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**Senate**

**State of Minnesota**

# S.F. No. 69 - Stem Cell Research

**Author:** Senator Richard Cohen

**Prepared by:** Katie Cavanor, Senate Counsel (651/296-3801) KTC

**Date:** March 30, 2005

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**S.F. No. 69** establishes state policy for stem cell research.

**Section 1 [137.45]** authorizes the University of Minnesota to spend state appropriated funds on stem cell research.

**Section 2 [145.426]** states the findings and declarations of the Legislature.

**Section 3 [145.427]** establishes state policy for stem cell research.

**Subdivision 1** states that the policy of the state is that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source shall be permitted and that full consideration of the ethical and medical implications of this research are given. States that such research shall be reviewed by an approved institutional review board.

**Subdivision 2** requires a health care provider who is treating a patient for infertility to provide the patient with timely, relevant, and appropriate information sufficient to allow the patient to make an informed and voluntary choice regarding the disposition of any human embryos remaining after fertility treatment. Requires the patient to be presented with the option of storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research. Requires a patient who elects to donate embryos for research to provide a written consent for that donation.

**Subdivision 3** states that a person may not knowingly for valuable consideration purchase, sell, or otherwise transfer or obtain, or promote the sale or transfer of embryonic or cadaveric fetal tissue for research purposes. States that embryonic or cadaveric fetal tissue may be donated for research purposes. Defines "valuable consideration." States that a violation of this subdivision is a gross misdemeanor.

**Section 5** establishes an effective date of August 1, 2005.

KC:ph

**Senator Cohen introduced--**

**S.F. No. 69:** Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; establishing state policy for stem cell research; providing criminal penalties; proposing coding for new law in Minnesota Statutes, chapters 137; 145.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. [137.45] [STEM CELL RESEARCH.]

The University of Minnesota may spend state-appropriated funds on stem cell research.

Sec. 2. [145.426] [LEGISLATIVE FINDINGS.]

The legislature finds and declares all of the following:

(a) An estimated 128,000,000 Americans suffer from the crippling economic and psychological burden of chronic, degenerative, and acute diseases, including diabetes, Parkinson's disease, cancer, and Alzheimer's disease.

(b) The costs of treatment and lost productivity of chronic, degenerative, and acute diseases in the United States constitute hundreds of billions of dollars every year. Estimates of the economic costs of these diseases do not account for the extreme human loss and suffering associated with these conditions.

(c) Stem cell research offers immense promise for developing new medical therapies for these debilitating diseases and a critical means to explore fundamental questions of biology. Stem cell research could lead to unprecedented treatments and

potential cures for diabetes, Alzheimer's disease, cancer, and other diseases.

(d) The United States and Minnesota have historically been a haven for open scientific inquiry and technological innovation and this environment, coupled with the commitment of public and private resources, has made the United States the preeminent world leader in biomedicine and biotechnology.

(e) The biomedical industry is a critical and growing component of Minnesota's economy and would be significantly diminished by limitations imposed on stem cell research.

(f) Open scientific inquiry and publicly funded research will be essential to realizing the promise of stem cell research and to maintain Minnesota's leadership in biomedicine and biotechnology. Publicly funded stem cell research, conducted under established standards of open scientific exchange, peer review, and public oversight, offers the most efficient and responsible means of fulfilling the promise of stem cells to provide regenerative medical therapies.

(g) Stem cell research, including the use of embryonic stem cells for medical research, raises significant ethical and policy concerns and, while not unique, the ethical and policy concerns associated with stem cell research must be carefully considered.

(h) Public policy on stem cell research must balance ethical and medical considerations. The policy must be based on an understanding of the science associated with stem cell research and grounded in a thorough consideration of the ethical concerns regarding this research. Public policy on stem cell research must be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of stem cell research.

Sec. 3. [145.427] [STATE POLICY FOR STEM CELL RESEARCH.]

Subdivision 1. [RESEARCH USE PERMITTED.] The policy of the state of Minnesota is that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic

cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given. Research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by an approved institutional review board.

Subd. 2. [INFORMED CONSENT.] A physician, surgeon, or other health care provider who is treating a patient for infertility shall provide the patient with timely, relevant, and appropriate information sufficient to allow the patient to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the fertility treatment. Any patient to whom information is provided under this subdivision shall be presented with the options of storing any unused embryos, donating the embryos to another individual, discarding the embryos, or donating the remaining embryos for research. Any patient who elects to donate embryos remaining after fertility treatments for research shall provide written consent to that donation.

Subd. 3. [PROHIBITING SALE OF FETAL TISSUE.] (a) A person may not knowingly, for valuable consideration, purchase, sell, or otherwise transfer or obtain, or promote the sale or transfer of, embryonic or cadaveric fetal tissue for research purposes. However, embryonic or cadaveric fetal tissue may be donated for research purposes under this section. For purposes of this subdivision, "valuable consideration" means financial gain or advantage, but does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of embryonic or cadaveric fetal tissue.

(b) Violation of this subdivision is a gross misdemeanor.

Sec. 4. [EFFECTIVE DATE.]

Sections 1 to 3 are effective August 1, 2005.

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State of Minnesota

# S.F. No. 730 - Stem Cell Research

**Author:** Senator Steve Kelley

**Prepared by:** Katie Cavanor, Senate Counsel (651/296-3801) KTC

**Date:** March 30, 2005

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**S.F. No. 730** establishes state policy for stem cell research.

**Section 1 [137.45]** permits the University of Minnesota to spend state-appropriated funds on stem cell research.

**Section 2 [145.426]** states the findings and declarations of the Legislature.

**Section 3 [145.427]** establishes state policy for stem cell research.

**Subdivision 1** states that the policy of the state is that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source shall be permitted and that full consideration of the ethical and medical implications of this research are given. States that such research shall be reviewed by an approved institutional review board.

**Subdivision 2** requires a health care provider who is treating a patient for infertility to provide the patient with timely, relevant, and appropriate information sufficient to allow the patient to make an informed and voluntary choice regarding the disposition of any human embryos remaining after fertility treatment. Requires the patient to be presented with the option of storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research. Requires a patient who elects to donate embryos for research to provide a written consent for that donation.

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**Section 4** appropriates money in fiscal year 2006 from the general fund to the University of Minnesota for stem cell research.

KC:ph

**Senators Kelley, Rest, Solon, Dibble and Marko introduced--**

**S.F. No. 730:** Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; establishing state policy for stem cell research; providing criminal penalties; appropriating money; proposing coding for new law in Minnesota Statutes, chapters 137; 145.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. [137.45] [STEM CELL RESEARCH.]

The University of Minnesota may spend state-appropriated funds on stem cell research.

Sec. 2. [145.426] [LEGISLATIVE FINDINGS.]

The legislature finds and declares all of the following:

(a) An estimated 128,000,000 Americans suffer from the crippling economic and psychological burden of chronic, degenerative, and acute diseases and conditions, including diabetes, Parkinson's disease, and cancer.

(b) The costs of treatment and lost productivity of chronic, degenerative, and acute diseases and conditions in the United States constitute hundreds of billions of dollars every year. Estimates of the economic costs of these diseases and conditions do not account for the associated extreme human loss and suffering.

(c) Stem cell research offers immense promise for developing new medical therapies for these debilitating diseases and conditions and a critical means to explore fundamental questions of biology. Stem cell research could lead to

unprecedented treatments and potential cures for diabetes, cancer, and other diseases and conditions.

(d) The United States and Minnesota have historically been a haven for open scientific inquiry and technological innovation and this environment, coupled with the commitment of public and private resources, has made the United States the preeminent world leader in biomedicine and biotechnology.

(e) The biomedical industry is a critical and growing component of Minnesota's economy and would be significantly diminished by limitations imposed on stem cell research.

(f) Open scientific inquiry and publicly funded research will be essential to realizing the promise of stem cell research and to maintain Minnesota's leadership in biomedicine and biotechnology. Publicly funded stem cell research, conducted under established standards of open scientific exchange, peer review, and public oversight, offers the most efficient and responsible means of fulfilling the promise of stem cells to provide regenerative medical therapies.

(g) Stem cell research, including the use of embryonic stem cells for medical research, raises significant ethical and policy concerns and, while not unique, the ethical and policy concerns associated with stem cell research must be carefully considered.

(h) Public policy on stem cell research must balance ethical and medical considerations. The policy must be based on an understanding of the science associated with stem cell research and grounded in a thorough consideration of the ethical concerns regarding this research. Public policy on stem cell research must be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of stem cell research.

Sec. 3. [145.427] [STATE POLICY FOR STEM CELL RESEARCH.]

Subdivision 1. [RESEARCH USE PERMITTED.] The policy of the state of Minnesota is that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic

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Subd. 3. [PROHIBITING SALE OF FETAL TISSUE.] (a) A person may not knowingly, for valuable consideration, purchase, sell, or otherwise transfer or obtain, or promote the sale or transfer of, embryonic or cadaveric fetal tissue for research purposes. However, embryonic or cadaveric fetal tissue may be donated for research purposes under this section. For purposes of this subdivision, "valuable consideration" means financial gain or advantage, but does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of embryonic or cadaveric fetal tissue.

(b) Violation of this subdivision is a gross misdemeanor.

Sec. 4. [APPROPRIATION.]

$..... in fiscal year 2006 is appropriated from the general fund to the Board of Regents of the University of Minnesota for the purposes of this act.

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March 30, 2005

Kelley

OP-ED CONTRIBUTOR

# In the Name of Politics

By JOHN C. DANFORTH

St. Louis — BY a series of recent initiatives, Republicans have transformed our party into the political arm of conservative Christians. The elements of this transformation have included advocacy of a constitutional amendment to ban gay marriage, opposition to stem cell research involving both frozen embryos and human cells in petri dishes, and the extraordinary effort to keep Terri Schiavo hooked up to a feeding tube.

Standing alone, each of these initiatives has its advocates, within the Republican Party and beyond. But the distinct elements do not stand alone. Rather they are parts of a larger package, an agenda of positions common to conservative Christians and the dominant wing of the Republican Party.

Christian activists, eager to take credit for recent electoral successes, would not be likely to concede that Republican adoption of their political agenda is merely the natural convergence of conservative religious and political values. Correctly, they would see a causal relationship between the activism of the churches and the responsiveness of Republican politicians. In turn, pragmatic Republicans would agree that motivating Christian conservatives has contributed to their successes.

High-profile Republican efforts to prolong the life of Ms. Schiavo, including departures from Republican principles like approving Congressional involvement in private decisions and empowering a federal court to overrule a state court, can rightfully be interpreted as yielding to the pressure of religious power blocs.

In my state, Missouri, Republicans in the General Assembly have advanced legislation to criminalize even stem cell research in which the cells are artificially produced in petri dishes and will never be transplanted into the human uterus. They argue that such cells are human life that must be protected, by threat of criminal prosecution, from promising research on diseases like Alzheimer's, Parkinson's and juvenile diabetes.

It is not evident to many of us that cells in a petri dish are equivalent to identifiable people suffering from terrible diseases. I am and have always been pro-life. But the only explanation for legislators comparing cells in a petri dish to babies in the womb is the extension of religious doctrine into statutory law.

I do not fault religious people for political action. Since Moses confronted the pharaoh, faithful people have heard God's call to political involvement. Nor has political action been unique to conservative Christians. Religious liberals have been politically active in support of gay rights and against nuclear weapons and the death penalty. In America, everyone has the right to try to influence political issues, regardless of his religious motivations.

The problem is not with people or churches that are politically active. It is with a party that has gone so far in adopting a sectarian agenda that it has become the political extension of a religious movement.

When government becomes the means of carrying out a religious program, it raises obvious questions under the First Amendment. But even in the absence of constitutional issues, a political party should resist identification with a religious movement. While religions are free to advocate for their own sectarian causes, the work of government and those who engage in it is to hold together as one people a very diverse country. At its best, religion can be a uniting influence, but in practice, nothing is more divisive. For politicians to advance the cause of one religious group is often to oppose the cause of another.

Take stem cell research. Criminalizing the work of scientists doing such research would give strong support to one religious doctrine, and it would punish people who believe it is their religious duty to use science to heal the sick.

During the 18 years I served in the Senate, Republicans often disagreed with each other. But there was much that held us together. We believed in limited government, in keeping light the burden of taxation and regulation. We encouraged the private sector, so that a free economy might thrive. We believed that judges should interpret the law, not legislate. We were internationalists who supported an engaged foreign policy, a strong national defense and free trade. These were principles shared by virtually all Republicans.

But in recent times, we Republicans have allowed this shared agenda to become secondary to the agenda of Christian conservatives. As a senator, I worried every day about the size of the federal deficit. I did not spend a single minute worrying about the effect of gays on the institution of marriage. Today it seems to be the other way around.

The historic principles of the Republican Party offer America its best hope for a prosperous and secure future. Our current fixation on a religious agenda has turned us in the wrong direction. It is time for Republicans to rediscover our roots.

*John C. Danforth, a former United States senator from Missouri, resigned in January as United States ambassador to the United Nations. He is an Episcopal minister.*

## Written Testimony from Frank Preston, MD in opposition to SF 69
## for the committee hearing on Mar. 31, 2005

It seems when embryo research is discussed there is always an elephant in the living room which goes unmentioned. The elephant is the true scientific, biological facts of human reproduction

There are some absolutes in science. The world IS round. The law of gravity is in effect. Louis Pasteur's Germ Theory of Disease was proven to be correct as recently the186o's.. In that same decade Dr Gregor Mendel proved, in a body of work known as the Mendelian Laws of Heredity, that the life of a new individual – of any species, plant or animal – begins with an event of fertilization.

*He proved it by artificially fertilizing fruit flies and peas and then keeping them separated. He found that he could predict physical characteristic to the 3d generation, proving that something happens at fertilization that makes an offspring what he or she is biologically.*

In the case of humans, that new individual, male or female, has a reasonable life expectancy of 65 to 75 years if not interrupted,. As an embryo he or she has his or her own cell boundaries within which that human creature is completely unique, self integrating (that is, puts itself together} and in the normal course of events needs only protection and nutrition, as do we all.

In addition, University of Minnesota researchers showed 10 or more years ago, in a study of identical twins raised apart, that much of the interests, talents and personalities are also instilled at fertilization

There cannot be any question that the life of an individual human begins at fertilization. This information has been confirmed and reconfirmed over and over again in the science of embryology and in the science of genetics..

Ideas to the contrary are completely without any scientific foundation. They are political opinions – or philosophical or even religious. *They relate to who can live and who must die*. In those areas scientists have no greater expertise than anyone else.

An embryo is not a road map to a human. When I get to Des Moines, there is the city in front of me and the map is in the glove compartment. They are different things.

