

4

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Thursday, October 04, 2001 3:45 PM
To: Dsida, Michael
Subject: Re: Embryo bill -- impairment of contracts and non-statutory provision

Mike,

I am not aware of any litigation regarding the language I suggested for the definition of research. The definition is from the Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects. The definition I used as a model is at section 46.102 (d) which can be found at

<http://squid.law.cornell.edu/cgi-bin/get-cfr.cgi?TITLE=45&PART=46&SECTION=102&TYPE=TEXT>

These rules were published in the June 18, 1991 Federal Register and there was no controversy over this definition. I have copies of these papers if you need to see them.

How is everything coming? I am anxious to see the draft. I will be here until 5:30 p.m. today.

Mary

"Dsida, Michael" wrote:

Having read the Forbes opinion, I understand why you want to include a definition of "research."
Has the language that you proposed been the subject of any litigation?

-----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

11/21/2001

"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: Boycks, Brad
Sent: Tuesday, August 28, 2001 12:59 PM
To: Dsida, Michael
Subject: RE: Use of stem cells

Bob is in today, I will need to check in with him and see what he wants to do.

-----Original Message-----

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
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michael.dsida@state.legis.wi.us

Dsida, Michael

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 create a 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

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

Dsida, Michael

From: Boycks, Brad
Sent: Thursday, September 06, 2001 10:46 AM
To: Richard, Rob; Dsida, Michael
Subject: RE: Embryo/cloning bill

We are fine with that as well.

Brad

-----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

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

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Wednesday, September 26, 2001 4:37 PM
To: Dsida, Michael
Subject: Re: Using your definition while avoiding potential drafting problems

Mike,

This is not the ideal result, but it will work.

Mary

"Dsida, Michael" wrote:

> I have spoken to Debora Kennedy and several other colleagues about the
> question of whether I should define "human embryo" instead of "in
vitro
> human embryo." Based on what they have told me, it would ordinarily
be our
> practice to use the latter definition, since using the former
definition in
> the prohibitions: 1) will require using the phrase "living outside of
a
> woman's body" repeatedly (a problem that a definition is used to
avoid); and
> 2) may make the language of the prohibitions unduly cumbersome.
>
> One attorney, however, suggested defining both terms, which will
accomplish
> your stated objective while avoiding the problems described above.
That
> seems to be a reasonable approach to me. So here is what I propose:

>
> 1. Using the following definitions:
>
> (a) "Human embryo" means [here I will insert a definition based on
the
> language that you suggested -- I am still working on that]
>
> (b) "In vitro human embryo" means a human embryo, whether
cryopreserved or
> not, living outside of a woman's body.
>
> 2. Using the term "in vitro human embryo" in the prohibitions
contained
> beginning in sub. (2).
>
> I believe that this approach should work. Please e-mail me to let me
know
> if you think it does too.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Richard, Rob
Sent: Thursday, September 27, 2001 11:14 AM
To: Dsida, Michael
Cc: 'mklaver@wrtl.org'; Boycks, Brad

Mike:

To expedite the process and to get a final draft into Rep. Freese's and Sen. Welch's hands soon, we are giving full drafting authority to Mary Klaver. As I said earlier, please submit all constitutional concerns or other questions you may have in the drafter's note. Freese and Welch will then determine where to go from there.

Thank you, Mike!

Rob Richard
Freese Office
266-7502

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Thursday, September 27, 2001 1:45 PM
To: Dsida, Michael
Subject: Re:

Mike,

Your assumption is correct. We prefer the term "who" and encourage its use. It should be clear that this legislation is not treating a human embryo as property.

Mary

"Dsida, Michael" wrote:

> I assume that you would prefer that a dependent clause modifying the term
> "human embryo" not begin with the word "that." In other words, I assume
> that you object to the word "that" on page 2, line 4 of the P2 draft.
If
> so, I will do my best to avoid that construction.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Thursday, September 27, 2001 2:36 PM
To: Dsida, Michael
Subject: Re: Human embryo bill

Mike,

The definition of "research" is absolutely necessary. Many state laws banning "experimentation" on the remains of an aborted baby have been ruled unconstitutional on vagueness grounds. The term "experimentation" (and "research" is in the same category) was held to cover a wide range of activities from pure research (our definition) to clinical trials to clinical applications where a physician is using a procedure for the first time or is using the procedure in a novel way. So, the definition is needed to avoid a constitutional challenge on vagueness grounds.

For your information, the definition of "research" is identical to the one used in the federal law protecting human subjects in research situations. We had added the word "medical", but that is not needed now.

Regarding the pages faxed to me:

1. The proposed changes to the definition of human embryo are fine.
2. For the definition of "nontherapeutic human embryo research", we would like to continue to use the term "protect". Although there are many similarities in the terms "protect" and "preserve", "protect" seems to speak more to taking safety precautions and "preserve" does a better job of addressing nurturing the embryo. We like your addition of the term "promote". The resulting phrase would be "to help protect, preserve and promote the life or health of the . . . embryo".

Looking forward to more pages.

Mary

"Dsida, Michael" wrote:

> I am about to fax you the first couple pages of the bill. I have been
> working on another draft and responding to inquiries from other
legislators
> this morning, so I have only had an hour or so to work on this. I
thought
> it would make sense, however, to send you what I have completed now
because
> I know that Rep. Freese would like to get this draft done as soon as
> possible.
>
> Two substantive comments:
>
> 1. I am not sure that the definition of medical research is necessary
or
> helpful.
> 2. The definition of "in vitro human embryo" (Insert 2/6) will be
what I
> described in my e-mail to you on Tuesday. ("In vitro human embryo"
means a
> human embryo, whether cryopreserved or not, living outside of a
woman's
> body.)
>
> 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 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, see generally Davies 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

Subject: FW: Embryo bill

-----Original Message-----

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.

(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.

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."

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.

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?

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

Dsida, Michael

Subject: FW: Embryo bill -- impairment of contracts and non-statutory provision

-----Original Message-----

From: Mary Klaver [mailto:mklaver@wrtl.org]

Sent: Thursday, October 04, 2001 3:45 PM

To: Dsida, Michael

Subject: Re: Embryo bill -- impairment of contracts and non-statutory provision

Mike,

I am not aware of any litigation regarding the language I suggested for the definition of research. The definition is from the Code of Federal Regulations, Title 45, Public Welfare, Part 46, Protection of Human Subjects. The definition I used as a model is at section 46.102 (d) which can be found at

<http://squid.law.cornell.edu/cgi-bin/get-cfr.cgi?TITLE=45&PART=46&SECTION=102&TYPE=TEXT>

These rules were published in the June 18, 1991 Federal Register and there was no controversy over this definition. I have copies of these papers if you need to see them.

How is everything coming? I am anxious to see the draft. I will be here until 5:30 p.m. today.

Mary

11/21/2001

Dsida, Michael

Subject: FW: Cloning provisions; "savings" clause for s. 940.17

-----Original Message-----

From: Dsida, Michael

Sent: Friday, October 05, 2001 10:47 AM

To: 'mklaver@writl.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."
2. I assume that the term "product" in sub. (2) (c) includes cells and tissues.
3. Do you want a definition of "embryo" for this section?
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.)
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.

Dsida, Michael

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

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?

Dsida, Michael

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

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.
3. Subsection (4) is unnecessary, for the same reasons that your s. 940.17 (9) is unnecessary.

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

Dsida, Michael

From: Dsida, Michael
Sent: Wednesday, October 10, 2001 11:36 AM
To: 'mklaver@wrtl.org'
Subject: RE: For Mary Klaver



Nothing in this
section.doc

-----Original Message-----

From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Monday, October 08, 2001 4:59 PM
To: Dsida, Michael
Subject: Re: For Mary Klaver

Mike,

I am open to considering this, but I have never heard of this approach before. Usually, the legislative analysis just explains background and the provisions in the bill. Do you have any examples I could see? [Dsida, Michael] "The purpose of an analysis is to describe clearly and objectively, in understandable language, the substance and effect of a legislative proposal without describing every detail of the measure." LRB Drafting Manual, s. 4.03(2)(a). In some cases, that goal can be met by including a "This bill does not..." provision.

I am faxing you a list of introduced bills from the current session that contain such a provision. (There are plenty of un-introduced drafts with the provision as well.) If you would like me to send you the PDF version of any of these bills (by e-mail), let me know.

Wouldn't this would still entail a legislative history search, since it would not be in the published statute? [Dsida, Michael] You are right. Including the provision in the analysis, however, would certainly make it much more accessible. The bills are available in books, but other legislative history is essentially only available on microfiche.

It seems to me that there must be other places in our statutes that have provisions that say "Nothing in this section . . ." Can you do a search for these provisions? [Dsida, Michael] There are hundreds of them in the statutes but only a few in the criminal code (see attached). Many of those statements would not have been included in the statutes under our current drafting conventions. As I have indicated, a sentence like that is appropriate if the provision does not otherwise make that point clearly. If the provision does, then there is no need for the "nothing in this ____" statement. (Subsection (10) of my draft provides an example of the proper use of this statement.)

