where such

Box 10. Policies on Embryonic Stem Cell and Cloning Research

National policies on stem cell and cloning research are changing rapidly. The policies shown below were in effect as of mid-2006.[98]

Embryonic stem cell research is banned in:

Austria	Ireland	Lithuania	Poland

It is tightly restricted in Germany and Italy.

Embryonic stem cell research using spare IVF embryos only is allowed (in some cases implicitly, in others explicitly) in:

Australia	Estonia	Hungary	Slovenia
Brazil	Finland	Japan	Spain
Canada	France	Latvia	Switzerland
Denmark	Greece	Netherlands	Taiwan

Many countries have *explicitly banned research cloning,* including:

Argentina	France	Lithuania	Slovenia
Canada	Germany	Netherlands	Spain
Denmark	Iceland	Norway	Switzerland
Estonia	Italy	Peru	
Finland	Japan	Romania	

Several others have *banned research cloning implicitly* or via governmental guidelines, including:

Austria	Slovakia	Tunisia
Costa Rica	South Africa	

Countries that *explicitly allow research cloning* (with varying degrees of regulatory oversight) include:

Belgium	India	South Korea
China	Israel	Sweden
Cuba	Singapore	United Kingdom

research is legal, on the condition that clonal embryos are not involved.

Human biotechnologies, beginning with stem cell and cloning technologies, are likely to surface as central issues on international and foreign policy agendas very soon. In recent years, competition for national prestige, projections of economic benefits, fears of losing one sort of "race" or another, and similar arguments have been used to justify support for stem cell research programs in many countries. In South Korea, the stem cell controversy has been steeped in nationalist fervor. Supporters of stem cell research have physically attacked critics, and one supporter committed ritual suicide.[99]

In sum, there is an urgent need for formal international agreements addressing these technologies, as an increasing number of scientists, health policy experts, and civil society leaders are recognizing. (See Box 11.)

Regulatory Oversight in the United States

In the absence of federal legislation governing stem cell research in the United States, responsibility for existing oversight lies with several federal agencies.

- The National Institutes of Health (NIH) is the government's principal biomedical research organization and the major funder of stem cell research at the federal level. In 2004, NIH spent $553 million on stem cell research, of which $24.3 million supported efforts involving human embryonic stem cells. These amounts represent only a small part of the total NIH budget of close to $29 billion.[100] The NIH maintains the national human embryonic stem cell registry, with information on those stem cell lines that have been authorized for research using federal funds. It also oversees the Office of Biotechnology Activities (OBA), which houses the Recombinant DNA Advisory Committee (RAC), responsible for oversight of human gene-transfer experiments.[101]

Box 11. On the Need for Global Governance of Human Biotechnologies

In materials prepared for the 2006 World Economic Forum in Davos, Professor George Annas of the Department of Health Law, Bioethics and Human Rights at the Boston University School of Public Health and founder of Global Lawyers and Physicians said,

> We need to exercise our moral imaginations to create a structure that can act as a virtual global conscience for the scientific community pursuing species-altering and potentially species-endangering biotechnologies. An ethical oversight structure must be global and should include representatives from governments, industry, non-governmental organizations and the public. The group should be charged with articulating substantive global research rules (using existing international human-rights documents, like the Nuremberg Code, the Covenant on Civil and Political Rights, and the European Convention on Human Rights and Biomedicine as a basis), reviewing and approving (or declining) all proposals to do species-altering or potentially species-endangering procedures, and monitoring these experiments as they are performed.
>
> That we can imagine the horrors of an avian flu pandemic or a bioterrorist attack, but cannot imagine ways to develop and exercise a "species conscience," is a potentially lethal attribute of today's humans.[102]

- The Food and Drug Administration (FDA) is responsible for the safety of food, drugs, cosmetics and medical devices. It sets standards and oversees and approves clinical trials. The Center for Biologics Evaluation and Research (CBER) is the office charged with overseeing stem cell and cloning technology.

  In the absence of a federal ban, the FDA claims to have the authority to prohibit reproductive cloning. Toward that end, it has elected to treat clonal embryos as if they were "biologics," a term otherwise used to designate drugs.[103] But the FDA's authority is compromised by its legislative requirement to eschew any

moral, ethical, or social considerations in coming to its decisions as to whether a new biologic should be approved for use or not. Rather, it must rule based on the "safety and efficacy" of a drug or procedure. If reproductive cloning, or some other patently unacceptable genetic procedure, were to be judged to be safe and efficacious, the FDA would be required to approve it. This narrow criterion for decisionmaking differs from the situation in European countries, where most regulatory bodies are authorized and expected to take social and ethical factors into account.

Many human biotechnologies do not fit neatly into the established regulatory categories (drugs, devices, transplants, and so on), and may require new regulatory structures. The Human Genome Project was run, in substantial part, as a subsidiary of the Department of Energy.[104] The only federal supervision of the assisted reproductive technology industry is conducted under the aegis of the Centers for Disease Control and Prevention.[105] Such arrangements are in large part ad hoc, incremental responses to new technologies.

The Need for Oversight of U.S. Embryonic Stem Cell Research

The need for oversight of stem cell research became clear as state governments, universities, and private firms began establishing stem cell research programs lacking regulations of the sort that usually accompany federal research funding. In April 2005, a joint committee of the Institute of Medicine and the National Research Council, under the auspices of the National Academies, released a set of guidelines.[106] Though they are voluntary, it is hoped that the prestige of the National Academies will motivate compliance. Key sections call for:

- establishment of embryonic stem cell research oversight (ESCRO) committees by every laboratory, clinic, or other institution doing work involving embryonic stem cells;

- no payments for eggs, sperm, embryos, or tissues beyond direct expenses, and a requirement for fully informed consent by those who provide them;

- a ban on research with embryos after the first fourteen days of development (that is, when the early nervous system begins to develop); and

- bans on placing human embryonic stem cells into nonhuman primate blastocysts, on placing any embryonic stem cells into human blastocyts, and on breeding animals that include human embryonic stem cells.

The National Academies guidelines were welcomed by most supporters of stem cell research as an overdue measure that would help reassure the general public "that this research is being done for the best interests of tens of millions of patients."[107] Some religious conservatives who oppose embryonic stem cell research criticized the guidelines as an attempt to further legitimize unacceptable practices.[108]

Some who support embryonic stem cell research felt that the guidelines should have been more sharply drawn. They pointed to the lack of mechanisms to enforce the guidelines, to questions about whether oversight committees based at research institutes would apply the guidelines consistently and be able to avoid conflicts of interest, to the absence of recommendations about how to monitor clonal embryos to prevent their unauthorized use, and to the failure to consider issues that will arise at the start of any clinical trials, such as the use of children as research subjects.[109]

Comprehensive Policy Models

Although the United States has not yet been able to establish regulatory mechanisms beyond voluntary guidelines, this situation is unlikely to persist. Given the power for both good and ill that the new human biotechnologies represent, at some point federal regulation will be called for. Fortunately, comprehensive national policies that can serve as models for governing stem cell research and other human biotechnologies do exist. Three of the most highly developed systems are those of the United Kingdom, Canada, and Australia.

United Kingdom

The United Kingdom was the first nation to adopt a system of comprehensive oversight for assisted reproduction and research involving human embryos. At the center of this system is the Human Fertilisation and Embryology Authority (HFEA). It was established in 1991 with a mandate "to safeguard the interests of patients, children, the general public, doctors, service providers, the scientific community, and also future generations."