*An embryo is not a blueprint for a human, When finished, the house in on the lot and the blueprint goes back in the drawer. They are different things.*

*The embryo is not a tool to make a human. When the job is done the tool goes back in the toolbox. The completed project does not. They are completely different things.*

Not so the embryo. It is the very thing. It is exactly the same thing as the child, the youth and the adult. Your embryo now sits in your chair. To kill an embryo is to kill an entire human life. It denies to that individual all the human and civil rights your generation and mine have struggled to obtain. That individual is denied the right to equal education, the right to vote, equal employment opportunities and all the choices life may bring. These individuals will never enjoy childhood or youth, nor the joys of marriage and family.

*Individual human lives begin at fertilization. That scientific fact was recognized by previous Minnesota legislatures in 1973 and again in 1984, anticipating and fearing that some day human experiments would be proposed on the most vulnerable humans.*

Not in the 6000 or more years that there have been healers and physicians has it been seen as part of that profession to deliberately kill human beings in medical experiments. An exception was the lethal experiments in Germany preceding and during world war II. The University's justification is very similar to theirs. Unwanted, they will die any way.

Such research is the ultimate violation of research ethics and of medical ethics.

Ah, but these embryos are frozen, you may say. Please consider who it was that froze them. *In the words of Edwin Markham in The Man With the Hoe: "Who made him dead to rapture and despair, a thing that grieves not and never hopes:* They were frozen by the very physicians who now come to you and say, in effect, "because they are frozen you must let us kill them".

The University may say, "but these will otherwise be discarded". Embryos do not discard themselves. They will not be discarded unless the University of Minnesota in its wisdom decides to discard them

But what then can we do with these unwanted embryos? We should do with them what we do with other left-over, unwanted humans in our midst – under our bridges, in our prisons, in our mental hospitals. In consideration of our common humanity we sustain them as best we can given the circumstances. We do not kill them as human subjects in lethal medical experiments.

*Embryo adoption is becoming more frequent.* Healthy twins have been born after being frozen as embryos for 12 years. Many in this room will not live 12 more years. *Artificial wombs are in the offing ( New Republic, 8/18/03). The literature is increasingly in favor of fertilization of only those which are certain to be implanted, That is the law in Germany. And finally, these frozen embryos may die a natural death, aggravated, of course, by what has been done to them.*

*But we must not kill them. Please do not vote to kill them. A recent documentary on the history channel pointed out that the practice of slavery served to corrupt the lives of the slave owners and merchants as well as much of southern society.*

*If you want to find cures in the lifetime of those present here today, give the University whatever it needs to continue it's leadership in the exciting and promising field of adult-type stem cell research.*

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# The Secular Argument against Embryo Research

**By Frank S. Preston, M.D.**

When we express opposition to embryonic stem cell research, done in a way that destroys the embryo, we are sometimes accused of being insensitive to the plight of people suffering from dread diseases which might be cured by such research.

As do most physicians, I chose medicine because I hoped for the personal satisfaction of helping people recover from disease or at least suffer less.

## HUMAN REPRODUCTION AND DEVELOPMENT

One of the first courses in medical school is embryology where we learned the facts of human reproduction and development. Let's review:

These are the known scientific facts to which everyone agrees.[1] The ovum contains half of the mother's genetic material. And the sperm contains half of the father's genetic material. When they mysteriously combine, there is a new creature who is different from either parent. The combination is unique. Scientists know this well and it is an important reason why they are interested in the embryo's properties. That genetic material stays with that human, and can identify that human as a unique, specific human individual, different from all others, throughout his or her life however long.

## TERMS

But though everyone knows these scientific facts, sometimes different names for things are used, and that can lead to confusion and disagreement.

For instance, Dr Susan Wolf, university law professor and advisor to the Stem Cell Institute, said to the Minnesota Academy of Medicine on April 30, 2002, that the human embryo would grow to become a human being. I did not know what she meant and went to the Edina public library where each of the five dictionaries agreed that the word "being" means "something that exists."

The embryo is human and exists. It is clearly already a human being.

When "human being" is used to somehow distinguish certain humans from others, it is always intended to deny some civil rights or human rights to those that are not called "beings."

For instance, Sebastian Haffner, in his 1939 memoirs of life as a law clerk in Nazi Germany, wrote: "The Germans were informed through pamphlets, papers and meetings that it had been a mistake to consider the Jews as human beings."[2] In the proposal now under discussion, the human right that is violated is the simple human right not to be killed in lethal medical experiments.

## WHAT IS IT?

But it doesn't matter what things are called. It matters what things are. The embryo is a new individual human in the earliest stage of development.

People who believe that the use of unborn humans in research should be permitted are, I know, gifted and caring persons. They are focused on the possibility of curing disease.

But to do this



lethal work they must convince themselves, and say to others, that the embryo is only a clump of
cells or a bit of laboratory tissue, and not really a human being. These statements, which pose as scientific information, but which are not true, are a poor basis for public policy.

The embryo is not just a glob of tissue. My brain is a glob of tissue. And some very important parts of it are no larger than an embryo. The embryo can and will make a brain and I cannot. A glob of tissue in my heart, called the pacemaker, has kept my heart beating for more years than I wish to say. But it is a glob of tissue no bigger than an early embryo. The embryo makes its own heart which I cannot do.

The embryo is not a road map to make a human. If I drive to LaCrosse I will take a road map so as not to miss the turn off. When I come to the river, I see LaCrosse ahead of me, and the road map is in the glove compartment. They are different things.

The embryo is not a blueprint for a human. When the house is built, the blueprint is stored in a desk drawer. They are different things.

Not so the embryo. It is very the thing itself. It goes through stages of growth and development to which different descriptive names apply such as youth, adult and senior citizen, but is always the same thing. An embryo destroyed or killed is an entire human life destroyed.

The embryo is a human in an early stage of development. He or she is a complete and entire, full-blown human for his or her stage of development, just as a newborn infant or toddler is complete for his or her stage of development.

**GROWTH AND DEVELOPMENT**

I have a picture at home of myself as an infant. You would not know it was me. (My mother wrote on the back, but today you could check my DNA). I grew through a stage described as child, then a stage called youth, then adult. But I was always me. Never something or someone else.

And before the picture was taken, I was at a stage called fetus. Many people have pictures of that stage. And before that my stage of development was called embryo.

Every one who reads this was once an embryo. If we had been used in lethal medical research none of us would exist. You are the same thing as your embryo. Your embryo now sits in your chair.

**WHY KILL THE EMBRYO?**

Why should a human embryo be chosen for this lethal research?

Because it is so small? Why does size matter? Does a tall person have more right to life?

Because it is silent and can't complain?

Because it is so dependent? So also is the newborn. Aren't we all dependent on one another?

Because it is not complete? Surely it is complete for its stage. Is the one-year old complete? Is the retarded person complete? The quadriplegic? The victim of thalidomide? Who will decide what is complete?

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Because it is not sensate? Because it would not know the difference, having not been aware of life? That implies that if you kill silently without anxiety or pain it should be permitted.

Because he or she is left over and unwanted? Look under our bridges, in our prisons, our nursing homes, our mental hospitals. Will we be allowed to conduct lethal medical experiments? The organs would save many lives. And who put the embryo in this state? Who made them left over and unwanted? The very scientists who now wish to kill them in their research.

Because the research "holds promise"? The human embryo left alone holds much more promise.

Because embryos take up too much room in our laboratories? I don't think so. Each one "is smaller than the period at the end of this sentence" as we have so often heard.

Because they will soon die anyway? Won't we all? Can we kill the cancer victim? The elderly for research? Anyone with a shortened life-span?

No. We sustain all these people as best we can under their particular circumstances, but we do not kill them for medical research. These embryos will "die anyway" only if we kill them or "discard" them while they are alive.

**AND WHY NOT?**

The moral argument (not religious) is that humans should not kill other humans. Because humans should not kill other humans, physicians in their experiments should not kill other humans. We must mourn deeply for the lost life of that innocent individual and the injustice of the killing. It is not just a tiny bit of tissue, and it is not just 5 days of life. When an embryo is killed, an entire life is lost, with all its joys and comforts.

**THE "SLIPPERY SLOPE"**

Another argument against lethal embryo research is the so-called slippery slope. The killing cannot stop once society places a utilitarian value on individual human life.

In another society of very recent memory, lethal medical experiments were carried out on political prisoners of an unwanted race. And many of those lethal medical experiments were intended to find cure for diseases such as induced infections. Some were done to save lives. Humans were frozen in ice water to see how long downed pilots would survive in the North Atlantic.[3] And the subjects, of course, were scheduled "to die anyway." Have we forgotten?

It should be noted that the scientific facts of human reproduction and development we have discussed are well known even to those of us who would engage in lethal human research. Surely when we are accustomed to do this, they will be quick to point out that

stem cells taken at a later stage would be even more useful, and, after all, there is no moral difference between 14 days and 30 days, etc., etc. The slippery slope is very, very real.

For instance, Dr. Drazen, in his commentary on the 17 Harvard stem cell lines, calls for increased differentiation before harvesting the cells.[4] University of Minnesota bioethicists now approve making offspring to be aborted later for their tissue or organs.[5] Senator Dayton has co-sponsored legislation which would allow designer babies to be implanted in some other mammalian womb so long as a child was not born.[6] Some ethicists would permit killing undesirable children up to one month of age.[7]

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The only morally and scientifically feasible clear line is at the beginning of a new individual human life.

**AND WHAT ABOUT GENOCIDE?**

In stem cell research, and even in the in-vitro fertilization programs, humans with genetic defects are destroyed. They are killed for the wrong genes. Is that eugenics? Genocide?

Presumably the "left over, unwanted" embryos which will be subjected to lethal research are those which, on the balance, have less desirable genes because the preferred ones were implanted. Eugenics? Genocide?

**EMBRYONIC VS. ADULT CELLS**

I cut my hand not long ago. Fibroblasts, the stem cells for fibrous tissue, came from my blood or bone marrow and made a scar. Over time stem cells in the skin layer or blood began to build new skin from the sides. Now the wound is invisible. These adult stem cells are everywhere in the body, in greater supply in some tissue than others.

It is intuitive that cells which have progressed in natural development toward a specific tissue type surely can be coaxed the rest of the way with greater ease than starting with an embryo. That is not only intuitive, but is clearly working out in practice. Surely money spent on such stem cells is more wisely spent.

**MOTIVE**

In view of the scientific facts, which are well known, and the moral issues, which must be troubling even to the researchers involved, and the fact that more acceptable research will be more likely of success, what is our motivation?

Of course, our emphasis is on the possible cure of serious disease. However, it is very difficult to separate other motives which also exist.

When we say, "Wisconsin will get ahead of us" what motive does that speak of? How altruistic is that?

Also, for the reasons mentioned above concerning the relative likelihood of success with embryos vs. adult cells, Wisconsin is unlikely to be more successful if there is a race. Duplicating their work here, which requires crossing a moral boundary, also would not

be economically wise.

Other motives, which are not inherently bad motives, include personal satisfaction, prestige and professional advancement for the researchers, and the value of patents. Those motives are not bad but they need to be balanced against the moral considerations that exist.

**WHY KILL THE EMBRYO?**

Why did I say in the introduction that I would discuss embryonic stem cell research "in a way that destroys the embryo"? Perhaps the research could be done in a moral way. It is little bit overreaching to take all the cells from the central core of the blastocyst resulting in its death.



For instance, in the case of in-vitro fertilization, one cell is removed from an eight-cell embryo for genetic testing. Dr John Wagner, speaking to a group of doctors on April 4, 2002, said he did
not "think" that the embryo is harmed. But one cell is, after all, one-eight of that human's entire body mass. Follow-up studies would be easy to do, to see if in-vitro children are as healthy as others. Some studies have suggested they are not.(8)

But if we do believe that one cell out of eight is safe, surely one cell out of 100 should be safe. If we believe each of these cells is truly "totipotent," then one cell-line from each genetically distinct human being should be enough. There would need to be some way to provide medical evidence that removing one cell of 100 does no harm.

Significant surgery can be done in utero. If there was compelling need and evidence that no harm would result, stem cells from the developing embryo might be available without abortion.

**CONCLUSION**

It is important to remember that the human embryo is a distinct, new individual human being in its earliest stage of life. By approving embryonic stem cell research, we accept the social and political principle that people who are in a position of authority – in this case physicians and medical researchers – have the right to kill other helpless humans.

By not allowing embryonic stem cell research, we will take the higher moral and humanitarian road to alleviating human suffering and finding cures to disease.

I encourage you to join me in insisting that our fine university reject this lethal research on the youngest members of the human family.

**REFERENCES**

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(7) Dr Peter Singer, Center for Human Values, Princeton University, Princeton, New Jersey, 08544
(8) New England Journal of Medicine, Mar 7, 2002, v. 346, no. 10, (pp. 725-730)

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**Please submit this testimony in opposition to SF 430 for the Senate Hearing of your committee on Mar. 31, 2005.**

MCCL
Since 1968
Minnesota Citizens Concerned for Life www.mccl.org

Dear Senator,

The 77,000 Minnesota Citizens Concerned for Life contributors urge the Minnesota Senate to oppose S.F. 69 and S.F. 730. These bills would permit the manufacture and destruction of thousands of nascent human beings.

Advocates of "therapeutic cloning" present it as different from "reproductive cloning," but it is in fact the same procedure. Only the intention—to let the cloned embryo develop or to destroy it—varies. A human embryo, however created, is alive; it is not dead or inanimate. A human embryo is human, not a carrot. It is a complete human organism, a member of the human species with its entire DNA, at an early stage of development. It is what each of us once was; nothing that is not a living human being becomes one.

Creating embryos for lethal experimentation will ultimately predispose us to a ruthless utilitarianism regarding life. The disabled and elderly are safe in a society that honors life and treats humanity with respect. But if we violate an embryo today, the practice will inure us to violating a fetus and then infants with defects; then anyone else with a defect. It's the path to social engineering that decides which human lives have value and dignity, and which do not.

Those in favor of embryonic stem-cell research have argued that "we must do the greatest good for the greatest number of people." Such reasoning is self-defeating; it would lead to the euthanizing of disabled persons.

Research cloning is incompatible with the principal ethical foundations of medicine ("First, do no harm,") and the harms research cloning would bring to medicine would exceed the anticipated benefits. We cannot look upon human lives merely as sources for scientific research material.

Proponents of embryo-destroying research often suggest that a human being must also have mental functioning to be worth protecting. But this argument proves too much: What about infants? The retarded? The comatose? Drawing the line is impossible. But we don't need to draw a line. Minnesotans can, if we want, protect all human beings in law.

Embracing embryonic stem-cell research would create, for the first time in Minnesota law, a class of human beings that it is a duty to destroy. That is a line we must not cross.

MCCL urges the State of Minnesota and the University of Minnesota to pursue non-embryonic stem-cell research and other promising research that does not depend on human cloning or the destruction of human embryos.

Laura Gese

Laura Gese
MCCL Legislative Associate

4249 Nicollet Avenue • Minneapolis, MN 55409 • Tel. 612.825.6831 • Fax 612.825.5527

**Senate Committee: Health and Family Security**
**Chair: Senator Becky Lourey**
**Thursday, March 31, 2005, 12 noon**
**Room 15 Capitol**
**Agenda:** S.F. 69-Cohen: Stem cell research state policy.
S.F. 730-Kelley: Stem cell research state policy.

