Approved: March 6, 2007
Date

MINUTES OF THE HOUSE HEALTH AND HUMAN SERVICES COMMITTEE

The meeting was called to order by Vice-Chair Peggy Mast at 1:30 P.M. on February 12, 2007 in Room 526-S of the Capitol.

All members were present except:
Clark Shultz- excused

Committee staff present:
Norman Furse, Revisor's Office
Renae Jefferies, Revisor's Office
Melissa Calderwood, Legislative Research
Mary Galligan, Legislative Research
Patti Magathan, Committee Assistant

Conferees appearing before the committee:
Mary Lou Davis, Kansas Board of Cosmetology
Malinda McHenry, owner of the Academy of Aesthetic Arts in Shawnee
Representative Lance Kinzer
Judy Smith, Concerned Women of America
Duane Simpson, Biotechnology Industry Organization
Drew Dimmel, Parkinson Foundation
Durant Abernath, Kansas University Medical Center Student
Nick Nikas, Bio Ethics Defense Fund

Others Attending:
See Attached List.

Vice-Chair Mast opened hearings on **HB2174** - Board of cosmetology; standards of practice.

Melissa Calderwood, Legislative Research. presented an overview of **HB2174.** This bill would amend the statue that allows the board of cosmetology to adopt rules and regulations as necessary for administrative matters within the board's jurisdiction, including standards of practice. The bill was introduced by this committee and introduced by **Representative Storm**. Fiscal note indicates that any costs associated with this bill would not be significant.

Mary Lou Davis, Executive Director of the Board of Cosmetology, testified as a proponent of **HB2174**. This bill enables the board to establish standards of practice through the administrative process for each profession. This will assure continuing competence in both practice skills and safety. Cosmetologists provide nail, skin, and hair services. (Attachment 1)

Malinda McHenry, owner of the Academy of Aesthetic Arts in Shawnee, testified as a proponent of **HB2174**, stating that this bill will allow the board to expand the standards of practice to accommodate the rapid changes and demands for skills related to our industry. By allowing the board to set the standards of practice in regulations, they can also insure that educational requirements are expanded within our schools. (Attachment 2)

Chair Landwehr closed the hearings on **HB2174** and opened hearings on **HB2255** - Human cloning, prohibiting certain expenditures of moneys appropriated from the state treasury by state agencies.

Representative **Lance Kinzer** testified as a proponent, stating that he had proposed a similar bill last year which passed the House but not the Senate. This bill has the exact same purpose as last year's bill. He believes that there is a dangerous principle at work if we say that certain types of life are treated as a product rather than as a person. (Attachment 3)

Nikolas T. Nikas, President and General Counsel of the Bioethics Defense Fund, testified as neutral on **HB 2255.** He explained that he is not here to support or oppose **HB2255.** He is here because of his experience in this area to testify about the legal issues surrounding the bill.

Seven states have banned cloning for research. These states have seen no decrease in their biotech industry. Mr. Nikas supported the wording and approach of this bill by stating that the purpose of this bill is to ensure that Kansas taxpayers are not forced to fund research that a large majority of the population finds morally unacceptable. The bill does not address or disallow embryonic stem cell research, but disallows research done at taxpayer expense. He also stated that this bill is substantially the same as Kansas' current law which prohibits taxpayer funding of abortion in most cases. (Attachment 4)

Proponents providing Written testimony:
Concerned Women for America of Kansas (Attachment 5)
Kansans for Life (Attachment 6)
Kansas Catholic Conference (Attachment 7)
Diane Beeson, Medical Sociologist at California State Univeristy and M.L. Tina Stevens, Author, "Bioethics in America", San Francisco State University (Attachment 8)

Duane Simpson, representing Biotechnology Industry Organization (B.I.O) of Washington, D.C., testified as an opponent of **HB2255**, stating that Kansas has established itself as a leader in the area of biomedical and life science research and development. The Kansas Economic Growth Act and the creation of the Kansas Bioscience Authority are model pieces of legislation for the rest of the country. We are now seeing the fruits of this Legislature's labor as we attempt to recruit the National Bio and Agro Defense Facility to Kansas. The current growth in the Kansas economy is due to biotechnology and the future of the Kansas economy depends on expansion of Kansas' role in biotechnology research.

He added that there is a significant difference between cloning to create a new human being (reproductive cloning) and cloning specific human cells, genes and other tissues for therapeutic purposes (therapeutic cloning). Not only does **HB2255** not recognize the difference, it intentionally encompasses all forms of therapeutic cloning. In fact, the definition of "human cloning" in **HB2255** is not the same definition as the one written in **HB2098**. There is a significant difference in regenerative nature of stem cells depending on amount of differentiation that has gone on in the cells. For instance adult stem cells are rather specialized, cord blood stem cells are less specialized but are still differentiated to a degree, while embryonic stem cells are "pluripotent" in that they can become just about any cell in the body given the proper differentiation. That's why these cells hold so much potential for researchers.

We support recommendations by the National Academies of Science that the cloning of human beings for reproductive purposes should be prohibited; but that therapeutic cloning should be permitted. The Academy has taken steps to provide guidelines for research on embryonic stem cells, including a recommendation that institutions conducting embryonic stem cell research establish oversight committees. We support these recommendations.

HB2255 does not just prohibit funding from the State General Fund; it prohibits funding from any money in the state treasury including special revenue funds. By placing a limit on all of these funds, **HB2255** effectively bans any money that touches a state agency, whether it is a tax dollar or not. (Attachment 9)

Drew Dimmel, Opponent and Chairman of the Board of Directors of the Parkinson Foundation of the Heartland, stated that this bill unfairly "taints" Somatic Cell Nuclear Transfer (S.C.N.T.) research, which many experts believe could eventually cure diseases and injuries that afflict more than two hundred thousand Kansas adults and children. One of those diseases is Parkinson's. No one wants human reproductive cloning. The potential for medical solutions to many debilitating and deadly conditions is the reason that so many groups, such as the National Parkinson's Foundation, The Parkinson's Action Network and the Parkinson Foundation of the Heartland support S.C.N.T. research. (Attachment 10)

Durant Abernathy identified himself as a student at the University of Kansas Medical Center and as a person who may one day be cured through embryonic stem cell research. He said that he has been diagnosed as a Type 1 diabetic and would die without insulin. Insulin is not a cure for diabetes, but remains the only treatment since 1922. Adult stem cells are unlikely to produce a cure for diabetes, however, embryonic stem cell research is likely to produce a cure. **HB2255** fails to differentiate between reproductive and therapeutic

cloning. It erroneously defines S.C.N.T. as human cloning when it is instead therapeutic cloning. A ban on the use of state funds for S.C.N.T. research would have the effect of shutting down any current or future S.C.N.T. research in Kansas, and it could unfairly prevent Kansas residents from having access to therapies and cures available to the citizens of other states. (Attachment 11)

Opponents providing written testimony were:
Kansas Coalition for Lifesaving Cures (Attachment 12)
American's for Stem Cell Therapies & Cures (Attachment 13)

Neutral written testimony was provided by Dr. Paul Terranova, Vice Chancellor for Research, Office of the Executive Vice Chancellor, University of Kansas Medical Center. (Attachment 14)

Chair Landwehr closed hearings on HB2255 and adjourned the meeting. Next meeting is Feb. 13th at 1:30.

HOUSE HEALTH AND HUMAN SERVICES
COMMITTEE GUEST LIST

DATE: February 12, 2007

NAME	REPRESENTING
Shar Hoffman	Concerned Women for America - KS
Judy Smith	"
Dorothea Hughes	KU Medical Center
Drew Dimmel	Parkinson Foundation of the Heartland
Durant Abernethy	American Medical Association - Medical Student Section
Laurie Roberts	Kansas Coalition for Lifesaving Cures
Mary Lou Davis	Ks Board of Cosmetology
Nikolas T. Nikas	Bioethics Defense Fund
Kathy Ostrowski	Kansans for Life
Duane Simpson	Biotechnology Industry Org.
Jeanie Gawdun	KFL
Beatrice Swoopes	KS CATHOLIC CONFERENCE
Therese Hartnett	CLS at Washburn Law
Lindsey Douglas	Heim Law Firm
Bob Vancrum	Greater KC Chamber
Bill Calvin	
Ron Kelson	
Sandy Braden	Civic Council of KC

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KANSAS BOARD OF COSMETOLOGY

KATHLEEN SEBELIUS, GOVERNOR

House Committee on Health and Human Services
Wednesday, February 12, 2007
House Bill 2174
Testimony presented by Mary Lou Davis, Executive Director

Madam Chair and Members of the Committee:

Individuals who provide cosmetology, nail technology, esthetics (skin care) and electrology services must be licensed by the Kansas Board of Cosmetology. Statute defines the practice of each profession and outlines requirements for initial licensure; regulation outlines the training curriculum for each profession.

Licensure is granted once an individual attains the required training and successfully completes the licensure examinations. The licensee enters the workforce with entry level skills.

House Bill 2174 would enable the Board to establish standards of practice through the administrative process for each profession. This will assure continuing competence in both practice skills and safety.

As in most professions, trends impact the cosmetology professions. To address these trends, but maintain a balance between the Board's responsibility to protect the health and welfare of the consuming public, but not unnecessarily restrict cosmetology practices, the definitions for these professions were revised through legislative action in 2002. Prior to 2002 skin care was limited to "the scalp, face, neck, arms or hands." The cosmetology and esthetic definitions now allow a "noninvasive beautifying process on any skin surface."

The definition for cosmetology and esthetics states a service may be provided that involves "cleansing, stimulating or performing any other non-invasive beautifying process on any skin surface by means of hands or mechanical or electrical appliances for purposes other than treatment of medical, physical or mental ailments." Misunderstandings remain about which "mechanical or electrical appliances" may be used for providing cosmetology/esthetic services. In recent situations Kansas Board of Cosmetology licensees have provided services with "mechanical or electrical appliances" that are restricted for medical use. Although manufacturers of medical devices must register with the Food and Drug Administration (FDA) manufacturers will sell equipment to individuals for whom the equipment is not intended. This has compounded the dilemma before the Board and its' licensees.

To more readily address trends and practices this revision would permit the Board to establish standards of practice through the regulation process, but within statutory authority. The Board appreciates your favorable consideration of this provision.

The following reflects the number of licensees and licensed facilities in each cosmetology profession:

Profession:		*Facilities:*	
Cosmetologists	20,501	Cosmetology	3,464
Cosmetology technicians	55	Electrology	22
Electrologists	46	Esthetics	82
Estheticians	554	Nails	316
Total	24,321	Total	3,884

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ATTACHMENT 1

MALINDA MCHENRY TESTIMONY
HEALTH AND HUMAN SERVICES COMMITTEE
HB 2174
February 12, 2007

Good afternoon, Madam Chairman and Committee Members. My name is Malinda McHenry. I am the owner of the Academy of Aesthetic Arts in Shawnee. I want to thank the committee for considering the request of HB 2174. I support this change in the statute so that our governing board will be able to expand the standards of our practice to accommodate the rapid changes and demands for skills related to our industry. Some of the different skills required currently include technology such as micro dermabrasion, cosmetic chemical applications, possible light sources and even old technology such as the proper use of lancets and facial toning. These treatments are being used in spas and medical spas across the country. By allowing our board to set the standards of practice in regulations, they can also insure that educational requirements are expanded within our schools so that our instructors are prepared to educate future graduates to meet our ever-growing market. In addition, it is my hope that the board will also consider the possibility of dual licensure for cosmetologists who graduated before the expansion of esthetic hours to grandfather in under the current esthetics license. This will make for a clearer understanding of the public and the differences in levels of training received by practitioners in our industry.

It is the policy of most states that cosmetology encompasses hair and nails only, and that due to the level of knowledge required in skin care applications, that a separate field of esthetics was needed.

Malinda McHenry
Academy of Aesthetic Arts
10316 Shawnee Mission Parkway
Shawnee KS 66203

Licensed Cosmetologist
Licensed Cosmetology Instructor

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ATTACHMENT 2

STATE OF KANSAS
HOUSE OF REPRESENTATIVES

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STATE CAPITOL
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kinzer@house.state.ks.us

COMMITTEE ASSIGNMENTS
TAXATION
JUDICIARY
FEDERAL AND STATE AFFAIRS

TOPEKA

LANCE KINZER
REPRESENTATIVE, 14TH DISTRICT

TESTIMONY REGARDING HB 2255

Last year I carried a proviso to the appropriations bill that would have banned for one year, the use of any taxpayer dollars for human cloning, defined to include Somatic Cell Nuclear Transfer (SCNT). That proposal did not ban the procedure; it just said taxpayers should not be forced to pay for it. That proposal passed the House, but not the Senate. This bill has the exact same purpose as last year's proviso.

In considering this matter let me suggest how I believe we should think about the issues of embryonic stem cell research and human cloning. Now all too often this debate gets couched as a religious one, and particularly an issue that is driven by a specific brand of Christian theology. If possible I'd like to take that issue out of it for a moment by framing my remarks by giving consideration to a pre-Christian conflict over what I think are the issues truly before us; does might make right and do the ends justify the means.

One of the most famous considerations of these related questions come to us via Thucydides, as he recounts for us the Melian Dialogue. For those who are rusty on their Thucydides, Melos was a small island in the Cretan sea allied with the Spartans, but neutral in the Peloponnesian war. The Athenian Navy came to Melos and asked that they ally with them and pay them tribute. The Melian's refused.

