Sperm-Free Fertilization

In a bizarre reproductive biology advance, researchers have fertilized mouse eggs with cells from another mouse--in place of sperm. The work is the first to show that embryos can develop from the union of an intact egg and a nonreproductive cell. But don't discount the importance of sperm just yet--it's not clear whether any of the early-stage embryos could develop further.

Just before normal fertilization, each of an egg's chromosomes consists of two identical copies, each called a chromatid. After the sperm enters the egg, the egg ejects one of the copies, while the other combines with the sperm's half-complement of genetic material to form a complete genome. In past experiments, however, scientists have shown that immature sperm that contain a full set of genetic material can spark normal development, meaning the egg must be able to expel two extra sets of chromosomes.

Fertility researchers Orly Lacham-Kaplan and Rob Daniels of Monash University in Melbourne, Australia, wondered if they could use other cells that also have two copies of each chromosome to fertilize an egg. The answer appears to be yes, Kaplan told a meeting of the European Society of Human Reproduction and Embryology in Lausanne, Switzerland, earlier this month. But success was slim. Just 13 of the 725 mouse eggs that they injected with nuclei from other cells eventually formed blastocysts--hollow balls of cells that normally implant themselves in the uterus.

Producing a handful of blastocysts is a long way from producing live offspring, cautions cloning pioneer Ian Wilmut of the Roslin Institute outside Edinburgh, Scotland. If the Australian team had tried implanting the embryos, he says, past experience suggests that they would have been lucky to have any survive. "There could still be chromosome damage and breakage," he says, that would interrupt development at a later stage.

Science Volume 293, Number 5529, Issue of 20 July 2001

Post-it® Fax Note 7671	Date 8/28/01	# of pages ▶ 1
To Mike Dsida	From Mary Klaver	
Co./Dept.	Co. WRL	
Phone #	Phone # 414-778-5780	
Fax # 608-264-6948	Fax #	

NATIONAL INSTITUTES OF HEALTH
January 26, 1999

Office of the Director

Statement of
Harold Varmus, M.D.
Director, National Institutes of Health
Before the Senate Appropriations Subcommittee on
Labor, Health and Human Services, Education and Related Agencies

Mr. Chairman and Members of the Subcommittee:

I would like to thank you for the opportunity to discuss the recent decision by the Department of Health and Human Services concerning HHS funding for research utilizing human pluripotent stem cells. In testimony to this Subcommittee on December 2, 1998, I presented the exciting science of human pluripotent stem cells and described how the isolation of these cells could radically change the landscape of biomedical research. At that time, the NIH was awaiting a legal opinion from DHHS to determine whether or not the NIH could fund research utilizing these cells. The legal opinion is now available and states that research utilizing human pluripotent stem cells can be supported with Federal funds. What then are the next steps?

First, let me say that we understand and respect the different points of view that have been expressed about the important ethical and moral issues involved in this research. In developing the important safeguards that will govern funding for this research, NIH intends to consult with those representative of a broad range of views. We welcome the input of Congress as we move forward in this area.

Today, I would like to very briefly review some features of human pluripotent stem cells -- how they are derived and the promises they hold for medical research and practice. I will then describe the legal opinion and the plans for the development of guidelines and oversight that will be in place before NIH would fund research with these cells. We are committed to proceeding in a careful and deliberate manner that recognizes the ethical, societal, and scientific issues of this area of research.

I refer you to my previous testimony for a fuller description of the scientific aspects of this research. Stem cells are cells that have the ability to reproduce themselves and to give rise to other more specialized types of cells. Totipotent stem cells -- such as the product of fertilization of an ovum and its progeny -- are stem cells that have total potency, which means that they have the ability to form an entire mature organism, e.g., a human being, although only if placed in a woman's uterus. In contrast, human pluripotent stem cells, which are under discussion today, do not have total potency, and hence cannot form an entire organism under any known condition. But pluripotent stem cells can give rise to all of the different types of specialized cells in the body.

The methodologies for deriving human pluripotent stem cells are not really new; pluripotent stem cells have been derived from mice since the early 1980s and, since then, from non-human primates and other animals. The first reports of deriving human pluripotent stem cells were published in November 1998 by Dr. John Gearhart and Dr. James Thomson. Neither of these investigations were supported with DHHS funds, although Dr. Gearhart's work could have been supported with Federal funds, because he and his colleagues derived human pluripotent stem cells from primordial gonadal tissue which was taken from a non-living fetus. Federal laws and

regulations already exist that govern research on fetal tissue. Dr. Thomson and his co-workers derived pluripotent stem cells from the blastocyst stage of an early embryo--the embryos used were donated by couples who were receiving infertility treatment; this derivation of stem cells from the embryo does fall under the ban on Federal funding in the HHS/Labor/Education Appropriations Bill. The pluripotent stem cells derived by each of these means appear to be very similar or identical in structure, function, and potential; but it will take more research to verify this.

The isolation and culturing of human pluripotent stem cells opens certain avenues of research for the first time. Let me mention just three potential applications of human pluripotent stem cells. The first is research focused on how stem cells differentiate into specific types of cells. The goal is to identify the genetic and environmental signals that direct the specialization of a stem cell to develop into specific cell types. Studying normal cell and tissue development will provide an understanding of abnormal growth and development which, in turn, could lead to the discovery of new ways to prevent and treat birth defects and even cancer.

A second and more practical application of research using these cells is in pharmaceutical development. Use of human pluripotent stem cells could allow researchers to study the beneficial and toxic effects of candidate drugs in many different cell types and potentially reduce the numbers of animal studies and human clinical trials required for drug development.

The third and most obvious potential application of these human pluripotent stem cells is to direct the specialization of the cells into cells and tissues that could be transplanted into patients for the purpose of repairing injury and pathological processes. A number of such examples are described in my December testimony, but two are worth mentioning here.

(i) Transplantation of healthy heart muscle cells could provide new hope for patients with heart disease. The hope is to develop heart muscle cells from human pluripotent stem cells and then transplant them into the failing heart muscle in order to augment the function of the 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 integrate with the host cells. These experiments show that this type of transplantation is feasible.

(ii) In many individuals with Type I diabetes, the production of insulin in the pancreas by specialized cells called islet beta 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 this critical research and, ultimately, for transplantation.

Because human pluripotent stem cells continue to replicate robustly, stem cells derived from a few embryos or from a few fetuses could potentially be used in hundreds of individual research protocols.

Briefly, that is the science and the promise. We are here today to discuss the role of the Federal Government in the future of this area of research.

There are a number of advantages to using public funding for research. Perhaps the most important reason is the fact that Federal involvement creates a more open research environment -- with better exchange of ideas and data among scientists -- more public engagement and more

oversight. In addition, Federal support increases the fiscal resources and expands the pool of talented investigators -- particularly in academia -- both of which accelerate the tempo of scientific discovery.

In response to the recent announcements concerning the isolation of human pluripotent stem cells, I requested an opinion from DHHS on the legality of using DHHS funds to support or conduct research that utilizes these cells, in light of existing restrictions on human fetal tissue research and the amendment in our Appropriations bill governing human embryo research.