The HFEA licenses and monitors all institutions whose work involves human gametes or embryos, including fertility clinics, gamete and embryo banks, universities, and nonprofit and commercial research institutions.[110] It plays a crucial role in the first stages of embryonic stem cell research, during which stem cell lines are established. By statute, a majority of the authority's governing board, including its chair and deputy chair, must be "neither doctors nor scientists involved in human embryo research or providing infertility treatment."[111]

In 2002, the United Kingdom established the world's first nationally sponsored stem cell bank to facilitate the sharing of stem cell lines for research. A Stem Cell Steering Committee (SCSC) was set up to develop a national code of conduct for stem cell research and to oversee the operations of the bank. The SCSC members include ethicists, theologians, scientists, and lay members. All institutions that wish to conduct stem cell research, or to deposit or have access to cell lines held by the stem cell bank, first must be licensed by the HFEA.[112]

In August 2004, the HFEA issued the first license allowing the use of cloning procedures to produce human embryonic stem cells for research purposes.[113] The researchers are associated with Newcastle University and the Newcastle Fertility Centre. In early 2005, the Newcastle researchers used eggs donated by clients of the Newcastle Fertility Centre to produce a human blastocyst, but it did not survive long enough for stem cells to be extracted.[114] The Newcastle researchers want to create clonal embryos using nuclei from patients suffering from type 1 diabetes, in order to study the development of

the disease. In February 2005, the HFEA granted a license to the Edinburgh Roslin Institute to extract stem cells from clonal embryos created to study motor neuron disease (known in the United States as amyotrophic lateral sclerosis [ALS] or Lou Gehrig's disease).[115] The experiments will be conducted by Ian Wilmut, whose laboratory cloned the first sheep.[116]

Canada

Stem cell research proposals in Canada are reviewed by the twelve-member Stem Cell Oversight Committee (SCOC), appointed by the Governing Council of the Canadian Institutes of Health Research (CIHR).[117] The SCOC ensures that the research will be carried out in accordance with guidelines set by the CIHR.[118] The SCOC also is charged with monitoring ongoing research and reporting on the progress of the research to key authorities.

In 2004, after over a decade of deliberation, Canada passed the Assisted Human Reproduction Act (AHRA), which established a comprehensive structure of oversight and control for many new genetic and reproductive technologies.[119] The act created the Assisted Human Reproduction Agency of Canada, to be governed by a board of up to thirteen directors appointed after an elaborate outreach process, including screening by a panel consisting "mainly of external experts and stakeholders, including women's groups."[120] The core principles informing the work of the agency include:[121]

- protecting the health and well-being of women and children,
- preventing the commercial exploitation of reproduction, and
- protecting "human individuality and diversity, and the integrity of the human genome."

Under the AHRA, fertility clinics, research facilities, and other institutions whose work involves human eggs, sperm, or embryos must be licensed and monitored.[122] Embryos created in the course of IVF procedures may be used for research, including stem cell research, given the explicit consent of the gamete donors. However,

the creation of human embryos explicitly for research, including by SCNT, is banned, as is the creation of chimeric embryos, social sex selection, reproductive cloning, the sale of human sperm and eggs, and contractual surrogacy arrangements.[123] The agency created by the AHRA is expected to be in full operation by 2007.

Australia

Australia has two basic laws regulating the new human genetic technologies, both passed in 2002. The Prohibition of Human Cloning Act (PHCA) draws the fundamental lines as to what is allowed and what is not. The Research Involving Human Embryos Act (RIHEA) establishes the guidelines for research involving those activities that are allowed.[124]

Activities banned under the 2002 PHCA include both reproductive and research cloning, inheritable genetic modification, the artificial creation of twins, and experimentation using embryos more than fourteen days old. Activities that are allowed include stem cell research using IVF embryos and genetic screening and testing. The 2002 PHCA contained a three-year sunset provision, and a proposal to relax the ban on research cloning may be voted on during 2006.

Like the United Kingdom and Canada, Australia requires all institutions that wish to conduct research using human embryos or stem cells to obtain a license. The licensing body, called the Embryo Research Licensing Committee, is a branch of the National Health and Medical Research Council, the Australian equivalent of the National Institutes of Health.

The Australian system relies heavily on self-enforcement by researchers, but imposes fairly strict penalties for violations of the two laws: up to fifteen years in prison for those who violate provisions of the PHCA, and up to five years in prison for violations of the RIHEA.

A Comprehensive Policy for the United States?

The United States is a world leader in biotechnology research and development, and very likely will continue as one. But the lack of a comprehensive national regulatory system makes it an outlier among countries with active and growing biotechnology sectors. Many informed observers acknowledge that neither voluntary guidelines developed by professional or commercial associations, nor existing federal agencies, can address adequately the challenges posed by the new human biotechnologies.[125]

What might a comprehensive federal regulatory regime look like? It would need to address both research and applications involving genetic and reproductive technologies, whether publicly or privately funded. It would require federal legislation establishing broad policies and a new regulatory agency or commission. The new body would develop rules and regulations governing the creation, use, alteration, and storage of gametes and embryos; issue licenses; and monitor and inspect facilities to ensure compliance. A separate, broadly representative advisory body might be called for as well, to deliberate on new technologies and other concerns, encourage public engagement, and recommend additional or modified policies as needed.[126]

In developing national policy, the United States should look to emerging areas of international agreement. The United Kingdom, Canada, and Australia all allow adult stem cell research, embryonic stem cell research using spare IVF embryos, and pre-implantation screening for genetic disease. Similarly, they all prohibit reproductive cloning, inheritable genetic modification, experimentation on human embryos beyond fourteen days, and patenting of human embryos. An important area where differences exist concerns research cloning (SCNT). The United Kingdom allows it, Canada prohibits it, and Australia has imposed a moratorium on it.

The current political environment in the United States makes the establishment of a comprehensive policy on human biotechnologies a challenging prospect. Success will require that elected leaders, encouraged by an informed civil society, recognize both the deficits of the status quo and the opportunities at hand to move forward with effective and democratic oversight of robust and responsible research programs.

VI. Conclusion

Stem cell research and its applications hold scientific and medical promise. Like other powerful technologies, they pose challenges and risks as well. If we are to realize the benefits, meet the challenges, and avoid the risks, stem cell research must be conducted under effective, accountable systems of social oversight and control, at both national and international levels.

Comprehensive policies already in effect can serve as models for the United States and other countries that still lack oversight at the national level. Although countries may differ over many aspects of stem cell policy, the transnational mobility of technology requires that at least a minimal set of policies must be universal. For the sake of the research itself, as well as for the public interest and the common good, responsible governance of human biotechnologies is needed at all levels and in all parts of the world.

APPENDIXES

STEM CELLS AND PUBLIC POLICY: CHRONOLOGY OF KEY EVENTS

1981 Mouse embryonic stem cells isolated and cultured.

1991 United Kingdom establishes the Human Fertilisation and Embryology Authority (HFEA) to provide regulatory oversight and control of assisted reproduction and research using human embryos.

1996 U.S. Congress passes the Dickey-Wicker Amendment, prohibiting the use of federal funds for research that creates or destroys embryos.

1997 Ian Wilmut and colleagues at the Roslin Institute in Scotland announce that they have produced the first cloned mammal (Dolly the sheep, born in 1996).

Several bills to ban human cloning stall in the U.S. Senate after opposition from scientists and the biotechnology industry. California issues a moratorium on cloning and establishes an Advisory Committee on Human Cloning.

The Council of Europe approves the Convention on Biomedicine and Human Rights, banning the creation of human embryos for research purposes, reproductive cloning, and inheritable genetic modification.

1998 Human embryonic stem cells are isolated in culture by James Thomson at the University of Wisconsin and by John Gearhart at Johns Hopkins University, both using funds from the Geron Corporation.

1999 The National Bioethics Advisory Commission, appointed by President Clinton, recommends that research involving the

derivation and use of human embryonic stem cells from embryos remaining from infertility treatments (but not from embryos created by IVF or SCNT expressly for research purposes) should be eligible for federal funding, and that regulations to ensure noncommercialization, voluntariness, and careful oversight should be adopted.

