

03



---

Office of the Circuit Executive  
U.S. Court of Appeals for the Ninth Circuit

---

Case Name:

**FORBES V NAPOLITANO**

Case Number:

**99-17372**

Date Filed:

**04/11/01**

FOR PUBLICATION

UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUITFRED FORBES; MARGARET BOHN;  
JOHN L. SUMMERS; ANN S.  
ANDERSON, STUART R. SNIDER;  
GEORGE MELCHER, JR.; CHRISTOPHER  
TISCH; PLANNED PARENTHOODOF

CENTRALAND NORTHERN ARIZONA,

INC.; ROBERT TAMIS,  
Plaintiffs-Appellees,

v.

JANET NAPOLITANO, in her capacity

as Attorney General, State of  
Arizona; STEPHEN NEELY, in his  
capacity as County Attorney, Pima  
County, Arizona,  
Defendants-Appellants.Appeal from the United States District Court  
for the District of Arizona  
William D. Browning, District Judge, PresidingArgued and Submitted  
October 3, 2000--San Francisco, CaliforniaFiled December 29, 2000  
Order Amending Opinion Filed April 11, 2001Before: Joseph T. Sneed, Mary M. Schroeder, and  
Richard A. Paez, Circuit Judges.Opinion by Judge Schroeder;  
Concurrence by Judge Sneed

No. 99-17372

D.C. No.  
CV-96-00288-WDB

ORDER AND

AMENDED

OPINION

4503

COUNSEL

Bebe J. Anderson, The Center for Reproductive Law & Pol-  
icy, New York, N.Y. and Michael Owen Miller, Miller Smith  
LLP, Tucson, Arizona for the plaintiffs-appellees.

Charles R. Pyle, Assistant Attorney General, Tucson, Arizona, for the defendants-appellants.

---

ORDER

Appellants have filed a petition for rehearing that pertains to one sentence of the court's opinion. The sentence reads: "But where a statute criminalizes conduct, the law may not be impermissibly vague in any of its applications." *Forbes v. Napolitano*, No. 99-17372, slip op. at 16672 (9th Cir. Dec. 29, 2000). The petition for rehearing is GRANTED to the extent

4506

that the sentence in question is deleted, and the following substituted: "But where a statute criminalizes conduct, the law may be invalidated on vagueness grounds even if it could conceivably have some valid application."

---

OPINION

SCHROEDER, Circuit Judge

Plaintiffs challenge the constitutionality of an Arizona statute that criminalizes any medical "experimentation" or "investigation" involving fetal tissue from induced abortions unless necessary to perform a "routine pathological examination" or to diagnose a maternal or fetal condition that prompted the abortion. The plaintiffs include individuals suffering from Parkinson's disease who because of the statute are unable in Arizona to receive transplants of fetal brain tissue that many medical experts believe hold out promise for eventual amelioration or treatment of the disease. Plaintiffs also include doctors in Arizona who fear possible criminal prosecution if they provide services to their patients that the doctors would like to provide.

The district court held on summary judgment that the statutes are unconstitutionally vague, and permanently enjoined their enforcement. It did not reach various other theories presented in plaintiffs' complaint for invalidation of the statute. In so ruling the district court followed the holdings of three other circuits that considered similar statutes and held them all unconstitutionally vague. See *Jane L. v. Bangerter*, 61 F.3d 1493, 1499-1502 (10th Cir. 1995), Rev'd and remanded on other grounds sub. nom., *Leavitt v. Jane L.*, 518 U.S. 137 (1996); *Margaret S. v. Edwards*, 794 F.2d 994, 998-99 (5th Cir. 1986); *Lifchez v. Hartigan*, 735 F.Supp. 1361, 1363-76 (N.D.Ill.), aff'd mem., 914 F.3d 260 (7th Cir. 1990). In this appeal by the state, we affirm the district court holding. Its

4507

decision is published at 71 F.Supp. 2d 1015 (D. Ariz. 1999). We do not repeat the procedural background.

The principal statute with which we are concerned is A.R.S. § 36-2302, subpart (A). It provides:

A person shall not knowingly use any human fetus or embryo, living or dead, or any parts, organs, or fluids of any such fetus or embryo resulting from an

induced abortion in any manner for any medical experimentation or scientific or medical investigation purposes except as is strictly necessary to diagnose a disease or condition in the mother of the fetus or embryo and only if the abortion was performed because of such disease or condition.

Section 36-2302, subpart (C) provides an exception:

This section shall not prohibit any routine pathological examinations conducted by a medical examiner or hospital laboratory provided such pathological examination is not a part of or in any way related to any medical or scientific experimentation.

Thus the statute does not outlaw all use of fetal tissue derived from induced abortions. Instead it generally outlaws the use of such tissue for experimentation, subject to certain exceptions.

Persons violating Section 36-2302 commit a class 5 felony, a crime punishable by one-and-a-half years in prison, and face fines up to \$150,000, see A.R.S. S 36-2303. Doctors found to have violated the statute also face censure, probation, suspension of license, revocation of license, or any combination of these. See A.R.S. SS 13-701, 13-801, 32-1451, 32-1844.

In their complaint and supporting affidavits and depositions, the plaintiff physicians explain the types of procedures

4508

involving the use of fetal tissue that they would use, were it not for the statute. They believe these procedures would fulfill their obligations to promote the health of their patients, and would also advance medical knowledge. Dr. Snider, one of the plaintiffs in this case, stated in his deposition that the statute prevented him from prescribing and managing a course of treatment for his Parkinson's disease patients that includes fetal tissue transplantation. Another plaintiff, Dr. Melcher, submitted an affidavit indicating that fetal tissue transplantation holds considerable promise for some of his Parkinson's disease patients.

Fetal tissue is also useful in diagnosing and testing for fertility problems. One of the plaintiff physicians who specializes in fertility treatments, Dr. Tamis, was the target of a potentially criminal investigation some years ago when he endeavored to study the effects on the fetus of a drug ingested by pregnant women before an induced abortion was performed. The study was to determine whether the drug passed through the placental wall. Although the state eventually dismissed the grand jury subpoenas issued to Dr. Tamis, he is still uncertain about the proper interpretation of the statute.

Other physicians and expert witnesses explain that many established treatments for illness have developed from fetal research and experimentation, including the polio vaccine. They point out the difficulties of knowing at what stage or point in time "experiments" become recognized as "treatment." They also point out that the terms "investigation" and "routine examination" are fundamentally ambiguous. In particular, the experts highlight doctors' lack of consensus about what procedures are purely experimental. In the view of one expert submitted to the district court, virtually every procedure with a therapeutic objective is experimental to some extent.

[1] The due process clause of the Fourteenth Amendment guarantees individuals the right to fair notice of whether their

4509

conduct is prohibited by law. *Colautti v. Franklin*, 439 U.S. 379, 390-91, 99 S.Ct. 675, 58 L. Ed. 2d 596 (1979), citing *United States v. Harriss*, 347 U.S. 612, 617, 74 S.Ct. 808, 98 L. Ed. 989 (1954). Although only constructive rather than actual notice is required, individuals must be given a reasonable opportunity to discern whether their conduct is proscribed so they can choose whether or not to comply with the law. *Giaccio v. Pennsylvania*, 382 U.S. 399, 402-03, 86 S.Ct. 518, 15 L. Ed. 2d 447 (1966). Statutes need not be written with "mathematical" precision, nor can they be thus written. *Grayned v. City of Rockford*, 408 U.S. 104, 108-09, 92 S.Ct. 2294, 33 L. Ed. 2d 222 (1972). But they must be intelligible, defining a "core" of proscribed conduct that allows people to understand whether their actions will result in adverse consequences. *Planned Parenthood v. Arizona*, 718 F.3d 938, 947 (9th Cir. 1983) (holding that a statute is void for vagueness if persons of common intelligence must necessarily guess at its meaning).