By the way, my e-mail works now, so you can send messages directly to me. It was a technical problem which has now been fixed.

Mary

"Dsida, Michael" wrote:

Over the weekend, I thought of one approach to the "Nothing in this section" provisions that we have been discussing. What if, as an alternative to your approach, I included similar language in the bill analysis? That way, no one would have to dig into the legislative history to find it. (I could also include language in the analysis relating to existing contracts to explain the effect of the initial applicability provision.)

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

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Wednesday, October 10, 2001 4:02 PM
To: Dsida, Michael
Subject: Re: For Mary Klaver

Mike,

As I understand your objection to adding our sub. (9), you do not see anything in the draft that would criminalize ethical infertility treatments, so it is not needed. (See your response to my "5:32 PM email on 9/28", point #4.)

One could argue that sub. (3) of your draft could be interpreted to apply to infertility treatments. The primary purpose of this provision is to prevent the purchase, sale or transfer of a so-called "spare embryo" from an infertility clinic to a research lab that intends to kill the embryo for stem cells. It can also be read to apply to the transfer of an embryo to another infertility clinic for implantation into a woman. Since the success rate for IVF is low (meaning the embryo will die), then someone could argue that "the actor . . . is aware that his or her conduct is practically certain to cause that result." Therefore, our sub (9) is necessary to prevent that interpretation.

Also, as you know, Rep. Freese does not want to have a political battle on ethical infertility treatments.

If you have any questions or concerns, please call me at 414-778-5780.

Mary

"Dsida, Michael" wrote:

-----Original Message-----

From: Mary Klaver [<mailto:mklaver@wrtl.org>]
Sent: Monday, October 08, 2001 4:59 PM
To: Dsida, Michael
Subject: Re: For Mary Klaver

Mike,

I am open to considering this, but I have never heard of this approach before. Usually, the legislative analysis just explains background and the provisions in the bill. Do you have any examples I could see? [Dsida, Michael] "The purpose of an analysis is to describe clearly and objectively, in understandable language, the substance and effect of a legislative proposal without describing every detail of the measure." LRB Drafting Manual, s. 4.03(2)(a). In some cases, that goal can be met by including a "This bill does not..." provision.

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Wouldn't this would still entail a legislative history search, since it would not be in the published

statute? [Dsida, Michael] You are right. Including the provision in the analysis, however, would certainly make it much more accessible. The bills are available in books, but other legislative history is essentially only available on microfiche.

It seems to me that there must be other places in our statutes that have provisions that say "Nothing in this section . . ." Can you do a search for these provisions? [Dsida, Michael] There are hundreds of them in the statutes but only a few in the criminal code (see attached). Many of those statements would not have been included in the statutes under our current drafting conventions. As I have indicated, a sentence like that is appropriate if the provision does not otherwise make that point clearly. If the provision does, then there is no need for the "nothing in this ___" statement. (Subsection (10) of my draft provides an example of the proper use of this statement.)

By the way, my e-mail works now, so you can send messages directly to me. It was a technical problem which has now been fixed.

Mary

"Dsida, Michael" wrote:

Over the weekend, I thought of one approach to the "Nothing in this section" provisions that we have been discussing. What if, as an alternative to your approach, I included similar language in the bill analysis? That way, no one would have to dig into the legislative history to find it. (I could also include language in the analysis relating to existing contracts to explain the effect of the initial applicability provision.)

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

Dsida, Michael

From: Dsida, Michael
Sent: Friday, October 12, 2001 4:16 PM
To: 'Mary Klaver'
Subject: Your sub. (9)

I haven't done much looking at this, but given what I have found on the internet (success rates ranging from 14% to over 50%), I don't think that a court would determine that the embryo's death is or was "practically certain" to occur. Nevertheless, I see your point. (It also applies to sub. (2).)

Good luck on Monday.

-----Original Message-----

From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Wednesday, October 10, 2001 4:02 PM
To: Dsida, Michael
Subject: Re: For Mary Klaver

Mike,

As I understand your objection to adding our sub. (9), you do not see anything in the draft that would

criminalize ethical infertility treatments, so it is not needed. (See your response to my "5:32 PM email on 9/28", point #4.)

One could argue that sub. (3) of your draft could be interpreted to apply to infertility treatments. The primary purpose of this provision is to prevent the purchase, sale or transfer of a so-called "spare embryo" from an infertility clinic to a research lab that intends to kill the embryo for stem cells. It can also be read to apply to the transfer of an embryo to another infertility clinic for implantation into a woman. Since the success rate for IVF is low (meaning the embryo will die), then someone could argue that "the actor . . . is aware that his or her conduct is practically certain to cause that result." Therefore, our sub (9) is necessary to prevent that interpretation.

Also, as you know, Rep. Freese does not want to have a political battle on ethical infertility treatments.

If you have any questions or concerns, please call me at 414-778-5780.

Mary

"Dsida, Michael" wrote:

-----Original Message-----

From: Mary Klaver [<<mailto:mklaver@wrti.org>>]

Sent: Monday, October 08, 2001 4:59 PM

To: Dsida, Michael

Subject: Re: For Mary Klaver

Mike,

I am open to considering this, but I have never heard of this approach before. Usually, the legislative analysis just explains background and the provisions in the bill. Do you have any examples I could see? [Dsida, Michael] "The purpose of an analysis is to describe clearly and objectively, in understandable language, the substance and effect of a legislative proposal without describing every detail of the measure." LRB Drafting Manual, s. 4.03(2)(a). In some cases, that goal can be met by including a "This bill does not..." provision.

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By the way, my e-mail works now, so you can send messages directly to me. It was a technical

problem which has now been fixed.

Mary

"Dsida, Michael" wrote:

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

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Wednesday, October 17, 2001 12:13 PM
To: Dsida, Michael
Subject: Re: Human embryo bill

Yes, that is an improvement we like. -- Mary

"Dsida, Michael" wrote:

> Do you want me to use both "protect" and "preserve"?
>
> -----Original Message-----
> From: Mary Klaver [mailto:mklaver@wrtl.org]
> Sent: Thursday, September 27, 2001 2:36 PM
> To: Dsida, Michael
> Subject: Re: Human embryo bill
>
> Mike,
>
> The definition of "research" is absolutely necessary. Many state laws
> banning
> "experimentation" on the remains of an aborted baby have been ruled
> unconstitutional on vagueness grounds. The term "experimentation" (and
> "research" is in the same category) was held to cover a wide range of
> activities from pure research (our definition) to clinical trials to
> clinical
> applications where a physician is using a procedure for the first time
> or is
> using the procedure in a novel way. So, the definition is needed to
> avoid a
> constitutional challenge on vagueness grounds.
>
> For your information, the definition of "research" is identical to the
> one
> used
> in the federal law protecting human subjects in research situations.
We had
> added the word "medical", but that is not needed now.
>
> Regarding the pages faxed to me:

>
> 1. The proposed changes to the definition of human embryo are fine.
>
> 2. For the definition of "nontherapeutic human embryo research", we
would
> like
> to continue to use the term "protect". Although there are many
similarities
> in
> the terms "protect" and "preserve", "protect" seems to speak more to
taking
> safety precautions and "preserve" does a better job of addressing
nurturing
> the
> embryo. We like your addition of the term "promote". The resulting
phrase
> would be "to help protect, preserve and promote the life or health of
the .
> . . .
> embryo".
>
> Looking forward to more pages.
>
> Mary
>
> -----
> "Dsida, Michael" wrote:
>
> > I am about to fax you the first couple pages of the bill. I have
been
> > working on another draft and responding to inquiries from other
> legislators
> > this morning, so I have only had an hour or so to work on this. I
thought
> > it would make sense, however, to send you what I have completed now
> because
> > I know that Rep. Freese would like to get this draft done as soon as
> > possible.
> >
> > Two substantive comments:
> >
> > 1. I am not sure that the definition of medical research is
necessary or
> > helpful.
> > 2. The definition of "in vitro human embryo" (Insert 2/6) will be
what I
> > described in my e-mail to you on Tuesday. ("In vitro human embryo"
means a
> > human embryo, whether cryopreserved or not, living outside of a
woman's
> > body.)
> >
> > Mike Dsida
> > Legislative Reference Bureau
> > 608/266-9867
> > michael.dsida@state.legis.wi.us

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Thursday, October 18, 2001 11:35 AM
To: Dsida, Michael
Subject: Re: Fine

Mike,

I am unable to get in touch with Dave Christensen in Congressman Weldon's office -- probably because most of the congressional offices are closed due to the anthrax problem. So, I am trying to get an answer from another reliable source. As soon as I get the information I will get back to you.