2000 Department of Health and Human Services rules that pluripotent stem cells are not covered by the Dickey-Wicker Amendment and issues regulations allowing funding for research that uses, but does not derive, such cells.

2001 Secretary of Health and Human Services Tommy G. Thompson halts the process of funding the first round of grants for research using human embryonic stem cells and announces that federal rules will be reviewed.

President Bush approves federal support of research with certain embryonic stem cells, limiting researchers to using only lines established before August 9, 2001, and establishes the President's Council on Bioethics.

France and Germany propose that the United Nations negotiate an international treaty to ban human reproductive cloning.

2002 A second series of anticloning bills stalls in Congress; support for bans on reproductive cloning is unanimous but polarization over research cloning prevents passage of any legislation.

Announcement of the first cloned pet cat.

California bans reproductive cloning and explicitly legalizes research cloning.

2003 The U.S. House of Representatives approves a bill banning all cloning (241 to 155), and defeats a bill that would have allowed research cloning (231 to 174); the bills die following the Senate's failure to address the issue.

2004 South Korean researcher Hwang Woo Suk and his team at Seoul National University claim to have created the first clonal human embryos.

Canada approves the Assisted Human Reproduction Act, establishing regulatory control over many new human genetic and reproductive technologies.

Stem cell research plays a role in the 2004 U.S. presidential campaign.

California passes Proposition 71, authorizing the state to issue $3 billion in bonds over ten years for stem cell research.

2005 Human embryonic stem cell lines available for federal funding are found to be contaminated with a nonhuman molecule that compromises their potential use with human subjects.

The U.S. House of Representatives passes a bill permitting funding for research using human embryonic stem cells derived from embryos left over after fertility treatment (238 to 194); support grows in Senate for similar legislation but President Bush threatens a veto.

The United Nations concludes more than three years of debate over human cloning with a divided vote: 84 countries support bans on all cloning, 34 support bans on reproductive cloning only, 37 abstain, and 36 do not vote.

The U.S. Institute of Medicine and National Research Council issue voluntary guidelines for embryonic stem cell research.

Claims by Hwang Woo Suk to have created clonal human embryos and to have derived stem cells from them are revealed to have been fabrications.

Controversy mounts around the use of women's eggs for stem cell research, following abuses in Korea and elsewhere.

GLOSSARY

Adult stem cells—Multipotent stem cells, found within specialized tissues in embryos, fetuses, children, and adults, that have the ability to renew themselves and also to produce each of the variety of cells within that tissue. There are many types, but how many is still unknown.

Blastocyst—The embryo five to seven days after conception, consisting of an inner cell mass surrounded by a hollow sphere of cells; about 100–150 cells in all.

Chimera—An organism containing cells from more than one species. See also *transgenic organism.*

Cloning—The process of creating identical copies of a molecule, cell, embryo, or organism.

Embryo—The developing organism during the eight weeks after the first division of a zygote.

Embryonic stem cells (ESCs)—Pluripotent stem cells, that is, stem cells having the ability to differentiate into any of the over two hundred types of cells that make up the human body. Embryonic stem cells are generated in culture from embryonic cells at about five days of development.

Embryonic stem cell lines—Self-replicating colonies of embryonic stem cells maintained in culture for extended periods of time, thus providing researchers with quantities of genetically identical stem cells.

Eugenics—The intent to improve the human species by selective breeding, by sterilizing or terminating those considered unfit, or perhaps by inheritable genetic modification (IGM) if that becomes practicable.

Fetus—The developing organism from about eight weeks until birth.

Gene therapy—The proposed treatment of disease by the replacement or modification of genes.

In vitro fertilization (IVF)—The fertilization of an egg outside the body ("in glass"), now a standard part of assisted reproduction techniques.

Inheritable genetic modification (IGM)—Modifying the genes that are passed on to descendants, as would be the case with "designer babies" with genes modified to produce selected traits.

Multipotent—Able to produce a limited range of specialized cells; for example, the various kinds of blood cells, bone cells, or muscle cells; in general, adult stem cells are multipotent.

Parthenote—A zygote generated from an unfertilized egg; the process, parthenogenesis, is common among certain organisms, and some researchers are considering it as a way of generating embryonic stem cells without generating and destroying conventional embryos.

Pluripotent—Able to produce all but a limited number of cell types; a characteristic of embryonic stem cells.

Pre-implantation genetic diagnosis (PGD)—A technique performed when a fertilized egg has developed to the eight-cell stage, at which all eight cells are identical and one can be safely removed and analyzed for possible genetic abnormality, or for a particular genetic combination.

Reproductive cloning—The process of creating, implanting, gestating, and giving birth to a clone.

Research cloning—The process of creating a clonal embryo to be used for the derivation of embryonic stem cells or other research purposes. See also *therapeutic cloning* and *somatic cell nuclear transfer*.

Somatic cell nuclear transfer (SCNT)—The process by which a clonal embryo is created, involving the removal of the nucleus of an egg and its replacement with the nucleus of a donor's cell; the egg is then artificially stimulated to begin developing into an embryo, whose genes are essentially identical to those of the donor. See also *research cloning* and *therapeutic cloning*.

Therapeutic cloning— The process of creating a clonal embryo to be used for the derivation of embryonic stem cells. See also *research cloning* and *somatic cell nuclear transfer*.

Totipotent—Able to differentiate, directly or indirectly, into any kind of human cell, including an entire embryo and extra-embryonic tissues such as the placenta; such cells exist only for a few days, in the very earliest stage after fertilization.

Transgenic organism—An organism containing genetic material from more than one species. See also *chimera*.

Zygote—A fertilized egg.

Resources

The Web sites and other resources listed below are just a few of the many institutions and information sources addressing stem cells, cloning, and related topics.

International Bodies

World Health Organization: http://www.who.int/ethics/en/

United States Federal Bodies

The National Institutes of Health (NIH):
http://stemcells.nih.gov
NIH's Bioethics Resources on the Web:
http://www.nih.gov/sigs/bioethics/
The President's Council on Bioethics: http://www.bioethics.gov

Stem Cell Research and Public Affairs Organizations

Coalition for the Advancement of Medical Research:
http://www.camradvocacy.org
International Society for Stem Cell Research:
http://www.isscr.org
The Stem Cell Research Foundation:
http://www.stemcellresearchfoundation.org

Nonprofit Research and Public Affairs Organizations

Center for Bioethics and Human Dignity: http://www.cbhd.org/
Center for Genetics and Society:
http://www.genetics-and-society.org
Genetics Policy Institute: http://www.genpol.org/
The Genetics and Public Policy Center:
http://www.dnapolicy.org/
The Hastings Center: http://www.thehastingscenter.org/
The Institute on Biotechnology and the Human Future:
http://www.thehumanfuture.org/
Women's Bioethics Project: http://www.womensbioethics.org/

University Bioethics Centers

NIH Directory of University Bioethics Centers:
http://www.nih.gov/sigs/bioethics/academic.html

Industry Organizations

The Biotechnology Industry Organization (BIO):
http://www.bio.org/

Publications/Weblogs

American Journal of Bioethics: http://blog.bioethics.net/
American Journal of Law and Medicine:
http://www.aslme.org/pub/ajlm/index.php
California Stem Cell Report:
http://californiastemcellreport.blogspot.com/
Hastings Center Report:
http://www.thehastingscenter.org/publications/hcr/hcr.asp
The New Atlantis: http://www.thenewatlantis.com/

NOTES

1. Much useful information is available online at the National Institutes of Health (NIH) Web site, http://stemcells.nih.gov/index.asp. The President's Council on Bioethics issued a comprehensive report, *Monitoring Stem Cell Research,* Washington, D.C., 2004, available online at http://www.bioethics.gov/reports/stemcell/index.html. See also the discussion on the Web site of the Center for Genetics and Society, at http://www.genetics-and-society.org/technologies/.

