Approved: May 3, 2002
Date

MINUTES OF THE SENATE FEDERAL AND STATE AFFAIRS COMMITTEE.

The meeting was called to order by Chairperson Senator Nancey Harrington at 10:30 a.m. on April 9, 2002 in Room 245-N of the Capitol.

All members were present.

Committee staff present: Russell Mills, Legislative Research Department
Dennis Hodgins, Legislative Research Department
Theresa Kiernan, Office of the Revisor
Nikki Kraus, Committee Secretary

Conferees appearing before the committee:
Representative Mary Pilcher Cook
Jessica Welch
Dr. David Prentice, PhD Indiana University
John Morris, PhD Rockhurst University
Jan Coles, PhD Kansas State University

Others attending: Please see attached

Chairperson Harrington continued the public hearing on:

HB 2736–Human cloning, criminal and civil penalties
HB 2737–Destructive human embryo research act

Theresa Kiernan, Office of the Revisor, presented the committee with information on the Congressional act concerning "Human Cloning Prohibition Act of 2001." (Attachment 1)

Dennis Hodgins, Legislative Research Department, presented information about Human Embryonic Stem Cell Research. (Attachment 2)

Representative Mary Pilcher Cook presented testimony in favor of the bills. (Attachment 3)

Jessica Welch presented testimony in favor of the bills. (Attachment 4)

Dr. David Prentice, PhD Indiana University, presented testimony in favor of the bills. (Attachment 5)

John Morris, PhD Rockhurst University, presented testimony in favor of the bills. (Attachment 6)

Jan Coles, PhD Kansas State University, presented testimony in favor of the bills. (Attachment 7)

Dr. Prentice presented slides to the committee in favor of the bill also. (Attachment 8)

Senator Teichman asked the speakers if they could tell her who in the state of Kansas is doing cloning research. Representative Cook stated that no one is on a public level, but there is no way to know about the private sector.

Chairperson Harrington stated that the committee would not be working the bills today, but would consider looking at them tomorrow.

Senator Gilstrap asked the committee for the introduction of a bill to expand gaming in Kansas in a way which was different from that which had been proposed in the past six years.

MINUTES OF THE SENATE FEDERAL AND STATE AFFAIRS COMMITTEE at on March 9, 2002 in Room 245-N of the Capitol.

Senator Gilstrap made a motion to introduce the bill. Senator O'Connor seconded the motion. The bill was introduced.

The committee meeting adjourned at 12:05 p.m. The next meeting will be at 10:30 a.m. in Room 245-N on April 10, 2002.

SENATE FEDERAL AND STATE AFFAIRS COMMITTEE
GUEST LIST

DATE: April 9, 2002

NAME	REPRESENTING
Dr. David Prentice	Do No Harm
John F. Morris, Ph.D.	
Brendan Sweetman, Ph.D.	
Julie Sheerin	Intern - Rep. Cook
Justin McGarity	
Jan Coles, Ph.D.	
Dan Martin	
Helen Martin	
Jessica Welch	Rep. Cook
Tyrone Bush	Topeka Independent Living

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Bill 1 of 4

There are 3 other versions of this bill.

GPO's PDF version of this bill	References to this bill in the Congressional Record	Link to House Committee Report 170	Link to the Bill Summary & Status file.	*Full Display* - 5,023 bytes.[Help]

Human Cloning Prohibition Act of 2001 (Engrossed in House)

HR 2505 EH

107th CONGRESS

1st Session

H. R. 2505

AN ACT

To amend title 18, United States Code, to prohibit human cloning.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `Human Cloning Prohibition Act of 2001'.

SEC. 2. PROHIBITION ON HUMAN CLONING.

(a) IN GENERAL- Title 18, United States Code, is amended by inserting after chapter 15, the following:

`CHAPTER 16--HUMAN CLONING

`Sec.

`301. Definitions.

`302. Prohibition on human cloning.

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Attach #1

`Sec. 301. Definitions

`In this chapter:

`(1) HUMAN CLONING- The term `human cloning' means human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism (at any stage of development) that is genetically virtually identical to an existing or previously existing human organism.

`(2) ASEXUAL REPRODUCTION- The term `asexual reproduction' means reproduction not initiated by the union of oocyte and sperm.

`(3) SOMATIC CELL- The term `somatic cell' means a diploid cell (having a complete set of chromosomes) obtained or derived from a living or deceased human body at any stage of development.

`Sec. 302. Prohibition on human cloning

`(a) IN GENERAL- It shall be unlawful for any person or entity, public or private, in or affecting interstate commerce, knowingly--

`(1) to perform or attempt to perform human cloning;

`(2) to participate in an attempt to perform human cloning; or

`(3) to ship or receive for any purpose an embryo produced by human cloning or any product derived from such embryo.

`(b) IMPORTATION- It shall be unlawful for any person or entity, public or private, knowingly to import for any purpose an embryo produced by human cloning, or any product derived from such embryo.

`(c) PENALTIES-

`(1) CRIMINAL PENALTY- Any person or entity that violates this section shall be fined under this title or imprisoned not more than 10 years, or both.

`(2) CIVIL PENALTY- Any person or entity that violates any provision of this section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not less than $1,000,000 and not more than an amount equal to the amount of the gross gain multiplied by 2, if that amount is greater than $1,000,000.

`(d) SCIENTIFIC RESEARCH- Nothing in this section restricts areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.'.

(b) CLERICAL AMENDMENT- The table of chapters for part I of title 18, United States Code, is

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amended by inserting after the item relating to chapter 15 the following:

301'.

SEC. 3. STUDY BY GENERAL ACCOUNTING OFFICE.

(a) IN GENERAL- The General Accounting Office shall conduct a study to assess the need (if any) for amendment of the prohibition on human cloning, as defined in section 301 of title 18, United States Code, as added by this Act, which study should include--

(1) a discussion of new developments in medical technology concerning human cloning and somatic cell nuclear transfer, the need (if any) for somatic cell nuclear transfer to produce medical advances, current public attitudes and prevailing ethical views concerning the use of somatic cell nuclear transfer, and potential legal implications of research in somatic cell nuclear transfer; and

(2) a review of any technological developments that may require that technical changes be made to section 2 of this Act.

(b) REPORT- The General Accounting Office shall transmit to the Congress, within 4 years after the date of enactment of this Act, a report containing the findings and conclusions of its study, together with recommendations for any legislation or administrative actions which it considers appropriate.

Passed the House of Representatives July 31, 2001.

Attest:

Clerk.

107th CONGRESS

1st Session

H. R. 2505

AN ACT

To amend title 18, United States Code, to prohibit human cloning.

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SCIENCE AND ETHICS
NOVEMBER 1999
NATURAL SCIENCE

Holy Grail or Pandora's Box?

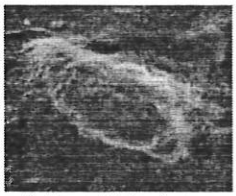
Evaluating Human Embryonic Stem Cell Research

By M. Therese Lysaught

Research on human embryonic stem cells has numerous potential medical applications, but should it be pursued at the risk of imperiling our collective moral soul and social infrastructure?

Imagine yourself, 12 years from now, sitting in your doctor's office. The doctor has just informed you that you have a serious, debilitating disease. Treatment options are limited. Describing these options and following the canons of informed consent, your physician neutrally adds a caveat about one: the therapy is derived from human embryos. You must make a choice. What would you do?

A hypothetical scenario? Maybe not. Although floating in legal limbo and ensnared in an ethical quagmire, human embryonic stem (ES) cell research will most likely continue. Flourishing in the private sector, it may soon gain further momentum from an influx of federal money.


A stem cell taken from a human embryo.

It has been a tumultuous 12 months since November 1998, when two research groups independently announced that they had achieved a major technical breakthrough: They had isolated human stem cells from embryonic tissues, cultivated the cells in laboratories for several months, and shown that these cells could develop into all three basic layers of cells in the human embryo. Because these cells, under the right conditions, can potentially "differentiate" (develop) into nearly every type of cell and tissue in the human body, they hold great promise for applications in medicine as

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well as for research into human development.

Hearing the news, the biological research community buzzed with excitement. Harold Varmus, director of the National Institutes of Health (NIH), was quoted as saying that human ES cell research "had the potential to revolutionize the practice of medicine and improve the quality and length of life." At the same time, ethical and moral critiques resounded. The central concern expressed was that the techniques by which the stem cells were derived involved the destruction of human embryos, depriving them of their potential to develop into full human beings. A related concern is whether this research would open one more door by which some might tinker with human life, possibly in some grand experiment in eugenics. Will the efforts at pursuing the holy grail of regenerative medicine open up a Pandoras box of undesirable moral and social consequences?

The quest

Interest in embryonic stem cells dates back to at least 1981, when they were first cultured successfully from mouse embryos. Since then, ES cells have been isolated from various other animals, including sheep, hamsters, pigs, cows, rabbits, mink, rhesus monkeys, and marmosets. But culturing human ES cells proved difficult: Once isolated, they refused to stay undifferentiated, seemingly driven to spontaneously differentiate and form primitive structures. The first publicly anowledged attempt to isolate and culture ES cells from human embryos in vitro was published in 1994. That attempt was unsuccessful.

Given these difficulties, biologists were especially impressed when, on November 6, 1998, James Thomson and his research team at the University of Wisconsin, Madison, reported in Science that they had successfully maintained human ES cells in laboratory culture for a number of months. The cells were derived from "spare," week-old embryos produced by in vitro fertilization at a fertility clinic, after obtaining consent from the gamete contributors. Thomson's group further showed that the ES cells could differentiate into a variety of tissue types--including the gut lining, muscle, cartilage, bone, and neural epithelium--representing derivatives of all three basic layers of the mammalian embryo.

From the moment it was announced, human ES cell research has found itself fighting a war on two fronts: the legal and the ethical.

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Four days later, the work of John Gearhart and his group at Johns Hopkins University was published in the Proceedings of the National Academy of Sciences, announcing that they had isolated and grown similar stem cells in culture. Their work differed from Thomson's in two significant ways. First, Gearhart's group isolated what are called primordial germ (PG) or embryonic germ (EG) cells, which are precursors of sperm and egg cells. Second, the cells were obtained not from embryos made in vitro but from aborted fetuses that were 5--9 weeks old. Tests showed that these cells had a number of characteristics typical of stem cells and could further develop into the three embryonic germ layers.

Excitement about these reports was sparked by the many ways in which the cells could be useful. Researchers could now design experiments to determine how human embryonic cells differentiate into various types of tissues, leading to the development of the human body. Moreover, because ES cells are capable of giving rise to nearly every type of cell in the human body, a wide range of clinical applications has been predicted. Consider some of these:

- ES or EG cells may be coaxed to differentiate into nerve or brain cells, and the latter could then be used to treat neurological disorders--including Alzheimer's and Parkinson's diseases--for which no viable therapy currently exists.
- Likewise, if ES cells were transformed into heart muscle cells, the latter may be used to replace damaged tissue in the hearts of those who have suffered heart attacks or congestive heart failure.
- lOr ES cells may be used to produce pancreatic islet cells in culture, and these may then be injected into the pancreas of a diabetic to manufacture insulin, reducing or eliminating the need for daily injections.
- Some cell lines (derived from ES cells) might be used to grow entire organs for replacement, providing a ready supply of organs and tissues, reducing the need to depend on organ donation.
- Other cell lines may be developed for use as human tissue banks against which pharmaceuticals and other chemicals could be tested for toxicity and effectiveness.
- Some scientists have thought of making genetic alterations to ES cells, with the purpose of growing tissues with specific characteristics and using these tissues to compensate for defective ones.

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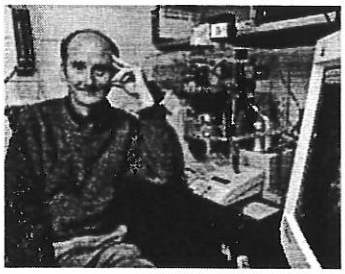
- Others envision genetic engineering of whole embryos.
- Additional possibilities include the treatment of spinal cord injury, stroke, burns, arthritis, muscular dystrophy, kidney disease, liver disease, and macular degeneration (which causes blindness).

It is clear, however, that for any of these applications to come to fruition, much research remains to be done. At this time, scientists have yet to discover how to direct the cells to become particular types of tissues. The process of generating organs (or even parts of organs) is a lot more complex. When researchers injected ES cells into mature mice, the result was a tumor called a teratoma. Thus, special techniques will need to be developed and various tests performed before ES cells are allowed for therapeutic use in humans.

Legal and ethical battles

From the moment it was announced, human ES cell research has found itself fighting a war on two fronts: the legal and the ethical. Clearly, the ethical debate centers on the destruction of human embryos and, relatedly, the destruction of human fetuses. For many, this in and of itself raises insurmountable moral barriers. Such research represents one more step toward transforming human beings into biological products to be mined and exploited as raw materials so that some may benefit and a few may hugely profit.



Developmental biologist James Thomson and his colleagues at the University of Wisconsin were the first to derive stem cells from human embryos.

The legal dispute focuses on funding. A mere two weeks before Thomson's article appeared, Congress passed Public Law 105--277, the Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA). This legislation allocated funds for fiscal year 1999, including money to support the National Institutes of Health (NIH). As with similar bills passed since 1995, OCESAA included an appropriations rider banning the use of federal funds to pay for "research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero."

The impetus for this restriction was the 1994 Report

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of the Human Embryo Research Panel. In this report, an advisory panel to the director of the NIH recommended lifting the de facto funding ban on embryo research that had been in place sin 1980, arguing that some embryo research could be justified. Actually, except for 9 states that ban such research entirely and 16 that ban the sale of parts of human embryos, it is not illegal in other parts of the United States to conduct research on human embryos. The congressional ban applies to NIH funding for human embryo research but leaves open the possibility of funding by private sources. Consequently, Thomson's and Gearhart's projects were funded by a biotechnology company, Geron Corporation of Menlo Park, California.

With the congressional ban in effect, the NIH could not fund research in which human embryos would be destroyed. But the ban did not specify that NIH money could not be used for research on stem cells that were purchased from a private source such as Geron. Recognizing this loophole, Harriet Rabb, general counsel for the Department of Health and Human Services, sent Varmus a memo on January 15, 1999. In this memo, Rabb opined that the congressional ban "would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo." In other words, there is a difference between conducting research that destroys an embryo and conducting research with products derived from a destroyed embryo.

Many, however, found this distinction to be sophistry. In February, 70 members of the House of Representatives protested Rabb's decision in a letter to Secretary of Health and Human Services Donna Shalala. Clearly, they maintained, such a distinction violates both the letter and the spirit of the law. Since Thomson's method requires the destruction of embryos prepared in vitro, human ES cell research cannot be separated, conceptually or morally, from the initial act. Researchers using human ES cells, in other words, would be complicit, cooperating with evil after the fact.

In June, the National Bioethics Advisory Commission (NBAC) concurred in part with the representatives. This panel of experts was inaugurated by President Clinton in 1995 to advise the National Science and Technology Council on ethical matters pertaining to research in the United States. It is morally inconsistent, NBAC held, to allow scientists to conduct research on cells that they legally could not derive. Nonetheless, contrary to the elected officials, NBAC concluded that federally funded scientists should be allowed to do both. While the

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NBAC statement will not change the legal context, it will undoubtedly influence the debate, as Congress heads back to session in the fall and considers whether to extend the appropriations rider another year.

One option would render the legal impasse on federal funding moot: Researchers could employ Gearhart's method, which, although funded by Geron, would have been eligible for federal funding under existing law. One may recall that the Reagan administration had placed a moratorium on federal funding of fetal tissue research, following the 1988 report of another NIH advisory panel, the Human Fetal Tissue Transplant Research Panel. But this moratorium was lifted by President Clinton when he took office in 1992. Guidelines for the conduct of fetal tissue research were subsequently developed and implemented in 1993.

Thus, although fetal tissue research remains contentious, due to its inevitable connection with abortion, federal funding is permitted within certain guidelines. But advocates of human ES cell research raise two objections to this comomise. First, they maintain that deriving ES cells from fetuses is more difficult than deriving them from in vitro embryos. Moreover, it remains unclear whether the cells Gearhart derived from embryonic germ cells are equivalent to Thomson's embryonic stem cells.

Who can claim ownership of human tissue, and can it be bought and sold? What are the social ramifications when we begin to see human biological material as having cash value--something that can be patented and traded?

Others argue that permitting federal moneys to be used for deriving human ES cells would bring embryo research under federal oversight. Currently, embryo research is conducted in the private sector, beyond public control or purview. With the allied area of technological reproduction, it remains one of the least researched and regulated areas of biotechnology in the United States.

Even if the legal challenges are resolved, a number of ethical issues will remain. For instance, fostering practices based on Thomson's and Gearhart's methods could pose intrinsic conflicts of interest for those who own and run fertility clinics. If embryos and aborted fetuses become commodities to be sold to researchers, might financial and commercial interests distract from

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the patients' best interests? If a profitable market develops for "leftover" embryos made in vitro, might there be an inducement to produce "extras"?

Would women be prescribed excessive doses of fertility drugs so that they produce more eggs? Even current levels of these drugs present significant risks to the women who take them. Might clients feel subtly coerced into donating their embryos for research (rather than storing them or donating them to another infertile couple), to please the physician who either holds their happiness in his hands or has provided them with the child they always wanted?

Behind these issues lurks the increasing specter of the commodification and commercialization of human tissue. Geron funded Thomson's and Gearhart's work and now holds an exclusive license on their techniques. But who can claim ownership of human tissue, and can it be bought and sold? What are the social ramifications when we begin to see human biological material as having cash value--something that can be patented and traded? What happens to our social philosophy when we begin to conceive of persons as parts? Who stands to profit from such research? Certainly not those who "donate" the tissue.

Finally, one of the most troubling questions concerns the potential of human ES (or EG) cells themselves. Are they capable of developing into a human person? Or can the cells, under proper conditions, develop into a viable human embryo? While a number of scientific voices maintain that the answer is no, both Thomson's and Gearhart's initial articles suggest that cultured human ES and EG cells have embryonic characteristics. In addition, the animal data on such questions are ambiguous. If each of these cells is capable of growing into an embryo, then embryo destruction multiplies exponentially. Can medical advances be grounded in a systematic practice that destroys human life (or even potential human life)? Would such an internal conflict ultimately destroy medical practice from within?

An alternative route

The benefits of regenerative medicine are significant. But ought significant benefits be pursued at the risk of imperiling our collective moral soul and social infrastructure? An alternative approach would advance many of the benefits of human ES research, yet render most of the ethical questions moot: Obtain stem cells from adult humans or placentas instead of from embryos. Although difficult to locate and isolate, stem

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cells stock the human body--in the liver, bone marrow, brain, and so on--replenishing aging and damaged tissues.