[2] If a statute subjects transgressors to criminal penalties, as this one does, vagueness review is even more exacting. See *Kolender v. Lawson*, 461 U.S. 352, 357, 103 S.Ct. 1855, 75 L. Ed. 2d 903 (1983) (holding that penal statutes must define criminal offenses with "sufficient definiteness," and "in a manner that does not encourage arbitrary and discriminatory enforcement"); *Winters v. New York*, 333 U.S. 507, 515, 68 S.Ct. 665, 92 L. Ed. 840 (1948) (holding that where a statute imposes criminal penalties, the standard of certainty involved in vagueness review is higher). In addition to defining a core of proscribed behavior to give people constructive notice of the law, a criminal statute must provide standards to prevent arbitrary enforcement. *City of Chicago v. Morales*, 527 U.S. 41, 52, 119 S.Ct. 1849, 144 L. Ed. 2d 67 (1999). Without such standards, a statute would be impermissibly vague even if it did not reach a substantial amount of constitutionally protected conduct, because it would subject people to the risk of arbitrary deprivation of their liberty. *Id.* Regardless of what type of conduct the criminal statute targets, the arbitrary

4510

deprivation of liberty is itself offensive to the Constitution's due process guarantee. *Smith v. Goguen*, 415 U.S. 566, 575, 94 S.Ct. 2294, 33 L. Ed. 2d 222 (1972).

[3] The district court correctly applied these principles in this case. It recognized that a challenged statute enjoys a presumption of constitutionality. *Baggett v. Bullitt*, 377 U.S. 360, 372, 84 S.Ct. 1316, 12 L. Ed. 2d 377 (1964). But where a statute criminalizes conduct, the law may be invalidated on vagueness grounds even if it could conceivably have some valid application. *Kolender*, 461 U.S. at 357, 103 S.Ct. 1855; *Jane L.*, 61 F.3d at 1500.

[4] The district court concluded that these criminal statutes fail to establish any "core" of unquestionably prohibited activities. It explained this conclusion with reference to three of the statute's key terms: "experimentation," "investigation" and "routine," none of which the statute defines. With respect to "experimentation," the district court pointed out two difficulties. First, the term is ambiguous, lacking a precise definition to focus application of the statute. *Forbes*, 71 F.Supp. 2d

at 1019, citing *Jane L.*, 61 F.3d at 1500. Second, the distinction between experimentation and treatment changes over time. *Id.*, citing *Margaret S.*, 794 F.3d at 999. The district court also found the term "investigation" to be ambiguous, since common definitions of the term can encompass pure research as well as more common, therapeutic medical techniques. *Id.* In examining the statute's use of "routine pathological examinations" to carve out an exception to criminal liability, the district court determined that the term "routine" was also ambiguous. *Id.*, at 1020. The statute itself does not define "routine," see A.R.S. S 36-2302, nor does the medical community provide any official standards to help. The district court was thus concerned that any examination of post-abortion fetal tissue beyond simply mounting fetal tissue on a slide could expose doctors to criminal liability.

The district court relied upon the decisions of our sister circuits and held they applied to the contentions of the plaintiffs

4511

in this case. See *Jane L.*, 61 F.3d at 1500 (finding that a Utah statute prohibiting "experimentation" on "live unborn children" was void for vagueness); *Margaret S.*, 794 F.2d at 998 (holding that a Louisiana statute prohibiting "experimentation" on unborn child or post-abortion fetal tissue also was vague to the point of being unconstitutional, in part because it did not distinguish between medical experiments and medical tests); *Lifchez*, 735 F.Supp. at 1363 (holding unconstitutionally vague an Illinois statute that prohibited "experimentation" on human fetuses unless such activity was "therapeutic" to the fetus).

The state in this appeal endeavors to distinguish the statutes involved in those cases on the ground that those statutes were not limited to fetal experimentation and investigation occurring after abortions. The vagueness of the words when applied to medical procedures is exactly the same, however, regardless of whether the fetus has been aborted or not.

The state also contends that the statute is clear, because a doctor can avoid violating the statute by performing no tests or other procedure on fetal tissue from induced abortions. This argument ignores the exceptions built into the statute that creates the confusion. For example, it is not clear if a doctor would run afoul of the statute if called upon to perform a DNA test involving post-abortion fetal tissue to test for paternity, or to diagnose a medical condition unrelated to the patient's decision to have an abortion.

Under both the Arizona statute and the statutes invalidated in our sister circuits, doctors might undertake a procedure involving fetal tissue that they consider to be primarily therapeutic, perhaps even routine, but the state might consider such a procedure illegal under the statute. The distinction between experiment and treatment in the use of fetal tissue is indeterminate, regardless of whether the tissue is obtained after an induced abortion. That distinction is not clarified by the statute's scienter requirement. See A.R.S. S 36-2302 (providing

4512

that a person shall not "knowingly use any human fetus . . . for any medical experimentation . . ." ). A doctor might knowingly use fetal tissue from an induced abortion for a test that the physician considers primarily in furtherance of a patient's medical interest, but which the state considers to be impermissible. Neither the statute nor the record before the district

court provide any clues about how the statute would be applied to such a test.

[5] A criminal statute such as A.R.S.S 36-2302 that prohibits medical experimentation but provides no guidance as to where the state should draw the line between experiment and treatment gives doctors no constructive notice, and gives police, prosecutors, juries, and judges no standards to focus the statute's reach. The dearth of notice and standards for enforcement arising from the ambiguity of the words "experimentation," "investigation," and "routine" thus renders the statute unconstitutionally vague. Kolender, 461 U.S. at 358, 103 S.Ct. 1855, Papachristou v. City of Jacksonville, 405 U.S. 156, 162, 92 S.Ct. 839, 31 L. Ed. 2d. 110 (1972).

The state also contends that these particular statutes are not impermissibly vague, at least not in Arizona, because the Arizona physicians in this record do not harbor any uncertainty or disagreement about what procedures they will in fact avoid in light of this statute. This does not mean that the statute has any more clarity than the statutes struck down by other circuits; it does not. This means only that at this particular stage of medical research, the physicians do not disagree about the risks of prosecution they are willing to endure.

The judgment of the district court is AFFIRMED.

4513

SNEED, J., Circuit Judge, concurring:

I agree with the majority's conclusion that Section 36-2302 of the Arizona Revised Statutes is unconstitutional. This section appears to be part of Arizona's regulation of abortion. Following the Supreme Court's decision in *Roe v. Wade*, 410 U.S. 113 (1973), many states enacted statutes designed to regulate or prohibit experimentation on fetuses and fetal tissues. These statutes were frequently incorporated into the states' abortion laws. Often, the statutes applied only to aborted tissue. Similarly, S 36-2302 of the Arizona Revised Statutes appears in Chapter 23 entitled "Protection of Fetus or Embryo," while Chapter 20, entitled "Abortion," sets forth several provisions designed to regulate and curb access to abortion. In determining what question is specifically at issue, "a reviewing court should not confine itself to examining a particular statutory provision in isolation." *FDA v. Brown &*

*Williamson Tobacco Corp.*, 120 S. Ct. 1291, 1300 (2000). Rather, the "words of the statute must be read in their context and with a view to their place in the overall statutory scheme." *Id.* at 1301 (quoting *Davis v. Michigan Dept. of Treasury*, 489 U.S. 803, 809 (1989)). Section 36-2302, with which we are concerned, appears to be consistent with the