2. A. Maitra et al., "Genomic Alterations in Cultured Human Embryonic Stem Cells," *Nature Genetics* 37 (2005): 1099–1103, abstract available online (full text available to subscribers) at http://www.nature.com/ng/journal/v37/n10/abs/ng1631.html; see also "Embryonic Stem Cells Accrue Genetic Changes," Johns Hopkins Medicine press release, September 4, 2005, available online at http://www.hopkinsmedicine.org/Press_releases/2005/09_04_05.html.

3. The current use of SCNT procedures is for research purposes, not therapy, and thus the frequently used descriptor "therapeutic cloning" is inaccurate. Many prefer the terms "research cloning" or "somatic cell nuclear transfer" (SCNT).

4. The Raelian extraterrestrial cult made global headlines in 2002 and 2003 with unsubstantiated claims that they had created a clonal child ("Eve") and then supposedly others. No reputable scientist gives these claims any credence. A more plausible candidate, the Italian maverick Severino Antinori, suggested several times that one or more women were pregnant with clones but has never announced a birth. His former partner, Panayiotis Zavos, disparaged Antinori's claims (Roger Highfield, "Cloned Baby Row Doctor 'Has Run Out of Patients,'" *Daily Telegraph* (London), April 27, 2002, available online at http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2002/04/27/nclone27.xml). Zavos himself is more cautious in his claims, though in 2003 he published a paper in which he said that he had created, but not implanted, a clonal human embryo, working in an unidentified laboratory outside the United States. Panayiotis M. Zavos, "Human Reproductive Cloning: The Time Is Near," *Reproductive Biomedicine Online* 6, no. 4 (2003),available online at http://www.zavos.org/library/timeisnear2003.htm. Little has been heard from either Antinori or Zavos since 2003.

5. See the NIH Stem Cell Information Web page at http://stemcells.nih.gov/info/basics/basics6.asp; also Rohwedel, J. et al., "Embryonic Stem Cells as an In Vitro Model for Mutagenicity, Cytotoxicity, and Embryotoxicity Studies: Present State and Future Prospects," *Toxicology In Vitro* 15 (2001): 741–53, cited in *Monitoring Stem Cell Research*.

6. *Monitoring Stem Cell Research,* p. 130.

7. The National Marrow Donor Program, Frequently Asked Questions, available online at http://www.marrow.org/PATIENT/patient_faqs.html.

8. The Stem Cell Research Foundation maintains a useful list of newspaper articles and press releases at http://www.stemcellresearchfoundation.org/. For the heart muscle trials, see "Johns Hopkins Begins Human Trials with Donor Adult Stem Cells to Repair Muscle Damaged from Heart Attack," Johns Hopkins Medicine press release, March 25, 2005, available online at http://www.hopkinsmedicine.org/Press_releases/2005/03_25_05.html. A bioartificial kidney partly generated from stem cells is discussed in "First Human Trial of Bioartificial Kidney Shows Promise for Acute Renal Failure, U-M Researchers Report," University of Michigan press release, November 2, 2004, available online at http://www.med.umich.edu/opm/newspage/2004/kidney.htm.

9. Kristen Philipkoski, "Race to Human Stem-Cell Trials," *Wired*, April 19, 2005, available online at http://www.wired.com/news/medtech/0,1286,67266,00.html.

10. "How Many Spinal Cord Injuries Occur in the U.S. Each Year?" Spinal Cord Injury Information Network, available online at http://www.spinalcord.uab.edu/show.asp?durki=20184.

11. The scientific paper is Hans S. Keirstead et al., "Human Embryonic Stem Cell-Derived Oligodendrocyte Progenitor Cell Transplants Remyelinate and Restore Locomotion after Spinal Cord Injury," *The Journal of Neuroscience* 25 (2005): 4694–4705, available online at http://www.jneurosci.org/cgi/content/full/25/19/4694. A good summary is in Kristen Philipkoski, "Paralyzed Rats Walk; Humans Next?" *Wired*, May 12, 2005, available online at http://www.wired.com/news/medtech/0,1286,67501,00.html.

12. Rick Weiss, "Stem Cell Injections Repair Spinal Cord Injuries in Mice," *Washington Post,* September 20, 2005, available online at http://www.washingtonpost.com/wp-dyn/content/article/2005/09/19/AR2005091901365.html. The scientific publication is Brian J. Cumming et al., "Human Neural Stem Cells Differentiate and Promote Locomotor Recovery in Spinal Cord-Injured Mice," *Proceedings of the National Academy of Sciences* 102, no. 39 (2005): 14069–74, available online at http://www.pnas.org/cgi/content/full/102/39/14069.

13. Kim Tae-gyu, "Korean Scientists Succeed in Stem Cell Therapy," *Korea Times,* November 26, 2004, available online at http://times.hankooki.com/lpage/200411/kt2004112617575710440.htm; Kang et al., "A 37-Year-Old Spinal Cord-Injured Female Patient, Transplanted of Multipotent Stem Cells from Human UC Blood, with Improved Sensory Perception and Mobility, Both Functionally and Morphologically: A Case Study," *Cytotherapy* 7 (2005): 368–73.

14. Barbara Demick, "Faith in 'Miracle Cures' Is Fading in South Korea," *Los Angeles Times,* March 5, 2006, available online at http://genetics-and-society.org/newsdisp.asp?id=973.

15. National Diabetes Information Clearinghouse, "Diabetes Overview," available online at http://diabetes.niddk.nih.gov/dm/pubs/overview/index.htm.

16. "Paths to a Cure," Juvenile Diabetes Research Foundation International, available online at http://www.jdrf.org/index.cfm?page_id=101979; Annual Reports, 2003 and 2004, Juvenile Diabetes Research Foundation International, available online at http://www.jdrf.org/files/Annual_Report_2003/JDRF_Annual_1.pdf and http://www.jdrf.org/files/Annual_Report_2004/ar2004.pdf.

17. Gina Kolata, "A Controversial Therapy for Diabetes Is Verified," *New York Times,* March 24, 2006, available online at http://www.nytimes.com/2006/03/24/health/24diabetes.html?ex=1147147200&en=18365a1dc8e10702&ei=5070; Sharon Begley, "After Initial Rejection, Scientists Back Work on Cure for Diabetes," *Wall Street Journal,* March 24, 2006, online at http://www.joinleenow.org/WSJ%20Article.pdf; Gina Kolata, "I Beg to Differ: A Diabetes Researcher Forges Her Own Path to a Cure," *New York Times,* November 9, 2004, available online at http://www.joinleenow.org/html/press/110904.php. See also Martin Jensen, "Why Did the JDRF Try to Discredit Cure Research?" *Diabetes Health Magazine,* May 2005, available at http://www.diabeteshealth.com/read,1048,4126.html.

18. National Institutes of Health, *Stem Cells: Scientific Progress and Future Research Directions,* Washington, D.C., 2001, Chapter 3, "The Human Embryonic Stem Cell and the Human Embryonic Germ Cell," available online at http://stemcells.nih.gov/info/scireport/chapter3.asp. Mouse embryonic stem cells have frequently been observed to cause teratomas in mice; G. R. Martin, "Isolation of a Pluripotent Cell Line from Early Mouse Embryos Cultured in Medium Conditioned by Teratocarcinoma Stem Cells," *Proceedings of the National Academy of Sciences* 78 (1981): 7634–8. Much recent research is focused on the possibility of cancer in general being linked to stem cells, and the fact that ESCs can self-replicate long enough to develop harmful mutations is a cause for significant concern. For a popular overview, see Scott LaFee, "Stem Cells Promise Medical Miracles, but There's a Dark Side, Too," *San Diego Union-Tribune*, August 17, 2005, available online at http://www.signonsandiego.com/news/science/20050817-9999-lz1c17cells.html.