## Testimony opposed to legislation to legalize and fund human cloning in Minnesota

Jean Swenson, MA
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651 690-0645
jswenson@usfamily.net

Good afternoon. My name is Jean Swenson. I've been an active advocate for cure research since my motor vehicle spinal cord injury nearly twenty-five years ago. I appreciate the opportunity to share with you some information that I hope you will find enlightening and helpful as you carefully weigh the pros and cons of allowing human cloning in Minnesota.

First, it's important to define the terms. Please refer to the handout entitled "Somatic Cell Nuclear Transfer." Note the two types of cloning currently under debate, "Reproductive Cloning" (or "Cloning-To-Produce-Children)" and "Therapeutic Cloning" (or "Cloning-For-Biomedical-Research").

Also note that the cloning ***process*** is identical in both procedures. The only difference is the intended ***use*** of the cloned human embryo. In one case the embryo is implanted in the womb to develop into whatever stage is desired for experimental purposes. In the other the embryo is destroyed at about 4-5 days when its inner cell mass is extracted.

The bills under consideration today are no longer about using "leftover embryos" from fertility clinics. According to Wesley Smith, a lawyer and journalist who has researched this extensively, if SF 730 passes in its current form, "Minnesota would explicitly permit human cloning, implantation of cloned or natural embryos, and their destruction for obtaining stem cells through the ninth month." Although this cannot yet technologically be done, the legal groundwork is being laid. See the handout entitled "Minnesota Now Has Legislation to Clone and Gestate" for further information.

This extreme legislation would allow the creation of a human being in order to destroy it for its tissues, something most other nations vehemently oppose. How many of you are aware that the United Nations General Assembly recently passed a non-binding resolution to ban human cloning by a nearly 3-1 vote? (90 members for, 34 against, rest abstaining or absent) This resolution urges member states to: "*prohibit **all** forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life.*" [my emphasis] Please note the handout listing nations opposed to human cloning.

It is considered a crime in nations such as Canada, France, and Germany. Why do the Canadians think you should get five years in jail for "therapeutic cloning" if it is only cloning cells? Is Canada run by pro-life extremists? What about France? Don't the Germans know about unethical science? (Germany, unlike France and Canada, does not allow ***any*** destructive embryo research - the Germans only allow the importation of cell lines along the lines of the Bush funding policy.)

And what about the potential exploitation of women? As you can see from the first handout, cloning involves transferring nuclear material into a human egg. Pro-therapeutic cloning researcher Peter Mombaerts estimates that, because of inefficiencies in the cloning process, it would likely take about *100 eggs per patient* just to obtain *one* cloned embryonic stem cell line. Think about this—there are 17 million diabetes patients in the U.S. If it only took 50 eggs per patient, it would require 850 million eggs harvested from at least *85 million women*! In addition, many people foresee the exploitation of women in poverty who would be willing to go through the painful and potentially dangerous process called ovarian hyperstimulation in order to sell their eggs.

Judy Norsigian, pro-choice author of *Our Bodies, Ourselves*, states: "*Because embryo cloning will compromise women's health, turn their eggs and wombs into commodities...and with virtual certainty, lead to the production of 'experimental human beings,' we are convinced that the line must be drawn here* [all forms of human cloning]." (from *Boston Globe,* August 3, 2001) If you go to her website you can read other statements by her against all forms of human cloning, including one signed by over 100 women's rights activists and organizations. (http://www.bwhbc.org/clone3.htm)

I've been actively supporting spinal cord research for over twenty years. I'm familiar with the most practical and promising research that needs to be developed to reverse my condition. Time does not permit me to go into this, but you can see on the handout that currently there are over 56 successful treatments using adult stem cells, while embryonic stem cells have produced absolutely no safe and effective human treatments. Check it out for yourselves—the facts support what I am saying.

It is wrong to kill and it is wrong to lie. Extracting stem cells from an embryo, whether from an IVF clinic or through the cloning process, destroys a living human being. Misleading patients, journalists, and political leaders into believing that the technologies being promoted here offer the best hope for cure is an outright lie.

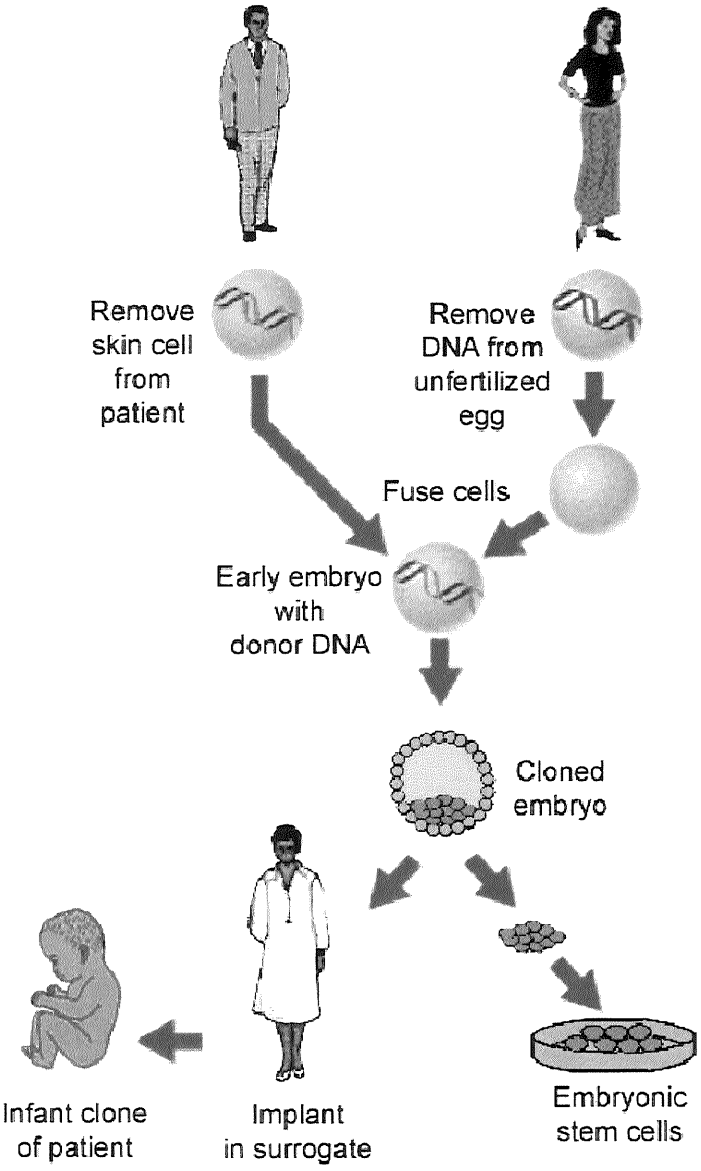
If the senate wants to support those whose research ambitions are banned and criminalized in other progressive nations, whose technologies would involve the exploitation of women, and whose quest for funding would divert precious research dollars from far more promising cure technologies, then by all means support this present legislation.

But please, don't use my life or the lives of others who are desperately hoping for a cure to justify your decision.

# Somatic Cell Nuclear Transfer (Cloning)

Cloning-To-Produce-Children
"Reproductive" Cloning

Cloning-For-Biomedical-Research
"Therapeutic" Cloning




Adapted From Diagram By David Prentice

There are two types of cloning currently under debate. The first is often referred to as "Reproductive Cloning," but the term recommended by the President's Council on Bioethics (PCB), a group that covers the entire political spectrum, is "Cloning-To-Produce-Children." The second is often referred to as "Therapeutic Cloning," but the term recommended by the PCB is "Cloning-For-Biomedical-Research."

The cloning *process* is identical in both procedures. The only difference is the intended *use* of the cloned human embryo. In one case the embryo is implanted in the womb to develop into whatever stage is desired for experimental purposes. In the other the embryo is destroyed at about 4-5 days when its inner cell mass is extracted.

# Stem Cells

**Stem cells** are cells found in embryos and humans throughout their lifespan that have the ability to proliferate (divide many times) and differentiate (change into specialized cells).

Stem cells in the inner cell mass form most or all of the 210 tissue types in the human body. Stem cells found throughout the adult form specific cells needed by the body to generate replacements for old or damaged cells. For example, bone marrow stem cells continually replenish red blood cells, white blood cells, and platelets.

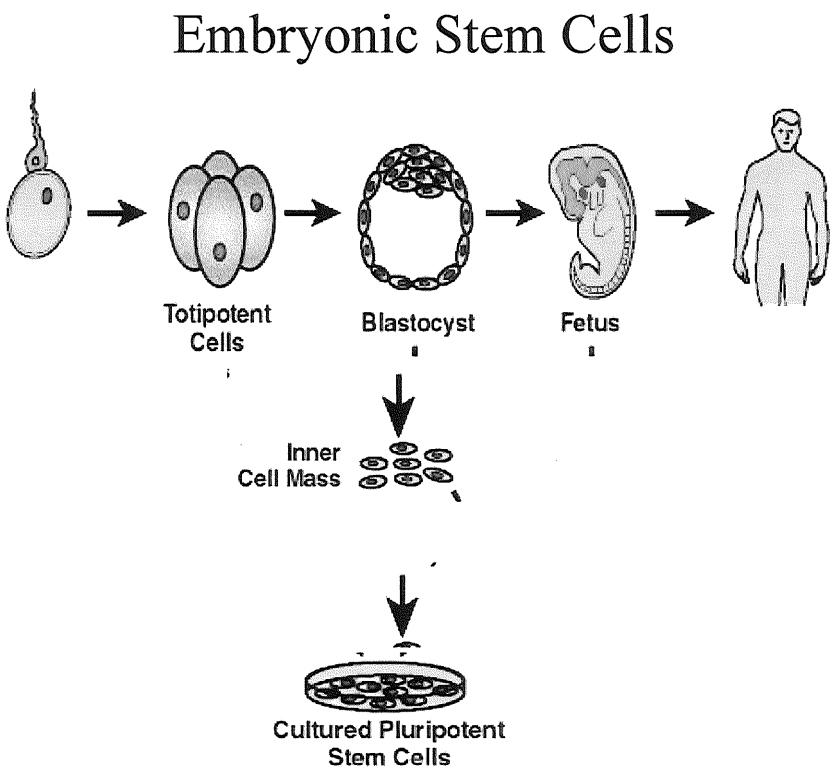



Diagram adapted from NIH website

**Embryonic stem cells** were first obtained from mice in 1981 and from humans in 1998. One source of human embryonic stem cells would be excess embryos from in vitro fertilization clinics. This diagram shows how stem cells are obtained from embryos.

Human development begins when a sperm fertilizes an egg and creates a single cell (zygote). This cell continues to divide, and approximately four days after fertilization these cells form a hollow sphere of cells, called a **blastocyst**. Inside this sphere is a cluster of cells called the **inner cell mass**.

It is this inner mass of stem cells that is extracted from the embryo and cultured for research. Extracting these cells essentially destroys the embryo.

In a healthy embryo, the cells in the outer layer of the blastocyst (trophoblast) form the placenta and other tissues needed for fetal development. The cells in the inner cell mass develop into the fetus, and eventually the baby.

# SECONDHAND SMOKE

THIS WEB LOG CONSIDERS ISSUES INVOLVING ASSISTED SUICIDE/EUTHANASIA, BIOETHICS, HUMAN CLONING, BIOTECHNOLOGY, AND THE DANGERS OF ANIMAL RIGHTS/LIBERATION. MY VIEWS EXPRESSED HERE, AS IN MY BOOKS AND OTHER WRITINGS, REFLECT MY UNDERSTANDING THAT THE PHILOSOPHY OF HUMAN EXCEPTIONALISM IS THE BEDROCK OF UNIVERSAL HUMAN RIGHTS. OR, TO PUT IT ANOTHER WAY: HUMAN LIFE MATTERS.

THURSDAY, FEBRUARY 17, 2005

## Minnesota Now Has Legislation to Clone and Gestate

The days when researchers "only" wanted to derive embryonic stem cells solely from embryos leftover from IVF treatments that were doomed to be discarded anyway, are long gone. Last year, New Jersey legalized human cloning, implantation of cloned embryos into wombs, and gestation through the ninth month. In the last two years, Illinois, Delaware, Maryland, and Texas, tried unsuccessfully to legalize the same thing. Current legislation in Washington would also permit cloning through the ninth month, as I reported two days ago. Now, it turns out, Minnesota also has a cloning bill pending that would explicitly legalize human cloning (somatic cell nuclear transfer), and permit implantation of cloned embryos and their gestation through the ninth month for purposes of obtaining stem cells. Specifically, Senate File No 730 states:

"The policy of the state of Minnesota is that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from ANY SOURCE, including SOMATIC CELL NUCLEAR TRANSFER, shall be permitted and that full consideration of the ethical and medical implications of this research be given." (My emphasis.)

Notably, the bill does NOT outlaw implanting embryos--whether cloned or natural--into natural or artificial uteri for purposes of gestating late stage embryos or fetuses for use in deriving stem cells. This means implantation of human embryos for research and

Wesley J. Smith

PREVIOUS POSTS

destruction would be legal, since, by definition, that which is not illegal is legal. It is also important to note that embryos can only be maintained in Petri dishes for up to about 10 days. Human embryonic germ cells, which are specifically referenced in S.F. 730, are derived from gestated embryos at between 6-8 weeks of development. Moreover, adult stem cells can be obtained from fetuses, infants, and children, as well as adults.

Put this altogether, and if this bill passes in its current form, Minnesota would explicitly permit human cloning, implantation of cloned or natural embryos, and their destruction for obtaining stem cells through the ninth month.

This bill marks the seventh attempt of which I am aware, to permit radical research on human life well beyond the Petri dish stage. This can't be done yet technologically, but the legal groundwork is clearly being laid today for very radical work. e.g. fetal farming, that is anticipated to be done tomorrow. Indeed, anyone who still believes that therapeutic cloning and embryonic stem cell research is intended to be restricted to leftover embryos from IVF procedures and cloned embryos in Petri dishes is simply not paying attention to the facts.