---

1 Ark. Stat. Ann. S 20-17-802 (1987); Cal. Health & Safety code S 25965 (1984); Fla. Stat. Ann. S 390.001(6) (1986); Ill. Ann. Stat. ch 38 SS 81-26m 81-32, 81-32.1 (1977 & Supp. 1987); Ind. Code Ann. S 35-1-58.5-6 (1985); Ky. Rev. Stat. Ann. S 436.026 (1985); La. Rev. Stat. Ann. SS 40:1299.35.13 (1988), 14:87.2 (1986); Me. Rev. Stat. Ann. tit. 22. S1593 (1980); Mass. Ann. Laws ch. 112 SS 12J & 12K (1985); Mich. Comp. Laws Ann. SS 333-2685 -2692 (1980); Minn. Stat. Ann. S 145.421-.422 (1988); Mo. Ann. Stat. SS 188.015, .037 (1983); Mont. Code Ann. S 50-20-108(3) (1987); Neb. Rev. Stat. S 28-346 (1985); N.M. Stat. Ann. S 24-9A-3 (1986); N.D. Cent. Code SS 14-02.2-01-02 (1985); Ohio Rev. Code Ann. S 2919.14 (Baldwin 1986); Okla. Stat. Ann. tit. 63, S1-735 (1984); R.I. Gen. Laws SS 11-54-1-2 (1987); S.D. Codified Laws Ann. S34-23A-17 (1986); Tenn. Code Ann S39-4-208 (1982); Utah Code Ann.

S 76-7-310 (1978); Wyo. Stat. S 35-6-115 (1977). Many of these statutes have been declared unconstitutional.

4514

purposes of Chapter 20, and with a statutory scheme that curbs access to abortion.

Roe v. Wade held that the constitutional right to personal privacy encompasses a woman's decision whether or not to terminate her pregnancy. Roe and its progeny established that the pregnant woman has a right to be free from state interference with her choice to have an abortion. These cases do not hold that the State is under an affirmative obligation to ensure access to abortions for all who may desire them. Rather they require that the State refrain from wielding its power and influence in a manner that might burden the pregnant woman's freedom to choose whether to have an abortion.

A prohibition on aborted fetal tissue research could burden the rights of women and couples to make both present and future reproductive choices. Fetal tissue experimentation may aid in the development and continued improvement of techniques and procedures necessary to make such choices.<sup>2</sup> Prohibiting research on aborted fetal tissue could prevent the advancement of important diagnostic techniques, the creation of safer abortion techniques, and the discovery of medical defects that would influence a woman's decision regarding future pregnancies.

Experimentation on aborted fetal tissue may foster the development of reproductive technology that is related to reproductive decisions. Governmental restrictions on reproductive decisions are only justifiable given compelling state interests. *Carey v. Population Services Int'l*, 431 U.S. 678, 688 (1977). The Supreme Court has identified three state interests in regulating abortion: safeguarding the health of the woman; protecting the potential life of the fetus; and regulating the medical profession. None justify Arizona's prohibitions of fetal experimentation.

---

<sup>2</sup> Marilyn J. Clapp, *State Prohibition of Fetal Experimentation and the Fundamental Right of Privacy*, 88 COLUM. L. REV. 1073, 1086 (1988).

4515

[Go to top](#)



PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

THURS  
5 PM

retrieve from hold

✓  
the purchase or sale  
of in vitro human  
embryos,

Regen

1 AN ACT to create 940.17 of the statutes; relating to: intentionally causing the

2 death of an in vitro human embryo, nontherapeutic research ~~undertaken on~~ <sup>involving</sup> an

3 in vitro human embryo, <sup>the</sup> use of cells <sup>or tissue</sup> derived from an in vitro human embryo,

4 requesting the joint legislative council to conduct a study on how to reduce the

5 number of in vitro human embryos that are created by fertility clinics and how

6 to facilitate the adoption of <sup>unused</sup> ~~those~~ in vitro human embryos <sup>and human cloning</sup> ~~that~~ are not used by

7 their female donors, and providing penalties.

**Analysis by the Legislative Reference Bureau**

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

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

INsect  
1/7

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

9 940.17 In vitro human embryos ~~and cells derived from them.~~ <sup>INsect 1/9</sup> (1) In this

10 section:



*derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.*

SECTION 1

*"Human embryo" includes a zygote but does not include a human organism at or beyond the NO*

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

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

2. ~~A multicell human organism that is living outside of a woman's body and that~~

~~has not reached the stage of development at which the major body structures are~~

present.

*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*

(b) "Nontherapeutic human embryo research" means ~~subjecting an~~ in vitro

human embryo to conditions or procedures that are not intended to help promote its

~~development into a born individual.~~

(2) Whoever intentionally causes the death of an in vitro human embryo is

guilty of a Class E felony.

*any person will intentionally cause the death of*

(3) Whoever, with the knowledge that the in vitro human embryo ~~will~~

~~intentionally be destroyed, purchases or sells an in vitro human embryo or transfers~~

~~an in vitro human embryo to another person is guilty of a Class E felony.~~

(4) Whoever intentionally subjects an in vitro human embryo to a substantial

risk of injury or death ~~while engaging in~~ nontherapeutic human embryo research is

guilty of a Class E felony.

*for the purpose of*

(5) Whoever, with the knowledge that the in vitro human embryo will

intentionally be subjected to a substantial risk of injury or death ~~during~~

~~nontherapeutic human embryo research, purchases or sells an in vitro human~~

~~embryo or transfers an in vitro human embryo to another person is guilty of a Class~~

E felony.

(6) Subsections (2) to (5) do not apply if the death of the in vitro human embryo

or the substantial risk of injury to or death of the in vitro human embryo results from

the cryopreservation of the in vitro human embryo and the cryopreservation was

✓ N Sect 216

*or not*

*1*

*1*

*2*

*3*

*4*

*5*

*6*

*7*

*8*

*9*

*10*

*11*

*12*

*13*

*14*

*15*

*16*

*17*

*18*

*19*

*20*

*21*

*22*

*23*

*24*

*25*

(5) STUDY OF ADOPTION OF EMBRYOS  
AND REGULATION OF FERTILITY CLINICS.

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

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

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

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

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

19 **SECTION 2. Nonstatutory provisions.**

(5) JOINT LEGISLATIVE  
COUNCIL STUDY.

20 ~~(1) In this SECTION:~~

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

23 ~~the~~ "in vitro human embryo" has the meaning given in section 940.17 (1) (a) of  
24 the statutes.

Nonstat (#) (a) In this subsection, "in

Insert  
3/18

MC - Does "derived" include...?

a  
a  
b

✓ Insert  
4-5

WMM

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

**SECTION 3. Initial applicability.**

(8)

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

(END)

Insert 4/9 ✓

2001-2002 DRAFTING INSERT  
FROM THE  
LEGISLATIVE REFERENCE BUREAU

LRB-2888/P3ins  
MGD:....kjf

proofed  
10/30

Insert 4/5

LPS-INSERTS OUT OF  
ORDER

1 (b) The joint legislative council is requested to study the issues relating to the  
2 adoption of in vitro human embryos and the regulation of fertility clinics and to  
3 prepare proposed legislation with a view toward accomplishing all of the following:

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

6 2. Facilitating the adoption and implantation of unused in vitro human  
7 embryos created by infertility clinics.

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

10 4. Requiring that persons undergoing fertility treatment be informed of the  
11 option of relinquishing their unused in vitro human embryos for adoption and  
12 implantation.

13 (c) If the joint legislative council conducts the study, it shall include in the study  
14 a study of current law relating to the adoption of children and other current law that  
15 might be relevant to the adoption of in vitro human embryos with a view toward  
16 modeling the proposed legislation relating to the adoption of in vitro human embryos  
17 after that current law.

18 4 (d) (ND)  
(P)

48  
5/1/06

1           **INSERT 1/7**

2           **SECTION 1.** 146.347 of the statutes is created to read:

3           **146.347 Human cloning.** (1) In this section:

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

6           (b) "Denucleated human oocyte" means a fertilized or unfertilized human  
7 oocyte, the nuclear material of which has been removed or inactivated.