19. Other animal studies include the generation of liver tissue in rats from bone marrow stem cells; generation of heart muscle in mice by using human fetal stem cells and also by using human blood stem cells; and kidney repair in rats, using bone marrow stem cells. See "Stem Cells Used to Make New Liver Tissue," Associated Press, May 13, 1999, available online at http://www.cordblood.com/cord_blood_news/stem_cell_news/a_ap_online.asp; "Human Stem Cells Can Develop Into Functional Vascularized Muscle Tissue, Weill Cornell Team Finds," Weill Medical College of Cornell University

press release, March 22, 2005, available online at http://global.med.cornell.edu/news/wcmc/wcmc_2005/03_22_05.shtml; "Researchers Describe How Human Blood Stem Cells Transform Themselves To Repair Injured Animal Hearts," *Science Daily,* January 3, 2005, available online at http://www.sciencedaily.com/releases/2004/12/041219183402.htm; Morgan Ratcliffe, "Study Shows Possibility for Kidney Disease Cure," *Daily Utah Chronicle,* September 21, 2005, available online at http://www.dailyutahchronicle.com/media/paper244/news/2005/09/21/News/Study.Shows.Possibility.For.Kidney.Disease.Cure-992586.shtml.

20. Professor Robert Winston, "Presidential Address to the British Association Festival of Science," September 5, 2005, available online at http://www.the-ba.net/the-ba/Events/FestivalofScience/FestivalNews/_BAPresidentialAddress2005.htm.

21. Stem Cell Research Foundation, Frequently Asked Questions, available online at http://www.stemcellresearchfoundation.org/About/FAQ.htm.

22. Denise Gellene, "Clone Profit? Unlikely: The Technology's Commercial Viability Faces Many Hurdles," *Los Angeles Times,* May 10, 2002, available online at http://genetics-and-society.org/resources/items/20020510_latimes_gellene.html.

23. There is a useful discussion, including many different points of view, in Chapter 3 of *Monitoring Stem Cell Research*.

24. The American Bar Association described the freedom of scientific inquiry as "a cherished principle of American law" in a letter sent to members of Congress on May 19, 2005, available online at http://www.abanet.org/poladv/letters/109th/healthlaw/stemcell051905.pdf.

25. See, for example, the NIH *Guidelines for the Conduct of Research Involving Human Subjects,* 5th printing, Washington, D.C., 2004, available online at http://ohsr.od.nih.gov/guidelines/guidelines.html. Links to other relevant documents can also be found there.

26. See, for example, Peter Mombaerts, "Therapeutic Cloning in the Mouse," *Proceedings of the National Academy of Sciences* 100 (2003): 11924–5, available online at www.pnas.org/cgi/content/full/100/suppl_1/11924.

27. An estimate of $22,000 was made by Advanced Cell Technology (ACT), which was experimenting on the creation of clonal embryos; Kyla Dunn, "Cloning Trevor," *Atlantic Monthly,* June 2002, available online at http://www.theatlantic.com/doc/prem/200206/dunn. Another estimate of $25,500 can be found on the Web site of the Bedford Stem Cell Research Foundation, which built on ACT's work, at http://www.bedfordresearch.org/aboutus/aboutus.php. Both estimates presumably include $4,000 compensation paid to the woman who provides the eggs, as determined by ACT's ethics committee; see Wendy Goldman Rohm, "Seven Days of Creation: The Inside Story of a Human Cloning Experiment," *Wired*, January 2004, available online at http://www.wired.com/wired/archive/12.01/clones.html.

28. See, for example, the testimony of John Yuasa, health policy director at the Greenlining Institute, before the California Senate in March 1995, available online at http://www.sen.ca.gov/ftp/sen/committee/standing/health/_home/prop_71_oversight_transcript.doc.

29. Council on Governmental Relations, "The Bayh-Dole Act: A Guide to the Law and Implementing Regulations," September 1999, available online at http://ucop.edu/ott/bayh.html.

30. Clifton Leaf, "The Law of Unintended Consequences," *Fortune*, September 7, 2005, available online at http://money.cnn.com/magazines/fortune/fortune_archive/2005/09/19/8272884/index.htm.

31. Bernadette Tansey, "Proposition 71," *San Francisco Chronicle,* November 4, 2004, available online at http://sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2004/11/04/BUGBB9LCAL1.DTL.

32. Searches were run on October 8, 2005, at the United States Patent and Trademark Office Web site, http://www.uspto.gov/patft/. They found 1,085 applications with abstracts that included "stem and cell or cells," and 755 of these were issued patents; 25,012 patents mentioned the same expression, and 26,159 applications.

33. The Human Genome Project from its inception ran a program on the ethical, legal, and social issues (ELSI) connected with genetic research; much of their work is still available online at http://www.ornl.gov/sci/techresources/Human_Genome/research/elsi.shtml.

34. The process of inheritable genetic modification, or "germline" genetic engineering, is used today to create animals with desired genes, and some have proposed that techniques be developed that would allow this to be done with human beings. Germline modification techniques currently used to create transgenic animals would not be acceptable for human applications. But in theory, the use of stem cell and SCNT technologies might allow germline modification to happen in a manner that would be clinically acceptable.

35. "Center Publishes Two New Reports," Genetics and Public Policy Center eNews, Issue 7, July 2005, available online at http://www.dnapolicy.org/news.enews.php?action=detail&newsletter_id=18&newsletter_title=Issue+7.

36. Shirley M. Tilghman, "Address to the Stem Cell Institute of New Jersey," November 11, 2004, available online at http://www.princeton.edu/president/speeches/20041111/index.xml.

37. "Forget About Therapeutic Cloning, Says Alan Trounson," *BioEdge*, May 10, 2005, available online at http://www.australasianbioethics.org/Newsletters/158-2005-05-10.html#story3.

38. Jonathan Amos, "Winston Warns of Stem Cell 'Hype,'" *BBC News,* September 5, 2005, available online at http://news.bbc.co.uk/1/hi/sci/tech/4213566.stm.

39. See the testimony of public health expert Francine Coeytaux, of the Pro-Choice Alliance for Responsible Research, before the California legis-

lature, March 9, 2005, available online at http://www.sen.ca.gov/ftp/sen/committee/standing/health/_home/prop_71_oversight_coeytaux.doc. See also The Boston Women's Health Book Collective, *Our Bodies, Ourselves* (New York: Simon and Schuster, 2005), and the companion Web site, specifically at http://www.ourbodiesourselves.org/book/companion.asp?id=25&compID=97.

40. Ursula Brigitte Kaiser, M.D., "The Pathogenesis of the Ovarian Hyperstimulation Syndrome," *New England Journal of Medicine,* 349 (2003): 729–32, available online at http://content.nejm.org/cgi/content/short/349/8/729.

41. In the absence of federal regulations, the National Academies (a set of independent organizations that advise the federal government) has released voluntary guidelines. See the National Academies, *Guidelines for Human Embryonic Stem Cell Research,* Washington, D.C., 2005, especially Chapter 4, available online a http://www.nap.edu/books/0309096537/html/.

42. Carl T. Hall, "'Stem Cell Hub' Cloning Network Project Folding," *San Francisco Chronicle,* November 15, 2005, available online at http://sfgate.com/cgi-bin/article.cgi?file=/c/a/2005/11/15/MNGH3FOIDT1.DTL.

43. For more details, and a list of recommendations for best-practice guidelines, see the fact sheet prepared by the Center for Genetics and Society, available online at http://www.genetics-and-society.org/resources/background/eefactsheet.html.

44. Sujatha Byravan, "The Year of the Stem Cell," *GeneWatch,* September-October, 2005, available online at http://www.gene-watch.org/genewatch/articles/18-5Annas.html.

