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(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2005-06
(session year)

Senate
(Assembly, Senate or Joint)

Committee on Judiciary, Corrections and Privacy...

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
  (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Stefanie Rose (LRB) (July 2012)

Senate

Record of Committee Proceedings

Committee on Judiciary, Corrections and Privacy

Senate Bill 243

Relating to: human cloning and parthenogenesis and providing penalties.

By Senators Leibham, S. Fitzgerald, Lazich, A. Lasee, Reynolds, Kanavas, Kedzie, Roessler and Grothman; cosponsored by Representatives Kestell, Kleefisch, LeMahieu, Suder, Towns, Moulton, Krawczyk, Strachota, Gielow, Nass, Ott, Van Roy, Kreibich, Pettis, Gundrum, Townsend, Owens, Gunderson, J. Fitzgerald and Hahn.

June 16, 2005 Referred to Committee on Judiciary, Corrections and Privacy.

June 20, 2005 **PUBLIC HEARING HELD**

Present: (5) Senators Zien, Roessler, Grothman, Taylor and Risser.
Absent: (0) None.

Appearances For
- Steve Kestell, Elkhart — Representative
- Jean Papuzzi, Milwaukee — Dr., Wisconsin Right to Life
- Barbara Lyons, Milwaukee — Wisconsin Right to Life
- Judy Puchner, Menomenee Falls — Dr.
- John Huebscher, Madison — Wisconsin Catholic Conference
- Matt Sande, Cambridge — Pro-Life Wisconsin
- Kirby Brant, Madison — Pro-Life Wisconsin

Appearances Against
- Ron Kuehn, Madison
- Andrew Cohn, Madison — WI Cell
- Rick Wiley, Madison — Chancellor, University of Wisconsin
- Alta Charo, Madison — University of Wisconsin

Appearances for Information Only
- None.

Registrations For
- Scott Suder, Madison — Representative, 69th Assembly District
- Dan Vrakas, Madison — Representative
- Mary Klaver, Milwaukee — Wisconsin Right to Life
- Joe Leibham, Madison — Senator
- Susan Armacost, Milwaukee — WI right to life

- Alan Lasee, Madison — Senator
- Judith Braut, Madison — Pro-Life Wisconsin
- Julaine Kappling, Madison — Family Research Institute of WI
- Ted Kanavas, Madison — Senator, State Senator
- Carol Owens, Madison — Representative
- Mark Pettis, Madison — Representative
- Scott Fitzgerald, Madison — Senator
- Tom Reynolds, Madison — Senator
- Steve Nass, Whitewater — Representative
- E. Dagny Coe, Madison
- Debbie Towns, Janesville — Representative
- Judy Krawzyk, Green Bay — Representative

Registrations Against

- Vaughn Vance, Madison — JDRF
- Pete Christianson, Fitchburg
- Jack O'Meara, Madison — Professor Inc. (Faculty at UW-Madison)

September 20, 2005 EXECUTIVE SESSION - POLLING

Moved by Senator Zien, seconded by Senator Zien that **Senate Amendment 1** be recommended for adoption.

Ayes: (3) Senators Zien, Roessler and Grothman.
Noes: (2) Senators Taylor and Risser.

ADOPTION OF SENATE AMENDMENT 1 RECOMMENDED, Ayes 3, Noes 2

Moved by Senator Zien, seconded by Senator Zien that **Senate Amendment 2** be recommended for adoption.

Ayes: (3) Senators Zien, Roessler and Grothman.
Noes: (2) Senators Taylor and Risser.

ADOPTION OF SENATE AMENDMENT 2 RECOMMENDED, Ayes 3, Noes 2

Moved by Senator Zien, seconded by Senator Zien that **Senate Amendment 3** be recommended for adoption.

Ayes: (3) Senators Zien, Roessler and Grothman.
Noes: (2) Senators Taylor and Risser.

ADOPTION OF SENATE AMENDMENT 3 RECOMMENDED, Ayes 3, Noes 2

Moved by Senator Zien, seconded by Senator Zien that **Senate Bill 243** be recommended for passage as amended.

Ayes: (3) Senators Zien, Roessler and Grothman.
Noes: (2) Senators Taylor and Risser.

PASSAGE AS AMENDED RECOMMENDED, Ayes 3, Noes 2

Brian Deschane
Committee Clerk

MOTION

Recommend Senate Bill 243, relating to: human cloning and parthenogenesis and providing penalties, for passage.

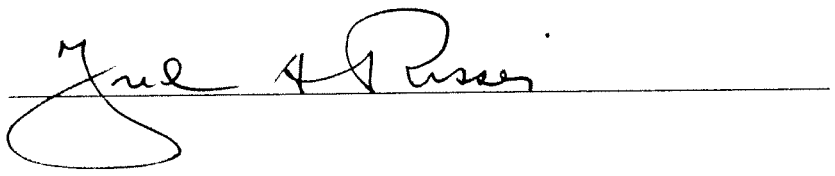
Aye X No _____

Signature _____

MOTION

Recommend Senate Bill 243, relating to: human cloning and parthenogenesis and providing penalties, for passage.

Aye _____ No ✓

Signature 

MOTION

Recommend Senate Bill 243, relating to: human cloning and parthenogenesis and providing penalties, for passage.

Aye X No _____

Signature Carol Roessler

MOTION

Recommend Senate Bill 243, relating to: human cloning and parthenogenesis and providing penalties, for passage.

Aye _____ No ✓

Signature _____

MOTION

Recommend Senate Bill 243, relating to: human cloning and parthenogenesis and providing penalties, for passage as amended.

Aye X No _____

Signature _____

MOTION

Recommend Senate Bill 243, relating to: human cloning and parthenogenesis and providing penalties, for passage as amended.

Aye _____ No ✓

Signature _____ 9/20/05

STATE SENATOR DAVE ZIEN

PRESIDENT PRO TEMPORE

CHAIRPERSON
COMMITTEE ON JUDICIARY, CORRECTIONS AND PRIVACY
VICE CHAIRPERSON
COMMITTEE ON VETERANS, HOMELAND SECURITY, MILITARY AFFAIRS, SMALL BUSINESS AND GOVERNMENT REFORM
MEMBER
COMMITTEE ON JOB CREATION, ECONOMIC DEVELOPMENT AND CONSUMER AFFAIRS
SENTENCING COMMISSION
COUNCIL ON TOURISM
JUDICIAL COUNCIL
JOINT LEGISLATIVE COUNCIL
BUILDING COMMISSION

MEMORANDUM

TO: Senator Carol Roessler, Member, Senate Committee on Judiciary, Corrections & Privacy

FR: Senator Dave Zien, Chair, Senate Committee on Judiciary, Corrections & Privacy

DT: September 20, 2005 (hand delivered 3:00pm)

RE: Executive Action Paper Ballot

Please consider the following bills and vote on the following motions. **Return this ballot to Senator Dave Zien, Room 15 South, no later than 10:00am (Wednesday), September 21, 2005.** Committee members' ballots not received by the deadline will be marked as not voting.

Carol Roessler

Senator Carol Roessler

OFFICE: P.O. BOX 7882 • STATE CAPITOL • MADISON, WI 53707-7882
PHONE (608) 266 7511 • FAX (608) 267 8794 **E-MAIL** SEN.ZIEN@LEGIS.STATE.WI.US • **Website:** WWW.LEGIS.STATE.WI.US
SENATE DISTRICT: 505 S. DEWEY STREET, SUITE 214 • EAU CLAIRE, WI 54702 • **PHONE:** (715) 834 7723

MOTION

Recommend Senate Bill 243, relating to: human cloning and parthenogenesis and providing penalties, for passage as amended.

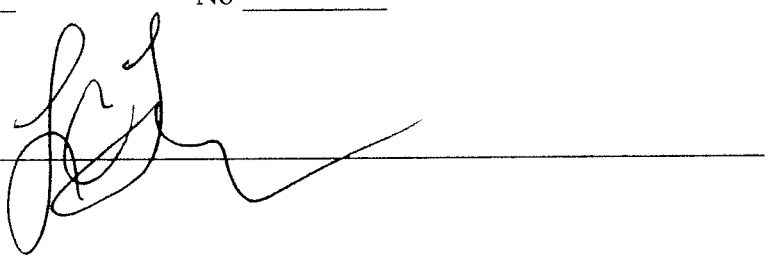
Aye X No _____

Signature Carol Roessler

MOTION

Recommend Senate Bill 243, relating to: human cloning and parthenogenesis and providing penalties, for passage as amended.

Aye _____ No ✓

Signature 


FORWARD

JUN 21 2005

MEDICAL COLLEGE OF WISCONSIN

Office of the President

MEMORANDUM

TO: Honorable Members of the Wisconsin Legislature

FROM: T. Michael Bolger, J.D.
President & CEO

DATE: June 15, 2005

RE: Support for Embryonic Stem Cell Research

On behalf of the Medical College of Wisconsin, I am writing to express my support for embryonic stem cell research and to urge members to reject any effort to prohibit state funds or state buildings from being used for this important research. While the Joint Finance Committee wisely determined that the State Budget was not the appropriate vehicle to pass such wide-sweeping public policy, I urge members to oppose initiatives that would potentially stymie the advancement of treatments and cures for the devastating illnesses and injuries that impact the lives of millions of Americans.

The efforts to restrict Wisconsin's stem cell research come at a time when other states are significantly increasing their investment of public funds in this ground-breaking research. Not only do these states recognize the importance of this research in terms of finding cures for disease, they also understand the critical impact this research has on the economy.