What has made this story a classic in Western thought was the argument of the Athenians. While the dialogue itself is too lengthy to recite in full I do want to give you a brief taste:

The Athenians argued as follows: "We then, we Athenians, will use no fine words, we will not go out of our way to prove that we have a right to rule... But you and we should say what we really think, and aim only at what is possible, for we both alike know that in the discussion of human affairs the question of justice only enters where there is equal power to enforce it, and that the powerful exact what they can, and the weak grant what they must."

To which the Melians responded: "Well then since you set aside justice and invite us to speak of expediency, in our judgment it is certainly expedient that you should respect a principle which you know if for the common good; that to every man in peril a reasonable claim should be accounted a claim of right... Your interest in this principle is quite as great as ours, in as much as you, if you fail, will incur the heaviest vengeance, and will be the most terrible example to mankind."

Now in the end the Melians decided not to yield, and as a result the Athenians blockaded the city until the Melians capitulated in the face of starvation, at which point the Athenians killed every male citizen of Melos and carried off the women and children into slavery.

In this case the Athenian argument was a simple one, might makes right. They argued in essence that because they had the power to act it was therefore right for them to act. The Melian's in their response made a crucial point; that those who violate principle in the name of expediency may

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ATTACHMENT 3 -1

well themselves someday find it necessary to rely upon the very principle they have discarded. But under such circumstances they may find that they won their initial argument too convincingly, that the principle upon which they now need to rely no longer holds sway.

Now let's step away from ancient Greece for a moment and talk about stem cell research. Let me start with a personal point. 30 years ago my sister Darian was born with Spina-bifida and Hydrocephalus. I have participated at very close range in the innumerable struggles associated with her disability. I could have no greater joy than seeing a treatment or cure for the many problems that afflict her.

Simply put, I get it. I understand very well the desire to pursue any avenue that seems to provide opportunities for treatments and cures for the disabled. But, even in these cases, indeed perhaps especially in these cases, we must not neglect the ends vs. means question.

As an aside allow me to note that in framing the question this way I am conceding the possibility that embryonic stem cell research may in fact lead to treatments and cures, something that I believe is very far from certain. But I want to confront this issue as honestly as possible, at the level of principle. And at that level the choice set before us is a clear one:

The whole question that we are faced with is whether the ends justify the means. That's it. In order to answer the question of whether the ends justify the means we must, in this case, ask what is the nature of the cloned embryo that is destroyed in order to extract embryonic stem cells. I believe the way that we answer this question is of crucial importance to the whole issue of human dignity. As for myself, I believe that human dignity is inherent not instrumental.

Think about it this way, Christopher Reeve's value as a human being did not change one iota as a result of his accident. Or put it another way, my sister's value as a human being is not in any way denigrated by her disability. We can say these things only because we acknowledge that human begins have intrinsic value. Human are not instrumentally valuable depending upon their social utility.

But for this argument to be true, for human life to have value that is truly inherent, so that an instrumental argument does not sneak in the back door, then that value must be the same as all other human beings, regardless of their size, their level of development, their environment, or their degree of dependency.

I believe that the evidence is simply overwhelming that the embryo that is destroyed by embryonic stem cell research is a human being that is just smaller, more dependent, in a different location, and less developed than you and me. It's valuable because of what it is, not how it can be used. To say anything different is to place at risk the very concept of the inherent value of human life. It is to say that in some circumstances some human begins can be treated as products rather than people.

My simple point here this morning is this, if the embryo that is destroyed in embryonic stem cell research is human then the ends to be achieved by this research can not justify the means of the embryos destruction without placing the entire concept of inherent human dignity at risk.

If we disagree as to that point than our disagreement truly does go all the way down and there is little possibility of meaningful discussion. But if we can agree as to that point than a very useful dialogue is possible; one that I would be pleased to take up with any one of you in.

BIOETHICS DEFENSE FUND
BDF
Human Rights from Beginning to End

Nikolas T. Nikas
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Dorinda C. Bordlee
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MEMORANDUM

To: Kansas House Committee on Health and Human Services
From: Nikolas T. Nikas, Esq.
President and General Counsel, Bioethics Defense Fund
Date: February 12, 2007
Re: KS H.B. 2255, Human Cloning Funding Ban

Representative Landwehr and members of the Committee:

My name is Nikolas T. Nikas, and I am president and general counsel of the Bioethics Defense Fund, a public-interest law firm that advocates for human rights in the bioethical fields of human cloning and embryonic stem cell research, abortion and end-of-life decisions.

I am here today as a bioethics attorney to address and answer questions regarding the legal issues surrounding House Bill 2255, but not to advocate for or against the bill. My legal experience in this new field includes consultation in the court challenge to California's Prop. 71, as well as serving as lead trial counsel in the case challenging the deceptiveness of Missouri's Amendment 2, which this past November passed by just over 1% to create a state constitutional right to clone human embryos for the purpose of destroying them as raw material for science experiments. I was also the drafter of the Arizona cloning funding ban that was passed and signed into law in 2005.

Kansas H.B. 2255 is a reasonable and measured response to the issue of human cloning for three reasons:

- This sole purpose of this short bill is to ensure that Kansas taxpayers not be forced to fund research that a large majority of the population finds morally unacceptable, namely the use of **human cloning** to create cloned human lives for the sole purpose of using them as raw material in science experiments.

- This bill **does not** address or disallow embryonic stem cell research involving so-called "left over" embryos in fertility clinics, nor does it even ban the practice of human cloning itself. It simply draws the line at taxpayer funding of human cloning research.

- This bill is substantially the same as Kansas' current law that prohibits taxpayer funding of abortion in most cases. Abortion funding bans have been upheld as constitutional, and there is no constitutional problem with this legislative body making a determination that it will not publically fund human cloning for destructive human embryo research. If Kansas passes this legislation, it will join Arizona, a leading biotech state, in reaching a policy decision that promotes ethics in science and the dignity of human life.

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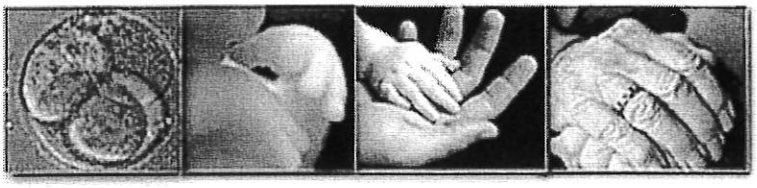
ATTACHMENT 4-1

Is SCNT really Human Cloning?

Leading Medical Organizations say <u>Yes</u>



National Academies of Science[1]

"**<u>Cloning</u>** using somatic cell nuclear transfer (SCNT). . . **leads to** the formation of a blastocyst, or pre-implantation **embryo**."

"**Stem cells derived from embryos** are called embryonic stem cells. . ."

The American Medical Association[2]

"<u>Human therapeutic cloning</u> involves the **cloning of human embryos** for the purpose of extracting stem cells that can be used to repair tissues and organs."

The International Society for Stem Cell Research[3]

"Therapeutic **cloning**: **somatic cell nuclear transfer** for the isolation of embryonic stem cells."

The American Association for the Advancement of Science[4]

"While use of the term *embryo* can be polarizing, it can also promote clarity, even where some feel it has too great a political, emotional, or social 'charge.' Thus, for the purposes of this report, we have chosen to use the term ***cloned embryo*** to describe the **product of nuclear transplantation**."

UK Human Fertilization & Embryology Authority[5]

"The **cloning technique**, cell nuclear replacement, involves removing the nucleus of a human egg cell and replacing it with the nucleus from a human body cell, such as a skin cell. The egg is then artificially stimulated. This causes the egg to divide and behave in a similar way to a standard **embryo** fertilized by sperm."

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[1] *Scientific and Medical Aspects of Human Reproductive Cloning*, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington, DC, Jan. 2002; pg. 2-2, 2-4 (preprint).

[2] *AMA Basic Genetics – FAQs*, www.ama-assn.org/ama/pub/category/print/4646.html.

[3] *Glossary of Stem Cell-Related Terms,* International Society for Stem Cell Research, http://www.isscr.org/public/glossary.htm (last checked January 8, 2006).

[4] *Regulating Human Cloning*, American Assoc. for the Advancement of Science, Washington, DC, April 2003; pg. 4.

[5] *HFEA grants the first therapeutic cloning license for research*, Press Release of the UK Human Fertilisation & Embryology Authority, August 11, 2004, (http://www.hfea.gov.uk/PressOffice/Archive/1092233888)(last checked January 8, 2006).

February 12, 2007

Chairwoman Landwehr and Members of the House Health and Human Services Committee:

My name is Judy Smith, and I am the State Director of Concerned Women for America of Kansas. Our organization is in support of **HB 2255**. We support research; however, state moneys should be spent on research that is non-controversial and has yielded the most concrete promise. Stem cell research using adult stem cells, placenta and cord blood have yielded incredible results, including over eighty treatments, cures, and promising therapies to date. We urge the state to fund research that is proven, ethical and non-controversial rather than research that relies on human subjects that cannot speak for themselves.

"It is so easy for scientists to step over the edge and make science a god." These words were spoken by Susan Vigorito, a survivor of Dr. Josef Mengele's notorious "twin" experiments while speaking at Kent State University in 1990. Just because science thinks it can do something and believes that the end justifies the means does not make it right. The state of Kansas should not be a party to permitting science to conduct research that involves cloning human beings. A cloned embryo, albeit very tiny, is not without human rights. The Nuremberg Code, Principle 5(1948) states, "No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except perhaps, in those experiments where the experimental physicians also serve as subjects." The implication is clear: research should not be done on human beings without their consent. The World Medical Association in a Declaration of Helsinki, Sections 1.5, 111.4 (1975) states: "Concern for the interests of the subject must always prevail over the interest of science and society. … In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject." Science has not even yet produced a documented "clone." The attempts to produce a human clone will result in the deaths of hundreds, if not thousands, of tiny human beings. In addition, in animal experiments, horrible defects and malformations occur frequently.

Kansas tax dollars should not be spent on research that involves human cloning or somatic cell nuclear transfer (the scientific name for cloning).

Thank you for the opportunity to submit testimony to this committee.

Judy Smith, State Director
Concerned Women for America of Kansas

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913-491-1380

House Health and Human Services
DATE: 2-12-07
ATTACHMENT 5

Kansans for Life
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Fax (316) 687-0303
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Proponent, HB 2255
House Committee on Health & Human Services **Feb. 12, 2007**

Good afternoon Chairwoman Landwehr and committee members,

In the movie, *Mr. Smith Goes to Washington,* a massive graft project is exposed by a naïve Senator, (Jimmy Stewart), after which the full force of a sophisticated political machine rains down on Smith and his supporters. The national media orchestrates public antagonism toward the hero, and it is only the remorseful conscience of one lawmaker that turns the tide, and crumbles the machine.

I only hope that the well-oiled political machine wrongly promoting cloning and destructive embryonic research would similarly admit its error and close shop.

People loathe cloning; for decades, movies and sci-fi TV series have depicted the havoc resulting from such biological intervention. That is why pro-cloners have struggled to create terms sanitizing their intent.

Last year the House final budget contained a 1 year proviso prohibiting tax payer monies from going to cloning. Stowers, Big BIO, and other similarly minded lobbyists successfully confused lawmakers that cloning and SCNT were different activities. An impasse was broken with a good faith deal that a LEGISLATIVE committee would issue a state "bio-tech dictionary" for future public policy.

Unfortunately, Stowers' influence continued to blight the Legislative Coordinating Council and the 2006 dictionary task was erroneously sent to a state agency deeply under the influence of the pro-cloners.

Scientists are NOT immune to coercion. Researchers depend on NIH and disease advocacy groups for funding. Tragically, the big lie is that innocent, tiny cloned human embryos must be sacrificed in the search for cures. Advocacy groups have fallen for the lie about cures and have endorsed the Coalition groups in Kansas and Missouri that are funded over 98% by Mr. & Mrs. Stowers. In fact at least $30 million was spent by these people to change Missouri's Constitution to enshrine cloning.

But the real goal is to have the KU system doing the cloning that Stowers is currently funding at Harvard.

The National Academy of Sciences has published voluntary guidelines to govern so-called "therapeutic cloning" and embryonic stem cell research. They don't offer much in the way of limitations, which is not surprising given the bias of their committees. (see attachment A).

For example, the NAS would permit biotechnologists to create embryos--either naturally or through cloning--solely for the purpose of research. Of course, there is talk of having Institutional Review Boards monitor the research --but that is no protection at all since those review boards would be made up of scientists and others committed to moving human cloning research forward.

Kansans for Life unabashedly stands opposed to human cloning. The act of cloning culminates in the creation of a new human embryo, and all honest scientists in the field acknowledge it.

The first two cloned primate births were reported in 1997. (1) The two cloned monkey babies were created asexually--that is, through cell nuclear transfer technology--just as the first cloned lambs brought to birth by Ian Wilmut were created asexually using cells from sheep embryos. This means that unless society outlaws all human cloning, it is only a matter of time until the first cloned baby is on the way.