You raise some pertinent questions. When we first spoke about this, we were not exactly sure what the federal bill meant for the criminal fine. That is what we are trying to find out today.

At this point, we believe there should be both a criminal penalty and a civil penalty. The civil penalty should be the same as the one in HR 2505.

I will check out the cases in the meantime. Thanks for the links.

Mary

"Dsida, Michael" wrote:

> In one of your e-mails from yesterday you wrote that the fine amount should
> be \$1million. Is that the maximum fine? Does that instruction override
> your previous instruction that I turn into a fine what you included in your
> draft as a civil penalty?
>
> If you want me to stick with your previous instructions...
>
> If there has been no pecuniary gain, what is the maximum fine (if any)? Is
> there also a minimum? (Most offenses do not carry a mandatory minimum fine.
> The court has discretion to assess or not to assess one.)
>
> In any event, you should be aware that a \$1 million fine may be viewed as
> violating the 8th Amendment's prohibition against excessive fines. See U.S.
> v. Bajakajian, 524 U.S. 321,
> <http://supct.law.cornell.edu/supct/html/96-1487.ZS.html> (1998). Bajakajian
> involved a civil forfeiture, and most of the cases relying upon it have
> addressed the constitutionality of forfeitures and other non-traditional
> assessments. See, e.g., State v. Boyd, 2000 WI App. 208,
> <http://www.wisbar.org/wisctapp2/3q00/99-2633.htm>. But it has also been

> applied to conventional fines in a very small number of cases. See,
e.g.,
> Minnesota v. Rewitzer, 617 N.W. 2d 407,
> <http://www.lawlibrary.state.mn.us/archive/supct/0009/c499807.htm>
(2000);
> Tennessee v. Taylor, 2001 Tenn. Crim. App. Lexis 311,
> <http://www.tsc.state.tn.us/PDF/tcca/012/TaylorAlvinRay.pdf> (2001).
> Moreover, in each of the cases that I have seen that involves fines,
the
> court has found the fine to be unconstitutional.
>
> I know that there are controlled substance offenses in the Wisconsin
> statutes that permit \$1 million fines. See, e.g., s. 961.41 (1) (d)
6. But
> those statutes were enacted before Bajakajian.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Thursday, October 18, 2001 12:38 PM
To: Dsida, Michael
Subject: Re: Fine

Mike, while I am waiting for answers from our consultants, could you give us some guidance? What is the highest amount of a criminal penalty that you believe would not be subject to an 8th Amendment challenge?

Also, do any criminal statutes set forth a minimum fine as well as a maximum fine? I have seen this with civil forfeitures, but I am not that familiar with the criminal fines.

Thanks, Mary

"Dsida, Michael" wrote:

> In one of your e-mails from yesterday you wrote that the fine amount
should
> be \$1million. Is that the maximum fine? Does that instruction
override
> your previous instruction that I turn into a fine what you included in
your
> draft as a civil penalty?
>
> If you want me to stick with your previous instructions...
>
> If there has been no pecuniary gain, what is the maximum fine (if
any)? Is
> there also a minimum? (Most offenses do not carry a mandatory minimum
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> <http://www.tsc.state.tn.us/PDF/tcca/012/TaylorAlvinRay.pdf> (2001).
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> those statutes were enacted before Bajakajian.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Monday, October 22, 2001 3:41 PM
To: Dsida, Michael
Subject: Re: cloning provisions

Mike,

As per our conversation today, based on my consultation with Dr. David Prentice, the term "asexual reproduction" will remain in the definition of human cloning.

Also, Dr. Prentice says that "oocyte" is the correct term to use, not "ovum" because procedure this is done at the oocyte stage.

Mary

"Dsida, Michael" wrote:

1. I may be missing something, but I still don't think that you have answered my question. I'll try it another way -- is it possible to "introduc[e] 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" without it being "asexual reproduction"?

2. The term "oocyte" is often (and perhaps generally) defined to mean an immature ovum. It probably makes more sense to use the term "ovum."

-----Original Message-----

From: Mary Klaver [<<mailto:mklaver@wrtl.org>>]

Sent: Wednesday, October 17, 2001 11:21 AM

To: Dsida, Michael

Subject: Re: cloning provisions

Mike,

It is extremely important that the term "asexual reproduction" be used.

Cloning

is a form of "reproduction" and that is an essential part of the definition.

This distinguishes cloning from other procedures that have nothing to do

with

reproduction.

It is also essential to designate this as an "asexual" form of reproduction

because that distinguishes it from sexual reproduction. Please note that

this

definition only describes one form of cloning. For example, artificial

twinning

at the 4 to 8 embryonic cell stage is another form of cloning and that is

not

prohibited by this legislation. This later form of cloning is sexual

reproduction since, at this point in time, it is always initiated by the

union

of a sperm and egg.

Mary

"Dsida, Michael" wrote:

> I think there was still at least one thing that you need to address: the
use

> of the term "asexual reproduction." When we talked last, I told you that

> there was no need to use it. You said that you were going to check with

> your expert.

>

> Mike Dsida

> Legislative Reference Bureau

> 608/266-9867

> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Monday, October 22, 2001 5:35 PM
To: Dsida, Michael
Subject: Re: Your subs. (8) and (9)

Mike,

Based upon your comments (Points # 1, 2 and 4) and review by our staff, we suggest the following rewrite of proposed sub. (8):

"(8) This section does not apply to any of the following:

- (a) Cryopreserving an in vitro human embryo if the actor uses all available means to protect, preserve, and promote the life and health of the embryo.
- (b) Thawing an in vitro human embryo if the thawing is done for the purpose of facilitating the implantation of the embryo in a woman's uterus consistent with the criteria listed in par. (c) and if the actor uses all available means to protect, preserve, and promote the life and health of the embryo.
- (c) Implanting or attempting to implant an in vitro human embryo created by fertilization in a woman's uterus if done for the purpose of human reproduction and if the woman intends to carry any resultant pregnancy to term.
- (d) The transfer of an in vitro human embryo if the actor intends that the embryo be cryopreserved consistent with the criteria listed in par. (a), thawed consistent with the criteria listed in par. (b), or implanted in a woman's uterus consistent with the criteria listed in par. (c).
- (e) The donor of any gamete from which an in vitro human embryo is derived."

Regarding Point #3, yes, we would like the bill to explicitly prohibit the purchase and sale of human embryos (Class E felony).

Regarding Point #5, this is an issue that cannot be completely resolved until the adoption program for human embryos is put into place. At this point in time we will have to take the position that as long as the embryo is being implanted in a woman's uterus consistent with the criteria listed in par. (c), then there is no liability. As you noted in your Fri, 12 Oct 2001 16:16:04 e-mail entitled "Your sub. (9)", a court is not likely to determine an embryo's death is or was "practically certain" to occur if success rates range from 14% to over 50% (numbers you obtained from your internet search).

I will get back to you on the criminal fine tomorrow.

Mary

"Dsida, Michael" wrote:

1. Re (a) -- If a clinic has embryos that parents do not want to use and the parents refuse to permit the "adoption" of those embryos, would par. (a) apply to the clinic, or would it be subject to prosecution for (eventually) causing the death of the embryos? A prosecutor might argue that any cryopreservation done at that point is no longer being done for the purpose of facilitating the implantation of the embryos.2. Also re (a) -- If parents refuse to permit adoption of

"spare" embryos, does the clinic, under the "all available means" requirement, have to implant the embryos without the parents' consent? Initiate litigation to force the parents to consent or to get court approval to have the embryos implanted without the parents' consent? Perhaps this can be addressed by making it clear that the "all available means" provision only applies to the what the clinic does during cryopreservation and thawing.³ Re (c) -- I am not sure what you are getting at with this point. Are you just trying to make sure that the bill does not appear to endorse purchasing or selling embryos? Or should the bill explicitly prohibit those practices?⁴ Re (d) -- I understand that you are not trying to protect gametes. But as I have explained (see point 1b. of my e-mail of 10/4 at 5:08 PM), without this provision, parents may be liable if the clinic does not properly care for the embryos. In addition, without this provision, the parents would be liable for causing the death of spare embryos (even if only by having them cryopreserved past the point at which they can be used) unless they permit the embryos' adoption by others. 5. Re Point 2 -- (This becomes moot if you agree with the change that I proposed above regarding par. (a).) I understand what you are saying, but that doesn't answer my question. If the clinic determines after several tries that the woman is a poor candidate for implantation, but continues to try to implant embryos in her, is it covered by par. (a)? Or does it have to counsel the woman to authorize releasing the embryos for use by a woman who is more likely to be able to carry the pregnancy to term?

-----Original Message-----

From: Mary Klaver [<<mailto:mkklaver@wrtl.org>>]

Sent: Wednesday, October 17, 2001 4:06 PM

To: Dsida, Michael

Subject: Re: Your subs. (8) and (9)

Mike,

Point #1: We think this approach will work with a few changes. Note I am substituting brackets for deletions because I do not have "strike through" as an option in e-mail. I hope the underlining comes through. If not, let me know.

