



TO: Technology, Energy and Communications Committee
FROM: Sharon Quick, MD, FCP, FAAP
Washington State Coordinator, American Academy of Medical Ethics
RE: **OPPOSE E2SSB 5581**

SUMMARY

“Life sciences research,” is so broadly defined in this bill as to include virtually any type of research. It is imperative that this bill is amended to prohibit funding of research that is both unethical and amounts to gambling with public dollars.

The **cloning ban amendment is not properly worded** so that, in reality, **cloning is not banned**. Only birthing of cloned humans is prohibited. **Formation of human cloned embryos and fetal farming of cloned humans is still allowed, as well as destructive human embryo research, animal-human hybrids, chimeras, fetal parts research, etc.** E2SSB 5581 doesn't limit research to these unethical types, but allows researchers to compete for the funds available with minimal ethical restrictions other than the inadequate cloning ban.

To illustrate why limitations on research are necessary, consider the following examples of nightmarish science-fiction type research that is being suggested or tried:

- Dr. Irv Weissman at Stanford has proposed to make a mouse with a human brain, promising to kill the mice if they appear “too human.”
- A doctor merged human male & female embryos to make a "she-male" last year
- Suggestion to make mice that produce human eggs and sperm (the resulting human embryo has mice as parents)
- Inserting human DNA into animal eggs to create an organism with features of 2 species

While some mixing of human/animal (e.g. pig heart valve replacements in humans) or human/human cells (e.g. transplants) is acceptable, other forms of mixing human/animal or human/human DNA via various genetic engineering projects are unacceptable.

Human cloning and destructive embryo research (e.g. human embryonic stem cell (HESC) research) are unsafe, unethical, largely unsuccessful, impractical, and unnecessary. This is in spite of 20 years of embryonic stem cell (ESC) research in animals and 6 years of lab research using HESCs. This kind of research is **harmful not only to human embryos, but to women and patients** as well.

In contrast, **adult stem cell (ASC) research is already accomplishing many of the same clinical goals in a safe and ethical manner.** The score for successful stem cell treatments in human clinical applications is **ASC research = 58, HESC research = 0.**

ASC research or other therapies that compete with ESC research actually threaten the income of scientists, institutions, and companies that generate this income from patenting of human embryonic stem cell lines and methodology in using them. There are greater opportunities, and thus greater commercial imperatives, for patenting cells and procedures related to ESC research rather than ASC research.

Many scientists who support human embryonic stem cell research have a financial bias that is often not made public in the media. In other words, **some may be evaluating the science and the ethics of this research through a lens of dollar signs.**

In fact, destructive human embryo research will probably not help patients so much as it will increase the revenue (at least in the short term) of biotech companies, scientists, and research institutions.

Eventually, though, this research without clinical results will implode. As Dr. Daryl Sas (Professor of Biology) says, “Does the state of Washington really want to tie its economic hopes to another Titanic?”

It is unconscionable to use public dollars in research ventures that are not only unethical but a huge gamble. The scientific data support adult stem cell research as being the best investment for our research dollars with the most likely chance of producing new, safe, and ethical cures in the lifetimes of those patients who are living now. If Washington State invests its limited research dollars into adult stem cell research, it will be a leader in making the hope for a cure a reality, instead of wasting dollars on unsafe, unethical, and unnecessary research with human cloning and human embryonic stem cells.

Please do not pass E2SSB **5581** without amending it to prohibit unethical research.

“THERAPEUTIC” HUMAN CLONING AND HUMAN EMBRYONIC STEM CELL RESEARCH are....

Harmful to embryos:

- **This research discriminates based on developmental age—by creating a class of humans (cloned and noncloned embryos) whose sole purpose is destruction for their stem cells.** This violates worldwide medical codes established to protect human research subjects.
- **The poorly constructed cloning ban in E2SSB 5581 does not really ban cloning and allows “fetal farming” of cloned embryos** (implanting and growing cloned humans in a uterus up to 9 months gestation, as long as they are aborted prior to birth for use of cells and tissues)
- **This bill does not limit research funding to “leftover” human embryos from in vitro fertilization (IVF); that is, it does not prohibit human egg and sperm donation to manufacture human embryos for the sole purpose of destructive research.** Even proponents of embryonic stem cell research repudiate this practice

Harmful to women

- **“Therapeutic” cloning**
 - Would require 50 to 100 human eggs per patient. There are not enough women of child-bearing age in the US to donate eggs if eligible patients were to receive this “therapy” which is estimated to cost \$200,000 per patient
 - Eggs would become a commodity, exploiting women
 - Health risks involved with egg harvesting
- **Embryonic stem cell (ESC) research**
 - **Cannot be done on a large scale with the current number of available frozen embryos** (According to the Rand study, less than 3% of the 400,000 frozen human embryos in the US are designated for research. It is estimated that only 275 ESC lines could be produced—not enough for widespread use even if the problems with human ESC research could ever be overcome)
 - Not all fertility centers in the US or elsewhere create excess human embryos or freeze them. Germany prohibits the freezing of human embryos because of the high mortality rate when unfreezing them
 - Egg freezing technology is improving so that excess human embryos may not be made in the future, thus eliminating the supply of embryos for research
 - Would require biological “factories” creating human embryos for the sole purpose of their destruction
 - Women could be exploited to provide eggs for these “factories”

Harmful to patients

- Cells or tissue from cloned embryonic stem cells (“therapeutic” cloning)
 - Are diseased; current health standards would not allow their use in patients
 - Can be rejected (explanation complex)
 - Have not been very successful in animal studies—it would be unsafe and unconscionable to proceed with human trials
 - Have not been used for one single human clinical study
- **Embryonic stem cells...**
 - Can form tumors in animal studies
 - May be rejected
 - Can have genetic or other abnormalities after being grown in a culture
 - Have had few successes in animal studies--it would be unsafe and unconscionable to proceed with human trials
 - Have not been used for one single human clinical study

An alternative approach to accomplish the same clinical goals is **ADULT STEM CELL (ASC) RESEARCH** which....