It also means that if birthing cloned human babies is technically possible--which the primate studies seem to demonstrate--then cloned human embryos are indeed a form of human life that some scientists plan to create as a commodity to be harvested and destroyed.

President Clinton's National Bioethics Advisory Commission, in its 1997 report titled *Cloning Human Beings*, explicitly stated:

"The Commission began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term."

The current President's Council on Bioethics offers the following definitions:

"Cloned human embryo: (a) A human embryo resulting from the nuclear transfer process (as contrasted with human embryo arising from the union of egg and sperm). (b) The immediate (and developing) product of the initial act of cloning, accomplished by successful SCNT, whether used subsequently in attempts to produce children or in bio-medical research." (Human Cloning and Human Dignity: An Ethical Inquiry Executive Summary 2002.)

Human cloning is not the birth of a cloned baby. Cloning doesn't produce a baby. It isn't the act of implantation. It isn't the creation of stem cells. Cloning produces a new human organism. After that, the only question is what to do with the organism that was created.

Seven states have all passed comprehensive bans on human cloning, and others are considering it. (See attachment B for listing of bans and funding bans.) These states have not compromised their bio-tech economic development. Michigan bans both human cloning and destructive embryonic research and has been in the top 10 states for bio tech.

The United Nations has recommended all member nations ban human cloning. This measure passed with the support of the Green movement and the feminist movement. Author Judy Norsigian has said:

"Because embryo cloning will compromise women's health, turn their eggs and wombs into commodities, compromise their reproductive autonomy and, with virtual certainty, lead to the production of 'experimental' human beings, we are convinced that the line must be drawn here."

Scientists are not gods. In the World War II era, scientists performed inhumane experiments on the aged, the disabled and the non-Aryans. Then they acknowledged the Nuremberg protocol to prevent cruelty and insure informed consent by those being experimented upon. But research continues to run amok. Not so long ago, Canada performed cruel experiments on orphans; and our government has formally apologized for the mistreatment of black men with syphilis at Tuskegee.

The purpose of government is to provide for the common welfare and keep safety and order. A ban on human cloning is needed. Until that time, let us at least agree to ban tax-funded destruction of the tiniest members of the human family.

Please pass HB 2255. I stand for questions.

Kathy Ostrowski, Legislative Director, Kansans for Life

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(1)"Rhesus Monkeys Produced by Nuclear Transfer," published in the peer-reviewed journal *Biology of Reproduction;* *http://weeklystandard.com/Content/Public/Articles/000/000/005/534cbsan.asp?pg=2*

The NIH is a federal agency operating under federal administrative guidelines.

The NAS (National Academy of Sciences) is an independent group, and is not part of the U.S. administration, nor does it exist by creation of the government. It is free to select its members and issue its opinions.

In April 2005, it issued its opinions on so-called ethical guidelines for SCNT and embryonic stem cell research. The Kansas Health Policy Authority included these opinions in its report, and Kansas University Prof. Terranova also recommended them when he appeared before this committee last Monday February 5, 2007.

It is important to note that **no governmental agency requested the creation of these NAS guidelines, and they remain solely the opinions of the NAS.**

The inferred validity and impartiality of these ethical opinions are not supported by the **biases of the members of the committee** which authored them.

2005 Committee for Ethical Guidelines:

Pro-cloning members (7)

Richard O. **Hynes**(cancer professor) Jonathan D. **Moreno** (bio-ethicist), Norman C. **Fost,** (pediatrics & ethics), H. Robert **Horvitz** (molecular biologist) Janet D. **Rowley**(geneticist), Janet **Rossant** (biologist), Elizabeth Price **Foley** (attorney),

Cloning position undeterminable (3)

Terry **Magnuson**, Ph.D prof, Marcia **Imbrescia,** Trustee of Arthritis foundation, Cheryl **Mwaria**, Ph.D. African studies & anthropology professor

This 2005 pronouncement reflected a continuance of the NAS pro-cloning philosophy. NAS issued a 2002 statement of support for nuclear transplant research, i.e. "therapeutic cloning" or cloning without gestation to birth. This 2002 opinion supported "development of new embryonic stem cell lines, research on somatic cell nuclear transfer to generate stem cells, and human stem cell research that is publicly funded."

2002 Committee for Ethical Guidelines:

Pro-cloning members (8)

Richard O. **Hynes** (cancer professor), Jonathan D. **Moreno** (bio-ethicist), Norman C. **Fost,** (pediatrics & ethics), H. Robert **Horvitz** (molecular biologist), Janet D. **Rowley** (geneticist), Janet **Rossant** (biologist), Elizabeth Price **Foley** (attorney),
Joseph L. **Goldstein,** M.D

Cloning position undeterminable (2)

Marcia **Imbrescia**, Trustee of Arthritis foundation, Cheryl **Mwaria**, Ph.D. African studies & anthropology professor

The inclusion of these NAS opinions, a pro-cloning body without government authority, suits the pro-cloning Stowers Institute, which heavily influenced the Health Policy Authority report. The inclusion of the 2005 NAS Guidelines was NOT part of the interim committee mandate passed into law in 2006.

State Human Cloning Laws

Updated April 18, 2006 National Conference of State Legislatures *http://www.ncsl.org/programs/health/genetics/rt-shcl.htm*

Fifteen states have laws pertaining to human cloning. The issue was first addressed by California legislature, which banned reproductive cloning, or cloning to initiate a pregnancy, in 1997. Since then Arkansas, Connecticut, Indiana, Iowa, Maryland, Massachusetts, Michigan, Rhode Island, New Jersey, North Dakota, South Dakota, and Virginia have enacted measures to prohibit reproductive cloning. Arizona and Missouri have measures that address the use of public funds for cloning, and Maryland prohibits the use of state stem cell research funds for reproductive cloning and possibly therapeutic cloning depending on how one interprets the definition of human cloning in the statute. Louisiana also enacted legislation that prohibited reproductive cloning, but the law expired in July 2003.

Arkansas, Indiana, Iowa, Michigan, North Dakota and South Dakota laws extend their prohibitions to therapeutic cloning, or cloning for research purposes. Virginia's law also may ban human cloning for any purpose, but it may be open to varying interpretations because the law does not define the term "human being," which is used in the definition of human cloning. Rhode Island law does not prohibit cloning for research, and California and New Jersey human cloning laws specifically permit cloning for the purpose of research.

For a discussion of issues related to cloning in further detail, please see NCSL's magazine article on human cloning "Attack of the Clones" published in the April 2003 issue of *State Legislatures*. NOTE: This article does not reflect subsequent changes to state human cloning laws. Please see the table below for current state laws.

State	Statute Citation	Summary	Prohibits Reproductive Cloning	Prohibits Therapeutic Cloning	Expiration
Arizona	HB 2221 (2005)	Bans the use of public monies for reproductive or therapeutic cloning.	Prohibits use of public monies	Prohibits use of public monies	
Arkansas	§20-16-1001 to 1004	Prohibits therapeutic and reproductive cloning; may not ship, transfer or receive the product of human cloning; human cloning is punishable as a Class C felony and by a fine of not less than $250,000 or twice the amount of pecuniary gain that is received by the person or entity, which ever is greater	yes	yes	
California	Business And	Prohibits reproductive cloning; permits	yes	no	

	Professions §16004-5 Health & Safety §24185, §24187, §24189, §12115-7	cloning for research; provides for the revocation of licenses issued to businesses for violations relating to human cloning; prohibits the purchase or sale of ovum, zygote, embryo, or fetus for the purpose of cloning human beings; establishes civil penalties			
Connecticut	2005 SB 934	Prohibits reproductive cloning, permits cloning for research; punishable by not more than one hundred thousand dollars or imprisonment for not more than ten years, or both	yes	no	
Indiana	2005 Senate Enrolled Act No. 268	Prohibits reproductive and therapeutic cloning; allows for the revocation of a hospital's license involved in cloning; specifies that public funds may not be used for cloning; prohibits the sale of a human ovum, zygote, embryo or fetus;	yes	yes	
Iowa	707B.1 to 4	Prohibits human cloning for any purpose; prohibits transfer or receipt of a cloned human embryo for any purpose, or of any oocyte, human embryo, fetus, or human somatic cell, for the purpose of human cloning; human cloning punishable as Class C felony; shipping or receiving punishable as aggravated misdemeanor; if violation of the law results in pecuniary gain, then the individual is liable for twice the amount of gross gain; a violation is grounds for revoking licensure or denying or revoking certification for a trade or occupation	yes	yes	
Maryland	2006 SB 144	Prohibits reproductive cloning; prohibits donation of oocytes for state-	yes	no	

		funded stem cell research but specificies that the law should not be construed to prohibit therapeutic cloning; prohibits purchase, sale, transfer or obtaining unused material created for in vitro fertilization that is donated to research; prohibits giving valuable consideration to another person to encourage the creation of in vitro fertilization materials solely for the purpose of research; punishable by up to three years in prison; a maximum fine of $50,000 or both			
Massachusetts	2005 SB 2039	Prohibits reproductive cloning; permits cloning for research; prohibits a person from purchasing, selling, transfering, or obtaining a human embryonic, gametic or cadaveric tissue for reproductive cloning; punishable by imprisonment in jail or correctional facility for not less than five years or more than ten years or by or by imprisonment in state prison for not more than ten year or by a fine of up to one million dollars; in addition a person who performs reproductive cloning and derives financial profit may be ordered to pay profits to Commonwealth	yes	no	
Michigan	§§333.2687-2688, §§333.16274-16275, 333.20197, 333.26401-26403, 750.430a	Prohibits human cloning for any purpose and prohibits the use of state funds for human cloning; establishes civil and criminal penalties	yes	yes	
Missouri	§1.217	Bans use of state funds for human cloning research which seeks to develop embryos into newborn child	Prohibits the use of state funds	no	

New Jersey	§2C:11A-1, §26:2Z-2	Permits cloning for research; prohibits reproductive cloning, which is punishable as a crime in the first degree; prohibits sale or purchase, but not donation, or embryonic or fetal tissue, which is punishable as a crime in the third degree and a fine of up to $50,000	yes	no	
North Dakota	§12.1-39	Prohibits reproductive and therapeutic cloning; transfer or receipt of the product of human cloning; transfer or receipt, in whole or in part, any oocyte, human embryo, human fetus, or human somatic cell, for the purpose of human cloning; cloning or attempt to clone punishable as a class C felony; shipping or receiving violations punishable as class A misdemeanor	yes	yes	
Rhode Island	§23-16.4-1 to 4-4	Prohibits human cloning for the purpose of initiating a pregnancy; for a corporation, firm, clinic, hospital, laboratory, or research facility, punishable by a civil penalty punishable by fine of not more than $1,000,000, or in the event of pecuniary gain, twice the amount of gross gain, whichever is greater; for an individual or an employee of the firm, clinic, hospital, laboratory, or research facility acting without the authorization of the firm, clinic, hospital, or research facility, punishable by a civil penalty punishable by fine of not more than $250,000, or in the event of pecuniary gain, twice the amount of gross gain, whichever is greater	yes	no	July 7, 2010

South Dakota	§34-14-27	Prohibits reproductive and therapeutic cloning; transfer or receipt of the product of human cloning; transfer or receipt, in whole or in part, any oocyte, human embryo, human fetus, or human somatic cell, for the purpose of human cloning; cloning or attempt to clone is punishable as a felony and a civil penalty of two thousand dollars or twice the amount of gross gain, or any intermediate	yes	yes	
Virginia	§32.1-162.32-2	Prohibits reproductive cloning; may prohibit therapeutic cloning but it is unclear because human being is not defined in the definition of human cloning; human cloning defined as the creation of or attempt to create a human being by transferring the nucleus from a human cell from whatever source into an oocyte from which the nucleus has been removed; also prohibits the implantation or attempted implantation of the product of somatic cell nuclear transfer into an uterine environment so as to initiate a pregnancy; the possession of the product of human cloning; and the shipping or receiving of the product of a somatic cell nuclear transfer in commerce for the purpose of implantation of such product into an uterine environment so as to initiate a pregnancy. The law establishes civil penalty not to exceed $50,000 for each incident.	yes	unclear	

ealth & Human Services
February 12, 2007

6301 ANTIOCH • MERRIAM, KANSAS 66202 • PHONE/FAX 913-722-6633 • WWW.KSCATHCONF.ORG

TESTIMONY IN SUPPORT OF H.B. 2255

Madame Chair and Members of the Committee:

Thank you for the opportunity to offer testimony in support of H.B. 2255 prohibiting the expenditure of state funds for human cloning. My name is Beatrice Swoopes, the Associate Director of the Kansas Catholic Conference, the public policy office for the Catholic Church in Kansas.

The Catholic Church teaches: "Nothing and no one can in any way permit the killing of an innocent human being, whether a fetus or an embryo, an infant or an adult, an old person or one suffering from an incurable disease, or a person who is dying." (Pope John Paul II, ***The Gospel of Life***)

Human cloning as defined in H.B. 2255 is necessary in order to create human embryonic stem cells for research. The human clone is destroyed at the embryonic stage to extract these human embryonic stem cells.

The Catholic Church believes there are moral as well as scientific problems with Embryonic Stem Cell Research. It dehumanizes humanity by reducing human life to a commodity. It corrupts all scientific inquiry by creating a category of science that has few legal or moral constraints. It kills developing human beings. It harms and exploits women by subjecting them to harmful methods of egg harvesting. It is a biological fact that a unique human being exists from the moment of fertilization and at SCNT cloning. (SCNT – Somatic Cell Nuclear Transfer is cloning.)