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

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

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

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

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

19           1. Perform or attempt to perform human cloning.

20           2. Transfer or acquire for any purpose a human embryo produced by human  
21 cloning or any product derived from such an embryo.

22           (b) If a person violates par. (a) by creating, attempting to create, transferring,  
23 or acquiring more than one human embryo, the creation, attempted creation,

1 transfer, or acquisition of each individual human embryo constitutes a separate  
2 violation.

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

5 INSERT 1/9

6 ~~§~~ (1)

(a) *Legislative findings.* The legislature finds that:

7 1. There are no laws in this state specifically regulating the procedures used  
8 at an infertility clinic that provides infertility treatments for an infertile couple or  
9 other couples using the clinic's services.

10 2. The procedures used at an infertility clinic in this state are governed by a  
11 private contract between the clinic and the couple using the clinic's services.

12 3. It is quite common for an infertility clinic to create more human embryos  
13 than the number needed to reasonably meet the reproductive purposes of the couples  
14 using its services.

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

18 5. It is also possible for the couple to choose to have their unused human  
19 embryos donated to another couple for implantation into the woman's uterus for the  
20 purpose of having a child. This option is often part of the private contract.

21 6. A substantial number of citizens have objections to the destruction of unused  
22 human embryos or the use of these embryos for nontherapeutic research that  
23 subjects them to a substantial risk of injury or death.



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

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

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

13           ¶ (2) (NO  
                  ¶)

14           INSERT 2/6

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

17           INSERT 3/18

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

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

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



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

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

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

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

12 INsert 4/9

13 ~~(9)~~ (9) The treatment of section 940.17 (3) to (7) and (10) of the statutes first applies  
14 to offenses committed on the effective date of this subsection.



Insert 4-5

is requested to

(b) The joint legislative council ~~is~~ ~~shall~~ study the issues relating to the adoption of in vitro human embryos and the regulation of fertility clinics ~~with a view toward~~ <sup>to</sup> and prepare proposed legislation with a view toward accomplishing all of the following:

2. Facilitating the adoption ~~of~~ and implantation of <sup>unused</sup>

in vitro human embryos ~~donated or abandoned~~ by their genetic parents, created by infertility clinics.

3. Providing a procedure ~~for~~ by which those ~~donated or~~

unused

by their genetic parents

~~abandoned~~ in vitro human embryos may be relinquished for adoption and implantation.

4. Requiring that persons undergoing fertility treatment

unused

be informed of the option of relinquishing their in vitro human embryos for adoption and implantation

~~to~~ ~~(end of insert)~~

1. Reducing the number of in vitro human embryos created

by infertility clinics to a reasonable number needed for reproductive purposes.

(C) If the joint legislative council conducts the study, it shall include in the study a study of current law relating to the adoption of children and other current law that might be relevant to the ~~issue of~~ 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.

(d)

(not insert)



FRIDAY

~~PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION~~

2  
retrieve  
from hold

WAA

Reger

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 that are created by fertility clinics and how  
 7 to facilitate the adoption of unused in vitro human embryos, and human cloning  
 8 and providing penalties.

*Analysis by the Legislative Reference Bureau*

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

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

9 SECTION 1. 146.347 of the statutes is created to read:  
 10 146.347 Human cloning. (1) In this section:

✓ analysis  
insert

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

3 (b) "Denucleated human oocyte" means a fertilized or unfertilized human  
4 oocyte, the nuclear 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 <sup>an</sup> a denucleated human  
7 oocyte so as to produce a living organism having genetic material that is virtually  
8 identical to the genetic material of an existing or previously existing human  
9 organism.

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

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

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

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

- 16 1. Perform or attempt to perform human cloning.
- 17 2. Transfer or acquire for any purpose a human embryo produced by human
- 18 cloning or any product derived from such an embryo.

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

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

25 SECTION 2. 940.17 of the statutes is created to read:

21  
INS 2/24  
22

assisted reproductive services ✓

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

3 1. There are no laws in this state specifically regulating the procedures used  
4 at an ~~infertility~~ clinic that provides <sup>assisted reproductive services</sup> ~~infertility treatments~~ for ~~an~~ infertile couple <sup>or</sup>  
5 other couples <sup>or individuals</sup> using the clinic's services.

6 2. The procedures used at an infertility clinic in this state are governed by a  
7 private contract between the clinic and the couple <sup>or individual</sup> using the clinic's services.

8 3. It is quite common for an ~~infertility~~ clinic to create more human embryos  
9 than the number needed to reasonably meet the reproductive purposes of the couples <sup>or individuals</sup>  
10 using its services.

11 4. The private contract usually contains a provision regarding the disposition  
12 of human embryos not used by the couple. Often this provision permits the couple  
13 to choose to have their unused human embryos destroyed or donated for research.

14 5. It is also possible for the couple to choose to have their unused human  
15 embryos donated to another couple for implantation into the woman's uterus for the  
16 purpose of having a child. This option is often part of the private contract.

17 6. A substantial number of citizens have objections to the destruction of <sup>any</sup> ~~unused~~  
18 human embryos or the use of <sup>any human</sup> ~~these~~ embryos for nontherapeutic research that  
19 subjects them <sup>embryo</sup> to a substantial risk of injury or death.

20 <sup>move</sup> 7. The donation of unused human embryos for adoption by another couple is a  
21 positive, life-affirming alternative to having the embryos destroyed or donated for  
22 research.

23 (b) *Policy declaration.* It is declared to be the public policy of this state that a  
24 human embryo living outside a woman's body should be protected from intentional  
25 destruction or research that causes the embryo's death or unnecessarily subjects the

1 embryo to a substantial risk of harm. The legislature reaffirms the positive value  
2 of human life at all stages of development and promotes the adoption of unused  
3 human embryos. A human embryo is a human being at an early stage of  
4 development, not an item of property.

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

7 (2) In this section:

8 (a) "Human embryo" means a human organism derived by fertilization,  
9 parthenogenesis, cloning, or any other means from one or more human gametes or  
10 human diploid cells. "Human embryo" includes a zygote but does not include a  
11 human ~~organization~~<sup>organism</sup> at or beyond the stage of development at which the major body  
12 structures are present.

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

15 (c) "Nontherapeutic human embryo research" means research involving an in  
16 vitro human embryo that is not intended to help protect or preserve the life or protect,  
17 preserve, or promote the health of the in vitro human embryo.

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

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

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

INS  
4/17

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

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

9           (8) Whoever <sup>uses,</sup> transfers or acquires any living cell or tissue that the actor knows  
10 was obtained through conduct that is described under sub. (3), (5), or (7) is guilty of  
11 a Class E felony. This subsection does not apply to a person who transfers or acquires  
12 an in vitro human embryo for the purpose of having it implanted in a woman's uterus.

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

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

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

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

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

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

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

8 **SECTION 3. Nonstatutory provisions.**

9 (1) STUDY OF ADOPTION OF EMBRYOS AND REGULATION OF ~~FERTILITY~~ CLINICS. (a) In  
10 this subsection, "in vitro human embryo" has the meaning given in section 940.17 (2)  
11 (b) of the statutes. *Q 2.*  
*Q 1. "Clinic" means a clinic that provides*

12 (b) The joint legislative council is requested to study the issues relating to the  
13 adoption of in vitro human embryos and the regulation of ~~fertility~~ clinics and to  
14 prepare proposed legislation with a view toward accomplishing all of the following:

15 1. Reducing the number of in vitro human embryos created by ~~infertility~~  
16 to a reasonable number needed for reproductive purposes.

17 2. Facilitating the adoption and implantation of unused in vitro human  
18 embryos created by ~~infertility~~ clinics.

