LRB-2888

2001 DRAFTING REQUEST

Bill

Received: **03/17/2001**

Received By: **mdsida**

Wanted: **As time permits**

Identical to LRB:

For: **Stephen Freese (608) 266-7502**

By/Representing: **Mary Klaver**

This file may be shown to any legislator: **NO**

Drafter: **mdsida**

May Contact:

Addl. Drafters:

Subject: **Criminal Law - miscellaneous**

Extra Copies: **rlr**
dak

Submit via email: **YES**

Requester's email: **Rep.Freese@legis.state.wi.us**

Carbon copy (CC:) to: **mklaver@wrtl.org**

Pre Topic:

No specific pre topic given

Topic:

Destruction of human embryo; use of human embryo for nontherapeutic purpose

---

Instructions:

See Attached

Drafting History:

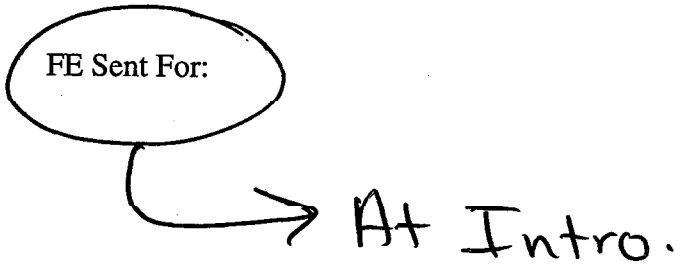
Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/P1	mdsida 08/08/2001	jdyer 08/13/2001 jdyer 09/07/2001	pgreensl 08/13/2001	_____ _____ _____ _____	lrb_docadmin 08/13/2001		
/P2		jdyer	kfollet	_____	lrb_docadmin		

LRB-2888

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
		11/01/2001	09/07/2001	_____	09/07/2001		
/P3	mdsida 11/01/2001	jdyer 11/15/2001	kfollet 11/01/2001	_____ _____	lrb_docadmin 11/01/2001		
/1		jdyer 11/19/2001	jfrantze 11/15/2001	_____ _____	lrb_docadmin 11/15/2001		S&L
/2	mdsida 12/12/2001	jdyer 12/12/2001	pgreensl 11/19/2001	_____ _____	lrb_docadmin 11/19/2001	lrb_docadmin 11/20/2001	S&L
/3			pgreensl 12/12/2001	_____ _____	lrb_docadmin 12/12/2001	lrb_docadmin 12/12/2001	S&L

FE Sent For:

<END>



2001 DRAFTING REQUEST

Bill

Received: **03/17/2001**

Received By: **mdsida**

Wanted: **As time permits**

Identical to LRB:

For: **Stephen Freese (608) 266-7502**

By/Representing: **Mary Klaver**

This file may be shown to any legislator: **NO**

Drafter: **mdsida**

May Contact:

Addl. Drafters:

Subject: **Criminal Law - miscellaneous**

Extra Copies: **rlr**
dak

Submit via email: **YES**

Requester's email: **Rep.Freese@legis.state.wi.us**

Carbon copy (CC:) to: **mklaver@wrtl.org**

Pre Topic:

No specific pre topic given

Topic:

Destruction of human embryo; use of human embryo for nontherapeutic purpose

---

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/P1	mdsida 08/08/2001	jdyer 08/13/2001 jdyer 09/07/2001	pgreensl 08/13/2001 12/12	12/12 DS1	lrb_docadmin 08/13/2001		
/P2		jdyer 13 12/12 jld	kfollet P9		lrb_docadmin		

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
		11/01/2001	09/07/2001	_____	09/07/2001		
/P3	mdsida 11/01/2001	jdyer 11/15/2001	kfollet 11/01/2001	_____ _____	lrb_docadmin 11/01/2001		
/1		jdyer 11/19/2001	jfrantze 11/15/2001	_____ _____	lrb_docadmin 11/15/2001		S&L
/2			pgreensl 11/19/2001	_____ _____	lrb_docadmin 11/19/2001	lrb_docadmin 11/20/2001	S&L

FE Sent For:

<END>

2001 DRAFTING REQUEST

Bill

Received: **03/17/2001**

Received By: **mdsida**

Wanted: **As time permits**

Identical to LRB:

For: **Stephen Freese (608) 266-7502**

By/Representing: **Mary Klaver**

This file may be shown to any legislator: **NO**

Drafter: **mdsida**

May Contact:

Addl. Drafters:

Subject: **Criminal Law - miscellaneous**

Extra Copies: **rlr**
dak

Submit via email: **YES**

Requester's email: **Rep.Freese@legis.state.wi.us**

Carbon copy (CC:) to: **mklaver@wrtl.org**

Pre Topic:

No specific pre topic given

Topic:

Destruction of human embryo; use of human embryo for nontherapeutic purpose

---

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/P1	mdsida 08/08/2001	jdyer 08/13/2001 jdyer 09/07/2001	pgreensl 08/13/2001	_____ _____ _____ _____	lrb_docadmin 08/13/2001		
/P2		jdyer	kfollet	_____	lrb_docadmin		

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
		11/01/2001	09/07/2001	_____	09/07/2001		
/P3	mdsida 11/01/2001	jdyer 11/15/2001	kfollet 11/01/2001	_____ _____	lrb_docadmin 11/01/2001		
/1		jdyer 11/19/2001	jfrantze 11/15/2001	_____ _____	lrb_docadmin 11/15/2001		S&L
/2			pgreensl 11/19/2001	_____ _____	lrb_docadmin 11/19/2001		S&L

FE Sent For:

<END>

2001 DRAFTING REQUEST

Bill

Received: **03/17/2001**

Received By: **mdsida**

Wanted: **As time permits**

Identical to LRB:

For: **Stephen Freese (608) 266-7502**

By/Representing: **Mary Klaver**

This file may be shown to any legislator: **NO**

Drafter: **mdsida**

May Contact:

Addl. Drafters:

Subject: **Criminal Law - miscellaneous**

Extra Copies: **rlr**
dak

Submit via email: **YES**

Requester's email: **Rep.Freese@legis.state.wi.us** ✓

Carbon copy (CC:) to: **mklaver@wrtl.org** ✓

Pre Topic:

No specific pre topic given

Topic:

Destruction of human embryo; use of human embryo for nontherapeutic purpose

---

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/P1	mdsida 08/08/2001	jdyer 08/13/2001 jdyer 09/07/2001	pgreensl 08/13/2001	11/ 11/19 PS 11/19	lrb_docadmin 08/13/2001		
/P2		jdyer	kfollet		lrb_docadmin		

/2 11/19 jd 11/19 PS

LRB-2888

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
		11/01/2001	09/07/2001	_____	09/07/2001		
/P3	mdsida 11/01/2001	jdyer 11/15/2001	kfollet 11/01/2001	_____ _____	lrb_docadmin 11/01/2001		
/1			jfrantze 11/15/2001	_____ _____	lrb_docadmin 11/15/2001		S&L

FE Sent For:

<END>

LRB-2888

2001 DRAFTING REQUEST

Bill

Received: **03/17/2001**

Received By: **mdsida**

Wanted: **As time permits**

Identical to LRB:

For: **Stephen Freese (608) 266-7502**

By/Representing: **Mary Klaver**

This file may be shown to any legislator: **NO**

Drafter: **mdsida**

May Contact:

Addl. Drafters:

Subject: **Criminal Law - miscellaneous**

Extra Copies: **rlr**
dak

Submit via email: **YES**

Requester's email: **Rep.Freese@legis.state.wi.us**

Carbon copy (CC:) to: **mklaver@wrtl.org**

Pre Topic:

No specific pre topic given

Topic:

Destruction of human embryo; use of human embryo for nontherapeutic purpose

---

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/P1	mdsida 08/08/2001	jdyer 08/13/2001 jdyer 09/07/2001	pgreensl 08/13/2001	_____ _____ _____ _____	lrb_docadmin 08/13/2001		
/P2		jdyer	kfollet	_____	lrb_docadmin		

1 11/14 jls 11/15 11/15

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
		11/01/2001	09/07/2001	_____	09/07/2001		
/P3	mdsida 11/01/2001		kfollet 11/01/2001	_____ _____	lrb_docadmin 11/01/2001		

FE Sent For:

<END>

LRB-2888

2001 DRAFTING REQUEST

Bill

Received: **03/17/2001**

Received By: **mdsida**

Wanted: **As time permits**

Identical to LRB:

For: **Stephen Freese (608) 266-7502**

By/Representing: **Mary Klaver**

This file may be shown to any legislator: **NO**

Drafter: **mdsida**

May Contact:

Addl. Drafters:

Subject: **Criminal Law - miscellaneous**

Extra Copies: **rlr**
dak
mklaver@wrtl.org

Submit via email: **NO**

Pre Topic:

No specific pre topic given

Topic:

Destruction of human embryo; use of human embryo for nontherapeutic purpose

---

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/P1	mdsida 08/08/2001	jdyer 08/13/2001 jdyer 09/07/2001	pgreensl 08/13/2001	_____ _____ _____ _____	lrb_docadmin 08/13/2001		
/P2	/P3 11/1 jld	kfollet 09/07/2001	_____ _____	lrb_docadmin 09/07/2001		

FE Sent For:

<END>

LRB-2888

2001 DRAFTING REQUEST

Bill

Received: **03/17/2001**

Received By: **mdsida**

Wanted: **As time permits**

Identical to LRB:

For: **Stephen Freese (608) 266-7502**

By/Representing: **Mary Klaver**

This file may be shown to any legislator: **NO**

Drafter: **mdsida**

May Contact:

Addl. Drafters:

Subject: **Criminal Law - miscellaneous**

Extra Copies: **rlr**
dak

Submit via email: **NO**

Pre Topic:

No specific pre topic given

Topic:

Destruction of human embryo; use of human embryo for nontherapeutic purpose

---

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/P1	mdsida 08/08/2001	jdyer 08/13/2001	pgreensl 08/13/2001	_____ _____	lrb_docadmin 08/13/2001		

/P2 9/7 jld

FE Sent For:

<END>

LRB-2888

2001 DRAFTING REQUEST

Bill

Received: **03/17/2001**

Received By: **mdsida**

Wanted: **As time permits**

Identical to LRB:

For: ~~**Mark Gundrum**~~ Freese **(414) 778-5780**

By/Representing: **Mary Klaver**

This file may be shown to any legislator: **NO**

Drafter: **mdsida**

May Contact:

Addl. Drafters:

Subject: **Criminal Law - miscellaneous**

Extra Copies: **rlr**
dak

Pre Topic:

No specific pre topic given

Topic:

Destruction of human embryo; use of human embryo for nontherapeutic purpose

---

Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	mdsida	/P1 8/13 jld	8/13 P8	8/13 PS/HS			

FE Sent For:

<END>

99-4717

WISCONSIN RIGHT TO LIFE

life without limits

State Affiliate of the National Right to Life Committee, Inc., Washington, DC 20004-1199

Wisconsin Right to Life, Inc.
10625 W. North Ave., Suite LL
Milwaukee, WI 53226-2331
Ph: 414-778-5780
Fax: 414-778-5785
Toll Free: 877-855-5007
Home Page: www.wrtl.org

FAX COVER SHEET

OPERATOR: PLEASE NOTIFY THE PERSON NAMED BELOW THAT THIS FAX HAS ARRIVED. THANK YOU

Important Notice: The information contained in this transmission is intended for the specific person(s) addressed. If you have received this fax in error please contact us immediately at the phone number below. Thank You !