Research using adult stem cells is very much supported by the Church, because these stem cells can be harvested without any harm to the donor. Adult stem cells have already been used to treat more than 65 human ailments and diseases with many more trials underway. Embryonic stem cells have never treated a human patient with success.

Science makes it clear that human embryos are human beings and taxpayer money should not be used to destroy them for research. The Kansas Catholic Conference asks for your support of H.B. 2255.

Respectfully submitted,

Beatrice E. Swoopes
Associate Director

House Health and Human Services
DATE: 2-12-07

ATTACHMENT 7

Testimony Submitted to Kansas State Legislature Concerning House Bill No. 2255

February 12, 2007

Diane Beeson, PhD
Medical Sociologist
Professor Emerita
Department of History
California State University, East Bay
Hayward, CA

M.L.Tina Stevens, PhD
Author, Bioethics in America
Department of History
San Francisco State University
San Francisco, CA

We are writing in support of House Bill No. 2255, which will prohibit the use of spending state funds for human embryo cloning. As pro-choice feminists and scholars who study developments in biotechnology we support many forms of stem cell research, including stem cell research on embryos left over from fertility treatments.

Our major, and most immediate concern regarding research cloning is that it requires large numbers of human eggs for highly speculative research. The harvesting of human eggs is a highly risky process that has been poorly studied. What we do know is that the Korean scientist who fraudulently claimed in 2004 to have successfully obtained stem cells used over 2000 human eggs. Thirty-six Korean Women's organizations have since sued on behalf of women who were harmed in the process of donating eggs for this research. We also know that six women have died in the UK as a result of the short term effects of undergoing ovarian stimulation for the purpose of egg harvesting in recent years. Many tragic responses are known to have occurred in the US as well, including a massive stroke that paralyzed a Stanford University student a few years ago. Because there are no requirements that adverse effects be reported in the U.S. and there is no national registry thorough documentation of such problems is unavailable. Furthermore, the IVF industry has changed repeatedly the definition of one of the most serious short-term side effects, ovarian hyperstimulation syndrome. Some studies on the long-term effects have linked this process to ovarian and other forms of cancer, others have not found such links, but experts agree that more data are needed and we are only now entering a period when such long-term effects may become apparent. Significantly, South Korea, a global leader in stem cell research, is expected to ban egg donation in light of its cloning scandal.

House Health and Human Services

DATE: 2-12-07

Attachment 8-1

It took several decades to become apparent that the first hormone widely used on women, diethylstilbestrol (DES) was linked to a virulent form of vaginal cancer. The Centers for Disease Control is still studying the tragic side effects in the grandchildren of women who received this hormone. More recently epidemiologists have been astonished to see that a sharp decline in breast cancer rates has coincided with women giving up hormone replacement therapy after some long term studies finally revealed its destructive effects. We cannot move forward with research cloning in light of the history of exogenous hormone use and its links to cancer. The health and safety of the large numbers of young women who would be needed as egg donors must be protected.

We are including some documents to make it clear that pro-choice feminists have been concerned about this potential threat to women's health for some time and have challenged proponents of cloning in other states and nationally. Many are calling for a moratorium on egg harvesting until the appropriate research on its short and long-term consequences can assure us of its safety for the very young women who are being targeted as donors.

We urge you to consider this information in casting your vote on House Bill 2255.

Thank you.

February 9, 2006

Statement by the Pro-Choice Alliance for Responsible Research

Contact:
Susan Berke Fogel
818.621.7358 (cell)

The Pro-Choice Alliance for Responsible Research released this statement in response to the release of the Institute of Medicine report on the health risks for women who provide eggs for research, "Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research."

This statement can be attributed to Susan Berke Fogel, Coordinator

The Institute of Medicine has released a new report of its assessment of the health risks for women who may be asked to provide their eggs for embryonic stem cell research. The report documents how little scientific data exists about the health risks of egg retrieval, but misses an important opportunity to lead the way by requiring critically important safety evidence before we ask women to take potentially serious unknown risks with their health.

There are many paths of investigation in embryonic stem cell research that can move forward while this safety data are being gathered. Scientists can use embryos initially created for in vitro fertilization, but not ultimately used for this purpose and thus available to researchers with the donor's consent. They can also use stem cells found in amniotic fluid. Even somatic cell nuclear transfer is possible using eggs that do not fertilize during in vitro fertilization.

Much attention has been given to the known risks of ovarian hyperstimulation that can result from drugs used to stimulate the ovaries to produce multiple eggs. But the risks of drugs used to *suppress* the ovaries before such controlled hyperstimulation have been much less studied, and the drug most commonly used for this purpose – leuprolide acetate (Lupron) – has never been approved by the FDA for this purpose. We know from the anecdotal reports of hundreds of women harmed by Lupron that such research is essential to establishing an adequate picture of the risks involved. Moreover, the recent drop in breast cancer rates and its link to a decline in hormone replacement therapy (HRT) is a timely reminder of how little is known about the long term effects of large doses of hormones.

The IOM report accurately states, "one of the most striking facts about in vitro fertilization is just how little is known with certainty about the long-term health outcomes for the women who undergo the procedure." It goes on to acknowledge that even "that limited knowledge is not directly applicable to the safety of ooctye donation for research." The report then rightfully suggests the need to collect good data, engage in long-term studies, and reduce risks to women.

Unfortunately, the IOM report elevates SCNT over other avenues of research in the development of future stem cell therapies. By suggesting that researchers must have thousands of women's eggs now, despite the critical absence of safety data, the report does women a great disservice. A more responsible conclusion would be to call for:

1. Research endeavors that do not require egg extraction procedures solely for research purposes; and
2. Research that will better define the risks of multiple egg extraction, so that meaningful informed consent will be possible. This will serve not only women who may want to donate eggs for research, but women who now undergo these procedures as part of infertility treatments.

Much scientific progress can be made by pursuing avenues of embryonic stem cell research that do not require women to sacrifice their health and well-being while important safety data are being gathered. The decision of whether to proceed with egg procurement for research should be based on adequate scientific evidence. It is premature to ask women to put their health on the line.

The Pro-Choice Alliance for Responsible Research is a coalition of reproductive health and justice advocates, bio-ethicists, academics, and researchers working to ensure safety, accountability, and transparency in bio-technology from a women's rights perspective.

Statement of Judy Norsigian
Executive Director, Our Bodies Ourselves

Subcommittee on Criminal Justice, Drug Policy and Human Resources
Government Reform Committee
U.S. House of Representatives

Hearing on Human Cloning and Embryonic Stem Cell Research after Seoul: Examining Exploitation, Fraud, and Ethical Problems in the Research
March 7, 2006

I am Judy Norsigian, the Executive Director of Our Bodies Ourselves, a women's health education and advocacy organization now in its 37th year. We are best know for our landmark book about women's health and sexuality - ***Our Bodies, Ourselves*** - which appeared in its 8th edition as a major revision last May. Thank you for this opportunity to speak.

At the outset, let me make clear, as I did at similar hearings four and five years ago, that my organization supports most embryonic stem cell (ESC) research. We fully support ESC research that utilizes otherwise-discarded embryos from IVF clinics. At the same time, we have serious concerns about a small subset of ESC research known as somatic cell nuclear transfer (SCNT) and more commonly referred to as "research cloning," "therapeutic cloning," or "embryo cloning." We believe that our country should follow the prudent example already adopted by Canada and place a moratorium on all SCNT research until better safety data are available for some of the drugs used during multiple egg extraction procedures.

There are several reasons for this position, but I will focus my remarks primarily upon our concerns regarding the risks of multiple egg extraction required for research cloning. Although women who undergo multiple egg extraction procedures experience similar risks whether doing this for reproductive purposes (as is the case in an IVF clinic) or for research purposes, there is a critical difference. In the former instance, there is a 10-40% chance that someone – either the woman herself or another woman who is seeking to become pregnant at an IVF clinic – will be able to have a baby. That is a clear benefit. In the latter instance, where a woman undergoes these procedures solely for research purposes, the benefits to her or someone else are far more dubious at this time.

Although some stem cell researchers have discussed this matter and even share our concerns, few have been willing to write about these issues. It may be that one positive outcome of the scandal in South Korea will be greater recognition of just how risky multiple egg extraction can be, as well as how easily frenetic competition and unjustified hype can lead to a more ready dismissal of these risks. In a recent issue of the *American Journal of Bioethics*[1], Stanford researchers David Magnus and Mildred Cho write the following:

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[1] **A Commentary on Oocyte Donation for Stem Cell Research in South Korea**
by David Magnus, Mildred K. Cho. 2006. *The American Journal of Bioethics* 6(1):W23

> "In a previous paper ('Issues in oocyte donation for stem cell research.' Science, v.308: 1747-1748, 2005), we argued that there were risks associated with being an oocyte donor that were not given adequate attention in the informed consent process. This claim was based upon the informed consent documents by the South Korean researchers, an accompanying written description of the consent process, and their responses to questions posed. We argued that it would be easy to give short shrift to the small, but serious, risks that typically arise in a clinical setting precisely because these risks are not associated with the research aspects of oocyte donation. We therefore recommended recognition of a new category of research participants—research donors."

They go on to say:

> "The language used to describe scientific experiments also makes a great deal of difference in how accurately we convey the nature of stem cell research. We argued, for example, that referring to the process of deriving stem cells by somatic cell nuclear transfer as "therapeutic cloning" reinforces the mistaken impression that experiments are therapeutic in nature. In fact, there is no therapy currently associated with SCNT."

Furthermore, they take a cautious position regarding egg procurement procedures for research cloning:

> "....there is an important distinction between oocyte donation for research and live organ donation for transplantation. Live organ donation has a clearly established clinical value — stem cell research does not. If that should change, we would agree that allowing women to donate oocytes for stem cell-based treatments would be permissible, if conducted properly. But allowing research donation to take place under these circumstances is an invitation for a new kind of therapeutic misconception, and should be avoided at this early stage of scientific development."

The risks of multiple egg extraction are still not well-enough studied, especially the risks associated with the drugs that first suppress the ovaries. (Afterwards, different drugs are used to create controlled ovarian hyperstimulation.) The drug most often used to suppress a woman's ovaries is Lupron™ (leuprolide acetate), a GnRH agonist. Adverse reactions to this and similar drugs include the following: anemia; high blood pressure; formation of blood clots that could potentially cause damage to vital organs; fluid accumulation in the limbs; thyroid enlargement; liver function abnormality; joint, muscle and bone pain; chest pain; difficulty in swallowing; intestinal bleeding; headaches and migraines; dizziness and blackouts; memory disturbances; depression; anxiety; numbness; swelling of hands; constipation; nausea; vomiting; diarrhea; and vision abnormalities. Many people assume that this drug has been approved by the FDA for this particular indication, but that is not the case. All use of Lupron in the IVF setting is "off-label" use, and as former Chief Medical Officer Dr. Suzanne Parisian points out in the attached memorandum, there are serious safety concerns yet to be resolved. Only well-designed research will answer critical questions that would then allow true informed consent for women undergoing multiple egg extraction procedures for any purpose.

The drugs used to "hyperstimulate" the ovaries after ovarian suppression also have negative effects, most notably Ovarian Hyperstimulation Syndrome (OHSS), a condition in which the ovaries continue to enlarge even after the eggs have been collected. Serious cases of this syndrome involve the development of many cysts and enlargement of the ovaries, along with

massive fluid build-up in the body. As noted in an article about OHSS, "the reported prevalence of the severe form of OHSS is small, ranging from .5 to 5%. Nevertheless, as this is an iatrogenic complication of a non-vital treatment with a potentially fatal outcome, the syndrome remains a serious problem for specialists dealing with infertility."[2] In her memo, Dr. Parisian also notes that ovarian stimulation in rare cases can lead to stroke and "arterial occlusion with loss of a limb and death."

These risks were also noted in the informed consent document developed at the Bedford Stem Cell Institute several years ago (see "Consent to Participate in a Study Involving Egg Donation for Stem Cell Research"). Following is an excerpt from this document: "Complications associated with being an egg donor include unpredictable response to the hormones provided to you, surgical complications during the egg collection, and unknown long-term side effects from the hormones. If any of these complications arise the reproductive biologists involved in this research may choose, at their discretion, to terminate your continued participation in this research." What is unclear, however, is whether or not the costs of medical treatments for problems resulting from these procedures would be covered.

And it is not only the women undergoing the procedure who may be at risk from ovarian hyperstimulation. An article published in the past month by a Dutch team including medical and basic scientists suggests that their infants may also suffer adverse consequences.[3] This group has shown that female mice subjected to ovarian hyperstimulation had offspring with reduced birth weight as well as a high incidence of congenital anomalies, including delayed formation of bones and an eight-fold increase over background levels of cervical ribs, a condition which, when present in human infants, is associated with stillbirth and cancer.

Should SCNT research go forward despite the concerns mentioned here, it will be left to women's health advocates to emphasize the inadvisability of women undergoing these procedures (especially younger women, whose risk of Ovarian Hyperstimulation Syndrome is greater than that for older women).