The Medical College of Wisconsin is sensitive to the ethical issues surrounding research on embryonic stem cells. As an institution, the College has taken the position that research should only take place on embryos that would be discarded, such as those created for the purpose of fertility treatment that were in excess of clinical need. While we recognize the legitimate issues raised by this research, embryos used in fertility treatments will continue to be discarded. Given the great hope that stem cell research provides to those suffering or dying from devastating illnesses, it would be tragic to lose the opportunity to pursue this research.

It is important to note that the majority of Americans, including many Wisconsin citizens, support stem cell research. As you know, a recent survey conducted by Public Opinion Strategies found that there is broad bipartisan support for embryonic stem cell research, with 69% of Wisconsin citizens favoring this research. Of the 69% that support this

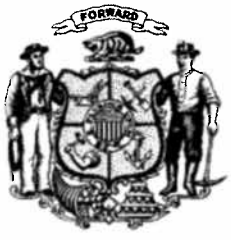
8701 Watertown Plank Road
Post Office Box 26509
Milwaukee, Wisconsin 53226-0509
(414) 456-8225

research, 59% believe the State of Wisconsin should support this research with state tax dollars.

Wisconsin is a world leader in embryonic stem cell research and, as noted, to move forward with legislation that would limit or prohibit this research would stymie the advancement of treatments for debilitating disease. In addition, this policy would have a tremendous impact on MCW and UW-Madison's ability to recruit top scientists to the state and could have a devastating impact on Wisconsin's bioscience economy.

I urge you to reject any efforts to restrict or prohibit embryonic stem cell research. Thank you for considering my comments.

WISCONSIN STATE LEGISLATURE



THE Family
★ RESEARCH
INSTITUTE OF
Wisconsin
★ ★ ★ ★ ★

PO Box 2075 • Madison WI • 53701-2075
608-256-3228 • 888-378-7395 (toll free) • 608-256-3370 (fax)
Web site: www.fri-wi.org • E-mail: fri@fri-wi.org

Testimony of Julaine K. Appling, Executive Director
The Family Research Institute of Wisconsin
Joint Hearing of Assembly Children and Families &
Senate Judiciary, Privacy and Corrections Committees
on AB 499 and SB 243
Monday, June 20, 2005, 1:00 p.m.

Thank you for the opportunity to submit written testimony on AB 499 and SB 243, companion bills that would ban all forms of human cloning in Wisconsin.

The Family Research Institute of Wisconsin (FRI) strongly supports a ban of all forms of human cloning. Biotechnology has raised hopes for progress in treating and even curing dread diseases, but technology must not outstrip ethical and moral considerations of the dignity of each person from the moment of fertilization until natural death. A ban on all forms of human cloning will protect human beings in their most vulnerable state and acknowledge their intrinsic dignity and value.

Cloning of human embryos—for any purpose— reduces these human beings to mere commodities. It verges on the barbaric and is something no civilized society should sanction. Allowing it will lead inevitably to a tyranny of someone or some group deciding who should live and who should die, who is worthy of protection and who is not.

Those who oppose a ban on all human cloning want no restrictions whatever on their research; they view themselves as a law unto themselves. But they do not work in a vacuum—their experiments and findings will inevitably have public policy implications. We continue down that road at our peril.

Banning all forms of human cloning, as AB 499 and SB 243 do, is sound public policy and affirms the dignity and worth of all Wisconsin citizens.

#

Wisconsin Right to Life

Wisconsin Right to Life
10625 W. North Avenue
Milwaukee, WI 53226
414-778-5780 or toll free: 877-855-5007

The following memo has been sent by Wisconsin Right to Life to state lawmakers in anticipation of public hearing and likely floor votes on bill to ban human cloning

TO: Members of the Assembly Children and Families Committee
Members of the Senate Judiciary, Corrections and Privacy Committee
cc: Members of the State Assembly
Members of the State Senate

FROM: Susan Armacost, Legislative Director

RE: Wisconsin Right to Life urges you to **vote for the Kestell/Leibham legislation** to ban the cloning of human embryos in Wisconsin (AB 499/SB243) and to **reject all amendments that would permit the cloning of human embryos for <u>any</u> reason.**

Wisconsin Right to Life strongly supports the Kestell/Leibham legislation (AB 499/ SB 243), which would prohibit the cloning of human embryos in Wisconsin, and urges you to support this important legislation both at the committee level and on the floor of your respective houses.

There are a number of false statements being made by the proponents of human cloning which need to be addressed with facts.

<u>FACT: There is no scientific difference between "therapeutic cloning" and "reproductive "cloning.</u>

When the public thinks of human cloning, they think of creating a human being who is the exact replica of another individual. Human cloning done for this purpose is commonly referred to as "reproductive cloning."

However, there is another purpose for human cloning and that is to create human embryos via cloning and then destroy those cloned embryos for medical experiments. When human cloning is done for this purpose, the biotech industry refers to it as "therapeutic" cloning, although there is nothing therapeutic about it for the cloned embryos!

- more -

In reality, there is no scientific difference between the two terms. **The only difference is the purpose for which a cloned embryo has been created ... to implant the cloned embryo in a woman's body or to destroy the cloned embryo for medical experiments.** In either case, the cloned embryo is capable of developing into a cloned baby.

FACT: The Kestell/Leibham legislation would NOT ban embryonic stem cell research.

The Kestell/Leibham legislation does not ban embryonic stem cell research whereby embryos are created from sperm and egg in IVF clinics. These embryos are not created by human cloning. Thus, the Kestell/Leibham bans neither the creation or the use of these embryos. Representatives of the biotech industry and UW have continually said that they simply want to use the "spare" embryos in IVF clinics for research and have no intention of engaging in human cloning for research purposes. If the biotech industry and UW have been honest regarding this, then they should have no reason to object to the Kestell/Leibham legislation.

FACT: Embryos cloned for research are indeed HUMAN Embryos:

The biotech industry has been dishonest when they describe the embryos cloned for research as "unfertilized eggs" or "activated oocytes."

Even though the embryos who are cloned for the purpose of being destroyed in medical experiments do not involve fertilization by sperm, the result is still human embryos that are indistinguishable from embryos created by fertilization.

President Clinton's National Bioethics Advisory Commission, in its 1997 report *Cloning Human Beings* said, "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 a human embryo, with the apparent potential to be implanted in utero and developed to term."

FACT: Cloning human embryos for research has not yielded one single cure. In fact, adult stem cells are far superior to embryonic stem cells regardless of how the embryos are created.

Human cloning done for the purpose of destroying human embryos for research has not produced one single cure in animal models for any disease and has produced no cures in human clinical trials. In fact, embryonic stem cells derived from embryos created in any manner have demonstrated no success.

On the other hand, researchers have shown that adult stem cells, which do not involve the destruction or harm to human life, have had tremendous success. Adult stem cells have been successfully used on human persons to treat over 58 conditions, including brain and many other cancers, multiple sclerosis, Crohn's disease, rheumatoid arthritis, sickle cell anemia, stroke, limb gangrene, corneal regeneration, heart damage, Parkinson's disease, and spinal cord injury. And the list is still growing!

- more -

In summary then, the cloning of human embryos in Wisconsin for any purpose should be soundly rejected. The cloning of human embryos in order to destroy them in medical experiments involves the creation of human lives in order to destroy them. Although Wisconsin Right to Life opposes all embryonic stem cell research because it always involves the destruction of human life, we enthusiastically support the Kestell/Leibham legislation even though it would not affect embryonic stem cell research on embryos who have not been cloned. The goal of the biotech industry and UW is to eventually engage in human cloning for research purposes and Wisconsin Right to Life believes this must be stopped in its tracks. Finally, with the tremendous successes of adult stem cells and the complete lack of success using embryonic stem cells, it behooves the State of Wisconsin to prohibit research that is both unethical and unsuccessful and to encourage research on adult stem cells that is ethical and highly successful.

Wisconsin Right to Life urges you to vote in favor of the Kestell/Leibham legislation and to reject any amendments that would permit the cloning of human embryos in Wisconsin for any reason.


FORWARD

Testimony of R. Alta Charo
Elizabeth S. Wilson – Bascom Professor of Law & Bioethics
UW Law School and UW Medical School Department of Medical History and Bioethics
Regarding AB 499 and SB 243
June 20, 2005

Senator Zien, Representative Kestell and committee members,

Thank you for the opportunity to testify today. My name is Alta Charo, and I am the Elizabeth S. Wilson Professor of Law and Bioethics at the University of Wisconsin, with appointments in both the Law and Medical Schools. I am pleased to testify in support of legislation that criminalizes irresponsible experimentation that involves the use of somatic cell nuclear transfer - that is, cloning - to produce a live-born child, but urge you to resist efforts to ban potentially life-saving research that relies on the same cloning techniques but in no way is related to reproductive cloning.

Because cloning is not, and may well never be, a safe method for conceiving children, there is virtually perfect consensus that such attempts ought to be discouraged. Medical societies tell their members not to try it. The federal Food and Drug Administration has already effectively intervened to prevent it. It would be malpractice to attempt it, and there has been state and federal legislation introduced that would criminalize it. Clearly, there are many ways to stop the small number of publicity-hungry, irresponsible people who might want to risk the health of women and children by using reproductive cloning.