- Is **safe**--Usually involves use of a patient’s own cells
- **Does not harm human embryos**

- Is **successful**--Has been used in **over 50 human clinical applications** for a wide range of disorders (heart failure, stroke, immune disorders, cancers, spinal cord injury, diabetes, Parkinson's disease, many more.....)
 - Has also been successful in the lab, although more research is still necessary to develop repeatable methods of working with these cells
 - ASCs are found not only in bone marrow, but in other tissues like fat and heart
 - ASCs have been shown to turn into different tissue types in the lab
 - Bone marrow stem cells from human patients have been found to repair damaged tissue in organs outside the bone marrow. Whether they are actually turning into other cell types in vivo or simply inducing repair of native tissue may not be clear, but studies are showing success and some controlled trials have been done
- If limited resource dollars are put into human ESC research and "therapeutic" cloning, money will be diverted from much more promising research like that being done with adult stem cells.

Websites to explore for further information:

www.stemcellresearch.org

www.cloninginformation.org

Patents, Not Patients, May Drive Embryonic Stem Cell Research & Cloning

Scientists, research institutions, and biotech firms stand to benefit from embryonic stem cell research and cloning through patenting revenues. Human embryonic stem cell lines and methodology in using them can be patented. Many scientists who support human embryonic stem cell research have a financial bias that is often not made public in the media. In other words, some may be evaluating the science and the ethics of this research through a lens of dollar signs. For example:

"Many scientists also have financial interests in the extension or revocation of patents held by their academic competitors on lucrative procedures or products. Harvard's medical school and related institutions, for instance, generated almost \$20 million in 2001 from such biotech patents. But this is another area in which reporters are less than conscientious. For example, two top stem-cell researchers, James Thomson of the University of Wisconsin and John Gearhart of the Johns Hopkins University, won patents on the most widely used methods for extracting stem cells from human embryos and aborted fetuses. The revenue from those patents goes both to the two inventors and to their universities' deans, department chiefs, and many others. Should Congress decided to curb the use of Thomson and Gearhart's method, all of them stand to lose millions of dollars." (Neil Monro. Doctor who? Washington Monthly. Nov. 2002)

"Between 1992 to 2001, the NIH generated \$306 million in royalties from 1,615 licensed patents. Product sales from these NIH-owned patents are over \$3 billion annually." (From James Kelly's presentation)

This may give the NIH greater impetus to approve grants for ESC research than ASC research because the former is more likely to generate patents according to one source:

"Commercial imperatives are the major impetus for embryonic stem cell research, much more so than for adult stem cells. There are more opportunities for patenting cells and cell lines as well as isolation procedures." (Institute of Science in Society: 469 scientists from 57 nations who believe that Science should serve mankind, not the reverse—from James Kelly's presentation)

The Associated Press has uncovered evidence of scientists and administrators at NIH flagrantly disregarding ethical and legal requirements of financial disclosure: In all, 916 current and former NIH researchers are receiving royalty payments for drugs and other inventions they developed while working for the government. (From James Kelly's powerpoint presentation)

Adult stem cell (ASC) research or other therapies that compete with ESC research actually threaten the income of scientists, institutions, and companies that generate this income from patent royalties. The less embryonic stem cell research is done, the lower the income from patent royalties.

Embryonic stem cell research is unsafe, unethical, unnecessary, and largely unsuccessful in spite of 20 years of research in animals and 6 years of lab research using human embryonic stem cells (HESCs). In contrast, adult stem cell (ASC) research is already accomplishing many therapeutic goals in human patients safely and without ethical concerns. The score for benefits of stem cells to human patients is ASCs = 58, HESCs = 0.

In fact, destructive human embryo research will probably not help patients so much as it will increase the revenue of biotech companies, scientists, and research institutions. Eventually, though, this research without clinical results will implode. As Dr. Daryl Sas says, "Does the state of Washington really want to tie its economic hopes to another Titanic?"

Note:

James Kelly: Forty-eight year old spinal cord-injured research advocate who has testified at state and Federal hearings regarding the public health implications of directing crucial public resources to embryonic and cloning research. His positions are based on extensive peer-reviewed medical research and the advice of leading scientists and clinicians. He has appeared to speak on these issues at the New York Academy of Sciences and written for the *Washington Times*, *Detroit News*, *Manitou Magazine*, and the *National Review*.

Daryl Sas, Ph.D.: Professor of Biology at Geneva College; Doctorate from the University of Minnesota in Cell and Developmental Biology, 1983; Former research fellow at the Mayo Clinic