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

21 4. Requiring that persons undergoing fertility treatment be informed of the  
22 option of relinquishing their unused in vitro human embryos for adoption and  
23 implantation.

24 (c) If the joint legislative council conducts the study, it shall include in the study  
25 a study of current law relating to the adoption of children and other current law that



1 might be relevant to the adoption of in vitro human embryos with a view toward  
2 modeling the proposed legislation relating to the adoption of in vitro human embryos  
3 after that current law.

4 (d) If the joint legislative council conducts the study, it shall report its findings,  
5 conclusions, and recommendations to the legislature in the manner provided under  
6 section 13.172 (2) of the statutes by <sup>✓</sup>January 1, 2003.

7 **SECTION 4. Initial applicability.**

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

10 (2) The treatment of section 940.17 (8) of the statutes first applies to a <sup>use,</sup> transfer  
11 or ~~an~~ acquisition of a living cell or tissue occurring on the effective date of this  
12 subsection, even if the conduct that is described under section <sup>✓</sup>940.17 (3), (5), or (7)  
13 of the statutes and through which the cell or tissue was obtained occurred before the  
14 effective date of this subsection.

15

(END)

1

analysis INSERT

*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 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. "In vitro human embryo" also includes an embryo that has undergone cryopreservation (freezing), which is a process regularly used by clinics that provide assistive 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 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, acquiring, or possessing 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 gain.

*pecuniary*

***Legislative council study relating to in vitro human embryos***

The bill requests 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 undergoing fertility treatment be informed of the option of relinquishing their unused in vitro human embryos for adoption and implantation. If the joint legislative council conducts the study, it shall include in it 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.



In addition, if the joint legislative council conducts the study, it shall 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.

1

INSERT 2/24

2

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

3

4

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

5

6

INSERT 4/17

7

(d) "Research" ✓ means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

8

9

10

11



State of Wisconsin  
2001 - 2002 LEGISLATURE

LRB-2888(1)  
MGD&GMM:jld:jf

2

2001 BILL

MON

9  
Retrieve from hold

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 that are created <sup>by assisted reproductive services clinics</sup> and how to facilitate the  
 7 adoption of unused in vitro human embryos, and human cloning and providing  
 8 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

**BILL**

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. "In vitro human embryo" also includes an embryo that has undergone cryopreservation (freezing), which is a process regularly used by clinics that provide ~~assistive~~ 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

✓  
and  
regardless  
of whether  
the

9  
assisted

**BILL**

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, acquiring, or possessing 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 ~~requests~~ <sup>requires</sup> 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 ~~undergoing fertility treatment~~ <sup>receiving assisted reproductive services at clinics</sup> be informed of the option of relinquishing their unused in vitro human embryos for adoption and implantation. ~~If~~ <sup>its</sup> the joint legislative council ~~conducts the study, it~~ shall include in ~~it~~ <sup>its</sup> 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.

~~In addition, if~~ the joint legislative council ~~conducts the study, it shall~~ <sup>must</sup> 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:

**BILL**

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 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 ~~the~~ <sup>✓</sup> twice the gross amount of the person's  
4 pecuniary 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 ~~(assistive)~~ reproductive services for infertile couples, other  
10 couples, or individuals using the clinic's services. ~~(assistive)~~ *assisted*

11 2. The procedures used at an ~~assistive~~ 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 ~~assistive~~ 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****SECTION 2**

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.

**BILL**

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**

**SECTION 2**

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

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.

**SECTION 3. Nonstatutory provisions.**

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

25 (a) In this subsection:

ASSISTIVE  
assisted ← (CS)

**BILL**

- 1           1. "Clinic" means a clinic that provides <sup>assisted</sup> ~~assistive~~ 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 <sup>shall</sup> ~~is requested to~~ study the issues relating to the
- 5 adoption of in vitro human embryos and the regulation of clinics and <sup>shall</sup> ~~to~~ prepare
- 6 proposed 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. <sup>receiving assisted reproductive services at clinics</sup>
- 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 ~~(undergoing fertility treatment)~~ be informed of the
- 14 option of relinquishing their unused in vitro human embryos for adoption and
- 15 implantation.
- 16           (c) ~~If~~ <sup>=</sup> the joint legislative council ~~conducts the study, it~~ shall include in the study
- 17 a study of current law relating to the adoption of children and other current law that
- 18 might be relevant to the adoption of in vitro human embryos with a view toward
- 19 modeling the proposed legislation relating to the adoption of in vitro human embryos
- 20 after that current law.
- 21           (d) ~~If~~ <sup>=</sup> the joint legislative council ~~conducts the study, it~~ shall report its findings,
- 22 conclusions, and recommendations to the legislature in the manner provided under
- 23 section 13.172 (2) of the statutes by January 1, 2003.

24           **SECTION 4. Initial applicability.**



**Emery, Lynn**

---

**From:** Emery, Lynn  
**Sent:** Monday, November 19, 2001 2:02 PM  
**To:** 'mklaver@wrtl.org'  
**Subject:** LRB-2888/2 (attached as requested)

Lynn Emery

Lynn Emery - Program Asst. (PH. 608-266-3561)  
(E-Mail: lynn.emery@legis.state.wi.us) (FAX: 608-264-6948)

Legislative Reference Bureau - Legal Section - Front Office  
100 N. Hamilton Street - 5th Floor  
Madison, WI 53703

11/19/2001

**Emery, Lynn**

---

**From:** Richard, Rob  
**Sent:** Tuesday, November 20, 2001 11:10 AM  
**To:** LRB.Legal  
**Subject:** Draft review: LRB-2888/2 Topic: Destruction of human embryo; use of human embryo for nontherapeutic purpose

It has been requested by <Richard, Rob> that the following draft be jacketed for the ASSEMBLY:

Draft review: LRB-2888/2 Topic: Destruction of human embryo; use of human embryo for nontherapeutic purpose





**NATIONAL CONFERENCE  
of STATE LEGISLATURES**

Home  
My NCSL  
Contact/Ask NCSL  
Search  
Site map

You are logged in

NCSL Services    Policy Issues    State Legislatures    Information Exchange    State-Federal Relations    Legislative Staff

## BRP Committee: Reproductive Technologies

# State Human Cloning Laws

Current as of 5/14/01

Currently five states prohibit the cloning of human beings. In most states, specific exceptions are provided for the purpose of scientific research and cell-based therapies. With the exception of Missouri, all states with human cloning laws set forth civil penalties for violations, as high as ten million dollars in Louisiana and Michigan. Criminal sanctions for the cloning of human beings exist only in the state of Michigan, where human cloning is a felony punishable by imprisonment for up to 10 years.

State	Citation	Summary
California	Business And Professions §16004, §16105	Provides for the revocation of licenses issued to businesses for violations relating to human cloning
California	Health & Safety §24185, §24187, §24189	Prohibits cloning of human beings and the purchase or sale of ovum, zygote, embryo, or fetus for the purpose of cloning human beings; establishes civil penalties
Louisiana	40 §1299.36.6	Prohibits human cloning; provides exceptions for scientific research and cell-based therapies; establishes civil penalties
Michigan	§§333.26401 to 06	Prohibits use of state funds for human cloning except for the purpose of scientific research or cell-based therapies; establishes civil penalties
Michigan	§333.16274, §16275, §20197, §750.430a	Prohibit human cloning, provides exceptions for research and cell-based therapies, and establishes civil and criminal penalties
Missouri	§1.217	Limits use of state funds for human cloning research
Rhode	§23-16.4-1 to 4-	Prohibits human cloning; provides exceptions for

Island	4	biomedical, microbiological, and agricultural research; establishes civil penalties for corporations/hospitals and individuals
Virginia	§32.1-162.32-2	Prohibits human cloning or implanting or attempting to implant the product of somatic cell nuclear transfer; allows for somatic cell nuclear transfer or other cloning technologies to clone molecules for research purposes; establishes civil penalty not to exceed \$50,000 for each incident