TO (Name): Mike Dsida

LOCATION: LRB

AT FAX #: 608-264-8522 **AT PHONE#** 608-266-9867

FROM: [redacted] Mary Klaver

WRL Fax: 414/778-5785
WRL Phone: 414/778-5780

Date Sent: 3/16/01

Pages: 3 (including this cover sheet)

Time Sent: _____ a.m. / p.m.

MESSAGE: Please draft this Human Embryo Protection Act for Rep. Mark Gundrum.
Call me if you have any questions.
Mary

HUMAN EMBRYO PROTECTION ACT

940.105 Human embryo. (1) In this section:

(a) "Human embryo" includes any organism, including the single cell stage, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. A human embryo is a human being, not an item of property.

(b) "Medical research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable medical knowledge.

(c) "Nontherapeutic research" means research that is not intended to help protect and preserve the life or health of the particular living human embryo who is outside a woman's body and being subjected to risk.

(2) Whoever intentionally destroys a living human embryo who is outside a woman's body is guilty of a Class D felony.

partial birth ? abortion decision

(3) Whoever sells or transfers a living human embryo who is outside a woman's body to another person with the knowledge that the embryo will be intentionally destroyed is guilty of a Class D felony.

(4) Whoever intentionally subjects a living human embryo who is outside a woman's body to substantial risk of injury or death for the purpose of nontherapeutic research is guilty of a Class E felony.

(5) Whoever sells or transfers a living human embryo who is outside a woman's body to another person with the knowledge that the embryo will be intentionally subjected to sustantial risk of injury or death for the purpose of nontherapeutic research is guilty of a Class E felony.

(6) Whoever creates a living human embryo outside a woman's body for the purpose of nontherapeutic research is guilty of a Class E felony.

(7) Whoever uses, sells or transfers for the purpose of medical research any cell or tissue that the person knows was obtained by performing the activities described in sub. (2), (4), or (6) is guilty of a Class E felony.

(8) Nothing in this section prohibits the creation of a human embryo for the purpose of reproduction as long as the embryo is given the optimum chance to survive and continue to develop by being transferred to the uterus of a woman who is willing and able to carry the pregnancy to term.

Recommended addition: Add a provision creating a legislative council study committee to: (1) create legislation to amend Wisconsin's adoption laws to facilitate adoption of "spare" human embryos, and (2) regulate infertility clinics to (a) reduce the number of excess embryos created to a reasonable number needed for reproductive purposes, and (b) release unwanted and abandoned embryos for adoption.

P/c from Rep. Gundrum

Go ahead + draft the way I think it will accomplish his intent

(Initially he wanted Klaver I as the draft, then as a sep. draft, but I explained that I wanted it to reflect his intent.

Told him I would note difference + q's.

Dsida, Michael

From: Dsida, Michael
Sent: Thursday, June 07, 2001 11:00 AM
To: 'Mary Klaver'
Cc: Gundrum, Mark
Subject: RE: Coverage of stem cells

01-2888.pdf

Mary-

First of all, I apologize for not responding to your e-mail more quickly. I had drafted most of my response earlier in the week and had thought I sent it. I guess I lost track of it while working on the budget.

Rep. Gundrum and I talked about this draft yesterday. I explained that I was trying to ensure that the draft reflected his intent. I also explained that I would try to explain any differences between what I draft and your suggested language in a drafter's note. He agreed that that approach makes sense.

In addition, as I explained to you on the phone last week, the definition of "human embryo" that you provided me in your suggested draft is so broad that it would include an adult human. Moreover, in contrast to what you have told me, the language that you suggested for the definition is not the same as what is contained in federal law. (Among other things, your language omits the "not protected as a human subject under 45 CFR 46" clause contained in the FY2001 Omnibus Appropriations Act.) But even if it were identical to federal law, that fact would not be dispositive, since Rep. Gundrum's objectives may be different from those which the federal law seeks to achieve. (In addition, federal law is not always well-drafted.) Since the language that you suggested will not help me accomplish his objectives, I intend to use other language to do so.

I would be happy to share what I am working on with you. A copy of what I have drafted thus far is attached. I do not believe, however, that you need any of it to answer the questions that I have asked regarding Rep. Gundrum's intent.

Mike Dsida
Legislative Reference Bureau
608/266-9867
michael.dsida@legis.state.wi.us

> -----Original Message-----
> From: Mary Klaver [mailto:mklaver@wrtl.org]
> Sent: Monday, June 04, 2001 1:05 PM
> To: Dsida Michael
> Cc: Mark Gundrum
> Subject: Re: Coverage of stem cells
>
>
> Mike,
>
> It seems apparent that you are creating a definition of
> "human embryo" that is
> quite different from the definition provided by Rep. Gundrum
> in the drafting
> request for protection of human embryos. Please send me your working
> definition(s) so we can see the context for your questions
> regarding stem cells
> and "pre-zygotes".
>
> Also, please note that the definition of "human embryo" we
> gave you is the same
> as the definition in AB 168, the conscience clause
> legislation. We see no reason
> to have a different definition in the Human Embryo Protection Act.

>
> Mary
>
> ----------
> "Dsida, Michael" wrote:
>
> > You indicated last week that you did not want the bill to
> cover adult stem
> > cells. Do you want it to cover all other types of stem
> cells? For example,
> > would you want it to cover stem cells derived from aborted
> fetuses (i.e., in
> > the method used by Gearhart at Johns Hopkins)?
> >
> > Thank you.
> >
> > Mike Dsida
> > Legislative Reference Bureau
> > 608/266-9867
> > michael.dsida@legis.state.wi.us
>

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Wednesday, July 11, 2001 11:35 AM
To: Dsida Michael
Subject: Re: Coverage of stem cells

Mike,

Now that the budget is in the conference committee mode, do you have time to get back to this draft? Please let me know.

Please note that the intent of this legislation is to protect human embryos. Stem cells are not embryos, so they should not be included.

Give me a call when you can.

Mary Klaver
Legislative Legal Counsel
Wisconsin Right to Life

"Dsida, Michael" wrote:

> You indicated last week that you did not want the bill to cover adult stem
> cells. Do you want it to cover all other types of stem cells? For example,
> would you want it to cover stem cells derived from aborted fetuses (i.e., in
> the method used by Gearhart at Johns Hopkins)?
>
> Thank you.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@legis.state.wi.us

NATIONAL INSTITUTES OF HEALTH
May 2000

Office of the Director

Stem Cells: A Primer

This primer presents background information on stem cells. It includes an explanation of what stem cells are; what pluripotent stem cells are; how pluripotent stem cells are derived; why pluripotent stem cells are important to science; why they hold such great promise for advances in health care; and what adult stem cells are.

Recent published reports on the isolation and successful culturing of the first human pluripotent stem cell lines have generated great excitement and have brought biomedical research to the edge of a new frontier. The development of these human pluripotent stem cell lines deserves close scientific examination, evaluation of the promise for new therapies, and prevention strategies, and open discussion of the ethical issues.

In order to understand the importance of this discovery as well as the related scientific, medical, and ethical issues, it is absolutely essential to first clarify the terms and definitions.

Definitions

DNA - abbreviation for deoxyribonucleic acid which makes up genes.

Gene - a functional unit of heredity which is a segment of DNA located in a specific site on a chromosome. A gene directs the formation of an enzyme or other protein.

Somatic cell - cell of the body other than egg or sperm.

Somatic cell nuclear transfer - the transfer of a cell nucleus from a somatic cell into an egg from which the nucleus has been removed.

Stem cells - cells that have the ability to divide for indefinite periods in culture and to give rise to specialized cells.

Pluripotent -capable of giving rise to most tissues of an organism.

Totipotent - having unlimited capability. Totipotent cells have the capacity to specialize into extraembryonic membranes and tissues, the embryo, and all postembryonic tissues and organs.

What is a stem cell?

Stem cells have the ability to divide for indefinite periods in culture and to give rise to specialized cells. They are best described in the context of normal human development. Human development begins when a sperm fertilizes an egg and creates a single cell that has the potential to form an entire organism. This fertilized egg is **totipotent**, meaning that its potential is total. In the first hours after fertilization, this cell divides into identical totipotent cells. (Figure I) This means that either one of these cells, if placed into a woman's uterus, has the potential to develop into a fetus. In fact, identical twins develop when two totipotent cells separate and develop into two individual, genetically identical human beings. Approximately four days after fertilization and after several cycles of cell division, these totipotent cells begin to specialize, forming a hollow sphere of cells, called a blastocyst. The blastocyst has an outer layer of cells and inside the hollow sphere, there is a cluster of cells called the inner cell mass.

The outer layer of cells will go on to form the placenta and other supporting tissues needed for fetal development in the uterus. The inner cell mass cells will go on to form virtually all of the tissues of the human body. Although the inner cell mass cells can form virtually every type of cell found in the human body, they cannot form an organism because they are unable to give rise to the placenta and supporting tissues necessary for development in the human uterus. These inner

cell mass cells are **pluripotent** — they can give rise to many types of cells but not all types of cells necessary for fetal development. Because their potential is not total, they are not totipotent and they are not embryos. In fact, if an inner cell mass cell were placed into a woman's uterus, it would not develop into a fetus.