There are certain limitations to the use of stem cells isolated from the adult body. First, each group of stem cells in an adult can differentiate into a limited number of cell types but not the wide variety produced by ES cells. Second, scientists have not yet discovered the full range of stem cells present in the adult human body. Nonetheless, stem cells obtained from an adult offer important advantages over ES cells. They are closer to the endpoint of differentiated cells, making it easier and faster to transform them into the specific tissues desired. And because the cells would be derived from the patient's own body, the problems of immune rejection and donor shortage would be eliminated.

Examples point the way. In an April 1999 issue of Science, researchers at Osiris Therapeutics reported that they could take what are called "mesenchymal" stem cells from adult human bone marrow and convert them into bone, cartilage, fat, and bone marrow stroma cells (the last of which provide support for blood-forming cells). They also raised the possibility of converting these stem cells into heart muscle cells. Likewise, in May, Byron Peterson of the University of Pittsburgh Medical Center reported in Science that his group was able to convert bone marrow stem cells into functioning liver tissue.

Harvesting Embryonic Stem Cells

Several organizations, such as the National Childrens Leukemia Foundation (NCLF), are encouraging the use of stem cells obtained from human placentas and umbilical-cord blood, which are otherwise discarded after childbirth. According to NCLF, a number of children's lives have been saved after receiving treatment with stem cells obtained from those sources.

In addition, two research groups--one led by Jonas Frisen at the Karolinska Institute of Stockholm and the other led by Arturo Alvarez-Buylla at Rockefeller University in New York--reported in Cell earlier this year that they had successfully isolated and transformed rat neural stem cells. While the two groups disagreed on the location of the neural stem cells, both succeeded in inducing the cells to produce the three main types (lineages) of brain cells.

How might neural stem cells be useful? Angelo Vescovi of NeuroSpheres Ltd. in Calgary, Alberta, reported in Science (January 1999) that his team had transplanted neural stem cells from the central nervous systems of mice into a second group of mice, where they

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fulfilled the function of bone marrow stem cells, producing different types of blood cells. And Evan Snyder's group at Harvard Medical School reported in a June issue of the Proceedings of the National Academy of Sciences that they had successfully transplanted neural stem cells from an adult mouse into a neurologically impaired newborn mouse, with therapeutic success.

In the final analysis, there is little doubt that stem cell research--both embryonic and adult--will continue. The legal issues will be resolved, one way or other. And if human ES cell research wins NIH funding, guidelines outlining proper procedures will be developed. But the moral and ethical issues will remain. And a decade from now, a multitude of patients may find themselves unwittingly dropped into the middle of our opening scenario. Will they have a choice?

M. Therese Lysaught is assistant professor in the Department of Religious Studies at the University of Dayton in Dayton, Ohio. She teaches bioethics at the university and has served on the Recombinant DNA Advisory Committee of the National Institutes of Health.

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HOUSE OF
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FEDERAL & STATE AFFAIRS
HIGHER EDUCATION
TAXATION

April 9, 2002

Madame Chairman, honorable members of the Committee, thank you for this opportunity to speak before you on the complicated subjects in **support of banning human cloning, HB2736 and destructive embryonic research, HB2737**. As legislators, we cannot use the excuse that we do not understand the science, as it is our duty to stay informed and educate others. We are at a time in our society where technology is moving very rapidly and we are in an information age that is moving at breakneck speed. With the advent of computers scientists now have the ability to streamline deductive reasoning and share their information fluently. This gives us new discoveries in biotechnology every day, and those findings offer the world extraordinary opportunities for good. However, if we ignore some basic ethics and do not use sound reason in our debates, these technologies could easily put the human race on the path to destruction.

It is the nature of a scientist to want complete freedom to experiment. For the most part, we give them that freedom. However, we know from history that we cannot give them a blank check.

When emotional rhetoric is added to the debate and long-term consequences are not considered, a climate is formed where scientists are empowered to become obsessed with the ability to create a master human race. We need the whole truth and nothing but the truth when we are discussing experimentation with human life.

We must be careful of scientists who are drawn by the power of being able to direct the future of humanity. Some are willing to change terminology to avoid the science. And despite the intentions claimed by those who predict breathtaking cures, there needs to be a calm but sensible judgment which shows the moral gravity of some of the methods being discussed.

Scientists can always find bioethicists to justify their behavior. Manufacturing a human is a terrible human rights abuse and manipulating terms is a sign that scientists are trying to evade an ethical responsibility.

It is up to each of us to pay close attention to this ground-breaking research. Life may be changed forever and we may not be able to reverse it later. It is our duty to stay informed and resist and educate those who are seeking the power to play with human life.

There was an explanation of vote in the House which was wholly inaccurate as it included the statement when describing the bill, "However, cloning human cells is beneficial to scientific research". That implies that the bill will not allow the cloning of human cells. Quite the contrary, the bill specifically states, "Nothing in this section shall restrict areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants or animals other than humans."

This legislation will not prohibit beneficial research for Kansas. The state of Pennsylvania ranks third in the nation in biotech investment and they have a ban on destructive embryonic research, which by definition precludes human cloning.

I have selected the speakers we have here today based their integrity and their ability to communicate the facts. Dr. Prentice especially has an extensive knowledge of the science behind human cloning and embryonic research.

I have great self-interest in biological research because of the Huntington's Disease in my family. My daughter will be speaking about the tragedy of that disease. It is not easy for her to speak before you today. Even though I have struggled to change things in our family, earlier generations were taught that this disease was never to be talked about in private, let alone in public. Family members who had the disease were shunned and avoided at all costs. Jessica is breaking that mold with an attitude of openness and inclusiveness.

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Human Cloning Ban
Destructive Embryonic Research
April 9, 2002

Madame Chairman, thank you for allowing me to testify today. My name is Jessica Welch and I am in support of **HB2736** and **HB2737**. Our state should ban human cloning and stop any destructive embryonic research.

I have great interest in this legislation because, in my family, we have Huntington's Disease. It is a devastating, degenerative brain disorder for which there is no treatment and no cure. It affects the ability to walk, talk, think and reason.

It is a tragic disease with the movements of Parkinson's, the mental degradation of Alzheimer's (only much worse), and the physical degeneration of Multiple Sclerosis.

Early symptoms include depression, mood swings, forgetfulness, clumsiness, involuntary twitching and lack of coordination. As the disease progresses, concentration and short-term memory diminish. Involuntary movements of the head, trunk and limbs increase. Walking, speaking and swallowing abilities deteriorate.

This is a family disease. People with Huntington's are often verbally and physically abusive to family members, and the suicide rate is extremely high. My dad committed suicide a few years ago.

Eventually the person is unable to care for him or herself. Death follows from complications such as choking, infection or heart failure. The HD patient can be in a nursing home for 10 or more years.

I am at-risk for this disease. So are my brother and sister. We each have a 50-50 chance of getting HD and the age of onset is usually around 35. I am 25. If I get the disease, each of my children will have a 50-50 chance of getting the disease.

I saw my dad deteriorate with this disease. The person with Huntington's becomes totally dependent on others for their care. Huntington's Disease has an overwhelming effect on the lives of entire families, emotionally, socially and economically.

We need a cure. We are desperate for a cure.

But, creating human embryos for the purpose of research does not provide an answer for my family. I do not believe it is morally right to demand that someone else must give up his or her life for me.

Money used for embryonic research takes away funding needed for the adult stem cell studies, which has already shown incredible success. Adult stem cell research has returns that are immediate. Embryonic stem cell research is only based on theory and scientists who are only speculating. Every dollar that goes towards embryonic research is a dollar taken away from the adult stem cell studies. We need cures that will be morally acceptable and we need them quickly. We need them now.

Adult stem cells are cheaper, easier to attain, do not have the tumor risks or the tissue rejection factor, and are curing diseases in human patients today. Everyone benefits from this research.

Scientists have been promising HD patients for years that they are on the verge of a cure. They have heralded the use of fetal tissue for 10 years in experimentation that has had no success. In fact, experiments with Parkinson's patients have produced nightmarish and tragic results that were irreversible. In one case, the cells grew hair and fingernail tissue in the patient's brain, killing him. In another study, the condition of 15 percent of the patients was irreversibly worsened, and "the patients writhed and jerked uncontrollably." (The New York Times, March 8, 2001).

Please ban destructive embryonic research. It is not right to destroy lives. The end does not justify the means. Thank you for your attention.

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04/09/02
Attach #4

Testimony of Dr. David A. Prentice, Ph.D.
Professor of Life Sciences, Indiana State University
Adjunct Professor of Medical and Molecular Genetics, Indiana University School of Medicine
Founding Member, Do No Harm: The Coalition of Americans for Research Ethics

Department of Life Sciences
Indiana State University
Terre Haute, IN 47809

Kansas State Legislature
Senate Federal & State Affairs Committee
Hearing on Human Cloning Ban (HB2736) and Destructive Embryo Research (HB2737)
April 9, 2002

Madame Chair, distinguished Members of the Committee, thank you for the opportunity to testify today regarding human cloning.

Human cloning is human asexual reproduction. It may be accomplished by introducing the nuclear material from one or more human somatic cells into a fertilized or unfertilized egg cell whose nuclear material has been removed or inactivated, producing a human embryo who is virtually genetically identical to an existing or previously existing human being.

Proponents of human cloning hold out two hopes for its use: (1) creating live born children for infertile couples or those grieving over the loss of a loved one, so-called "reproductive cloning", and (2) promises of medical miracles to cure diseases by harvesting embryonic stem cells from cloned embryos created from patients, euphemistically termed "therapeutic cloning".

First let us be clear on the terms. All human cloning is reproductive, in that it creates – reproduces – a new developing human intended to be virtually identical to the cloned subject. In point of fact, both "reproductive" (or live birth) cloning and "therapeutic" cloning (more properly termed experimental cloning) use exactly the same techniques to create the clone, and the cloned embryos are indistinguishable. The process, as well as the product, is identical. The only distinction between the embryos is the purpose to which the embryo is put—either implantation in the hopes of a live birth, or destruction in the hopes of a medical miracle.

The National Academy of Sciences panel report released Jan. 18, 2002 describes it this way:

> "The method used to initiate the reproductive cloning procedure is called either nuclear transplantation or somatic cell nuclear transfer."...
> "If the procedure is successful, the cell will divide several times to produce a pre-implantation embryo – "blastocyst" -- that is composed of about 150 cells."...
> "If the blastocyst is placed in a uterus, it can implant and form a fetus, which then may develop further and result in a newborn."...
> "Unlike reproductive cloning, the creation of embryonic stem cells by nuclear transplantation does not involve implantation of a blastocyst in a uterus. Instead, cells are isolated from a blastocyst about five days after the nuclear transplantation procedure and used to make stem cell lines..."

Thus, the only difference in the procedure is whether the embryo is implanted or destroyed. A ban only on implantation of the embryos is completely unenforceable. As cloned embryos are

produced they will become widely available, and inevitably some will be implanted. Will the law then mandate an abortion, the destruction of a born child, or incarceration of the mother and/or child?

In point of fact, the embryo at that stage, whether produced by cloning or by the old-fashioned method of joining egg and sperm, is the same—embryos produced by the different methods could not be distinguished under the microscope. (Please see diagram appended to my written submission.) And despite the attempts to employ various euphemisms, scientifically, genetically, what is created is a human being; its species is *Homo sapiens*, it is neither fish nor fowl, monkey nor cow—it is human. The use of disingenuous euphemisms to describe the embryo as something other than an embryo likewise are not scientific, and diverge from the accepted definitions as put forth by the National Academy of Sciences, the National Institutes of Health, and others.

There are good scientific reasons why live birth cloning should be banned. It has an enormous failure rate—95-99% of clones die before or soon after birth. Out of 277 cloned embryos, one Dolly the sheep was produced, and even this "successful" clone is beset with abnormalities—it was recently disclosed that she has developed early onset arthritis and may need to be put down. This past summer a group at the Whitehead Institute achieved 5 born mice from 613 cloned embryos, and all of the born mice showed abnormalities in expression of their genes.
We can expect that of those few cloned humans who survive to live birth, most will die shortly thereafter and the others be plagued by abnormalities due to the cloning process. In addition, the surrogate mothers of clones experience physiological problems. Because of the clone's abnormalities, carrying a clonal pregnancy to term will pose unique threats to the woman involved. In short, this whole notion is fraught with peril, constitutes an unethical form of human experimentation, and should be banned.

No human cloning is therapeutic cloning. In medical ethics, "therapeutic research" is defined as research that could provide therapeutic benefit to the individual subjected to research risks. Thus "therapeutic cloning" is obviously not therapeutic for the embryo—the new human is specifically created in order to be destroyed as a source of tissue. For clarity's sake this practice should be called human experimental cloning.

Creating new human life solely to destroy it for the potential benefit of others is unethical. It turns human life into a commodity, creating a caste system of lesser humans for scientific sacrifice, what the renowned biochemist Erwin Chargaff calls "a kind of capitalist cannibalism." The real question which much be addressed: Is the young human a person or a piece of property?

Human experimental cloning is also unnecessary for medical progress. Theoretically the embryonic stem cells from the cloned human embryo would be used to generate matched tissues for transplant into the patient from whom the embryo was cloned. However, the promises put forth for therapeutic use of embryonic stem cells are not supported by the scientific literature, and numerous promising non-embryonic alternatives, including adult stem cells, are available for producing the therapies about which cloning advocates can only speculate.

On examining the promises, premises, and published data regarding embryonic stem cells, the claims for embryonic stem cells, as well as their supposed advantages over adult stem cells, are unsubstantiated, and remain speculative, a scientific fad. There are no current clinical treatments based on embryonic stem cells, and in fact very few published successes using animal models of

disease. In fact, those who work with embryonic stem cells even have difficulty obtaining pure cultures of specific cell types in the laboratory dish. For example, an Israeli group reported in the summer of 2001that they had obtained insulin-secreting cells from human embryonic stem cells. While this might initially sound like a potential treatment for diabetes, what the popular press did not report, and what was revealed by the scientific paper, was that only 1% of the cells in the culture dish secreted insulin. The remaining 99% of the cells were a mixture of other cell types, including nerve, muscle, a few beating heart cells, and also cells which continued to proliferate. Those growing cells point out another problem with embryonic stem cells—the potential for tumor formation. Proponents of embryonic stem cell research readily admit that when injected, embryonic stem cells tend to form tumors. In a report in January 2002 on the possibility that embryonic stem cells could treat Parkinson's disease in rats, 20% of rats injected with embryonic stem cells died from tumors formed in their brains. A treatment which kills one-fifth of the patients is not very promising. And this past summer, a group from the Whitehead Institute reported that embryonic stem cells are genomically unstable, meaning that the expression of their genes is unstable. This might in fact explain why there is such difficulty in obtaining pure cultures and why they tend to form tumors.

Too often a false choice has been put forth—that we must either destroy embryos or allow patients to die. However, there are other choices and alternatives, in particular adult stem cells. Those who say adult stem cells are not a valid alternative are relying on obsolete, outdated information. A wealth of scientific papers published over the last few years documents that adult stem cells are a much more promising source of stem cells for regenerative medicine. They do show capacity to generate all adult tissues. Most, if not all, tissues appear to contain stem cells, or can be formed from stem cells from other body tissues. Even fat has been found to contain stem cells that can be transformed into other tissues. Frankly, this could constitute an unlimited supply of stem cells. In point of fact, any time someone has looked in a tissue for stem cells, they have found them. Adult stem cells are easy to find and easy to isolate.

Many published references now also show that adult stem cells can multiply almost indefinitely, providing sufficient numbers for clinical treatments. Adult stem cells have been shown to be effective in treating animal models of disease, including such diseases as diabetes, stroke, Parkinson's disease, spinal cord injury, and heart disease. A direct comparison of the successes of adult stem cells versus the three most best results using embryonic stem cells (diabetes, Parkinson's disease, spinal cord injury) clearly documents the greater success and potential of adult stem cells. (Please see comparison table attached to this submission.)

Moreover, adult stem cells are already being used clinically to treat many human diseases, including various cancers, autoimmune diseases such as multiple sclerosis, lupus, and arthritis, and anemias including sickle cell anemia. Adult stem cells are being used to form new cartilage so that children can walk, grow new corneas to restore sight to blind patients, treat stroke patients, and repair damage after heart attacks. And just announced, the first Parkinson's patient to be treated, using the patient's own adult brain stem cells, has achieved an 80% recovery one year after treatment. The patient's own stem cells can be used for the treatment, preventing the problems of immune rejection, and there is no tumor formation. More scientists now admit that adult stem cells will be the ones to provide therapeutic benefits to patients. Attached to my written submission I have provided an abbreviated list of references regarding scientific advances in adult stem cell research for the Committee. An extensive reference list can be found at the web site of Do No Harm (http://www.stemcellresearch.org).

The National Academy of Sciences report also spoke of the risk to women's health from cloning:

> "Because many eggs are needed for human reproductive cloning attempts, human experimentation could subject more women to adverse health effects -- either from high levels of hormones used to stimulate egg production or because more women overall would be sought to donate eggs, which involves surgery with its own inherent risks."

But since the same procedure is used to create embryos for the harvest of embryonic stem cells, the same problem applies. In fact, the problem will be even greater, because the procedure used to create embryonic stem cell lines is itself inefficient. An enormous supply of human eggs will need to be made available to treat even a small group of patients, subjecting a large population of women of childbearing age to unethical health risks inherent in harvesting the necessary quantities of eggs for cloning. A calculation based on the published scientific literature for cloning of animals and derivation of embryonic stem cells, both extremely inefficient procedures, reveals that to treat just one patient group, the 16 million diabetes patients in the U.S., will require at least 800 million human eggs, or approximately 80 million women of childbearing age to "donate" eggs. As the NAS panel points out, this subjects a large number of women to adverse health effects. The result will be that human eggs will also become a commodity, with the resultant exploitation of disadvantaged women in this country and abroad.

Indeed, the obstacles to human cloning as a source of medical benefits will likely prove insurmountable. Recent overviews in the journals *Nature, Science, Stem Cells* and *New Scientist* all point out that the idea of therapeutic cloning is falling from favor because researchers are finding it to be too costly, inefficient, and unnecessary—those who still support it are relying on obsolete information. (Please see quotes appended to my written submission.) A recent scientific report that supposedly showed success of therapeutic cloning to treat a genetic defect in mice actually was a failure in terms of the use of therapeutic cloning; indeed, the only real success in the experiment was achieved by bringing cloned mice to birth and using the born mouse bone marrow to treat the disease. Does this mean we should allow reproductive cloning, so that we can provide born individuals to serve as tissue donors? It should also be noted that the similar genetic defect in humans, severe combined immunodeficiency syndrome ("boy in the bubble disease"), was cured in infants in 2000 using gene therapy of the infants' own bone marrow adult stem cells.