But the legislation now before you would ban not only the irresponsible use of cloning to make babies, but also the responsible use of non-reproductive cloning for research or therapy. Debates over reproductive and therapeutic cloning as well as stem cell therapy have become almost hopelessly entangled in the last five years. I urge you today to separate these debates, both to protect the valuable scientific and medical advances that may emerge from non-reproductive cloning research, and to pave the way to effective action to discourage attempts to use this technique to produce children.

Critics express concern that legislation that simply outlaws reproductive cloning will be difficult to enforce, and they urge policymakers to ban basic research, lest it lead to the prohibited act of transferring a cloned embryo into a womb for development. But criminal law is almost always grounded in a theory of deterrence. We do not prohibit the manufacture of guns in order to guard against the possibility of their future misuse in homicide. Rather, we criminalize misuse of guns and prosecute the offenders accordingly. The same can and should be done for reproductive cloning. Many states, including California, New Jersey, Connecticut and Massachusetts have done this, by criminalizing any effort to initiate a pregnancy with an embryo created by somatic cell nuclear transfer, that is, by cloning. At the same time, these states have left potentially life-saving research that uses cloning techniques legal and regulated.

Opponents of non-reproductive uses of cloning techniques for research and therapy argue that

the technique creates embryos solely to use and destroy them. Yet even prominent and lifelong opponents of abortion have nonetheless become strong proponents of research and therapeutic cloning. Senator Orrin Hatch and the late Senator Strom Thurmond, for example, introduced federal legislation to regulate non-reproductive uses of cloning rather than to ban it. Senator Hatch has stated that he does not view the cloned embryo in the same way that he views a developing fetus. Similarly, the Missouri legislature, which has frequently passed measures to restrict access to abortion, has concluded that the use of cloned embryos in research is actually less problematic than the use of so-called "surplus" embryos left in fertility clinics. For some, the distinction lies in the fact that a cloned embryo does not represent a new and novel potential person in our human community. For others, tolerance of this research comes from the fact that cloned embryos have little potential for healthy development and, in the absence of transfer to a woman' s body, no potential at all for development into a fetus or a baby. However one arrives at the distinction, it is important to note that for many members of Congress and for many state legislators around the country, opposition to abortion does not require opposition to non-reproductive research and therapeutic uses of cloning techniques.

Furthermore, we know - indeed, we fully expect - that embryos will be lost by the thousands every year at in vitro fertilization (IVF) clinics. Every couple who begins an attempt at IVF for purely reproductive purposes is the beneficiary of research that involved the deliberate creation of IVF embryos, solely for the purpose of doing research designed to increase the safety and efficiency of the procedure for infertile couples. And even now, every couple who begins an attempt at IVF for purely reproductive purposes knows that many, if not most, of the embryos they create will never develop into babies. Even if in vitro fertilization is done perfectly, and even if everyone who wants to "adopt" an embryo is successful, thousands would still be left behind. Criminalizing therapeutic cloning cannot alter the scale of embryo loss that we anticipate and tolerate each year. And since almost no one thinks in vitro fertilization could be outlawed, criminalizing a technique that might involve an exceedingly small number of embryos represents at best a symbolic effort at embryo protection.

Now, symbolic efforts are both powerful and important. They remind us that life is a gift that should be experienced with awe and gratitude. But a symbol can be badly tarnished if it is adopted at the expense of pain and suffering.

While reproductive cloning is a danger to children, non-reproductive cloning could save their lives. Cloning cells from someone with a genetic disease could produce tissue in which we study how the defective gene malfunctions, and help us develop drug treatments, perhaps reducing the number of human volunteers at risk in later clinical trials. Used to generate stem cells, it might become the fastest route to transplantation without risk of rejection. And perhaps most importantly, studying how cloning reprograms adult cells will help us learn how to reprogram cells directly, without cloning and without the use of embryos, to create tissue for research, transplantation and organ regeneration to alleviate paralysis and extend healthy life.

Let me give you an example. A tragically large number of younger women are destined to develop breast or ovarian cancer because they have the BRCA-1 or BRCA-2 mutation, a genetic defect. Today, we can diagnose the mutation and then give these thousands of women two terrible options. They can have their breasts and ovaries removed, maiming their bodies,

destroying their fertility, and putting them into menopause as early as the age of 21. Or they can engage in so-called "watchful waiting," in which they are monitored so that when the cancer appears – and it will appear – they have a somewhat better chance that the chemotherapy and radiation treatment will kill the cancer before the cancer kills them.

The reason these women have such terrible options is that while we can diagnose the mutation, we simply do not know how or why the mutation causes cancer. But cloning techniques may hold the key.

Today we can scrape some tissue from the inside of the mouth of one of these women. Then we use cloning techniques to activate the mouth tissue, creating a so-called "cloned embryo" from the activated cells of the mouth. After a few days, embryonic stem cells can be removed and used to grow breast and ovarian tissue in the laboratory that has the same genetic defect, the same BRCA-1 mutation that causes cancer. Now there is a laboratory model of the disease, one where scientists can observe how the mutation functions, and test methods to slow or stop its lethal march toward breast cancer.

And it isn' t just breast cancer that might be understood using this technique. It' s any disease that has a genetic component, whether diseases of the elderly like Alzheimer' s or the devastating, heartbreaking birth defects suffered by our children.

Yes, there are other promising avenues of research, and although none of them offer all the promise of cloning research, they most certainly should be pursued. But that is no argument for criminalizing this research. America is not a country in which basic research or personal choices are illegal until someone has persuaded the government to grant permission. Quite the contrary: We celebrate the freedom to think and to act and to inquire into the secrets of nature, until a compelling case can be made that it must be stopped. Identifying complementary areas of research falls far short of making that case.

You will also hear some argue that cloning research is only the tip of the iceberg, and that underneath the surface lies the spectre of eugenics. But research and therapeutic cloning is neither the beginning nor the end of a slippery slope toward eugenics. It is not even the most important landmark.

Our power over human reproduction is as old as ancient contraceptive potions. And the first announcements about in vitro fertilization were greeted with the same chorus of concerns about genetic engineering, designer babies, and the commodification of life, because it was in vitro fertilization that first made the embryo amenable to study and manipulation outside the body.

By contrast, therapeutic cloning does not design or engineer the embryo, and precisely because it is not about making babies, it neither designs nor engineers our children. It is not basic research, but rather our choices about its applications, that will shape the future.

Legislation that protects valuable non-reproductive uses of cloning technology while also guarding against its dangerous use to make a baby is consistent with the recommendations of the National Bioethics Advisory Commission and with the recommendations in the National

Academy of Sciences' two reports on stem cell research and reproductive cloning. The National Academy of Science Committee on the Biological and Biomedical Application of Stem Cell Research states in its report to the National Academy that "there is a scientific rationale for not foreclosing this avenue of research and for distinguishing clearly between SCNT (somatic cell nuclear transfer) to prevent transplant rejection and SCNT to create a fetus." Similarly, after two years of review, the California Advisory Committee on Human Cloning, which was commissioned by the California Legislature to conduct a comprehensive review of the issues raised by human cloning, unanimously recommended that California should ban human reproductive cloning but should not introduce legislation that would prohibit therapeutic cloning.

Nor is research cloning an unregulated field. Quite the contrary. In addition to banning reproductive cloning, the FDA also regulates how people donate eggs and cells for cloning research; how good laboratory practices are ensured; and how and when we proceed to human clinical trials of any therapies related to this research. Other federal regulations that apply include the human research subjects protections overseen by the Office of Human Research Protections at HHS and implemented at every institution by their local Institutional Review Board; oversight of recombinant DNA research and therapy by the Recombinant DNA Advisory Committee and implemented at every institution by their local Institutional Biosafety Committee; protection of medical confidentiality through the Health Insurance and Portability Protection Act; and, where applicable, coverage by the federal Animal Welfare Act and the local Institutional Animal Care and Use Committee.

In light of recent developments, the National Academy of Sciences has also developed a supplementary comprehensive set of ethical guidelines designed for self-regulation by the research community. These guidelines include a requirement for justification for the use of cloning techniques to derive customized stem cells; special oversight by a new local committee; and additional protections for the human subjects who donate their biological materials. Much of the impetus for this effort and much of the work that went into drafting the guidelines was done by two members of the UW-Madison faculty, myself and professor of pediatrics and bioethics, Dr. Norman Fost. These guidelines have already been adopted in California, have been endorsed by the American Association of Medical Colleges, and are in the process of being implemented in institutions across the country, including the UW-Madison. It would be ironic if UW-Madison faculty had led the way toward national regulation for the ethical management of this research, but UW itself was unable itself to pursue this research due to legislative prohibitions enacted in this state.

I would also suggest to you that given the extensive regulation that already exists, and the proposals for extending that regulation even further, outright prohibitions on cloning research are unduly burdensome and subject to constitutional challenge.

For thirty years, federal courts and nationally recognized scholars have discussed the scope of the First Amendment and its protection of scientific research as part of the freedom of thought, inquiry, and dissemination of knowledge that is at the core of that aspect of the Bill of Rights. Research is an integral part of the scientific method, a form of inquiry that fits uniquely within the purposes, histories, and structures of the First Amendment. Thought and the testing of thoughts through science facilitates the dissemination of ideas just as much as monetary

contributions to political candidates facilitates the expression of political ideas.