45. The history of the Korean cloning scandal has been heavily covered in the press. Three good overviews are David Cyranoski, "Rise and Fall: Why Did Hwang Fake His Data, How Did He Get Away with It, and How Was the Fraud Found Out?" *Nature*, January 11, 2006, available online at http://www.nature.com/news/2006/060109/full/060109-8.html; Sei Chong, "Scientific Misconduct: Investigations Document Still More Problems for Stem Cell Researchers," *Science* 311, no. 5762 (February 10, 2006): 754–55, available online at http://www.sciencemag.org/cgi/content/full/311/5762/754; and Pete Shanks, "The Hwang Saga Continues," OhMyNews, May 17, 2006, available online at http://english.ohmynews.com/articleview/article_view.asp?at_code=331539&no=292505&rel_no=1.

46. Theresa Kim Hwa-young, "Ova donors demand compensation from government," *AsiaNews.it*, February 7, 2006, available online at http://www.asianews.it/view.php?l=en&art=5322.

47. Peter Aldhous, "Miracle Postponed," *New Scientist,* March 11, 2006, available online at http://genetics-and-society.org/newsdisp.asp?id=976.

48. David A. Shaywitz, "Stem Cell Hype and Hope," *Washington Post,* January 12, 2006, available online at http://www.washingtonpost.com/wp-dyn/content/article/2006/01/11/AR2006011102040.html.

49. "Con Men in Lab Coats," *Scientific American,* March 2006, available online at http://www.sciam.com/article.cfm?chanID=sa006&colID=2&articleID=00032973-42CE-13F3-B85583414B7F0101.

50. Rob Stein, "Ethics in Research Debated," *Washington Post,* December 25, 2005, available online at http://www.washingtonpost.com/wp-dyn/content/article/2005/12/24/AR2005122400735_pf.html.

51. Jennifer Bails, "Fake Findings Used to Secure $16M Grant," *Pittsburgh Tribune Review,* February 22, 2006, available online at http://www.pittsburghlive.com/x/pittsburghtrib/s_426357.html.

52. Rick Weiss, "U.S. Stem Cell Researcher Rebuked," *Washington Post,* February 11, 2006, available online at http://www.washingtonpost.com/wpdyn/content/article/2006/02/10/AR2006021001842.html.

53. "CSPI Calls on Journals to Strengthen Disclosure of Conflicts," Center for Science in the Public Interest press release, available online at http://www.cspinet.org/integrity/press/200601121.html.

54. See John H. Evans, *Cloning Adam's Rib: A Primer on Religious Responses to Cloning,* The Pew Forum on Religion and Public Life, 2002, available online at http://www.pewtrusts.com/pdf/rel_pew_forum_adams_rib.pdf. There is a large collection of links on the Center for Genetics and Society's Web site at http://www.genetics-and-society.org/perspectives/religious.html.

55. The United States Conference of Catholic Bishops (USCCB) has been particularly active on these issues. Many documents, including examples of their congressional testimony, can be found on their Web site, at http://www.usccb.org/prolife/issues/bioethic/stemcell/index.htm.

56. National Bioethics Advisory Commission, *Ethical Issues in Human Stem Cell Research, Volume III, Religious Perspectives,* Rockville, Md., June 2000; available online at http://www.georgetown.edu/research/nrcbl/nbac/stemcell3.pdf.

57. National Council of Churches USA, *Fearfully and Wonderfully Made,* 2005, available online at http://www.ncccusa.org/news/051111BioTech.html.

58. "Adult Cells Transformed into Stem Cells," Harvard University press release, August 23, 2005, available online at http://www.sciencedaily.com/releases/2005/08/050823081214.htm.

59. William B. Hurlbut, "Altered Nuclear Transfer as a Morally Acceptable Means for the Procurement of Human Embryonic Stem Cells," working paper commissioned by the President's Council on Bioethics, available online at http://www.bioethics.gov/background/hurlbut.html.

60. Gareth Cook, "Germans Announce Stem Cell Advance," *Boston Globe,* March 28, 2006, available online at http://www.boston.com/news/world/europe/articles/2006/03/25/germans_announce_stem_cell_advance/.

61. "New Poll: Americans Oppose Destructive Embryo Research, Support Alternatives," press release by the United States Conference of Catholic Bishops, June 8, 2001, available online at http://www.usccb.org/comm/archives/2001/01-101.shtml; the precise wording was: "Stem cells are the basic cells from which all of a person's tissues and organs develop. Congress is considering whether to provide federal funding for experiments using stem cells from human embryos. The live embryos would be destroyed in their first week of development to obtain these cells. Do you support or oppose using your federal tax dollars for such experiments?"

The CAMR results are summarized in B. A. Robinson, *Human Stem Cell Concerns,* Ontario Consultants on Religious Tolerance, November 9, 2003, available online at http://www.religioustolerance.org/res_stem5.htm, which details the lengthy procedure used but without quoting the text. See also Gary Langer, "Public Backs Stem Cell Research," *ABC News,* June 26, 2001, available online at http://abcnews.go.com/sections/politics/DailyNews/poll010626.html, which includes the quoted material; the complete wording is no longer available.

62. The figures in this list are not averages but estimates, with more weight given to polls conducted by and for universities and news organizations than those by advocacy groups. Many have been summarized by Polling Report, including those by Gallup/CNN/*USA Today; CBS;* ABC/*Washington Post;* NBC/*Wall Street Journal; Time; Newsweek;* and the University of Pennsylvania National Annenberg Election Survey; these are available online at http://www.pollingreport.com/science.htm.

The Virginia Commonwealth University (VCU) annual Life Sciences Surveys are particularly useful. They are available online at http://www.vcu.edu/lifesci/centers/cen_lse_surveys.html, as are the Genetics and Public Policy Center polls cited below.

Other sources consulted include: The Harris Poll, available online at http://www.harrisinteractive.com; Research America, available online at http://www.researchamerica.org; Results for America, available online at http://www.resultsforamerica.org; the United States Conference of Catholic Bishops, whose poll data is available online at http://www.usccb.org; the Coalition for the Advancement of Medical Research, whose polls are available online at http://www.camradvocacy.org/polls.aspx; the Juvenile Diabetes Research Foundation International, whose press releases are available online at http://www.jdrf.org; the University of New Hampshire Survey Center, whose publications are available online at http://www.unh.edu/survey-center/; the Cornell University Survey Research Institute, whose polls are available online at http://www.sri.cornell.edu; and the University of Texas Health Science Center at Houston, whose publications are available online at http://www.uth.tmc.edu.

63. Virginia Commonwealth University Life Sciences, *2005 VCU Life Sciences Survey,* available online at http://www.vcu.edu/uns/Releases/2005/oct/102405a.html.

64. Gail H. Javitt et al., *Cloning: A Policy Analysis,* Genetics and Public Policy Center, Washington, D.C., 2005, available online at http://www.dnapolicy.org/pub.html.

65. Kathy L. Hudson et al., *Values in Conflict: Public Attitudes on Embryonic Stem Cell Research,* Genetics and Public Policy Center, Washington, D.C., 2005, available online at http://www.dnapolicy.org/pub.html.

66. Ibid., p. 18.

67. Ibid., pp. 6–7.

68. Ibid., p. 6.

69. The University of New Hampshire Survey Center, "*Boston Globe* Poll: MA Gubernatorial Election," March 2005, available online at http://www.unh.edu/survey-center/. See also Frank Phillips, "Poll Backs Research on Stem Cells," *Boston Globe,* March 13, 2005, available online at http://www.boston.com/news/local/articles/2005/03/13/poll_backs_research_on_stem_cells/.