Even the idea that cloning is the only method for preventing immune rejection of transplanted embryonic stem cells is completely false. In an article published March 18, 2002 in the San Francisco Chronicle (appended to my written testimony), researchers with Geron Corp. and with Advanced Cell Technologies admit that there are ways to prevent rejection of transplanted cells without therapeutic cloning, but that "that message has not gotten out," and that "the need for cloning to overcome immune system rejection has been overstated." The report goes on to note "the scientific community has put out the message that a ban on therapeutic cloning will prevent researchers from solving the immune-system problem—an argument that seems at best a stretch, and at worst, a deception." In his own review on the science of embryonic stem cell research, Dr. James Thomson of the University of Wisconsin-Madison (who first derived human embryonic stem cells) noted that besides cloning (which he sees as unlikely to be successful) and immunosuppressive drugs, there are at least two other potential methods for preventing immune rejection of embryonic stem cells, co-transplantation with hematopoietic cells and genetic manipulation of the embryonic stem cells.

It should also be emphasized that the proposed ban on human cloning does not restrict any vital or viable medical research. Cloning and nuclear transfer techniques for production of DNA,

other molecules, cells other than human embryos, tissues, organs, plants, and animals are all allowed. The proposed ban does not even restrict research involving human embryonic stem cells. The proposed prohibition only restricts human cloning, for which there have been no federal funds and for which there will be no federal funds in the foreseeable future. Nine states now ban research that destroys human embryos (LA, ME, MA, MI, MN, ND, PA, RI, SD) and two states ban human cloning for any purpose (MI and VA). In terms of the effects of such bans on economic development, it is illustrative to note that PA, which passed its ban in the 1990's, is now ranked 3rd in the nation in biotechnology investment, and MI, which banned embryo destruction in 1978 and all human cloning in 1998, is considered one of the major growth sites for biotechnology in the U.S.

In summary, human cloning is unsafe, unethical, and unnecessary. There are no valid or compelling grounds—ethical, scientific, or medical—to proceed with human cloning. A comprehensive ban on human cloning is the only sufficient answer.

Madame Chair, distinguished Members, I thank you for the opportunity to provide testimony on this important issue, and I would be pleased to answer any questions.

Selected References Documenting Advances in "Adult" Stem Cell Research

Adult stem cells show pluripotent capacity in generation of virtually all adult tissues

A single adult bone marrow stem cell (multipotent adult progenitor cell) can form all body tissues and proliferate indefinitely in culture.

References: Westphal SP; "Ultimate stem cell discovered"; *New Scientist*; Jan 23, 2002

Reyes M *et al.*; "Origin of endothelial progenitors in human postnatal bone marrow"; Journal of Clinical Investigation 109, 337-346; Feb 2002.

Reyes M and Verfaillie CM; "Characterization of multipotent adult progenitor cells, a subpopulation of mesenchymal stem cells"; *Annals of the New York Academy of Sciences* 938:231-233; June 2001

Zhao L-R *et al.*, "Human bone marrow stem cells exhibit neural phenotypes and ameliorate neurological deficits after grafting into the ischemic brain of rats," *Experimental Neurology* 174, 11-20; 2002.

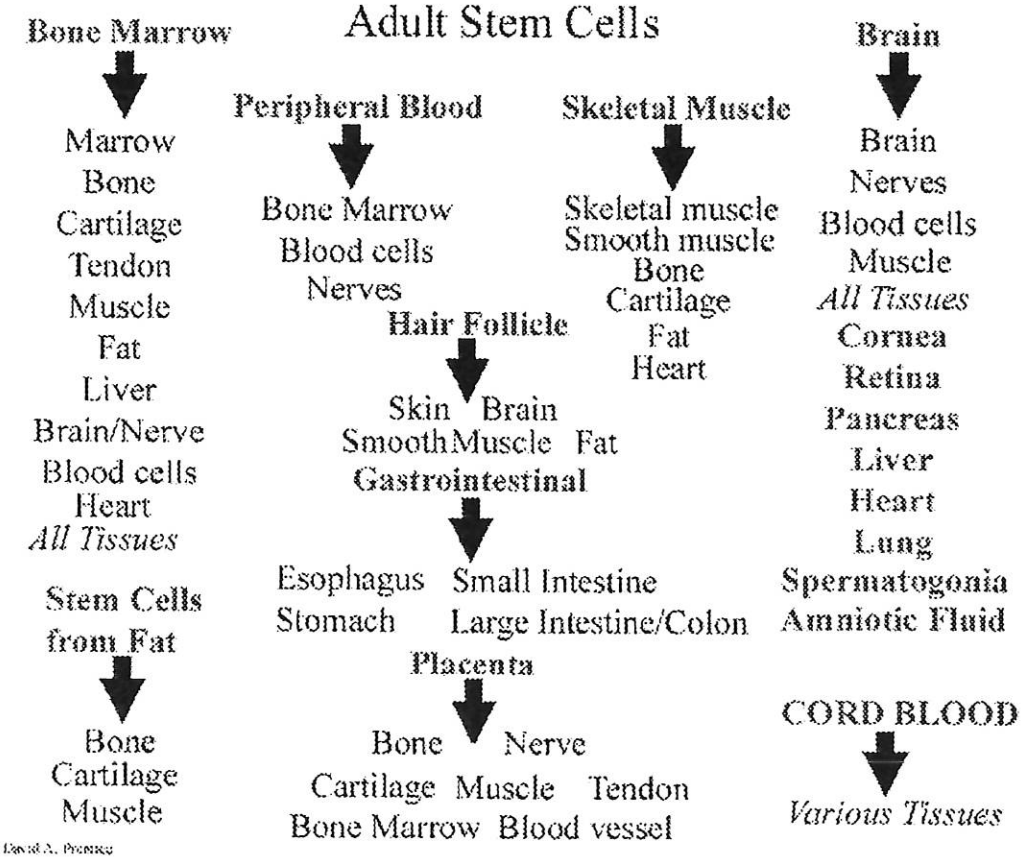
A single adult bone marrow stem cell could repopulate the bone marrow of mice. Formed functional marrow and blood cells, and also differentiated into liver, lung, gastrointestinal tract, and skin, as well as heart and skeletal muscle.

Reference: Krause DS *et al.*; "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell"; Cell 105, 369-377; May 4, 2001

Adult stem cells from brain can grow into a wide variety of organs—heart, lung, intestine, kidney, liver, nervous system, muscle, and other tissues.

Reference: Clarke *et al.*; "Generalized potential of adult neural stem cells"; Science 288, 1660-1663, June 2, 2000.

Some Post-Natal (non-embryonic) Stem Cells and their Known or Possible Derivatives



Adult stem cells can multiply almost indefinitely, numbers sufficient for clinical treatments

References: Westphal SP; "Ultimate stem cell discovered"; *New Scientist*; Jan 23, 2002
Reyes M *et al.*; "Purification and ex vivo expansion of postnatal human marrow mesodermal progenitor cells"; *Blood* 98, 2615-2625; Nov 1, 2001
Krause DS; "Multipotent human cells expand indefinitely", *Blood* 98, 2595; Nov 1, 2001
Gilmore GL *et al.*; "Ex vivo expansion of human umbilical cord blood and peripheral blood CD34(+) hematopoietic stem cells"; *Experimental Hematology* 28, 1297-1305; Nov 1 2000
Colter D *et al.*; "Rapid Expansion of recycling stem cells in cultures of plastic-adherent cells from human bone marrow"; Proc. Natl. Acad. Sci. USA 97, 3213-3218; March 28, 2000

Adult stem cells are effective in treating animal models of disease.

Diabetes—Pancreatic stem cells grown in culture formed insulin-secreting islets. When injected into diabetic mice, the mice survived without further need of insulin injections.
***Reference*:** Ramiya VK *et al*, "Reversal of insulin-dependent diabetes using islets generated *in vitro* from pancreatic stem cells," *Nature Medicine* 6, 278-282, March 2000.
Stroke—Adult bone marrow or umbilical cord blood stem cells, delivered intravenously to brain tissue which has suffered stroke damage in rats, provide therapeutic benefit after stroke. The cells appeared to "home" to sites of damage.
***References*:** Chen J *et al.*, "Intravenous administration of human umbilical cord blood reduces behavioral deficits after stroke in rats," *Stroke* 32, 2682-2688; November 2001
Chen J *et al.*, "Therapeutic benefit of intravenous administration of bone marrow stromal cells after cerebral ischemia in rats," *Stroke* 32, 1005-1011; April 2001
Heart Disease—Bone marrow stem cells injected into heart or which migrate to site of heart damage can regenerate heart tissue.
***References*:** Orlic D *et al.*, "Mobilized bone marrow cells repair the infarcted heart, improving function and survival," *Proceedings of the National Academy of Sciences USA* 98, 10344-10349, August 28, 2001
Jackson KA *et al.*, "Regeneration of ischemic cardiac muscle and vascular endothelium by adult stem cells," *Journal of Clinical Investigation* 107, 1395-1402; June 2001
Orlic D *et al.*, "Bone marrow cells regenerate infarcted myocardium," *Nature* 410, 701-705; April 5, 2001
Kocher AA *et al.*, "Neovascularization of ischemic myocardium by human bone-marrow-derived angioblasts prevents cardiomyocyte apoptosis, reduces remodeling and improves cardiac function," *Nature Medicine* 7, 430-436; April 2001.

Current Clinical Uses of Adult Stem Cells

- **Cancers**—Lymphomas, multiple myeloma, leukemias, breast cancer, neuroblastoma, renal cell carcinoma, ovarian cancer
- **Autoimmune diseases**—multiple sclerosis, systemic lupus erythematosus, juvenile rheumatoid arthritis, rheumatoid arthritis, scleroderma, scleromyxedema, Crohn's disease
- **Anemias** (incl. sickle cell anemia)
- **Immunodeficiencies**—including first successful human gene therapy
- **Bone and cartilage deformities**—treating children with osteogenesis imperfecta
- **Corneal scarring**-generation of new corneas to restore sight
- **Stroke**—neural cell implants in clinical trials
- **Repairing cardiac tissue after heart attack**
- **Skin**—grafts; growth from hair follicle stem cells, after plucking a few hairs from patient
- **Parkinsons**—first patient treated with own adult neural stem cells

Comparison of successes with Adult stem cells and Embryonic stem cells

DIABETES

Adult Stem Cells

Scientists "retrained" immune cells to reverse diabetes in mice. The autoimmunity that was previously directed against insulin-secreting cells was reversed, and adult stem cells in the mice formed insulin-secreting cells. The treatment was "...thus able to effect an apparent cure of established Type 1 diabetes in the [diabetic] mouse".
S. Ryu et al.; "Reversal of established autoimmune diabetes by restoration of endogenous ß cell function," J. Clin. Invest. 108, 63-72; July 2001

Pancreatic adult stem cells grown in culture formed insulin-secreting islets. When injected into diabetic mice, the mice survived without further need of insulin injections.
V.K. Ramiya et al.; "Reversal of insulin-dependent diabetes using islets generated in vitro from pancreatic stem cells," Nature Medicine 6, 278-282, March 2000.

Embryonic Stem Cells

Researchers reported the conversion of mouse embryonic stem cells into insulin producing pancreatic islet cells. The mouse embryonic stem cells secreted only 1/50th the normal amount of insulin, and diabetic mice implanted with the cells still died.
N. Lumelsky et al.; "Differentiation of embryonic stem cells to insulin-secreting structures similar to pancreatic islets," Science 292, 1389-1394; May 18, 2001

PARKINSON'S DISEASE

Adult Stem Cells

Injection of growth protein into brains of Parkinson's rats caused their neural stem cells to grow, migrate to the site of damage, and begin to replace missing nerve cells. Eighty percent (80%) of the rats received a benefit from the treatment, with no tumor formation.
J. Fallon et al.; "In vivo induction of massive proliferation,directed migration, and differentiation of neural cells in the adult mammalian brain," Proc. Natl. Acad. Sci. USA 97, 14686-14691; December 19, 2000

Embryonic Stem Cells

Parkinson's rats injected with mouse embryonic stem cells showed a modest benefit for just over 50% of the rats, but one-fifth (20%) of the rats died of brain tumors caused by the embryonic stem cells.
L.M. Bjorklund et al.; "Embryonic stem cells develop into functional dopaminergic neurons after transplantation in a Parkinson rat model," Proc. Natl. Acad. Sci.USA www.pnas.org/cgi/doi/10.1073/pnas.022438099 (PNAS Early Edition) Jan 8, 2002

SPINAL CORD INJURY

Adult Stem Cells

Several labs have shown adult stem cells capable of re-growth and reconnection in spinal cord injury, allowing functional recovery. Adult stem cell transplants "promote functional recovery of paraplegic adult rats and long-distance motor axon regeneration in their completely transected [severed] spinal cords," and showed "dramatic functional improvement and anatomical repair" (Ramon-Cueto et al; 2000).

Others, using transplanted adult stem cells or injection of growth proteins to stimulate existing adult stem cells, achieved re-growth of neurons and re-myelination (sheathing) of neurons.

18-year old Melissa Holley, a paraplegic with a severed spinal cord, was treated with her own immune cells, and regained movement of her toes and bladder control. (no peer-reviewed paper yet; Globe and Mail (Toronto), June 15, 2001]

*M. Sasaki et al., "Transplantation of an acutely isolated bone marrow fraction repairs demyelinated adult rat spinal cord axons," Glia 35, 26-34; July 2001

*A. Ramon-Cueto et al., "Functional recovery of paraplegic rats and motor axon regeneration in their spinal cords by olfactory ensheathing glia," Neuron 25, 425-435; February 2000.

*M.S. Ramer et al.; "Functional regeneration of sensory axons into the adult spinal cord," Nature 403, 312-316; January 20, 2000S.

*Shihabuddin et al.; "Adult spinal cord stem cells generate neurons after transplantation in the adult dentate gyrus," J Neuroscience 20, 8727-8735; December 2000.

*Barnett et al.; "Identification of a human olfactory ensheathing cell that can effect transplant-mediated remyelination of demyelinated CNS axons," Brain 123, 1581-1588, August 2000

*A. Ramon-Cueto et al., "Long-distance axonal regeneration in the transected adult rat spinal cord is promoted by olfactory ensheathing glial transplants," J Neuroscience 18, 3803-3815; May 15, 1998

Embryonic Stem Cells

A study by McDonald et al. study showed some functional improvement in rats with spinal cord injury, slightly better than no treatment alone.Studies by Liu et al. and Brüstle et al. showed that ES cells could form protective myelin sheaths around nerves in rats with spinal cord, but they did not show or test for any functional recovery of the animals.

*J.W. McDonald et al., "Transplanted embryonic stem cells survive, differentiate and promote recovery in injured rat spinal cord," Nature Medicine 12, 1410-1412, December 1999

*S. Liu et al., "Embryonic stem cells differentiate into oligodendrocytes and myelinate in culture and after spinal cord transplantation," Proc. Natl. Acad. Sci. USA 97, 6126-6131; May 23, 2000

*O. Brüstle et al., "Embryonic Stem Cell-Derived Glial Precursers: A Source of Myelinating Transplants," Science 285, 754-756, July 30, 1999

Quotes from major scientific journals regarding "therapeutic cloning"

•"...Ministers in Britain have too easily swallowed the line that cloning human embryos is essential to medical progress. It is not. ...Like stuck records, ministers and policy makers continue to enthuse about therapeutic cloning even though the majority of bench scientists no longer think it's possible or practicable to treat patients with cells derived from cloned embryos. They have already moved on to investigating the alternatives."
Editorial, "Brave New Medicine", *New Scientist*, Dec 1, 2001

•"The idea of therapeutic cloning, which offers the potential of growing replacement tissues perfectly matched to their recipients, is falling from favour. But there are alternatives..."
"So to the casual observer, it may come as a surprise that many experts do not now expect therapeutic cloning to have a large impact. Aside from problems with the supply of human egg cells, and ethical objections to any therapy that requires the destruction of human embryos, many researchers have come to doubt whether therapeutic cloning will ever be efficient enough to be commercially viable. 'It would be astronomically expensive,' says James Thomson of the University of Wisconsin in Madison."
"Peter Mountford, chief scientific officer of Stem Cell Sciences, believes these problems can be overcome, and argues that it is too early to give up on therapeutic cloning—but his has become a minority view."
Peter Aldhous, "Can they rebuild us?", *Nature* 410, 622-625; April 5, 2001

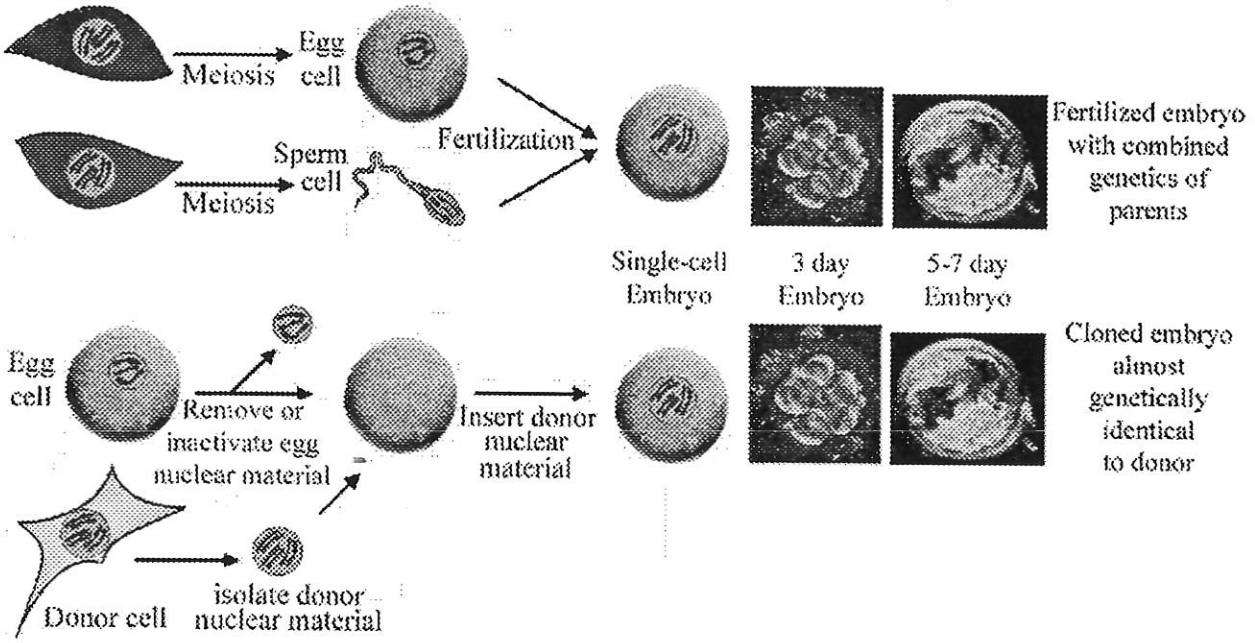
•"But the idea of 'therapeutic cloning' seems to be on the wane. By creating cloned human blastocysts, some experts have argued that it should be possible to derive ES cells perfectly matched to individual patients. But most now believe this will be too expensive and cumbersome for regular clinical use."
Peter Aldhous, "A world of difference", *Nature* 414, 838; Dec 20/27, 2001

•"[John] Gearhart [of Johns Hopkins University] also says that many scientists 'feel there are ways of getting around [the rejection problem] without the nuclear transfer paradigm.' "
Constance Holden, "Would cloning ban affect stem cells?", *Science* 293, 1025; Aug 10, 2001

•"[T]he poor availability of human oocytes, the low efficiency of the nuclear transfer procedure, and the long population-doubling time of human ES cells make it difficult to envision this [therapeutic cloning] becoming a routine clinical procedure..."
Odorico JS, Kaufman DS, **Thomson JA**, "Multilineage differentiation from human embryonic stem cell lines," *Stem Cells* 19, 193-204; 2001

Both Fertilization and Cloning (somatic cell nuclear transfer) Produce Embryos

The cloning process and the cloned embryo produced <u>are identical</u> for both "reproductive" (live birth) cloning and "therapeutic" (experimental) cloning. The only difference is the subsequent use of the embryo (implantation for live birth or destruction for stem cells.)