POSTED BY WESLEY J. SMITH AT 1:21 PM

0 COMMENTS:

POST A COMMENT

<< Home

| Country | Reproductive cloning prohibited by national law | Research cloning prohibited by national law | Germline engineering prohibited by national law |
|---|---|---|---|
| **Australia** | Yes | Yes | Yes |
| **Austria** | Yes (implicitly) | Yes (implicitly) | Yes (implicitly) |
| **Argentina** | Yes | Yes | No |
| **Belgium** | Yes | Allowed | Yes |
| **Bulgaria** | Yes | No | Yes |
| **Brazil** | Yes | No | Yes |
| **Canada** | Yes | Yes | Yes |
| **China** | No (Guidelines prohibit it) | No (Allowed underguidelines) | No |
| **Colombia** | Yes | Allowed | No |
| **Costa Rica** | Yes | Yes (implicitly) | Yes |
| **Denmark** | Yes | Yes | Yes |
| **Estonia** | Yes | Yes | No |
| **Finland** | Yes | Yes | Yes |
| **France** | Yes | Yes | Yes |
| **Georgia** | Yes | No | Yes |
| **Germany** | Yes | Yes | Yes |
| **Greece** | Yes (implicitly) | No | No |
| **Hungary** | Yes | No | Yes |
| **Iceland** | Yes | Yes | No |
| **India** | No (Prohibited under guidelines) | No (Prohibited under guidelines) | No (Prohibited under guidelines) |
| **Ireland** | Yes (implicitly) | No | No |
| **Israel** | Yes | Yes | Yes |
| **Italy** | Yes | Yes | Yes |
| **Japan** | Yes | Yes | Yes |

| Country | Reproductive cloning prohibited by national law | Research cloning prohibited by national law | Germline engineering prohibited by national law |
|---|---|---|---|
| **Latvia** | Yes | Yes | No |
| **Lithuania** | Yes | Yes | No |
| **Netherlands** | Yes | Yes | No |
| **New Zealand** | Yes | No | No |
| **Norway** | Yes | Yes | Yes |
| **Panama** | Yes | Yes | No |
| **Peru** | Yes | Yes | No |
| **Poland** | Yes | No | No |
| **Portugal** | No (Prohibited under guidelines) | No | No |
| **Romania** | Yes | | |
| **Russia** | Moratorium | No | No |
| **Singapore** | Yes | No | No |
| **Slovakia** | Yes | Yes (implicitly) | No |
| **Slovenia** | Yes | Yes | Yes |
| **Spain** | Yes | Yes | Yes |
| **South Africa** | Yes | No (Prohibited under guidelines) | Yes |
| **South Korea** | Yes | No | No |
| **Sweeden** | Yes | Yes | Yes |
| **Switzerland** | Yes | Yes | Yes |
| **Tunisia** | No (Prohibited under guidelines) | No (Prohibited under guidelines) | No |
| **Thailand** | Yes | No | No |
| **Turkey** | Yes | No | No |
| **United Kingdom** | Yes | No | No |
| **Vietnam** | Yes | No | No |

**Key**
Yes - prohibition by law
No - no legislation in place

# Current Stem Cell Treatments

**Successful Embryonic Stem Cell Treatments: 0**
**Successful Adult Stem Cell treatments: 56**

1. Brain Cancer
2. Retinoblastoma
3. Ovarian Cancer
4. Merkel Cell Cancer
5. Testicular Cancer
6. Lymphoma
7. Acute Lymphobolastic Leukemia
8. Acute Myelogenous Leukemia
9. Chronic Myelogenous Leukemia
10. Juvenile Myelomonocytic Leukemia
11. Angioimmunoblastic Lymphadenopathy with Dysproteinemia
12. Multiple Myeloma
13. Myelodysplasia
14. Breast Cancer
15. Neuroblastoma
16. Non-Hodgkin's Lymphoma
17. Hodgkin's Lymphoma
18. Renal Cell Carcinoma
19. Various Solid Tumors
20. Soft Tissue Sarcoma
21. Scleromyxedema
22. Multiple Sclerosis
23. Crohn's Disease
24. Rheumatoid Arthritis
25. Juvenile Arthritis
26. Systemic Lupus
27. Polychondritis
28. Systemic Vasculitis
29. Sjogren's Syndrome
30. Behcet's Disease
31. Myasthenia
32. Red Cell Aplasia
33. Autoimmune Cytopenia
34. X-Linked Lymphoproliferative Syndrome
35. X-Linked Hyperimmunoglobuline-M Syndrome
36. Severe Combined Immunodeficiency Syndrome-X1
37. Sickle Cell Anemia
38. Sideroblastic Anemia
39. Waldenstrom's Macroglobulinemia
40. Aplastic Anemia
41. Amegakaryocytic Thrombocytopenia
42. Chronic Epstein-Barr Infection
43. Fanconi's Anemia
44. Diamond Blackfan Anemia
45. Thalassemia
46. Stroke
47. Osteogenesis Imperfecta
48. Sandhoff Disease
49. Corneal Regeneration
50. Hemophagocytic Lymphohistiocytosis
51. Primary Amyloidosis
52. Limb Gangrene
53. Surface Wound Healing
54. Heart Damage
55. Parkinson's Disease
56. Spinal Cord Injury

www.stemcellresearch.org

# Differentiating stem-cell research fact from fiction

JEAN SWENSON

Christopher Reeve and I had several things in common — we were both born in 1952, we both shattered our spinal cords and our lives through unforeseen accidents, and we've both wanted desperately to be free from our wheelchairs and the many medical problems associated with spinal cord injury.

I was saddened to hear of Reeve's death, as I've appreciated the awareness he's brought to curing spinal cord injuries. However, I believe he and many of us have been misled by the promises we keep hearing about embryonic stem cells being the key to curing Alzheimer's, Parkinson's, diabetes and a host of other maladies. After supporting spinal cord research for years and exploring the possibilities, I believe adult stem cells, not embryonic, are far more likely to produce successful treatments.

Although we hear plenty of general testimonies that play on our emotions, there appears to be almost a blackout of accurate scientific information about stem cells.

Stem cells are cells that can proliferate (duplicate many times) and differentiate (change into specialized cell types needed by the body). For example, stem cells in your blood continuously produce new blood cells to replace worn-out ones.

Stem cells found in both adults and embryos are currently being studied by researchers to replace cells lost through disease or injury. However, research is showing that adult stem cells are actually medically superior to embryonic stem cells.

First, a patient's body will reject embryonic stem cells as foreign. Adult stem cells obtained from the patient's own body are perfectly matched genetically and do not cause tissue rejection. Also, embryonic stem cells are prone to abnormal genetic "expression," and scientists acknowledge a lack of suitable tests to detect such abnormalities.

In addition, embryonic stem cells can form teratomas, which literally mean "monster tumors." These tumors often contain different cell types, such as teeth, hair or bone tissue. Adult stem cells, which are easier to control, do not form these tumors.

Proponents of embryonic stem cells allege that only embryonic stem cells can form all body tissue types, but researchers are continually showing that adult stem cells can also form specialized cells of other tissues.

For example, a University of Minnesota research team has discovered adult stem cells in human bone marrow that can be made to differentiate into many different cell types and that do not form teratomas.

Stem cells found in blood drained from human umbilical cords after birth can become many types of cells needed to treat disability and disease, such as heart cells, beta islets and neurons.

Embryonic stem cell researchers admit they are years away from effective procedures safe enough for human use, while the medical world is continually exploding with new treatments using adult stem cells.

For example, American spinal cord injured patients have gained some return of function after traveling to Portugal to have tissues rich in stem cells from their own nasal cavities transplanted into their spinal cords. The Spinal Cord Society, to which I belong, will be undertaking human trials in January, using this technique in combination with other treatments.

Stem cells isolated from the blood of a teen, whose heart was pierced with a 3-inch nail, were injected into the coronary artery that supplies blood to the heart. A few days later, his heart's functioning began improving, indicating possible rebuilding of heart muscle. Today, he's again playing high school soccer.

Christopher Reeve

A California man with Parkinson's disease was treated by removing tissue from his own brain, culturing stem cells from this tissue and then injecting them back into his brain. A year later, the man's symptoms were reduced by more than 80 percent. He has remained in clinical remission for four years.

One astute participant in the second presidential debate asked the candidates:

"Thousands of people have already been cured or treated by the use of adult stem cells or umbilical-cord stem cells. However, no one has been cured by using embryonic stem cells. Wouldn't it be wise to use stem cells obtained without the destruction of an embryo?"

We who have a vested interest in cure would like to ask our politicians and researchers the same question.

*Swenson, of St. Paul, has been a quadriplegic since a 19[illegible] accident and has been actively supporting spinal cord injury cure research. E-mail her at jswenson@usfamily.net.*

Dr. Kirk Allison

**Human Life Alliance Committee Testimony**

Human Life Alliance (HLA), an association of pro-life Minnesotans founded in 1977, encourages you to consider the ramifications of State investment in stem cell research. Whereas HLA is in full support of stem cell research, we are directly opposed to embryonic stem cell research while encouraging adult and cord blood stem cell research.

First let me say the reason we are opposed to embryonic stem cell research is because it is a destruction of human life at its very beginning. This is not philosophy or religious conjecture, it is scientific fact. A newly conceived child of a woman and a man, the joining of the sperm and the fertilized egg, can only be human, it cannot be a dog, cat, or any other animal. Two human parents can only produce a human offspring; all major biologists are in agreement with this statement. On the other hand, both adult stem cell and cord blood stem cell research provide us with the hope of lifesaving and life changing medical treatments. However, embryonic stem cell research has yet to provide any successful treatments despite over 20 years of private funding.

For example, look at the fruits of recent adult and cord blood stem cell treatment:

**Korean Woman Walks with Successful Transplant**
A South Korean woman who was paralyzed and bedridden for 20 years is walking again after stem cells harvested from umbilical cord blood were injected into her spinal cord. At a news conference with South Korean researchers, 37-year-old Hwang MiSoon walked and told members of the press she considered it a miracle. One of the researchers told the press, "We were all surprised at the fast improvements in the patient. We have glimpsed a silver lining over the horizon." *(LifeNews.com 11/30/04)*

**Brazilian Woman Regains Ability to Talk**
A 54-year-old Brazilian woman recovered from a brain hemorrhage that left her paralyzed and unable to talk after scientists transplanted adult stem cells from her pelvis into her brain. Hers is the first reported successful treatment of this condition. *(LifeNews.com 11/23/04)*

**Leukemia Patients Benefit from Umbilical Cord Blood**
Recent European and US studies have found that leukemia patients who received umbilical cord blood were just as likely to be leukemia-free two years later as those who received bone marrow. Umbilical cord blood offers an advantage in that it is unlikely to attack a patient's immune system. It is estimated that adult stem cell transplants save 20 to 30 percent of patients who hope to develop new immune systems. Umbilical cords that are normally discarded after birth could provide new hope for these patients. *(LifeNews.com 11/27/04)*

**Spinal Cord Injuries Improved**
Laura Dominguez and Susan Fajt, both paralyzed in automobile accidents, can now walk with the aid of braces or a "walker" frame. Dr. Carlos Lima of Portugal has successfully treated them and dozens of other patients by transplanting stem cells from their own olfactory mucosa to the site of the spinal cord injury. Their rehabilitation continues, with the goal of being able to walk unassisted. *(Life Insight Nov./Dec. 2004)*

**20-Year-Old Spinal Injury Reversed**
Hwang Mi-soon of South Korea now walks with a frame after being paralyzed for 20 years. She received transplanted cord blood stem cells at the site of her spinal injury. *(Life Insight Nov./Dec. 2004)*

Thank you for your time.

*The handout and this statement were prepared by Human Life Alliance. Further documentation is available upon request through email at director@humanlife.org or by calling our Saint Paul office at 651 484 1040.*

## Human Life Alliance and Stem Cell Research

First of all we must clarify that there are two distinctly different sources from which to gather stem cells: embryonic and adult. Embryonic stem cell research uses stem cells obtained from live human embryos that are 5-7 days old. The process of harvesting the stem cells kills the human child. Adult stem cell research uses stem cells from many different places in the adult body as well as from umbilical cord blood (neither of which harm the donors).

We at Human Life Alliance are **against embryonic stem cell research** for the following reasons:

1. It kills a living, growing human child that is unique with its own unique DNA blueprint that establishes immediately upon conception whether that child is female or male, blue-eyed or brown-eyed, etc.
2. There has never been a successful clinical use for embryonic stem cells. The head of the US National Institute of Health, Elias Zerhouni, said "…there has been no research verifying that embryonic stem cells can be medically useful."[1]
3. Embryonic stem cell research in clinical trials with rats has been very problematic as it causes tumors in the rats. In a human embryonic stem cell trial in China, the stem cells were injected into a woman's brain. She died and the autopsy revealed a tumor filled with hair, bone, and skin at the injection site.[2] Other human trials in the US on Parkinson's patients caused uncontrollable movements and jerking that the doctors could not reverse.[3]
4. Embryonic stem cell research is closely tied to cloning (another name for cloning is Somatic Cell Nuclear Transfer). If it ever becomes widely used, the embryos that are already made will not be sufficient, and scientists will begin pushing to be allowed to clone embryos to use for research.

Human Life Alliance strongly **supports adult stem cell research** for the following reasons:

1. Research by Catherine Verfaillie at the University of Minnesota suggests that adult stem cells "..have all the potential of embryonic stem cells and even have an advantage: They seem incapable of growing into tumors."[4] Adult stem cells seem to be just as flexible as embryonic stem cells in changing into other types of tissues.
2. Since stem cells can be drawn right from the patient, anti-rejection drugs to suppress the immune system are not needed with adult stem cells.
3. Adult stem cells are very easy to harvest (skin, muscle, marrow, fat, umbilical cord blood, placenta, nasal epithelium, etc.)
4. Harvesting adult stem cells does no harm to the donor.
5. **Adult stem cells are already extremely successful in curing or treating over a 100 different kinds of diseases!**

See attached page for a list of current ADULT stem cell applications and committee testimony.