Indeed, in many cases, research is in and of itself a form of challenging political ideas. In other places and other times, governments have sought to ban the dissection of human bodies, because it would interfere with deeply felt notions of the body as a reflection of the divine order, or have sought to ban investigation of the orbits of the planets, as it would interfere with essential views about the place of humankind in the universe. So, too, does investigation of the origins of life, of the secrets of conception and development, threaten our deepest views concerning the sources of life. But the First Amendment exists precisely to protect the development and dissemination of knowledge and truth and opinion, so that they may be tested and re-tested over time in the marketplace of ideas.

Of course even protected activities are subject to reasonable regulation to avoid interfering with the rights of others. But where prohibitions are designed merely to guard against the development of knowledge, for fear it might someday lead to new and controversial ways to manipulate cells and genes, those prohibitions run afoul of the very basis of the First Amendment protection of inquiry, association, and dissemination. Any law that goes beyond reasonable regulation of cloning research and bans this form of scientific inquiry is thus vulnerable to challenge in court as an interference with the First Amendment rights of patients and researchers.

In sum, if the legislature wishes to take action with regard to reproductive cloning, I urge it to focus on legislation that prevents that unsafe practice. But to ask for more, to halt basic research, is to sacrifice the diabetic children, the paralyzed veterans, the surgically maimed breast cancer victims, the skin-scorched firefighters and the declining elderly of the present for a future that is neither certain nor imminent.

To be sure, we should deter those who would use cloning for reproductive ends despite its dangers. But we should go no further. Criminalizing research and therapeutic cloning is not the way to protect embryos or to guard against the future. It merely gambles with the hope held by many people today that they may live to see tomorrow, whatever it holds.

Thanks very much.


FORWARD
E PLURIBUS UNUM

TESTIMONY OF ANDREW COHN
GOVERNMENT RELATIONS DIRECTOR
WISCONSIN ALUMNI RESEARCH FOUNDATION
AB 499 & SB 243
June 20, 2005

Thank you Chairpersons Zien, Kestell and members of the committee I am pleased to be able to appear before you today to discuss the practical effects of AB 499 and SB 243. My name is Andrew Cohn and I am the Government Relations Manager for the Wisconsin Alumni Research Foundation and the WiCell Research Institute. WARF is an independent non-profit organization that has been providing support to the University of Wisconsin-Madison for over 80 years. We carry out this mission by moving technology from the laboratory to the marketplace for the benefit of the university, the inventors and humankind. Revenue received from this transfer is invested by WARF and at the end of each year we provide a grant to the university that is primarily used to support research. Last year, WARF gave the university approximately $50 million. WARF has contributed or committed over $750 million to the university since 1925. WARF receives absolutely no state funding to support its programs. All of the revenues derive from licensing income paid by private companies, that develop products based on university inventions. We also generate income through investments in our endowment.

WARF's success has furthered economic development in Wisconsin and beyond. Currently we have equity in 34 companies that have been built around WARF technology WARF technologies at the core of their business.

The WiCell Research Institute is a non profit subsidiary whose mission is two fold: 1) to provide human embryonic stem cells for research purposes to academic scientists and train scientists on how to work with these incredible cells, and 2) to engage in hes cell research utilizing the expertise of our staff and the University of Wisconsin scientific community.

WARF is speaking in opposition to AB 499 and SB 243 because the bill contains provisions that would send a message to scientists on campus and to excellent scientists we are trying to recruit that the state of Wisconsin is a hostile environment for stem cell research. HES cell research provides an incredible economic development opportunity for the State of Wisconsin. Dr. James Thomson, The WiCell Research Institute and the University of Wisconsin-Madison are recognized as world leaders in this important scientific endeavor.

I hope that you understand that other states are trying desperately to compete with Wisconsin in human embryonic stem cell research. I am sure you are aware that California has approved spending $3 billion on stem cell research in order to find treatments and cures for the world's most devastating diseases but also to capture the economic development potential of this science. Universities in California and other states are recruiting our scientists with funds provided by the states to support hES research. Passing legislation that makes the top scientists in the world felons is not a viable retention or recruitment strategy. The legislature in Massachusetts has just overturned a veto of stem cell legislation that allowed research cloning in that state. Even Connecticut has provided $100 million in funding for hES cell research over the next ten years. Wisconsin is in a global competition that is being waged with government funding and support for scientific freedom. This bill will add to Wisconsin's disadvantages in that competition.

Wisconsin holds a strong patent position in this emerging field. It makes no sense to waste that advantage by passing this legislation. WARF is currently negotiating with several companies interested in locating in Wisconsin to pursue business opportunities provided by this important discovery. The provisions of this bill would be a major disincentive for these companies to locate their business in Wisconsin. Their entire reason for being here would be to engage in this research to help find treatments and cures for the world's most devastating diseases. Why would they locate in a state that would dictate limitations on this research not imposed by the federal government or many state governments?

This legislature has consistently been concerned about how legislation affects small business and non profits. This legislation would add significant roadblocks to small companies interested in operating in this exciting new field.

Thank you for your attention and I would be happy to answer any questions you may have.

Phone: 263 2821 e-mail: cohn@warf.org


FORWARD
E PLURIBUS UNUM

Joe Leibham

State Senator
9th State Senate District

Testimony Submitted to the
Senate Committee on Judiciary, Corrections and Privacy and the
Assembly Committee on Children and Families
Senate Bill 243 and Assembly Bill 499
June 20, 2005

Thank you Chairman Kestell, Chairman Zien, committee members and concerned citizens. It's an honor to submit this testimony in favor of Senate Bill 243 and Assembly Bill 499. I thank you for your service to our state.

The cloning of human life is biologically and scientifically questionable and ethically and morally wrong. SB 243 and AB 499 are companion pieces of important legislation that will provide a comprehensive ban on human cloning in Wisconsin while promoting ethical research in our state. This legislation seeks to ensure that the uniqueness of human life is not degraded and commercialized, but is instead dignified and cherished.

Specifically, SB 243 and AB 499 prohibit:

- "Reproductive" cloning – bringing a cloned embryo to birth;
- "Therapeutic" cloning – cloning a human embryo for the purpose of experimentation; and
- Parthenogenesis – the manipulation of a human egg cell to develop into an embryo without fertilization.

While these bills provide a comprehensive ban on human cloning and parthenogenesis, they will not hinder life-saving medical research. The cloning of tissue and the promising adult stem cell and umbilical cord blood research will still be allowed and I am proud to be a supporter of such ethical research. The bill will not hamper or criminalize any research currently taking place at the UW or in Wisconsin.

The cloning of a human being is not without risk of peril. There is the potential for serious scientific and biological problems with human cloning, and the possibility that deformities and abnormalities may result has never been ruled out.

Research cloning would contradict the most fundamental principle of medical ethics – that no human life should be exploited or extinguished for the benefit of another.

The prospect that a human life could be cloned here In Wisconsin is alarming. The interest and realization of the need to ban human cloning is being recognized all across our country. Many other states have human cloning bans on their books. Among them are our neighbors in Iowa and Michigan. It is my strong belief that Wisconsin should follow suit.

Thank you again for this hearing, and thank you again for your service to our great state!

It is an honor representing the residents of the 9th District in the State Senate!

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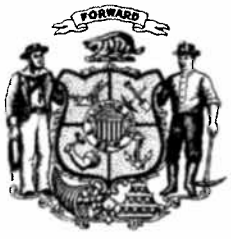
WISCONSIN STATE LEGISLATURE



WISCONSIN CATHOLIC CONFERENCE

STATEMENT IN SUPPORT OF A PROPOSED CLONING BAN
Presented by John Huebscher, Executive Director
June 20, 2005

On behalf of the Wisconsin Catholic Conference I speak in support of both Assembly Bill 499 and Senate Bill 243.

Every generation must seek to define the relationship between means and ends as it addresses the question of how or whether to use new technologies. The realization that something can be done must always be accompanied by the question should it be done.

The capacity to engage in human cloning compels us to evaluate anew the moral question of whether the end justifies the means. This is not a question for scientists alone to answer, nor solely the concern of researchers, venture capitalists, or patients. It is a question for all of us.

Any decision or policy regarding human cloning must always be assessed in view of its impact on the dignity of human life. And there can be no doubt that the embryos created via cloning are human life. Indeed, it is the very fact that embryos are human that drives the desire to create them.

As an intrinsic good, human life may not be reduced to a means to some other end. No person should be intentionally sacrificed for someone else's advancement. Cloning, whether undertaken for reproductive purposes or research purposes, does just that.

Reproductive cloning is nothing more than an attempt to design human beings to human specifications. This is wrong.

Research cloning, on the other hand, contemplates the creation of human life for the express purpose of destroying it. This too, is wrong.

When we say cloning is wrong, we do so not as a religious sect seeking to impose our dogma on a pluralistic society. Rather, we speak as citizens, grounded in our religious values, urging other citizens to reaffirm a "self-evident truth" on which our state and nation was founded. Specifically, that every member of the human family is endowed by our Creator with an inalienable right to life.

The Founders recognized that no human being depends on another for his or her right to exist. Our lives do not belong to someone else, not to a king asserting dominion, not to a plantation owner pursuing profit, not to a scientist seeking cures, not to a wealthy individual seeking to recreate himself.

Human beings are neither beasts nor gods. We cannot rule other people as we would rule beasts or as God would rule us. No one in this room chose to be born. Nor did we choose to be born as people. We did not choose our race, our sex, or our intelligence. As we were not able to choose our humanity, neither are we free to deny or define the humanity in others.