70. Matthew C. Nisbet, "Public Opinion about Stem Cell Research and Human Cloning," *Public Opinion Quarterly* 68 (2004): 131–54, available online at http://poq.oupjournals.org/cgi/content/full/68/1/131.

71. Stephen S. Hall, *Merchants of Immortality: Chasing the Dream of Human Life Extension* (Boston and New York: Houghton Mifflin Company, 2003).

72. George W. Bush, "President Discusses Stem Cell Research," August 9, 2001, available online at http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html.

73. Zachary Coile, "Stem Cell Decision Balances Interests," *San Francisco Chronicle,* August 11, 2001, available online at http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2001/08/11/mn102182.dtl.

74. Hall, *Merchants of Immortality,* p. 304.

75. National Institutes of Health Human Embryonic Stem Cell Registry, available online at http://stemcells.nih.gov/research/registry/.

76. Sheryl Gay Stolberg, "Stem Cell Research Is Slowed by Restrictions, Scientists Say," *New York Times,* September 26, 2002, available online at http://www.nytimes.com/2002/09/26/politics/26STEM.html.

77. Maria J. Martin et al., "Human Embryonic Stem Cells Express an Immunogenic Nonhuman Sialic Acid," *Nature Medicine* 11 (2005): 228–32, available online at http://ntp.neuroscience.wisc.edu/neuro675/reqreading/HumanEmbryonicStemCells.pdf.

78. Meredith Wadman, "Licensing Fees Slow Advance of Stem Cells," *Nature* 435 (2005): 272–73, available online at http://www.nature.com

/news/2005/050516/pf/435272a_pf.html.

79. California Secretary of State, "Campaign Finance Activity: Propositions & Ballot Measures," available online at http://cal-access.ss.ca.gov/Campaign/Measures/.

80. The Center for Genetics and Society (CGS), along with the California Nurses Association and a group of women's health advocates organized as the Pro-Choice Alliance Against Proposition 71, opposed the initiative. For a summary of pro-choice liberal concerns before the elections, see the CGS "Archived Campaign Webpage," available online at http://www.genetics-and-society.org/policies/california/prop71.html.

81. Center for Genetics and Society, *The California Stem Cell Program at One Year: A Progress Report,* available online at http://www.genetics-and-society.org/policies/california/200601report.pdf. Coverage of controversies concerning the program was widespread. The CIRM board was described, in the first paragraph of a December 2005 *New York Times* story, as asking its president "to draw up a plan for how to draw up a strategic plan." Andrew Pollack, "California's Stem Cell Program Is Hobbled but Staying the Course," *New York Times,* December 10, 2005, available online at http://www.nytimes.com/2005/12/10/business/10stem.html.

82. Rep. Mike Castle, "Embryonic Stem Cell Research," available online at http://www.house.gov/castle/Castle%20DeGette%20ESCR.html.

83. The National Conference on State Legislatures, "NCSL Genetics Tables: State Embryonic and Fetal Research Laws," available online at http://www.ncsl.org/programs/health/genetics/embfet.htm. See also National Conference of State Legislatures, "State Human Cloning Laws," available online at http://www.ncsl.org/programs/health/genetics/rt-shcl.htm.

84. Ross Kerber, "Spread the Wealth," *Boston Globe,* January 15, 2005, available online at http://www.boston.com/business/technology/biotechnology/articles/2005/01/15/spread_the_wealth/.

85. See, for example, "Promises to Keep," *Los Angeles Times* editorial, January 17, 2006, available online at http://www.genetics-and-society.org/newsdisp.asp?id=923; "Stem Cell Institute Responsive, to a Point," *Sacramento Bee* editorial, February 14, 2006, available online at http://www.genetics-and-society.org/newsdisp.asp?id=956; Daniel Sarewitz, "Proposition 71: Vulgar Democracy in Action," paper presented at the AAAS Symposium on Stem Cells and Society, February 17, 2006, available online at http://www.cspo.org/ourlibrary/presentations/AAAS%2006%20Prop%2071%20final.pdf.

86. State funding of embryonic stem cell research is in a state of continual flux. The Grassroots Connection, an advocacy group for patients with Parkinson's, maintains updates that are available online at http://grassrootsconnection.com/state_stem_cell_resources.htm. See also Martin Kasindorf, "States Play Catch-up on Stem Cells," *USA Today,* December

17, 2004, available online at http://www.usatoday.com/news/nation/2004-12-16-stem-cells-usat_x.htm; Ronald Bailey, "Do We Really Need the Feds?" *Reason*, August 24, 2005, available online at http://www.reason.com/rb/rb082405.shtml; the Center for Genetics and Society, "State Policies," available online at http://www.genetics-and-society.org/policies/us/state.html; the Institute on Biotechnology and the Human Future, "Human Cloning," available online at http://www.thehumanfuture.org/topics/human cloning/policy_uslaws.html; and the National Conference on State Legislatures, "State Human Cloning Laws," available online at http://www.ncsl.org/programs/health/genetics/rt-shcl.htm.

87. "California Stem Cell Research and Cures Initiative" (Proposition 71), available online at http://vote2004.ss.ca.gov/voterguide/propositions/prop71text.pdf. California Secretary of State, "Statement of Vote," November 2, 2004, available online at http://www.ss.ca.gov/elections/sov/2004_general/contents.htm. The California Institute for Regenerative Medicine Web site available online at http://www.cirm.ca.gov.

88. State of Connecticut, SB934, "An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings," June 15, 2005, available online at http://cga.ct.gov/2005/ACT/Pa/pdf/2005PA-00149-R00SB-00934-PA.pdf. For SCNT, see William Hathaway, "Scientist Working Against the Odds," *Hartford Courant,* September 12, 2005, available online at http://www.uchc.edu/ocomm/features/stories/stories05/feature_scientist.html.

89. See Maura Kelly Lannan, "Ill. Plans $10M for Stem Cell Research," Associated Press, July 13, 2005, available online at http://www.sfgate.com/cgi-bin/article.cgi?file=/news/archive/2005/07/12/national/a125342D56.DTL. "The Illinois Regenerative Medicine Institute Act" (SB2100, as proposed but not enacted), February 25, 2005, is available online at http://www.ilga.gov/legislation/94/sb/09400sb2100.htm; its disposition is available online at http://www.ilga.gov/legislation.

90. "$5M for Stem Cell Research Available," *Times of Trenton,* August 15, 2005, available online at http://www.genetics-and-society.org/news-disp.asp?id=826; John Sullivan, "Codey to Seek Ethics Panel on Stem Cells," *New York Times,* April 15, 2005, available online at http://www.nytimes.com/2005/04/15/nyregion/15stem.html. The high end of the governor's proposals is in Tina Kelley, "In Race to Stem Cell Center, New Jersey's Efforts Stall," *New York Times,* July 31, 2005, available online at http://www.nytimes.com/2005/07/31/nyregion/31stem.html. Juliann Walsh, "New Jersey Senate Approves $250 Million Stem-Cell Research Plan," Bloomberg News, May 18, 2006, available online at http://www.bloomberg.com/apps/news?pid=10000103&sid=ai3xH7nbQJUA&refer=us. The New Jersey Stem Cell Research Initiative Web site is available online at http://www.state.nj.us/scitech/stem_home.html.

91. "Maryland Stem Cell Research Act of 2006" (SB144), signed April 6, 2006, available online at http://mlis.state.md.us/2006rs/billfile/SB0144.htm.

92. Mark Hollis, "House Retreats on Stem-Cell Bill," *Orlando Sentinel,* January 26, 2006, available online at http://grassrootsconnection.com/state_stem_cell_resources.htm.

93. "New York State Institute for Stem Cell Research and Regenerative Medicine Support Act" (A06300), passed assembly January 10, 2006, available online at http://assembly.state.ny.us/leg/?bn=A06300.