The pluripotent stem cells undergo further specialization into stem cells that are committed to give rise to cells that have a particular function. Examples of this include blood stem cells which give rise to red blood cells, white blood cells and platelets; and skin stem cells that give rise to the various types of skin cells. These more specialized stem cells are called **multipotent**. (Figure II)

While stem cells are extraordinarily important in early human development, multipotent stem cells are also found in children and adults. For example, consider one of the best understood stem cells, the blood stem cell. Blood stem cells reside in the bone marrow of every child and adult, and in fact, they can be found in very small numbers circulating in the blood stream. Blood stem cells perform the critical role of continually replenishing our supply of blood cells — red blood cells, white blood cells, and platelets — throughout life. A person cannot survive without blood stem cells.

How are pluripotent stem cells derived?

At present, human pluripotent cell lines have been developed from two sources[1] with methods previously developed in work with animal models.

(1) In the work done by Dr. Thomson, pluripotent stem cells were isolated directly from the inner cell mass of human embryos at the blastocyst stage. Dr. Thomson received embryos from IVF (In Vitro Fertilization) clinics-these embryos were in excess of the clinical need for infertility treatment. The embryos were made for purposes of reproduction, not research. Informed consent was obtained from the donor couples. Dr. Thomson isolated the inner cell mass (see Figure III) and cultured these cells producing a pluripotent stem cell line.

(2) In contrast, Dr. Gearhart isolated pluripotent stem cells from fetal tissue obtained from terminated pregnancies. Informed consent was obtained from the donors after they had independently made the decision to terminate their pregnancy. Dr. Gearhart took cells from the region of the fetus that was destined to develop into the testes or the ovaries. Although the cells developed in Dr. Gearhart's lab and Dr. Thomson's lab were derived from different sources, they appear to be very similar. (Figure III)

The use of somatic cell nuclear transfer (SCNT) may be another way that pluripotent stem cells could be isolated. In studies with animals using SCNT, researchers take a normal animal egg cell and remove the nucleus (cell structure containing the chromosomes). The material left behind in the egg cell contains nutrients and other energy-producing materials that are essential for embryo development. Then, using carefully worked out laboratory conditions, a somatic cell - any cell other than an egg or a sperm cell - is placed next to the egg from which the nucleus had been removed, and the two are fused. The resulting fused cell, and its immediate descendants, are believed to have the full potential to develop into an entire animal, and hence are totipotent. As described in Figure I, these totipotent cells will soon form a blastocyst. Cells from the inner cell mass of this blastocyst could, in theory, be used to develop pluripotent stem cell lines. Indeed, any method by which a human blastocyst is formed could potentially serve as a source of human pluripotent stem cells (Figure IV).

Potential Applications of Pluripotent Stem Cells

There are several important reasons why the isolation of human pluripotent stem cells is important to science and to advances in health care (Figure V). At the most fundamental level, pluripotent stem cells could help us to understand the complex events that occur during human development. A primary goal of this work would be the identification of the factors involved in the cellular decision-making process that results in cell specialization. We know that turning genes on and off is central to this process, but we do not know much about these "decision-making" genes or what turns them on or off. Some of our most serious medical conditions, such as cancer and birth defects, are due to abnormal cell specialization and cell division. A better understanding of normal cell processes will allow us to further delineate the fundamental errors that cause these often deadly illnesses.

Human pluripotent stem cell research could also dramatically change the way we develop drugs and test them for safety. For example, new medications could be initially tested using human cell lines. Cell lines are currently used in this way (for example cancer cells). Pluripotent stem cells would allow testing in more cell types. This would not replace testing in whole animals and testing in human beings, but it would streamline the process of drug development. Only the drugs that are both safe and appear to have a beneficial effect in cell line testing would graduate to further testing in laboratory animals and human subjects.

Perhaps the most far-reaching potential application of human pluripotent stem cells is the generation of cells and tissue that could be used for so-called "cell therapies." Many diseases and disorders result from disruption of cellular function or destruction of tissues of the body. Today, donated organs and tissues are often used to replace ailing or destroyed tissue. Unfortunately, the number of people suffering from these disorders far outstrips the number of organs available for transplantation. Pluripotent stem cells, stimulated to develop into specialized cells, offer the possibility of a renewable source of replacement cells and tissue to treat a myriad of diseases, conditions, and disabilities including Parkinson's and Alzheimer's diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis and rheumatoid arthritis. There is almost no realm of medicine that might not be touched by this innovation. Some details of two of these examples follow.

- Transplant of healthy heart muscle cells could provide new hope for patients with chronic heart disease whose hearts can no longer pump adequately. The hope is to develop heart muscle cells from human pluripotent stem cells and transplant them into the failing heart muscle in order to augment the function of the failing heart. Preliminary work in mice and other animals has demonstrated that healthy heart muscle cells transplanted into the heart successfully repopulate the heart tissue and work together with the host cells. These experiments show that this type of transplantation is feasible.

- In the many individuals who suffer from Type I diabetes, the production of insulin by specialized pancreatic cells, called islet cells, is disrupted. There is evidence that transplantation of either the entire pancreas or isolated islet cells could mitigate the need for insulin injections. Islet cell lines derived from human pluripotent stem cells could be used for diabetes research and, ultimately, for transplantation.

While this research shows extraordinary promise, there is much to be done before we can realize these innovations. Technological challenges remain before these discoveries can be incorporated into clinical practice. These challenges, though significant, are not insurmountable.

First, we must do the basic research to understand the cellular events that lead to cell specialization in the human, so that we can direct these pluripotent stem cells to become the type (s) of tissue needed for transplantation.

Second, before we can use these cells for transplantation, we must overcome the well-known problem of immune rejection. Because human pluripotent stem cells derived from embryos or fetal tissue would be genetically different from the recipient, future research would need to focus on modifying human pluripotent stem cells to minimize tissue incompatibility or to create tissue banks with the most common tissue-type profiles.

The use of somatic cell nuclear transfer (SCNT) would be another way to overcome the problem of tissue incompatibility for some patients. For example, consider a person with progressive heart failure. Using SCNT, the nucleus of virtually any somatic cell from that patient could be fused with a donor egg cell from which the nucleus had been removed. With proper stimulation the cell would develop into a blastocyst: cells from the inner cell mass could be taken to create a culture of pluripotent cells. These cells could then be stimulated to develop into heart muscle cells. Because the vast majority of genetic information is contained in the nucleus, these cells would be essentially identical genetically to the person with the failing heart. When these heart muscle cells were transplanted back into the patient, there would likely be no rejection and no need to expose the patient to immune-suppressing drugs, which can have toxic effects.

Adult Stem Cells

As noted earlier, multipotent stem cells can be found in some types of adult tissue. In fact, stem cells are needed to replenish the supply cells in our body that normally wear out. An example, which was mentioned previously, is the blood stem cell.

Multipotent stem cells have not been found for all types of adult tissue, but discoveries in this area of research are increasing. For example, until recently, it was thought that stem cells were not present in the adult nervous system, but, in recent years, neuronal stem cells have been isolated from the rat and mouse nervous systems. The experience in humans is more limited. In humans, neuronal stem cells have been isolated from fetal tissue and a kind of cell that may be a neuronal stem cell has been isolated from adult brain tissue that was surgically removed for the treatment of epilepsy.

Do adult stem cells have the same potential as pluripotent stem cells?

Until recently, there was little evidence in mammals that multipotent cells such as blood stem cells could change course and produce skin cells, liver cells or any cell other than a blood stem cell or a specific type of blood cell; however, research in animals is leading scientists to question this view.

In animals, it has been shown that some adult stem cells previously thought to be committed to the development of one line of specialized cells are able to develop into other types of specialized cells. For example, recent experiments in mice suggest that when neural stem cells were placed into the bone marrow, they appeared to produce a variety of blood cell types. In addition, studies with rats have indicated that stem cells found in the bone marrow were able to produce liver cells. These exciting findings suggest that even after a stem cell has begun to specialize, the stem cell may, under certain conditions, be more flexible than first thought. At this time, demonstration of the flexibility of adult stem cells has been only observed in animals and limited to a few tissue types.

Why not just pursue research with adult stem cells?

Research on human adult stem cells suggests that these multipotent cells have great potential for use in both research and in the development of cell therapies. For example, there would be many advantages to using adult stem cells for transplantation. If we could isolate the adult stem cells from a patient, coax them to divide and direct their specialization and then transplant them back into the patient, it is unlikely that such cells would be rejected. The use of adult stem cells for such cell therapies would certainly reduce or even avoid the practice of using stem cells that were derived from human embryos or human fetal tissue, sources that trouble many people on ethical grounds.

While adult stem cells hold real promise, there are some significant limitations to what we may or may not be able to accomplish with them. First of all, stem cells from adults have not been isolated for all tissues of the body. Although many different kinds of multipotent stem cells have been identified, adult stem cells for all cell and tissue types have not yet been found in the adult human. For example, we have not located adult cardiac stem cells or adult pancreatic islet stem cells in humans.

Secondly, adult stem cells are often present in only minute quantities, are difficult to isolate and purify, and their numbers may decrease with age. For example, brain cells from adults that may be neuronal stem cells have only been obtained by removing a portion of the brain of epileptics, not a trivial procedure.

Any attempt to use stem cells from a patient's own body for treatment would require that stem cells would first have to be isolated from the patient and then grown in culture in sufficient numbers to obtain adequate quantities for treatment. For some acute disorders, there may not be enough time to grow enough cells to use for treatment. In other disorders, caused by a genetic defect, the genetic error would likely be present in the patient's stem cells. Cells from such a patient may not be appropriate for transplantation. There is evidence that stem cells from adults may have not have the same capacity to proliferate as younger cells do. In addition, adult stem cells may contain more DNA abnormalities, caused by exposure to daily living, including sunlight, toxins, and by expected errors made in DNA replication during the course of a lifetime. These potential weaknesses could limit the usefulness of adult stem cells.

Research on the early stages of cell specialization may not be possible with adult stem cells since they appear to be farther along the specialization pathway than pluripotent stem cells. In addition, one adult stem cell line may be able to form several, perhaps 3 or 4, tissue types, but there is no clear evidence that stem cells from adults, human or animal, are pluripotent. In fact, there is no evidence that adult stem cells have the broad potential characteristic of pluripotent stem cells. In order to determine the very best source of many of the specialized cells and tissues of the body for new treatments and even cures, it will be vitally important to study the developmental potential of adult stem cells and compare it to that of pluripotent stem cells.