On January 15, 1999, DHHS delivered the following opinion. DHHS funds can be used to support research utilizing human pluripotent stem cells that are derived from human embryos: the statutory prohibition on human embryo research does not apply to research utilizing human pluripotent stem cells because human pluripotent stem cells are not embryos. The statute that bans the use of Federal funds for embryo research defines embryo as an organism derived by fertilization and other means. The statute does not, however, define organism. Therefore, the legal opinion relied on the broadly accepted science-based definition of organism: an individual constituted to carry out all life functions. By this definition -- and as you heard from all the witnesses that responded to that question at your hearing on this matter on December 2, 1999 -- pluripotent stem cells are not and cannot develop into organisms. Therefore, human pluripotent stem cells are not embryos and are not covered by this prohibition on Federal funding. In addition, the legal opinion states that DHHS funds can be used for research using human pluripotent stem cells that were derived from fetal tissue if the existing laws and regulations governing fetal tissue research are obeyed.

Now that the legal opinion has been rendered, what are the next steps? The approach will be careful and deliberative, recognizing the important ethical concerns that surround this area of research. I want to emphasize that NIH will not use Federal funds for research using human pluripotent stem cells until guidelines and procedures to oversee the research are developed. Let me describe the process that we have planned to ensure that any research involving human pluripotent stem cells is appropriately and carefully conducted. And as I mentioned earlier, we are interested in hearing a broad range of views.

First, all researchers currently receiving NIH support have been notified, via the NIH web site, that they cannot use DHHS funds to begin research using human pluripotent stem cells until further notice. We have made every effort to include this policy in all of our public statements. In addition, NIH program staff have been requested to notify those grantees who are most likely to have an interest in this work about this present policy. The Deputy Director for Intramural Research has also notified intramural scientists of these requirements.

Second, I will convene a subcommittee of the Advisory Committee to the Director (ACD) to develop Guidelines that specify what work using these cells can and cannot be supported with DHHS funds and outline restrictions on the use of such funds in the derivation of the cells. They will also be asked to develop an oversight mechanism to review research proposals seeking to conduct research utilizing these pluripotent stem cells. The subcommittee will meet in public session and will be composed of scientists, the lay public, ethicists, and lawyers; former members of the Human Embryo Research Panel may be asked to participate. They will be asked to consider advice from the National Bioethics Advisory Commission (NBAC), the newly established Council of Public Representatives (COPR), the public, and the Congress. NIH already has two thoughtful sets of Guidelines which will inform these efforts--the 1994 Report of the Human Embryo Research Panel and the regulations regarding Research on Transplantation of Fetal Tissue (section 498A of the Public Health Services Act). Once developed, Guidelines for research

utilizing human pluripotent stem cells will be published in the Federal Register for public comment. We hope the Guidelines and oversight process will be operational within the next several months.

In conclusion, the promise of human pluripotent stem cell research is great. And we are committed to addressing important issues surrounding this research in a deliberative and careful process to ensure that this research is conducted in an ethical, scientifically valid, and legal manner.

This concludes my statement. I would be pleased to respond to any questions you may have.

By West S.B. No. 1209
77R7256 JAT-F

A BILL TO BE ENTITLED
AN ACT

relating to the regulation of cloning of human beings; providing penalties.

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

SECTION 1. Chapter 161, Health and Safety Code, is amended by adding Subchapter Q to read as follows:

SUBCHAPTER Q. HUMAN CLONING

Sec. 161.401. DEFINITIONS. In this subchapter:

(1) "Human cloning" means the use of human somatic cell nuclear transfer technology to produce a human embryo.

(2) "Human embryo" means a human egg cell with a full genetic composition capable of differentiating and maturing into a complete human being.

(3) "Human somatic cell" means a cell of a developing or fully developed human being that is not and will not become a sperm or egg cell.

(4) "Human somatic cell nuclear transfer" means the transfer of the nucleus of a human somatic cell into an egg cell from which the nucleus has been removed or rendered inert.

Sec. 161.402. HUMAN CLONING PROHIBITED. (a) A person may not engage in or attempt to engage in human cloning.

(b) This subchapter does not restrict scientific research or a cell-based therapy unless the research or therapy is expressly prohibited by this subchapter.

Sec. 161.403. HEALTH FACILITIES. (a) A health facility may not permit a person to violate Section 161.402 in or on the premises of the facility.

(b) A health care facility that violates this section, in addition to the penalties provided by this subchapter, is subject to the same consequences that the facility would be subject to if the facility had violated the regulatory law applicable to the facility, including any applicable regulatory rules.

Sec. 161.404. CIVIL PENALTY. (a) A person that violates this subchapter is liable for a civil penalty of not more than $10 million for each violation.

(b) The attorney general may sue to collect the penalty.

Sec. 161.405. CRIMINAL OFFENSE. (a) A person commits an offense if the person intentionally engages in human cloning.

(b) An offense under this section is a felony of the second degree.

SECTION 2. This Act takes effect September 1, 2001.

Dsida, Michael

From: Dsida, Michael
Sent: Tuesday, August 28, 2001 12:58 PM
To: Boycks, Brad
Subject: Use of stem cells

According to David Prentice, an expert whom Mary Klaver has consulted, stem cells may be inserted into a blastocyst (see http://www.advancedfertility.com/revblast.htm for a definition) from which the inner cell mass has been removed. That blastocyst can then develop into a born individual. How (if at all) do you want to treat embryos that are created that way?

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

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Thursday, August 30, 2001 5:33 PM
To: Dsida, Michael; Boycks, Brad
Cc: Rep.Freese; Sue Armacost; Philip Barber
Subject: Stem cells

Mike,

I dropped in for a few minutes in my office and found the e-mail you sent to Brad Boycks regarding embryos created by inserting stem cells into a blastocyst from which the inner cell mass has been removed. Good question!

These embryos should be protected. In fact, they are already protected in the draft by the definition of human embryo provided to you because all of these cells are diploid cells and the definition covers a human embryo "who is derived by . . . any other means from one or more . . . human diploid cells."

If you have any further questions, I will be back in the office on Wednesday, September 5.

Mary Klaver
Legislative Legal Counsel

Dsida, Michael

From: Dsida, Michael
Sent: Thursday, August 30, 2001 11:33 AM
To: 'mklaver@wrtl.org'
Subject: LRB-2888

The prohibitions in the first draft of this bill did not apply if the embryo had ever been located in a woman's body. While I understand your interest in covering "embryo flushing," you should be aware that eliminating the exception for embryos that were in utero makes the bill more susceptible to a constitutional challenge.

Based on what I have learned from my limited research, mifeprestone/RU-486 can result in the embryo being born alive. Apparently, the likelihood of that occurring is extremely small. But physicians prescribing mifeprestone/RU-486 would likely be aware of that remote possibility, and presumably, in prescribing the drug, they would intend that the miscarriage cause the death of any embryo born alive. A court might view the possibility of criminal liability in such a case as an unconstitutional burden on a woman's right to use mifeprestone/RU-486 under Casey. Although saline injections are relatively rare, see Centers for Disease Control and Prevention, Abortion Surveillance -- United States, 1997, p. 43 (December 8, 2000), (http://www.cdc.gov/nccdphp/drh/pdf/mmwr_ss/ss4911.pdf), the bill would be subject to the same constitutional problem with respect to them.

One way to lessen the risk of these provisions being held unconstitutional on this ground would be to include a cross-reference to s. 940.17 in s. 939.75.

5

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

Mary —
Include non-applicability provision
re s. 940.17 akin to 939.75
but only to procedures
while emb is in woman's body

From: Dsida, Michael
Sent: Thursday, August 30, 2001 4:03 PM
To: 'mklaver@wrtl.org'
Subject: Cloning definition

In view of the report from Science magazine and David Prentice's comments, your definition of cloning is problematic in two respects. First, if a human being can be produced by using somatic cells from two different people and an egg, the resulting organism will not be genetically identical to either of the somatic cell donors. Second, although Prentice does not say as much, it may be possible to use the approach he describes to a create human being by using an egg that has had its genetic material deactivated and the nuclear material from two other gametes (as opposed to somatic cells).