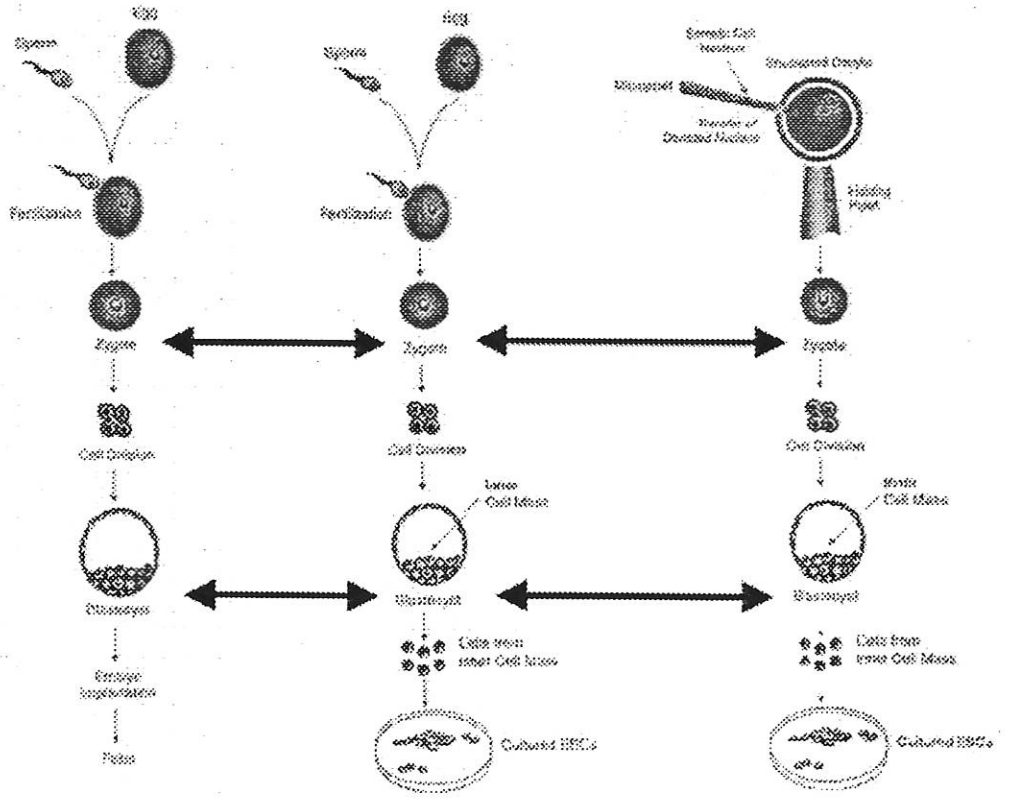


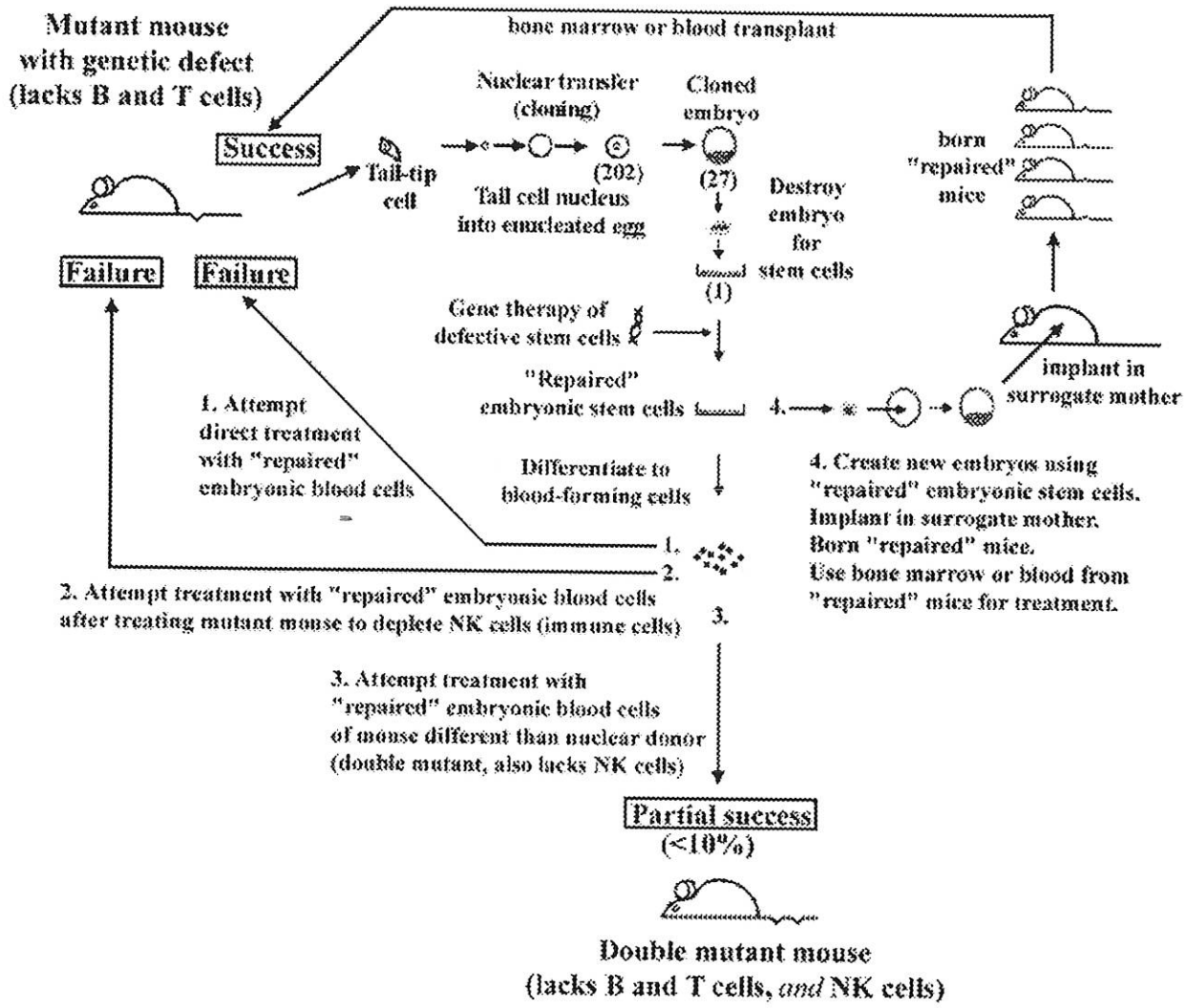
Figure 1 Stages of Development of the Human Embryo

Figure 2 Isolation and Culture of Human ESCs from Blastocysts

Figure 4 Somatic Cell Nuclear Transfer (SCNT)

[From: Stem Cells and the Future of Regenerative Medicine, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington, DC, Sept 2001, Pg 10, 11, 26]

THERAPEUTIC CLONING UNSUCCESSFUL



The authors note: "Our results raise the provocative possibility that even genetically matched cells derived by therapeutic cloning may still face barriers to effective transplantation for some disorders."

W.M. Rideout et al., "Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy," *Cell* Immediate Early Publication, published online March 8, 2002

Drugs posited as stand-in for stem cell cloning
Tom Abate
Monday, March 18, 2002 Page E – 1 San Francisco Chronicle

http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2002/03/18/BU94198.DTL

A scientist working with Geron Corp. said he plans to seek government approval to test whether embryonic stem cells can repair spinal injuries in paralyzed patients without cloning the cells to overcome immune system rejection.

Hans Keirstead, a researcher at the University of California at Irvine, said that when he seeks permission to conduct these human trials, he intends to propose using immune-suppression drugs to prevent rejection of the transplanted stem cells.

Keirstead's disclosure, made in response to a Chronicle reporter's questions, undercuts the notion that scientists must use cloning to turn versatile embryonic cells into replacement nerves, muscles or other tissues.

The concern has been that a patient's immune system would reject transplanted cells. In theory, by taking the nucleus from a patient's cell and inserting that nucleus into the stem cells, researchers hope to create genetically compatible transplants.

That argument was advanced earlier this month, when paralyzed actor Christopher Reeve was wheeled into a Senate hearing room to testify in favor of a bill by Sen. Dianne Feinstein. The California Democrat wants to ban the cloning of babies but to permit so-called therapeutic cloning to advance stem cell studies.

"Why do we need therapeutic cloning?" asked Reeve, who told senators that "implantation of human embryonic stem cells is not safe unless they contain the patient's own DNA."

Reeve testified against a competing proposal from Sen. Sam Brownback, R-Kan. , who wants the Senate to adopt the no-exceptions ban on human cloning that has passed the House of Representatives.

But in response to questions, Keirstead said scientists could use off-the- shelf medicines to prevent immune system rejection of certain stem cell transplants, without therapeutic cloning.

"That message has not gotten out," said Keirstead, who was among the scientists who testified against Brownback's ban at a recent public hearing at Stanford University.

At that hearing, Keirstead said he had spent six months treating rodents with Geron's human embryonic stem cells. He showed a video of two rats with spinal column injuries. The untreated rat dragged its rear. The other rat, which had been treated with human embryonic stem cells, regained partial use of its legs.

After the presentation, Keirstead, in answer to a reporter's question, said he had used immunosuppressants to prevent the rat from rejecting the transplanted human cells. He said that if the rat experiments continue to go well, he would ask university officials to seek the U.S. Food and Drug Administration's approval to test the human embryonic stem cells on human patients with spinal cord injuries.

Initially, Keirstead said he might be ready to take this step in about a year. But university officials later suggested that time line was unduly optimistic.

In a follow-up interview last week, Keirstead said he would propose immunosuppressants to prevent rejection of the transplanted cells in those human trials.

NEED FOR CLONING OVERSTATED

Robert Lanza, chief scientist at Advanced Cell Technology in Worcester, Mass., an ardent advocate for both embryonic stem cell studies and therapeutic cloning, agreed that in the course of the political debate, the need for cloning to overcome immune system rejection has been

overstated, especially in such conditions as paralysis, Parkinson's disease, multiple sclerosis and other conditions of the central nervous system.

"It's not all or nothing. You can move ahead," said Lanza, explaining that the central nervous system is what scientists call "immune privileged."

This means brain and nerve tissues have little or no immune system protection and are less likely than other organs to reject transplants, he said.

IMMUNE SYSTEM HAZARDS

But Lanza said scientists probably couldn't use immune suppression drugs to test stem cell therapies on conditions like diabetes. Weakening the immune system leaves patients open to infection, and the negative effects of immune suppression would outweigh the benefits of stem cell therapy for diseases that are not life-threatening or debilitating, he said.

So while therapeutic cloning is not a prerequisite for all stem cell studies, Lanza said to deny scientists that option "would be like moving ahead with one hand tied behind your back."

In a telephone interview, Reeve said he was familiar with Keirstead's work - - the actor's foundation supports the research -- but played down the importance of the immunosuppressive strategy and restated the need for therapeutic cloning.

"For some patients, it may be possible to safely treat them with immunosuppressants, but for others we may have to have cloning," he said.

For instance, Reeve said many paralysis patients suffer from lung or bladder infections and could not afford to have their immune systems weakened. He believes scientists must be able to pursue nonreproductive cloning as an alternative.

"I believe that both approaches need to be tried: immunosuppressants and therapeutic cloning," Reeve said.

Oswald Steward, director of the Reeve-Irvine Research Center and Keirstead's boss, said "there is really a lot of divergent opinion" in the scientific community about differing strategies for controlling rejection. Steward said he believes therapeutic cloning is the safer, quicker way to advance stem cell medicines.

But whatever its internal disagreements, the scientific community has put out the message that a ban on therapeutic cloning will prevent researchers from solving the immune-system problem -- an argument that seems at best a stretch, and at worst, a deception.

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Kansas State Legislature
Senate Federal & State Affairs Committee
Hearing on Human Cloning Ban (HB2736) and Destructive Embryo Research (HB2737)
April 9, 2002

Madame Chair and distinguished Members of the Committee, my name is John F. Morris. I am a philosopher with specialties in ethics and bioethics, and am active in the public discourse of issues in medical ethics. It is a privilege to be here today and to have the opportunity to provide this testimony regarding human cloning and destructive embryonic research.

Now immediately some may object that as a philosopher, and not a scientist, I have no business testifying before you today. I have been told that I, and others like myself who question cloning and destructive embryonic research, should simply "leave science to the scientists."

The thrust of this statement is, I believe, twofold. First, the implication is that science and technological development are, and must remain, autonomous and pure in order to maintain the integrity of the scientific process.[1] Second, the more subtle implication is that if problems do arise with science or technology, scientists will police themselves and prevent harm being done to society.

My response to the suggestion to "leave science to the scientists" is simple and direct – ABSOLUTELY NOT!

In the late 1950s, the English philosopher Bertrand Russell led an effort known as "The Pugwash Movement," with the goal of global nuclear disarmament. In his own words, Russell noted:

> My purpose was to secure cooperation between Communist and anti-Communist scientists on matters lying within their technical competence, and, if possible, also on international measures related to nuclear weapons. I thought that a statement signed by some twelve of the ablest men living at that time would, perhaps, have some effect upon Governments and the public. (Russell, 1961)

Among the signatories was none other than Professor Albert Einstein.

Certainly Russell led a noble cause here. Yet, Russell was by no means the only person concerned with the development of weapons of mass destruction. Countless other groups of people from all walks of life protested and fought for the same goal of nuclear disarmament – indeed, that struggle continues today. My point is this: was Russell's document any more valid than the multitude of other protests simply because he gathered the signatures of prominent physicists involved with atomic theory to point out the dangers of nuclear warfare? Such a suggestion is ludicrous. The development of nuclear weaponry is more than a matter of atomic physics – it involves *ethical* issues that are appropriate for all human beings to be concerned about.

In the same vein, I would argue that myself, as well as every human being, has both a **right** and an **obligation** to become involved with the debate regarding human cloning as well as the issue of destroying embryos for research purposes. The destruction of embryos for research and the technology of cloning both impact the nature and future of humanity. These are issues for all of us, not scientists alone. As the legislature of the State of Kansas, your actions today are therefore both appropriate and laudable, as you are serving your constituents by examining the issue of cloning and destructive embryonic research in the public interest.

And so, it is in this spirit that I offer my remarks to you today – as a philosopher, ethicist, and fellow human being who is concerned with the awesome impact that human cloning and destructive embryonic research would have upon our lives together, as well as all future generations.

Actual, *Not* Simply Potential

To begin with, we must be absolutely clear about the subject of this controversy: an embryo – whether developed by cloning or *in vitro* fertilization – from the beginning of its development on. As a society, we cannot understand our obligations towards an embryo, cloned or otherwise, until we understand what it is, and determine its moral status.

Now some argue that a zygote, blastocyst, pre-embryo, embryo, and fetus, represent only "potential" human life. But contemporary embryology tells us that this is not the case. While a zygote, blastocyst, pre-embryo, embryo, or fetus – whether from cloning, *in vitro* fertilization, or natural reproduction – may potentially one day be an astronaut, a musician, or a future President of the United States, what it IS is quite clear – it is ACTUAL human life.

To exist, something has to be in ACT – that is, it must actually be something. Further, while it is true that an actual being also possesses many future possibilities, those possibilities must relate to *real* potencies within the being in question. What this means, practically speaking, is that if one were to say that a human zygote was only "potential" human life, then that zygote must also at the same time have the potency to become something else entirely – which contemporary genetics points out is untrue. In fact, from the very moment of fertilization, a human is distinguishable from a pig, a cow, and even from a chimpanzee – which we are told bears only a 5% genetic difference from a human being. And so, it is inappropriate to refer to any zygote as "potential" human life as if it could become something else. A fertilized ovum coming from human gametes is at its very moment of fertilization something actual – and what it IS, is actual human life. It is "human" because of its human genetic material, and it is "life" because it is a *self-developing* entity.[2]

The argument that a fertilized human ovum is only "potentially" human life rests upon the mistaken notion that human development goes through "ontological" stages – that is, stages in which the being is actually changed when it passes through. Embryologists point out that while terms like zygote, blastocyst, pre-embryo, embryo, and fetus have become convenient for discussing the progress of human development, they do not refer to what could be called actual stages of development except in an artificial sense. Our growing knowledge of genetics, fostered by the Human Genome Project, affirms that human development is a continuum – not a series of stages.[3]

Now, when specifically discussing a clone, all of the above would also be true. Life is exhibited in the activity of *self-development* – which a clone exhibits. Like all organisms, zygotes of all types (cloned or not) depend upon their environment for sustenance. But the program of development is internal,

although still capable of being influenced externally. Thus, what a clone IS, is also clear – *a human clone is actual human life.*

The Unique Individuality of *All* Zygotes (cloned or otherwise)

Now, by accepting a fertilized human ovum as actual human life, and not simply something that has the potential to become human, what are our obligations as a society towards human embryos developed for research purposes, or towards clones?

To begin with the specific case of cloning, some argue that even if a clone is human life, that does not entail any obligations on our part, since the clone is not a unique individual, but a copy of an individual. It is further suggested that all zygotes, both clones and embryos developed through *in vitro* fertilization, are not unique because during the first few divisions, the cells of any zygote are generic cells that have undergone no differentiation. In technical language, the cells of the zygote in its first few days are totipotent. A totipotent cell can become any cell in the body, or even a whole human being.[4] Because these cells are undifferentiated, they would be indistinguishable from any other totipotent cell. The implication is that in the first few days of every human being's development, we are all identical and not unique.

However, both of these arguments against the unique individuality of zygotes are fallacious.