Source: NCSL

For more information, please contact:

Cheye Calvo, Alissa Johnson  
 NCSL, Employment and Insurance  
 (303) 830-2200



**National Conference of State Legislatures**  
 INFO@NCSL.ORG (autoresponse directory)

Denver Office:  
 1560 Broadway, Suite 700  
 Denver, CO 80202  
 Tel: 303-830-2200  
 Fax: 303-863-8003

Washington Office:  
 444 North Capitol Street, N.W., Suite 515  
 Washington, D.C. 20001  
 Tel: 202-624-5400  
 Fax: 202-737-1069

## EXECUTIVE SUMMARY

---

The idea that humans might someday be cloned—created from a single somatic cell without sexual reproduction—moved further away from science fiction and closer to a genuine scientific possibility on February 23, 1997. On that date, *The Observer* broke the news that Ian Wilmut, a Scottish scientist, and his colleagues at the Roslin Institute were about to announce the successful cloning of a sheep by a new technique which had never before been fully successful in mammals. The technique involved transplanting the genetic material of an adult sheep, apparently obtained from a differentiated somatic cell, into an egg from which the nucleus had been removed. The resulting birth of the sheep, named Dolly, on July 5, 1996, was different from prior attempts to create identical offspring since Dolly contained the genetic material of only one parent, and was, therefore, a "delayed" genetic twin of a single adult sheep.

This cloning technique is an extension of research that had been ongoing for over 40 years using nuclei derived from non-human embryonic and fetal cells. The demonstration that nuclei from cells derived from an adult animal could be "reprogrammed," or that the full genetic complement of such a cell could be reactivated well into the chronological life of the cell, is what sets the results of this experiment apart from prior work. In this report the technique, first described by Wilmut, of nuclear transplantation using nuclei derived from somatic cells other than those of an embryo or fetus is referred to as "somatic cell nuclear transfer."

Within days of the published report of Dolly, President Clinton instituted a ban on federal funding related to attempts to clone human beings in this manner. In addition, the President asked the recently appointed National Bioethics Advisory Commission (NBAC) to address within ninety days the ethical and legal issues that surround the subject of cloning human beings. This provided a welcome opportunity for initiating a thoughtful analysis of the many dimensions of the issue, including a careful consideration of the potential risks and benefits. It also presented an occasion to review the current legal status of cloning and the potential constitutional challenges that might be raised if new legislation were enacted to restrict the creation of a child through somatic cell nuclear transfer cloning.

The Commission began its discussions fully recognizing that any effort in humans to transfer a somatic cell nucleus into an enucleated egg involves the creation of an embryo, with the apparent potential to be implanted in utero and developed to term. Ethical concerns surrounding issues of embryo research have recently received extensive analysis and deliberation in the United States. Indeed, federal funding for human embryo research is severely restricted, although there are few restrictions on human embryo research carried out in the private sector. Thus, under current law, the use of somatic cell nuclear transfer to create an embryo solely for research purposes is already restricted in cases involving federal funds. There are, however, no current federal regulations on the use of private funds for this purpose.

The unique prospect, vividly raised by Dolly, is the creation of a new individual genetically identical to an existing (or previously existing) person—a "delayed" genetic twin. This prospect has been the source of the overwhelming public concern about such cloning. While the creation of embryos for research purposes alone always raises serious ethical questions, the use of somatic cell nuclear transfer to create embryos raises no new issues in this respect. The unique and distinctive ethical issues raised by the use of somatic cell nuclear transfer to create children relate to, for example, serious safety concerns, individuality, family integrity, and treating children as objects. Consequently, the Commission focused its attention on the use of such techniques for the purpose of creating an embryo which would then be implanted in a woman's uterus and brought to term. It also expanded its analysis of this particular issue to encompass activities in both the public and private sector.

In its deliberations, NBAC reviewed the scientific developments which preceded the Roslin announcement, as well as those likely to follow in its path. It also considered the many moral concerns raised by the possibility that this technique could be used to clone human beings. Much of the initial reaction to this possibility was negative. Careful assessment of that response revealed fears about harms to the children who may be created in this manner, particularly psychological harms associated with a possibly diminished sense of individuality and personal autonomy. Others expressed concern about a degradation in the quality of parenting and family life.

In addition to concerns about specific harms to children, people have frequently expressed fears that the widespread practice of somatic cell nuclear transfer cloning would undermine important social values by opening the door to a form of eugenics or by tempting some to manipulate others as if they were objects instead of persons. Arrayed against these concerns are other important social values, such as protecting the widest possible sphere of personal choice, particularly in matters pertaining to procreation and child rearing, maintaining privacy and the freedom of scientific inquiry, and encouraging the possible development of new biomedical breakthroughs.

To arrive at its recommendations concerning the use of somatic cell nuclear transfer techniques to create children, NBAC also examined long-standing religious traditions that guide many citizens' responses to new technologies and found that religious positions on human cloning are pluralistic in their premises, modes of argument, and conclusions. Some religious thinkers argue that the use of somatic cell nuclear transfer cloning to create a child would be intrinsically immoral and thus could never be morally justified. Other religious thinkers contend that human cloning to create a child could be morally justified under some circumstances, but hold that it should be strictly regulated in order to prevent abuses.

The public policies recommended with respect to the creation of a child using somatic cell nuclear transfer reflect the Commission's best judgments about both the ethics of attempting such an experiment and its view of traditions regarding limitations on individual actions in the name of the common good. At present, the use of this technique to create a child would be a premature experiment that would expose the fetus and the developing child to unacceptable risks. This in itself might be sufficient to justify a prohibition on cloning human beings at this time, even if such efforts were to be characterized as the exercise of a fundamental right to attempt to procreate.

Beyond the issue of the safety of the procedure, however, NBAC found that concerns relating to the potential psychological harms to children and effects on the moral, religious, and cultural values of society merited further reflection and deliberation. Whether upon such further deliberation our nation will conclude that the use of cloning techniques to create children should be allowed or permanently banned is, for the moment, an open question. Time is an ally in this regard, allowing for the accrual of further data from animal experimentation, enabling an assessment of the prospective safety and efficacy of the procedure in humans, as well as granting a period of fuller national debate on ethical and social concerns. The Commission therefore concluded that there should be imposed a period of time in which no attempt is made to create a child using somatic cell nuclear transfer.<sup>1</sup>

Within this overall framework the Commission came to the following conclusions and recommendations:

I. The Commission concludes that at this time it is morally unacceptable for anyone in the public or private sector, whether in a research or clinical setting, to attempt to create a child using somatic cell nuclear transfer cloning. The Commission reached a consensus on this point because current scientific information indicates that this technique is not safe to use in humans at this point. Indeed, the Commission believes it would violate important ethical obligations were clinicians or researchers to

attempt to create a child using these particular technologies, which are likely to involve unacceptable risks to the fetus and/or potential child. Moreover, in addition to safety concerns, many other serious ethical concerns have been identified, which require much more widespread and careful public deliberation before this technology may be used.

The Commission, therefore, recommends the following for immediate action:

- A continuation of the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.
- An immediate request to all firms, clinicians, investigators, and professional societies in the private and non-federally funded sectors to comply voluntarily with the intent of the federal moratorium. Professional and scientific societies should make clear that any attempt to create a child by somatic cell nuclear transfer and implantation into a woman's body would at this time be an irresponsible, unethical, and unprofessional act.