Addressing the former case is easy. It would just require deleting the reference to the organisms being genetically identical. Addressing the former case may be a bit more challenging, but it can probably be done too.

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

9/4/01
Mary — Cloning (to be) covered by cloning prohibition only if it results in a genetically identical human.

Dsida, Michael

From: Richard, Rob
Sent: Thursday, September 06, 2001 10:36 AM
To: Dsida, Michael
Subject: RE: Embryo/cloning bill

I understand. I still think the answer is "yes". I'm going to have to get my Ph.D in biology and chemistry before this is all over.

-----Original Message-----
From: Dsida, Michael
Sent: Thursday, September 06, 2001 10:21 AM
To: Richard, Rob
Subject: RE: Embryo/cloning bill

Just to clarify -- I was not asking about whether to treat the single-cell embryo generally as an embryo. The bill already does that. I was more concerned about whether to include a provision to cover the situation described below, in view of the unlikelihood (but not the impossibility) of it occurring.

-----Original Message-----
From: Richard, Rob
Sent: Thursday, September 06, 2001 10:16 AM
To: Dsida, Michael
Cc: Boycks, Brad; Sen.Welch
Subject: RE: Embryo/cloning bill

Mike:

I would say "yes". I think that Steve and Bob both believe that life begins once the egg is fertilized, no matter how many cells are involved.

But before you include it, please get confirmation from Welch's office. Brad, what do you think?

Rob

-----Original Message-----
From: Dsida, Michael
Sent: Wednesday, September 05, 2001 5:31 PM
To: Richard, Rob
Subject: RE: Embryo/cloning bill

The bill may not need to address this scenario because, as far as I know, IVF clinics have fertilized egg cells divide several times before freezing the embryo. But in reviewing my revisions to the P1 draft, I realized that the bill does not cover the use of a single cell embryo to develop specialized cells if the embryo was originally created by an IVF clinic for potential implantation. (The development of the single cell into a specialized cell would probably not be construed as "injury" or "death.") Should the bill cover that scenario?

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

State of Wisconsin
2001 – 2002 LEGISLATURE

LRB–2888/P2
MGD:jld:pg

9/10 MONDAY 10:00 am.

D-Note

&GMM

PRELIMINARY DRAFT – NOT READY FOR INTRODUCTION

) requesting the joint legislative council to conduct a study on how to reduce the number of in vitro human embryos that are created by fertility clinics ~~a reasonable number needed for reproductive purposes~~ and how to facilitate the adoption of those ~~not~~ in vitro human embryos that are not used by their female donors,

Regen

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:

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.~~

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

(a) "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~~ and that has not reached the stage of development at which the major body structures are present.

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

(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~~ destroyed 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 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~~ 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) ~~(a)~~ 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.~~

Insert 4-2A ✓

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)

MD Insert 4/2B ✓

D-note ↓

LPS - INSERTS OUT OF ORDER

INSERT 2/22

(6) Subsections (2) to (5) do not apply if the death of the in vitro human embryo or the substantial risk of injury to or death of the in vitro human embryo results from the cryopreservation of the in vitro human embryo and the cryopreservation was undertaken with due care and in accordance with generally accepted medical procedures.

(7) Whoever intentionally causes a fully undifferentiated cell of an in vitro human embryo to develop into a more specialized cell in a way that precludes the in vitro human embryo's development into a born individual is guilty of a Class E felony.

(8) Whoever, with the knowledge that another person will intentionally cause a fully undifferentiated cell of the in vitro human embryo to develop into a more specialized cell in a way that precludes the in vitro human embryo's development into a born individual, purchases or sells an in vitro human embryo or transfers an in vitro human embryo to any person is guilty of a Class E felony.

INSERT 2/23

NO creates an in vitro human embryo outside of a woman's body, including through the removal of one or more cells from an existing in vitro human embryo, NO

INSERT 3/5

NO This subsection does not apply if a person transfers or acquires an in vitro human embryo for the purpose of having it implanted in a woman's uterus.

INSERT 4/2 B

SECTION 1. Initial applicability.

(1) The treatment of section 940.17 (8) of the statutes first applies to a transfer or an acquisition of a living cell or tissue occurring on the effective date of this subsection, even if the conduct that is described under section 940.17 (2), (4), (7), or (9) of the statutes and through which the cell or tissue was obtained occurred before the effective date of this subsection.

(end ins 4-2B)

Insert 4-2A

nonstat (#) The joint legislative council (shall) is requested to conduct a study on how to reduce the number of in vitro human embryos (by infertility clinics) that are created to a reasonable number needed for reproductive purposes and how to facilitate the ~~uterine implantation~~ (adoption) of those in vitro human embryos that are not used by their female donors (and their uterine implantation) in women other than the female donors. If the joint legislative council conducts the study, it shall report its findings, conclusions, and recommendations to the legislature in the manner provided under section 13.172 (2) of the statutes by January 1, 2003.

(end of insert 4-2A)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB–2888/P2dn
MGD:...:...
JLd

Rob:

This bill is based on the instructions that Rep. Freese and Sen. Welch provided at our meeting last month and additional instructions that you and Mary Klaver have provided. It does not yet contain the cloning prohibitions. In addition, please note the following:

1. Section 940.17 (6) contains language that would exempt cryopreservation from the prohibitions in s. 940.17 (2) to (5). We did not discuss how the bill should cover a living embryo that is no longer a viable candidate for implantation, either because of problems in its early development or (in the case of a thawed embryo) because of harm that resulted from cryopreservation. If the clinic freezes or refreezes the embryo, the language that I added will exempt them from liability if the embryo suffers additional harm or dies as a result. But the bill does not authorize the clinic to do anything else that might cause the death of that damaged embryo. Is that okay? **(If you want to take a different approach, I may need to revise the "described under" language in sub. (7), since that language may include cryopreservation.)**

Note that, as a practical matter, because of the time and costs involved with thawing and refreezing, this approach may require clinics to maintain unused embryos in a cryopreserved state indefinitely, including embryos that are not viable.

2. Based on what I have learned in limited research, mifepristone/RU–486 can result in an embryo being born alive. Apparently, the likelihood of that occurring is extremely small. But some physicians prescribing mifepristone/RU–486 would likely be aware of that remote possibility, and presumably, in prescribing the drug, they would intend that the miscarriage cause the death of any embryo born alive. A court might view the possibility of criminal liability in such a case as an unconstitutional burden on a woman's right to use mifepristone/RU–486 under *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992). Although saline injections are relatively rare, *see* Centers for Disease Control and Prevention, Abortion Surveillance — United States, 1997, p. 43 (December 8, 2000), (http://www.cdc.gov/nccdphp/drh/pdf/mmwr_ss/ss4911.pdf), the bill would be subject to the same constitutional problem with respect to them. I suggested to Mary Klaver that the bill include a cross–reference in s. 939.75 so that the bill does not apply to abortion procedures or the prescription or use of contraceptives. She suggested another alternative, which I think is problematic. In the interest of getting this to you more quickly, rather than try to

develop language that Mary supports and that works, I decided to wait until the next redraft to include a provision to address this problem.