First, in regard to the suggestion that a clone is a copy, and thus not "unique," a simple error of equivocation is made. It is true that one common understanding of unique is "one of a kind." Thus, if one is told they are buying a unique, one of a kind dress, and then later sees the same dress on someone else at the dance – then one has been swindled. However, one could in all honesty be told they are buying a unique dress because it is a new style, or out of the ordinary – these are other meanings for the term unique. Another meaning of the term unique is something that is special to a particular being, even if other particular beings share the same characteristic. For example, a person's musical ability is unique and special to them, even though a lot of people are musically gifted. It is in this sense that a clone – although not a "one of a kind" – is still unique. Of course, practically speaking, all of this is easy to recognize. Identical twins and triplets are quite unique even though very much alike. Indeed, each of us sitting here today exists by virtue of copied genes – the genes of our parents, and their parents, and so on. When my father and I go to a store together, there simply is no mistaking that I am his son. Does the fact that I am a "copy" of my dad make me any less unique? Absolutely not. The simple fact is that the genes a clone possesses are its own genes from the moment of its existence – they are no longer the genes of the donor.

Second, in regard to the suggestion that by virtue of possessing only undifferentiated cells any zygote is not truly a unique individual yet, there is a misunderstanding of genetics. To imply that an undifferentiated cell is not yet unique because it can become any type of cell, and even a whole being on its own, forgets the fact that those totipotent cells contain a complete genetic code within their DNA. If these totipotent cells did not carry a whole genetic code, they would not be *self-developing*, nor would they have the information needed to become every type of cell. Rather than think of these cells as generic cells, it is better to think of them as master cells. A generic cell is thought of as a blank page upon which anything can be written. The notion of a master cell reflects the idea of blueprints containing the plans for the whole project. Our totipotent cells are not blank, but rather are loaded with complex information – our unique, individual information.

The Fallacy of "Personhood"

Now why is the issue of individuality important for us to consider, and why did I spend a significant amount of time addressing the issue today?

It has been argued that individuality is a key component of personhood. Thus, if a being is not a unique individual, then it cannot be a person. The implication, of course, is that we only have social and ethical obligations towards persons. And so, if an embryo or clone is not unique, and so not a person, then even if one agrees that either is human life, the use and destruction of any embryo for personal or social benefit would appear to be permissible.

In the previous section, it was argued that *all* zygotes are unique individuals from the very beginning of their existence. However, individuality is not the *only* criterion for those who use the personhood argument. And so, even if one grants the arguments about individuality, it is still argued back that clones and embryos are not persons, and so do not have the same standing as a fetus, or a newborn baby, or you and I.

The term "person" is certainly an important one in our contemporary vocabulary. However, we must recognize that "person" is a term that is given numerous social and political definitions. That is, personhood is only "asserted" of an individual based upon certain criteria established by the group in power. This leads to many problems and disagreements in the usage of the term "person."

Now we must not gloss too quickly over these concerns raised by the notion of personhood and its restrictive applications. During the debates leading up to the Civil War in this country, it was consistently argued by proponents of slavery that the Africans were not fully persons. Male slaves could be counted as part of the census by Southern States, but not as representing a whole man. Yet, if a slave could escape to the North, or become free in some other manner, then he suddenly became a person and could become an American citizen. This fact illustrates the arbitrary manner in which personhood is assigned by various social groups.

It is worth noting that at the same time male slaves could be partially counted in the population during a census as part of determining representation in the legislatures, women and children – both African and American – did not count at all. Throughout human history, women and children have not been fully treated as persons.

It would also serve us well to reflect upon the atrocities committed by the Nazis upon the Jewish people during the Holocaust. The Nazi propaganda machine focused upon physical attributes of Jews that they argued were signs of genetic inferiority. The goal of Nazi propaganda was to argue that the Jews were dispensable.

Now, given that to the naked eye Africans were much more similar to Americans, and Jews much more similar to Germans, and women much more similar to men, than zygotes during their first several days of existence are to you and I, the risk of depersonalizing zygotes is great. Many people just assert that a few cells do not resemble a person. However, as Sidney Callahan, feminist and author, noted:

> [C]ertain philosophers set the standard of personhood so high that half the human race could not meet the criteria during most of their waking hours (let alone their

> sleeping ones). Sentience, self-consciousness, rational decision-making, social participation? Surely no infant, or child under two, could qualify. Either our idea of person must be expanded or another criterion, such as human life itself, be employed to protect the weak in a just society. (Callahan, 1986)

In this light, I argue that "personhood" is incapable of serving as a clear criterion for determining our social and ethical responsibility towards zygotes, cloned or otherwise. Rather, the only clear criterion that can be applied categorically within society is "human life." The criterion of human life is scientifically verifiable, and does not fall into the confusions noted above. As Judge John T. Noonan argued many years ago:

> Humanity does not depend upon social recognition, though often failure of society to recognize the prisoner, the alien, the heterodox as human has led to the destruction of human beings. Anyone conceived by a man and a woman is human. Recognition of this condition by society follows a real event in the objective order, however imperfect and halting the recognition. Any attempt to limit humanity to exclude some groups runs the risk of furnishing authority and precedent for excluding other groups in the name of the consciousness or perception of the controlling group in the society. (Noonan, 1970)

Even though Noonan is specifically referring to natural reproduction in this quote, the import of his words include any fertilized human ovum or clone. In short, the notion of "personhood" is applied in a manner that is designed to exclude certain individuals or groups from the larger group. Such exclusion marks those not deemed as persons as vulnerable to the whims and desires of the larger group. But the criterion of human life avoids this exclusiveness, and is instead an inclusive criterion. And, since life has been determined to be an inalienable right, then we avoid the danger of letting society – via common assent or actual legislation – arbitrarily determine who counts and who does not. Our obligation is to respect all human beings as equals.[5]

Call for a Total Ban on Human Cloning

In this testimony, I have argued that all human beings have a right and an obligation to be involved with the debates over human cloning and destructive embryonic research. I have also explained that any human zygote is not simply "potential," but actual human life. I have further argued that as an actual human life, a zygote is a unique individual. And in my last section, I pointed out that arguments about the personhood of a clone or zygote are fallacious, and thus personhood cannot serve as an appropriate criterion for determining who does and does not count within human society. The only objective criterion that can clearly guide us in determining our obligations towards other beings is the determination of human life, which it must be noted is a scientific determination. All human beings must be treated as equals.

Based upon the above reasoning, I now argue for a total ban on both human cloning and on destructive embryonic research.

First, the development of a clone or embryo for research purposes – even if called "therapeutic" – is **unethical**. Taking the needed stem cells, or perhaps even fully developed organs, from a clone or embryo will at best harm that unique being, and most often will destroy it. This is tantamount to taking the heart from a living person, resulting in death, in order to transplant that heart into another

person to save their life.[6] In this specific case, cloning and embryonic research are never truly "therapeutic," because the clone and the embryo never benefit from the procedures done to it. Simply put, we cannot actively and directly harm or kill one human life to save another. And so, the process of developing a clone or embryo and destroying it for the sole purposes of using its tissue in research or therapy is **unethical**.

Second, the case of developing a clone for the purposes of reproduction might, at first glance, seem a more difficult problem – why ban a life-giving procedure? The first argument to this is that at this point the technology of cloning is fraught with problems. At best, the procedure has to be described as inefficient. As such, the process of cloning will not improve and become more efficient without further research. But that means creating clones for the sole purpose of doing research upon them, which I just argued was **unethical**. The hope of some future good does not make an **unethical** action good, nor acceptable.

But what if the technology becomes perfected, perhaps by other countries that do not ban its development? At that point, would cloning become ethical and acceptable?

First, I would say that if a human clone is developed, since it is a unique individual human life, it must be allowed to develop fully. A clone would not be responsible for how it was developed.

However, even if the cloning process ever becomes perfected, the decision to allow cloning in the United States would still not be automatic. As many others have pointed out in testimonies regarding cloning, there will inevitably be social, psychological, economic, legal, and spiritual difficulties. All of these would have to be considered. In short, there would be new ethical questions that would have to be addressed first – questions that we can only speculate about now. And so, further ethical analysis would be required.

However, let me add that I concur with many others who simply find no acceptable reason to develop a clone. None of the arguments offered to support cloning seem to stand up under ethical scrutiny. Thus, a total ban on cloning is the only appropriate recourse at this time in our history.

Conclusion

Two final reflections will serve as a conclusion to my testimony today.

First, even though it is helpful to point out the shortcomings of the technology behind cloning and destructive embryonic research, it must be recognized that the heart of the *ethical* issue at stake here is the status of a human zygote from its very beginning on. A human zygote is actual human life. Human life must be respected by human society, which would obligate us to avoid harm and damage to a zygote. Thus, even if there were no other promising technologies in development at this time, even if adult stem cell research was not showing better results than therapies developed using cloned cells or embryonic stem cells, cloning and destructive embryonic research would still be **unethical**. *We simply cannot harm or kill one human life to save another.*

My second reflection flows from comments that I often receive when I offer my first reflection. I am often told that I am callous and uncaring about the suffering that families are going through with loved ones who have Parkinson's, or Huntington's, or MD, or spinal injuries, and so on. It is even suggested that if I had a sick child with severe health problems that I would change my views and be

pushing rigorously for the research in question here today. Now what should one make of such a charge? It is nothing more than an *ad hominem* attack – but pointing that out to those who challenge me would serve no real purpose, for they are simply speaking from their pain and fear. And while I believe that such an argument is invalid, for me personally it is also *untrue*. On June 10, 1995, my wife gave birth to our first children, twin boys Patrick and Michael. They were slightly premature, as sometimes happens with twins, and so our first few weeks together were very challenging. But that was only the beginning. Patrick had Down Syndrome. He had a stomach blockage that had to be operated upon at two days of age. He came through that fine. But Patrick also had a heart defect that is common with Down Syndrome, a hole in his heart. Patrick's hole was severe, and would require surgery. For one long year, we worked on getting Patrick's weight up, and building up his strength for surgery. Just after his first birthday he went into Cardinal Glennon Children's Hospital in St. Louis, MO. They did a marvelous job, and hung with our little boy the whole way – but Patrick was simply too tiny and weak to make it through. He eventually succumbed to a staff infection and died on July 24th of 1996 at thirteen months of age. Now stem cell research from umbilical cord blood may one day make the surgery Patrick needed unnecessary. If heart muscle can be regenerated within the heart, it could seal holes in the heart – I pray that one day that will be achieved. However, I would not have agreed to such a procedure if the cells had come from the destruction of a clone or other embryo any more than I would have asked the surgeons to cut out my other son's heart, or to take the heart of some other child. *We simply cannot harm or kill one life to save another.*

I know the pain. I know the suffering. I know the tears. I know the loss.

But I also know the limits.

I urge you to pass these bills and to make the limits clear in the State of Kansas regarding human cloning and destructive embryonic research.

Thank you.

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NOTES

[1] It is even suggested that to question the work of scientific researchers *at all* comes dangerously close to repeating the Galileo affair and hindering the pursuit of scientific knowledge.

[2] The issue of *self-development* is crucial to understand, as it clarifies the confusion that some people raise regarding human gametes considered individually. Some try to argue that if one claims that the fertilized ovum is called "human life," then we must also call a human sperm or a human egg "human life" as well, since sperm and eggs are "alive" and they are "human." And so, they try to reduce the argument that a fertilized ovum is "human life" to absurdity. But their approach fails for the simple reason that sperm and eggs by themselves are not *self-developing*. Unless a complete genetic code is actuated within an ovum (either through natural reproduction, *in vitro* fertilization, or one of the various cloning techniques), there will be no new human entity or being. But once a complete genetic code is actuated, a new, *self-developing* entity begins to unfold. To put this in philosophical terms, at fertilization a substantial change takes place and a new being begins to exist.

[3] For example, for two key examples see Lee M. Silver, *Remaking Eden: Cloning and Beyond in a Brave New World*, (1997, Avon Books, New York, NY), or Ronan O'Rahilly and Fabiola Muller, *Human Embryology & Teratology*, Third Ed. (2001, Wiley-Liss, New York, NY).

[4] In fact, one method of cloning is to separate out one of these totipotent cells in an artificial form of twinning.

[5] The debate over the term "person" simply a matter of rhetoric. The dangers involved with allowing society to determine who is a person and who is not are quite real, and jeopardize all of the vulnerable within a society. It has been said many times, by many others, that the true mark of the character and success of a society is seen most clearly in how that society treats its most vulnerable members. I believe this to be one of the truest and wisest things any human being has ever said.

[6] Even if one tried to argue that only "spare organs" (a kidney) or "partial organs" (a lobe of the lungs or half of the liver) would be used from clones after they have been born, this would still be untenable because the clone would not have *true freedom* in the decision process, which is an *ethical* requirement of **informed consent.**

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Senate Federal & State Affairs Committee
Hearing on Human Cloning Ban (HB2736) and Destructive Embryo Research (HB2737)
April 9, 2002

Madame Chair, distinguished Members of the Committee, thank you for the opportunity to testify today regarding human cloning and stem cell research, particularly the use of embryonic stem cells. I speak to you as both a biologist and a bioethicist.

Researchers in the U.S. (and to some extent in Europe) have established a precedence of finding cures for diseases that formerly killed thousands of patients each year. And Americans have come to expect a certain level of medical care. Essentially we have adopted the notion that medicine should be able to cure whatever disease ails us or someone we love. Is this a realistic notion? Are we morally obligated to find treatment for every disease? I realize this is not an easy question to answer, particularly when you or someone you love is dying from a disease for which there is no cure. But we must consider whether we have essentially adopted the attitude that we no longer accept death and disease as a part of life.

If we decide that we *are* morally obligated to find a cure for every disease, then we must answer two important questions. While neither are easy questions to answer, the first is probably easier than the second to answer from a moral perspective: how do we prioritize which diseases we find cures for first? The second question is more problematic: are we obligated to find treatments regardless of the cost? That is, to what lengths are we willing to go to find treatments? Are we willing to become a society that values the life of extant individuals at the cost of making a commodity of those who are not yet sentient and able to chose for themselves?

We must consider the public understanding of what ES cell use is and what it is not. Consider that euphemistic terms have evolved during most political debates that are morally contentious (e.g. pro-life vs. pro-choice). The issues of cloning and ES cell research are not exempt from this level of "public education." Consider the terms, "therapeutic cloning," "pre-embryo," and "activated egg." As pointed out by my colleagues, these terms are nothing but obfuscations. Presumably by inventing new words we can hide the truth of what really happens. Let us not stoop to misleading those whom we profess to serve by using disingenuous thinking in the pursuit of worthy goals (treatment and elimination of disease).

The general public does not understand what is involved in cloning, nor have they thought about the repercussions of cloning, except perhaps to say they are against creating a new human via cloning. Few understand that scientists expect to provide embryos for ES cells using cloning techniques. In fact, confusion abounds regarding the difference between reproductive and therapeutic cloning. And no wonder. There is essentially no difference between the two. The creation and culturing of the embryos are identical in both reproductive and therapeutic cloning. They both involve the creation of a human embryo that has the genetic potential to grow into an entirely new human. The only difference is the fate of the embryo. In the case of reproductive cloning, the embryo is transplanted to a uterus for gestation and development. "Therapeutic" clones are broken apart and the stem cells contained within them are then cultured to grow a desired tissue. Interesting that the same public who is against reproductive cloning (i.e. ensuring the human clone lives) supports therapeutic cloning (i.e. supports the destruction of a human clone).

Embryonic stem cells (ES cells) have a tremendous capacity for culturing and high rates of cellular division, making them ideal for growing new tissues in culture prior to using them in human medical therapy. Additionally, ES cells are *totipotent*, meaning that they can be used to grow tissues of any kind given the proper stimulus. Theoretically, scientists could grow new organs for a patient who is waiting for a transplant. Scientists have long believed that after the embryo begins to form different types of tissue, cells lose the ability to form any kind of tissue, even though they have all the genetic information to do so. Thus, ES cells have offered the hope of providing new tissues to treat many diseases including Parkinson's disease, diabetes, and organ failure. Unfortunately, scientists estimate that obtaining enough ES cells to treat just one patient suffering from Parkinson's disease will require cells from at least six embryos. ~~Given that there are over~~

Until recently, scientists thought that cells harvested from adults do not have the ability to grow into new types of tissues. Although no researcher has yet been able to identify *totipotent* adult stem cells, they have been able to identify and culture *multipotent* adult stem cells (multipotent adult progenitor cells, or MAPCs). These cells appear to have many of the same traits as ES cells (e.g. ability to form many types of tissues). Further, the MAPCs eliminate some serious problems associated with using ES cells, namely uncontrolled growth (leading to the development of tumors) and the ethical issues associated with embryo destruction. Thus, efforts to promote research on MAPCs would be a more prudent use of money and research effort.

Even if MAPCs do not live up to our "expectations," there are research avenues to pursue may lead to developing therapies for many diseases without crossing ethically shaky ground. For example, research focusing on the controls of cellular growth (e.g. cellular division rate) and what controls the "type" of cell a stem cell becomes will provide invaluable information for developing treatment therapies in many areas of medicine, including cancer, spinal cord and other nerve tissue injuries, and organ failure. If we can use cells derived from the patient, we incur yet another advantage over ES cell therapy: overcoming the risk of the patient rejecting the new tissue via autoimmune responses.

A utilitarian view of human life has never been acceptable in our culture. For example, "sacrificing" a healthy human (we'll call him Homer) to provide organs for six unhealthy humans would be unethical, primarily because it violates the intrinsic rights of Homer to make choices for himself as well as violating his right to a life. How then can we justify a utilitarian approach to human embryos, particularly when the cost to benefit ratio is reversed (i.e. destroying six embryos to save one patient). But this is exactly what bioethics committees across the nation have been doing. Leon Kass suggests this occurs because we break down "large questions of morals into small questions of procedure." Whereas we might find utilitarian thinking to be abhorrent when dealing with the larger moral question, we suddenly find ourselves agreeing to a utilitarian viewpoint when addressing whether we have a mandate to develop new medical treatments. At what cost do we agree with this utilitarian mindset? We couch cloning and the use of embryonic stems cells in the cloak of compassion: providing children for infertile couples, avoiding genetic disease in our children, and obtaining genetically perfect tissue matches for transplants. But our compassion comes at the expense of potential human lives. Is this truly *compassion*?

Human beings have what philosophers call the "right to a life." This means humans have the right not to be created as objects of experimentation or to be used as a commodity. Assume for a moment that embryos also have a "right to a life," that is, they do have a moral status. This means that creating and destroying embryos at will reduces them to a commodity used solely at the discretion and demands of humans. Furthermore, if human embryos do have a right to a life, can we justify the cost of "killing" six lives to save or extend one life?