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Some will argue that the embryo is not a human being and that we impose religious dogma when we say that it is. But the Catholic Church has been informed by what science has to say on the question of when life begins.

Science tells us that from the time an embryo is formed a new life has begun. Science tells us that this being is unique with its own genetic code. Science tells us that an embryo possesses a unity in which the parts of the embryo interact with each other to sustain the embryo's life and foster its development.

Some may argue that life at this early stage does not deserve respect or legal protection. They argue that opponents of cloning extend the concept of the human person too far.

If the law in fact treated only those born of a woman as legal persons, this argument might be persuasive. But Courts and legislators have not been so rigid. For instance, the Supreme Court held--and continues to hold--that a corporation is a legal person covered by the terms of the Fourteenth Amendment and thus entitled to the state's protection. So, too, a ship is a legal person, similarly protected in its rights.

It takes more creativity than I have to argue that an embryo is less like a fully developed adult human being than is a corporation or a ship. If our laws can hold that a ship or a corporation has rights due a person than it is hardly a "stretch" for our laws to hold that an embryo is also a person, at least to the extent of deserving to be protected from actions that intend its destruction.

Some try to distinguish between reproductive cloning and research cloning, arguing that the latter is acceptable.

My question is "Why?" If one truly believes that an embryo does not merit the respect due a human person, why make such a distinction at all?

The best cloning supporters seem to offer is that research cloning promotes a public purpose that is somehow more laudable than the private purpose served by reproductive cloning. Thus does the end of better health care seem to justify the means of cloning – and destroying – a human being.

In our debate over slavery, Lincoln asserted that the freedom of all was undermined by the denial of freedom to some, whatever the justification for doing so. Thus it is unlikely he would have accepted the argument that it was unjust to enslave a human being for the private purpose of working a plantation but acceptable to enslave another human being for the public good of building a railroad or digging a canal. The common good is not served by denying the moral status of the most vulnerable members of our human family.

We can do better. We can reaffirm the self-evident truth that the right to life is inalienable. We can and should support AB 499 and SB 243.

Thank you.


FORWARD
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Pro-Life Wisconsin

Defending them all...

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Testimony in support of AB 499 / SB 243:
Comprehensive Human Cloning Ban
Assembly Children and Families Committee / Senate Judiciary, Corrections and Privacy Committee
By Matt Sande, Director of Legislative Affairs

June 20, 2005

Good afternoon Chairman Kestell, Chairman Zien, and committee members. Pro-Life Wisconsin appreciates the opportunity to express our strong support for Assembly Bill (AB) 499 and Senate Bill (SB) 243, companion legislation that has been carefully crafted to ban all forms of human cloning – including parthenogenesis. Cloning perverts God's design for creating new life. In cloning, a child is not created; a new life is simply manufactured. A child becomes a product, and a product is never considered equal to its producer. In short, cloning is a perverse mode of generating human life that affronts the dignity, equality and freedom of human life at its very beginning.

Before discussing the ethical and public policy issues surrounding the creation of human embryos through cloning, we must answer the *scientific* question of what these early human embryos are. *When does human life begin?** **Human embryologists** – the real scientific experts in the area of human development – authoritatively conclude that a human embryo is a human being, immediately beginning at fertilization or cloning. At no other logical or scientifically sound point can we say that human life begins.** The embryo is not an organ or some pre-human cellular glob without purpose or plan. Embryologists categorically reject the notion of a "pre-embryo" or some form of evolving "human-being-on-the-way." From its inception, the embryo contains its entire genetic makeup and needs only time to grow and develop into a recognizable human person.

AB 499 and SB 243 ban so-called "reproductive cloning," where a cloned human embryo is brought to birth, and so-called "therapeutic cloning," where a cloned human embryo is experimented upon and killed in the name of scientific progress. The terminology is, of course, problematic because it implies that there is a difference between "reproductive" and

*"**At the moment the sperm cell of the human male meets the ovum of the female and the union results in a fertilized ovum (zygote), a new life has begun.**" Considine, Douglas (ed.). *Van Nostrand's Scientific Encyclopedia*. 5th edition. New York: Van Nostrand Reinhold Company, 1976, p. 943.

Ronan O'Rahilly is one of the international "deans" of human embryology and the developer of the *"Carnegie Stages of Early Human Development,"* which classify human embryology. He sits on the international board (Nomina Embryologica**), which determines the terminology to be used in this field. In his book, the leading text on human embryology, he confirms that human life begins at fertilization and repudiates the term "pre-embryo" as scientifically ill-defined, equivocal, unjustified and politically motivated.

"therapeutic" cloning. But the distinction between the two is illusory, and it is intentionally misleading. **Both involve the reproduction of a fully human life.** Once the nucleus of a somatic cell is injected into an empty egg and stimulated to begin development, it is a human embryo. The difference lies in the intended use of that human embryo – whether it is to be implanted in the womb and brought to birth (reproductive cloning) or whether it is to be eviscerated by extracting its stem cells (therapeutic cloning). Either intention is repugnant, in that the dignity and individuality of the human person is thoroughly disregarded.

The primary argument against "reproductive" cloning is straightforward and widely shared – it is dangerous. Cloning is an assault on human life, both physically and psychologically. It carries "massive risks of producing unhealthy, abnormal and malformed children," according to Dr. Leon Kass, chairman of the President's Council on Bioethics. Most cloned sheep embryos have died soon after being produced (during gestation or soon after birth) due to congenital disorders. The report of the one successfully cloned sheep in Scotland was preceded by 277 failures. One can reasonably expect that similar results would hold true for humans. Producing a child of known genetic makeup implies conditional parental acceptance, which is harmful to a child's social and psychological development.

The primary argument against "therapeutic" cloning is also straightforward but less widely shared – it intentionally kills another human being. Supporters of "therapeutic" cloning often say that they support cloning only to "produce stem cells," evading the fact that they must create and then destroy fully human embryos to produce those stem cells. "Therapeutic cloning" is really just the opposite, because it involves nontherapeutic experiments on a defenseless human being – experiments that kill the human being solely for the benefit of others.

Banning only so-called "reproductive cloning" would allow "therapeutic cloning" to proceed with impunity. In fact, by prohibiting the placement of cloned human embryos in wombs (natural or artificial), **a ban on only reproductive cloning would necessarily mandate that *all* cloned human embryos be destroyed. That is why it is referred to as "clone to kill."** Such a ban would create a new crime: the crime of trying to "initiate a pregnancy" with a cloned human embryo. Will the law then mandate an abortion, the destruction of a born child, or imprisonment of the mother and/or child? The only thing that an exclusive ban on reproductive cloning would ban is the survival of persons created by cloning. It is worse than doing nothing at all.

Therapeutic cloning will pave the way for reproductive cloning, realizing our worst fears. President Bush has warned that it will be next to impossible to prevent multitudes of cloned human embryos from being implanted in wombs. According to the President, "Once cloned embryos (are) available, implantation would take place. Even the tightest regulations and strict policing would not prevent or detect the birth of cloned babies." The U.S. Department of Justice has declared that a prohibition on transferring cloned human embryos into wombs would be unenforceable.

Often overlooked is the negative impact therapeutic cloning would have on women's health and dignity. It would require countless numbers of women to donate their eggs through a painful and dangerous extraction process, and it would turn women into human egg factories to be commercially exploited.

Concerning women's health, the use of superovulatory drugs and the invasive egg extraction procedure are linked to grave health risks: severe pelvic pain, nausea, rupture of the ovaries, bleeding into the abdominal cavity, respiratory problems, liver dysfunction, blocking of blood vessels by blood clots, and on rare occasions surgery may be required which may leave a patient infertile.*

Concerning women's dignity, research cloning commodifies women by creating a massive market of female eggs that women would produce solely for monetary compensation. The trafficking of female body parts for cloning is a natural result, as is the victimization of marginalized women. Scientists have acknowledged that treating just one major disease, such as diabetes, would require up to 800 million eggs harvested from about 80 million women. Research cloning would undoubtedly initiate a new exploitation of women, especially those of low socioeconomic status.

To be sure, **a ban on human cloning will not hinder lifesaving medical research in Wisconsin**. AB 499 and SB 243 allow stem cell research. Ethically unproblematic adult stem cells have helped hundreds of thousands of patients, and new clinical uses are discovered almost weekly. Adult stem cells have already been used to treat cancers, restore vision, repair damaged spinal cords, and treat juvenile diabetes and Parkinson's disease.

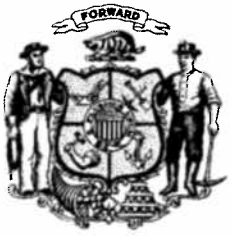
Pro-Life Wisconsin is proud to continue are work with Representative Kestell and Senator Leibham on this critical legislation. We too want to see research move forward in the hopes of discovering treatments for disease, and we *can* move forward ethically so long as we do not create life simply to kill it for the benefit of others. **Wisconsinites deserve the assurance that their state can build on its lead in biotechnology without compromising its bioethics.**

I urge the committees to recommend adoption of AB 499 and SB 243, and I would like to conclude with a quote from President Bush that, in my opinion, sums up the debate:

> *"Advances in biomedical technology must never come at the expense of human conscience. As we seek what is possible, we must always ask what is right, and we must not forget that even the most noble ends do not justify any means...Research cloning would contradict the most fundamental principle of medical ethics, that no human life should be exploited or extinguished for the benefit of another."*
>
> Remarks by the President on Human Cloning Legislation, April 10, 2002.