"(8) This section does not apply to any of the following:

(a) Cryopreserving or thawing an in vitro human embryo if the cryopreserving or thawing is done for the purpose of facilitating the implantation of the embryo in a woman's uterus consistent with the criteria listed in par. (b) and if the actor uses all available means to protect, and preserve, and promote the life and [promote the] health of the embryo.

(b) Implanting or attempting to implant an in vitro human embryo created by fertilization in a woman's uterus if done for the purpose of human reproduction and if the woman intends to carry any resultant pregnancy to term.

(c) The [purchase, sale, or] transfer of an in vitro human embryo if the actor intends that the embryo be cryopreserved or thawed or both consistent with the criteria listed in par. (a) or be implanted in a woman's uterus consistent with the criteria listed in par. (b).

[(d) The donor of any gamete from which an in vitro human embryo is derived, if the donor intends that the embryo be cryopreserved or thawed or both consistent with the criteria listed in par. (a) or be implanted in a woman's uterus consistent with the criteria listed in par. (b).]"

Discussion:

(a) The verbs "protect, preserve and promote" should modify both "life" and "health".

(b) Only embryos "created by fertilization" should be exempted. Otherwise embryos created by asexual means would also be exempted and that would be inconsistent with the ban on cloning.

(c) There should be no "sale" or "purchase" of human embryos. The exemption should only apply to "transfer".

(d) We do not see any need for (d) since we are trying to protect embryos, not gametes. If we are missing something, let me know.

Point #2: There can be numerous reasons why an embryo does not implant in the female donor's uterus. It is not unusual for the woman to undergo several cycles before it can be medically determined that the embryo will not implant or that she cannot carry the pregnancy to term. It could be due to a medical problem with the woman or the particular procedure used. Until we can pass language dealing with releasing embryos for adoption, we will have to be satisfied with the principle laid out in sub. (b).

The fine for the criminal penalty for cloning should be \$1,000,000. That is the intent of the federal bill and is okay with Rep. Freese's office.

By the way, are you working with Debora Kennedy on the ban on cloning? Both Rep. Freese and Rep. Kestell want to have the same language. Rob in Freese's office has been talking to Dave in Kestell's office and that is their understanding as well as mine.

I think this answers all outstanding questions you have sent me.

Mary

"Dsida, Michael" wrote:

I have combined the language from the two provisions so that it reads:(8) This section does not apply to any of the following:(a) Cryopreserving or thawing an in vitro human embryo if the cryopreserving or thawing is done for the purpose of facilitating the implantation of the embryo in a woman's uterus consistent with the criteria listed in par. (b) and if the actor uses all available means to protect and preserve the life and promote the health of the embryo.(b) Implanting or attempting to implant an in vitro human embryo in a woman's uterus if done for the purpose of human reproduction and if the woman intends to carry any resultant pregnancy to term.(c) The purchase, sale, or transfer of an in vitro human embryo if the actor intends that the embryo be cryopreserved or thawed or both consistent with the criteria listed in par. (a) or be implanted in a woman's uterus consistent with the criteria listed in par. (b).(d) The donor of any gamete from which an in vitro human embryo is derived, if the donor intends that the embryo be cryopreserved or thawed or both consistent with the criteria listed in par. (a) or be implanted in a woman's uterus consistent with the criteria listed in par. (b).1. Is this language okay?2. I just thought of a reason why you might want something other than "all available means" for the standard in par. (a). If a woman has been involved with prior unsuccessful efforts to have an embryo implanted, it may be that implanting an embryo in her uterus is a very poor way to protect or preserve the life of the embryo, if there are other women who are willing to have the embryo implanted in them and who are more likely candidates for successful implantation. I guess it ultimately turns on what "available" means. If the female donor does not want to release the embryos for implantation in another woman, that option may be viewed as unavailable. What do you think?
****The only other questions that I have relate to the fine for cloning. I'll try to get those to you this afternoon. I should be able to finish the draft when you address those questions and the others that are outstanding.

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

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Tuesday, October 23, 2001 12:59 PM
To: Dsida, Michael
Subject: Re: Fine

Mike,

We are still trying to come up with a strategy for the criminal fine without creating a constitutional problem. One of our legal consultants brought the Spallone v. U.S. case to our attention regarding the 8th Amendment concerns. In this case the court reaffirmed that the Excessive Fines Clause of the 8th Amendment does not apply to civil contempt sanctions. See --

<<http://caselaw.lp.findlaw.com/scripts/getcase.pl?navby=search&court=US&case=/us/487/1251.html>>

For your information, the final decision is at --

<<http://caselaw.lp.findlaw.com/scripts/getcase.pl?navby=search&court=US&case=/us/493/265.html>>

So, one possibility would be to give standing to someone (who?) to obtain an injunction to stop a person from engaging in human cloning. Once the injunction is granted, then the court could use its contempt power to double or treble the usual \$10,000 fine, for continuing violations.

Another approach could be to have the criminal fine apply to every attempt to create a human embryo by cloning. It took 277 tries to get Dolly, the sheep created by cloning. At \$10,000 per try that would end up being a \$2,770,000 fine. There would be no need to increase the prison term, just the fine part of the penalty.

We would welcome your thoughts on these suggestions.

Mary

"Dsida, Michael" wrote:

In one of your e-mails from yesterday you wrote that the fine amount should be \$1million. Is that the maximum fine? Does that instruction override your previous instruction that I turn into a fine what you included in your draft as a civil penalty?

If you want me to stick with your previous instructions...

If there has been no pecuniary gain, what is the maximum fine (if any)? Is there also a minimum? (Most offenses do not carry a mandatory minimum fine. The court has discretion to assess or not to assess one.)

In any event, you should be aware that a \$1 million fine may be viewed as violating the 8th Amendment's prohibition against excessive fines. See U.S. v. Bajakajian, 524 U.S. 321, <<http://supct.law.cornell.edu/supct/html/96-1487.ZS.html>> (1998). Bajakajian

involved a civil forfeiture, and most of the cases relying upon it have addressed the constitutionality of forfeitures and other non-traditional assessments. See, e.g., *State v. Boyd*, 2000 WI App. 208, <http://www.wisbar.org/wisctapp2/3q00/99-2633.htm>. But it has also been applied to conventional fines in a very small number of cases. See, e.g., *Minnesota v. Rewitzer*, 617 N.W. 2d 407, <http://www.lawlibrary.state.mn.us/archive/supct/0009/c499807.htm> (2000); *Tennessee v. Taylor*, 2001 Tenn. Crim. App. Lexis 311, <http://www.tsc.state.tn.us/PDF/tcca/012/TaylorAlvinRay.pdf> (2001). Moreover, in each of the cases that I have seen that involves fines, the court has found the fine to be unconstitutional.

I know that there are controlled substance offenses in the Wisconsin statutes that permit \$1 million fines. See, e.g., s. 961.41 (1) (d) 6. But those statutes were enacted before *Bajakajian*.

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

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Wednesday, October 24, 2001 12:38 PM
To: Dsida, Michael
Subject: Re: cloning provisions

Mike,

This reply is to this e-mail and the one you sent about 4 minutes previous to this one.

Dr. Prentice says that "oocyte" is the correct term throughout. In mammals, you never get a mature ovum, which is an egg with a haploid set of chromosomes. Before fertilization, the oocyte has two sets of chromosomes. During fertilization, one set is ejected. After fertilization, you have a zygote. There are some species, such as worms, that have mature ovum, but not in mammals.

Dr. Prentice says that the term "ovum" is often used generically, but it is technically inaccurate.

Mary

"Dsida, Michael" wrote:

on the same note, since an oocyte is immature, is the phrase "fertilized or unfertilized" necessary in the definition of "human cloning"? At the least, you should get rid of "fertilized or", since an oocyte can't be fertilized... or can it? Can you check with Prentice on this and the previous email?

-----Original Message-----

From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Monday, October 22, 2001 3:41 PM
To: Dsida, Michael
Subject: Re: cloning provisions

Mike,

As per our conversation today, based on my consultation with Dr. David Prentice, the term "asexual reproduction" will remain in the definition of human cloning.

Also, Dr. Prentice says that "oocyte" is the correct term to use, not "ovum" because procedure this is done at the oocyte stage.

Mary

"Dsida, Michael" wrote:

1. I may be missing something, but I still don't think that you have answered my question. I'll try it another way -- is it possible to "introduc[e] 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" without it being "asexual reproduction"?
2. The term "oocyte" is often (and perhaps generally) defined to mean an immature ovum. It probably makes more sense to use the term "ovum."

-----Original Message-----

From: Mary Klaver [<<mailto:mklaver@wrti.org>>]
Sent: Wednesday, October 17, 2001 11:21 AM
To: Dsida, Michael
Subject: Re: cloning provisions

Mike,

It is extremely important that the term "asexual reproduction" be used. Cloning is a form of "reproduction" and that is an essential part of the definition. This distinguishes cloning from other procedures that have nothing to do with reproduction.