3. Based on instructions that I received from Mary Klaver, the bill no longer would prohibit the possession of stem cells or tissue derived from them. In view of that, the bill does not have a delayed effective date. Please let me know if you want me to include one.

4. In lieu of characterizing the separation of an embryo into separate living cells as "causing the death of the embryo," the bill treats the separation as creating an in vitro human embryo, which is prohibited under sub. (7) if done for the purpose of stem cell research. This made sense conceptually and made the bill simpler than it would have been if we defined "death."

5. The addition of "into a born individual" at the end of the definition of "nontherapeutic human embryo research" is intended to ensure that the definition does not include the development of embryonic cells into specialized cells.

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

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB–2888/P2dn
MGD:jld:kjf

September 7, 2001

Rob:

This bill is based on the instructions that Rep. Freese and Sen. Welch provided at our meeting last month and additional instructions that you and Mary Klaver have provided. It does not yet contain the cloning prohibitions. In addition, please note the following:

1. Section 940.17 (6) contains language that would exempt cryopreservation from the prohibitions in s. 940.17 (2) to (5). We did not discuss how the bill should cover a living embryo that is no longer a viable candidate for implantation, either because of problems in its early development or (in the case of a thawed embryo) because of harm that resulted from cryopreservation. If the clinic freezes or refreezes the embryo, the language that I added will exempt them from liability if the embryo suffers additional harm or dies as a result. But the bill does not authorize the clinic to do anything else that might cause the death of that damaged embryo. Is that okay? **(If you want to take a different approach, I may need to revise the "described under" language in sub. (7), since that language may include cryopreservation.)** Note that, as a practical matter, because of the time and costs involved with thawing and refreezing, this approach may require clinics to maintain unused embryos in a cryopreserved state indefinitely, including embryos that are not viable.

2. Based on what I have learned in limited research, mifepristone/RU–486 can result in an embryo being born alive. Apparently, the likelihood of that occurring is extremely small. But some physicians prescribing mifepristone/RU–486 would likely be aware of that remote possibility, and presumably, in prescribing the drug, they would intend that the miscarriage cause the death of any embryo born alive. A court might view the possibility of criminal liability in such a case as an unconstitutional burden on a woman's right to use mifepristone/RU–486 under *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992). Although saline injections are relatively rare, *see* Centers for Disease Control and Prevention, Abortion Surveillance — United States, 1997, p. 43 (December 8, 2000), (http://www.cdc.gov/nccdphp/drh/pdf/mmwr_ss/ss4911.pdf), the bill would be subject to the same constitutional problem with respect to them. I suggested to Mary Klaver that the bill include a cross–reference in s. 939.75 so that the bill does not apply to abortion procedures or the prescription or use of contraceptives. She suggested another alternative, which I think is problematic. In the interest of getting this to you more quickly, rather than try to

develop language that Mary supports and that works, I decided to wait until the next redraft to include a provision to address this problem.

3. Based on instructions that I received from Mary Klaver, the bill no longer would prohibit the possession of stem cells or tissue derived from them. In view of that, the bill does not have a delayed effective date. Please let me know if you want me to include one.

4. In lieu of characterizing the separation of an embryo into separate living cells as "causing the death of the embryo," the bill treats the separation as creating an in vitro human embryo, which is prohibited under sub. (7) if done for the purpose of stem cell research. This made sense conceptually and made the bill simpler than it would have been if we defined "death."

5. The addition of "into a born individual" at the end of the definition of "nontherapeutic human embryo research" is intended to ensure that the definition does not include the development of embryonic cells into specialized cells.

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

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB–2888/P2dn
MGD:jld:kjf

September 7, 2001

Rob:

This bill is based on the instructions that Rep. Freese and Sen. Welch provided at our meeting last month and additional instructions that you and Mary Klaver have provided. It does not yet contain the cloning prohibitions. In addition, please note the following:

1. Section 940.17 (6) contains language that would exempt cryopreservation from the prohibitions in s. 940.17 (2) to (5). We did not discuss how the bill should cover a living embryo that is no longer a viable candidate for implantation, either because of problems in its early development or (in the case of a thawed embryo) because of harm that resulted from cryopreservation. If the clinic freezes or refreezes the embryo, the language that I added will exempt them from liability if the embryo suffers additional harm or dies as a result. But the bill does not authorize the clinic to do anything else that might cause the death of that damaged embryo. Is that okay? (If you want to take a different approach, I may need to revise the "described under" language in sub. (7), since that language may include cryopreservation.) Note that, as a practical matter, because of the time and costs involved with thawing and refreezing, this approach may require clinics to maintain unused embryos in a cryopreserved state indefinitely, including embryos that are not viable.

2. Based on what I have learned in limited research, mifepristone/RU–486 can result in an embryo being born alive. Apparently, the likelihood of that occurring is extremely small. But some physicians prescribing mifepristone/RU–486 would likely be aware of that remote possibility, and presumably, in prescribing the drug, they would intend that the miscarriage cause the death of any embryo born alive. A court might view the possibility of criminal liability in such a case as an unconstitutional burden on a woman's right to use mifepristone/RU–486 under *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992). Although saline injections are relatively rare, *see* Centers for Disease Control and Prevention, Abortion Surveillance — United States, 1997, p. 43 (December 8, 2000), (http://www.cdc.gov/nccdphp/drh/pdf/mmwr_ss/ss4911.pdf), the bill would be subject to the same constitutional problem with respect to them. I suggested to Mary Klaver that the bill include a cross–reference in s. 939.75 so that the bill does not apply to abortion procedures or the prescription or use of contraceptives. She suggested another alternative, which I think is problematic. In the interest of getting this to you more quickly, rather than try to

develop language that Mary supports and that works, I decided to wait until the next redraft to include a provision to address this problem.

3. Based on instructions that I received from Mary Klaver, the bill no longer would prohibit the possession of stem cells or tissue derived from them. In view of that, the bill does not have a delayed effective date. Please let me know if you want me to include one.

4. In lieu of characterizing the separation of an embryo into separate living cells as "causing the death of the embryo," the bill treats the separation as creating an in vitro human embryo, which is prohibited under sub. (7) if done for the purpose of stem cell research. This made sense conceptually and made the bill simpler than it would have been if we defined "death."

5. The addition of "into a born individual" at the end of the definition of "nontherapeutic human embryo research" is intended to ensure that the definition does not include the development of embryonic cells into specialized cells.

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

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

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

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.

Calendar No. 140

107TH CONGRESS
1ST SESSION

H. R. 2505

IN THE SENATE OF THE UNITED STATES

AUGUST 1, 2001
Received

AUGUST 2, 2001
Read the first time

AUGUST 3, 2001
Read the second time and placed on the calendar

AN ACT

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

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

SECTION 1. SHORT TITLE.

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

SEC. 2. PROHIBITION ON HUMAN CLONING.

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

"CHAPTER 16—HUMAN CLONING

"§ 301. Definitions

"In this chapter:

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

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

"(3) SOMATIC CELL.—The term 'somatic cell' means a diploid cell (having a complete set of chro-

mosomes) obtained or derived from a living or deceased human body at any stage of development.

"§ 302. Prohibition on human cloning

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

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

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

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

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

"(c) PENALTIES.—

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

"(2) CIVIL PENALTY.—Any person or entity that violates any provision of this section shall be subject to, in the case of a violation that involves the derivation of a pecuniary gain, a civil penalty of not

less than $1,000,000 and not more than an amount equal to the amount of the gross gain multiplied by 2, if that amount is greater than $1,000,000.