*(FDA TAP Holdings, September 12, 1996; September 4, 1997; "Lupron and Synarel Patient Information," *Specialists in Reproductive Medicine and Surgery*, P.A., 2001; FDA, Review of Lupron 1999.)

WISCONSIN STATE LEGISLATURE



THE UNIVERSITY of WISCONSIN MADISON

Testimony of John D. Wiley
Chancellor
Regarding AB 499
June 20, 2005

Senator Zien, Representative Kestell and committee members,

My name is John Wiley, and I am the Chancellor at UW-Madison. Thank you for the opportunity to testify today. UW-Madison is pleased to testify in support of legislation that criminalizes irresponsible experimentation that involves the use of somatic cell nuclear transfer - that is, reproductive cloning - to produce a live-born child.

However, this bill isn't about cloning. It is a back-door attempt to criminalize some forms of embryonic stem cell research. In some respects, this is an anti-stem cell bill dressed up like Dolly.

No one at the university or anywhere else is planning or engaged in cloning experiments, therapeutic or otherwise. Reproductive cloning is not only impractical, but has already been condemned by the scientific community. Therapeutic cloning, while not planned at the university, is a technique that may have great promise for helping treat and prevent disease. In science, no one can predict where the next best research tool or therapy will come from. We should not be ruling out legitimate avenues of biomedical research.

Closing the door on therapeutic cloning would be a mistake and deprive us of any future -- and now unknowable -- opportunities to treat disease and develop new biomedical tools. For example, therapeutic cloning may provide a window to the genetic origins of many diseases, including some forms of cancer, Parkinson's, diabetes, heart disease and others. Such insight may actually help us figure out ways to prevent theses terrible diseases.

If legislators are interested in passing a bill to ban reproductive cloning, we'll be on board. The language of this bill, however, makes it clear that some are more interested in putting a halt to stem cell research than they are to dealing with research excess that now is only the stuff of science fiction. This bill can easily be amended to ban reproductive cloning once and for all while preserving the promise of science.

Many of the concerns raised in this legislation are already encompassed by many levels of existing federal rules and regulations. In addition, the UW-Madison Bioetchics Advisory Committee has not been silent on these topics and has issued clear guidelines for the campus. Finally, the university is now in the process of adopting the recent National Academies of Science guidelines on stem cell research, which will add yet another layer of regulation on this field of research. It is not occurring in a regulatory vacuum and legislators should resist pressure to blindly regulate a promising area of biomedical science.

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This bill, and others like it send a chilling message to researches around the world that Wisconsin does not welcome them or this promising science. This message will be heard by not only stem cell biologists, but other scientists across many disciplines. Wisconsin should not be known as the state that is not friendly to research and biotechnology industry investment.

Finally, we are not alone in our desire to see stem cell research advanced while still banning reproductive cloning. It is clear that the public broadly supports embryonic stem cell research. In fact, a recent survey shows that 69 percent of Wisconsin voters approve of the science.

Thank you for the opportunity to testify, I will address any questions you may have.

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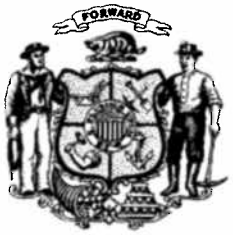


JUN 21 2005

REPRESENTING WISCONSIN BUSINESS

WISCONSIN TECHNOLOGY COUNCIL

UNIVERSITY RESEARCH PARK
UNIVERSITY OF WISCONSIN-MADISON

June 21, 2005

TO: Members of the Wisconsin Legislature

FROM: James S. Haney, Wisconsin Manufacturers and Commerce
Mark D. Bugher, University Research Park
Tom Still, Wisconsin Technology Council

RE: SB243/AB499/ Therapeutic cloning legislation

We write to urge amending a bill that would effectively ban all cloning-related research in our state. While we oppose on moral and ethical grounds human embryonic cloning for purposes of **reproduction**, carefully regulated **therapeutic** cloning for the purposes of medical research and the development on new diagnostic and therapeutic treatments and drugs is worthwhile and ethically defensible.

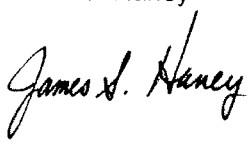
The bill before you would effectively ban both types of cloning and related research, without regard to the possible -- even likely -- human benefits of therapeutic cloning. While there are similarities between the two processes in the earliest stage, reproductive and therapeutic cloning are remarkably different in their goals and applications over time.

Any effort to ban therapeutic cloning would chill stem cell research in Wisconsin, which pioneered this science, and send the disturbing message that Wisconsin does not welcome responsible, ethical research conducted by our top scientists.

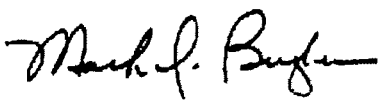
Wisconsin is one of only a few states that can lead in stem cell research. That cannot happen, however, if our research and development institutions are asked to compete with their hands tied behind their backs.

We urge you to vote against the legislation as proposed until it distinguishes between reproductive and therapeutic human cloning. Please amend the bill to allow carefully regulated therapeutic cloning.

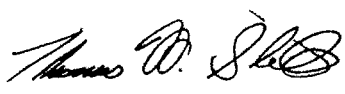
James S. Haney



Mark D. Bugher



Thomas W. Still



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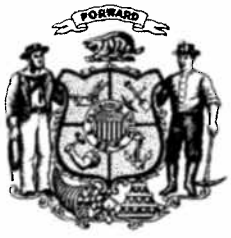

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SCIENTIFIC COMMUNITY

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Creative Science Will Resolve Stem-Cell Issues

By Markus Grompe
And Robert P. George

The House of Representatives recently passed legislation to loosen President Bush's restrictions on federal funding of embryonic stem-cell research. The president has promised to veto the bill, however, and the legislation lacks the support of a veto-proof majority. So regardless of what happens in the Senate, it is clear that, at least until 2009, there will be no federal money for research involving stem cells derived from embryos destroyed after Aug. 9, 2001. Americans are divided as to whether this is good or bad, but it is the one thing about which there is now no debate.

President Bush's veto need not mean that new embryonic or embryonic-type stem-cell lines eligible for federal funding cannot be developed, however. The President's Council on Bioethics, in a recent White Paper, identified several possible methods for producing such lines that do not require the destruction or harming of living human embryos. There is good scientific reason to believe that this can be done using existing biotechnologies. These possibilities point the way towards a resolution of our nation's divisive debate over embryonic stem-cell harvesting—one that can be embraced in good conscience by people on both sides of the ethical divide.

* * *

What is fascinating about embryonic stem cells, and makes many people believe that someday they will have important therapeutic value (though they have not demonstrated such value as yet), is their "pluripotency"—their capacity to form any and every type of human body cell. But a stem cell (even an embryonic stem cell) is not an embryo; it is not "totipotent"—that is, capable of developing to the next stage of maturity as a new individual of the species. Unlike an embryo, a stem cell is not a complete organism in the beginning stages of its natural development. It is merely part of the larger organism, like any other body cell.

The ethical problem arises because human pluripotent stem cells are obtained today by destroying living human embryos. The solution, if technically feasible, is to produce human pluripotent stem cells directly, that is, without first creating an embryo which must be destroyed or damaged in the process of harvesting stem cells.

One promising option is called oocyte assisted reprogramming (OAR). This is a variation of a broader concept known as altered nuclear transfer. It combines basic cloning technology with what is known as epigenetic reprogramming.

In cloning, the nucleus of a somatic cell (such as a skin cell) is transferred to an egg cell whose nucleus has been removed. An electrical stimulus is administered in a way that, if all goes as planned, triggers the development of a new and distinct organism, an embryo, that is virtually identical in its genetic constitution to the organism from which the somatic cell was taken. In OAR, however, the somatic cell nucleus or the egg cytoplasm or both would first be altered before the nucleus is transferred. The modifications would change the expression of certain "master genes"—transcription factors that control expression of many other genes by switching them on or off.

These genetic alterations would permit the egg to reprogram the somatic cell nucleus directly to a pluripotent, but not a totipotent (i.e., embryonic) state. The altered expression of the powerful control gene would ensure that the characteristics of the newly produced cell are immediately different from, and incompatible with, those of an embryo. For optimal reprogramming, master genes known to control the pluripotency of embryonic stem cells would be used, for example the transcription factor known as "nanog." Thus, we would reasonably expect to obtain precisely the type of stem cells desired by advocates of embryonic stem-cell research, without ever creating or killing embryos.

This method of obtaining human pluripotent stem cells would not only be morally unimpeachable (assuming nothing unethical is done in obtaining somatic cells or oocytes used in the process), it would have other important advantages over using so-called spare embryos left over from in vitro fertilization efforts. Unlike stem cells from IVF embryos, scientists could control the genetic structure of OAR-produced stem cells. Their genetic constitution would be virtually identical to that of the donor, thus helping to overcome the problem of immune rejection.

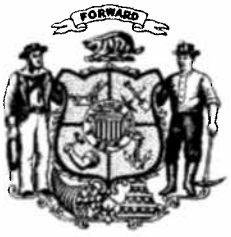
* * *

Our proposal is not the only possible way for pluripotent stem-cell science to work around the ethical impasse. Progress has recently been reported on another strategy similar to OAR, but using embryonic stem cells, rather than eggs, for reprogramming adult cells to the pluripotent state. Like OAR, further research is needed to confirm that this "cell fusion" strategy will work. If it does, the required embryonic cells could be taken from lines created prior to Aug. 9, 2001, making this research eligible for federal funding.