Also, if such research goes forward, certain regulations and oversight of the research with respect to egg procurement are essential. The following policies should be adopted:

1. Eggs should be obtained without any hormonal stimulation, since there is still insufficient information to get true informed consent from would-be egg providers. Although Antagon, a GhRH antagonist, IS approved for such use, there are no long term safety data for this drug. Thus, only single cycling or extraction at the time of a sterilization or ovariectomy should be allowed for extracting eggs for SCNT research.

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[2] Delvigne, Annick and Rozenberg, Serge. "Epidemiology and prevention of ovarian hyperstimulation syndrome (OHSS): a review" *Human Reproduction Update*, vol. 8, no. 6, 2002, pp 559-577.

[3] Steigenga, Marc J., Helmerhorst, Hans M., De Koning, Jurien, Tijseen, Ans M.I., Ruinard, Sebastiaan, A.T. and Galis, Frietson. Evolutionary conserved structures as indicators of medical risks: increased incidence of cervical ribs after ovarian hyperstimulation in mice *Animal Biology*, vol. 56, no. 1, 2006, pp. 63-68.

2. No relatives or co-workers of those doing research on eggs should be allowed to provide eggs for research.

3. All medical expenses resulting from egg extraction for research should be covered. In cases where cycles would be hormonally manipulated, longer-term health care coverage may be necessary to provide medical care for certain delayed health problems.

4. Those performing egg extraction for research purposes should function totally separate from IVF services (an effective firewall is needed to avoid both financial and professional conflicts of interest).

5. No research should be allowed on eggs or stem cell lines developed from eggs procured by means other than those described in #1-4. This would avoid the use of stem cell lines created in other countries or regions, where safeguards to women's health might not be in place.

6. No patents should be allowed for products that might result from research on these eggs. Without such a policy, many therapies will likely never be accessible to the wider public. In addition, it would be extraordinarily difficult to avoid a problematic commercial market in women's eggs.

7. No payments to egg providers beyond direct expenses (eg, no payment for lost wages) should be allowed.

Many scientists now acknowledge that "individualized" disease therapies will not result from embryo cloning research anyway (see "Cloning: Mining the secrets of the egg," by Carina Dennis, *Nature,* February 9, 2006) The main benefit of embryo cloning would be the ability to develop research models for studying particular diseases and conditions, but some of this type of work can be done already with otherwise-discarded embryos that result from PGD (Preimplantation Genetic Diagnosis) testing. At this point in time, given both the known and unknown risks involved in multiple egg extraction procedures, these procedures should not be done solely for SCNT (embryo cloning) research.

Some researchers are already investigating alternatives such as nurturing immature eggs, growing artificial eggs in the lab, and using animal egg substitutes. Although each of these approaches has its own technical and ethical challenges, this trend does recognize how strikingly inefficient embryo cloning is, and that it will likely require – at least for a long time to come – that hundreds of eggs be extracted to obtain even one viable clonal embryo. Dr. Arnold Kriegstein, Director of the Institute of Stem Cell and Tissue Biology at the University of California, San Francisco, takes the approach that "We'll have to wait and see how difficult human eggs are to acquire" (see *Nature* article cited above), but I would hope researchers would follow the more cautious approach suggested by Drs. Magnus and Cho.

Congressional Hearings
March 7, 2006

House Government Reform Subcommittee on Criminal Justice, Drug Policy and Human Resources -- Hearing on Stem Cell Research

Statement by Diane Beeson, PhD

Chairman Souder, Representative Waxman, and Members of the Committee, thank you for inviting me to testify today on exploitation, fraud, and ethical problems related to human embryo cloning and embryonic stem cell research.

My name is Diane Beeson. I am a medical sociologist and Professor Emerita of Sociology at California State University, East Bay. I received my PhD at the University of California, San Francisco (UCSF) and was a Pew Postdoctoral Research Fellow at UCSF's Institute for Health Policy Studies. I have a long-standing professional interest in reproductive genetics and have worked at UC Berkeley's Center for the Study of Social Change on several federally funded studies on the social implications of genetic technologies. I have also been a Visiting Fellow at Stanford University's Center for Bioethics and have served on many review committees for the Human Genome Research Institute's Ethical, Legal and Social Implications Research Program. I am currently an affiliated scholar with the Institute on Biotechnology and the Human Future at the Illinois Institute of Technology and the Chicago-Kent College of Law.

First, I would like to emphasize that I am a life-long supporter of women's abortion rights and I support embryonic stem cell research using embryos left over from IVF treatments. However, in 2004 when the California Stem Cell Initiative was placed on the ballot asking voters to authorize $3 billion in state bonds for research that prioritized the development of human cloning technologies, I decided to speak publicly about my concerns and became a founder of the Pro-Choice Alliance Against Proposition 71.

Like many social scientists I have broad concerns related to the wisdom of developing cloning technologies. However, my comments today will focus on social and ethical problems created by the demand for human eggs needed in experimental cloning, a process also known as somatic cell nuclear transfer, or SCNT. Specifically, the concerns I will raise today are related to the exploitation of women necessary for the development of SCNT. These are the same problems that have been uncovered in the scandal surrounding Dr. Hwang's research and that we can expect to persist wherever SCNT is pursued.

Dr. Hwang Woo-suk's original claim to have successfully used SCNT to create a human embryo from which stem cells were extracted was first announced in February 2004. California was then in the early stages of a $35 million political campaign and media blitz to assure voters that if they supported massive public funding of this research miracle cures would soon be available for an unlimited list of lethal disorders.

Initial reports indicated Hwang's team used 242 human eggs to create one embryo in 2004. Then in 2005 he claimed to have generated "11 patient-specific stem-cell lines with a success rate of 1 line for approximately every 20 oocytes."[1] This created the illusion that significant progress had

[1] Snyder, E.Y. and J.F. Loring. Beyond Fraud—Stem-Cell Research Continues. *New England Journal of Medicine* 2006; Vol. 354, No. 4, pp. 321-324.

been made in bringing down the number of eggs SCNT would require. It has now been revealed that Dr. Hwang used over 2000 eggs in his discredited research.[2] His failure to produce even one cloned embryo reminds us that we still do not know how many thousands, or possibly even millions of eggs it may require to perfect SCNT. Furthermore, it has become clear that payment, coercion, and lying were used to acquire the eggs that we were told many women were eager to donate.

Californians, influenced by irresponsibly inflated claims of imminent cures, reinforced by excitement over Hwang's fraudulent research successes, have already cast their votes to massively fund SCNT; but the public has yet to be adequately informed about the human costs of such research. Today I would like to make three points in that regard:

1. Egg extraction as currently practiced poses inadequately understood, yet clearly significant, risks to the health of women.

2. Under current conditions informed consent to participate in egg extraction for research purposes is not possible.

3. The same social conditions that drive the demand for women's eggs set the stage for other violations of the public trust.

In light of this situation, I support the call for a moratorium on SCNT. This is a position supported by the feminist pro-choice women's health organization, Our Bodies Ourselves, the California Nurses Association,[3] and many other pro-choice progressives.

To explain my position, let me begin with a brief background on egg extraction. Because such practices have come into expanded use since the birth of the nation's first test tube baby in December 1981, it is widely assumed that they have been proven to be safe. Unfortunately, this is not the case.

Extraction of multiple eggs involves both ovarian suppression and what is known as "ovarian hyperstimulation" using powerful hormones into a woman's body to manipulate it into producing many—often a dozen or more—eggs at a time rather than the normal one or two. The mature eggs are then collected for use in infertility treatments, in vitro fertilization, or research.

Contrary to common assumptions, these procedures have not been adequately studied. For example, one drug commonly used in egg extraction, Lupron, has not been approved for this purpose, but rather is used off label. Another such drug, Antigon, has been approved for such use, but no data are available on its long-term safety.[4]

As Suzanne Parisian, former Chief Medical Officer of the Food and Drug Administration, explains, "Pharmaceutical firms have not been required by either the government or physicians to collect safety data for IVF drugs regarding risk of cancer or other serious health conditions despite the drugs having been available in the United States for several decades." [5]

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[2] Steinbrook, R. Egg Donation and Human Embryonic Stem Cell Research. *New England Journal of Medicine* 2006; Vol. 354, No. 4, pp. 324-326.
[3] See Appendix A. California Nurses Association Position Statement on Embryonic Stem Cell Research.
[4] See Appendix B. Letter from Dr. Suzanne Parisian, Former Chief Medical Officer, FDA. Also on-line at http://www.genetics-and-society.org/resources/items/200502_letter_parisian.html.
[5] See Appendix B.

The FDA currently has on file over 6000 complaints regarding Lupron, including 25 reported deaths.[6] These complaints must be investigated and analyzed.

In the absence of long-term follow-up it is impossible to assess accurately the seriousness of the risks to women's health from the expanding use of egg extraction. One study reports that up to 14 percent of patients undergoing ovarian hyperstimulation experience some form of ovarian hyperstimulation syndrome, or OHSS.[7] This is a condition whose pathophysiology remains unclear. Common symptoms of mild OHSS include abdominal discomfort, ovarian enlargement, nausea and vomiting. Those who develop severe OHSS may experience a wide range of serious conditions including loss of future fertility, kidney or multiple organ failure, and death. The frequency of severe OHSS is estimated to be as high as 10 per cent of women who undergo the procedure.[8]

We don't yet know the full extent of the damage to the health of the Korean women who provided the eggs used by Dr. Hwang. But we do know that a coalition of 35 women's groups is suing the South Korean government on behalf of women who have been harmed in the process of egg extraction. Reports are that about 20 percent of the donors have experienced side-effects.[9] We also know that serious problems with egg extraction are not unique to the Korean experience.

Jacqueline Rushton, who died as a direct result of OHSS in Dublin, Ireland, in 2003, suffered a gradual deterioration of her organs, virtually all of which were slowly destroyed.[10] Temilola Akinbolagbe, a young woman who died last April in London, suffered a more sudden death from a massive heart attack linked directly to OHSS.[11]

While such events seem to be rare, it is possible that many deaths and other longer-term side effects of ovarian hyperstimulation have simply not been linked officially to the egg extraction procedures that preceded them. For example, Dr. Parisian reminds us that "studies to date have not ruled out a possible link between stimulation drugs and increased risk of ovarian cancer." She concludes that it is very likely that "those promoting SCNT research may be unknowingly tackling a far more costly and serious health burden by allowing the expanded use of current IVF stimulation drugs for SCNT." [12]

One of most destructive consequences of ovarian hyperstimulation for women may be serious abnormalities in their children. Just this month a new study reports that ovarian hyperstimulation treatment in mice results in several significant abnormalities in their later offspring. These effects include growth retardation, a delay in ossification (bone development) and an eight-fold increase in a significant rib deformity. This particular deformity in humans is associated with an increased incidence of abnormalities and cancer. Because of these associations, the authors conclude that it is possible that their findings may have implications for the use of ovarian hyperstimulation

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[6] Lazar, Kay. Wonder Drug for Men Alleged to Cause Harm in Women. *Boston Herald*, August 22, 1999.
[7] Hugues, in Vayena, E. *et al.* (eds). *Current Practices and Controversies in Assisted Reproduction.* World Health Organization, Geneva, Switzerland, pp 102-125 (2002).
[8] Magnus, D. and M.K. Cho. Issues in Oocyte Donation for Stem Cell Research. *Sciencexpress/www.sciencexpress.org* May 19, 2005, p.1.
[9] Hwa-young, Ova Donors Demand Compensation from Government. *AsiaNews.it.* 2-7-2006. www.asianews.it/view_p.php?l=en&art=5322
[10] See Appendix C. Letter from Rushton's mother. Mrs. Angela Hickey.
[11] Woman died after starting IVF treatment. Richmond & Twickenham Times. 20 April 2005. http://www.richmondandtwickenhamtimes.co.uk/mayor/other/display.var.589076.0.0.php
[12] See Appendix B

treatments in women. This question must be answered before involving thousands of women in ovarian hyperstimulation purely for research purposes.[13]

Scientists and other proponents of SCNT have been reluctant to confront forthrightly the dangers related to egg extraction. This reluctance has been demonstrated repeatedly in recent California politics. For example, during the campaign to pass Proposition 71 its proponents took legal action in an effort to prevent opponents from explaining in the state Voters' Guide that the measure involved human embryo cloning, requiring thousands of women's eggs.[14]

Although efforts to keep this information out of the Voters' Guide failed, the heavily funded campaign nevertheless successfully undermined broader public dialogue on this issue. It did so by incorrectly characterizing all opposition to the measure as motivated primarily by concern with the moral status of the embryo. To the very limited extent that the term "cloning" entered the discussion, it was invariably inaccurately termed "therapeutic cloning," in spite of the fact that no therapies have yet been associated with SCNT. It was not until the election was over that the press began to raise many of the ethical problems implicit in the initiative.

A series of recent legal developments have fueled scientists' reluctance to confront ethical difficulties with SCNT. In 1980, the U.S. Supreme Court, in *Chakrabarty v. Diamond,* affirmed a right to patent genetically engineered life forms.[15] In the same year, Congress passed the Bayh-Dole Act, which allowed universities and their researchers to patent even those research products funded by the federal government.[16] As a result, the field of embryonic stem cell research has become the focus of a virtual biotech gold rush, inevitably creating gross conflicts of interest.