If human embryos do *not* have a "right to a life," then by pursuing human cloning and the destructive use of human embryos, we seriously endanger many of our existing laws and cultural mores. Indeed, we should be very careful to consider whether allowing the destructive use of embryos and/or cloning will lead to an empirical or a conceptual slippery slope. Many might argue that once human cloning is permitted, a moral "threshold" will be crossed and genetic manipulations will become rampant. Eugenic breeding and designer babies will become the standard, perhaps on the order of *Brave New World* (an empirical slippery slope).

Opponents of the bills before you might argue that this empirical slippery slope arguments assumes the worst in humans; an advance in technology does not mean that there is some evil person waiting to use it to control a sector of the world or the population. In fact, many would argue that humans are not that bad; i.e. there is no latent evil just waiting for a breach in the rules that hold us back. These are reasonable arguments, although the validity of them is probably best left to the theologians.

As a proponent of HB2736 and HB2737, I would argue that we should be very concerned about the *conceptual* slippery slope. That is, once we decide that destructive use of human embryos under a certain age is permissible, how do we deal with cases where the embryo is only slightly older? Similar situations require similar reasoning. What reasons will we give to disallow the use of these slightly older embryos? What reasoning do we use to establish the new "age cut-off?" If we allow the creation of embryos for the purpose of treating disease, what reasoning will we use to decide whether it is ethical to clone an embryo to produce a child, selected for

certain genetic traits, in order to produce a tissue or organ donor for a sibling or a parent? Again, similar situations demand similar reasoning. How far are we willing to allow this conceptual slippery slope to go?

The conceptual slippery slope brings other problems. If the embryo does not have right to a life, at what age *does* it have this right? Are we creating a seemingly arbitrary time line that dictates the age at which an embryo may be used for medical therapy and when it is "too old" to be used because it now has an inalienable human right? What happens when the embryo is one day beyond this cutoff? Are we obligated to implant and gestate the new life? Does this violate the reproductive rights of women to force them to gestate these embryos? Or do we destroy the embryo at the day before it becomes "too old" in a misguided effort to avoid giving the embryo the right to a life?

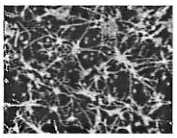
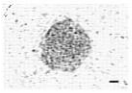
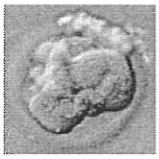
The moral status of human embryos will not be decided in a legislative hearing, or in political debate. This issue is best left to bioethicists and those trained to deal with moral issues. Once a consensus has been reached, we can bring that consensus back into the governmental chambers. Until then, it seems most prudent to err on the side of caution. Better to not destroy embryos and later decide the act is amoral rather than destroy them later and discover our actions have been immoral.

In light of our inability to determine the moral status of the embryo, it seems reasonable, therefore, to disallow any human cloning and to put our effort and financial investments into stem cell research that does not carry moral consequences. The recent developments that suggest scientists can recover and culture adult stem cells (MAPCs) with nearly the same potential for medical use as embryonic stem cells makes this an even more viable option than it was even six months ago. Who knows what scientific progress the next six months, year or ten years will bring?

It is imperative that we address these issues *now*. The late philosopher and bioethicist Paul Ramsey wrote, "[We must] raise the ethical questions with a serious and not a frivolous conscience. A man of frivolous conscience announces that there are ethical quandaries ahead that we must consider before the future catches up with us. By this he often means that we need to devise a new ethics that will provide the rationalization for doing in the future what men are bound to do because of new actions and interventions science will have made possible. In contrast, a man of serious conscience means to say in raising urgent ethical questions that there may be some things that men should never do. The good things that men do can be made complete only by the things they refuse to do."

Madame Chair and distinguished members of the Committee: Thank you for the opportunity to testify regarding this matter. I would be more than happy to answer any questions.

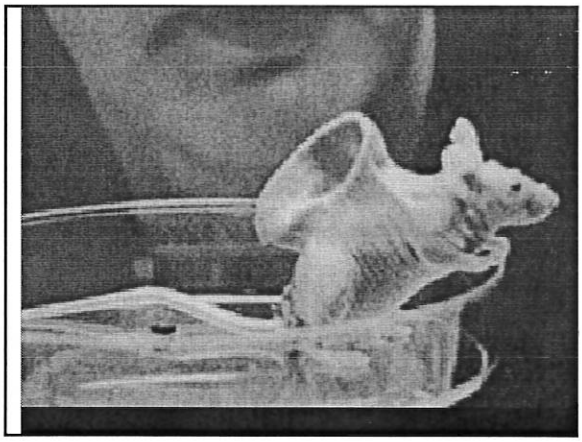
The Science of Stem Cell Research and Human Cloning

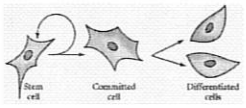




Dr. David A. Prentice, Ph.D.
Department of Life Sciences
Indiana State University, USA

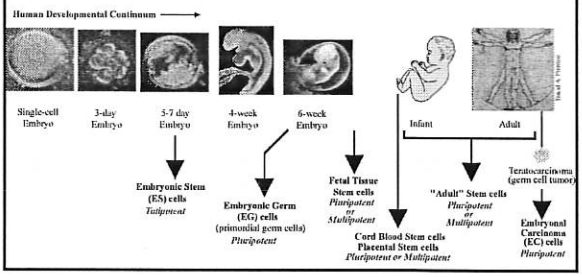
Why use stem cells? Degenerative diseases…

Rank (1998)	Cause of Death	Number of Deaths	Death Rate per 100,000	% of Total Deaths
1	Heart Disease	724,859	268.2	31.0
2	Cancer	541,532	200.3	23.2
3	Stroke	158,448	58.6	6.8
4	Chronic Obstructive Lung Disease	112,584	41.7	4.8
5	Accidents	97,835	36.2	4.2
6	Pneumonia/Influenza	91,871	34.0	3.9
7	Diabetes	64,751	24.0	2.8
8	Suicide	30,575	11.3	1.3
9	Kidney Disease	26,182	9.7	1.1
10	Chronic Liver Disease & Cirrhosis	25,192	9.3	1.1
11	Septicemia		8.8	1.0
12	Alzheimer's Disease		8.4	1.0
13	Homicide & legal intervention		6.8	0.8
14	Atherosclerosis		5.7	0.7
15	Hypertension		5.3	0.6





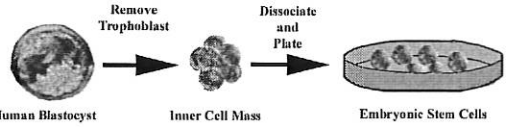
Stem Cells

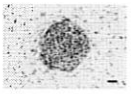


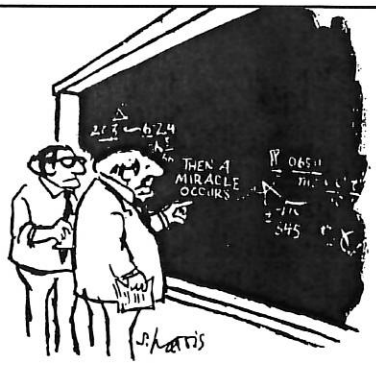
Derivation of Embryonic Stem Cells

Method patented
U.S. patent held by Univ. Wisconsin

Purported Advantages:
1) Proliferate indefinitely
2) Form any tissue





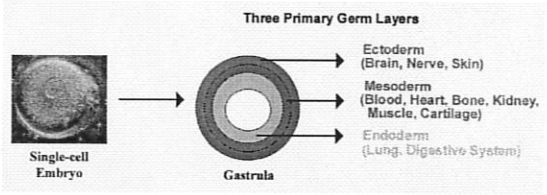
"I think you should be more explicit here in step two."

SnFedSt
04/09/02
Attach #8

Claims for embryonic stem cell advantages over adult stem cells are unsubstantiated…

Current and potential embryonic stem cell problems:

- No current clinical treatments
- Few successes in animal models
- Difficulty in obtaining pure cultures in the dish
- Difficult to establish and maintain
- Problem of immune rejection
- Potential for tumor formation
- Genomic instability



"Scientific experts"
(the National Institutes of Health, the National Academy of Sciences, 80 Nobel Laureates) are not necessarily unbiased arbiters…

"There is no evidence of an adult stem cell that is pluripotent. It has not been demonstrated that one adult stem cell can be directed to develop into any cell type of the body. That is, *no adult stem cell has been shown to be capable of developing into cells from all three embryonic germ layers.*"

Stem Cells: Scientific Progress and Future Research Directions, National Institutes of Health, June 2001; Pg. ES-6

(emphasis added)

"Some adult stem cells appear to have the capability to differentiate into tissues other than the ones from which they originated; this is referred to as plasticity. Reports of human or mouse adult stem cells that demonstrate plasticity and the cells they differentiate or specialize into include: 1) *blood and bone marrow (unpurified hematopoietic) stem cells differentiate into the 3 major types of brain cells (neurons, oligodendrocytes, and astrocytes) [ectoderm], skeletal muscle cells, cardiac muscle cells [mesoderm], and liver cells [endoderm]*; 2) bone marrow (stromal) cells differentiate into cardiac muscle cells, skeletal muscle cells, fat, bone, and cartilage; and 3) brain stem cells differentiate into blood cells and skeletal muscle cells."

Ibid, Pg. ES-7 *[emphasis added]*

Adult stem cells show pluripotent capacity and can form all adult tissues.

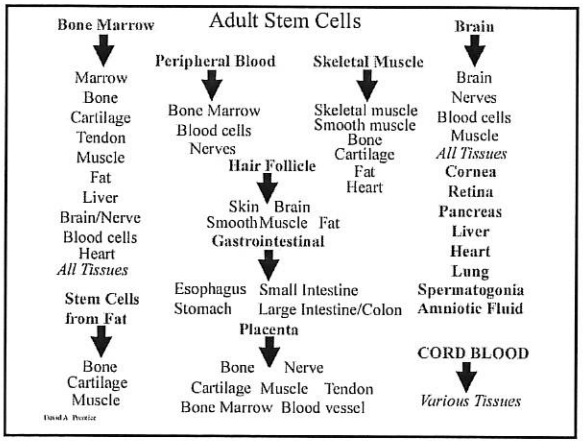
Adult stem cells from bone marrow can form all body tissues and be grown indefinitely.
--Westphal SP; "Ultimate stem cell discovered"; *New Scientist*, Jan 23, 2002
--Reyes M *et al.*; "Origin of endothelial progenitors in human postnatal bone marrow"; *Journal of Clinical Investigation* 109, 337-346; Feb 2002.
-- Reyes M *et al.*; "Purification and ex vivo expansion of postnatal human marrow mesodermal progenitor cells"; *Blood* 98, 2615-2625; Nov 1, 2001
--Reyes M and Verfaillie CM; "Characterization of multipotent adult progenitor cells, a subpopulation of mesenchymal stem cells"; *Annals of the New York Academy of Sciences* 938, 231-233; June 2001

A single adult mouse bone marrow stem cell can form functional marrow and blood cells, liver, lung, gastrointestinal tract, and skin, as well as heart and skeletal muscle.
--Krause DS *et al.*; "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell"; Cell 105, 369-377; May 4, 2001

Adult stem cells from brain can grow into a wide variety of organs—heart, lung, intestine, kidney, liver, nervous system, muscle, and other tissues.
--Clarke *et al.*; "Generalized potential of adult neural stem cells"; *Science* 288, 1660-1663, June 2, 2000.

Adult stem cells can multiply almost indefinitely, providing numbers sufficient for clinical treatments

--Reyes M *et al.*; "Purification and ex vivo expansion of postnatal human marrow mesodermal progenitor cells"; *Blood* 98, 2615-2625; Nov 1, 2001
--Krause DS; "Multipotent human cells expand indefinitely", *Blood* 98, 2595; Nov 1, 2001
--Laughlin MJ *et al.*; "Hematopoietic engraftment and survival in adult recipients of umbilical-cord blood from unrelated donors", *New England Journal of Medicine* 344, 1815-1822; June 14, 2001



Adult stem cells effective treating animal models of disease

Diabetes—Pancreatic stem cells grown in culture formed insulin-secreting islets of Langerhans. When injected under the skin of diabetic mice, the mice were able to regulate the levels of glucose in their blood and survived without further need of insulin injections.
-- Ramiya VK *et al.*, "Reversal of insulin-dependent diabetes using islets generated *in vitro* from pancreatic stem cells," *Nature Medicine* 6, 278-282, March 2000.
"Retraining" of autoimmune lymphocytes (Type 1 diabetes) allows regrowth of pancreatic islets.
--Ryu S *et al.*, "Reversal of established autoimmune diabetes by restoration of endogenous β cell function," *J. Clin. Invest.* 108, 63-72; July 2001

Stroke—Adult bone marrow stem cells or umbilical cord blood stem cells, even delivered intravenously to brain tissue which has suffered stroke damage in rats, provide therapeutic benefit after stroke. The cells appeared to "home" to sites of damage.
--Zhao L-R et al.; "Human bone marrow stem cells exhibit neural phenotypes and ameliorate neurological deficits after grafting into the ischemic brain of rats", *Experimental Neurology* 174, 11-20; 2002.
--Chen J *et al.*; "Intravenous administration of human umbilical cord blood reduces behavioral deficits after stroke in rats"; *Stroke* 32, 2682-2688; November 2001

Heart Damage—Bone marrow stem cells injected into heart, blood stream, or "mobilized" from the bone marrow, repair damage after heart attack.
--Orlic D *et al.*, "Mobilized bone marrow cells repair the infarcted heart, improving function and survival"; *Proceedings of the National Academy of Sciences USA* 98, 10344-10349, August 28, 2001.
--Jackson KA *et al.*; "Regeneration of ischemic cardiac muscle and vascular endothelium by adult stem cells"; *Journal of Clinical Investigation* 107, 1395-1402; June 2001
--Orlic D *et al.*; "Bone marrow cells regenerate infarcted myocardium"; *Nature* 410, 701-705; April 5, 2001

Parkinson's Disease

Adult Stem Cells

Injection of growth protein into brains of Parkinson's rats caused their neural stem cells to grow, migrate to the site of damage, and begin to replace missing nerve cells.

Eighty percent (80%) of the rats received a benefit from the treatment, with no tumor formation.

J. Fallon et al.; "In vivo induction of massive proliferation,directed migration, and differentiation of neural cells in the adult mammalian brain," Proc. Natl. Acad. Sci. USA 97, 14686-14691; December 19, 2000

Embryonic Stem Cells

Parkinson's rats injected with mouse embryonic stem cells showed a modest benefit for just over 50% of the rats, but one-fifth (20%) of the rats died of brain tumors caused by the embryonic stem cells.

L.M. Bjorklund et al.; "Embryonic stem cells develop into functional dopaminergic neurons after transplantation in a Parkinson rat model," Proc. Natl. Acad. Sci.USA www.pnas.org/cgi/doi/10.1073/pnas.022438099 (PNAS Early Edition) Jan 8, 2002

Diabetes

Adult Stem Cells

Scientists "retrained" immune cells to reverse diabetes in mice. The autoimmunity that was previously directed against insulin-secreting cells was reversed, and adult stem cells in the mice formed insulin-secreting cells. The treatment was "…thus able to effect an apparent cure of established Type 1 diabetes in the [diabetic] mouse".

S. Ryu et al.; "Reversal of established autoimmune diabetes by restoration of endogenous ß cell function," J. Clin. Invest. 108, 63-72; July 2001

Pancreatic adult stem cells grown in culture formed insulin-secreting islets. When injected into diabetic mice, the mice survived without further need of insulin injections.

V.K. Ramiya et al.; "Reversal of insulin-dependent diabetes using islets generated in vitro from pancreatic stem cells," Nature Medicine 6, 278-282, March 2000.

Embryonic Stem Cells

Researchers reported the conversion of mouse embryonic stem cells into insulin producing pancreatic islet cells. The mouse embryonic stem cells secreted only 1/50th the normal amount of insulin, and diabetic mice implanted with the cells still died.

N. Lumelsky et al.; "Differentiation of embryonic stem cells to insulin-secreting structures similar to pancreatic islets," Science 292, 1389-1394; May 18, 2001

Spinal Cord Injury

Adult Stem Cells

Several labs have shown adult stem cells capable of re-growth and reconnection in spinal cord injury, allowing functional recovery. The cells "promote functional recovery of paraplegic adult rats and long-distance motor axon regeneration in their completely transected [severed] spinal cords," and showed "dramatic functional improvement and anatomical repair" (Ramon-Cueto et al; 2000).

Transplanted adult stem cells or stimulation of existing adult stem cells achieved re-growth of neurons and re-myelination (sheathing) of neurons.

*M. Sasaki et al., "Transplantation of an acutely isolated bone marrow fraction repairs demyelinated adult rat spinal cord axons," Glia 35, 26-34; July 2001

*A. Ramon-Cueto et al., "Functional recovery of paraplegic rats and motor axon regeneration in their spinal cords by olfactory ensheathing glia," Neuron 25, 425-435; February 2000.

*M.S. Ramer et al.; "Functional regeneration of sensory axons into the adult spinal cord," Nature 403, 312-316; January 20, 2000S.

*Shihabuddin et al.; "Adult spinal cord stem cells generate neurons after transplantation in the adult dentate gyrus," J Neuroscience 20, 8727-8735; December 2000.

*Barnett et al.; "Identification of a human olfactory ensheathing cell that can effect transplant-mediated remyelination of demyelinated CNS axons," Brain 123, 1581-1588, August 2000

*A. Ramon-Cueto et al., "Long-distance axonal regeneration in the transected adult rat spinal cord is promoted by olfactory ensheathing glial transplants," J Neuroscience 18, 3803-3815; May 15, 1998

Embryonic Stem Cells

McDonald et al. showed some functional improvement in rats with spinal cord injury, slightly better than no treatment alone. Studies by Liu et al. and Brüstle et al. showed that ES cells could form protective myelin sheaths around nerves in rats with spinal cord injury, but they did not show or test for any functional recovery of the animals.