Summary

Given the enormous promise of stem cells to the development of new therapies for the most devastating diseases, it is important to simultaneously pursue all lines of research. Science and scientists need to search for the very best sources of these cells. When they are identified, regardless of their sources, researchers will use them to pursue the development of new cell therapies.

The development of stem cell lines, both pluripotent and multipotent, that may produce many tissues of the human body is an important scientific breakthrough. It is not too unrealistic to say that this research has the potential to revolutionize the practice of medicine and improve the quality and length of life.

---

[1] Michael Shamblott, *et al*, Derivation of pluripotent stem cells from cultured human primordial germ cells. *PNAS*, 95: 13726-13731, Nov. 1998.

James Thomson, *et al*, Embryonic stem cell lines derived from human blastocysts. *Science*, 282: 1145-1147, Nov. 6, 1998.

NIH FACT SHEET ON HUMAN PLURIPOTENT STEM CELL RESEARCH GUIDELINES

Updated January 2001

The Promise of Stem Cell Research

Human pluripotent stem cells are a unique scientific and medical resource. In 1998, scientists at the University of Wisconsin and at Johns Hopkins University isolated and successfully cultured human pluripotent stem cells. The pluripotent stem cells were derived using non-Federal funds from early-stage embryos donated voluntarily by couples undergoing fertility treatment in an in vitro fertilization (IVF) clinic or from non-living fetuses obtained from terminated first trimester pregnancies. Informed consent was obtained from the donors in both cases. Women voluntarily donating fetal tissue for research did so only after making the decision to terminate the pregnancy.

Because pluripotent stem cells give rise to almost all of the cells types of the body, such as muscle, nerve, heart, and blood, they hold great promise for both research and health care. This advance in human biology continues to generate enthusiasm among scientists, patients suffering from a broad range of diseases, including cancer, heart disease and diabetes, and their families. For example, further research using human pluripotent stem cells may help:

- Generate cells and tissue for transplantation. Pluripotent stem cells have the potential to develop into specialized cells that could be used as replacement cells and tissues to treat many diseases and conditions, including Parkinson's disease, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis.

- Improve our understanding of the complex events that occur during normal human development and also help us understand what causes birth defects and cancer.

- Change the way we develop drugs and test them for safety. Rather than evaluating the safety of candidate drugs in an animal model, drugs might be initially tested on cells developed from pluripotent stem cells and only the safest candidate drugs would advance to animal and then human testing.

The Potential of Adult Stem Cell Research

Questions have been raised about the usefulness of adult stem cells in research and treatment, especially as compared to pluripotent stem cells derived from embryos or fetal tissue. Indeed, there is enormous potential for research using such cells. Human adult stem cells have been isolated from tissues such as blood, brain, intestine, skin, and muscle. Furthermore, some adult stem cells have been shown to be more "plastic" than first thought — that is, some of these stem cells appear to be capable of developing into different kinds of cells than first predicted.

There is, however, considerable evidence that adult stem cells may have limited potential compared to pluripotent stem cells derived from embryos or fetal tissue. Human adult stem cells have not yet been isolated from all cell and tissue types, and they have not been shown to be capable of developing into all of the different cell and tissue types of the body. Furthermore, adult stem cells are difficult to obtain, since they are often present in only minute quantities. They are difficult to isolate and purify, and their numbers appear to decrease with age. Moreover, adult stem cells may have more DNA damage, and

they appear to have a shorter life span than pluripotent stem cells. For all of these reasons, and because of the enormous potential of stem cell approaches to research and treatment, it is vitally important that scientists study and compare both pluripotent and adult stem cells.

The Need for Guidelines to Govern Research Using Pluripotent Stem Cells

The NIH is prohibited from using any appropriated funds for "... (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed. discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))." Because of the enormous potential of human pluripotent stem cells to medical research, the NIH asked the General Counsel of the Department of Health and Human Services (DHHS) to determine whether research utilizing pluripotent stem cells is permissible under existing Federal law governing embryo and fetal tissue research. After careful consideration, the DHHS concluded that because human pluripotent cells are not embryos, current Federal law does not prohibit DHHS funds from being used for research utilizing these cells.

Recognizing the ethical and legal issues surrounding human pluripotent stem cell research and the need for stringent oversight of this class of research — oversight that goes beyond the traditional rigorous NIH scientific peer review process — the NIH issued a moratorium on the funding of this research until Guidelines could be developed and an oversight process could be implemented.

In April 1999, the NIH convened a working group of the Advisory Committee to the Director (ACD), NIH, to provide advice to the ACD relevant to guidelines and oversight for this research. The working group met in public session and included scientists, clinicians, ethicists, lawyers, patients, and patient advocates. During their deliberations, the group considered advice from the National Bioethics Commission, the public, and scientists. Draft guidelines for this research were published for public comment, and, after reviewing and considering all comments received, the *NIH Guidelines for Research Using Human Pluripotent Stem Cells* (*NIH Guidelines*) were published in the *Federal Register* and became effective on August 25, 2000. (Because the *NIH Guidelines* contained a few incorrect citations and other minor errors, a notice of correction (65 FR 69951) was published on November 21, 2000.) The revised *NIH Guidelines* and other information about stem cell research can be found at the URL: http://www.nih.gov/news/stemcell/index.htm.

Specifics of the *Guidelines*

The purpose of the *NIH Guidelines* is to set forth procedures to help ensure that NIH-funded research in this area is conducted in an ethical and legal manner. By issuing these *Guidelines*, the NIH aims to enhance both the scientific and ethical oversight of this important arena of research and the pace at which scientists can explore its many promises. These *Guidelines* will encourage openness, provide appropriate Federal oversight, help make certain that all researchers can make use of these critical research tools, and help assure full public access to the practical medical benefits of research using these cells.

The *Guidelines* prescribe the documentation and assurances that must accompany requests for NIH funding for research using human pluripotent stem cells derived from human embryos or fetal tissue. These include the following:

- For studies using human pluripotent stem cells derived from human embryos, NIH funds may be used only if the cells were derived from frozen embryos that were created for the purposes of

fertility treatment, were in excess of clinical need, and were obtained after the consent of the donating couple.

- The *NIH Guidelines* prohibit the use of inducements, monetary or otherwise, for the donation of the embryo. There must also have been a clear separation between the fertility treatment and the decision to donate embryos for this research.

- The *NIH Guidelines* require that the informed consent specify whether or not information that could identify the donor(s) will be retained.

- Investigators who propose using NIH funds to conduct research using human pluripotent stem cells derived from fetal tissue are expected to follow both the *NIH Guidelines* and all Federal and state laws and regulations governing human fetal tissue and human fetal tissue transplantation research.

- The *Guidelines* require that the donation of human embryos or fetal tissue be made without any restriction or direction regarding the individual(s) who may be the recipient of the cells derived from the human pluripotent stem cells.

- They also require review and approval of the derivation protocol by an Institutional Review Board.

- The informed consent should include statements that the embryos or fetal tissue will be used to derive human pluripotent stem cells for research that may include human transplantation research; that derived cells may be kept for many years; that the research is not intended to provide direct medical benefit to the donor; and that the donated embryos will not be transferred to a woman's uterus and will not survive the stem cell derivation process.

- The informed consent must also state the possibility that the results of the research may have commercial potential, and that the donor will not receive any benefits from any such future commercial development.

- The *Guidelines* also set forth the areas of research that are ineligible for NIH funding, including: 1) as required by law, research involving the derivation of pluripotent stem cells from human embryos; 2) research in which human pluripotent stem cells are utilized to create or contribute to a human embryo; 3) research utilizing pluripotent stem cells that were derived from human embryos created for research purposes; 4) research in which human pluripotent stem cells are derived using somatic cell nuclear transfer; 5) research utilizing human pluripotent stem cells that were derived using somatic cell nuclear transfer; 6) research in which human pluripotent stem cells are combined with an animal embryo; and 7) research in which human pluripotent stem cells are derived using somatic cell nuclear transfer for the purposes of reproductive cloning of a human.

Requirements for Investigators Applying for Funds

With the issuing of the *Guidelines*, the moratorium was lifted, and NIH is accepting applications for this class of research. A request for NIH funds for research using these cells must include a signed assurance that the cells were derived from human embryos or fetal tissue in accordance with the *Guidelines* and that the institution will maintain documentation in support of the assurance.

This assurance must also affirm that the human pluripotent stem cells to be used in the research were obtained through a donation or through a payment that does not exceed the reasonable costs associated with the quality control, processing, transportation, preservation, and storage of the stem cells. It must state that the proposed research is not a class of research that is ineligible for NIH funding.

Investigators must also submit a sample informed consent document, with patient identifier information removed, and a description of the informed consent process along with documentation of IRB approval of the derivation protocol. They must also provide an abstract of the scientific protocol used to derive human pluripotent stem cells along with a title of the research proposal that proposes the use of human pluripotent stem cells.

Ensuring Compliance with the *Guidelines*

Investigators requesting NIH funds for research using pluripotent stem cells will need to provide documentation that they are in compliance with the *Guidelines* prior to receiving NIH funds for this class of research. Submitted documentation will be reviewed by a newly-created NIH working group called the Human Pluripotent Stem Cell Review Group (HPSCRG).

Members of the working group will review documentation of compliance with the *Guidelines* for funding requests that propose the use of human pluripotent stem cells. They will also advise the NIH Center for Scientific Review Advisory Committee (CSRAC) of the outcome of their review, which, if appropriate, will be approved by the CSRAC. This decision will be forwarded to the funding Institute or Center. The HPSCRG will also hold public meetings when a request proposes the use of a line of human pluripotent stem cells that has not been previously reviewed by the HPSCRG.

The NIH is in the process of finalizing the members of the HPSCRG in preparation for a March deadline for the receipt of requests for NIH funding for human pluripotent stem cell research. The Agency has not, to date, received any applications for this class of research. In no event will NIH fund research or allow existing funds to be used for research using human pluripotent stem cells derived from human embryos or human fetal tissue until the derivation protocol has received HPSCRG review and CSRAC approval. Continued compliance with the *Guidelines* is a term and condition of the NIH award.