It is also essential to designate this as an "asexual" form of reproduction because that distinguishes it from sexual reproduction. Please note that this definition only describes one form of cloning. For example, artificial twinning at the 4 to 8 embryonic cell stage is another form of cloning and that is not prohibited by this legislation. This later form of cloning is sexual reproduction since, at this point in time, it is always initiated by the union of a sperm and egg.

Mary

"Dsida, Michael" wrote:

> I think there was still at least one thing that you need to address: the
use
> of the term "asexual reproduction." When we talked last, I told you that
> there was no need to use it. You said that you were going to check with
> your expert.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Thursday, October 25, 2001 11:18 AM
To: Dsida, Michael
Subject: Re: Fine

Mike,

We just got an answer from Rep. Freese regarding the criminal penalty for violating the ban on cloning. Instead of having the fine be \$1,000,000, he would prefer a mandatory fine of \$10,000 per occurrence (creating a human embryo by cloning).

Do "per occurrence" penalties also increase the prison time? If they usually do, then that would be okay. If these type of penalties usually only apply to the fine part of the penalty, that would also be okay. On this point, we would prefer to follow the usual practice. Please let us know what that is.

Mary

"Dsida, Michael" wrote:

I haven't found anything that would preclude citizen standing. A colleague pointed out a couple of statutes that authorize individual actions in environmental cases: ss. 166.20 (9) and 293.89. Another colleague reminded me that there was a citizen standing provision (relating to the use of MA funds in connection with union or anti-union activities) in the Senate's version of the budget.

Dsida, Michael

From: Dsida, Michael
Sent: Thursday, October 18, 2001 4:14 PM
To: 'Mary Klaver'
Subject: RE: Fine

It's difficult for me to respond to your first paragraph. First, the constitutionality of a fine under Bajakajian is best determined on a case-by-case basis. See Tennessee v. Taylor, 2001 Tenn. Crim. App. Lexis 311, <http://www.tsc.state.tn.us/PDF/tcca/012/TaylorAlvinRayD.pdf> (Witt, Jr., J., dissenting) (2001). That makes it difficult to determine an appropriate ceiling generally for the penalty. (It also means that you might be comfortable just setting the maximum at \$1 million and letting the appellate courts address the issue if it ever arises.)

Second, under the standards that the Bajakajian court adopted for assessing a fine's constitutionality, see 524 U.S. at 330-31, a court must assess, among other things, "the gravity of the offense and the harshness of the penalty." Solem v. Helm, 463 U.S. 277, 290, 103 S.Ct. 3001, 77 L.Ed.2d 637 (1983), overruled on other grounds by Harmelin v. Michigan, 501 U.S. 957, 111 S.Ct. 2680, 115 L.Ed.2d 836 (1991). Given the nonpartisan nature of my work, I cannot apply that standard. I can, however, help with the last two criteria: "(ii) the sentences imposed on other criminals in the same jurisdiction; and (iii) the sentences imposed for commission of the same crime in other jurisdictions." Id.

As I noted earlier, the maximum fine for several controlled substance offenses under current Wisconsin law is \$1 million. Many other controlled substance offense statutes permit a fine of up to \$500,000. Outside of ch. 961, there are only a few crimes setting a maximum fine of over \$100,000. See ss. 49.127 (8) (c) (food stamp fraud; maximum fine, \$250,000); 132.20 (2) (trafficking in counterfeit goods; maximum fine, \$250,000 (for individuals) and \$1 million for corporations or partnerships); 291.97 (2) (c) 2. (unlawfully transporting or treating hazardous waste -- second offense; maximum fine, \$150,000). Within the criminal code, however, the maximum fine for any offense is generally \$10,000. See s. 939.50 (3). Two statutes in the criminal code permit higher fines: ss. 939.648 (terrorism; maximum fine that may otherwise be imposed may be increased by \$50,000) and 946.84 (racketeering; fine may be increased to twice the relevant loss or gain).

According to the National Conference of State Legislatures, as of May 14, five states prohibit human cloning. Virginia's penalty is \$50,000 per incident. The others all permit (at least in some circumstances) penalties of \$1 million or more.

In response to your second question -- ch. 961 is filled with mandatory minimum penalties. Certain other criminal statutes outside of the criminal code are structured similarly. Within the criminal code, however, there appear to be mandatory minimum fines only in ss. 943.014 (2), 949.165 (14), and 949.17 (2).

By the way, I made a mistake in my earlier e-mail. The last sentence of the paragraph about Bajakajian should have read: "Moreover, in each of the criminal cases that I have seen that involves fines, the court has found the fine to be unconstitutional." There have been cases in which courts have upheld the constitutionality of civil fines. Sorry about that.

-----Original Message-----

From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Thursday, October 18, 2001 12:38 PM
To: Dsida, Michael
Subject: Re: Fine

Mike, while I am waiting for answers from our consultants, could you give us some guidance? What is the highest amount of a criminal penalty that you believe would not be subject to an 8th Amendment challenge?

Also, do any criminal statutes set forth a minimum fine as well as a maximum fine? I have seen this with civil forfeitures, but I am not that familiar with the criminal fines.

Thanks, Mary

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Monday, October 29, 2001 11:42 AM
To: Dsida, Michael
Subject: Re: Cloning

Mike,

As I said on the phone, we are trusting scientists like Dr. Prentice on this one. As long as a human embryo is not created, by any means, the exception is ethical and needed to address valid research.

Mary

"Dsida, Michael" wrote:

> I'm still puzzled on this one. How can human tissue be created using
> a
> human oocyte without the process creating an embryo?
>
> -----Original Message-----
> From: Mary Klaver [mailto:mklaver@wrtl.org]
> Sent: Wednesday, October 24, 2001 12:27 PM
> To: Dsida, Michael
> Subject: Re: Cloning
>
> Mike,
>
> Dr. Prentice says that sub. (4) was put into the current federal bill
> banning
> cloning because the previous bill did not have this exception and
> there were
> valid scientific objections that, without this exception, the bill
> could
> prohibit valuable and ethical scientific research. He says that
> creating
> human
> tissue or organs can be ethical if it does not involve creating an
> embryo.
> As
> you know, the exception does not apply to creating a human embryo.
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> If you need to talk more about this, let me know. I am aware of
> research
> where
> they are trying to create human organs, such as a bladder, using human
> tissue
> and a mold. There is no ethical problem with this.
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> "Dsida, Michael" wrote:
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> > We talked briefly a couple of weeks ago about your sub. (4). I'm
> still
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> > sure why it is necessary. In fact, if I use the language that you
> provided
> > me, it might be construed to permit cloning if it is done for the

purpose
> of
> > creating human tissue or organs -- which I know you do not want to
permit.
> >
> > Perhaps we can talk about this on Wed. I have a meeting at 10 am
but I
> > should be around the rest of the day.

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Monday, October 29, 2001 5:21 PM
To: Dsida, Michael
Subject: Re: Cloning; analysis

Mike,

Point #1: Okay.

Point #2: No. We do not want embryos to be bought and sold, just like
born
children cannot be bought and sold. When we get to the legislative
council
study, we intend that the adoption of embryos will allow for
reimbursement of
expenses, etc. (I assume there are provisions in the adoption laws
prohibiting
the purchase of a child -- or words to that effect.)

Point #3: The human embryo provisions are more important. They set the
stage
for the human cloning provisions which can be viewed as a subset of the
overall
theme of protecting human embryos.

Mary

"Dsida, Michael" wrote:

> 1. A person can't possess without first acquiring a cloned human
embryo.
> Therefore, there's no need for a separate prohibition on possession.
>
> 2. Do you want an exception in the purchase or sale prohibition for
cases
> in which a person purchases an embryo from someone who otherwise might
> destroy the embryo, if the purchaser intends to have the embryo
implanted in
> a woman's uterus? (See my s. 940.17 (10).)
>
> 3. Which part of the bill is more important -- the human embryo
provisions
> or the cloning provisions? I have to decide which provisions should
be
> summarized first in the analysis.
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Dsida, Michael
Sent: Tuesday, October 30, 2001 10:31 AM
To: 'mklaver@wrtl.org'
Subject: Findings, etc.

I am not sure what the effect of your "Legislative findings, policy declaration and construction of act" provision will be. In addition, because all such provisions need to be approved by the LRB Chief, I asked Debora Kennedy to review them. She had two concerns:

1. Debora pointed out that the first statement is inaccurate. Common law (such as tort and contract law) regulates the procedures used by the clinic. In addition, certain state statutes and rules may also apply. See, e.g., s. 448.30. This inaccuracy may cause a court to disregard the findings altogether. Debora also informed me that she would advise our chief not to approve the inclusion of this provision.