*J.W. McDonald et al., "Transplanted embryonic stem cells survive, differentiate and promote recovery in injured rat spinal cord," Nature Medicine 12, 1410-1412, Dec 1999

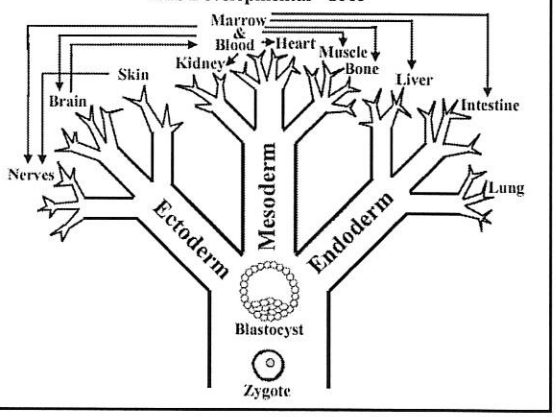
*S. Liu et al., "Embryonic stem cells differentiate into oligodendrocytes and myelinate in culture and after spinal cord transplantation," Proc. Natl. Acad. Sci. USA 97, 6126-6131; May 23, 2000

*O. Brüstle et al., "Embryonic Stem Cell-Derived Glial Precursors: A Source of Myelinating Transplants," Science 285, 754-756, July 30, 1999

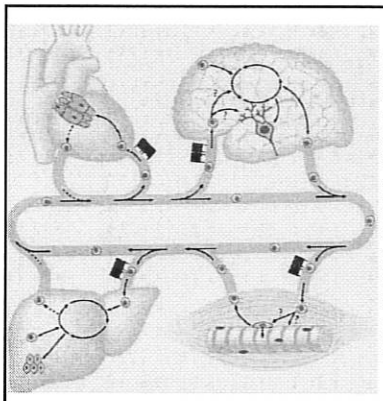
Current Clinical Uses of Adult Stem Cells

- **Cancers**—Lymphomas, multiple myeloma, leukemias, breast cancer, neuroblastoma, renal cell carcinoma, ovarian cancer
- **Autoimmune diseases**—multiple sclerosis, systemic lupus erythematosus, juvenile rheumatoid arthritis, rheumatoid arthritis, scleroderma, scleromyxedema, Crohn's disease
- **Anemias** (incl. sickle cell anemia)
- **Immunodeficiencies**—incl. first successful human gene therapy
- **Bone and cartilage deformities**—treating children with osteogenesis imperfecta
- **Corneal scarring**—generation of new corneas to restore sight
- **Stroke**—neural cell implants in clinical trials
- **Repairing cardiac tissue after heart attack**—2 papers, more clinical trials underway
- **Skin**—grafts; growth from hair follicle stem cells, pluck a few hairs from patient
- **Parkinson's**—first patient treated with own adult neural stem cells

The Developmental "Tree"



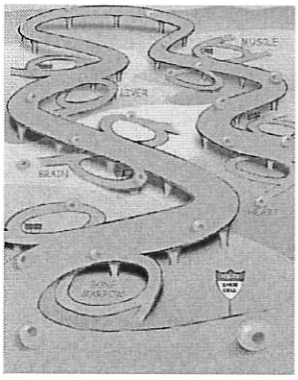
Evolving Concepts of Stem Cell Plasticity



Documented (solid arrows) and hypothesized (dashed arrows) transitions in stem cell identity and differentiation are illustrated. In addition to tissue-specific stem cells, some stem cells may travel throughout the body via the circulation. The scheme also suggests that cell fate decisions may not be irreversible. Flexibility is the hallmark of this depiction allowing for regeneration and changes in cell fate in response to need.

from Blau HM, Brazelton TR, Weimann JM, "The evolving concept of a stem cell: entity or function?", *Cell* 105, 829-841, June 29, 2001

Route Stem Cell



The stem cell landscape depicted here illustrates the emerging characteristics of adult stem cells that include plasticity in cell fate, diversity of origin, and a multiplicity of tissue potentials. Stem cells (blue) are able to enter diverse tissue compartments from the bloodstream (the stem cell highway) via "on ramps" and generate appropriate cell types in response to homing signals or growth factors depicted on "billboards." In theory, all choices are reversible.

from Blau HM, Brazelton TR, Weimann JM, "The evolving concept of a stem cell: entity or function?", *Cell* 105, 829-841, June 29, 2001

Adult Stem Cells

DO NO HARM
The Coalition of Americans for Research Ethics

www.stemcellresearch.org

More promising alternative for treatments
Vast biomedical potential

Able to generate virtually all adult tissues

Can multiply almost indefinitely, providing numbers sufficient for clinical treatments

Proven success in laboratory culture

Proven success in animal models of disease

Proven success in current clinical treatments

Show ability to "home" in on damaged tissue

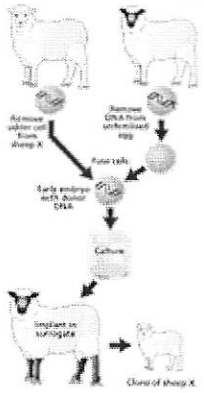
Avoid problems with tumor formation

Avoid problems with transplant rejection

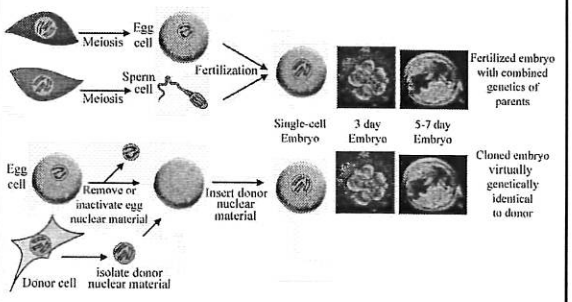
Avoid ethical quandary

Classmates Weekly Cartoon

"Apparently it's OK to clone sheep, but not hundred-dollar bills."



Fertilization *vs.* Cloning (somatic cell nuclear transfer)



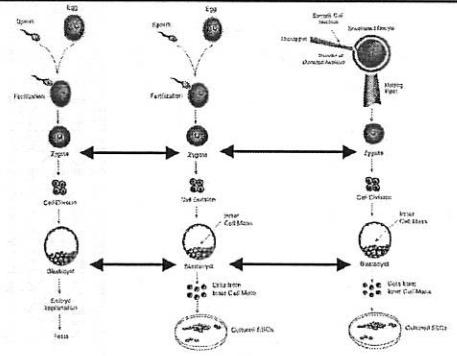
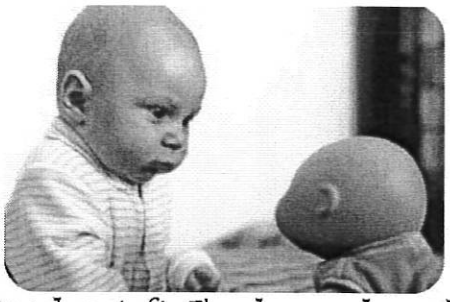


Figure 1 Stages of Development of the Human Embryo | Figure 2 Isolation and Culture of Human ESCs from Blastocysts | Figure 4 Somatic Cell Nuclear Transfer (SCNT).

[From: Stem Cells and the Future of Regenerative Medicine, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington DC, Sept. 2001, Pg. 10, 11, 26]

Human Cloning

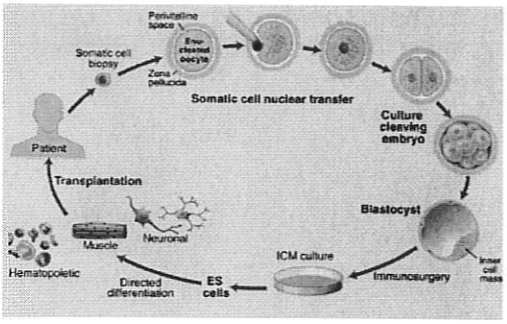


Good grief! I've been cloned!!

Cloning is unsafe for the clone and the surrogate mother

- "[O]nly a few percent of nuclear transfer embryos develop to term. Even those clones that survive to term frequently die of respiratory and circulatory problems and show increased placental and birth weights."
  "Our results indicate that even apparently healthy cloned animals can have gene expression abnormalities that are not severe enough to impede development to birth but that may cause subtle physiological abnormalities which could be difficult to detect."
  Reference: Humpherys D *et al.*; "Epigenetic instability in ES cells and cloned mice"; Science 293, 95-97; July 6, 2001
- Dolly the sheep, first cloned mammal: 1 live birth out of 277 cloned embryos (0.4%)
- Cloned mice: 5 live births out of 613 cloned embryos (0.8%)
  5 live births out of 314 cloned embryos implanted (1.6%) (0.8%; 1 survived)
  26 live births out of 312 cloned embryos implanted (8.3%) (4.2%; 13 survived)
- Cloned pigs: 5 live births out of 72 cloned embryos implanted (7%)
- Cloned goats: 3 live births out of 85 cloned embryos implanted (3.5%)
- Cloned cattle: 30 live births out of 496 cloned embryos implanted (6%) (4.8%; 24 survived)
- Cloned cat: 1 live birth out of 188 cloned embryos (0.5%); of 87 embryos implanted (1.1%)
- **Health risk for the surrogate mother—"large offspring syndrome"**

"Therapeutic cloning" (Experimental Cloning) to obtain ES cells



Human embryo cloning places women at risk

To treat just the 16 million Diabetes patients in the United States:

At *generous* 20% cloning efficiency (to achieve blastocyst stage)

At *generous* 10% efficiency at initiating ES cell culture

Will require 800 million eggs (2% overall efficiency)

(Rideout *et al.* 0.5%, >3.2 billion eggs; Hochedlinger *et al.* 0.2%, > 7.8 billion eggs)

Collecting 10 eggs/donor (ACT--71 eggs from 7 donors)

Will require 80 million women of childbearing age as donors

Health risks—High-dose hormone therapy and surgery used to obtain eggs risks the donor's health and future reproductive success

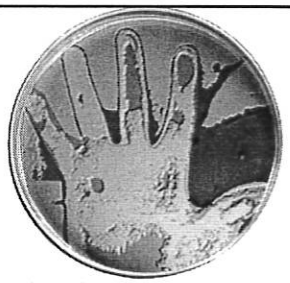
Commercial exploitation—disadvantaged women in U.S. and abroad

8-5

Human cloning and embryo destruction: Unsafe, Unethical, Unnecessary

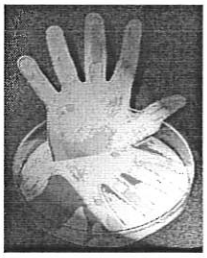
- Bans do not prohibit vital and legitimate research.
- No evidence that cloning is necessary or useful for medical treatments.
- Alternatives to embryonic stem cells are more successful, more promising.
- Creates a class of humans who exist only as means to achieve the ends of others.
- Human beings have the right not to be created as objects of experimentation.
- Human embryo cloning risks women's health and exploitation.
- Banning only implantation of clones is unenforceable.
- Cloning leads to commodification, commercialization of human life.
- Confuses kinship, parent-child identity, parental expectations.
- Possible reproduction of living or deceased persons without knowledge or consent.
- Gateway to genetic manipulation and control of human beings.

Total ban on human cloning and human embryo destruction needed



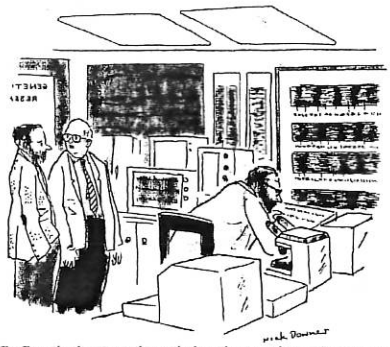
- **What does it mean to be human?**
- **Person or property?**
- **To whom do we choose to assign value?**
- **Who will benefit? Who will decide?**

The Future?



- Continuing debate…
- Legislative and Legal Challenges
- Accumulating Scientific Data

- Stem Cells
- Cloning
- Creation of embryos for research
- Genetic Engineering
- Chimeras (human-animal hybrids)
- Use of products from stem cells



"Dr. Prentice is attempting to isolate the gene that makes people do this sort of thing for a living."

DO NO HARM
The Coalition of Americans for Research Ethics

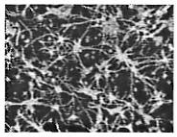
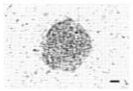
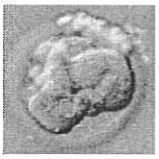
AMERICANS TO BAN CLONING

THE WILBERFORCE FORUM

Council for Biotechnology Policy

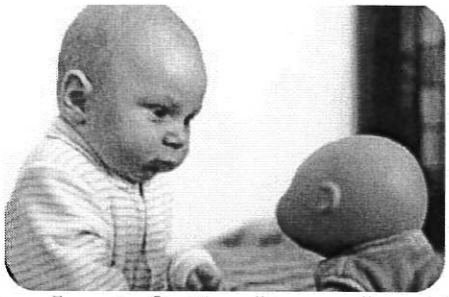
www.stemcellresearch.org **www.cloninginformation.org** **www.wilberforce.org**

Scientific Perspectives on Human Cloning and Embryo Research

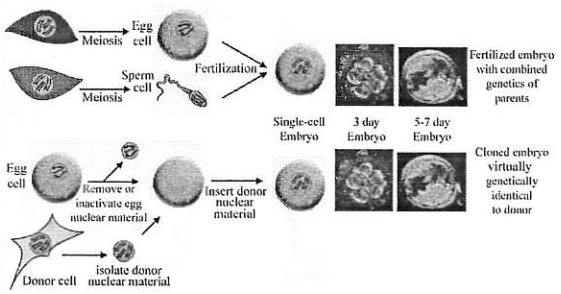
Dr. David A. Prentice, Ph.D.
Department of Life Sciences
Indiana State University, USA

Human Cloning



Good grief! I've been cloned!!

Fertilization *vs.* Cloning (somatic cell nuclear transfer)



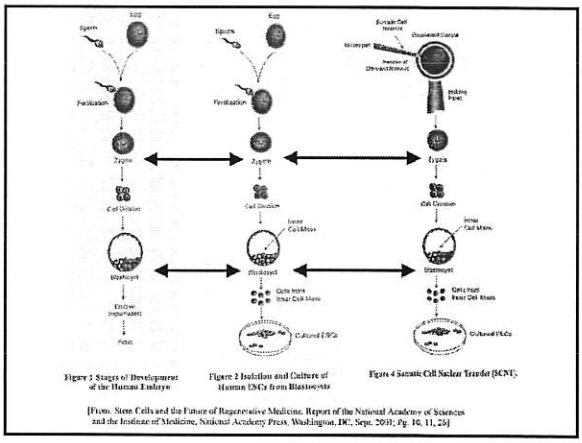


Figure 1 Stages of Development of the Human Embryo | Figure 2 Isolation and Culture of Human ESCs from Blastocysts | Figure 4 Somatic Cell Nuclear Transfer (SCNT)

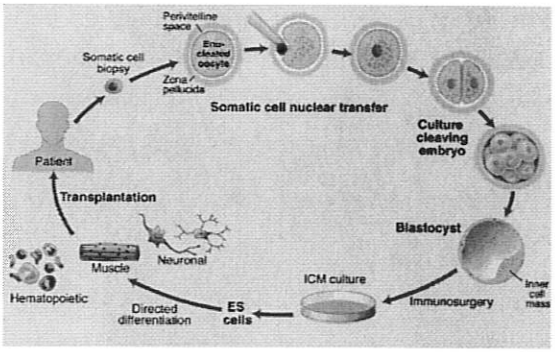
[From: Stem Cells and the Future of Regenerative Medicine, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington, DC, Sept. 2001; Fig. 10, 11, 25]

Cloning is unsafe for the clone and the surrogate mother

- "[O]nly a few percent of nuclear transfer embryos develop to term. Even those clones that survive to term frequently die of respiratory and circulatory problems and show increased placental and birth weights."
  "Our results indicate that even apparently healthy cloned animals can have gene expression abnormalities that are not severe enough to impede development to birth but that may cause subtle physiological abnormalities which could be difficult to detect."
  Reference: Humpherys D *et al.*; "Epigenetic instability in ES cells and cloned mice"; Science 293, 95-97; July 6, 2001

- Dolly the sheep, first cloned mammal: 1 live birth out of 277 cloned embryos (0.4%)
- Cloned mice: 5 live births out of 613 cloned embryos (0.8%)
  5 live births out of 314 cloned embryos implanted (1.6%) (0.8%; 1 survived)
  26 live births out of 312 cloned embryos implanted (8.3%) (4.2%; 13 survived)
- Cloned pigs: 5 live births out of 72 cloned embryos implanted (7%)
- Cloned goats: 3 live births out of 85 cloned embryos implanted (3.5%)
- Cloned cattle: 30 live births out of 496 cloned embryos implanted (6%) (4.8%; 24 survived)
- Cloned cat: 1 live birth out of 188 cloned embryos (0.5%); of 87 embryos implanted (1.1%)
- **Health risk for the surrogate mother—"large offspring syndrome"**

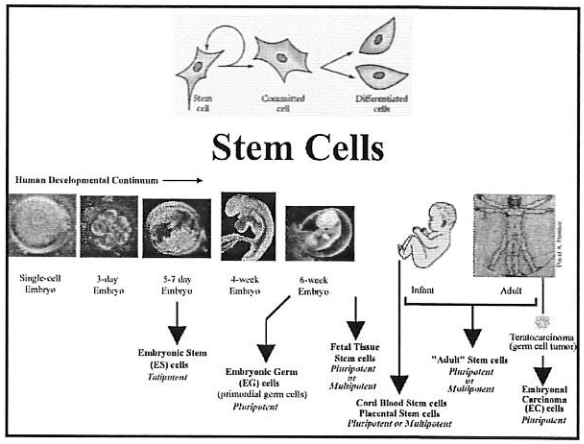
"Therapeutic" (Experimental) Cloning to obtain Embryonic Stem cells



8-7

Why use stem cells? Degenerative diseases…

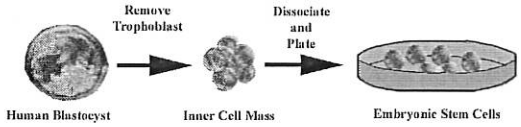
Rank (1998)	Cause of Death	Number of Deaths	Death Rate per 100,000	% of Total Deaths
1	Heart Disease	724,859	268.2	31.0
2	Cancer	541,532	200.3	23.2
3	Stroke	158,448	58.6	6.8
4	Chronic Obstructive Lung Disease	112,584	41.7	4.8
5	Accidents	97,835	36.2	4.2
6	Pneumonia/Influenza	91,871	34.0	3.9
7	Diabetes	64,751	24.0	2.8
8	Suicide	30,575	11.3	1.3
9	Kidney Disease	26,182	9.7	1.1
10	Chronic Liver Disease & Cirrhosis	25,192	9.3	1.1
11	Septicemia		8.8	1.0
12	Alzheimer's Disease		8.4	1.0
13	Homicide & legal intervention		6.8	0.8
14	Atherosclerosis		5.7	0.7
15	Hypertension		5.3	0.6

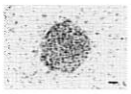


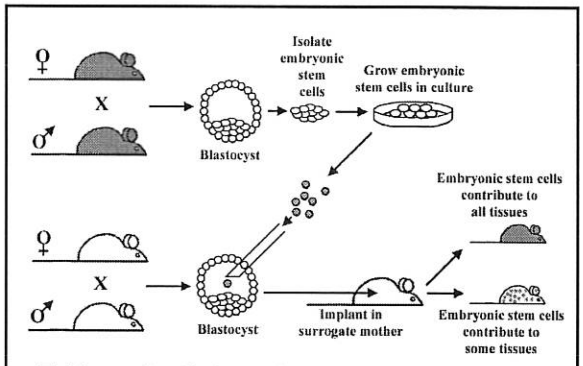
Derivation of Embryonic Stem Cells

Method patented
U.S. patent held by Univ. Wisconsin

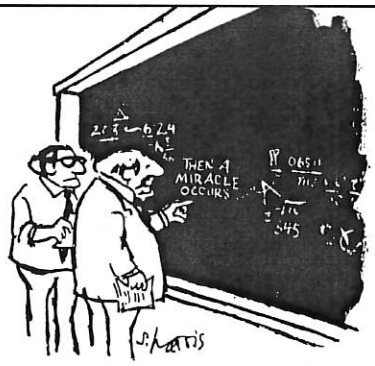
Purported Advantages:
1) Proliferate indefinitely
2) Form any tissue







Evidence for Embryonic Stem Cell Pluripotency



"I think you should be more explicit here in step two."