These conflicts of interest have been built into the structure of the newly established California Institute of Regenerative Medicine (CIRM). For example, at least half of its inaccurately named governing board (Independent Citizen's Oversight Committee [ICOC]) represent institutions likely to conduct stem cell research. In addition, at least seven of the 29 ICOC members have significant business relationships, including substantial equity investments and board memberships, with companies involved in stem cell research.[17]

California's Stem Cell Initiative campaign illustrates how the need to secure massive amounts of funding has led advocates to obscure major scientific and technical obstacles to the research.

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[13] Steigenga, MJ, et al. Evolutionary Conserved Structures as Indicators of Medical Risk: Increased Incidence of Cervical Ribs After Ovarian Hyperstimulation in Mice. *Animal Biology*, vol 56, No. 1, pp. 63-68 (2006). See Appendix D for full text.

[14] Memorandum of Points and Authorities in Support of Petition for Writ of Mandate and Alternative Writ of Mandate/Order to Show Cause. (7-28-04, Case No. 04C501015) Paul Berg, Robert Klein, and Larry Goldstein, Petitioners vs. Kevin Shelly, Secretary of State of California, Respondent, Geoff Brandt, State Printer; Bill Lockyer. Attorney General of California ; Tom McClintock; H. Rex Green; John M. W. Moorlach; Judy Norsigian; Francine Coeytaux; Tina Stevens; Does I through X, inclusive, Real Parties In Interest. See also Declaration of Dr. Stuart A. Newman, PhD. In Opposition to Petition for Writ of Mandate and alternative Writ of Mandate/Order to Show Cause.

[15] 447 U.S. 303(1980).

[16] For the Bayh-Dole legislation see, Government Patent Policy Act of 1980, Pub. L. No. 96-517, 94 Stat. 3019.

[17] Reynolds and Darnovsky, Reynolds, J. and M. Darnovsky, et al. *The California Stem Cell Program at One Year: A Progress Report.* Center For Genetics and Society. January 2006, p 26. http://www.genetics-and-society.org

These include difficulties in restricting the potential of embryonic stem cells to desired differentiated types, as well as their tendency to form tumors in adult hosts.[18]

Disclosures to women who are being asked to take significant risks to their health and fertility by making altruistic donations of eggs should not be limited to acknowledging potential negative consequences to the donor's health. They should also reveal the researchers' intent to develop patents using these donated eggs and the potential of these patents to harm the public health and to impede other research. These problems with patenting have been described in detail by Andrews.[19]

Until financial conflicts of interest are brought under control we can expect the pursuit of profit to trump humanitarian concerns in determining the directions science takes. We also can expect continuing challenges to established ethical norms. The conflicts of interest and pressures that existed for Dr. Hwang and his colleagues, two of whom were American, are not unique to Korea. They operate very strongly within the borders of the United States as well.

Some liberal and progressive supporters of stem cell research who are concerned with preventing these abuses have argued that what is needed is "public sector bodies with the power to establish and enforce comprehensive regulations that apply to both publicly and privately funded research."[20] They call for prohibitions on payments to egg providers except for out-of-pocket expenses to prevent the emergence of a market in eggs, a requirement that egg extraction be carried out by those not involved in stem cell research, and follow-up medical care to treat adverse reactions that women who provide eggs suffer.

However, due to rampant conflicts of interest among those involved in the field, I have serious doubts that any regulatory structure could avoid implicitly condoning SCNT, and therefore it would be ineffective in protecting women's health. Proposed regulations are particularly silent on the long-term threats to the health of egg providers, for which researchers must be held responsible.

As a society we are at a turning point in our relationship to science. We are being asked to make women the servants of biotechnology, rather than insisting on a biotechnology that promotes the well-being of all people. For these reasons, until we understand more fully its human costs, I strongly urge your support for a moratorium on SCNT.

Appendices available with testimony at:
http://reform.house.gov/UploadedFiles/Beeson%20Testimony%20with%20attachments.pdf

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[18] Newman, S. A. (2003). Averting the Clone Age: Prospects and Perils of Human Developmental Gene Manipulation. *J. Cont. Health Law and Policy* 19, 431-463.

[19] See Appendix E. Andrews, L.B. "Genes and Patent Policy: Rethinking Intellectual Property Rights." Nature Reviews/Genetics, Vol. 3, October 2002.

[20] Reynolds, J. and M. Darnovsky, et al. The California Stem Cell Program at One Year: A Progress Report. Center For Genetics and Society. January 2006, p 17. www.genetics-and-society.org

BIO
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

Statement in Opposition to House Bill 2255
House Health and Human Services Committee
Representative Brenda Landwehr, Chair

Thank you Madam Chair and members of the Health and Human Services Committee, my name is Duane Simpson and I am testifying on behalf of the Biotechnology Industry Organization (BIO) in opposition to House Bill 2255.

BIO is the national trade association representing more than 1100 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 US states and 33 foreign nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology projects.

Kansas has established itself as a leader in the area of biomedical and life science research and development. The Kansas Economic Growth Act and the creation of the Kansas Bioscience Authority are model pieces of legislation for the rest of the country. We are now seeing the fruits of this Legislature's labor as we attempt to recruit the National Bio and Agro Defense Facility to Kansas. The current growth in the Kansas economy is due to biotechnology and the future of the Kansas economy depends on expansion of Kansas' role in biotechnology research.

There is a significant difference between cloning to create a new human being (reproductive cloning) and cloning specific human cells, genes and other tissues for therapeutic purposes (therapeutic cloning). Not only does the HB 2255 not recognize the difference, it intentionally encompasses all forms of therapeutic cloning. In fact, the definition of 'human cloning' in HB 2255 is not the same definition as the one written in HB 2098, a bill written by the same proponents.

The regenerative nature of human embryonic stem cells makes them ideal for research in numerous diseases areas. These areas include spinal cord injury, Alzheimer's and Parkinson's disease, diabetes, heart disease, regeneration of tissues for burn victims as well as promising new research in cancer.

There is a significant difference in regenerative nature of stem cells depending on amount of differentiation that has gone on in the cells. For instance adult stem cells are rather specialized - in other words, they have specific missions within the human body. Cord blood stem cells are less specialized, but are still differentiated to a degree to make them more difficult to work with than embryonic stem cells. Embryonic stem cells are "pluripotent" in that they can become just

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about any cell in the body given the proper differentiation. That's why these cells hold so much potential for researchers. Embryonic stem cells are essentially like blank CD-ROMs that you would use in your computer. They can be programmed to perform numerous functions within the human body. Adult stem cells and cord blood stem cells have the ability to be reprogrammed, but are not as capable as embryonic stem cells.

HB 2255 bans state funding from going to all forms of human cloning, including the potential therapeutic application of somatic cell nuclear transfer to create customized embryonic stem cells. We support recommendations by the National Academies of Science (NAS) that the cloning of human beings for reproductive purposes should be prohibited; but that therapeutic cloning should be permitted. A recent report issued by the NAS states:

> "The scientific and medical considerations that justify a ban on human reproductive cloning at this time are not applicable to nuclear transplantation to produce stem cells. Because of the considerable potential for developing new medical therapies to treat life-threatening diseases and advancing biomedical knowledge, the panel supported the conclusion of a previous National Academies' report—*Stem Cells and the Future of Regenerative Medicine*—that recommends that biomedical research using nuclear transplantation to produce stem cells be permitted."

While therapeutic cloning has yet to be a proven source for developing stem cells, many scientists think that it has significant potential to lead to the development of truly individualized treatments. The cells generated using therapeutic cloning would be genetically identical to the patient's own cells thereby reducing the threat that the cells will be rejected by the patient's own body. For example, suppose a middle-aged man suffers a serious heart attack while harvesting wheat in North Central Kansas. By the time he reaches the hospital, only a third of his heart is still working, and it is unlikely he will be able to return to his formally active life. He provides scientists a small sample of skin cells. Technicians remove the genetic material from the cells and inject it into donated human eggs from which the chromosomes have been removed. These altered eggs will yield stem cells that are able to form heart muscle cells. Since they are a perfect genetic match for the patient, these cells can be transplanted into his heart without causing his immune system to reject them. They grow and replace the cells lost during the heart attack, returning him to health and strength.

The NAS has taken steps to provide guidelines for research on embryonic stem cells. The Academies' guidelines include a recommendation that institutions conducting embryonic stem cell research establish Embryonic Stem Cell Research Oversight (ESCRO) committees. We support these recommendations.

Stem cell research and human cloning presents complex issues and requires thoughtful debate. Recent efforts in the U.S. Congress to address these issues are a clear example of the complicated scientific, ethical and moral issues at stake. Many states have taken steps to encourage all forms of stem cell research, including embryonic stem cell research. States like California, Massachusetts and New Jersey (all significant leaders in biotechnology and pharmaceutical industry presence) have passed laws to prohibit reproductive cloning at the same

time creating safe harbors for all forms of stem cell research. These states have a vested interest in retaining their biotech leadership positions and their legislatures have taken steps accordingly.

The proponents of HB 2255 argue that state tax dollars should not go to SCNT research. Of course, this bill is just one more step in the process of trying to make criminals out or researchers, doctors and patients as envisioned in HB 2252 and HB 2254. There is not any SCNT research being done in Kansas with either private or public funds; that is clearly not the issue of this bill. Instead, the proponents have written this bill so broadly that it will prevent this promising research from ever curing diseases for Kansas patients.

Specifically, HB 2255 will prohibit any state research institution from using its facilities to perform privately or federally funded SCNT research. The bill prohibits hospitals that receive Medicaid payments from receiving cures developed from SCNT for future patients. In the example I mentioned, the heart attack victim would be unable to go to a Kansas hospital and have a sample of his skin cells sent to a lab and he would not be able to have the heart muscle cells transplanted into his heart. The opponents of SCNT say that this research will not provide cures, yet they are trying to prevent Kansas patients from accessing those cures.

HB 2255 also would prohibit any state university, public elementary or secondary school, or any state funded library from receiving published studies that result from SCNT research. Potentially, the bill could prohibit internet access at any state funded institution because of the ability to receive the product of human cloning.

HB 2255 does not just prohibit funding from the State General Fund; it prohibits funding from any money in the state treasury including special revenue funds. By placing a limit on all of these funds, HB 2255 effectively bans any money that touches a state agency, whether it is a tax dollar or not.

The State of Kansas is in a position now to capitalize significantly on the promise of bioscience research and development. HB 2255 threatens to seriously impair the state's reputation as a center of excellence for scientific research. It has the potential to shut down research that was never intended to be included under this ban. It has the potential to take Kansas schools off of the information superhighway and to censor public libraries. Kansas families have a right to access the best research and cures available and HB 2255 denies them that right. Madam Chair and members of the committee I strongly urge you to oppose HB 2255.

Drew Dimmel
10425 Nieman Road
Overland Park, Kansas 66214

Feb. 12, 2007

House Health & Human Services Committee
Statement opposing HB 2255
Drew Dimmel
Chairman/Board of Directors, Parkinson Foundation of the Heartland

Madam Chair, Committee Members:

I appreciate the opportunity to speak to you today about my opposition to House Bill 2255. Although the bill purports only to ban state funding for SCNT research, I believe that by doing so, the bill unfairly "taints" SCNT research …which many medical experts believe could eventually cure diseases and injuries that afflict more than two hundred thousand Kansas adults and children.

One of those diseases is Parkinson's. I was diagnosed with Parkinson's 5 years ago, and I'm currently Chairman of the Board of Directors of the Parkinson Foundation of the Heartland. But primarily, I'm here today as a citizen of Kansas just like yourselves. I'll acknowledge that there are differing opinions of SCNT research, and I wouldn't presume to impose my opinion on you or anyone else.

But I do think it's fair to ask why so many Kansans, of good moral character, are at odds with each over SCNT research.

Why would people consider it wrong to ATTEMPT TO HEAL THE SICK using the organic material from the SCNT process — a process that no one I know of wants to use to create a human clone or even thinks would work to create one?

In fact, is harvesting stem cells from a bundle of organic tissue really the issue? Or is the problem that this is unfamiliar scientific territory … territory that has become the scapegoat for the real monster that we all fear … HUMAN CLONING?

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No one wants human reproductive cloning. But no one wants to suffer — or watch a loved one suffer — a degenerative condition like Parkinson's, either. That's why SCNT research is strongly supported by groups like the National Parkinson's Foundation, the Parkinson's Action Network and my organization, the Parkinson Foundation of the Heartland. In fact, dozens of other medical organizations and patient groups also support SCNT research, including the American Medical Association, the American Diabetes Association, the Christopher Reeve Paralysis Foundation, and the Leukemia and Lymphoma Society.

Some object to SCNT research by saying that it is human reproductive cloning. But it is not. SCNT is a process for making embryonic stem cells that are a genetic match for a particular patient. SCNT doesn't make a copy of a human being; it makes a dish of stem cells in a laboratory. These are cells that are likely to lead to treatments for some of humankind's most debilitating and deadly conditions — conditions for which we have no cures now and which are unlikely to be cured by other kinds of stem cell research, such as work using adult stem cells.

HB 2255 would unfairly shackle Kansas medical researchers. It would potentially deprive Kansas patients of the benefits of future stem cell cures approved by the Food and Drug Administration and available to patients in other states. It suggests that somehow SCNT research is objectionable. But what I find objectionable is that the state might discourage medical research that might one day relegate Parkinson's to the historical waste bin, the way the Salk vaccine did with polio.