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

(b) CLERICAL AMENDMENT.—The table of chapters for part I of title 18, United States Code, is amended by inserting after the item relating to chapter 15 the following:

SEC. 3. STUDY BY GENERAL ACCOUNTING OFFICE.

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

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

and potential legal implications of research in somatic cell nuclear transfer; and

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

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

Passed the House of Representatives July 31, 2001.

Attest: JEFF TRANDAHL,

Clerk.

General Counsel – NIH
- 301 496 - 4000
- 4108

PK6Z@NIH.GOV
Patricia Kvochak

Sent e-mail 8/16

P/c from Mary Klaver –

~~XXXX~~.

Do not want it to be a crime to possess stem cells

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Thursday, September 06, 2001 3:34 PM
To: Dsida, Michael
Cc: Sen.Welch; Rep.Freese; Sue Armacost; Philip Barber
Subject: Re: Abortion exception

Mike,

On further reflection, I believe the "intentional" requirement will answer this. Even in the infertility clinic setting or a research lab, the bill would not, and is not intended to, apply to accidents or even to reckless conduct. Unless the intentional requirement would cover acts of omission, then I think the abortion exemption will work. Let me know your thoughts.

Mary

"Dsida, Michael" wrote:

> I am not sure that your suggestion will work. Limiting the exemption to
> acts undertaken while the embryo is in a woman's body might still leave the
> physician (and possibly the mother?) liable for causing the death of the
> embryo if the embryo is still alive after being expelled or extracted. (I
> am assuming that the physician does not take any steps to preserve the life
> of the embryo at that point.) Even if the possibility of the embryo being
> alive after being expelled or extracted is very remote, and even if the
> possibility of prosecution is remote, those possibilities may be enough to
> render unconstitutional the prohibition on causing the death of the embryo
> outside of a woman's body.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Richard, Rob
Sent: Friday, September 21, 2001 3:17 PM
To: Dsida, Michael
Cc: Boycks, Brad; 'mklaver@wrtl.org'

Mike:

In review of LRB-2888/P2dn, please refer to Mary Klaver for answers to these questions. Steve and Bob note your concerns and questions, but they'd also like to see how the language would read as Mary suggest. On point #3, I don't believe we need a delayed effective date.

As was discussed in the meeting in Freese's office, we'd like to keep to what was suggested for each main point on the first draft. Mary, if you have additions, especially in regards to definitions, please suggest them to Mike, but I don't believe that Steve and Bob want to deviate far from the main points originally agreed upon in the meeting.

Mike, I ask that you please work with Mary and use her definitions. Also, please note all the concerns you may have with those suggestions on the drafter's note.

Brad, please keep me and Mary informed of any concerns that Bob may have.

If anyone has any questions, please e-mail or call me at 266-7502. Thank you!

Rob Richard
Freese Office

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~~ a human 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:

Ignore 4. for now

"Any person who proposes to provide a medical treatment o patient using any cell or tissue that the person knows was obtained described under s. 940.17 (2), (4), or (6) shall inform the patient, or ... 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.

DRAFTER'S NOTE FROM THE LEGISLATIVE REFERENCE BUREAU

LRB-2888/P2dn
MGD:jld:kjf

September 7, 2001

Rob:

This bill is based on the instructions that Rep. Freese and Sen. Welch provided at our meeting last month and additional instructions that you and Mary Klaver have provided. It does not yet contain the cloning prohibitions. In addition, please note the following:

1. Section 940.17 (6) contains language that would exempt cryopreservation from the prohibitions in s. 940.17 (2) to (5). We did not discuss how the bill should cover a living embryo that is no longer a viable candidate for implantation, either because of problems in its early development or (in the case of a thawed embryo) because of harm that resulted from cryopreservation. If the clinic freezes or refreezes the embryo, the language that I added will exempt them from liability if the embryo suffers additional harm or dies as a result. But the bill does not auth~~orize the clinic~~ to do ~~anything else~~ that might cause the death of that damaged embryo. Is that okay? ~~(If you want to take a different approach, I may need to revise the "described under"~~ language in ~~sub. (7), since that language may include cryopreservation.)~~ Note that, as a practical matter, because of the time and costs involved with thawing and refreezing, this approach may require clinics to maintain unused embryos in a cryopreserved state indefinitely, including embryos that are not viable. yes

2. Based on what I have learned in limited research, mifepristone/RU-486 can result in an embryo being born alive. Apparently, the likelihood of that occurring is extremely small. But some physicians prescribing mifepristone/RU-486 would likely be aware of that remote possibility, and presumably, in prescribing the drug, they would intend that the miscarriage cause the death of any embryo born alive. A court might view the possibility of criminal liability in such a case as an unconstitutional burden on a woman's right to use mifepristone/RU-486 under *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833 (1992). Although saline injections are relatively rare, *see* Centers for Disease Control and Prevention, Abortion Surveillance — United States, 1997, p. 43 (December 8, 2000), (http://www.cdc.gov/nccdphp/drh/pdf/mmwr_ss/ss4911.pdf), the bill would be subject to the same constitutional problem with respect to them. I suggested to Mary Klaver that the bill include a cross-reference in s. 939.75 so that the bill does not apply to abortion procedures or the prescription or use of contraceptives. She suggested another alternative, which I think is problematic. In the interest of getting this to you more quickly, rather than try to

Can use language of 939.75(2)(b) 1 [1st sentence] + 4 cross reference would be

develop language that Mary supports and that works, I decided to wait until the next redraft to include a provision to address this problem.

3. Based on instructions that I received from Mary Klaver, the bill no longer would prohibit the possession of stem cells or tissue derived from them. In view of that, the bill does not have a delayed effective date. Please let me know if you want me to include one.

4. In lieu of characterizing the separation of an embryo into separate living cells as "causing the death of the embryo," the bill treats the separation as creating an in vitro human embryo, which is prohibited under sub. (7) if done for the purpose of stem cell research. This made sense conceptually and made the bill simpler than it would have been if we defined "death."

5. The addition of "into a born individual" at the end of the definition of "nontherapeutic human embryo research" is intended to ensure that the definition does not include the development of embryonic cells into specialized cells.

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

State of Wisconsin
2001 – 2002 LEGISLATURE

LRB-2989/P2
MGD&GMM:jld:kjf

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, use of cells derived from an in vitro human embryo, requesting the joint legislative council to conduct a study on how to reduce the number of in vitro human embryos that are created by fertility clinics and how to facilitate the adoption of those in vitro human embryos that are not used by their female donors, 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:

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:

The focus of this legislation is to protect human embryos

use is RL def as modified

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

please wants 3 yrs

1. A single-cell human organism that is living outside of a woman's body.

2. A multicell human organism that is living outside of a woman's body and that has not reached the stage of development at which the major body structures are present.

(b) "Nontherapeutic human embryo research" means subjecting an in vitro human embryo to conditions or procedures that are not intended to help promote its development into a born individual.

too narrow - would allow person to do anything as long as embryo allowed to be born - does not address protecting health

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

consistency?

(3) Whoever, with the knowledge that the in vitro human embryo will intentionally be destroyed, purchases or sells an in vitro human embryo or transfers an in vitro human embryo to another person is guilty of a Class E felony.

killed?