Government Affairs and Advocacy

HOME
WASHINGTON HIGHLIGHTS
ISSUE BRIEFS
CALENDAR
TESTIMONY
LINKS
CONTACTS
SEARCH

Related Resources

AAMC Documents:

Jan. 19, 2000 Letter on NIH Guidelines

NIH Documents:

NIH Draft Guidelines

NIH Stem Cell Information

Administration Documents:

Nov. 14, 1998, Letter from President Clinton to NBAC

NBAC Report and Recommendations

Feb. 29, 1999, Letter from Sec. Shalala to Rep. Dickey

Coalition Letters to Congress

Issue Briefs

Stem Cell Research

Current Status as of May 24, 2000

Anticipating a Senate vote on the question of whether the federal government should fund research using human embryonic stem cells, the Senate Labor-HHS-Education Appropriations Subcommittee on April 26 held the fifth in a series of hearings on this issue. Senators Arlen Specter (R-Pa.) and Tom Harkin (D-Iowa) have introduced legislation (S. 2015) that would provide a specific exception to the current ban on federal funding for embryo research to permit scientists to derive human embryonic stem cells from embryos in excess from IVF clinics. Senate Majority Leader Trent Lott (R-Miss.) has reportedly agreed to let the Senate vote on S. 2015 later this year.

The NIH issued draft guidelines on human pluripotent stem cell research on December 2, 1999. The AAMC commented favorably on these guidelines in a January 19, 2000, letter.

AAMC Activity

The AAMC concurs with the January 1999 legal determination of the Department of Health and Human Services that current law permits the use of federal funds to support research utilizing human pluripotent stem cells. Furthermore, the AAMC supports the decision of the National Institutes of Health to delay any research using pluripotent stem cells until clear guidelines can be developed to address the specific scientific, legal, and ethical issues surrounding stem cell research.

In response to requests for support from Senate Labor-HHS Appropriations Subcommittee Chairman Arlen Specter (R-Pa.) and Ranking Member Tom Harkin (D-Iowa), the AAMC organized a February 19, 1999 letter to the entire Congress in support of the

Feb. 19, 1999

July 29, 1999

April 25, 2000

Nobel Laureates Letter

Legislation:

S. 2015

Congressional Documents:

Feb. 11, 1999, Letter from Rep. Dickey to Sec. Shalala

Feb. 12, 1999, Letter from Rep. Brownback to Sec. Shalala

Testimony 4/26/2000 Hearing

Administration's interpretation. The letter was signed by 70 organizations representing the scientific, academic, patient advocacy, and industry communities.

The AAMC joined with 126 patient groups and scientific and medical organizations in a second letter to the House and Senate Appropriations Committees on July 29 supporting federal funding of research using human pluripotent stem cells. The letter also was released during a July 29, 1999, press briefing sponsored by the Patients Coalition for Urgent Research, which featured Senator Strom Thurmond (R-S.C.) and Rep. Brian Bilbray (R-Calif.), who both endorsed federal funding for stem cell research.

In a January 19, 2000, comment letter on proposed NIH guidelines for research utilizing human pluripotent stem cells, AAMC President Jordan J. Cohen, M.D., said that federal support for such research "should not only be viewed as permissible, but also as highly desirable, given the beneficial oversight that accompanies government funding, the tremendous promise of this type of research, and the fact that the results of federally funded research will flow into the public domain and not be sequestered in propriety databases."

In addition, the AAMC joined more than 100 patient, scientific, and medical organizations, on an April 26, 2000, letter in support of actor Christopher Reeve's advocacy on behalf of embryonic stem cell research.

Issue

A stem cell is a cell that is believed to have the ability to divide without limit and to give rise to daughter cells that can form specialized cells. These can be categorized as pluripotent, which are capable of specializing into many but not necessarily all tissues of an organism, or totipotent which have unlimited ability to differentiate into extraembryonic membranes, the embryo, and all postembryonic tissues and organs. Reports published in 1998 by scientists at the University of Wisconsin and Johns Hopkins University on the successful isolation and culturing of pluripotent human stem cells have created the prospect of developing an entire array of new cellular therapies. Stem cell research holds the promise of helping us better understand the most fundamental processes of human development and cellular specialization. In a letter organized by the American Association of Cell Biologists, 36 Nobel laureates contend that stem cell research will yield an understanding of "how to induce these cells to become bone marrow for treatment of cancer and other hematopoietic diseases, pancreatic cells for alleviating diabetes, and neuronal cells for treating Parkinson's disease, Alzheimer's and various forms of brain and spinal cord disorders." Stem cells could also change the way new drugs are tested for safety by selectively using specific human cell lines as the initial experimental tool.

However, the recent discoveries have also raised a number of ethical, legal, and moral issues. Under language included in the Labor-HHS Appropriations bill every year since 1996, the federal government is prohibited from funding research involving human embryos.

Administration Activity

In January 1999, the General Counsel of the Department of Health and Human Services determined that the federal government was not prohibited from funding research utilizing human pluripotent stem cells based on the scientific determination that stem cells are not "organisms" and therefore cannot be considered human embryos. In response to a letter from Representative Jay Dickey (R-Ark.) and 69 other Members of Congress that questioned the General Counsel's interpretation, Secretary Donna Shalala defended the policy and assured Representative Dickey that the NIH would develop guidelines for the conduct of such research and an appropriate oversight mechanism before any research would go forward.

In view of the scientific and medical benefits that may result from research using pluripotent stem cells, the NIH plans to fund stem cell research. To address the compelling ethical, legal, and social issues relevant to pluripotent stem cell research, the NIH Director commissioned a subcommittee of the Advisory Council to the Director with developing guidelines for the use of pluripotent stem cells in NIH-funded research. This group, composed of scientists, patients and/or their families, ethicists, clinicians, and lawyers, issued draft guidelines on human pluripotent stem cell research in the December 2, 1999, *Federal Register* with a 60 day public comment period. The comment period was subsequently extended until February 22, 2000.

The draft guidelines indicate that NIH will fund research using human pluripotent stem cells from early human embryos only if investigators use cells derived from frozen embryos that were created for purposes of infertility treatment and were in excess of clinical need. NIH also will support research to derive or use human pluripotent stem cells from fetal tissue. In addition, the draft guidelines identify areas of research that are ineligible for funding and also state that no NIH funds will be used to derive pluripotent stem cells from human embryos.

The draft guidelines outline in detail the methods and procedures by which NIH will fund this area of research, including the establishment of a Human Pluripotent Stem Cell Review Group (HPSCRG), which will hold public meetings when a funding request proposes the use of a newly derived line of human pluripotent stem cells.

The NIH has stated it will not fund research using human pluripotent

stem cells until final guidelines are published in the *Federal Register* and an oversight process is in place.

Meanwhile, on November 14, 1998, President Clinton requested that the National Bioethics Advisory Commission (NBAC) "undertake a thorough review of the issues associated with human stem cell research, balancing all ethical and medical considerations." In its report released in September 1999, NBAC recommended that federal funding for both the use and derivation of stem cells should be limited to cells derived from fetal tissue and embryos remaining after infertility treatments. The report rejects the use of federal funds to derive stem cells from embryos created strictly for research purposes.

Congressional Activity

Senate Labor-HHS-Education Appropriations Subcommittee Chairman Arlen Specter (R-Pa.) and Ranking Member Tom Harkin (D-Iowa) have held five hearings on stem cell research. The initial hearing, on December 2, 1998 addressed the potential therapeutic benefits, as well as the ethical concerns, posed by stem cell research. The January 12, 1999, hearing explored patent, technology transfer, and intellectual property implications of stem cell research. The January 26, 1999 hearing focused on the ethical, scientific, and legal implications of the Department's decision to permit federally funded stem cell research. The November 4, 1999, hearing examined the National Bioethics Advisory Commission's report "Ethical Issues in Human Stem Cell Research." And the April 26, 2000, hearing featured scientists and patients who cited the potential benefits of embryonic stem cell research and opponents of stem cell research who questioned the morality of and need for such studies.

Senators Specter and Harkin also introduced legislation (S. 2015) that would provide a specific carve-out from the existing ban on federal funding for embryo research to permit scientists to derive human embryonic stem cells from human embryos that are in clinical excess from IVF clinics. Senate Majority Leader Trent Lott (R-Miss.) reportedly has agreed to let the bill come the Senate floor for a vote later this year.

Congressional reaction to the HHS legal ruling has been confrontational. Representative Jay Dickey (R-Ark.) initiated a letter to Health and Human Services Secretary Donna Shalala signed by 69 other Members of Congress objecting to the ruling on the basis that it violated both the "letter and spirit of the federal law banning federal support for research in which human embryos are harmed or destroyed." Representative Dickey calls the HHS ruling a "carefully worded effort to justify transgressing that law," which he interprets as not only prohibiting research that destroys an embryo, but also research that depends on the previous destruction of an embryo. Senator Sam Brownback (R-Kan.) and 6 other Senators wrote a

similar letter to Secretary Shalala disagreeing with the HHS position.

Contacts

Dave Moore or Jonathan Fishburn, AAMC Office of Governmental Relations, 202-828-0525.

Revised: 25 May 2000

D-Note

jld

PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

TODAY

Soon

8/13

gen

AN ACT ...; **relating to:** intentionally causing the death of an in vitro human embryo, nontherapeutic research undertaken on an in vitro human embryo, and use of cells derived from an in vitro human embryo and providing a penalty.

penalties

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 940.17 of the statutes is created to read:

940.17 In vitro human embryos and cells derived from them. (1) In this section:

(a) "Cloning" means a human somatic cell nuclear transfer.

INSERT 8-7 move to next page

(b) "Extracted embryonic cell" means a human cell that has been extracted from an aggregation of living human cells described in par. (d) 2.

(c) "Nontherapeutic human embryo research" means a procedure undertaken upon an in vitro human embryo that is not intended to help promote its development.

(d) "In vitro human embryo" means any of the following, whether cryopreserved or not:

1. A diploid human cell, the immediate precursor of which is one or more human gametes, that is living outside of a woman's body.

2. An aggregation of two or more living human cells that has never been located in a woman's body and that is derived, through cell division, from a cell described in subd. 1., but that is not derived from an extracted embryonic cell.

→ INSERT 2-7 (from previous pages)

(2) Whoever intentionally causes the death of an in vitro human embryo is guilty of a Class D felony.

(3) Whoever transfers an in vitro human embryo to another person with the knowledge that it will intentionally be killed is guilty of a Class D felony.

(4) Whoever intentionally subjects an in vitro human embryo to a substantial risk of injury or death is guilty of a Class E felony. This subsection does not apply if the actor's acts or omissions are intended to help promote the embryo's development.