[1] Health and Medicine Week, Dec 22, 2003 p629
[2] Krauthammer, Charles. (August 20-27, 2001) The great stem cell hoax. *The Weekly Standard.* 6 (46)
[3] Kolata, Gina. (March 8, 2001) Parkinson's stem-cell implants yield nightmarish side effects. *The Tampa Tribune.*
[4] Weiss, Rick. (Feb 2, 2005). Marrow has cells like stem cells, tests show. *Washington Post.*

**Acute Leukemia's**
Acute Lymphoblast Leukemia (ALL)
Acute Myelogenous Leukemia (AML)
Acute Biphenotypic Leukemia
Acute Undifferentiated Leukemia

**Chronic Leukemia's**
Chronic Myelogenous Leukemia (CML)
Chronic Lymphocytic Leukemia (CLL)
Juvenile Chronic Myelogenous Leukemia (JCML)
Juvenile Myelomonocytic Leukemia (JMML)

**Myelodysplastic Syndromes**
Refractory Anemia (RA)
Refractory Anemia with Ringed Sideroblasts (RARS)
Refractory Anemia with Excess Blasts (RAEB)
Refractory Anemia with Excess Blasts in Transformation (RAEB-T)
Chronic Myelomonocytic Leukemia (CMML)

**Stem Cell Disorders**
Aplastic Anemia (Severe)
Fanconi Anemia
Paroxysmal Nocturnal Hemoglobinuria (PNH)
Pure Red Cell Aplasia

**Myeloproliferative Disorders**
Acute Myelofibrosis
Agnogenic Myeloid Metaplasia (myelofibrosis)
Polycythemia Vera
Essential Thrombocythemia

**Lymphoproliferative Disorders**
Non-Hodgkin's Lymphoma
Hodgkin's Disease

**Phagocyte Disorders**
Chediak-Higashi Syndrome
Chronic Granulomatous Disease
Neutrophil Actin Deficiency
Reticular Dysgenesis

**Other Inherited Disorders**
Lesch-Nyhan Syndrome
Cartilage-Hair Hypoplasia
Glanzmann Thrombasthenia
Osteopetrosis
Adrenoleukodystrophy

**Inherited Platelet Abnormalities**
Megakaryocytosis / Congenital Thrombocytopenia

**Inherited Metabolic Disorders**
Mucopolysaccharidoses (MPS)
Hurler's Syndrome (MPS-IH)
Scheie Syndrome (MPS-IS)
Hunter's Syndrome (MPS-II)
Sanfilippo Syndrome (MPS-III)
Morquio Syndrome (MPS-IV)
Maroteaux-Lamy Syndrome (MPS-VI)
Sly Syndrome, Beta-Glucuronidase Deficiency (MPS-VII)
Adrenoleukodystrophy
Mucolipidosis II (I-cell Disease)
Krabbe Disease
Gaucher's Disease
Niemann-Pick Disease
Wolman Disease
Metachromatic Leukodystrophy

**Histiocytic Disorders**
Familial Erythrophagocytic Lymphohistiocytosis
Histiocytosis-X
Hemophagocytosis

**Inherited Erythrocyte Abnormalities**
Beta Thalassemia Major
Sickle Cell Disease

**Inherited Immune System Disorders**
Ataxia-Telangiectasia
Kostmann Syndrome
Leukocyte Adhesion Deficiency
DiGeorge Syndrome
Bare Lymphocyte Syndrome
Omenn's Syndrome
Severe Combined Immunodeficiency (SCID)
SCID with Adenosine Deaminase Deficiency
Absence of T & B Cells SCID
Absence of T Cells, Normal B Cell SCID
Common Variable Immunodeficiency
Wiskott-Aldrich Syndrome
X-Linked Lymphoproliferative Disorder

**Plasma Cell Disorders**
Multiple Myeloma
Plasma Cell Leukemia
Waldenstrom's Macroglobulinemia
Amyloidosis

**Other Malignancies**
Ewing Sarcoma
Neuroblastoma
Renal Cell Carcinoma
Retinoblastoma

**Potential Future Applications**
Alzheimer's Disease
Cardiac Disease
Diabetes
Lupus
Multiple Sclerosis
Muscular Dystrophy
Parkinson's Disease
Rheumatoid Arthritis
Spinal Cord Injury
Stroke

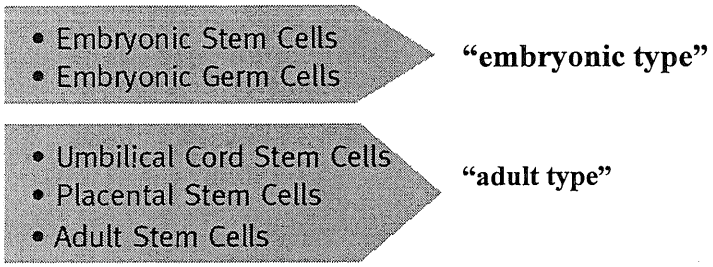
# Stem Cell Research, Cloning & Human Embryos

## Stem Cells

**WHAT IS A STEM CELL?**
A stem cell is essentially a "blank" cell, capable of becoming another more differentiated cell type in the body, such as a skin cell, a muscle cell, or a nerve cell.

**WHY ARE STEM CELLS IMPORTANT?**
Stem cells can be used to replace or heal damaged tissues and cells in the body.

**WHAT ARE THE TWO BROAD CLASSES OF STEM CELLS?**
The two basic types of stem cells are embryonic type and adult type.




**WHERE DO EMBRYONIC TYPE STEM CELLS COME FROM?**
**Embryos**—Embryonic stem cells are obtained by harvesting living embryos which are generally 5-7 days old. The removal of embryonic stem cells invariably results in the destruction of the embryo.

- **Fetuses**—Another kind of stem cell called an embryonic germ cell can be obtained from either miscarriages or aborted fetuses.

**WHERE DO ADULT TYPE STEM CELLS COME FROM?**
- **Umbilical Cords, Placentas and Amniotic Fluid**—Adult type stem cells can be derived from various pregnancy-related tissues.
- **Adult Tissues**—In adults, stem cells are present within various tissues and organ systems. These include the bone marrow, liver, epidermis, retina, skeletal muscle, intestine, brain, dental pulp, and elsewhere. Even fat obtained from liposuction has been shown to contain significant numbers of adult type stem cells.
- **Cadavers**—Neural stem cells have been re-moved from specific areas in post-mortem human brains as late as 20 hours following death.

**HOW DO EMBRYONIC AND ADULT STEM CELLS COMPARE?**
**Embryonic Stem Cell Advantages**

1 Flexible—appear to have the potential to make any cell

2 Immortal—one ES cell line can potentially provide an endless supply of cells with defined characteristics

3 Availability—embryos from in vitro fertilization clinics

**Embryonic Stem Cell Disadvantages**

1 Difficult to differentiate uniformly and homogeneously into a target tissue

` Immunogenic—ES cells from a random embryo donor are likely to be rejected after transplantation

Tumorigenic—Capable of forming tumors or promoting tumor formation

4 Destruction of developing human life

**Adult Stem Cell Advantages**

1 Special adult-type stem cells from bone marrow and from umbilical cord have been isolated recently which appear to be as flexible as the embryonic type

2 Already somewhat specialized—inducement may be simpler

3 Not immunogenic—recipients who receive the products of their own stem cells will not experience immune rejection

4 Relative ease of procurement—some adult stem cells are easy to harvest (skin, muscle, marrow, fat), while others may be more difficult to obtain (brain stem cells). Umbilical and placental stem cells are likely to be readily available

5 Non-tumorigenic—tend not to form tumors

6 No harm done to the donor

**Adult Stem Cell Disadvantages**

**1** Limited quantity—can sometimes be difficult to obtain in large numbers

**2** Finite—may not live as long as ES cells in culture

**3** Less flexible (with the exception of #1 above)—may be more difficult to reprogram to form other tissue types

## WHY ARE ADULT STEM CELLS PREFERABLE TO EMBRYONIC STEM CELLS?

Adult stem cells are a "natural" solution. They naturally exist in our bodies, and they provide a natural repair mechanism for ma tissues of our bodies. They belong in the microenvironment of an adult body, while embryonic stem cells belong in the microenvironment of the early embryo, not in an adult body, where they tend to cause tumors and immune system reactions. Most importantly, *adult stem cells have already been successfully used in human therapies for many years*. As of the date of this publication, *NO therapies in humans have ever been successfully carried out using embryonic stem cells*. New therapies using adult type stem cells, on the other hand, are being developed all the time. There are many examples of success stories using adult stem cells.

## TREATMENTS FROM ADULT STEM CELLS

### Spinal Cord Injury

Laura Dominguez is shown here in Washington D.C. at a 2004 hearing on adult stem cell research. As a result of a car accident in 2001, Laura broke her neck and was paralyzed from the chest down. She was treated with a mix of adult stem cells and other cells obtained from olfactory tissue inside her nose. The cells were transplanted across the injury site in her damaged spinal cord, and several months after the surgery, she was able to move her foot. She can now walk with braces. Her remarkable progress is continuing, and several other spinal cord injury patients like her are also showing benefits from the transplant surgery. Dr. Carlos Lima performed the surgery in Portugal, but neurologists in the U.S. are seeking FDA approval to begin offering Dr. Lima's therapy in the United States.

### Leukemia

Patrizia Durante was diagnosed with acute leukemia six months into her pregnancy. Her daughter, Victoria Angel, was born healthy, but Durante was given only six months to live. The stem cells from the blood of her daughter's umbilical cord were used for a transplant. Several years later, Durante is in full remission. "She saved her mommy," Durante told reporters. "She's a little miracle. That's why we named her Victoria Angel. She's my little angel."

### Krabbe's Leukodystrophy

Gina Rugari was born with Krabbe's leukodystrophy. This is a rare, degenerative enzyme disorder of the nervous system, in which the baby shows initial signs of irritability and developmental delay or regression. Seizures and fevers often follow, then blindness and deafness until the baby dies, usually before age 2. Gina was tested for Krabbe's leukodystrophy shortly after she was born, because she had a brother who had died from the disease. Doctors treated Gina with chemotherapy to destroy her immune system, and introduced new umbilical cord blood stem cells from a closely matched donor. The transplanted cells produced the missing enzyme. Her body accepted the cells, and she is thriving several years after the transplant.

### Parkinson's Disease

Dennis Turner was diagnosed with Parkinson's Disease and by early 1991 he suffered extreme shaking of the right side of his body and became unable to use his right arm. Neurosurgeon Dr. Michele Levesque removed a small tissue sample from Mr. Turner's brain, and isolated adult neural stem cells. He multiplied and matured these cells into nerve cells, and injected them back into the left side of Mr. Turner's brain, which controls the right side of the body. Soon afterwards, the Parkinson's symptoms began to improve in his right side. His trembling decreased, until to all appearances it disappeared. Neurological evaluation indicated a marked improvement in his symptoms, which lasted for about 5 years. Because Parkinson's is a progressive ailment, his condition is continuing to deteriorate, but as Mr. Turner recently testified at a U.S. Senate Committee hearing, "...I have no doubt that because of this treatment I've enjoyed five years of quality life that I feared had passed me by." He enthusiastically expressed a willingness to undergo a repeat surgery of this sort to further slow the progression of his symptoms.

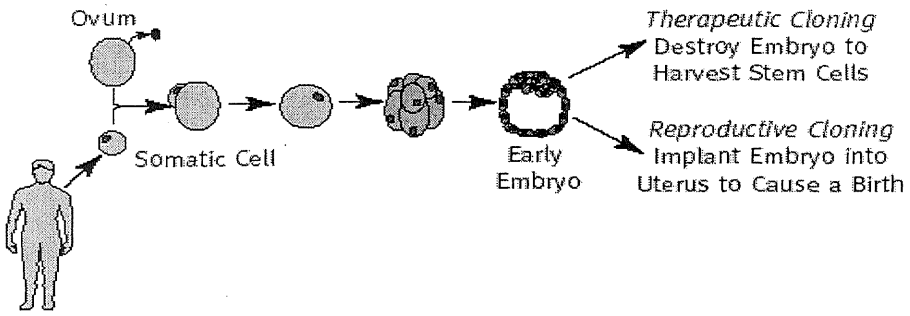
## IS STEM CELL RESEARCH ETHICAL?

Most types of stem cell research are morally acceptable and laudable. Only research using embryonic stem cells raises insuperable moral objections. An ethical overview:

- *Embryonic Stem Cells*—always morally objectionable, because the human embryo must be destroyed in order to harvest its st cells
- *Embryonic Germ Cells*—morally objectionable when utilizing fetal tissue derived from elective abortions, but morally acceptable when utilizing material from spontaneous abortions (miscarriages) if the parents give informed consent
- *Umbilical Cord Stem Cells*—morally accept-able, since the umbilical cord is no longer required once the delivery has been completed
- *Placentally-Derived Stem Cells*—morally acceptable, since the afterbirth is no longer required after the delivery has been completed
- *Adult Stem Cells*—morally acceptable, assuming informed consent from the adult donor

# Cloning

**WHAT ARE THE TWO TYPES OF CLONING?**
The first and most well known type of cloning is cloning to produce children, or "reproductive cloning." The second type of cloning is cloning for biomedical research, or "therapeutic cloning."




**WHAT IS REPRODUCTIVE CLONING (CLONING TO PRODUCE CHILDREN)?**
Humans may one day be able to be cloned using a procedure similar to the one used to generate Dolly the sheep. This kind of cloning involves taking the nucleus of a body (somatic) cell and introducing it into an egg cell (ovum) which has had its nucleus removed. The resultant cloned embryo is then implanted into a uterus to bring it to birth. The cloned embryo is an identical twin of the person who donated the starting somatic cell. Cloning is simply another approach to mimicking the biology that generates identical twins.

**WHAT IS THERAPEUTIC CLONING (CLONING FOR RESEARCH)?**
Therapeutic cloning involves making a cloned embryo by the same series of steps as reproductive cloning, but instead of implanting it into a uterus to be born, the embryo is destroyed to harvest its stem cells. Hence, therapeutic cloning is identical to reproductive cloning except for the final step. Therapeutic cloning is sometimes referred to as the "clone and kill" technique. The aim is to obtain rejection-proof stem cells for transplantation into the person from whom the clone was made. Because stem cells from the clone are actually from the identical twin of the person cloned, they should theoretically be a good match and not be rejected.

**WHY IS HUMAN REPRODUCTIVE CLONING WRONG?**
Cloning participates in the basic evil of moving human procreation out of the setting of committed marital intimacy and into the laboratory. Human procreation should not take place in the laboratory because it is inherently dehumanizing to bring a new human being into the world through means which replace the marital act. Each of us has a right to be brought into the world as the fruit and expression of marital love, rather than as the product of technical domination and manufacturing protocols. Procreation is not meant to be replaced by production. There is a dignity both to the process of procreation as established by God through sexual self-giving, and the dignity of the life itself which is engendered by that process. Cloning threatens human dignity on both of those levels.

Cloning also represents a sort of genetic engineering. Instead of choosing just a few of the features you'd like your offspring to have, like greater height or greater intelligence, cloning could allow you to choose all of the features, so it represents an extremely serious form of domination and manipulation by parents over their own children. It represents a type of parental power that parents are not intended to have. Ultimately, cloning is a type of human breeding, a despotic attempt by some individuals to dominate and pre-determine the make-up of others. With cloning you also distort the relationships between individuals and generations. If a woman were to clone herself, using her own egg, her own somatic cell, and her own womb, she wouldn't need to have a man involved at all.

Oddly, she would end up giving birth to her own identical twin—a twin sister who would also be her daughter.

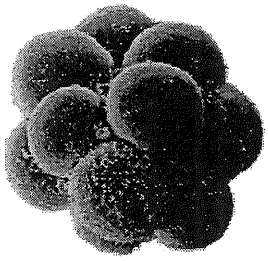
**WHY IS HUMAN THERAPEUTIC CLONING WRONG?**
If human reproductive cloning—the bringing to birth of a new child who is an identical twin to somebody else—is wrong, then therapeutic cloning is worse. Therapeutic cloning is the creation of that same identical twin for the premeditated purpose of ending her life in order to harvest her tissues. In sum, there is a grave evil involved in therapeutic cloning because life is created for the explicit purpose of destroying it. With a cloned birth, at least we would end up with a baby that is alive. Human therapeutic cloning, the artificial creation of a human life for the sole purpose of her exploitation and destruction will always be gravely unethical, even if the desired end is a very good one, namely the curing of diseases. Therapeutic cloning sanctions the direct and explicit exploitation of one human being by another, in this case, the exploitation of the weak by the powerful.

The danger of therapeutic cloning lies in the intentional creation of a subclass of human beings, made up of those still in their embryonic or fetal stages, who can be freely exploited and discriminated against by those fortunate enough to have already passed beyond those early embryonic stages.