II. The Commission further recommends that:

- Federal legislation should be enacted to prohibit anyone from attempting, whether in a research or clinical setting, to create a child through somatic cell nuclear transfer cloning. It is critical, however, that such legislation include a sunset clause to ensure that Congress will review the issue after a specified time period (three to five years) in order to decide whether the prohibition continues to be needed. If state legislation is enacted, it should also contain such a sunset provision. Any such legislation or associated regulation also ought to require that at some point prior to the expiration of the sunset period, an appropriate oversight body will evaluate and report on the current status of somatic cell nuclear transfer technology and on the ethical and social issues that its potential use to create human beings would raise in light of public understandings at that time.

III. The Commission also concludes that:

- Any regulatory or legislative actions undertaken to effect the foregoing prohibition on creating a child by somatic cell nuclear transfer should be carefully written so as not to interfere with other important areas of scientific research. In particular, no new regulations are required regarding the cloning of human DNA sequences and cell lines, since neither activity raises the scientific and ethical issues that arise from the attempt to create children through somatic cell nuclear transfer, and these fields of research have already provided important scientific and biomedical advances. Likewise, research on cloning animals by somatic cell nuclear transfer does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees.
- If a legislative ban is not enacted, or if a legislative ban is ever lifted, clinical use of somatic cell nuclear transfer techniques to create a child should be preceded by research trials that are governed by the twin protections of independent review and informed consent, consistent with existing norms of human subjects protection.
- The United States Government should cooperate with other nations and international organizations to enforce any common aspects of their respective policies on the cloning of human beings.

IV. The Commission also concludes that different ethical and religious perspectives and traditions are divided on many of the important moral issues that surround any attempt to create a child using somatic cell nuclear transfer techniques. Therefore, the Commission recommends that:

- The federal government, and all interested and concerned parties, encourage widespread and continuing deliberation on these issues in order to further our understanding of the ethical and social implications of this technology and to enable society to produce appropriate long-term policies regarding this technology should the time come when present concerns about safety have been addressed.

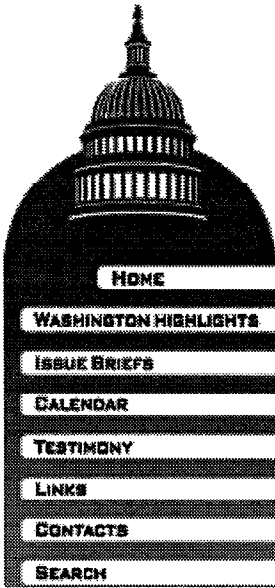
V. Finally, because scientific knowledge is essential for all citizens to participate in a full and informed fashion in the governance of our complex society, the Commission recommends that:

- Federal departments and agencies concerned with science should cooperate in seeking out and supporting opportunities to provide information and education to the public in the area of genetics, and on other developments in the biomedical sciences, especially where these affect important cultural practices, values, and beliefs.

---

**Note:**

<sup>1</sup> The Commission also observes that the use of any other technique to create a child genetically identical to an existing (or previously existing) individual would raise many, if not all, of the same non-safety-related ethical concerns raised by the creation of a child by somatic cell nuclear transfer.



## Testimony

# Statement on Cloning: Legal, Medical Ethical, and Social Issues

---

**Presented by:** David Korn, M.D. Senior Vice President, Division of Biomedical and Health Sciences Research

**Presented to:** Subcommittee on Health and Environment, Committee on Commerce, United States House of Representatives

**Date:** February 12, 1998

---

- [Summary of AAMC Statement on Cloning](#)
  - [Full Statement on Cloning: Legal, Medical, Ethical, and Social Issues](#)
  - [AAMC Issue Brief: Human Cloning](#)
  - [AAMC Group Letter to the Senate on Cloning](#)
- 

Mr. Chairman and members of the Subcommittee, I am David Korn, M.D., Senior Vice President for Biomedical and Health Sciences Research at the Association of American Medical Colleges (AAMC). On August 31, 1997, I became Vice President and Dean of Medicine and Professor of Pathology, Emeritus, at Stanford University, where I had been on the faculty for 29 years. The AAMC represents the nation's 125 accredited medical schools, nearly 400 major teaching hospitals, more than 87,000 faculty through 86 professional and scientific societies, and the nation's 67,000 medical students and 102,000 residents.

The AAMC commends the Subcommittee for convening this hearing to begin to explore the very sensitive and complex medical, ethical, legal and social issues surrounding "human cloning." As the last few weeks have demonstrated, the poorly-understood nascent technology of somatic cell nuclear transfer has raised difficult and emotionally charged questions that have proved difficult to discuss in simple, unambiguous English language. Even scientists and physicians may disagree on some of the points that have been raised today. It is for these reasons that we encourage you and your colleagues to continue to explore these issues, patiently and deliberately, with all of the interested stakeholders.

In particular, we are pleased that you have included representatives from the patient community at this forum. Their input is vital because as the major potential beneficiaries of this powerful new technology that you have been discussing here today, they are the ultimate stakeholders in this debate. The AAMC is gratified to be participating in the panel of patient advocates because we believe that fundamental to the mission of this nation's medical schools and teaching hospitals is the obligation to represent and protect the interests of our present patients and those who will seek our care in the future. It is because of this obligation that our medical schools and teaching hospitals have become world-leading citadels of basic and clinical biomedical research and education.

As you consider the myriad, and sometimes distracting, issues that have been raised in the course of the national debate that has raged for the past few weeks, we believe there are two fundamental points that must be emphasized. The first is that this debate to a large extent has been focused on the wrong questions. This debate should not be about creating life, it should be about saving lives.

We agree with the American public that the cloning of human beings should not proceed at this time. All responsible scientists and physicians find the prospect of attempting to produce human clones by somatic cell nuclear transfer - or any other technology, for that matter - as abhorrent as do the members of this Subcommittee. Let me be clear: The medical and research communities are not interested in making people. But we are committed to producing cures for the diseases and disabilities that plague our population, resulting in devastating emotional, social and economic costs and over \$1 trillion in health care expenditures each year.

The current opportunities in biomedical research to address these health challenges are unparalleled in our nation's history. This leads me to our second point. We have grave concerns that any legislative proposal that bans outright a specific scientific technology will have an extremely chilling effect on future progress in biomedical research and human healing.

It is important to keep in mind that the terms "cloning" and "somatic cell nuclear transfer" are not synonymous. Cloning refers to the production of an identical genetic copy. It occurs naturally in human beings and animals in the birth of identical twins. In contemporary biomedical research, the cloning of DNA molecules and individual cells has become commonplace, while the cloning of individual plants or animals is carried out today in both research and commercial settings. Somatic cell nuclear transfer is one specific process that can be used for cloning. The technique has been studied in amphibia and other lower animals for a very long time, and more recently has been successfully carried out in higher animals (cows and sheep) using fetal cells as the somatic cell nuclear donors.



To date, there has been only a single reported case of cloning in a higher animal using an adult somatic cell as the nuclear donor. That, of course, was the report about 1 year ago from Scotland in which Dr. Ian Wilmut described the production of Dolly. The Wilmut report contained a number of problematic features, including the fact that the technology had been successful in only one of 277 attempts. It is terribly important to understand that to date, the Wilmut result has not been successfully reproduced anywhere in the world. And within the past couple of weeks, two eminent scientists published a long letter in Science Magazine raising serious questions about the way in which Dr. Wilmut had performed and reported his experiment and interpreted his results. At the present time, the ability to use adult cells as donors in somatic cell nuclear transfer technology to produce a live-born, cloned animal has not been proved. As several eminent scientists have said, at the present time the experiment reported by Wilmut can only be considered an anecdote and not an established scientific fact.

It is also important to recognize that the somatic cell nuclear transfer technology has many exciting and potentially enormously important applications in research, medicine and industry, including the cloning of genetically engineered animals that produce large quantities of powerful pharmacological agents, or producing genetically engineered human cell cultures that would serve as "therapeutic tissues" in the treatment of currently intractable human diseases. The use of the technology to attempt to clone human beings is utterly unappealing scientifically, as well as being morally repugnant.