(5) Whoever transfers an in vitro human embryo to another person with the knowledge that it will intentionally be subjected to a substantial risk of injury or death is guilty of a Class E felony. This subsection does not apply if the acts or omissions that create the risk of injury or death are intended to help promote the embryo's development.

(6) Whoever does any of the following for the purpose of undertaking nontherapeutic human embryo research is guilty of a Class E felony:

(a) Fertilizes a human ovum outside of a woman's body.

(b) Directs or participates in the cloning of a human being.

(7) Whoever transfers or acquires any cell or tissue that the actor knows was obtained through conduct that is described under subs. (2), (4), or (6) and that takes place on or after the effective date of this subsection .... [revisor inserts date], is guilty of a Class D felony.

(8) Whoever possesses any cell or tissue that the actor knows was obtained through conduct that is described under subs. (2), (4), or (6) and that takes place on or after the effective date of this subsection .... [revisor inserts date], is guilty of a Class E felony.

SECTION 2. Nonstatutory provisions.

(1) In this section:

(a) "Female donor" means a woman from whose ovum an in vitro human embryo is derived.

(b) "In vitro human embryo" has the meaning given in section 940.17 (1) (d) of the statutes.

(2) The joint legislative council is requested to do all of the following and, if it does any of them, to report its findings, conclusions, and recommendations, together with any proposed legislation, to the 2003 legislature when it convenes:

(a) Study current laws regarding adoption, with a view toward facilitating the implantation of in vitro human embryos that are not used by their female donors in women other than the female donors.

(b) Study the regulation of infertility clinics, with a view toward doing all of the following:

1. Reducing the number of in vitro human embryos that are created to a reasonable number needed for reproductive purposes.

2. Facilitating the implantation of in vitro human embryos that are not used by their female donors in women other than the female donors.

(END)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB–2888/?dn
MGD.....

Rep. Freese:

1. From what I understand, an embryo cannot survive cryopreservation indefinitely. *See, e.g.*, http://www.ccivf.com/ivfcryopres.htm (website of Cooper Center for In Vitro Fertilization). Therefore, this bill may be construed as prohibiting the cryopreservation of human embryos or continuing their cryopreservation without a plan to implant them later. *See* s. 939.23 (3) ("[i]ntentionally" means that the actor either has a purpose to do the thing or cause the result specified, or *is aware that his or her conduct is practically certain to cause that result*" (emphasis added)). Is that your intent? (If it is, then, unless s. 940.17 (2) is ruled unconstitutional (*see* Items 2 and 3), sub. (2) (b) of the nonstatutory provision may be unnecessary.)

2. If the bill does not permit indefinite cryopreservation, the donors of the gametes from which in vitro embryos are derived must consent to the implantation of all of them in the uterus of the egg donor or another woman, even if one or both donors later object. Neither the U.S. Supreme Court nor the Wisconsin Supreme Court has addressed the constitutionality of such a requirement, but as you know, both courts have upheld a woman's right not to procreate. Those cases, however, have focused on a woman's constitutional right to decide matters relating to her own body, a right that might not be germane here. *See Kass v. Kass*, 91 N.Y.2d 554, 696 N.E.2d 174 (1998) (http://www.law.cornell.edu/ny/ctap/I98_0049.htm). Nevertheless, in cases involving in vitro fertilization, courts in other states have acknowledged that a person has a right not to procreate independent of his or her right to bodily autonomy. *See Davis v. Davis*, 842 S.W.2d 588, 601, 1992 Tenn. LEXIS 400, *45 (1992); *Litowitz v. Litowitz*, 102 Wash. App. 934, 944, 10 P.3d 1086, 1092, 2000 Wash. App. LEXIS 2012, *20 (2000). Thus, the prohibition on causing the death of an in vitro human embryo — particularly in a case in which the embryos already exist — may be ruled unconstitutional.

3. Existing contracts between IVF clinics and their clients may contain provisions regarding the disposition of unused embryos that conflict with what this bill requires. Therefore, this bill may be construed as an unconstitutional impairment of those contracts under Art. I, § 12 of the Wisconsin Constitution and Art. I, § 10 of the U.S. Constitution. *See Reserve Life Ins. Co. v. La Follette*, 108 Wis. 2d 637, 323 N. W. 2d 173 (Ct. App. 1982). One way to address this problem would be to include an initial applicability provision that would make the prohibition on causing the death of an in vitro human embryo inapplicable to contracts in force on the effective date of the bill.

(Such a provision might also reduce the risk that the statute would be found unconstitutional on autonomy or privacy grounds.)

4. The "any organism..." language that Mary Klaver proposed for defining "human embryo" is so broad that it covers adult human beings. I assume that you do not intend for the definition to be so broad, so I used a different definition for "in vitro human embryo."

5. With advances in technology, it may ultimately become possible to separate an embryo in the earliest stages of its development (for example, at the 2–cell or 4–cell stage) into single cells (from which stem cells might ultimately be generated) without subjecting the embryo to a substantial risk of death or bodily harm (although it is unclear how a court will interpret that prohibition if the original embryo is divided into separate living cells). As drafted, the bill does not prohibit that conduct. Should it?

6. The references in subs. (7) and (8) to "conduct that is described under subs. (2), (4), or (6)" include conduct that occurs outside of this state. Those provisions, however, do not cover materials (such as insulin or other biochemicals) that might be produced by cells derived from stem cells. Is that your intent?

7. Do you want to create an exception in subs. (7) and (8) that would permit a person to acquire and possess an embryo that was created for an unlawful purpose under sub. (6) if the person acquiring or possessing the embryo does so with the intent to have the embryo implanted in a woman?

8. At some point, stem cells may be used to produce cells or tissues for implantation in a human being. If those stem cells were the result of conduct described in sub. (2), (4), or (6), and the person in whom the cells or tissue have been implanted is in Wisconsin, the person arguably "possesses" cells or tissue in violation of sub. (8), even if the implantation procedure was legal in the state in which it occurred. Is that your intent?

9. This bill does not affect the disposition of an egg the cell wall of which has been penetrated by a sperm cell but whose genetic material has not yet fused with the genetic material from the sperm cell ("pre–zygotes"). Is that your intent?

Michael Dsida
Legislative Attorney
Phone: (608) 266–9867

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-2888/P1dn
MGD:jld:pg

August 13, 2001

create exception for cryopreservation

Rep. Freese:

1. From what I understand, an embryo cannot survive cryopreservation indefinitely. *See, e.g.*, http://www.ccivf.com/ivfcryopres.htm (Web site of Cooper Center for In Vitro Fertilization). Therefore, this bill may be construed as prohibiting the cryopreservation of human embryos or continuing their cryopreservation without a plan to implant them later. *See* s. 939.23 (3) ("[i]ntentionally" means that the actor either has a purpose to do the thing or cause the result specified, or *is aware that his or her conduct is practically certain to cause that result*" (emphasis added)). Is that your intent? (If it is, then, unless s. 940.17 (2) is ruled unconstitutional (*see* Items 2 and 3), sub. (2) (b) of the nonstatutory provision may be unnecessary.)

2. If the bill does not permit indefinite cryopreservation, the donors of the gametes from which in vitro embryos are derived must consent to the implantation of all of them in the uterus of the egg donor or another woman, even if one or both donors later object. Neither the U.S. Supreme Court nor the Wisconsin Supreme Court has addressed the constitutionality of such a requirement, but as you know, both courts have upheld a woman's right not to procreate. Those cases, however, have focused on a woman's constitutional right to decide matters relating to her own body, a right that might not be germane here. *See Kass v. Kass*, 91 N.Y.2d 554, 696 N.E.2d 174 (1998) (http://www.law.cornell.edu/ny/ctap/I98_0049.htm). Nevertheless, in cases involving in vitro fertilization, courts in other states have acknowledged that a person has a right not to procreate independent of his or her right to bodily autonomy. *See Davis v. Davis*, 842 S.W.2d 588, 601, 1992 Tenn. LEXIS 400, *45 (1992); *Litowitz v. Litowitz*, 102 Wash. App. 934, 944, 10 P.3d 1086, 1092, 2000 Wash. App. LEXIS 2012, *20 (2000). Thus, the prohibition on causing the death of an in vitro human embryo — particularly in a case in which the embryos already exist — may be ruled unconstitutional.

3. Existing contracts between IVF clinics and their clients may contain provisions regarding the disposition of unused embryos that conflict with what this bill requires. Therefore, this bill may be construed as an unconstitutional impairment of those contracts under article I, section 12, of the Wisconsin Constitution and article I, section 10, of the U.S. Constitution. *See Reserve Life Ins. Co. v. La Follette*, 108 Wis. 2d 637, 323 N. W. 2d 173 (Ct. App. 1982). One way to address this problem would be to include an initial applicability provision that would make the prohibition on causing the death of an in vitro human embryo inapplicable to contracts in force on the effective date of

add severability language

Dsida, Michael

From: Richard, Rob
Sent: Tuesday, August 14, 2001 2:51 PM
To: Dsida, Michael; Welch, Bob
Subject: RE: LRB-2888

Mike:

On behalf of Rep. Freese and Sen. Welch, yes, that is our intent.

Rob Richard
Freese Office

-----Original Message-----
From: Dsida, Michael
Sent: Tuesday, August 14, 2001 2:27 PM
To: Welch, Bob; Freese, Steve
Subject: LRB-2888

Before I resume work on this, I would like to get some clarification with respect to our discussion of item 5 in the drafter's note. Sen. Welch initially suggested that a cell may be extracted from an embryo if the extraction does not pose a substantial risk of harm to the embryo -- i.e., if the embryo can continue to develop. But both of you ultimately agreed that if an embryo is divided into totipotent cells (cells that can themselves develop into a human being), all of those cells should be treated under the bill in the same way that a normal single cell embryo is treated. Based on that latter instruction, I will draft the bill so that if a totipotent cell is extracted from an embryo, it is to be treated as an embryo, even if the embryo from which it is derived is capable of developing without that cell into a human being. If the cell is not totipotent, it may be removed, but only if the embryo may develop without it. Is that your intent?

Mike Dsida
Legislative Reference Bureau
608/266-9867
michael.dsida@state.legis.wi.us

Dsida, Michael

From: Dsida, Michael
Sent: Friday, August 17, 2001 9:54 AM
To: Boycks, Brad; Richard, Rob
Subject: Severability

Because of the possibility that this bill may be viewed as unconstitutionally impairing certain contracts (see item 3 of the drafter's note), Sen. Welch suggested at our meeting that I include a severability clause. But now that I have had a chance to think about it, I don't think that you need one. Under s. 990.001 (11), if part of a statute is ruled unconstitutional with respect to a contract in existence on the date of the bill's enactment, the provision would still apply to contracts entered into after that date.