I ask that you, the citizens we've elected to represent us and that we are depending upon to make the best, moral, factual choices on our behalf … deal squarely with TRUTH, JUSTICE and REALITY when casting your deciding vote … and relegate special interest and biased partisanship … to lesser men and women.

Thank you.

February 12, 2007

Durant Abernethy, Chapter Chairman
American Medical Association — Medical Student Section
University of Kansas Medical Center
4206 Cambridge St
Kansas City, KS 66103

Madam Chair, Committee Members:

I appreciate the opportunity to speak to you today about my opposition to House Bill 2255, which would prohibit the expenditure of state money on research involving somatic cell nuclear transfer, or SCNT.

I appear before you today both as a medical student who cares about the future of medical research in our state and as a person who may one day be cured through embryonic stem cell research. During my college years, I was diagnosed as a Type 1 (or juvenile) diabetic, which means my body has lost the ability to produce its own insulin. Consequently, I have to inject synthetic insulin several times a day. Without these injections, I would certainly die from the toxic levels of glucose that would accumulate in my blood. Actually, insulin injection has been the only treatment option since it was first used by Dr. James Collip in 1922. However, these insulin injections do not equate to a cure, and have even proven inadequate for successful diabetes management. As a result, millions of men, women and children have been devastated by the myriad of complications associated with diabetes, such as kidney failure, blindness and loss of limbs.

As of today, diabetes, Parkinson's, sickle cell, heart disease, some cancers and spinal cord injuries have no cures. An overwhelming majority of medical experts concur that adult stem cells are unlikely to yield cures for these diseases. Fortunately, these experts further agree that embryonic stem cell research is capable of generating cures for these and many other afflictions. The most promising form of embryonic stem cell research involves a process known as somatic cell nuclear transfer, or SCNT. It uses a person's own cell and a donated human egg to produce stem cells that nearly match that person's genetic makeup. In generating cures, it could provide critical cells that are customized to a particular, thus avoiding the numerous difficulties of conventional transplant rejection.

HB 2255 purports to ban state spending on human cloning, but it erroneously defines SCNT as human cloning. SCNT is not synonymous with "human cloning" because it produces potentially lifesaving cells in a laboratory setting, not cloned babies. This important difference is more clearly reflected by the terms "therapeutic cloning" and "reproductive cloning." Therapeutic cloning uses a cluster of cells in a

Petri dish to research cures for some of our most serious diseases and conditions. In contrast, reproductive cloning is an attempt to produce a living human being through implantation in a woman's uterus. There is general agreement that reproductive cloning is undesirable and can be regulated without hindering therapeutic cloning and its potential to save millions of lives. Therefore, we should focus our energies on preventing reproductive cloning and supporting lifesaving research like therapeutic cloning.

No one has actually proposed state funding for SCNT research. And some believe this important SCNT research would continue with private support, even if state funding were banned. But that is not true. By far the largest medical research institution in our state is the KU Medical Center. Since the buildings and equipment are state-owned, any research utilizing its facilities must be in compliance with state regulations. Therefore, KU would need private funding for new buildings, laboratories, equipment and staff that are completely separate from any resources funded by the state. Not only would this be extremely cost-prohibitive to SCNT research, but would create a redundancy in equipment and resources that would further exacerbate the rising cost of medical care.

Consider, too, all the hospitals and clinics in Kansas that receive state funding through Medicaid. Suppose an SCNT-derived cure for spinal cord injury was developed and approved by the FDA. Even if that cure did not directly utilize the SCNT process, HB 2255 would consider it a product of that research and Kansas care-givers would be forbidden from providing that cure.

So a ban on the use of state funds for SCNT research would have the effect of shutting down any current or future SCNT research in Kansas. And it could unfairly prevent Kansas residents from having access to therapies and cures available to the citizens of other states.

That's why writing into Kansas law a ban on state funding for SCNT is a mistake.

Embryonic stem cell research is a major new medical breakthrough, and I ask you to allow scientists in Kansas to pursue that research to find potential lifesaving cures. I ask you both as someone who may one day undertake such research and as someone whose life may some day be improved by it.

Thank you.

KANSAS COALITION for Lifesaving Cures
P.O. Box 188
Lawrence, KS 66044-0188
Tel 800.821.2658
Fax 800.820.3552
www.KansasCures.com

February 12, 2007
Statement in regard to HB 2255

Lori Hutfles, Executive Director

Madam Chair, Members of the Committee:

The Kansas Coalition for Lifesaving Cures has nearly 10,000 members from across the state, along with more than 60 medical research and patient advocacy organizations. Our members believe that any stem cell research, therapies, and cures that are allowed by federal law should be permitted in Kansas — as long as those activities are conducted ethically and safely and do not involve human reproductive cloning.

The coalition opposes HB 2255 for several important reasons. HB 2255 purports to ban only state funding for SCNT research, but it could have unintended consequences on a variety of research and bioscience initiatives in Kansas.

First, the bill could prohibit even privately funded research at state institutions.

Second, HB 2255 and other bills before this committee could have a chilling effect on our state's ability to attract researchers and research enterprises and facilities.

HB 2255 would ban expenditures in any and all future fiscal years. To our knowledge, there has never been such far-reaching legislative action in Kansas that would attempt to tie the hands of future Legislatures.

Finally, HB 2255 could prevent Kansas patients from having access to any future stem cell therapies and cures that are approved by the FDA and available to other Americans.

It would be a mistake to advance a bill with so great a potential for unintended consequences that could hurt so many Kansans.

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Americans for Stem Cell Therapies & Cures

February 9, 2007

Honorable Legislators:

Thank you for this opportunity to address you on House Bill No. 2255: "An Act concerning human cloning; prohibiting certain expenditures of moneys appropriated from the state treasury by stage agencies".

While HB 2255 prohibits the cloning of children (which we all agree is unethical and should be banned), it also would block **an entire field of promising medical investigation**. By denying this promising field of research, this legislation could prevent the discovery of potential therapies and cures that would alleviate human suffering..

No reputable scientist supports human reproductive cloning. To attempt to do for humans what was done to the sheep called Dolly would be—or should be—a crime. Reproductive cloning endangers both the mother and the prospective child, and **should never be allowed. In California, there is a ban human reproductive cloning and violation of the ban brings an automatic ten year jail term.**

Somatic Cell Nuclear Transfer (SCNT), sometimes called the therapeutic cloning of cells, differs from reproductive cloning just as the light bulb differs from a lightning bolt. The second is harmful, but the first offers the possibility of healing wounded limbs and devastated lives.

While it is true that the two processes begin similarly, it is false to say that SCNT for cells is the same as cloning for babies.

Consider the process. A q-tip is swabbed across the inner cheek of a patient. This yields a microscopic skin cell, which is then added to one emptied egg, an egg much like the ones women lose every month in their natural cycles. This new blastocyst (which looks like a lumpy soccer ball, far smaller than the dot at the end of this sentence) is placed in salt water, shocked gently with electricity, and let to sit for 5-7 days. Then it is taken apart, for the stem cells. That's it.

Notice: there is no sperm involved in the process at all. Neither is there implantation in the womb, no mother involved at all, and absolutely no child.

Kansas families deserve the best medicine science can provide. Blocking a promising new line of science will also block the hope of cure to those who fall ill with a life-threatening disease, or who suffer a devastating disability.

Who supports Somatic Cell Nuclear Transfer? Our late President Gerald Ford supported it, and spoke out against a law very similar to this one, saying:

550 S. California Ave, Suite 330 | Palo Alto, CA | 94306 | (650) 812-9304 | (650) 833-0105 *(fax)*

Americans for Stem Cell Therapies & Cures

"I write to indicate my strong opposition to the Brownback-Landrieu bill in the Senate, and H.R. 2505 in the House of Representatives. Both proposals would criminalize both reproductive cloning as well as medical research conducted for therapeutic purposes. While we both can agree that reproductive cloning should be banned, I believe that a more measured approach should be taken towards therapeutic cloning.

"Recently, 40 Nobel Laureates stated that "legislation such as that introduced by Senator Brownback would foreclose the legitimate use of nuclear transplantation… and impede progress against some of the most debilitating diseases known to man." Therapeutic cloning or nuclear transplantation may have enormous potential for the treatment of heart disease, diabetes, Alzheimer's disease, Parkinson's, spinal cord injury and a vast array of other disease and injuries. Unlike reproductive cloning, this approach will never produce a cloned human being. But it could result in the development of life-saving therapies that could improve the well-being of all Americans."—April 25, 2002

Who else supports SCNT?

The list is long, and follows.

It should be noted, however, that to the best of our knowledge, **not one major scientific or medical group has backed the attempt to shut down Somatic Cell Nuclear Transfer**.

Thank you,

Amy Daly, RN
Executive Director
Americans for Stem Cell Therapies & Cures

The following organizations publicly opposed the White House attempt to ban Somatic Cell Nuclear Transfer research in the United Nations. (Note: the American Medical Association has separately endorsed therapeutic cloning for stem cells.)

Ajou University Medical Center
Alliance for Aging Research
Alpha-1 Association, Alpha-1 Foundation
American Association for the Advancement of Science
American Association of Anatomists
American Association of Neurological Surgeons and
Congress of Neurological Surgeons
American Autoimmune Related Diseases Association
American College of Neuropsychopharmacology
American College of Obstetricians and Gynecologists
American Diabetes Association
American Gastroenterological Association
The American Fertility Association
American Pediatric Society
American Society for Biochemistry and MolecularBiology
American Society for Bone and Mineral Research
American Society for Cell Biology
American Society of Human Genetics

550 S. California Ave, Suite 330 | Palo Alto, CA | 94306 | (650) 812-9304 | (650) 833-0105 *(fax)*

Americans for Stem Cell Therapies & Cures

American Society for Pharmacology & Experimental Therapeutics
American Society for Reproductive Medicine
American Society of Hematology
Association for Research in Vision and Ophthalmology
Association of American Medical Colleges
Association of American Universities
Association of Medical School Pediatric Department Chairs
Axion Research Foundation
Baylor College of Medicine, Graduate School of Biomedical Sciences
Biotechnology Industry Organization
Boston University, Boston University School of Medicine
Californians for Cure
Cancer Research and Prevention Foundation
The Carl Riccio Trust
Centers for Emerging Technologies
Children's Neurobiological Solutions Foundation
Christopher Reeve Paralysis Foundation
Columbia University Medical Center
Committee for the Advancement of Stem Cell Research
CuresNow
The Daniel Heumann Fund for Spinal Cord Research
Diabetes Research Institute Foundation, Inc.
Duke University Medical Center
Elizabeth Glaser Pediatric AIDS Foundation
Emory University Woodruff Health Sciences Center
The Endocrine Society
Eulji University School of Medicine
The FAIR Foundation
Federation of American Societies for Experimental Biology (FASEB)
Finnish Bioindustries FIB
Genetics Policy Institute
Hadassah, the Women's Zionist Organization ofAmerica
Harvard University
Hereditary Disease Foundation
Instituto Chileno de Medicina Reproductiva
International Foundation for Anticancer Drug Discovery
International Federation of Fertility Societies (IFFS)
International Longevity Center
International Society for Stem Cell Research
International Committee Monitoring the Assisted Reproductive Technologies
Juvenile Diabetes Research Foundation International
Kidney Cancer Association
Korea Research Institute of Bioscience and Biotechnology
Korea University Medical Center
Luca Coscioni Association
Magee - Womens Health Corporation
The Miami Project to Cure Paralysis
The Michael J. Fox Foundation for Parkinson's Research
MizMedi Hospital (Seoul, Korea)
Monash Immunology and Stem Cell Laboratories
The Mount Sinai Medical Center
National Alopecia Areatea Foundation
National Association for Biomedical Research
National Coalition for Cancer Research
National Council on Spinal Cord Injury
National Eczema Association for Science and Education
National Health Council
National Venture Capital Association
Nebraskans for Research
Northwestern University Feinberg School of Medicine

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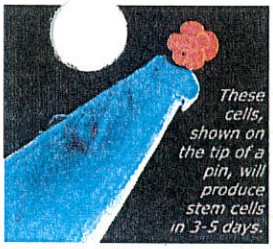

Americans for Stem Cell Therapies & Cures

Parkinson's Action Network
Parkinson's Alliance
The Parkinson's Disease Foundation, Inc.
Pochon CHA University and CHA General Hospital
Parkinson's Unity Walk
Project A.L.S.
Pro Rett Ricerca (Italy)
Quest for the Cure
Research!America
Research for Cure
Resolve: The National Infertility Association
Rett Syndrome Research Foundation
Rutgers University
Samsung Cheil Hospital (Seoul, Korea)
Scleroderma Foundation
Scottish Stem Cell Network
Sociedad Chilena de Fertilidad
Society for Pediatric Research
Society for Women's Health Research
The Spinal Cord Injury Project
Spinal Cure Australia
Stanford University School of Medicine
Stem Cell Action Network
Stem Cell Research Foundation
Steven and Michele Kirsch Foundation
Student Society for Stem Cell Research
Sungkyunkwan University School of Medicine
Take Charge Cure Parkinson's
Texans for the Advancement of Medical Research
United Kingdom BioIndustry Association
University of California System
University of Chicago
University of North Carolina at Chapel Hill
University of Pennsylvania
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University of Southern California
University of Washington
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Vanderbilt University Medical Center
Washington University in St. Louis
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KU MEDICAL CENTER
The University of Kansas

House Health and Human Services Committee
Monday, February 12, 2007

HB 2255
An Act concerning human cloning; prohibiting certain expenditures of moneys appropriated from the state treasury by state agencies
Neutral Testimony Offered by the University of Kansas Medical Center

Conferee: Paul Terranova, Ph.D.
Vice Chancellor for Research, Office of the Executive Vice Chancellor
University of Kansas Medical Center
Senior Associate Dean for Research and Graduate Education
School of Medicine
Director, Center for Reproductive Sciences
Professor, Department of Molecular & Integrative Physiology and Obstetrics & Gynecology

Testimony

Madam Chair, members of the committee, I am submitting neutral testimony today on HB 2255. Similar to my testimony on HB 2098 last week, this statement is meant to provide an objective, scientific perspective in the stem cell research policy debate. Currently I serve as Vice Chancellor for Research at the University of Kansas Medical Center (KUMC). As a scientist with considerable expertise in biology and reproductive sciences, I will point out the potential consequences of HB 2255.