2. Debora believes that the term "harmful research" in the policy declaration is unclear. Perhaps it should be "research that unnecessarily causes the embryo's death or subjects the embryo to a substantial risk of harm."

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

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Tuesday, October 30, 2001 3:01 PM
To: Dsida, Michael
Subject: Re: Findings, etc.

Mike,

We would be more than happy to amend the proposed language for the findings to accommodate the concerns Debora has raised.

Point #1: We can add appropriate modifiers to make the statement clearer and accurate. For example, we could say "There are no laws in this state [expressly] [specifically] regulating . . ." or "There are no [specific] [particular] laws in this state regulating . . ." We are open to other terms accomplishing the same purpose.

Point #2: Your suggested language would work with one modification: "research that causes the embryo's death or unnecessarily subjects the embryo to a substantial risk of harm."

Hope this is helpful.

Mary

"Dsida, Michael" wrote:

> I am not sure what the effect of your "Legislative findings, policy
> declaration and construction of act" provision will be. In addition,
> because all such provisions need to be approved by the LRB Chief, I
asked
> Debora Kennedy to review them. She had two concerns:
> 1. Debora pointed out that the first statement is inaccurate. Common
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> (such as tort and contract law) regulates the procedures used by the
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> 448.30. This inaccuracy may cause a court to disregard the findings
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> declaration is unclear. Perhaps it should be "research that
unnecessarily
> causes the embryo's death or subjects the embryo to a substantial risk
of
> harm."
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Mary Klaver [mklaver@wrti.org]
Sent: Tuesday, October 30, 2001 3:25 PM
To: Dsida, Michael
Subject: Re: Cloning sub. (4)

Mike,

Not being a scientist, I cannot readily give examples for the exception.
If you
feel that strongly, it can be omitted for now. Be aware, though, that it
will
come up in debate and we will probably have to add it back in as an
amendment.

Mary

"Dsida, Michael" wrote:

> I would like to try to accommodate you here, as I have elsewhere, but
I
> still can't come up with a single act, process or procedure that would
be
> inappropriately affected by the bill if sub. (4) were not included.
(Dr.
> Prentice may know the scientific and ethical issues involved here, but
that
> doesn't necessarily mean that the language that he chooses is
appropriate.)
> However important the prohibition may be, the only thing that s.
146.347
> does is PROHIBIT certain conduct. Nothing that is not prohibited by
that
> section is affected in any other way.
>

> -----Original Message-----
> From: Mary Klaver [mailto:mklaver@wrtl.org]
> Sent: Monday, October 29, 2001 11:42 AM
> To: Dsida, Michael
> Subject: Re: Cloning
>
> Mike,
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> As I said on the phone, we are trusting scientists like Dr. Prentice
on this
> one. As long as a human embryo is not created, by any means, the
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> is
> ethical and needed to address valid research.
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> -----
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> > I'm still puzzled on this one. How can human tissue be created
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> >
> > -----Original Message-----
> > From: Mary Klaver [mailto:mklaver@wrtl.org]
> > Sent: Wednesday, October 24, 2001 12:27 PM
> > To: Dsida, Michael
> > Subject: Re: Cloning
> >
> > Mike,
> >
> > Dr. Prentice says that sub. (4) was put into the current federal
bill
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embryo.
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> > you know, the exception does not apply to creating a human embryo.
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> > If you need to talk more about this, let me know. I am aware of
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> > of
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> permit.
> > >
> > > Perhaps we can talk about this on Wed. I have a meeting at 10 am
but I
> > > should be around the rest of the day.

Dsida, Michael

From: Mary Klaver [mklaver@wrtl.org]
Sent: Wednesday, October 31, 2001 9:46 AM
To: Dsida, Michael
Subject: Re: More questions

Mike,

We think you make a valid point. It would also apply to your sub. (3).
however,
we would still need sub. (3) and (4) for the transfer language.

Mary

"Dsida, Michael" wrote:

> Sometimes reading an analysis will help me identify other problems or
> issues. Here's one more:
>
> Section 940.17 (5) of the /P2 draft prohibits certain transfers,
purchases,
> or sales. Since purchases and sales of all types will already be
covered by
> a new provision, should I delete the "purchases or sells" reference in
what
> was sub. (5)?
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Dsida, Michael
Sent: Wednesday, November 21, 2001 2:50 PM
To: Dsida, Michael
Subject: FW: cloning provisions

-----Original Message-----

From: Dsida, Michael
Sent: Tuesday, October 23, 2001 2:38 PM
To: 'Mary Klaver'
Subject: RE: cloning provisions

on the same note, since an oocyte is immature, is the phrase "fertilized or unfertilized" necessary in the definition of "human cloning"? At the least, you should get rid of "fertilized or", since an oocyte can't be fertilized... or can it?

Can you check with Prentice on this and the previous email?

Dsida, Michael

From: Dsida, Michael
Sent: Tuesday, October 23, 2001 2:35 PM
To: 'Mary Klaver'
Subject: RE: cloning provisions

but I presume that "oocyte" in your definition of asexual reproduction should be replaced by "ovum" or "egg cell"

-----Original Message-----

From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Monday, October 22, 2001 3:41 PM
To: Dsida, Michael
Subject: Re: cloning provisions

Mike,

As per our conversation today, based on my consultation with Dr. David Prentice, the term "asexual reproduction" will remain in the definition of human cloning.

Also, Dr. Prentice says that "oocyte" is the correct term to use, not "ovum" because procedure this is done at the oocyte stage.

Mary

"Dsida, Michael" wrote:

1. I may be missing something, but I still don't think that you have answered my question. I'll try it another way -- is it possible to "introduc[e] 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" without it being "asexual reproduction"?

2. The term "oocyte" is often (and perhaps generally) defined to mean an immature ovum. It probably makes more sense to use the term "ovum."

-----Original Message-----

From: Mary Klaver [<<mailto:mklaver@wrtl.org>>]

Sent: Wednesday, October 17, 2001 11:21 AM

To: Dsida, Michael

Subject: Re: cloning provisions

Mike,

It is extremely important that the term "asexual reproduction" be used.

Cloning

is a form of "reproduction" and that is an essential part of the definition.

This distinguishes cloning from other procedures that have nothing to do with

reproduction.

It is also essential to designate this as an "asexual" form of reproduction because that distinguishes it from sexual reproduction. Please note that this

definition only describes one form of cloning. For example, artificial twinning

at the 4 to 8 embryonic cell stage is another form of cloning and that is not

prohibited by this legislation. This later form of cloning is sexual reproduction since, at this point in time, it is always initiated by the union

of a sperm and egg.

Mary

"Dsida, Michael" wrote:

> I think there was still at least one thing that you need to address: the use

> of the term "asexual reproduction." When we talked last, I told you that

> there was no need to use it. You said that you were going to check with

> your expert.

>

> Mike Dsida

> Legislative Reference Bureau

> 608/266-9867

> michael.dsida@state.legis.wi.us

Dsida, Michael

From: Dsida, Michael
Sent: Tuesday, October 30, 2001 2:04 PM
To: 'Mary Klaver'
Subject: RE: Cloning sub. (4)

I would like to try to accommodate you here, as I have elsewhere, but I still can't come up with a single act, process or procedure that would be inappropriately affected by the bill if sub. (4) were not included. (Dr. Prentice may know the scientific and ethical issues involved here, but that doesn't necessarily mean that the language that he chooses is appropriate.) However important the prohibition may be, the only thing that s. 146.347 does is PROHIBIT certain conduct. Nothing that is not prohibited by that section is affected in any other way.

-----Original Message-----

From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Monday, October 29, 2001 11:42 AM
To: Dsida, Michael
Subject: Re: Cloning

Mike,

As I said on the phone, we are trusting scientists like Dr. Prentice on this one. As long as a human embryo is not created, by any means, the exception is ethical and needed to address valid research.

Mary

"Dsida, Michael" wrote:

> I'm still puzzled on this one. How can human tissue be created using
> a
> human oocyte without the process creating an embryo?
>
> -----Original Message-----
> From: Mary Klaver [mailto:mklaver@wrtl.org]
> Sent: Wednesday, October 24, 2001 12:27 PM
> To: Dsida, Michael
> Subject: Re: Cloning
>
> Mike,
>
> Dr. Prentice says that sub. (4) was put into the current federal bill
> banning
> cloning because the previous bill did not have this exception and
> there were
> valid scientific objections that, without this exception, the bill
> could
> prohibit valuable and ethical scientific research. He says that
> creating
> human
> tissue or organs can be ethical if it does not involve creating an
> embryo.
> As
> you know, the exception does not apply to creating a human embryo.
>
> If you need to talk more about this, let me know. I am aware of

research
> where
> they are trying to create human organs, such as a bladder, using human
> tissue
> and a mold. There is no ethical problem with this.
>
> Mary
>
> -----
> "Dsida, Michael" wrote:
>
> > We talked briefly a couple of weeks ago about your sub. (4). I'm
still
> not
> > sure why it is necessary. In fact, if I use the language that you
> provided
> > me, it might be construed to permit cloning if it is done for the
purpose
> of
> > creating human tissue or organs -- which I know you do not want to
permit.
> >
> > Perhaps we can talk about this on Wed. I have a meeting at 10 am
but I
> > should be around the rest of the day.