(4) Whoever intentionally subjects an in vitro human embryo to a substantial risk of injury or death while engaging in nontherapeutic human embryo research is guilty of a Class E felony.

time frame is not correct

(5) Whoever, with the knowledge that the in vitro human embryo will intentionally be subjected to a substantial risk of injury or death during nontherapeutic human embryo research, purchases or sells an in vitro human embryo or transfers an in vitro human embryo to another person is guilty of a Class E felony.

time frame is not correct

unclear provision

(6) Subsections (2) to (5) do not apply if the death of the in vitro human embryo or the substantial risk of injury to or death of the in vitro human embryo results from the cryopreservation of the in vitro human embryo and the cryopreservation was

how can we prove this?

does not cover thawing
exemption is for acts of freezing + thawing, not the results

undertaken with due care and in accordance with generally accepted medical procedures.

(7) Whoever intentionally causes a fully undifferentiated cell of an in vitro human embryo to develop into a more specialized cell in a way that precludes the in vitro human embryo's development into a born individual is guilty of a Class E felony.

(8) Whoever, with the knowledge that another person will intentionally cause a fully undifferentiated cell of the in vitro human embryo to develop into a more specialized cell in a way that precludes the in vitro human embryo's development into a born individual, purchases or sells an in vitro human embryo or transfers an in vitro human embryo to any person is guilty of a Class E felony.

(9) Whoever creates an in vitro human embryo outside of a woman's body, including through the removal of one or more cells from an existing in vitro human embryo, for the purpose of undertaking nontherapeutic human embryo research is guilty of a Class E felony.

(10) Whoever transfers or acquires any living cell or tissue that the actor knows was obtained through conduct that is described under sub. (2), (4), (7), or (9) is guilty of a Class E felony. This subsection does not apply if a person transfers or acquires an in vitro human embryo for the purpose of having it implanted in a woman's uterus.

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) (a) of the statutes.

omitted provision requiring parents to be informed of the adoption option & provision re mechanism to release embryos for adoption

(2) The joint legislative council is requested to conduct a study on how to reduce the number of in vitro human embryos that/who are created by infertility clinics to a reasonable number needed for reproductive purposes and how to facilitate the adoption of those in vitro human embryos that/who are not used by their female donors/genetic parents and their uterine implantation in women other than the female donors. If the joint legislative council conducts the study, it shall report its findings, conclusions, and recommendations to the legislature in the manner provided under section 13.172 (2) of the statutes by January 1, 2003.

SECTION 3. Initial applicability.

(1) The treatment of section 940.17 (8) of the statutes first applies to a transfer or an acquisition of a living cell or tissue occurring on the effective date of this subsection, even if the conduct that is described under section 940.17 (2), (4), (7), or (9) of the statutes and through which the cell or tissue was obtained occurred before the effective date of this subsection.

(END)

Omitted severability provision

Omitted informed consent provision (at end of WRL draft) re use of cells or tissues obtained by prohibited activities

Plc from Mary Klaven

Wants def'n of "human embryo" (as opposed to in vitro human embryo) so that it can be used in future bills

- Wants it to include human

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Friday, September 28, 2001 3:21 PM
To: Dsida, Michael
Subject: Re: Embryo bill -- impairment of contracts and non-statutory provision

Mike,

Point #1: I think a statement of legislative findings would be very helpful. We have done that in s. 48.375 and s. 253.10. I did not know it could be done for a criminal statute. Since you are reluctant to have a legislative intent statement as well, I have added a policy statement and a construction statement. This was done for s. 20.927 which I just faxed to you. Here goes:

"(1) Legislative findings, policy declaration and construction of act. (a) The legislature finds that:
1. There are no laws in this state regulating the procedures used at an infertility clinic that provides infertility treatments for an infertile couple or other couples using the clinic's services.
2. The procedures used at an infertility clinic in this state are governed by a private contract between the clinic and the couple using the clinic's services.
3. It is quite common for an infertility clinic to create more human embryos than the number needed to reasonably meet the reproductive purposes of the couples using its services.
4. The private contract usually contains a provision regarding the disposition of human embryos who are not used by the couple. Often this provision permits the couple to choose to have their unused human embryos destroyed or donated for research.
5. It is also possible for the couple to choose to have their unused human embryos donated to another couple for implantation into the woman's uterus for the purpose of having a child. This option is often part of the private contract.
6. A substantial number of citizens have objections to the destruction of unused human embryos or the use of these embryos for nontherapeutic research which subjects them to a substantial risk of injury or death.
7. The donation of unused human embryos for adoption by another couple is a positive, life affirming alternative to having the embryos destroyed or donated for research.
(b) Policy declaration. It is declared to be the public policy of this state that living human embryos who are outside a woman's body should be protected from intentional destruction and harmful research. The legislature reaffirms the positive value of human life at all stages of development and promotes the adoption of unused human embryos. A human embryo is a human being at an early stage of development, not an item of property.
(c) Construction of act. The following statutory provisions shall be broadly construed to effect the objectives set forth in this section." [Can this be a statutory provision?]

Once the part of the bill on banning cloning is added, we may want to consider adding a few more findings to support that part of the bill.

Point #2: On initial applicability, I do not understand why we would not want the whole bill to apply upon enactment.

Is there any real harm to adding the "null and void" provision? If the concern is that it will just be ignored, then I do not see any harm in including it. We could also consider using a provision like s. 895.037 (3) (e), which deals with civil remedies for violation of the parental consent law, and states: "A contract is not a defense to an action under this subsection."

The issue concerning who has "control" of the embryos is quite complex and may best be addressed in the legislative council study. Our ultimate goal, in a custody dispute, would be to have a best interests of the embryo analysis used (similar to a child custody dispute in a divorce case). We strenuously object to human embryos being treated as property.

Point #3: Sorry for the confusion. The provision regarding contracts should not be in the legislative council provision.

Now I will turn my attention to your other e-mail.

Mary

"Dsida, Michael" wrote:

> 1. You may want to consider including a statement of legislative findings to support whatever claim you might ultimately need to make that the prohibition on causing the death of an embryo does not unconstitutionally impair contracts. See, e.g., State ex rel. Thomson v. Giessel, 265 Wis. 558 (1953); Overlook Farms v. Alternative Living, 143 Wis. 2d 485, 497-499 (Ct. App. 1988). 2. In order to accomplish your objective with respect to extant contracts, I will include one or more initial applicability provisions (e.g., "The treatment of section 940.17 (2) first applies to offenses committed on the effective date [of the bill]"), in lieu of the provision that you suggested stating that contractual provisions that conflict with the prohibitions in s. 940.17 are void. If a court needs to decide whether parties may enforce a provision calling for the destruction of embryos, the court will first determine (by looking at the initial applicability provision) that the legislature intended for the provision to apply to extant contracts. It will then decide whether the statute unconstitutionally impairs the parties' contract. When it does so, a provision of the type that you propose will not have any bearing on the court's determination. A statement of legislative findings will be far more relevant. Then, if the court determines that the prohibition is constitutional in that context, it will need to consider whether that contractual provision is severable, a question that goes to the intent of the parties, seegenerallyDavies v. J.D. Wilson Co., 1 Wis. 2d 443, 474-77 (1957), not the intent of the legislature. If the court gets that far and determines that the contractual provision would be severable, nothing in the bill addresses what happens to those embryos. Is it your intent that control over the embryo's fate would revert to the woman and man from whose gametes the embryos were derived? Should the bill include such a provision? 3. I had already asked Gordon not to include the provision regarding contracts in the nonstatutory provision. But since you didn't put an "X" by that provision in your last fax, it wasn't clear what you wanted to do with it.
>
> -----Original Message-----
> **From:** Mary Klaver [mailto:mklaver@wrtl.org]
> **Sent:** Thursday, September 27, 2001 5:34 PM
> **To:** Dsida, Michael
> **Subject:** Re: Embryo bill -- impairment of contracts and non-statutory provision
>
> Mike,
>
> Point #1: Yes. Freese wants to impair existing contracts. It is only necessary to void the objectionable provision, e.g., a provision allowing the embryos to be destroyed or donated for research. You may have forgotten that I told you a few weeks ago that I had mistakenly put the "null and void" provision in the part relating to the legislative council provision. It should be part of s. 940.17.
>
> Point # 2: The most recent case is Forbes v. Napolitano. All I have is the slip opinion. It is from the U.S. Court of Appeals for the 9th Circuit, Case No. 99-17372,

filed 12/29/00. It lists prior leading cases and there is a list of statutes in a footnote to Judge Sneed's concurring opinion.