Mike Dsida
Legislative Reference Bureau
608/266-9867
michael.dsida@state.legis.wi.us

WISCONSIN RIGHT TO LIFE
Life without limits
State Affiliate of the National Right to Life Committee, Inc., Washington, DC 20004-1199

Wisconsin Right to Life, Inc.
10625 W. North Ave., Suite LL
Milwaukee, WI 53226-2331
Ph: 414-778-5780
Fax: 414-778-5785
Toll Free: 877-855-5007
Home Page: www.wrtl.org

FAX COVER SHEET

OPERATOR: PLEASE NOTIFY THE PERSON NAMED BELOW THAT THIS FAX HAS ARRIVED. THANK YOU

Important Notice: The information contained in this transmission is intended for the specific person(s) addressed. If you have received this fax in error please contact us immediately at the phone number below. Thank You !

TO (Name): Mike Dsida

LOCATION: LRB

AT FAX #: 608-264-6948 AT PHONE# 608-266-9867

FROM: Mary Klaver

WRL Fax: 414/778-5785
WRL Phone: 414/778-5780

Date Sent: 8/20/01

Pages: 13 (including this cover sheet)

Time Sent: _____ a.m. / p.m.

MESSAGE: Instructions for redraft of LRB 2888/1 - Human Embryo Protection Act*. These changes were reviewed with Freese + Welch and okayed for drafting. Please call me to discuss. Thanks

* and some supporting documents

Help make Life Without Limits a reality for future generations

State of Wisconsin
2001 - 2002 LEGISLATURE

LRB-2888/P1
MGD:jld:pg

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

AN ACT *to create* 940.17 of the statutes; **relating to:** intentionally causing the death of an in vitro human embryo, nontherapeutic research undertaken on an in vitro human embryo, and use of cells derived from an in vitro human embryo and providing penalties.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

Insert A. 146.347 Human cloning prohibited

SECTION 1. 940.17 of the statutes is created to read:

940.17 In vitro human embryos and cells derived from them. (1) In this section: (a) "Human embryo" means an organism of the species homo sapiens, who is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells, including the single cell zygote stage until the time when the major body structures are present.

~~(a) "Cloning" means a human somatic cell nuclear transfer.~~

~~(b) "Extracted embryonic cell" means a human cell that has been extracted from an aggregation of living human cells described in par. (c) 2.~~

SECTION 1

(b) "Medical research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable medical knowledge.

~~(c) "In vitro human embryo" means any of the following, whether cryopreserved or not:~~

~~1. A diploid human cell, the immediate precursor of which is one or more human gametes, that is living outside of a woman's body.~~

~~2. An aggregation of two or more living human cells that has never been located in a woman's body and that is derived, through cell division, from a cell described in subd. 1., but that is not derived from an extracted embryonic cell.~~

~~(d)~~ "Nontherapeutic ~~human embryo~~ research" means ~~a procedure undertaken upon an in vitro human embryo~~ that is not intended to help ~~promote its development.~~ protect and preserve the life or health of the particular living human embryo who is outside a woman's body and being subjected to risk.

(2) Whoever intentionally causes the death of ~~an in vitro human embryo~~ a living embryo who is outside a woman's body is guilty of a Class ~~D~~ E felony.

(3) Whoever transfers ~~an in vitro human embryo~~ to another person with the knowledge that the embryo it will intentionally be ~~killed~~ destroyed is guilty of a Class ~~D~~ E felony.

(4) Whoever intentionally subjects ~~an in vitro human embryo~~ to a substantial risk of injury or death for the purpose of nontherapeutic research is guilty of a Class E felony. ~~This subsection does not apply if the actor's acts or omissions are intended to help promote the embryo's development.~~

(5) Whoever transfers an in vitro human embryo purchases, sells or to another person with the knowledge that the embryo it will intentionally be subjected to a substantial risk of injury or death for the purpose of nontherapeutic research is guilty of a Class E felony. ~~This subsection does not apply if the acts or omissions that create the risk of injury or death are intended to help promote the embryo's development.~~

(6) Whoever creates a living human embryo outside a woman's body ~~does any of the following~~ for the purpose of ~~undertaking~~ nontherapeutic ~~human embryo~~ research is guilty of a Class E felony.

~~(a) Fertilizes a human ovum outside of a woman's body.~~

~~(b) Directs or participates in the cloning of a human being.~~

(7) Whoever transfers ~~or acquires~~ any cell or tissue that the actor knows was obtained through conduct that is described under sub. (2), (4), or (6) ~~and that takes place on or after the effective date of this subsection .... [revisor inserts date],~~ is guilty of a Class ~~D~~ E felony.

~~(8) Whoever possesses any cell or tissue that the actor knows was obtained through conduct that is described under sub. (2), (4), or (6) and that takes place on or after the effective date of this subsection .... [revisor inserts date], is guilty of a Class E felony.~~

SECTION 2. Nonstatutory provisions.

(1) In this SECTION:

~~(a) "Female donor" means a woman from whose ovum an in vitro human embryo is derived.~~

~~(b)~~ "~~In vitro~~ human embryo" has the meaning given in section 940.17 (1) ~~(c)~~ of the statutes.

(2) The joint legislative council is requested to do all of the following and, if it ~~does any of them,~~ to report its findings, conclusions, and recommendations, together with any proposed legislation, to the 2003 legislature when it convenes:

(a) Study current laws regarding adoption, with a view toward facilitating the adoption and implantation of ~~in vitro~~ human embryos ~~that are not used by their female donors in women other than the female donors.~~

(b) Study the regulation of infertility clinics, with a view toward doing all of the following:

1. Reducing the number of ~~in vitro~~ human embryos that are created to a reasonable number needed for reproductive purposes.

3. Providing a mechanism to release unwanted and abandoned embryos for adoption and implantation.

~~2. Facilitating the implantation of in vitro human embryos that are not used by their female donors in women other than the female donors.~~

4. Providing that any contractual provision that would violate s. 940.17 is null and void.

(END)

May move to substantive provision

(8) This section shall not apply to the act of cryopreserving a living human embryo or the act of thawing a living cryopreserved human embryo if the actor has used all available means to protect the life and health of the embryo during the time the embryo is in the actor's possession.

(9) Nothing in this section prohibits the creation by fertilization of a human embryo for the purpose of reproduction as long as the embryo is given the optimum chance to survive and continue to develop by being transferred to the uterus of a woman who is willing and able to carry the pregnancy to term.

add to s. 940.17

Add a provision (possibly in ch. 146 or 253) as follows:

"Any person who proposes to provide a medical treatment or surgical procedure to a patient using any cell or tissue that the person knows was obtained through conduct that is described under s. 940.17 (2), (4), or (6) shall inform the patient, orally and in writing, prior to obtaining the patient's consent to the medical treatment or surgical procedure that the cells or tissues were obtained by an activity described in s. 940.17 (2), (4), or (6)."

Add the following provision to Sen. Welch's draft (before the above provision):

"Any person who transfers any cell or tissue that the person knows was obtained through conduct that is described under s. 940.17 (2), (4), or (6) shall make a statement, in writing, to each and every recipient of the cell or tissue that the cell or tissue was obtained through conduct that is described under s. 940.17 (2), (4), or (6)."

Add a severability clause.

new provisions

HUMAN EMBRYO PROTECTION ACT

146.347 Human cloning prohibited. (1) In this section:

(a) "Asexual reproduction" means reproduction not initiated by the union of oocyte and sperm.

(b) "Human cloning" means asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte whose nuclear material has been removed or inactivated so as to produce a living organism at any stage of development who is genetically virtually identical to an existing or previously existing human organism.

(c) "Somatic cell" means a diploid cell (having a complete set of chromosomes) obtained or derived from a living or deceased human body at any stage of development.

(2) No person or entity, public or private, may knowingly do any of the following:

(a) Perform or attempt to perform human cloning.

(b) Participate in an attempt to perform human cloning.

(c) Ship, receive or import for any purpose an embryo produced by human cloning or any product derived from such embryo.

(3) PENALTIES. (a) CRIMINAL PENALTY. Any person or entity who violates this section shall be fined under this section or imprisoned not more than 10 years, or both.

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

(4) SCIENTIFIC RESEARCH. Nothing in this section restricts areas of scientific research not specifically prohibited by this section, including research in the use of nuclear transfer or other

cloning techniques to produce molecules, DNA, cells other than human embryos, tissues, organs, plants, or animals other than humans.

940.17 Human embryo. (1) In this section:

(a) "Human embryo" means an organism of the species homo sapiens, who is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells, including the single cell zygote stage until the time when the major body structures are present.

(b) "Medical research" means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable medical knowledge.

(c) "Nontherapeutic research" means research that is not intended to help protect and preserve the life or health of the particular living human embryo who is outside a woman's body and being subjected to risk.

(2) Whoever intentionally destroys a living human embryo who is outside a woman's body is guilty of a Class E felony.

(3) Whoever purchases, sells or transfers a living human embryo who is outside a woman's body to another person with the knowledge that the embryo will be intentionally destroyed is guilty of a Class E felony.

(4) Whoever intentionally subjects a living human embryo who is outside a woman's body to substantial risk of injury or death for the purpose of nontherapeutic research is guilty of a Class E felony.

(5) Whoever purchases, sells or transfers a living human embryo who is outside a woman's body to another person with the knowledge that the embryo will be intentionally

subjected to sustantial risk of injury or death for the purpose of nontherapeutic research is guilty of a Class E felony.

(6) Whoever creates a living human embryo outside a woman's body for the purpose of nontherapeutic research is guilty of a Class E felony.

(7) Whoever [uses, transfers <-- put this in Rep. Freese's draft, but not Sen. Welch's draft], purchases, or sells, for the purpose of medical research any cell or tissue that the actor knows was obtained through conduct that is described under sub. (2), (4), or (6) is guilty of a Class E felony.

(8) This section shall not apply to the act of cryopreserving a living human embryo or the act of thawing a living cryopreserved human embryo if the actor has used all available means to protect the life and health of the embryo during the time the embryo is in the actor's possession.

(9) Nothing in this section prohibits the creation by fertilization of a human embryo for the purpose of reproduction as long as the embryo is given the optimum chance to survive and continue to develop by being transferred to the uterus of a woman who is willing and able to carry the pregnancy to term.