When he announced his intention of vetoing the embryonic stem-cell bill, President Bush noted that researchers are exploring "different ethical ways of getting the same kind of cells now taken from embryos without violating human life or dignity." He added: "With the right policies and the right techniques, we can pursue scientific progress while still fulfilling our moral duties." The country will likely remain divided about the ethics of research using human embryos. But we believe that creative science can help us find a way forward and thus put pluripotent stem-cell research on a footing that all citizens can enthusiastically support. That would be a great day for science, for morality, and for our nation.

Dr. Grompe is a professor of genetics at the Oregon Health and Science University, director of the Oregon Stem Cell Center and a member of the International Society for Stem Cell Research. Mr. George is McCormick Professor of Jurisprudence and Director of the James Madison Program in American Ideals and Institutions at Princeton. He serves on the President's Council on Bioethics.

WISCONSIN STATE LEGISLATURE



MAKING STEM CELLS, NOT PEOPLE

Scientists believe there is great potential for creating new human embryonic stem cell lines using a method known as somatic cell nuclear transfer (SCNT—often called "therapeutic cloning.") But there is still widespread confusion over how the technique is used. When scientists use SCNT to create stem cells, no sperm is used and the resulting cell has no chance of developing into a human being because it is never placed in a uterus. This is a fundamentally different procedure from reproductive cloning, as was used by scientists in 1996 to create Dolly the sheep.

USING SCNT FOR CREATING STEM CELLS IS FUNDAMENTALLY DIFFERENT FROM USING IT FOR REPRODUCTIVE CLONING.

SCNT involves removing the nucleus of a donor's unfertilized egg and replacing it with the nucleus of an adult cell, such as a skin, heart or nerve cell. No sperm is used in the procedure. The goal is to create embryonic stem cells, and the cell, with its new nucleus, is placed in a lab dish and stimulated to begin dividing. After five or six days, it develops into a hollow cellular ball from which researchers can extract embryonic stem cells. The new cell is never placed in a uterus and thus will not develop into a human being. The first human embryonic stem cells created through SCNT were developed by scientists in South Korea in February 2004. With adequate support, other scientists using and refining this method will be able to produce more human stem cell lines.

SCIENTISTS BELIEVE SCNT OFFERS GREAT THERAPEUTIC AND RESEARCH POTENTIAL.

Embryonic stem cells derived through SCNT are unique in that they are genetically matched to the adult cell donor, meaning they might be transplanted into the donor without need for suppressing the immune system. For example, stem cell lines derived through SCNT from a person with a spinal cord injury could potentially be directed to develop into nerve cells, and these nerve cells could be used to treat the same patient. In addition to its therapeutic potential, SCNT offers a powerful way to gain insight into the development of diseases. A stem cell taken from a person with a complex genetic disease could be used to study how the disease develops from its earliest stages.

SCNT FOR STEM CELL PRODUCTION IS ENDORSED BY THE NATIONAL ACADEMY OF SCIENCES[1]

In a 2001 report assessing the potential of stem cells and how it can best be realized, the National Academy of Sciences (NAS) said that SCNT is essential to finding ways to overcome tissue rejection by producing cells that are a genetic match to a patient. In addition, 40 Nobel Laureates have released a letter expressing concern that a ban on all human cloning research would "have a chilling effect on all scientific research in the United States."[2]

A CLEAR MAJORITY OF AMERICANS SUPPORT THE USE OF SCNT TO PRODUCE STEM CELLS

A poll commissioned for the Coalition for the Advancement of Medical Research (CAMR) showed that 67 percent of Americans support the use of SCNT for stem cells and want the government to allow it to proceed. The poll surveyed 1,012 adult Americans on March 6, 2003, and was conducted by Opinion Research Corporation International.[3]

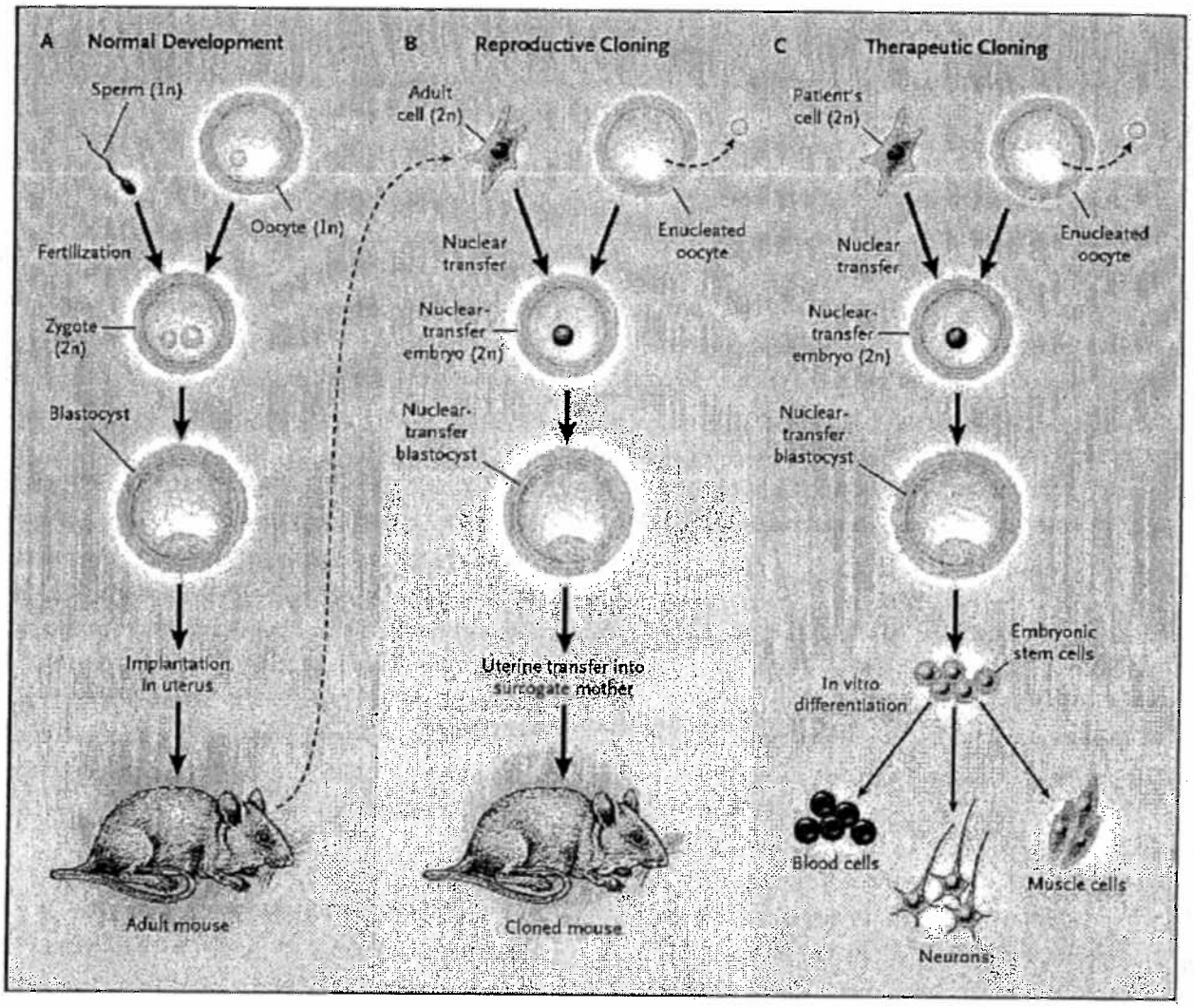
USING SCNT FOR HUMAN REPRODUCTIVE CLONING IS UNETHICAL. THERE IS ALMOST UNANIMOUS OPPOSITION TO HUMAN REPRODUCTIVE CLONING.

The most effective method for preventing human reproductive cloning is to pass federal legislation banning the practice and imposing severe penalties on those who violate the law. Such legislation will be re-introduced in the new Congressional session that could eliminate the threat quickly, while preserving scientific research.

[1] National Academy of Sciences, Stem Cells and the Future of Regenerative Medicine, 2001, "Recommendations," p. 5
[2] http://www.camradvocacy.org/fastaction/news.asp?id=210
[3] http://www.camradvocacy.org/fastaction/arc_news.asp?id=544

JDRF Juvenile Diabetes Research Foundation international

dedicated to finding a cure



SOMATIC CELL NUCLEAR TRANSFER (SCNT) TO PRODUCE STEM CELLS DOES NOT INVOLVE SPERM OR IMPLANTATION INTO A UTERUS. STEM CELLS ARE PRODUCED FOR CLINICAL OR RESEARCH PURPOSES.

JDRF Juvenile Diabetes Research Foundation International

dedicated to finding a cure

WHITE PAPER: Alternative Sources of Pluripotent Stem CellS

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The President's Council on Bioethics
Washington, D.C.
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http://bioethicsprint.bioethics.gov/

Glossary

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

Altered Nuclear Transfer (ANT): A proposed method, using a modified form of somatic cell nuclear transfer (SCNT), of producing a biological artifact from which human pluripotent stem cells could be derived.

Anencephalic fetus: A fetus with a congenital defect related to development of the brain, with absence of the bones of the cranial vault and absent or rudimentary cerebral and cerebellar hemispheres, brainstem, and basal ganglia. (SMD)

Aneuploid: Having an abnormal number of chromosomes. (SMD)

Autologous: Derived or transferred from the same individual's body.