94. See Kevin O'Hanlon, "Bill Aims to Separate Human Cloning, Stem Cell Issues," Associated Press, January 19, 2005, available online at http://www.usatoday.com/tech/science/ethics/2005-01-19-]stemcell-legislation_x.htm; J. L. Miller, "3-State 'Biotech Corridor' Considered," *Delaware News Journal,* January 18, 2005; Rep. Mike Veon "Veon Urges Expansion of Stem-Cell Research," press release, April 4, 2005, available online at http://www.pahouse.com/pr/Veon/014040405.htm; Ronald Bailey, "Do We Really Need the Feds?" *Reason*, August 24, 2005, available online at http://www.reason.com/rb/rb082405.shtml.

95. Carl T. Hall, "Koreans Plan to Create 100s of Stem Cell Lines," *San Francisco Chronicle,* October 19, 2005, available online at http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2005/10/19/MNG7PFAK2M1.DTL.

96. Kim Tae-gyu, "Korea Revamps Stem Cell Hub, Tries to Put Hwang Saga Behind," *Korea Times,* April 27, 2006, available online at http://times.hankooki.com/lpage/tech/200604/kt2006042717493811780.htm.

97. Beezy Marsh, "Doctors Sidestep Laws to Import Stem Cell 'Bank,'" *Daily Telegraph,* November 22, 2005, available online at http://www.telegraph.co.uk/connected/main.jhtml?xml=/connected/2005/11/22/ecnstem22.xml.

98. For overviews, see the Institute on Biotechnology and the Human Future, "International," available online at http://www.thehumanfuture.org/themes/international.htm; and the Center for Genetics and Society, "National Polices Governing New Technologies of Human Genetic Modification: A Preliminary Survey," available online at http://www.genetics-and-society.org/policies/survey.html.

99. "S. Korean Commits Suicide over Hwang Scientist Case," Reuters, February 3, 2006, available online at http://209.157.64.200/focus/f-news/1571603/posts; Barbara Demick, "South Korean Cloning Scandal Takes Toll on Whistle-Blowers," *Los Angeles Times,* February 16, 2006, available online at http://www.genetics-and-society.org/newsdisp.asp?id=958.

100. U.S. Department of Health and Human Services, "Budget Documents & Information," available online at http://www.hhs.gov/budget/docbudget.htm. There is a good overview of the funding debate in

Chapter 2 of *Monitoring Stem Cell Research,* available online at http://www.bioethics.gov/reports/stemcell/index.html.

101. National Institutes of Health, Office of Biotechnology Activities Web site, explanatory material available online at http://www4.od.nih.gov/oba/aboutoba.htm.

102. "Governing Biotechnology," *Global Agenda Magazine,* February 13, 2006.

103. Anthony Shadid, "Debate Flares over Cloning of Humans," *Boston Globe,* April 4, 2001.

104. "Genome Programs of the U.S. Department of Energy Office of Science," available online at http://doegenomes.org/.

105. See the Centers for Disease Control and Prevention Web site, available online at http://www.cdc.gov/.

106. *Guidelines for Human Embryonic Stem Cell Research,* available online at http://books.nap.edu/catalog/11278.html?onpi_newsdoc04262005; "Guidelines Released for Embryonic Stem Cell Research," press release, April 26, 2005, available online at http://www4.nationalacademies.org/news.nsf/isbn/0309096537?OpenDocument/.

107. Daniel Perry, president of the Coalition for the Advancement of Medical Research, quoted in Karen Kaplan and Megan Garvey, "Stem Cell Research Standards Offered," *Los Angeles Times,* April 27, 2005, available online at http://www-learning.berkeley.edu/cipolat/PDF/ISF60/2005/Articles/StemCellGuidelines05.pdf.

108. Ibid.

109. Lisa M. Krieger, "Experts Offer Stem-Cell Guides," *San Jose Mercury,* April 27, 2005. See also "Comments on the National Academies Report, Guidelines for Human Embryonic Stem Cell Research," media advisory, April 26, 2005, available online at http://genetics-and-society.org/resources/cgs/20050426_nas_press.html.

110. "About the Human Fertilisation and Embryology Authority," available online at http://www.hfea.gov.uk/AboutHFEA.

111. The Human Fertilisation and Embryology Authority, Frequently Asked Questions, available online at http://www.hfea.gov.uk/AboutHFEA/FAQs#1450.

112. U.K. Stem Cell Bank Web site, available online at http://www.ukstemcellbank.org.uk.

113. "HFEA Grants the First Therapeutic Cloning Licence for Research," press release, August 11, 2004, available online at http://www.hfea.gov.uk/PressOffice/Archive/1092233888.

114. Ian Sample, "UK Breakthrough as Human Embryo Cloned," *Guardian*, May 20, 2005, available online at http://www.guardian.co.uk/uk_news/story/0,3604,1488288,00.html.

115. "HFEA Grants Embryonic Stem Cell Research Licence to Study Motor Neuron Disease," press release, February 8, 2005, available online

at http://www.hfea.gov.uk/PressOffice/Archive/1107861560.

116. "Dolly Scientist to Clone Human Embryos," *Guardian*, February 8, 2005, available online at http://education.guardian.co.uk/higher/news/story/0,9830,1408287,00.html.

117. The Canadian Institutes of Health Research, "Stem Cell Oversight Committee: Mandate, Membership and Operations," available online at http://www.cihr-irsc.gc.ca/e/15298.html.

118. The Canadian Institutes of Health Research, "Updated Guidelines for Human Pluripotent Stem Cell Research," June 7, 2005, available online at http://www.cihr-irsc.gc.ca/e/28216.html.

119. Health Canada, "Assisted Human Reproduction Agency of Canada," available online at http://www.hc-sc.gc.ca/hl-vs/reprod/agenc/index_e.html.

120. Health Canada, "Assisted Human Reproduction Agency of Canada: Board of Directors—Recruitment Process," available online at http://www.hc-sc.gc.ca/hl-vs/reprod/agenc/recruitment-recrutement/index_e.html.

121. "Assisted Human Reproduction Act," March 29, 2004, available online at http://laws.justice.gc.ca/en/A-13.4/index.html.

122. Center for Genetics and Society, "Canadian Parliament Approves the 'Assisted Human Reproduction Act,' a Model of Responsible Policy," May 17, 2004, available online at http://www.genetics-and-society.org/policies/other/canada.html.

123. Ibid.

124. Australian National Health and Medical Research Council, "General Information about the Prohibition of Human Cloning Act 2002 and the Research Involving Human Embryos Act 2002," available online at http://www.nscc.edu.au/file_downloads/NHMRC_Info_Cloning_Acts.pdf. Australian Government Department of Health and Ageing, "New Licensing Committee for Human Embryo Research," available online at http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-mediarel-yr2003-ka-ka03157.htm.

125. See, for example, Erik Parens and Lori P. Knowles, "Reprogenetics and Public Policies: Reflections and Recommendations," a special supplement to the *Hastings Center Report,* July-August 2003.

126. See Parens and Knowles, ibid. Also see Francis Fukuyama and Franco Furger, *Beyond Bioethics: A Proposal for Modernizing the Regulation of Human Biotechnologies,* Paul H. Nitze School of Advanced International Studies, Washington, D.C., 2006, executive summary available online at http://www.biotechgov.org/. This is the most fully developed analysis published to date of the need for U.S. regulatory policy concerning the new human genetic and reproductive technologies.

Browsing the Web?

Visit The Century Foundation's Web site featuring other pamphlets in this series; excerpts from current books, papers, and reports; and information about the Foundation and how to order its publications.

You can find us at:
www.tcf.org

You can also contact us through our e-mail address:
info@tcf.org

Of course, we also can be reached by U.S. post or phone:

The Century Foundation
41 East 70th Street
New York, New York 10021

212-535-4441