Therapeutic cloning raises further serious slippery-slope concerns. The temptation to make embryos that can be exploited for their stem cells offers the further temptation to grow those cloned embryos within a uterus to the point of a fetus. Such a fetus can then be aborted and conveniently harvested for needed organs, avoiding the trouble of having to start from scratch with undifferentiated stem cells.

# Human Embryos

**WHERE DO HUMAN EMBRYOS COME FROM?**



4-day-old human embryo at the 16-cell stage

- From the combining of sperm and egg (fertilization)
- From embryo splitting (fission)
- From somatic cell nuclear transfer (cloning)

**ARE EMBRYOS HUMAN? ARE THEY REALLY ONE OF US?**

Embryos are no different in their essential humanity from a fetus in the womb, a 10 year-old boy, or a 100 year-old woman. At every stage of development, human beings (whether zygote, blastocyst, embryo, fetus, infant, adolescent, or adult) retain their identity as an enduring being that grows towards its subsequent stage(s); embryos are integral beings structured for maturation along their pror time line. Despite their unfamiliar appearance, embryos are what very young humans are supposed to look like.

**ISN'T IT A MATTER OF RELIGIOUS BELIEF AS TO WHEN HUMAN BEINGS BEGIN?**

It is not a matter of religious belief, but a matter of biology. A human embryo is a human being, a being that is clearly and unmistakably human. It is not a zebra-type of being, a plant-type of being or some other kind of being. Each of us was once an embryo, and this affirmation does not depend on religion, belief systems, or imposing anything on anyone. It depends only on a grasp of basic biology. It is a matter of empirical observation. Once you are constituted a human being (which always occurs at fertilization or at an event that mimics fertilization like cloning), you are a new member of the human race who must be protected unconditionally. The human embryo is a being that is human, and such beings are inviolable entities, because that's what we all directly spring from at the root level.

**WHY IS THE DESTRUCTION OF HUMAN EMBRYOS WRONG?**

The well-known moral principle that good ends do not justify immoral means applies directly here. Once you're a being who is *human*, you are the bearer of *human* rights and you should never be violated for any reason. We know that the human embryo is a human being because it possesses an internal code for self-actualization and is an organism with an independent and inherent teleology (goal-directedness) to develop into an adult, and is physiologically alive and genetically human. Our existence as human beings is a continuum that extends all the way back to our origins in that humble ball of cells we call an embryo. Each of us has our origins in such an embryo, and therefore human embryos should never be depersonalized or instrumentalized for research purposes by strip-mining them for their cells or tissues.

# The 10 Great Media Myths *in the Debate Over Stem Cell Research*

**Myth 1.** Stem cells can only come from embryos. In fact stem cells can be taken from umbilical cords, the placenta, amniotic fluid, adult tissues and organs such as bone marrow, fat from liposuction, regions of the nose, and even from cadavers up to 20 hours after death.

**Myth 2.** Christians are against stem cell research. There are four categories of stem cells: embryonic stem cells, embryonic germ cells, umbilical cord stem cells, and adult stem cells. Given that germ cells can come from miscarriages that involve no deliberate interruption of pregnancy, Christians in general oppose the use of only one of these four categories, i.e., embryonic stem cells. In other words, most Christians approve of three of the four possible types of stem cell research.

**Myth3.** Embryonic stem cell research has the greatest promise. Up to now, no human being has ever been cured of a disease using embryonic stem cells. Adult stem cells, on the other hand, have already cured thousands. For example, bone marrow cells from the hipbone have repaired scar tissue on the heart after heart attacks. Research using adult cells is 20-30 years ahead of embryonic stem cells and holds greater promise. This is in part because stem cells are part of the natural repair mechanisms of an adult body, while embryonic stem cells do not belong in an adult body (where they are likely to form tumors, and to be rejected as foreign tissue by the

recipient). Rather, embryonic stem cells really belong only within in the specialized microenvironment of a rapidly growing embryo, which is a radically different setting from an adult body.

**Myth 4**. Embryonic stem cell research is against the law. In reality, there is no law or regulation against destroying human embryos for research purposes. While President Bush has banned the use of federal funding to support research on embryonic stem cell lines created after August 2001, it is not illegal. Anyone using private funds is free to pursue it.

**Myth 5**. President Bush created new restrictions to federal funding of embryonic stem cell research. The 1996 Dickey Amendment rohibited the use of federal funds for research that would involve the destruction of human embryos. Bush's decision to permit esearch on embryonic stem cell lines created before a certain date thus relaxes this restriction from the Clinton era.

**Myth 6**. Therapeutic cloning and reproductive cloning are fundamentally different from each other. The creation of cloned embryos either to make a baby or to harvest cells occurs by the same series of technical steps. The only difference is what will be done with the cloned human embryo that is produced. Will it be given the protection of a woman's womb in order to be born? Or will it be destroyed for its stem cells?

**Myth 7**. Somatic nuclear cell transfer is different from cloning. In fact, "somatic cell nuclear transfer" is simply cloning by a different name. The end result is still a cloned embryo.

**Myth 8**. By doing somatic cell nuclear transfer, we can directly produce tissues or organs without having to clone an embryo. At the present stage of research, scientists are unable to bypass the creation of an embryo in the production of tissues or organs. In the future it may be possible to inject elements from the cytoplasm of a woman's ovum into a somatic cell to "reprogram" it into a stem cell. This is called "de-differentiation." If so, there would be no fundamental moral objection to this approach to getting stem cells.

**Myth 9**. Every body cell, or somatic cell, is somehow an embryo and thus a human life. People sometimes argue: "Every cell in the body has the potential to become an embryo. Does that mean that every time we wash our hands and are shedding thousands of cells, we are killing life?" The problem is that this overlooks the basic biological difference between a regular body cell, and one whose nuclear material has been fused with an unfertilized egg cell, resulting in an embryo. A normal skin cell will only give rise to more skin cells when it divides, while an embryo will give rise to the entire adult organism. Skin cells are not potential adults. Skin cells are potentially only more skin cells. Only embryos are potential adults.

**Myth 10**. Because frozen embryos may one day end up being discarded by somebody, that makes it allowable, even laudable, to violate and destroy those embryos. The moral analysis of what we may permissibly do with an embryo doesn't depend on its otherwise "going to waste," nor on the incidental fact that those embryos are "trapped" in liquid nitrogen. Consider a radical case in which a group of children are permanently trapped in a schoolhouse through no fault of their own; that would not make it morally acceptable to send in a remote control robotic device which would harvest organs from those children and cause their demise.

**About the Author:**

After earning a Ph.D. in Neuroscience from Yale University, Rev. Dr. Tadeusz Pacholczyk did post-doctoral research at Massachusetts General Hospital/Harvard Medical School. He later studied in Rome where he did advanced studies in theology and in bioethics. He has testified at state legislative hearings, and given presentations on stem cells, cloning and other biotechnologies throughout the U.S. and in Europe. He serves as Director of Education for the National Catholic Bioethics Center and on the Ethics Committee of St. Anne's Hospital in Fall River, Massachusetts. Visit *www.ncbcenter.org* and *www.donumvitaecenter.org* for further information on Rev. Dr. Tadeusz Pacholczyk.

**Committee: Health and Family Security Committee**
**Chair: Senator Becky Lourey**
**Hearing: Re. S.F. 69 (Cohen) – Stem cell research state policy. (Companion: H.F. 1734)**
**S.F. 730 (Kelly) – Stem cell research state policy. (Companion: H.F. 0013)**
**Date: March 31, 2005, 12:00 p.m.**
**Location: Room 12 State Capitol**

**"Stem Cell Research Policy: Is Ethics or Science Primary?"**

Kirk C. Allison, Ph.D., Associate Director
Program in Human Rights and Medicine, Medical School, University of Minnesota

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I appreciate the opportunity to address S.F. 69 and S.F. 730. I speak in opposition to their passage in their current form. Both contain inaccuracies in terminology and one in claim. Both suffer from a predisposed view of the relationship of science and ethics that will not serve the State or citizens well over the long term.

Both bills contradict the "United Nations Declaration on Human Cloning," adopted by more than a 2-1 margin in the General Assembly on 5 March 2005.[1] Member States, including the US, are called "to adopt all measures necessary to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life."[2] Such statutes are found in Canada[3] and Norway, to name only two, contra Great Britain[4] and Korea.

- First a simple terminological matter: the bills speak of "somatic cell nuclear *transplantation*" (ital. mine) - a phrase not found in the scientific literature. The correct phrase is 'somatic cell nuclear *transfer*,' or cloning.[5] This should be corrected and the common term included for transparency, as seen in the UN Declaration.

- S.F. 69 additionally claims that stem cell research may lead to "unprecedented treatments and potential cures for [...] Alzheimer's disease" (1.25-2.1). The Alzheimer's Association and leading researchers (e.g. Harvard's Dennis Selkoe) state Alzheimer's is not a promising candidate for stem cell therapy. The bill's claim at best misinforms vulnerable patients, their families, and resource allocators, disadvantaging more promising lines of inquiry.[6] Generally, an ethic of probity in the public representations of science is required – in contrast to the run-up to California's Proposition 71.[7]

- The bills do not address that the burden of derived oocytes for cloning is borne exclusively by women, involving many donors assuming risk for one cell line. Judy

Norsegian, Founder of *Our Bodies Ourselves*, strenuously opposed the California initiative due to this issue.[8] This concern is cited twice in the above UN Declaration.[9]

- Finally, in a just society, scientific and commercial practice must be limited by ethics. The alternative is to constrain ethics be the handmaid of what has been called the 'technological imperative.' These bills raise this issue and provide a clear answer: Ethics are to serve the predetermined outcome.

> (h) Public policy on stem cell research must balance ethical and medical considerations. The policy must be based on an understanding of the science associated with stem cell research and grounded in a thorough consideration of the ethical concerns regarding this research. Public policy on stem cell research must be carefully crafted to ensure that researchers have the tools necessary to fulfill the promise of stem cell research.

Specifically this means:

> Subdivision 1. [RESEARCH USE PERMITTED.] The policy of the state of Minnesota is that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given. Research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by an approved institutional review board.[10]

The order is clear: no ethical consideration can exclude *any* source of stem cells. No criterion marks "this far, but no further" for gestation prior to derivation of stem cells, tissue or the sacrificing a conceptus – even the customary 14 day limit circa neural streak development is lacking, which is present even in China.[11] One could scarcely write a less constrained policy.[12]

Jürgen Habermas, notes: "To the extent that the creation and destruction of embryos for purposes of medical research are extended and normalized, the cultural perception of antenatal human life will change, too, blunting our moral sensibility for the limits of cost-benefit analysis in general."[13] Longterm demand curves are generated in each succesive step as forms of human life become routinely disposable means.

Some, not all, members of the University's Stem Cell Institute's Stem Cell Ethics Advisory Board[14] have in the past raised the specter that in specific circumstances, were it legal, gestation of pregnancies with prior intent to abort to obtain stem cells for therapeutic purposes would be ethical.[15] And then?

Scientific, social and commercial practices impact core issues of human dignity and instrumentalization in this field. Lasalle noted over a century ago: "For so tangled are end and means on earth, / That one always turns with the other / And other means birth also other ends" – "[f]or means are ends in embryo."[16] We bear responsibility for current choices but others will carry the effects not only on health but on our collective humanity for the means chosen.

[1]At its 82nd meeting, on 8 March 2005, the General Assembly adopted resolution 59/280, containing in its annex the text of the United Nations Declaration on Human Cloning, by a recorded vote of 84 to 34, with 37 abstentions. For these and other acts developed through the Ad Hoc Committee on an International Convention against the Reproductive Cloning of Human Beings, see http://www.un.org/law/cloning/ . For broader principles involving genomic research generally, of which stem cell research is a constitutive element, cf. the *Universal Declaration on the Human Genome and Human Rights,* UNESCO Gen. Conf. Res. 29 C/Res.16, reprinted in Records of the General Conference, UNESCO, 29th Sess., 29 C/Resolution 19, at 41 (1997) (adopted by the UN General Assembly, G.A. res. 152, U.N. GAOR, 53rd Sess., U.N. Doc. A/RES/53/152 (1999)). This includes prohibition of reproductive cloning and considerations of genetic discrimination, privacy, informed consent and indigenous rights. http://www1.umn.edu/humanrts/instree/Udhrhg.htm.

[2] Acting on the recommendation of the Sixth Committee (Legal), in its report annex A/59/516/Add.1, the General Assembly adopted the text by a vote of 84 in favour to 34 against, with 37 abstentions. http://daccessdds.un.org/doc/UNDOC/GEN/N05/249/40/PDF/N0524940.pdf . The action points are:

> (a) Member States are called upon to adopt all measures necessary to protect adequately human life in the application of life sciences;
> (b) Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life;
> (c) Member States are further called upon to adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity;
> (d) Member States are called upon to take measures to prevent the exploitation of women in the application of life sciences;
> (e) Member States are also called upon to adopt and implement without delay national legislation to bring into effect paragraphs (a) to (d);
> (f) Member States are further called upon, in their financing of medical research, including of life sciences, to take into account the pressing global issues such as HIV/AIDS, tuberculosis and malaria, which affect in particular the developing countries.

[3] Statutory Instrument 2001 No. 188. The Human Fertilisation and Embryology (Research Purposes) Regulations 2001. 24 January 2001. http://www.hmso.gov.uk/si/si2001/20010188.htm . For a brief summary of policies in Europe, see "Stem Cell Research Regulations in the European Union," International Society for Stem Cell Research, (http://www.isscr.org/scientists/legislative.htm)

[4] *Assisted Human Reproduction Act*, Bill C-6, 3rd Session, 37th Parliament, 52-53 Elizabeth II, 2004. http://www.parl.gc.ca/37/3/parlbus/chambus/house/bills/government/C-6/C-6_3/90187bE.html . Specifically,

**5.** (1) No person shall knowingly

> (*a*) create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device;
>
> (*b*) create an *in vitro* embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures;
>
> (*c*) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or foetus or transplant an embryo so created into a human being;
>
> (*d*) maintain an embryo outside the body of a female person after the fourteenth day of its development following fertilization or creation, excluding any time during which its development has been suspended;
>
> (*e*) for the purpose of creating a human being, perform any procedure or provide, prescribe or administer any thing that would ensure or increase the probability that an embryo will be of a particular sex, or that would identify the sex of an *in vitro* embryo, except to prevent, diagnose or treat a sex-linked disorder or disease;

(*f*) alter the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants;

(*g*) transplant a sperm, ovum, embryo or foetus of a non-human life form into a human being;

(*h*) for the purpose of creating a human being, make use of any human reproductive material or an *in vitro* embryo that is or was transplanted into a non-human life form;

(*i*) create a chimera, or transplant a chimera into either a human being or a non-human life form; or

(*j*) create a hybrid for the purpose of reproduction, or transplant a hybrid into either a human being or a non-human life form.

[...]