Dsida, Michael

From: Dsida, Michael
Sent: Wednesday, October 31, 2001 9:51 AM
To: 'Mary Klaver'
Subject: RE: More questions

You are right. I would keep the transfer language.

-----Original Message-----
From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Wednesday, October 31, 2001 9:46 AM
To: Dsida, Michael
Subject: Re: More questions

Mike,

We think you make a valid point. It would also apply to your sub. (3).
however,
we would still need sub. (3) and (4) for the transfer language.

Mary

"Dsida, Michael" wrote:

> Sometimes reading an analysis will help me identify other problems or
> issues. Here's one more:
>
> Section 940.17 (5) of the /P2 draft prohibits certain transfers,
> purchases,
> or sales. Since purchases and sales of all types will already be
covered by
> a new provision, should I delete the "purchases or sells" reference in
what
> was sub. (5)?
>

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

Dsida, Michael

From: Dsida, Michael
Sent: Wednesday, November 07, 2001 1:39 PM
To: 'Mary Klaver'
Subject: RE: You refer to "infertility treatments" in your findings

-----Original Message-----

From: Mary Klaver [mailto:mklaver@wrtl.org]
Sent: Wednesday, November 07, 2001 1:29 PM
To: Dsida, Michael
Subject: Re: You refer to "infertility treatments" in your findings

Mike,

We have to get the word "clinic" in there somehow, because that is the entity that enters into the contracts and is responsible for the safekeeping of the embryos. We were thinking the phrase "clinic providing assisted reproductive services" would be the most accurate.

That's what I planned on using with the first reference. Subsequent references are to "assisted reproductive services clinics."

Maybe you could define "fertility clinic" to mean this, if the length of the phrase is truly a problem. The word "infertility" does not work because not all clients are infertile.

Assisted reproductive services accurately describes what the clinic does, but it does not describe the entity.

Mary

"Dsida, Michael" wrote:

> Should that be replaced with "assistive repro services"?
>
> Mike Dsida
> Legislative Reference Bureau
> 608/266-9867
> michael.dsida@state.legis.wi.us

Barman, Mike

From: Barman, Mike
Sent: Monday, November 26, 2001 8:47 AM
To: Freese, Steve
Subject: LRB-2888/2 (attached) (requested by Rob)



01-2888/2

Basford, Sarah

From: Basford, Sarah
Sent: Wednesday, November 28, 2001 9:06 AM
To: Pirlot, R.J.
Subject: LRB -2888/2 (attached)



01-2888/2

This is sent to you per Terri from Rep. Freese's office.

Sarah Basford
Program Assistant
State of Wisconsin
Legislative Reference Bureau
PH: (608) 266-3561/FAX: (608) 264-6948
sarah.basford@legis.state.wi.us <<mailto:sarah.basford@legis.state.wi.us>>



State of Wisconsin
2001 - 2002 LEGISLATURE

LRB-2888/2
MGD&GMM:jld:pg

2001 BILL

3

Soon

Regen

1 AN ACT to create 146.347 and 940.17 of the statutes; relating to: intentionally
2 causing the death of an in vitro human embryo, nontherapeutic research
3 involving an in vitro human embryo, the use of cells or tissue derived from an
4 in vitro human embryo, the purchase or sale of in vitro human embryos,
5 requesting the joint legislative council to conduct a study on how to reduce the
6 number of in vitro human embryos created by assisted reproductive services
7 clinics and how to facilitate the adoption of unused in vitro human embryos, and
8 human cloning and providing penalties.

Analysis by the Legislative Reference Bureau

Prohibitions relating to in vitro human embryos

Through a number of separate provisions, current law prohibits causing the death of an unborn child, other than through a legally authorized induced abortion. The penalties applicable to these prohibitions vary. For example, a person who intentionally causes the death of an unborn child may be sentenced to life imprisonment, while a person who causes the death of an unborn child by the negligent operation or handling of a vehicle may be fined not more than \$10,000 or imprisoned for not more than five years or both. Current law also prohibits a person from intentionally performing an abortion after the fetus or unborn child reaches

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viability, as determined by the reasonable medical judgment of the woman's attending physician. A person who violates this prohibition may be fined not more than \$10,000 or imprisoned for not more than five years or both.

Under this bill, no person may do any of the following: 1) intentionally cause the death of an in vitro human embryo; 2) intentionally subject an in vitro human embryo to a substantial risk of injury or death for the purpose of "nontherapeutic human embryo research," which is defined as research involving an in vitro human embryo that is not intended to help protect or preserve the life or protect, preserve, or promote the health of the in vitro human embryo; 3) create an in vitro human embryo outside of a woman's body for the purpose of nontherapeutic human embryo research; 4) use, transfer, or acquire any living cell or tissue that the actor knows was obtained through conduct that is described in the preceding three prohibitions; 5) with the knowledge that any person will intentionally cause the death of the in vitro human embryo, transfer an in vitro human embryo to another person; 6) with the knowledge that the in vitro human embryo will intentionally be subjected to a substantial risk of injury or death for the purpose of nontherapeutic human embryo research, transfer an in vitro human embryo to another person; or 7) purchasing or selling an in vitro human embryo. The bill defines "in vitro human embryo" as a human embryo living outside of a woman's body, regardless of how the embryo is derived and regardless of whether the embryo has undergone cryopreservation (freezing), which is a process regularly used by clinics that provide assisted reproductive services (clinics) to preserve embryos for implantation at a later date in a woman's uterus. A person who violates one of the prohibitions contained in the bill relating to in vitro human embryos may be fined not more than \$10,000 or imprisoned for not more than five years or both.

The prohibitions described in the preceding paragraph apply regardless of whether there is any contract currently in effect relating to the conduct involved. In addition, the fourth prohibition applies even if the conduct from which the cells or tissues were derived has already occurred or occurs outside of the state. On the other hand, the bill excepts the following conduct from all of the prohibitions described in the preceding paragraph, other than the prohibition on purchasing or selling an in vitro human embryo: 1) cryopreserving an in vitro human embryo, if the actor uses all available means to protect and preserve the life and protect, preserve, and promote the health of the embryo (the "cryopreservation exception"); 2) thawing an in vitro human embryo, if the thawing is done to facilitate a live birth and if the actor uses all available means to protect and preserve the life and protect, preserve, and promote the health of the embryo (the "thawing exception"); 3) implanting or attempting to implant an in vitro human embryo in a woman's uterus, if the embryo was created by fertilization and if the implantation or attempted implantation is done for the purpose of facilitating a live birth (the "implantation exception"); and 4) transferring or acquiring an in vitro human embryo, if the actor intends that the embryo be cryopreserved, thawed, or implanted consistent with the cryopreservation, thawing, or implantation exceptions. The prohibitions listed in the preceding paragraph — again, excluding the prohibition on purchasing or selling

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a human embryo — also do not apply to the donor of any sperm cell or egg cell from which an in vitro human embryo is derived.

Human cloning

This bill also prohibits human cloning; attempting to perform human cloning; or transferring or acquiring a human embryo produced by human cloning or any product derived from such an embryo. The bill defines “human cloning” as introducing nuclear material from one or more human somatic cells (a human cell with a complete set of chromosomes) into an egg cell, the nuclear material of which has been removed or inactivated, so as to produce a living organism, including a human embryo, having genetic material that is virtually identical to the genetic material of an existing or previously existing human organism. A person who violates one of the prohibitions against human cloning shall be fined not more than \$10,000 and may be imprisoned for not more than ten years. A person who violates one of the cloning prohibitions is also subject to a civil monetary penalty (a forfeiture) of \$1,000,000 if the person derives a pecuniary gain from the violation, unless the person’s gross pecuniary gain exceeds \$500,000. In that case, the amount of the forfeiture must be between \$1,000,000 and twice the amount of the person’s gross pecuniary gain.

Legislative council study relating to in vitro human embryos

The bill requires the joint legislative council to study the issues relating to the adoption of in vitro human embryos and the regulation of clinics and to prepare proposed legislation with a view toward accomplishing all of the following: 1) reducing the number of in vitro human embryos created by clinics to a reasonable number needed for reproductive purposes; 2) facilitating the adoption and implantation of unused in vitro human embryos created by clinics; 3) providing a procedure by which those unused in vitro human embryos may be relinquished by their genetic parents for adoption and implantation; and 4) requiring that persons receiving assisted reproductive services at clinics be informed of the option of relinquishing their unused in vitro human embryos for adoption and implantation. The joint legislative council shall include in its study a study of current law relating to the adoption of children and other current law that might be relevant to the adoption of in vitro human embryos with a view toward modeling the proposed legislation relating to the adoption of in vitro human embryos after that current law. The joint legislative council must report its findings, conclusions, and recommendations to the legislature by January 1, 2003.