I will respond to the other e-mail tomorrow. I need to leave now.

Mary

"Dsida, Michael" wrote:

1. Your notes on my draft indicate that you want a provision in s. 940.17

stating that contracts made in violation of that section are null and void. Is it your intent to cover contracts in effect on the bill's effective date? Also, why do you need sub. (2) (b) 4. of your nonstatutory provisions? And
is it your intent to have only the objectionable provision voided? Or do you want the entire contract voided?

2. Do you have cites for any of the cases that you mentioned in your e-mail
regarding the definition of research?

Those are the only other questions that I will have today.

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

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Friday, September 28, 2001 5:32 PM
To: Dsida, Michael
Subject: Re: Embryo bill

Mike,

Point #1: The purpose of the nonapplicability provision is very narrow. It is to prevent the mere act of freezing or thawing a human embryo for the purpose of implanting the embryo into a woman's uterus from being a criminal act. You are correct that this provision should not apply to the entire section. I believe it definitely applies to sub. (2) and may apply to sub. (3) since embryos can be transferred from one location to another for implantation purposes. Since sub. (4) and (5) are related to nontherapeutic research, which by definition is not for the embryo's benefit, then the nonapplicability provision would not make sense there. If I am missing something about sub. (4) and (5), let me know.

We would like a higher standard than "due care". We considered "all reasonable means" which would be an objective test and appears to be a higher standard than due care. The phrase "all available means" may lead to releasing the embryo for implantation at some point in time, but that is a good result if that is the only way to save the embryo or give the embryo the best chance to survive. I disagree that this would make the provision meaningless. If there are indeed limits to how long an embryo should remain frozen, then freezing and thawing can still take place within those limits.

I do not understand how the parents could be liable. Please explain.

Point #2. Good point. As long as the embryo is going to be implanted, then the exception would apply.

Point #3. I talked with Dr. Prentice and he said that theoretically a single cell embryo could be manipulated into a more specialized cell. The reverse is also possible -- specialized cells can be combined to create an embryo. I am thinking that sub. (7) is just another way someone could violate sub. (1), in which case it is not needed. What you are talking about here is a totipotent cell and that is what an embryo is. If you feel this covers something that sub. (1) would not cover, then let me know.

If we do use this provision, then we should probably use the term "totipotent
cell". A good definition of totipotent can be found in the Online Medical
Dictionary at
http://www.graylab.ac.uk/cgi-bin/omd?query=totipotent&action=Search+OMD

Point # 4: The purpose of our sub. (9) is to clarify that this statute does not
criminalize ethical infertility treatments. It is similar to s. 939.75 in that
respect. Maybe the other nonapplicability provision and this one could be
combined. It is very important to have sub. (9) for political reasons.

I read the second sentence of your sub. (10) to have the same purpose as our
sub. (9), i.e., to not criminalize infertility treatments. However, it seems out
of place in a provision that is addressing cells or tissues derived by killing
embryos, etc. Maybe I am misinterpreting this provision. Please clarify.

Please use our sub. (9).

Point #5: I understand there is no need for a separate severability provision.
I was merely repeating what Rep. Freese wanted. I suggest you explain why it is
not necessary in a drafter's note.

Point #6: The informed consent provision is definitely needed in Freeze's bill
as well as Welch's. There are many people who would refuse a medical treatment
if they knew it was using any cell or tissue obtained by killing a human
embryo. They have a right to know and to consider this as part of the informed
consent process. UW is forging ahead with its research and there may be such
treatments available before this legislation can be enacted.

Got to go. I will be back in the office on Thursday, 10/4. Sorry, but I will be
unreachable until then. (It is my 25th anniversary, you know, and we have no
intention of having a phone with us at our cottage.)

Good luck. I am looking forward to being able to review the completed draft when
I get back.

Mary

"Dsida, Michael" wrote:

> 1. I recognize that under the nonapplicability provision that I drafted (my
> sub. (6)), it may be difficult to prove causation. I do not believe that
> that is reason enough not to use it. But in an effort to use as much of
> your suggested language as possible, I have looked closely at the
> nonapplicability provision in your draft (your sub. (8)). That provision,
> however, probably would not accomplish your stated purposes.

>
> First, it is subject to the same causation-related problems as my proposed
> language. Determining whether the exemption would apply would require a
> court to determine if something else caused the death of the embryo.
> Second, the exemption might prevent the prosecution the clinic and its
> staff, but it would not definitively prevent the prosecution of a person who
> transfers an embryo to an IVF clinic. After all, the acts that are
> prohibited under subs. (3) and (5) are purchases, sales, and transfers.
> Third, under your draft, the nonapplicability provision applies to the
> entire section. Thus, a clinic might claim that the bill permits it to
> create a "living human embryo outside a woman's body" solely for the
> purposes of cryopreservation research (a claim that would be even stronger
> if my second contention above were seen as lacking merit). Finally, the
> "all available means" language might be construed to ultimately require the
> implantation of the embryo, since, given the limits of cryopreservation,
> that is the only way to "protect the life and health of the embryo." That
> would essentially make the nonapplicability provision meaningless.
>
> I have also just noticed a problem that affects both drafts. If an IVF
> clinic does not properly cryopreserve an embryo, the parents may be liable
> even if they reasonably believed that the clinic would follow the proper
> procedures.
>
> 2. Are you sure that you want to limit the thawing part of the
> nonapplicability provision to thawing done for infertility treatment? What
> if an embryo is implanted in the uterus of a fertile woman?
>
> 3. You asked what is the point of my subs. (7) and (8). The purpose is to
> prohibit splitting an embryo into separate cells if the cells are to be
> forced to differentiate into specialized cells. I realize that if this were
> done now, it would probably be considered research. But in the near future,
> scientists may be doing it for purposes other than research. The resultant
> cells may actually be used for treatment. Thus, my subs. (9) and (10) would
> not apply.
>
> If this is something you do not want the bill to address, let me know. If
> you do want it in the bill, feel free to make suggestions regarding the
> language I drafted.
>
> 4. We do not include provisions like your sub. (9) in any bills. If there
> is a provision that appears to prohibit fertilization for reproduction
> purposes (and you suggest that my sub. (10) may be such a provision --
> although I am not sure why), I will fix that provision.
>

> 5. As I previously indicated to Rob Richard, there is no need for a
> severability provision. See s. 990.001 (11).
>
> 6. I do not believe that an informed consent provision is needed in
Rep.
> Freese's draft, which is what I am working on now. I will include one
in
> Sen. Welch's draft.
>
> I have a few more comments, but I will send you this now so that you
can
> consider these points as soon as you get back to your office.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Dsida, Michael
Sent: Thursday, October 04, 2001 5:08 PM
To: 'mklaver@wrtl.org'
Subject: Embryo bill

(This is in response to your 3:21 PM email on 9/28.)