**60.** A person who contravenes any of sections 5 to 9 is guilty of an offence and

(*a*) is liable, on conviction on indictment, to a fine not exceeding $500,000 or to imprisonment for a term not exceeding ten years, or to both; or

(*b*) is liable, on summary conviction, to a fine not exceeding $250,000 or to imprisonment for a term not exceeding four years, or to both.

[5] Search: "somatic cell nuclear transplantation," all National Center for Biotechnology Information databases (including PubMed) , National Library of Medicine, accessed 5/30/2005 (http://www.ncbi.nlm.nih.gov). Result detail: *"Quoted phrase not found: 'somatic cell nuclear transplantation'."* In contrast: "somatic cell nuclear transfer" yielded 171 articles using that specific term in PubMed alone.

[6] Allison, Kirk C (2005). "Rhetoric and Research." *Minnesota Daily*, October 29, 2004. *Re.* Selkoe *see.* Krauthammer, Charles (2004), "An Edwards Outrage," Friday, October 15, 2004; Washington Post, Page A23.

[7] The "California Stem Cell Research and Cures Initiative." http://www.ss.ca.gov/elections/bp_nov04/prop_71_text_of_proposed_law.pdf . In the official *Voter's Information Guide* distributed to every voter (http://www.ss.ca.gov/elections/bp_nov04/prop_71_entire.pdf), the *pro* argument for Proposition 71 begins (p.72):

> Stem cells are unique cells that generate healthy new cells, tissues, and organs. Medical researchers believe stem cell research could lead to treatments and cures for many diseases and injuries, including:
> Cancer, heart disease, diabetes, Alzheimer's, Parkinson's, HIV/AIDS, multiple sclerosis, lung diseases, and spinal injuries.

This list and claims were signed by the President of the American Diabetes Association, Alan D. Cherrington, Ph.D., by the President of the National Coalition for Cancer Research, and by the President of the Parkinson's Action Network. Aside from the above discussion of Alzheimer's, HIV/AIDS is notably a viral disease and has no warrant in the list – yet it has great rhetorical sway. (Note the distinction between stem cell research and AIDS research in the *United Nations Declaration on Human Cloning*, under f) above.) On December 8, 2004, I raised this issue with the coordinator of the Southern California Stem Cell Consortium, Prof. Evan Snyder, MD, PhD, after his lecture "Stem Cell Biology: Good Ethics Depend on Good Facts" at the University of Minnesota. His response: a) The pro/con arguments in the *Voters Guide* were best interpreted as the politics, not the science of the issue. b) Given that, one couldn't take the list too seriously as it was based on polling data. (He did not claim responsibility for the situation.)

Opportunity costs in an environment of scarce resources quickly arose: While $3B was voted to the initiative, a rather modest levy to keep emergency rooms open, given uncompensated care, failed (Proposition 67). Could the marginalization of less spectacular programs important to vulnerable patient populations, such as the Occupational Therapy Program in the University Academic Health Center, not also reflect the 'cost of doing business' in the shifting resources to areas promising not only therapies but residuals? Cf. Grutchow, M (2004). "U to Suspend Occupational Therapy Program." *Minnesota Daily,* 7 October 2004. (http://www.mndaily.com/articles/2004/10/07/61568). Accessed 2/26/05.

[8] See *Voter's Information Guide,* "Rebuttal to Argument in Favor of Proposition 71," p. 72. This statement was by Judy Norsegian, Executive Director, Our Bodies Ourselves; Francine Coeytaux, Founder, Pacific Institute for Women's Health; Tina Stevens, Ph.D., author of *Bioethics in America: Origins and Cultural Politics.* Pro-choice

secular opposition arose from the Center of Genetics and Society, http://www.genetics-and-society.org/index.asp. In sum the proposition's critics involved a broad range of persons conflicting in other contexts across prolife/choice/religous/secular convictions.

[9]While cloning promises matched tissue, the first cloned embryo reduced to embryonic stem cells by Professor Hwang in Korea involved 16 female volunteers who underwent hormonal treatments to stimulate hyperovulation followed by the surgical extraction of 242 egg cells from which one cell line was derived. Levels of hormonal stimulation were not provided. (*See* Hwang WS, Ryu YJ, Park JH, Park ES, Lee EG, Koo JM, Jeon HY, Lee BC, Kang SK, Kim SJ, Ahn C, Hwang JH, Park KY, Cibelli JB, Moon SY. Evidence of a pluripotent human embryonic stem cell line derived from a cloned blastocyst. Science. 2004 Mar 12;303(5664):1669-74.) Presupposing an 8 fold increase in 'efficiency', a disease population of 20,000 persons would require 40,000 oocyte donors – the utopian vision of a tissue-matched repair kit for every person outstrips the available population of such donors, with social factors selecting donors to be determined (e.g. S.F. 730, 3.21-3.31).Thanks to Carol Tauer for information concerning hormonal stimulation levels for hyperovulation and oocyte harvesting in other contexts.

[10] Cited from S.F. 730.

[11] This is related to an empirical demarcation in embryological development after which twinning cannot occur. The argument that while twiinning may yet occur no organic unity can be assumed is disproved by the lowly flat worm counter-example –in adulthood it may be divided to produce two, both of which become independent organic unities, while what preceded was likewise an organic unity. I am indebted to Bryan Dowd and Patrick Lee for this example – separately. It is notable, that while extremely permissive, China enforces a 14 day limit. "Blastocyst obtained from IVF, human somatic cell nuclear transfer, parthenogenesis or genetic modification techniques, its *in vitro* culture period shall not exceed 14 days starting from the day when fertilization or nuclear transfer is performed." *Ethical Guiding Principles on Human Embryonic Stem Cell Research.* 2003-460. Promulgated by the Ministry of Science and Technology and the Ministry of Health, People's Republic of China on December 23, 2003. (http://www.chinaphs.org/bioethics/regulations_&_laws.htm#EGPHECR).

[12]The Public Health Provisions of Minnesota Statutes 145.421-422, even in the most permissive reading, will come to bear. MS 145.421 Human conceptus, experimentation, research or sale; definitions; MS 145.422 Experimentation or sale.

[13] The doyen of secular public sphere philosophy. Habermas, Jürgen (2003). *The Future of Human Nature.* Cambridge: Patmos, p. 20. Transl. of *Die Zukunft der menschlicher Natur: auf dem Weg zu einer liberalen Eugenik?* Frankfurt: Surkamp, 2001. The subtitle translates: "On the path to a liberal eugenics?" Regarding this he subsequently expands:

> Let us suppose that, with research involving the destruction of embryos, a practice will come to prevail for which the protection of prepersonal human life is secondary to "other ends", even if these ends consisted in nothing more than the prospect of developing high-ranking collective goods (such as new medical treatments). The desensitization of the way we look at human nature, going hand in hand with the *normalization* of this practice, would clear the path for liberal eugenics. Here we can already discern the future *fiat accompli,* by then a fact of the past, which later apologists will be able to refer to as the Rubicon that was crossed. Looking at a possible future for human nature makes us aware of the present need for regulation. Normative barriers in our dealings with embryos are the result of the point of view taken by a moral community of persons that fends off the pace-makers of a self-instrumentalization of the species in order to safeguard – let us say: out of concern for itself, but in the broader perspective of the ethics of the species [...] (p. 70-71)

[14] "Under the leadership of the senior vice president for health sciences, the University of Minnesota Academic Health Center has established a Stem Cell Ethics Advisory Board, which provides ethics guidance to all University investigators engaged in basic or clinical research related to human stem cells--including those derived from adults, embryos, and fetal tissue. " www.stemcell.umn.edu/stemcell/about/advisory/home.html. Accessed 3/31/05.

[15]Robertson JA, Kahn JP, Wagner JE. Conception to obtain hematopoietic stem cells. Hastings Cent Rep. 2002 May-Jun;32(3):34-40. The context concerns obtaining HLA matched tissue (here stem cells) for therapy for an existing child. Having assumed under a specific understanding of pro-choice assumptions that prenatal life has no interests or rights, and thus cannot be harmed by destruction, the authors' hypothetical opines:

> The logic of this position would extend even to aborting when the fetus is a good match and sufficient hematopoietic stem cells for transplant could be retrieved from fetal remains. On the pro-choice premises,

> the parents are not harming or wronging the fetus in either case, since it lacks inherent rights and the abortion is occurring as early as possible prior to viability. If parents are not ready to have another child, conception and abortion to obtain fetal tissue will enable them to obtain the stem cells while avoiding the later stages of pregnancy and the birth of a child they are not prepared to rear. For them, these are sufficiently worthy concerns to outweigh the negative symbolism of aborting in order to obtain fetal tissue for transplant.

This course is considered aesthetically troubling, but not ethically proscribed. What was once troubled aesthetically may, with repetition, trouble less. The premise that there are no antenatal interests runs counter to Judith Jarvis Thomson's classic "A Defense of Abortion" (*Philosophy and Public Affairs* 1 (1971): 47-66) which invokes a competing interests model. It also notes that freedom from pregnancy does not imply *per se* a 'right to a dead fetus;' similarly it does not imply a right to the post facto exploitation of fetal remains when motivating the same. Under the assumption of no inherent rights or interests, early gestation must also be an aesthetic (symbolic) consideration, but does not principally place a line at any particular point in gestation should utilitarian demand for more developed or differentiated tissue be extant. (While not proscribing abortion, Minnesota Statutes 609.266-609.269 illumine *contra* this assumption, aside from a teleological interest expressed in development, an interest that shows itself performatively, or interests present without knowledge or corresponding psychological states recognized in tort claims for ante-natal exposures.)

Restrictions alluded to are found in Public Law 103-43 of June 10, 1993, (*National Institutes of Health Reviatalizaiotn Act of 1993*, Title I, Subtitle A, Part II "Research on Transplanatation of Fetal Tissue") which would also include stem cell derivations thus obtained (www4.od.nih.gov/orwh/**revitalization**.pdf). *See* 498A of the Public Health Service Act (42 U.S.C. 289g-1). (http://www.hhs.gov/ohrp/humansubjects/guidance/publiclaw103-43.htm)

> `**(b) INFORMED CONSENT OF DONOR-(1) IN GENERAL** - In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring that—`**(A)** the woman donates the fetal tissue for use in research described in subsection (a); `**(B)** the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and `**(C)** the woman has not been informed of the identity of any such individuals.

[16] "Do not show the g o a l , show also the course. / For so tangled are end and means on earth, / That one always turns with the other / And other means birth also other ends," or: "For means are ends in embryo." *Franz von Sickingen. A Tragedy in Five Acts.* Translated from the German of Ferdinand Lassalle by Daniel De Leon. New York: Labor News Company, 1904. p. 64. Original: "Das Z i e l nicht zeige, zeige auch den Weg. / Denn so verwachsen ist hienieden Weg und Ziel, / Daß eines sich stets ändert mit dem andern / Und andrer Weg auch Andres Ziel erzeugt." Lassalle, Ferdinand (1859). *Franz von Sickingen. Eine historische Tragoedie.* Berlin: Verlag von Franz Duucker, p. 63.

As always, responsibility for my remarks is my own, not that of other members of the Program in Human Rights and Medicine.

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# S.F. No. 1892 - I-Save Rx Prescription Drug Program

**Author:** Senator Dick Day

**Prepared by:** Katie Cavanor, Senate Counsel (651/296-3801) KTC

**Date:** March 31, 2005

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**S.F. No. 1892** requires the state to participate in the Illinois prescription drug reimportation program (I-Save Rx).

**Section 1 (256.9551, subdivision 1)** requires the Commissioner of Human Services to enter into an agreement to participate in the I-Save Rx program in order to enable Minnesota residents to obtain prescription drugs from Canada, Ireland, and the United Kingdom.

**Subdivision 2** authorizes the commissioner to enter in this agreement to participate in the program. The commissioner is authorized to act jointly with other states to establish an agreed upon set of standards of practice to ensure the safety of participants. Illinois is to act as the primary administrator of the pharmacy benefits manager agreement.

**Subdivision 3** states that the commissioner must not enter into an agreement unless it contains the following provisions:

(1) specific standards for quality control and safety;

(2) specifies that inspections of participating pharmacies may be conducted by the commissioner or a designee;

(3) specifies that Minnesota citizens shall be provided with access to the program and shall be considered program participants;

(4) requires that the pharmacy benefits manager (PBM) immediately suspend a pharmacy upon receiving written notice of a violation of standards of practice from the commissioner;

(5) requires written notice to the commissioner when other states are added to the program as participating states; and

(6) provides that Minnesota may terminate the agreement with or without cause after giving written notice to the other participating states.

**Subdivision 4** states that Minnesota residents must be able to refill prescriptions for the most common brand name drugs used to treat chronic illnesses from a network of inspected and approved pharmacies. The mail order pharmacy program must be accessible through a Web site and a 24-hour toll-free telephone number. Program participants may order refills of three-months supply over the phone.

**Subdivision 5** requires the commissioner to maintain a separate web site that provides a link to www.ISaveRx.net. The operation and administration of the Web site accessed through this site shall be the responsibility of the PBM. The commissioner is required to work together with the other participating states to ensure an adequate supply of prescription drugs from the program countries. In the event that demand exceeds the supplies, the agreement may provide that Illinois residents have first priority over the other participating states.

**Subdivision 6** requires the state to take part in the joint work group that is composed of two representatives from each participating state. The Minnesota representatives are to be the Commissioner of Human Services and the executive director of the Board of Pharmacy or their designees.

**Subdivision 7** states that any reports issued by the PBM or local regulatory authorities regarding compliance or noncompliance with the standards of practice must be provided to the commissioner. The joint work group shall determine the specific types of data that is to be included in any reports issued by the PBM and on when the reports will be issued.

**Subdivision 8** states that if the standards of practice are violated, the commissioner shall provide written notice to the primary administrator and the PBM of any violation. Upon receiving notice, the pharmacy shall be immediately suspended from the pharmacy network pending further review by the PBM and the participating states.

**Subdivision 9** authorizes the commissioner to participate in inspections of pharmacies along with other states. The commissioner shall provide in writing to the primary administrator any plans or intentions to inspect a pharmacy independently 14 days prior to an inspection, unless the inspection is an investigation of a complaint.

**Subdivision 10** states that under Illinois' PBM agreement only those prescription drugs approved by Illinois may be filled by the network pharmacies for the program participants. The joint work group shall review the list periodically and consider any proposed changes. The approved drug list may not be modified without the consent of the joint work group.

**Subdivision 11** requires the commissioner to coordinate when mutually beneficial on media and outreach efforts with participating states. The commissioner shall promote the participation of Minnesota residents in the program. The state is authorized to use the name, logo, Web site, and marketing materials that have been developed by Illinois, but may add the state seal and the Governor's name to the materials. The PBM is to pay the I-Save Rx acquisition fees to the program.

**Subdivision 12** states that either Minnesota or Illinois may withdraw from this agreement at any time, with or without cause, upon written notice to the other states. Withdrawal may be accomplished by act of the Legislature or by the Governor with the approval of the Senate and House committees with jurisdiction over this matter.