Biological artifact: As employed here, this phrase denotes an artificially created non-embryonic but embryo-like cellular system, engineered to lack the essential elements of embryogenesis but still capable of some cell division and growth.

Biopsy: Process of removing tissue from patients for diagnostic examination. (SMD)

Blastocyst: In mammals, an early stage of embryonic development at which the embryo (roughly 100-200 cells) is a hollow sphere made up of an outer layer of cells (the trophectoderm), a fluid-filled cavity (the blastocoel), and a cluster of cells on the interior (the inner cell mass).

Blastomere: A cell contained within an early embryo (up to two days after conception, at which point the embryo comprises about 8 blastomeres).

Blastomere biopsy: Removal of one or two blastomeres from the embryo in vitro at about the 8-cell stage, usually in order to perform preimplantation genetic diagnosis and screening.

Blastula: An early stage of embryonic development (roughly 100-200 cells) at which the cells of the morula are rearranged to form a hollow sphere; at this stage of embryonic development in humans and other mammals, the embryo is generally called a *blastocyst*.

Bone marrow: The soft, fatty, vascular tissue that fills most bone cavities and is the source of red blood cells and many white blood cells.

Chimera: In experimental embryology, the individual produced by grafting an embryonic part of one animal on to the embryo of another, either of the same or of another species. (SMD)

Chromosomes: Structures inside the nucleus of a cell, made up of long pieces of DNA coated with specialized cell proteins, which are duplicated at each mitotic cell division. Chromosomes thus transmit the genes of the organism from one generation to the next. (CR)

Cleavage arrest: Spontaneous cessation of cell division in an early embryo.

Cloned embryo: An embryo arising from the somatic cell nuclear transfer process as contrasted with an embryo arising from the union of an egg and sperm. (CR)

Cloning:

Cloning-to-produce-children—Production of a cloned human embryo, formed for the (proximate) purpose of initiating a pregnancy, with the (ultimate) goal of producing a child who will be genetically virtually identical to a currently existing or previously existing individual.

Cloning-for-biomedical-research—Production of a cloned human embryo, formed for the (proximate) purpose of using it in research or for extracting its stem cells, with the (ultimate) goals of gaining scientific knowledge of normal and abnormal development and of developing cures for human diseases.

Human cloning—The asexual reproduction of a new human organism that is, at all stages of development, genetically virtually identical to a currently existing, or previously existing, human being. (CR)

Cord blood: Blood in the umbilical cord and placenta.

Cryopreservation and **Cryostorage:** Freezing of IVF embryos for later use.

Cytoplasmic: Of or pertaining to the substance of a cell, exclusive of the nucleus. (SMD)

Dedifferentiation: A procedure whereby differentiated, somatic cells are restored to a more undifferentiated, multipotent condition.

Diploid: Refers to the full complement of chromosomes in a somatic cell, distinct for each species (forty-six in human beings). (CR)

Embryo: (a) In humans, the developing organism from the time of fertilization until the end of the eighth week of gestation, when it becomes known as a fetus. (NIH) (b) The developing organism from the time of fertilization until significant differentiation has occurred, when the organism becomes known as a fetus. An organism in the early stages of development. (CR)

Embryogenesis: That phase of prenatal development involved in establishment of the characteristic configuration of the body of the embryo; in humans, embryogenesis is usually regarded as extending from the end of the second week to the end of the eighth week, after which the product of conception is usually spoken of as a fetus. (Based on SMD)

Embryonic germ layers: The three initial tissue layers arising in the embryo—endoderm, mesoderm, and ectoderm—from which all other somatic tissue-types develop. (NRC)

Embryonic stem cells (ESCs): Primitive (undifferentiated) cells, derived from the inner cell mass of the embryo, that have the potential to become a wide variety of specialized cell types. (Based on NIH)

Enucleated oocyte: An egg cell from which the nucleus has been surgically removed.

Ex vivo: Outside the body, frequently the equivalent of "in vitro"; the opposite of "in vivo."

Fertilization: The process whereby male and female gametes unite. (NIH)

Fetus: A developing human from usually two months after conception to birth. (NIH)

Gamete: A reproductive cell (egg or sperm). (CR)

Gene: A functional unit of heredity that is a segment of DNA located in a specific site on a chromosome. A gene directs the formation of an enzyme or other protein. (NIH)

Genome: The total gene complement of a set of chromosomes. (SMD)

Genotype: The genetic constitution of an organism or a group of organisms. (SMD)

Hydatidiform mole: An abnormality during pregnancy; a tissue mass or growth that forms within the uterus as the result of a genetic error during the fertilization process.

Implantation: The attachment of the blastocyst to the lining of the uterus, and its subsequent embedding there. (Based on SMD)

In vitro fertilization (IVF): The union of an egg and sperm, where the event takes place outside the body and in an artificial environment (the literal meaning of "in vitro" is "in glass"; for example, in a test tube). (CR)

Inner cell mass: The cluster of cells inside the blastocyst. These cells give rise to the embryonic disk of the later embryo and, ultimately, the fetus. (NIH)

IVF embryo: An embryo produced by in vitro fertilization.

Karyotype: The chromosome characteristics (number, shape, etc.) of an individual cell or cell line, usually presented as a systematized array in pairs. (SMD)

Lineage: The descendants of a common ancestor.

Mesenchymal stem cells: Cells from the immature embryonic connective tissue. A number of cell types come from mesenchymal stem cells, including chondrocytes, which produce cartilage. (NIH)

Morphology: Configuration or structure, shape.

Morula: An early stage of embryonic development (roughly 16-64 cells) at which the embryo is a solid spherical mass of cells, resulting from the early cleavage divisions of the zygote; so called because of its

resemblance to a "little mulberry" (in Latin, *morula*).

Mosaic: Possessing two or more genetically different cell types; an early embryo is said to be *mosaic* when some of its cells exhibit chromosomal abnormalities while others appear chromosomally normal.

Multipotent adult progenitor cells (MAPCs): Cells isolated from bone marrow that can be differentiated into cells with characteristics of cartilage, fat, and bone.

Multipotent cell: A cell that can produce two or more different types of differentiated cells; adult stem cells are *multipotent*.

Oocyte: Unfertilized egg cell.

Organismic death (of an embryo)—concept and**criterion:** As proposed by Landry and Zucker, the *concept* of *organismic death* for an early-stage human embryo is defined by irreversible loss of "the capacity for continued and integrated cellular division, growth, and differentiation"; their proposed *criterion* for determining organismic death is "irreversible cessation of cell division in the embryo observed in vitro."

Parthenogenesis: A form of reproduction in which an unfertilized egg develops into a new individual (SMD); the process of inducing an unfertilized egg to initiate cell division.

Parthenote: The primary product of parthenogenesis; more precisely, an unfertilized egg that has been activated to initiate cell division.

Placenta: The oval or discoid spongy structure in the uterus from which the fetus derives it nourishment and oxygen. (NRC)

Pluripotent cell: A cell that can produce all the cell types of the developing body; embryonic stem cells, as well as the inner cell mass cells of the blastocyst, are *pluripotent*.

Pluripotent stem cell: Any stem cell that has the same *functional capacity*—that is, stable pluripotency—as an embryonic stem cell, though not necessarily the same *origin*.

Preimplantation genetic diagnosis (PGD): A method of testing IVF embryos for chromosomal or genetic disorders before they are transferred to the uterus; typically one or two blastomeres are removed for genetic testing at about the 8-cell stage of embryonic development.

Somatic cell: Any cell of an organism other than the gametes. (Based on SMD)

Somatic cell nuclear transfer (SCNT): A method of cloning: transfer of the nucleus from a donor somatic cell into an enucleated oocyte to produce a cloned embryo.

Stem cells: Stem cells are undifferentiated multipotent precursor cells that are capable both of perpetuating themselves as stem cells and of undergoing differentiation into one or more specialized types of cells. (CR)

Stem cell line: Stem cells which have been cultured under in vitro conditions that allow proliferation without differentiation for months to years. (NIH)

Superovulation: Drug-induced stimulation of a woman's ovaries to produce many mature oocytes in a single menstrual cycle.

Teratoma: A tumor consisting of different types of tissue, as of skin, hair, and muscle, caused by the development of independent germ cells. (SMD)

Totipotent cell: A cell that can give rise to the entire organism, including the extra-embryonic membranes; the fertilized egg or zygote is *totipotent*.

Trophectoderm: In early embryos at the blastocyst stage, the outer layer of cells that will give rise to the placenta.

Uterine transfer: Transfer of an IVF embryo to a woman's uterus with a view to implantation and gestation.

Xenotransplantation: A transplant of tissue from an animal of one species to an animal of another species.

Zygote: The diploid cell that results from the fertilization of an egg cell by a sperm cell. (CR)

Definitions marked "(CR)" are from the Council's report on human cloning (*Human Cloning and Human Dignity: An Ethical Inquiry,* Washington, D.C.: Government Printing Office, 2002). Definitions marked "(NIH)" are from the National Institutes of Health online stem cell glossary at http://stemcells.nih.gov (accessed April 1, 2005). Definitions marked "(NRC)" are from the National Research Council report, *Stem Cell Research and the Future of Regenerative Medicine* (Washington, D.C.: National Research Council, 2001). Definitions marked "(SMD)" are from Stedman's Medical Dictionary.