According to the National Institutes of Health, somatic cell nuclear transfer technology could provide an invaluable approach by which to study how cells become specialized, which in turn could provide new understanding of the mechanisms that lead to the development of abnormal cells responsible for cancers and certain birth defects. Improved understanding of cell specialization may also provide answers to how cells age or are regulated -- leading to new insights into the treatment or cure of Alzheimer's and Parkinson's diseases, or other incapacitating degenerative disease of the brain and spinal cord. The technology might also help us understand how to activate certain genes to permit the creation of customized cells for transplantation or grafting. Such cells would be genetically identical to the somatic cell donor and could therefore be transplanted into that donor without fear of immune rejection, the major biological barrier to organ and tissue transplantation at this time.

Imagine, if you will, having the ability to clone cells from a diabetic patient, manipulate them genetically in the laboratory to turn on their genes that direct the synthesis of insulin, and then being able to propagate them in culture to generate large numbers of insulin producing cells that are genetically identical to one another and to the patient. The cells could be transplanted back into the patient without risk of rejection and with no need for the powerful, chronic

immunosuppressive therapy that is now mandatory for transplant recipients, and which ultimately fails.

Other types of specialized cells could be created to enable skin grafts for burn victims; bone marrow stem cells to treat leukemia and other blood diseases; nerve stem cells to treat neurodegenerative diseases such as multiple sclerosis, amyotrophic lateral sclerosis (Lou Gehrig's disease), Alzheimer's and Parkinson's disease, and to repair spinal cord injuries; muscle cell precursors to treat muscular dystrophy and heart disease; and cartilage-forming cells to reconstruct joints damaged by injury or arthritis. Somatic cell nuclear transfer technology could also be used potentially to accomplish remarkable increases in the efficiency and efficacy of gene therapy by permitting the creation of pure populations of genetically "corrected" cells that could then be delivered back into the patient, again with no risk of immune rejection. Indeed, this technology could well lead to the operationalization of gene therapy as a practicable and effective therapeutic modality - a goal which to date has proved elusive.

Can we guarantee that these dreams will come to fruition? Perhaps. We believe the prospects are very bright, building on the vast store of biomedical knowledge that has been amassed during the past five decades: with the continued generous support of the federal government through the National Institutes of Health and other federal research agencies, and of a robust pharmaceutical and biotechnology industry; and with the remarkable talents, and dedication of our academic and industrial scientists and other health professionals. But what we can guarantee is that we will never see the fulfillment of any of these promises if we choose to take the perilous path of banning the use of somatic cell nuclear transfer technology - or any other scientific technologies or areas of scientific inquiry - through legislation.

The United States has never, to our knowledge, banned an area of scientific exploration, or a scientific technology, by federal legislation. There are good reasons for this, and it is instructive to recall them. Legislation is a blunt instrument, and legislation of this kind, driven by emotionality, misunderstanding and fear, tends to be very difficult to modify or repeal. Any language, no matter how carefully crafted initially, can well emerge from the far end of the legislative process freighted with unintended side-effects that will limit or prohibit research progress and deny hope to tens of millions of Americans. To ban a nascent technology of such enormous potential benefit to our citizens and our economy solely for fear of a single odious application that has not even been proved to be possible would be tragic. In its June 1997 report "Cloning Human Beings," the National Bioethics Advisory Commission (NBAC) persuasively articulated several drawbacks to resorting to federal legislation to resolve issues of this kind. The report stated, "A legislative ban would represent a strong obstacle to changes in policy as scientific information develops.....It is notoriously difficult to draft legislation

at any particular moment that can serve to both exploit and govern the rapid and unpredictable advances of science." Far preferable in our judgment is to go the route of an organized, self-imposed moratorium, backed by appropriate regulatory oversight. Again to quote from the NBAC report: "Such moratoria avoid governmental intrusion into freedom of scientific inquiry via legislative fiat....[and are] largely immune from constitutional challenges....."

We know that a moratorium self-imposed by the scientific and professional communities can work. In the early 1970s, the American public and the scientific community faced a quite analogous dilemma with the emergence of another nascent technology of enormous promise that also generated widespread public fears -- recombinant DNA technology. As with any emerging technology, there were dazzling possibilities galore, but no certainties, about the potential uses of that technology, and profound concerns about its safety and potential for harm. Mass meetings were held in the research centers in which the technology had been discovered (Stanford and UCSF) or quickly applied (for example, Cambridge, MA and other major research university communities), at which prominent thought leaders predicted the undermining of the natural order, the desecration of nature, interference with Divine handiwork and other such catastrophes. The degree of passion, misunderstanding, perfervid oratory and fantasy was entirely reminiscent of that we are presently encountering with respect to somatic cell nuclear transfer technology.

At that time, the scientific community adopted a self-imposed nationwide moratorium on the use of the technology and convened the famous Asilomar Conference to begin the process of crafting the stringent guidelines and regulatory safeguards that were put in place. The guidelines were developed through a painstaking deliberative process that involved representatives from science, government, and the public - and they worked. There could easily have been prohibitive federal legislation enacted at that time, as many desired. But fortunately for all of us, reason prevailed.

The outpouring of scientific and technological advances that were unleashed by recombinant DNA technology has transformed biomedical research, is profoundly altering the practice of medicine, and spawned the biotechnology industry, one of the great economic success stories of the second half of the 20th century. The carefully overseen exploitation of recombinant DNA technology has provided tremendous benefits over the past two decades to the health and well being of all Americans, and to the vigor of our nation's economy.

Think for a moment how much poorer our world would be today if in a rush of impetuous lawmaking, recombinant DNA technology had been legislatively banned!

We strongly believe that the self-imposed nationwide five-year moratorium on the cloning of human beings, which has been adopted

by AAMC, the Federation of American Societies for Experimental Biology (FASEB), the American Society for Cell Biology, the Pharmaceutical Research and Manufacturers Association (PhRMA), the Biotechnology Industry Organization (BIO), the American Society for Reproductive Medicine and scores of others in the medical research community, and by the World Medical Association and the World Health Organization, is the appropriate and much preferred course of action. This approach has an inherent flexibility and the capability of responding to advancing scientific understanding, as well as to the evolution of public thought about the ethics and morality of particular scientific applications. The adoption of a moratorium to permit thoughtful public deliberation and debate is the only approach that will ensure continued medical progress while optimally protecting the public's interest.

As in the early 1970s during the recombinant DNA debate, we are at a cross-roads in medical science. A moratorium on human cloning, buttressed by appropriate regulations enforced by the FDA and other federal agencies, would permit academic and industrial scientists to continue to explore the potential benefits of somatic cell nuclear transfer technology while protecting the public from the single, and singular, outcome that no credible biomedical scientist or medical professional believes should be attempted -- the cloning of an entire human being. We must not impede the continued exploration of the potential of somatic cell nuclear transfer technology research opportunities in our eagerness to forestall an outcome that can be accomplished just as effectively with a self-imposed moratorium. This last point bears re-emphasis: the nationwide moratorium already adopted by the nation's scientific and medical organizations embraces all of the researchers and medical practitioners in the United States who possess the knowledge and technical capability required even to attempt to clone a human being. There is no crisis or public emergency here that could possibly justify a rush to legislate.

The AAMC appreciates this opportunity to present its views, and looks forward to working with your and your colleagues as this critically important debate moves forward.

---

[AAMC Home](#) | [Government Affairs](#) | [Newsroom](#) | [Publications](#) | [Meetings](#) | [Students and Applicants](#) | [About the AAMC](#) | [Search](#)  
[Questions and Comments](#) | © 1995-2001 AAMC [Terms and Conditions](#) | [Privacy Statement](#)

*Revised: 07 December 1999*