First of all, HB 2255 defines human cloning as, "human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated to produce a living organism at any stage of development with a human or predominantly human genetic constitution that is genetically virtually identical to an existing or previously existing human organism." This would ban human therapeutic cloning using somatic cell nuclear transfer (SCNT) because of the phrase "at all stages of development."

Human therapeutic cloning is the production of stem cells for directive development of specific cell types such as heart cells, bone cells, and nerve cells. The inability of Kansas scientists to perform human therapeutic cloning with SCNT technology will adversely compromise research in our state. University and biotechnology research using therapeutic cloning methods of SCNT will be stymied. My colleagues and I want to be sure you understand that the HB 2255 definition of human cloning lumps together reproductive and therapeutic cloning, thus blocking all cloning using SCNT.

House Health and Human Services
DATE: 12-12-07
ATTACHMENT 14-1

Faculty who wish to utilize these techniques will not be able to pursue lines of investigation that could lead to cures, grants, and knowledge regarding early development. This knowledge could be particularly useful in researching reasons for developmental disabilities. You also need to be aware that recruitment of scientific faculty by our universities and attraction to Kansas of biotechnology companies requiring this technology would be dealt a terrible blow if this legislation became law. In addition, faculty would be limited in their ability to collaborate with other universities outside of Kansas in this area.

Next, the term "asexual reproduction" in human cloning implies that a human individual is being produced. This is not the case for therapeutic cloning using SCNT since the cells will never be placed in a uterus. You should also be aware that the term "asexual reproduction" is not commonly used in scientific literature to refer to humans, but instead is primarily a term reserved for plants and invertebrates.

It is useful to look at the federal policy on stem cells. On August 9, 2001, President George W. Bush announced the U.S. policy on embryonic stem cell research. This policy states that cell lines are eligible for federal funds if:

- "The derivation process (which begins with the destruction of the embryo) was initiated prior to 9:00 P.M. EDT on August 9, 2001.
- The stem cells must have been derived from an embryo that was created for reproductive purposes and was no longer needed.
- Informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements."

Currently, two KUMC researchers are conducting stem cell research using stem cell lines approved by President Bush. This research is supported by grant funds from the National Institutes of Health (NIH). Because of the importance of NIH grant funds to biomedical research not just at KUMC but nationwide, I encourage you to carefully consider the implications of state laws that are more restrictive than federal policies.

Again, KUMC is neutral on HB 2255, but my colleagues and I do want to be sure you have all of the scientific facts as you proceed. As an appendix to this testimony, I have included the National Academies of Sciences glossary of terms from the 2005 peer-reviewed report on human embryonic stem cell research. Please contact me if you need further information.

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Appendix

National Academies of Sciences Definitions

- **Adult stem cell**—An undifferentiated cell found in a differentiated tissue that can renew itself and (with limitations) differentiate to yield the specialized cell types of the tissue from which it originated.

- **Autologous transplant**—Transplanted tissue derived from the intended recipient of the transplant. Such a transplant helps to avoid complications of immune rejection.

- **Blastocoel**—The cavity in the center of a blastocyst.

- **Blastocyst**—A preimplantation embryo of 50–250 cells depending on age. The blastocyst consists of a sphere made up of an outer layer of cells (the trophectoderm), a fluid-filled cavity (the blastocoel), and a cluster of cells on the interior (the inner cell mass).

- **Blastomere**—A single cell from a morula or early blastocyst, before the differentiation into trophectoderm and inner cell mass.

- **Chimera**—An organism composed of cells derived from at least two genetically different cell types. The cells could be from the same or separate species.

- **Differentiation**—The process whereby an unspecialized early embryonic cell acquires the features of a specialized cell, such as a heart, liver, or muscle cell.

- **Ectoderm**—The outermost of the three primitive germ layers of the embryo; it gives rise to skin, nerves, and brain.

- **Egg cylinder**—An asymmetric embryonic structure that helps to determine the body plan of the mouse.

- **Electroporation**— Method of introducing DNA into a cell.

- **Embryo**—An animal in the early stages of growth and differentiation that are characterized by cleavage, laying down of fundamental tissues, and the formation of primitive organs and organ systems; especially the developing human individual from the time of implantation to the end of the eighth week after conception, after which stage it becomes known as a fetus.*

- **Embryoid bodies (EBs)**—Clumps of cellular structures that arise when embryonic stem cells are cultured. Embryoid bodies contain tissue from all three germ layers: endoderm, mesoderm, and ectoderm. Embryoid bodies are not part of normal development and occur only in vitro.

- **Embryonic disk**—A group of cells derived from the inner cell mass of the blastocyst, which later develops into an embryo. The disk consists of three germ layers known as the endoderm, mesoderm, and ectoderm.

- **Embryonic germ (EG) cells**—Cells found in a specific part of the embryo or fetus called the gonadal ridge that normally develop into mature gametes. The germ cells differentiate into the gametes (oocytes or sperm).

- **Embryonic stem (ES) cells**—Primitive (undifferentiated) cells derived from the early embryo that have the potential to become a wide variety of specialized cell types.

- **Endoderm**—Innermost of the three primitive germ layers of the embryo; it later gives rise to the lungs, liver, and digestive organs.

- **Enucleated cell**—A cell whose nucleus has been removed.

- **Epidermis**—The outer cell layers of the skin.

- **Epigenetic**— Refers to modifications in gene expression that are controlled by heritable but potentially reversible changes in DNA methylation or chromatin structure without involving alteration of the DNA sequence.

- **Epithelium**—Layers of cells in various organs, such as the epidermis of the skin or the lining of the gut. These cells serve the general functions of protection, absorption, and secretion, and play a specialized role in moving substances through tissue layers. Their ability to regenerate is excellent; the cells of an epithelium may replace themselves as frequently as every 24 hours from the pools of specialized stem cells.

- **Fertilization**—The process whereby male and female gametes unite to form a zygote (fertilized egg).

- **Fibroblasts**—Cells from many organs that give rise to connective tissue.

- **Gamete**—A mature male or female germ cell, that is, sperm or oocyte, respectively.

- **Gastrulation**—The procedure by which an animal embryo at an early stage of development produces the three primary germ layers: ectoderm, mesoderm, and endoderm.

- **Genome**—The complete genetic material of an organism.

- **Genotype**— Genetic constitution of an individual.

- **Germ cell**—A sperm or egg or a cell that can become a sperm or egg. All other body cells are called somatic cells.

- **Germ layer**—In early development, the embryo differentiates into three distinct germ layers (ectoderm, endoderm, and mesoderm), each of which gives rise to different parts of the developing organism.

- **Germ line**—The cell lineage from which the oocyte and sperm are derived.

- **Hematopoietic**—Blood-forming.
- **Hematopoietic stem cell (HSC)**—A stem cell from which all red and white blood cells evolve and that may be isolated from bone marrow or umbilical cord blood for use in transplants.
- **Hepatocyte**—Liver cell.
- **Heterologous**—From genetically different individuals.
- **hES cell**—Human embryonic stem cell; a type of pluripotent stem cell.
- **Histocompatibility antigens**—Glycoproteins on the surface membranes of cells that enable the body's immune system to recognize a cell as native or foreign and that are determined by the major histocompatibility complex.
- **Homologous recombination**—Recombining of two like DNA molecules, a process by which gene targeting produces a mutation in a specific gene.
- **Hybrid**— An organism that results from a cross between gametes of two different genotypes.
- **Immune system cells**—White blood cells, or leukocytes, that originate in the bone marrow. They include antigen-presenting cells, such as dendritic cells, T and B lymphocytes, macrophages, and neutrophils, among many others.
- **Immunodeficient mice**—Genetically altered mice used in transplantation experiments because they usually do not reject transplanted tissue.
- **Immunogenic**—Related to or producing an immune response.
- **Immunosuppressive**— Suppressing a natural immune response.
- **Implantation**—The process in which a blastocyst implants into the uterine wall, where a placenta forms to nurture the growing fetus.
- **Inner cell mass**—The cluster of cells inside the blastocyst that give rise to the embryonic disk of the later embryo and, ultimately, the fetus.
- **Interspecific**—Between species.
- ***In utero***—In the uterus.
- ***In vitro***—Literally, "in glass," in a laboratory dish or test tube; in an artificial environment.

- ***In vitro* fertilization (IVF)**—An assisted reproductive technique in which fertilization is accomplished outside the body.

- ***In vivo***—In the living subject; in a natural environment.

- **Karyotype**—The full set of chromosomes of a cell arranged with respect to size, shape, and number.

- **Leukemia inhibitory factor (LIF)**—A growth factor necessary for maintaining mouse embryonic stem cells in a proliferative, undifferentiated state.

- **Mesenchymal stem cells**—Stem cells found in bone marrow and elsewhere from which a number of cell types can arise, including chondrocytes, which produce cartilage, and fibroblasts, which produce connective tissue.

- **Mesoderm**—The middle layer of the embryonic disk, which consists of a group of cells derived from the inner cell mass of the blastocyst; it is formed at gastrulation and is the precursor to bone, muscle, and connective tissue.

- **Morula**—A solid mass of 16–32 cells that resembles a mulberry and results from the cleavage (cell division without growth) of a zygote (fertilized egg).

- **Neural stem cell (NSC)**—A stem cell found in adult neural tissue that can give rise to neurons, astrocytes, and oligodendrocytes.

- **Nuclear transfer (NT)**—Replacing the nucleus of one cell with the nucleus of another cell.

- **Oocyte**—Developing egg; usually a large and immobile cell.

- **Phenotype**—Visible properties of an organism produced by interaction of genotype and environment.

- **Placenta**—The oval or discoid spongy structure in the uterus from which the fetus derives its nourishment and oxygen.

- **Pluripotent cell**—A cell that has the capability of developing into cells of all germ layers (endoderm, ectoderm, and mesoderm).

- **Precursor cells**—In fetal or adult tissues, partly differentiated cells that divide and give rise to differentiated cells. Also known as progenitor cells.

- **Preimplantation genetic diagnosis (PGD)**—A procedure applied to IVF embryos to determine which ones carry deleterious mutations predisposing to hereditary diseases.

- **Primary germ layers**—The three initial embryonic germ layers—endoderm, mesoderm, and ectoderm—from which all other somatic tissue types develop.

- **Primordial germ cell**—A cell appearing during early development that is a precursor to a germ cell.

- **Primitive streak**—The initial band of cells from which the embryo begins to develop. The primitive streak establishes and reveals the embryo's head-tail and left-right orientations.

- **Pseudopregnant**—Refers to a female primed with hormones to accept a blastocyst for implantation.

- **Somatic cells**—Any cell of a plant or animal other than a germ cell or germ cell precursor.

- **Somatic cell nuclear transfer (SCNT)**—The transfer of a cell nucleus from a somatic cell into an egg (oocyte) whose nucleus has been removed.

- **Stem cell**—A cell that has the ability to divide for indefinite periods in vivo or in culture and to give rise to specialized cells.

- **Teratoma**—A tumor composed of tissues from the three embryonic germ layers. Usually found in ovary or testis. Produced experimentally in animals by injecting pluripotent stem cells to determine the stem cells' abilities to differentiate into various types of tissues.

- **Tissue culture**—Growth of tissue *in vitro* on an artificial medium for experimental research.

- **Transfection**—A method by which experimental DNA may be put into a cultured cell.

- **Transgene**—A gene that has been incorporated into a cell or organism and passed on to successive generations.

- **Transplantation**—Removal of tissue from one part of the body or from one individual and its implantation or insertion into another, especially by surgery.

- **Trophectoderm**—The outer layer of the developing blastocyst that will ultimately form the embryonic side of the placenta.

- **Trophoblast**—The extraembryonic tissue responsible for negotiating implantation, developing into the placenta, and controlling the exchange of oxygen and metabolites between mother and embryo.

- **Undifferentiated**—Not having changed to become a specialized cell type.

- **Xenograft or xenotransplant**—A graft or transplant of cells, tissues, or organs taken from a donor of one species and grafted into a recipient of another species.

- **Zygote**—A cell formed by the union of male and female germ cells (sperm and egg, respectively).