**Subdivision 13** states that the state is immune from liability for the acts or omissions of participating states or its agencies, employees, agents, or representatives in carrying out the activities governed by this agreement. No participating state shall have any liability for the acts or omissions of Minnesota or its agencies, employees, agents, or representatives in carrying out the activities of this agreement.

**Subdivision 14** states that Minnesota is not liable for any injury or damage caused to a person from the products obtained through the program.

**Section 2 (256.9552)** gives the commissioner the responsibility for implementing this program. The commissioner is required to convene a work group within 21 days of passage of this act to develop outreach and promotion tools related to the program.

KC:ph

**Senators Day, Kleis, Fischbach, Wergin and Koering introduced--**
**S.F. No. 1892:** Referred to the Committee on Health and Family Security.

A bill for an act

relating to human services; establishing participation in the I-Save Rx prescription drug program; proposing coding for new law in Minnesota Statutes, chapter 256.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. [256.9551] [I-SAVE RX PRESCRIPTION DRUG PROGRAM.]

Subdivision 1. [ESTABLISHMENT.] Minnesota through the commissioner of human services shall enter into an agreement to participate in the Illinois prescription drug reimportation program (I-Save Rx) to enable Minnesota residents to obtain safe and affordable prescription drugs from Canada, Ireland, and the United Kingdom.

Subd. 2. [AUTHORITY TO ENTER INTO AGREEMENT; COMPLIANCE.] The commissioner of human services is authorized and directed to enter into an agreement with one or more states to participate in the I-Save Rx prescription drug program. In furtherance of the agreement, the commissioner is authorized to act jointly with other states that are members of the agreement to establish an agreed upon set of standards of practice to ensure the safety of participants. Illinois shall act as the primary administrator of the pharmacy benefits manager agreement. Any modification of the standards of practice must have the full and unanimous consent of the joint work group as defined in subdivision 6. Additionally, the joint work group

shall review the standards of practice periodically for the purpose of considering modifications or amendments.

Subd. 3. [AGREEMENT.] The commissioner of human services shall not enter into an agreement to participate in the I-Save Rx program unless the agreement contains the following provisions:

(1) has specific standards for quality control and safety;

(2) specifies that inspections of participating pharmacies may be conducted by the commissioner or the commissioners designee;

(3) specifies that citizens with Minnesota zip code addresses shall be provided access to the I-Save Rx program and shall be considered program participants;

(4) requires that the pharmacy benefits manager immediately suspend a pharmacy from the list of network pharmacies upon receiving a written notice of violation of the standards of practice from the commissioner;

(5) requires written notice to the commissioner of human services when other states are added to the I-Save Rx program as participating states; and

(6) provides that Minnesota may terminate the agreement with or without cause after giving written notice to the other participating states.

Subd. 4. [PROGRAM BENEFITS.] (a) Minnesota residents must be able to refill prescriptions for the most common brand name prescription drugs used to treat chronic illnesses from a network of inspected and approved pharmacies in Canada, Ireland, and the United Kingdom. The mail order pharmacy program must be accessible through a Web site and a 24-hour toll-free telephone number. Program participants may order refills of three months supply over the phone.

(b) The program must include provisions to ensure the safety and quality of the prescriptions by requiring the inspection and approval of the pharmacies who participate.

Subd. 5. [PROGRAM OPERATION.] For operation of the program, the provisions in paragraphs (a) and (b) apply.

(a) [WEB SITE.] The commissioner of human services shall maintain a separate Web site that provides a link to www.ISaveRx.net. Citizens with Minnesota zip code addresses shall be provided access to the services through the I-Save Rx program, and Minnesota residents shall be considered program participants. The operation and administration of the Web site accessed via the I-Save Rx site shall be the responsibility of the pharmacy benefits manager.

(b) [DRUG SUPPLY/CAPACITY.] The commissioner of human services shall work with other participating states to ensure an adequate supply of prescription drugs from the program countries. In the event that demand exceeds the supplies available, the agreement may provide Illinois residents shall have first priority over all other participating states. "Participating states" means Illinois and any other states that have an agreement with Illinois to participate in the I-Save Rx program.

Subd. 6. [JOINT WORK GROUP.] To ensure adequate input from Minnesota regarding the safe and effective administration of the I-Save Rx program, Minnesota shall take part in the joint work group that is composed of two representatives from each participating state. The joint work group shall meet or confer on an as needed basis. The Minnesota representatives shall be the commissioner of human services and the executive director of the Board of Pharmacy or their designees.

Subd. 7. [MONITORING.] Any reports issued by the pharmacy benefits manager or local regulatory authorities regarding the network pharmacies' compliance or noncompliance with the standards of practice shall be provided to the commissioner of human services. The joint work group shall determine the specific types of data that should be included in any reports issued by the pharmacy benefits manager and the periodic basis on which the reports will be issued.

Subd. 8. [VIOLATION.] In the event that the standards of practice are violated by one of the network pharmacies, the commissioner of human services shall provide written notice to

the primary administrator and the pharmacy benefits manager of any violation. Upon receiving the written notice from the commissioner of human services, the pharmacy shall be immediately suspended from the list of network pharmacies eligible to fill prescriptions for program participants, pending further review by the program benefits manager and the participating states, which may result in either reinstatement or exclusion from participation in the program.

Subd. 9. [INSPECTIONS.] The commissioner of human services may also participate in inspections of pharmacies along with other states. To the extent that additional pharmacies are added to the list of network pharmacies, the commissioner of human services may independently inspect those pharmacies. The commissioner shall provide in writing to the primary administrator any plans or intentions to inspect a pharmacy independently 14 days prior to an inspection, unless the inspection is an investigation of a complaint.

Subd. 10. [DRUG LIST.] Under Illinois' pharmacy benefits management agreement, only those prescription drugs approved by Illinois may be filled by the network pharmacies for the I-Save Rx program participants. The joint work group shall review the approved drug list periodically and consider any proposed changes. The approved drug list may not be modified without the consent of the joint work group.

Subd. 11. [MARKETING, MEDIA RELATIONS, AND OUTREACH.] The commissioner of human services shall coordinate, where mutually beneficial, media, and outreach efforts with participating states. Additionally, the commissioner shall promote the participation of Minnesota residents in the I-Save Rx program. Minnesota may use the name, logo, Web site, and marketing materials that have been developed by Illinois; however, the Minnesota state seal and the governor's name may be added to the materials. Minnesota understands that the pharmacy benefits manager shall pay I-Save Rx acquisition fees to the program to be used for activities as marketing, outreach, and additional inspections. Minnesota shall be entitled to the pool of

acquisition fees in an amount proportional to the percentage of I-Save Rx prescription drug sales attributable to Minnesota zip codes.

Subd. 12. [CANCELLATION.] Minnesota or Illinois may withdraw from this agreement and terminate this cooperative relationship at any time, with or without cause, upon written notice to the other states. Withdrawal by Minnesota may be accomplished by act of the legislature amending or repealing this section, or by the governor, with the approval of the senate and house committees with jurisdiction over this matter.

Subd. 13. [LIABILITY.] Neither Minnesota nor its agencies, employees, agents, or representatives taking any action as a result of this agreement shall have any liability for the acts or omissions of participating states or its agencies, employees, agents, or representatives in carrying out the activities governed by this agreement. No participating state or its agencies, employees, agents, or representatives taking any action as a result of this agreement shall have any liability for the acts or omissions of Minnesota or its agencies, employees, agents, or representatives in carrying out the activities governed by this agreement.

Subd. 14. [STATE IMMUNITY.] Minnesota shall not be liable for any injury or damage caused to a person from products obtained through the I-Save Rx program.

**[EFFECTIVE DATE.]** This section is effective the day following final enactment.

Sec. 2. [256.9552] [IMPLEMENTATION OF I-SAVE RX; PUBLICITY AND OUTREACH.]

(a) The commissioner of human services shall be responsible for implementing the I-Save Rx program.

(b) Within 21 days of passage of section 256.9551 and this section, the commissioner of human services shall convene a working group to develop outreach and promotion tools related to the I-Save Rx program.

(c) Members of the working group shall include the commissioners of human services and health, the ombudsman for

older Minnesotans, or their respective designees; and at least one representative from each of the following organizations: area agencies on aging, community action agencies, the Minnesota State Council on Disability, the Minnesota medical society, Minnesota Board of Pharmacy, and AARP Minnesota; as well as interested consumers, advocates, and providers appointed by the commissioner of human services.

**[EFFECTIVE DATE.]** This section is effective the day following final enactment.

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# S.F. No. 968 - AIDS Prevention Initiative Directed At African-Born Residents

**Author:** Senator D. Scott Dibble

**Prepared by:** David Giel, Senate Research (296-7178)

**Date:** March 30, 2005

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**S.F. No. 968** makes a onetime appropriation of $300,000 in fiscal year 2006 to the Commissioner of Health for AIDS prevention grants directed at African-born residents.

The grants must be designed to:

- promote knowledge and understanding about HIV to help eliminate and reduce the risk of infection;
- encourage HIV screening and testing; and
- connect individuals with public health and health care resources.

The grants must be awarded to collaborative efforts that bring together nonprofit community-based groups with demonstrated experience in addressing the health and social service needs of African-born communities.

DG:rdr

**Senators Dibble, Pappas, Moua, Kiscaden and Senjem introduced--**

**S.F. No. 968:** Referred to the Committee on Health and Family Security.

A bill for an act

relating to health; establishing grants for an AIDS prevention initiative focusing on African-born Minnesotans; appropriating money.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. [AIDS PREVENTION INITIATIVE FOCUSING ON AFRICAN-BORN RESIDENTS.]

The commissioner of health shall award grants in accordance with Minnesota Statutes, section 145.924, paragraph (b), for a public education and awareness campaign targeting communities of African-born Minnesota residents. The grants shall be designed to promote knowledge and understanding about HIV and to increase knowledge in order to eliminate and reduce the risk for HIV infection; to encourage screening and testing for HIV; and to link individuals to public health and health care resources. The grants must be awarded to collaborative efforts that bring together nonprofit community-based groups with demonstrated experience in addressing the public health, health care, and social service needs of African-born communities.

Sec. 2. [APPROPRIATION.]

$300,000 is appropriated for fiscal year 2006 from the general fund to the commissioner of health for the purpose of section 1. This appropriation is a onetime appropriation and shall not become part of the base-level funding for the 2006-2007 biennium.

Minnesota AIDS Project™

# MAP *Facts*

## Minnesota's Global Epidemic

## *MAP Action*

MAP seeks to promote awareness about the impact of the global HIV epidemic in Minnesota.

MAP supports one-time prevention funding to address the emerging epidemic among African-born immigrants in Minnesota.

### For Information:

Contact MAP community affairs
612-341-2060 (metro)
800-243-7321 (statewide)
612-341-4057 (fax)
www.mnaidsproject.org
community.affairs@
mnaidsproject.org

### The Global HIV Epidemic is in Our Backyard

African-born immigrants in Minnesota are disporortionately affected by HIV. Although African immigrants account for less than 1% of Minnesota's population, they make up one-fifth of the new infections in 2002. Of the new infections diagnosed in 2002, 21 percent were among African-born residents. 55 percent of these infections were among women. About 335 of the approximately 4600 people living with HIV in Minnesota today are African-born.

### Stigma, Lack of Knowledge Fuel Epidemic

There is a lack of accurate, complete basic knowledge about HIV transmission and risk reduction in Minnesota's African immigrant communities. There is also widespread fear and denial related to the very existence of HIV. Many of the same factors that fuel the spread of the disease on the African continent exist here – a reluctance to openly discuss sexual matters, limited social status for women and a lack of trust in and access to health care. Stigma and discrimination are a critical barrier to risk reduction. Lutheran Social Service interviewed HIV-positive African immigrants and found that 83% were unable to say when they were infected and 63% could not demonstrate how they had contracted HIV, despite having basic knowledge of transmission and prevention. Half had not told their families of their HIV status and only 41% had discussed protection with their partners.

### Cultural Differences Impact Prevention Efforts

The African-born community consists of many smaller groups from different countries with differing attitudes, practices and resources. To reach African-born immigrants, interventions must be culturally specific and linguistically accessible. Religious and cultural beliefs such as fatalism – AIDS is God or Allah's will – complicate prevention efforts. Attitudes towards sexuality and culturally defined gender roles can limit African-born women's ability to negotiate safer sex. Attitudes towards medicine make it less likely that people will seek medical care until they are very sick. Also, misperceptions and fears about maintaining legal status keep many from the open doors of public health and health care clinics. Work involving the African-born community needs to be done to create models of prevention and care that address these barriers and can reduce the spread of HIV in this group.

Effective: 2/7/2005
Revised:

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MINNESOTA LEGISLATURE

# Funding increase urged to fight AIDS

## Group says money needed to target African-born residents

BY TONI COLEMAN
*Pioneer Press*

African community leaders and lawmakers said Monday that Minnesota should more than double its funding for HIV awareness and prevention programs aimed at African-born residents, which make up a fast-growing subgroup of HIV/AIDS infections in the state.

The group used the occasion of National Black AIDS Awareness Day to call for $300,000 in new state funding. Minneapolis DFLers Sen. Scott Dibble and Rep. Karen Clark are the chief authors of bills to provide the funding.

Although they make up less than 1 percent of the state population, African-born immigrants accounted for 55 of 266, or 21 percent, of new HIV infections in Minnesota in 2003. Although there are waivers, immigration policy restricts HIV-positive people from entering the country, leading experts to believe most of those infections occurred in Minnesota.

Of the $5.3 million the Health Department spends each year on HIV educational programs, $200,000 is targeted to African-born immigrants.

The growing rate of HIV infection among blacks has been on the radar of public health officials for years. But by distinguishing between African-Americans (black, not African-born) and African-born immigrants, state officials are now able to tailor prevention messages.

"We do need to address this, and we need to address this immediately," said Gloria Lewis, director of the Office of Minority and Multicultural Health at the Health Department. "How do you reach people from a cultural standpoint, and how do we reach them with the message they need? For some, the disease is a spiritual issue."

Some African-born immigrants believe people infected with HIV have done something immoral to deserve it or have been cursed by God or Allah, said Elizabeth Dickinson, community affairs manager for the Minnesota AIDS Project.

Rep. Neva Walker, DFL-Minneapolis, a co-sponsor of the House bill for increased funding, said getting conservative lawmakers to support sex education in schools will be a hurdle. The state's tight budget also will make it hard to find additional money.

But African community leaders say they need help in addressing the stigma and misinformation within their communities.

Linus Nyambu, pastor of Ascending Praise Church, a nondenominational church in Bloomington, said immigrants aren't talking about HIV at home, so they need to get correct information from church, schools, and community and government leaders.

"Our culture, the African culture, is not designed to talk about HIV, or sex in general," said Kenyan-born Nyambu of Lakeville. While abstinence is the goal for many church leaders and parents, teenagers need to know the basics about HIV transmission and what role condoms play in prevention, Nyambu said.

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