Nonstatutory provisions.

(1) In this section, "human embryo" has the meaning given in section 940.17 (1) (a) of the statutes.

(2) The joint legislative council is requested to do all of the following and to report its findings, conclusions, and recommendations, together with any proposed legislation, to the 2003 legislature when it convenes:

(a) Study current laws regarding adoption, with a view toward facilitating the adoption and implantation of any living human embryo who is outside a woman's body and has been

donated for adoption by the genetic parents of the embryo or abandoned by the genetic parents of the embryo.

(b) Study the regulation of infertility clinics, with a view toward doing all of the following:

1. Reducing the number of human embryos who are created to a reasonable number needed for reproductive purposes.

2. Requiring that parents undergoing infertility treatments be informed of the option to allow unused embryos to be released for adoption and implantation.

3. Providing a mechanism to release unwanted and abandoned embryos for adoption and implantation.

4. Providing that any contractual provision that would violate s. 940.17 is null and void.

Add a provision (possibly in ch. 146 or 253) as follows:

"Any person who proposes to provide a medical treatment or surgical procedure to a patient using any cell or tissue that the person knows was obtained through conduct that is described under s. 940.17 (2), (4), or (6) shall inform the patient, orally and in writing, prior to obtaining the patient's consent to the medical treatment or surgical procedure that the cells or tissues were obtained by an activity described in s. 940.17 (2), (4), or (6)."

Add the following provision to Sen. Welch's draft (before the above provision):

"Any person who transfers any cell or tissue that the person knows was obtained through conduct that is described under s. 940.17 (2), (4), or (6) shall make a statement, in writing, to each and every recipient of the cell or tissue that the cell or tissue was obtained through conduct that is described under s. 940.17 (2), (4), or (6)."

Add a severability clause.

Subject: Re: Definition of human embryo
Date: Thu, 16 Aug 2001 11:57:49 -0500
From: David Prentice <prentice@indstate.edu>
To: Mary Klaver <mklaver@wrtl.org>

To Mary Klaver:
The definition of "human embryo" which you supply below is much clearer and direct than the wording in the draft legislation which you faxed to me ("An Act to create 940.17 of the statutes...")

> *"Human embryo" means a organism of the species homo sapiens, who is*
> *derived by fertilization, parthenogenesis, cloning, or any other means*
> *from one or more human gametes or human diploid cells, including the*
> *single cell zygote stage until the time when the major body structures*
> *are present, who is not located in a woman's body."*

What about in vitro procedure?

In the draft legislation, section 1(c)1 supplies an insufficient and inaccurate description of an embryo. By specifying a diploid cell, the possibility exists for use of a somatic cell rather than an egg as the recipient of gametic chromosomes or DNA; e.g., in this definition, a skin cell could have its nucleus removed and the nuclear material implanted from 2 eggs, 2 sperm, 1 egg + 1 sperm, or some mixture to equal a diploid chromosome content. This, however, would not create an embryo.
Likewise, this subsection could leave open the possibility of a variation of "sperm-free" fertilization to create an embryo, as recently described by an Australian group, in which a somatic cell nucleus is placed into an egg and then an electrical current is applied to remove half of the somatic cell chromosomes. If the egg nuclear material were removed prior to insertion of the somatic nucleus, this could be interpreted as cloning [which is not adequately defined in section 1(a)]. However, subsequent manipulation could remove half of the somatic chromosomes, followed by insertion of a second somatic nucleus and removal of half of its chromosomes to provide a diploid number (alternatively, chromosome constituents from multiple somatic nuclei could be inserted to give a diploid number). In these cases, an embryo would have been created by asexual means, utilizing genetic material solely from somatic cells, and technically not from gametes since no gametic nuclear material remains; this would not be covered under the current definition in section 1(c)1.

prohibit under — Welch bill?

Embryos which result in born individuals have also been created with mice using embryonic stem cells, either by insertion of cultured embryonic stem cells into empty blastocysts (only trophoblast) or normal blastocysts (creating a chimeric organism). Embryonic stem cells have also been used to create embryos resulting in born mice and cattle by wrapping cultured embryonic stem cells in tetraploid cells. Section 1(c)2 would preclude classifying the cases given above as embryos.

The analysis given is based on my 17 years experience teaching courses in Embryology, Developmental Biology, Cell & Tissue Culture, Cell & Molecular Biology, Medical Genetics, Medical Biochemistry, and General Biology, familiarity with both textbooks in the area and more importantly with the published primary scientific literature in this and related areas, and my 25 years experience in the research laboratory conducting experiments in cell biology, cell culture, molecular biology, genetics, and stem cells.

I received my B.S. in Cellular Biology in 1978 and my Ph.D. in Biochemistry in 1981 from the University of Kansas. I was a

Postdoctoral Fellow at Los Alamos National Laboratory (1981-1982) and Assistant Professor of OB/GYN and Reproductive Sciences at the University of Texas Medical School-Houston (1983-1984) before joining Indiana State University in 1985. My research, which has been funded by the National Institutes of Health, USDA, and the Eagles, investigates cell growth control; one current focus is adult stem cells and their transformation into other tissue types. I have reviewed for professional publications including The Journal of the American Medical Association, and have testified numerous times before Congress regarding stem cell research, cloning, and bioethics.

--

****
Dr. David A. Prentice
Professor, Life Sciences, Indiana State University
Adjunct Professor, Medical & Molecular Genetics
Indiana University School of Medicine
Founding Member, Do No Harm: The Coalition of Americans
for Research Ethics (http://www.stemcellresearch.org)
Voice: (812) 237-2421 FAX: (812) 237-4480
Prentice@indstate.edu
http://biology.indstate.edu/prentice/

Subject: [Fwd: Comments on definition of in vitro human embryo]
Date: Mon, 20 Aug 2001 09:52:51 -0500
From: "Barbara Lyons" <blyons@wrtl.org>
To: mklaver@wrtl.org

Subject: Comments on definition of in vitro human embryo
Date: Sun, 19 Aug 2001 23:08:00 -0400
From: "doerfling" <doerfling@msn.com>
To: <mklaver@wrtl.com>
CC: "Barbara Lyons" <blyons@wrtl.org>

TO Mary Klaver, Wisconsin Right to Life

Dear Mary:

You asked me for reactions to the proposed definition of "in vitro human embryo" in a draft human embryo protection act for the state of Wisconsin.

In what follows I do not speak for the Catholic bishops' conference, and I express no position for or against the proposed bill. I am speaking here as a policy analyst who has helped to craft and defend human embryo protection legislation at the state and federal level in recent years (e.g., the federal "Dickey amendment" forbidding federal funding of harmful human embryo research; the federal ban on human cloning recently passed by the House; South Dakota's law against harmful embryo research; Virginia's new ban on human cloning).

The definition has two parts. Taking each in turn:

1. An in vitro human embryo is "a diploid human cell, the immediate precursor of which is one or more human gametes, that is loving outside of a woman's body."

This part of the definition would have application only in the first few hours after fertilization, before cell division has begun. Possible problems:

- It does not specify that the cell is living. Is the bill intended to make policy regarding dead embryos?

- "immediate precursor" is somewhat confusing. What would be my "immediate precursor"? A sperm and egg? My father and mother? The version of me that existed a moment ago?

2. An in vitro human embryo is also "an aggregation of two or more living human cells that has never been located in a woman's body and that is derived, through cell division, from a cell described in subd. 1, but that is not derived from an extracted embryonic cell."

Here I see more problems:

- *Every* human being is "an aggregation of two or more living human cells... that is derived, through cell division, from a cell described in subd. 1." Am I a human embryo according to this bill? Apparently the only reason I cannot be seen as an "in vitro human embryo" is that I once was in a woman's womb. But

surely the sponsors did not intend to define an adult who had been gestated in an artificial womb as an in vitro human embryo!

- The requirement that such an embryo "has never been located in a woman's body" may also have a significant loophole. Embryo flushing from one woman's womb in order to implant the embryo in another woman's body is sometimes done now. If it were done to provide embryos for destructive experimentation outside the womb, those embryos would be exempt from the protection of this bill.

- The requirement that such an embryo not be "derived from an extracted embryonic cell" is problematic on two grounds:

(a) It means that any human embryo that was produced by induced twinning (or possibly even one that resulted from natural twinning, depending on the meaning of "extracted") would be free for harmful experimentation. Such an embryo has been created by being extracted from an embryo consisting of several cells. When such extraction is done in the first few days after fertilization, it produces not a "pluripotent stem cell" but another embryo.

(b) It creates a logically circular definitional system. An "extracted embryonic cell" is defined as a cell that has been extracted from the in vitro human embryo; but in vitro human embryo is defined as an entity that is not an extracted embryonic cell. Since one cannot know what either of these defined terms means without first knowing the definition of the other, a vicious circle is created, making the bill incoherent.

The definition offered by WRTL does not pose these problems and is much closer to definitions that seem to be working well in federal and state laws (e.g., in the federal Dickey amendment and South Dakota's embryo protection law), so I would see it as a better starting point.

Let me know if I can be of further help. Note, however, that as I mentioned on the phone, I will be out of town throughout the coming week and will be back in my office on Monday, August 27.

-Richard Doerflinger

Dsida, Michael

From: Dsida, Michael
Sent: Tuesday, August 28, 2001 2:10 PM
To: 'mklaver@wrtl.org'
Subject: Embryo definition

I may need to revise the definition that I used because Rep. Freese's instructions differ from those of Rep. Gundrum. I may also need to revise it in view of the comments of David Prentice and Richard Doerflinger, but I have a couple of questions about Prentice's concerns. Are the methods of creating embryos described in the two paragraphs immediately following your proposed definition of "human embryo" merely theoretically possible, or is there a relatively significant likelihood that embryos can be created that way. (He refers to an Australian group, but I was not sure if he is indicating that the group has actually created an embryo that way.)

We have also been talking only about in vitro procedures. If you talk to Prentice again, perhaps you can inquire if it is possible for stem cells to be extracted in utero. If so, that might require additional changes in how Rep. Freese's bill is drafted.

9/4/01 If it is possible to extract ~~[illegible]~~ a totipotent per more cell, it ~~is~~ should be covered ~~●~~ * after it is extracted

Mike Dsida
Legislative Reference Bureau
608/266-9867
michael.dsida@state.legis.wi.us