Promises, Premises, and Published Data…

Claims for embryonic stem cells unsubstantiated

Current and potential embryonic stem cell problems:

- No current clinical treatments
- Few successes in animal models
- Difficulty in obtaining pure cultures in the dish
- Difficult to establish and maintain
- Problem of immune rejection
- Potential for tumor formation
- Genomic instability

Adult stem cells show pluripotent capacity and can form all adult tissues.

Adult stem cells from bone marrow can form all body tissues and be grown indefinitely.
--Westphal SP; "Ultimate stem cell discovered"; *New Scientist*, Jan 23, 2002
--Reyes M *et al.*; "Origin of endothelial progenitors in human postnatal bone marrow"; *Journal of Clinical Investigation* 109, 337-346; Feb 2002.
-- Reyes M *et al.*; "Purification and ex vivo expansion of postnatal human marrow mesodermal progenitor cells"; *Blood* 98, 2615-2625; Nov 1, 2001
--Reyes M and Verfaillie CM; "Characterization of multipotent adult progenitor cells, a subpopulation of mesenchymal stem cells"; *Annals of the New York Academy of Sciences* 938, 231-233; June 2001

A single adult mouse bone marrow stem cell can form functional marrow and blood cells, liver, lung, gastrointestinal tract, and skin, as well as heart and skeletal muscle.
--Krause DS *et al.*; "Multi-Organ, Multi-Lineage Engraftment by a Single Bone Marrow-Derived Stem Cell"; Cell 105, 369-377; May 4, 2001

Adult stem cells from brain can grow into a wide variety of organs—heart, lung, intestine, kidney, liver, nervous system, muscle, and other tissues.
--Clarke *et al.*; "Generalized potential of adult neural stem cells"; *Science* 288, 1660-1663, June 2, 2000.

Adult stem cells can multiply almost indefinitely, providing numbers sufficient for clinical treatments

--Reyes M *et al.*; "Purification and ex vivo expansion of postnatal human marrow mesodermal progenitor cells", *Blood* 98, 2615-2625; Nov 1, 2001
--Krause DS; "Multipotent human cells expand indefinitely", *Blood* 98, 2595; Nov 1, 2001
--Laughlin MJ *et al.*; "Hematopoietic engraftment and survival in adult recipients of umbilical-cord blood from unrelated donors", *New England Journal of Medicine* 344, 1815-1822; June 14, 2001

Adult Stem Cells

Bone Marrow → Marrow, Bone, Cartilage, Tendon, Muscle, Fat, Liver, Brain/Nerve, Blood cells, Heart, *All Tissues*

Stem Cells from Fat → Bone, Cartilage, Muscle

Peripheral Blood → Bone Marrow, Blood cells, Nerves

Hair Follicle → Skin, Brain, Smooth Muscle, Fat

Gastrointestinal → Esophagus, Stomach, Small Intestine, Large Intestine/Colon

Placenta → Bone, Nerve, Cartilage, Muscle, Tendon, Bone Marrow, Blood vessel

Skeletal Muscle → Skeletal muscle, Smooth muscle, Bone, Cartilage, Fat, Heart

Brain → Brain, Nerves, Blood cells, Muscle, *All Tissues*, **Cornea, Retina, Pancreas, Liver, Heart, Lung, Spermatogonia, Amniotic Fluid**

CORD BLOOD → *Various Tissues*

David A. Prentice

Adult stem cells effective treating animal models of disease

Diabetes—Pancreatic stem cells grown in culture formed insulin-secreting islets of Langerhans. When injected under the skin of diabetic mice, the mice were able to regulate the levels of glucose in their blood and survived without further need of insulin injections.
-- Ramiya VK *et al.*, "Reversal of insulin-dependent diabetes using islets generated *in vitro* from pancreatic stem cells," *Nature Medicine* 6, 278-282, March 2000.
"Retraining" of autoimmune lymphocytes (Type I diabetes) allows regrowth of pancreatic islets.
--Ryu S *et al.*, "Reversal of established autoimmune diabetes by restoration of endogenous β cell function," *J. Clin. Invest.* 108, 63-72; July 2001

Stroke—Adult bone marrow stem cells or umbilical cord blood stem cells, even delivered intravenously to brain tissue which has suffered stroke damage in rats, provide therapeutic benefit after stroke. The cells appeared to "home" to sites of damage.
--Zhao L-R et al.; "Human bone marrow stem cells exhibit neural phenotypes and ameliorate neurological deficits after grafting into the ischemic brain of rats", *Experimental Neurology* 174, 11-20; 2002.
--Chen J *et al.*; "Intravenous administration of human umbilical cord blood reduces behavioral deficits after stroke in rats"; *Stroke* 32, 2682-2688; November 2001

Heart Damage—Bone marrow stem cells injected into heart, blood stream, or "mobilized" from the bone marrow, repair damage after heart attack.
--Orlic D *et al.*, "Mobilized bone marrow cells repair the infarcted heart, improving function and survival"; *Proceedings of the National Academy of Sciences USA* 98, 10344-10349, August 28, 2001.
--Jackson KA *et al.*; "Regeneration of ischemic cardiac muscle and vascular endothelium by adult stem cells"; *Journal of Clinical Investigation* 107, 1395-1402; June 2001
--Orlic D *et al.*; "Bone marrow cells regenerate infarcted myocardium"; *Nature* 410, 701-705; April 5, 2001

Parkinson's Disease

Adult Stem Cells

Injection of growth protein into brains of Parkinson's rats caused their neural stem cells to grow, migrate to the site of damage, and begin to replace missing nerve cells.

Eighty percent (80%) of the rats received a benefit from the treatment, with no tumor formation.
J. Fallon et al.; "In vivo induction of massive proliferation,directed migration, and differentiation of neural cells in the adult mammalian brain," Proc. Natl. Acad. Sci. USA 97, 14686-14691; December 19, 2000

Embryonic Stem Cells

Parkinson's rats injected with mouse embryonic stem cells showed a modest benefit for just over 50% of the rats, but one-fifth (20%) of the rats died of brain tumors caused by the embryonic stem cells.
L.M. Bjorklund et al.; "Embryonic stem cells develop into functional dopaminergic neurons after transplantation in a Parkinson rat model," Proc. Natl. Acad. Sci.USA www.pnas.org/cgi/doi/10.1073/pnas.022438099 (PNAS Early Edition) Jan 8, 2002

Diabetes

Adult Stem Cells

Scientists "retrained" immune cells to reverse diabetes in mice. The autoimmunity that was previously directed against insulin-secreting cells was reversed, and adult stem cells in the mice formed insulin-secreting cells. The treatment was "…thus able to effect an apparent cure of established Type 1 diabetes in the [diabetic] mouse".
S. Ryu et al.; "Reversal of established autoimmune diabetes by restoration of endogenous ß cell function," J. Clin. Invest. 108, 63-72; July 2001

Pancreatic adult stem cells grown in culture formed insulin-secreting islets. When injected into diabetic mice, the mice survived without further need of insulin injections.
V.K. Ramiya et al.; "Reversal of insulin-dependent diabetes using islets generated in vitro from pancreatic stem cells," Nature Medicine 6, 278-282, March 2000.

Embryonic Stem Cells

Researchers reported the conversion of mouse embryonic stem cells into insulin producing pancreatic islet cells. The mouse embryonic stem cells secreted only 1/50th the normal amount of insulin, and diabetic mice implanted with the cells still died.
N. Lumelsky et al.; "Differentiation of embryonic stem cells to insulin-secreting structures similar to pancreatic islets," Science 292, 1389-1394; May 18, 2001

Spinal Cord Injury

Adult Stem Cells

Several labs have shown adult stem cells capable of re-growth and reconnection in spinal cord injury, allowing functional recovery. The cells "promote functional recovery of paraplegic adult rats and long-distance motor axon regeneration in their completely transected [severed] spinal cords," and showed "dramatic functional improvement and anatomical repair" (Ramon-Cueto et al; 2000).

Transplanted adult stem cells or stimulation of existing adult stem cells achieved re-growth of neurons and re-myelination (sheathing) of neurons.

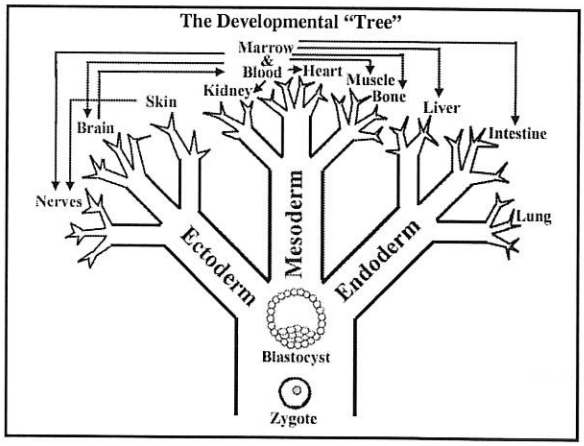
*M. Sasaki et al., "Transplantation of an acutely isolated bone marrow fraction repairs demyelinated adult rat spinal cord axons," Glia 35, 26-34; July 2001
*A. Ramon-Cueto et al., "Functional recovery of paraplegic rats and motor axon regeneration in their spinal cords by olfactory ensheathing glia," Neuron 25, 425-435; February 2000.
*M.S. Ramer et al.; "Functional regeneration of sensory axons into the adult spinal cord," Nature 403, 312-316; January 20, 2000S.
*Shihabuddin et al.; "Adult spinal cord stem cells generate neurons after transplantation in the adult dentate gyrus," J Neuroscience 20, 8727-8735; December 2000.
*Barnett et al.; "Identification of a human olfactory ensheathing cell that can effect transplant-mediated remyelination of demyelinated CNS axons," Brain 123, 1581-1588, August 2000
*A. Ramon-Cueto et al., "Long-distance axonal regeneration in the transected adult rat spinal cord is promoted by olfactory ensheathing glial transplants," J Neuroscience 18, 3803-3815; May 15, 1998

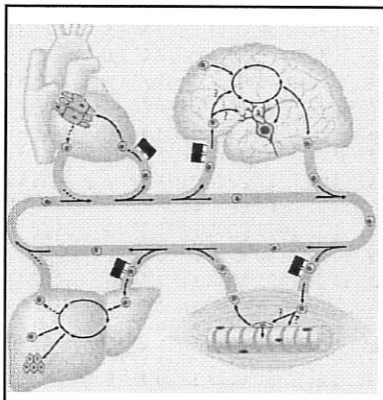
Embryonic Stem Cells

McDonald et al. showed some functional improvement in rats with spinal cord injury, slightly better than no treatment alone. Studies by Liu et al. and Brüstle et al. showed that ES cells could form protective myelin sheaths around nerves in rats with spinal cord injury, but they did not show or test for any functional recovery of the animals.
*J.W. McDonald et al., "Transplanted embryonic stem cells survive, differentiate and promote recovery in injured rat spinal cord," Nature Medicine 12, 1410-1412, Dec 1999
*S. Liu et al., "Embryonic stem cells differentiate into oligodendrocytes and myelinate in culture and after spinal cord transplantation," Proc. Natl. Acad. Sci. USA 97, 6126-6131; May 23, 2000
*O. Brüstle et al., "Embryonic Stem Cell-Derived Glial Precursors: A Source of Myelinating Transplants," Science 285, 754-756, July 30, 1999

Current Clinical Uses of Adult Stem Cells

- **Cancers**—Lymphomas, multiple myeloma, leukemias, breast cancer, neuroblastoma, renal cell carcinoma, ovarian cancer
- **Autoimmune diseases**—multiple sclerosis, systemic lupus erythematosus, juvenile rheumatoid arthritis, rheumatoid arthritis, scleroderma, scleromyxedema, Crohn's disease
- **Anemias** (incl. sickle cell anemia)
- **Immunodeficiencies**—including first successful human gene therapy
- **Bone and cartilage deformities**—treating children with osteogenesis imperfecta
- **Corneal scarring**-generation of new corneas to restore sight
- **Stroke**—neural cell implants in clinical trials
- **Repairing cardiac tissue after heart attack**
- **Skin**—grafts; growth from hair follicle stem cells, after plucking a few hairs from patient
- **Parkinson's**—first patient treated with own adult neural stem cells

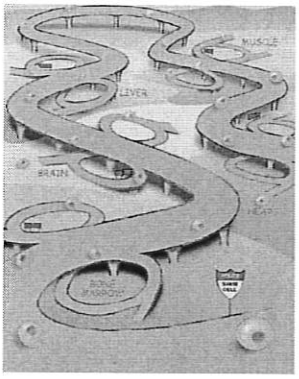




Evolving Concepts of Stem Cell Plasticity

Documented (solid arrows) and hypothesized (dashed arrows) transitions in stem cell identity and differentiation are illustrated. In addition to tissue-specific stem cells, some stem cells may travel throughout the body via the circulation. The scheme also suggests that cell fate decisions may not be irreversible. Flexibility is the hallmark of this depiction allowing for regeneration and changes in cell fate in response to need.

from Blau HM, Brazelton TR, Weimann JM, "The evolving concept of a stem cell: entity or function?", *Cell* 105, 829-841, June 29, 2001



Route Stem Cell

The stem cell landscape depicted here illustrates the emerging characteristics of adult stem cells that include plasticity in cell fate, diversity of origin, and a multiplicity of tissue potentials. Stem cells (blue) are able to enter diverse tissue compartments from the bloodstream (the stem cell highway) via "on ramps" and generate appropriate cell types in response to homing signals or growth factors depicted on "billboards." In theory, all choices are reversible.

from Blau HM, Brazelton TR, Weimann JM, "The evolving concept of a stem cell: entity or function?", *Cell* 105, 829-841, June 29, 2001

Adult Stem Cells

DO NO HARM
The Coalition of Americans for Research Ethics
www.stemcellresearch.org

More promising alternative for treatments
Vast biomedical potential

Able to generate virtually all adult tissues

Can multiply almost indefinitely, providing numbers sufficient for clinical treatments

Proven success in laboratory culture

Proven success in animal models of disease

Proven success in current clinical treatments

Show ability to "home" in on damaged tissue

Avoid problems with tumor formation

Avoid problems with transplant rejection

Avoid ethical quandary

Human embryo cloning places women at risk

To treat just the 16 million Diabetes patients in the United States:

At *generous* 20% cloning efficiency (to achieve blastocyst stage)

At *generous* 10% efficiency at initiating ES cell culture

Will require 800 million eggs (2% overall efficiency)

(Rideout *et al.* 0.5%, >3.2 billion eggs; Hochedlinger *et al.* 0.2%, > 7.8 billion eggs)

Collecting 10 eggs/donor (ACT--71 eggs from 7 donors)

Will require 80 million women of childbearing age as donors

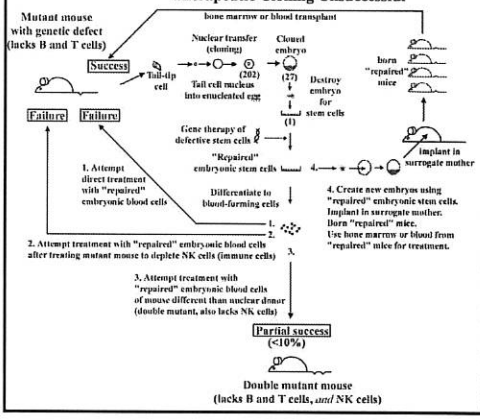
Health risks—High-dose hormone therapy and surgery used to obtain eggs risks the donor's health and future reproductive success

Commercial exploitation—disadvantaged women in U.S. and abroad

Quotes from major scientific journals regarding "therapeutic cloning"

- "…Ministers in Britain have too easily swallowed the line that cloning human embryos is essential to medical progress. It is not. …Like stuck records, ministers and policy makers continue to enthuse about therapeutic cloning even though the majority of bench scientists no longer think it's possible or practicable to treat patients with cells derived from cloned embryos. They have already moved on to investigating the alternatives."
  Editorial, "Brave New Medicine", *New Scientist*, Dec 1, 2001
- "The idea of therapeutic cloning, which offers the potential of growing replacement tissues perfectly matched to their recipients, is falling from favour. But there are alternatives…"
  Peter Aldhous, "Can they rebuild us?", *Nature* 410, 622-625; April 5, 2001
- "But the idea of 'therapeutic cloning' seems to be on the wane. By creating cloned human blastocysts, some experts have argued that it should be possible to derive ES cells perfectly matched to individual patients. But most now believe this will be too expensive and cumbersome for regular clinical use."
  Peter Aldhous, "A world of difference", *Nature* 414, 838; Dec 20/27, 2001
- "[John] Gearhart [of Johns Hopkins University] also says that many scientists 'feel there are ways of getting around [the rejection problem] without the nuclear transfer paradigm.' "
  Constance Holden, "Would cloning ban affect stem cells?", *Science* 293, 1025; Aug 10, 2001
- "[T]he poor availability of human oocytes, the low efficiency of the nuclear transfer procedure, and the long population-doubling time of human ES cells make it difficult to envision this [therapeutic cloning] becoming a routine clinical procedure…"
  Odorico JS, Kaufman DS, Thomson JA, "Multilineage differentiation from human embryonic stem cell lines," Stem Cells 19, 193-204; 2001

Therapeutic Cloning Unsuccessful



The authors note: "Our results raise the provocative possibility that even genetically matched cells derived by therapeutic cloning may still face barriers to effective transplantation for some disorders."

W.M. Rideout et al., "Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy," *Cell* Immediate Early Publication, published online March 8, 2002

Human cloning and embryo destruction: Unsafe, Unethical, Unnecessary

- Bans do not prohibit vital and legitimate research.
- No evidence that cloning is necessary or useful for medical treatments.
- Alternatives to embryonic stem cells are more successful, more promising.
- Creates a class of humans who exist only as means to achieve the ends of others.
- Human beings have the right not to be created as objects of experimentation.
- Human embryo cloning risks women's health and exploitation.
- Banning only implantation of clones is unenforceable.
- Cloning leads to commodification, commercialization of human life.
- Confuses kinship, parent-child identity, parental expectations.
- Possible reproduction of living or deceased persons without knowledge or consent.
- Gateway to genetic manipulation and control of human beings.

Total ban on human cloning and human embryo destruction needed

8-11