For further information see the *state and local* fiscal estimate, which will be printed as an appendix to this bill.

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

- 1 **SECTION 1.** 146.347 of the statutes is created to read:
- 2 **146.347 Human cloning.** (1) In this section:

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

3 (b) "Enucleated oocyte" means a fertilized or unfertilized oocyte, the nuclear
4 material of which has been removed or inactivated.

5 (c) "Human cloning" means asexual reproduction accomplished by introducing
6 nuclear material from one or more human somatic cells into an enucleated oocyte so
7 as to produce a living organism having genetic material that is virtually identical to
8 the genetic material of an existing or previously existing human organism.

9 (d) "Human embryo" has the meaning given in s. 940.17 (2) (a).

10 (e) "Living organism" includes a human embryo.

11 (f) "Somatic cell" means a cell that has a complete set of chromosomes and that
12 is obtained or derived from a living or dead human organism at any stage of
13 development.

14 (2) (a) No person may knowingly do any of the following:

15 1. Perform or attempt to perform human cloning.

16 2. Transfer or acquire for any purpose a human embryo produced by human
17 cloning or ^{cell, tissue, or} any product derived from such an embryo.

18 (b) If a person violates par. (a) by creating, attempting to create, transferring,
19 or acquiring more than one human embryo, the creation, attempted creation,
20 transfer, or acquisition of each individual human embryo constitutes a separate
21 violation.

22 (3) Any person who violates sub. (2) shall be fined not more than \$10,000 and
23 may be imprisoned for not more than 10 years.

24 (4) (a) Except as provided in par. (b), any person who violates sub. (2) and who
25 derives a pecuniary gain from the violation shall be required to forfeit \$1,000,000.

BILL

1 (b) Any person who violates sub. (2) and who derives a pecuniary gain of more
2 than \$500,000 from the violation shall be required to forfeit not less than \$1,000,000
3 nor more than an amount equal to twice the gross amount of the person's pecuniary
4 gain.

5 **SECTION 2.** 940.17[✓] of the statutes is created to read:

6 **940.17 In vitro human embryos.** (1) (a) *Legislative findings.* The
7 legislature finds that:

8 1. There are no laws in this state specifically regulating the procedures used
9 at a clinic that provides assisted reproductive services for infertile couples, other
10 couples, or individuals using the clinic's services.

11 2. The procedures used at an assisted reproductive services clinic in this state
12 are governed by a private contract between the clinic and the couple or individual
13 using the clinic's services.

14 3. It is quite common for an assisted reproductive services clinic to create more
15 human embryos than the number needed to reasonably meet the reproductive
16 purposes of the couples or individuals using its services.

17 4. The private contract usually contains a provision regarding the disposition
18 of human embryos not used by the couple or individual. Often this provision permits
19 the couple or individual to choose to have the unused human embryos destroyed or
20 donated for research.

21 5. It is also possible for the couple or individual to choose to have the unused
22 human embryos donated to another couple or individual for implantation into the
23 woman's uterus for the purpose of having a child. This option is often part of the
24 private contract.

BILL

1 6. The donation of unused human embryos for adoption by another couple or
2 individual is a positive, life-affirming alternative to having the embryos destroyed
3 or donated for research.

4 7. A substantial number of citizens have objections to the destruction of any
5 human embryo or the use of any human embryo for nontherapeutic research that
6 subjects the embryo to a substantial risk of injury or death.

7 (b) *Policy declaration.* It is declared to be the public policy of this state that a
8 human embryo living outside a woman's body should be protected from intentional
9 destruction or research that causes the embryo's death or unnecessarily subjects the
10 embryo to a substantial risk of harm. The legislature reaffirms the positive value
11 of human life at all stages of development and promotes the adoption of unused
12 human embryos. A human embryo is a human being at an early stage of
13 development, not an item of property.

14 (c) *Construction of act.* The following statutory provisions shall be broadly
15 construed to effect the objectives set forth in this section.

16 (2) In this section:

17 (a) "Human embryo" means a human organism derived by fertilization,
18 parthenogenesis, cloning, or any other means from one or more human gametes or
19 human diploid cells. "Human embryo" includes a zygote but does not include a
20 human organism at or beyond the stage of development at which the major body
21 structures are present.

22 (b) "In vitro human embryo" means a human embryo, whether cryopreserved
23 or not, living outside of a woman's body.

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1 (c) “Nontherapeutic human embryo research” means research involving an in
2 vitro human embryo that is not intended to help protect or preserve the life or protect,
3 preserve, or promote the health of the in vitro human embryo.

4 (d) “Research” means a systematic investigation, including research
5 development, testing, and evaluation, designed to develop or contribute to
6 generalizable knowledge.

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

9 (4) Whoever, with the knowledge that any person will intentionally cause the
10 death of the in vitro human embryo, transfers an in vitro human embryo to any
11 person is guilty of a Class E felony.

12 (5) Whoever intentionally subjects an in vitro human embryo to a substantial
13 risk of injury or death for the purpose of nontherapeutic human embryo research is
14 guilty of a Class E felony.

15 (6) Whoever, with the knowledge that the in vitro human embryo will
16 intentionally be subjected to a substantial risk of injury or death for the purpose of
17 nontherapeutic human embryo research, transfers an in vitro human embryo to
18 another person is guilty of a Class E felony.

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

23 (8) Whoever uses, transfers, or acquires any living cell or tissue that the actor
24 knows was obtained through conduct that is described under sub. (3), (5), or (7) is
25 guilty of a Class E felony. This subsection does not apply to a person who transfers

BILL

1 or acquires an in vitro human embryo for the purpose of having it implanted in a
2 woman's uterus.

The embryo ✓

3 (9) Subsections (3) to (8) do not apply to any of the following:

4 (a) Cryopreserving an in vitro human embryo if the actor uses all available
5 means to protect and preserve the life and protect, preserve, and promote the health
6 of the embryo.

7 (b) Thawing an in vitro human embryo if the thawing is done for the purpose
8 of facilitating the implantation of the embryo in a woman's uterus consistent with
9 the criteria listed in par. (c) and if the actor uses all available means to protect and
10 preserve the life and protect, preserve, and promote the health of the embryo.

11 (c) Implanting or attempting to implant an in vitro human embryo in a woman's
12 uterus if the embryo was created by fertilization, if the implantation or attempted
13 implantation is done for the purpose of human reproduction, and if the woman
14 intends to carry any resultant pregnancy to term.

15 (d) The transfer or acquisition of an in vitro human embryo if the actor intends
16 that the embryo be cryopreserved consistent with the criteria listed in par. (a),
17 thawed consistent with the criteria listed in par. (b), or implanted in a woman's
18 uterus consistent with the criteria listed in par. (c).

19 (e) The donor of any gamete from which an in vitro human embryo is derived.

20 (10) Whoever purchases or sells an in vitro human embryo is guilty of a Class
21 E felony.

22 **SECTION 3. Nonstatutory provisions.**

23 (1) STUDY OF ADOPTION OF EMBRYOS AND REGULATION OF ASSISTED REPRODUCTIVE
24 SERVICES CLINICS.

25 (a) In this subsection:

BILL

1 1. “Clinic” means a clinic that provides assisted reproductive services.

2 2. “In vitro human embryo” has the meaning given in section 940.17 (2) (b) of
3 the statutes.

4 (b) The joint legislative council shall study the issues relating to the adoption
5 of in vitro human embryos and the regulation of clinics and shall prepare proposed
6 legislation with a view toward accomplishing all of the following:

7 1. Reducing the number of in vitro human embryos created by clinics to a
8 reasonable number needed for reproductive purposes.

9 2. Facilitating the adoption and implantation of unused in vitro human
10 embryos created by clinics.

11 3. Providing a procedure by which those unused in vitro human embryos may
12 be relinquished by their genetic parents for adoption and implantation.

13 4. Requiring that persons receiving assisted reproductive services at clinics be
14 informed of the option of relinquishing their unused in vitro human embryos for
15 adoption and implantation.

16 (c) The joint legislative council shall include in the study a study of current law
17 relating to the adoption of children and other current law that might be relevant to
18 the adoption of in vitro human embryos with a view toward modeling the proposed
19 legislation relating to the adoption of in vitro human embryos after that current law.

20 (d) The joint legislative council shall report its findings, conclusions, and
21 recommendations to the legislature in the manner provided under section 13.172 (2)
22 of the statutes by January 1, 2003.

23 **SECTION 4. Initial applicability.**

24 (1) The treatment of section 940.17 (3) to (7) and (10) of the statutes first applies
25 to offenses committed on the effective date of this subsection.