2.a. The entire bill would take effect immediately. I did not mean to suggest otherwise.

b. Re the "null and void" provision -- Including provisions in the statutes that have no effect clutter up the statutes and make them more difficult to use.

ok

(This is in response to your 5:32 PM email on 9/28.)

1a. Have you talked to Rep. Freese's office about this yet? As I mentioned when we talked last week, it is my understanding that Rep. Freese and Sen. Welch do not want to impose criminal liability on an IVF clinic if it cryopreserves an embryo without knowing if the embryo will ever be implanted -- which would be the case if it implants other embryos at the same time as the cryopreservation. I believe that your approach to this issue would require the clinic to attempt to implant every single viable embryo, which, from what I remember, is not what the requesters want.

"all means necessary" ???

b. Assume that parents and IVF clinic 1 agree to have frozen embryos transferred to clinic 2, but with little expectation that they will have them implanted. If clinic 2 does not exercise "all available means" (or whatever standard the bill ultimately includes) to care for the embryo, the clinic will be liable, since the nonapplicability provision will not apply. But in that case, the parents may also be liable. Even if they anticipated that clinic 2 would care for the embryos appropriately, the parents may well have been aware that indefinite storage would be practically certain to cause the death of the embryo. (See s. 939.23 (3).) Thus, the parents would have transferred the embryos with the knowledge (see s. 939.23 (2)) that the embryos would intentionally be killed. And since the nonapplicability provision doesn't apply (it addresses what ultimately happens, not the intent of the parents), they would be liable.

Obviously, the scenario I just described is unlikely to occur. But the problem could be a bigger one, depending on the construction of the word "transfer." Is the initial decision by donor parents to have clinic 1 assume physical custody of an embryo a transfer?

3. Since the manipulation of the cell into a more specialized cell does not result in the cell's death, sub. (2) would not apply. If you ultimately decide to include this provision, I will define and use the term "totipotent."

4. The difference between your sub. (9) and s. 939.75 is that the provisions to which the latter section relates could otherwise be construed as covering conduct performed in an induced abortion or by providing birth control. There is no comparable problem here. There is nothing in this statute that will criminalize ethical infertility treatments, so there is no need to clarify anything on that point. Nevertheless, I recognize that you want to include this provision, so in an effort to use as much of your language as possible, I will talk to Debora Kennedy tomorrow to see if she thinks that it can be included.

The second sentence of sub. (10) covers item 7 in the drafter's note and nothing more. It relates only to that subsection.

5. I have already explained this issue in an e-mail to Rob, and that e-mail will be in the drafting file. ok

6. I understand your interest in letting patients refuse such treatment, but I still do not see why it is needed in Rep. Freese's bill. The bill prohibits the transfer of any cell or tissue that was obtained through killing an embryo, creating a substantial risk of harm to an embryo, and cloning. Any medical treatment that you are concerned about will entail such a transfer (and probably multiple transfers). Are you concerned that doctors will use cells or tissues derived from embryos in the face of this prohibition? Mary will talk her staff

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

Mary explained that she thought that the manipulation of the embryo into a non-totipotent cell causes its death. Therefore, subs. (7) + (8) aren't needed; This is already covered by sub (2)

Dsida, Michael

From: Dsida, Michael
Sent: Thursday, October 04, 2001 5:14 PM
To: 'Mary Klaver'
Subject: RE: Embryo bill

Mary — Use language like 2.(b)1. + 4.

It looks like your handwritten notes on the first page of the drafter's note may have been cut off at the bottom when you faxed it to me. After the reference to s. 979.75 (2) (b) 1. [1st sentence], I read "+ 4: cross-reference would be." Is there anything else after that?

confusing

Dsida, Michael

From: Dsida, Michael
Sent: Thursday, October 04, 2001 6:09 PM
To: 'mklaver@wrtl.org'
Subject: Cloning

will ✓ w/ her expert

I don't think the cloning provisions of the bill will be nearly as difficult to draft, but I do have 3 comments:

1. You do not need the term "asexual reproduction." The use of that term in the definition of "human cloning" adds nothing to the definition.

2. Sub. (2) (b) is unnecessary. See s. 939.05. agree

3. Subsection (4) is unnecessary, for the same reasons that your s. 940.17 (9) is unnecessary. Wants to avoid overbreadth challenge

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

Dsida, Michael

From: Dsida, Michael
Sent: Friday, October 05, 2001 10:47 AM
To: 'mklaver@wrtl.org'
Subject: Cloning provisions; "savings" clause for s. 940.17

1. Your definition of "somatic cells" may be construed under current abortion jurisprudence to exclude cells taken from an embryo or a fetus that has not reached viability -- notwithstanding your "any stage of development" language. I assume that is not your intent. If it is not your intent, perhaps the only change that needs to be made is replacing "human body" with "human organism." ok

2. I assume that the term "product" in sub. (2) (c) includes cells and tissues. yes (~~maybe~~ parts of cells too)

3. Do you want a definition of "embryo" for this section? Yes

4. What is the maximum fine for a criminal violation of this statute? (Class D felonies -- which, like this provision, carries a maximum term of imprisonment of 10 years -- permit a fine of up to $10,000.) ~~fine~~ Get rid of civil penalty. Use those amts for fine

5. In a case in which the person sells products derived from cloning, does "gross gain" mean the total sale price?

6. Subsection (4) is unnecessary in the same way that s. 940.17 (9) is. (See item 7.)

7. I talked to Debora Kennedy about your proposed s. 940.17 (9). She agrees that there is no need to include this provision in the bill. (When I mentioned s. 939.75 to her, she also noted -- before I even made the point myself -- that s. 939.75 was necessary because of ambiguities in the statutory sections to which it relates.) I anticipate that you still will want to include this provision, so I would be happy to talk with Rep. Freese or his staff to explain why your proposed s. 940.17 (9) should not be in the bill.

Dsida, Michael

To: Mary Klaver
Subject: RE: Embryo bill

-----Original Message-----
From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Monday, October 08, 2001 3:12 PM
To: Dsida, Michael
Subject: Re: Embryo bill

Mike,

Point #1a: I have spoken with our staff and to Rob in Freese's office. We all agree that the exemption from criminal liability is for the mere act of freezing and thawing a living human embryo for the purpose of implantation as long as the embryo is given a high degree of care. The degree of care can be "all available means", "all means necessary", "every measure possible", or words to that effect. If the only option available to meet this standard is to have the embryo implanted, then so be it.

Point #1b: With regard to transfers, the immunity only applies for the purpose of immediate or future implantations. The question of physical custody is secondary at this point. Since the embryos are very fragile, it is common sense that the laboratory would have physical custody since they have the specialized equipment for preserving and protecting the embryos.

Once the legislative council study completes its work, some of these finer details will come together. In the meantime, all we have to work with is intent. If the intent of the parents, in a transfer context, is to enable an implantation or to continue to preserve the embryo for a future implantation, then there should be no liability.

Point # 3: As we discussed on the phone last Friday, this is just a subset of sub. (2) because the embryo will be killed in the process of deriving the specialized cell. The cells may be living in the general sense, but the human organism would be destroyed in the process.

Point #4: We still want our sub (9).

Point #5: Okay.

Point #6. We see your point. Save this provision for the Welch draft.

I hope this helps to clarify these issues.

Mary