Committee Name:
Senate Committee – Judiciary, Corrections and Privacy (SC–JCP)

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WISCONSIN CATHOLIC CONFERENCE

STATEMENT IN SUPPORT OF A PROPOSED CLONING BAN
Presented by John Huebscher, Executive Director
May 20, 2003

On behalf of the Wisconsin Catholic Conference I speak in support of both Assembly Bill 104 and Senate Bill 45.

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 exists. 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 end 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 104 and SB 45.

Thank you.

Pro-Life Wisconsin

Defending them all...

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Testimony in support of AB 104 / SB 45:
Comprehensive Human Cloning Ban
By Matt Sande, Director of Legislative Affairs

May 20, 2003

Good morning Chairman Hines, Chairman Zien, and committee members. Pro-Life Wisconsin appreciates the opportunity to express our strong support for Assembly Bill (AB) 104 and Senate Bill (SB) 45, 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 – 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 104 and SB 45 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 experimented upon and killed (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 104 and SB 45 allow animal cloning and 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, and treat juvenile diabetes and Parkinson's disease.

Pro-Life Wisconsin is proud to be a founding member of the *Coalition for Ethical Research*, working 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 both committees to recommend adoption of AB 104 and SB 45, 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.)

NATIONAL CATHOLIC PARTNERSHIP ON DISABILITY

(formerly National Catholic Office for Persons with Disabilities)

NCPD. . . *Advancing Inclusion in Church and Society*

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MARY JANE OWEN, TOP, MSW
Executive Director

Testimony in Support of Assembly Bill 104 and Senate Bill 45

By Donna Arciszewski On behalf of the *National Catholic Partnership on Disability*

May 20, 2003

Good morning Committee members. On behalf of the National Catholic Partnership on Disability (NCPD), I thank you for this opportunity to express our strong support for a ban on all forms of human cloning.

The National Catholic Partnership on Disability (NCPD) was established in 1982 to foster implementation of the *Pastoral Statement of U.S. Catholic Bishops on People with Disabilities.* The idealism of the church is also expressed in their 1999 statement, *Welcome and Justice for Persons with Disabilities: A Framework for Access and Inclusion*. Both documents call for justice for over fourteen million Catholics who are disabilities and for their full integration within the church and the total fabric of society. In addition, NCPD is guided by the policy statements and resolutions passed by the NCPD Board of Directors.

The Board has adopted a *Resolution on Defending and Celebrating the Culture of Life.*

Those who value God's gift of life and who can share their positive experiences of physical, sensory, and cognitive disabilities are powerful allies in the struggle to promote the culture of life. We recognize disability and vulnerability as a normal, anticipated reality of the living process. In sharing this truth, we can allay society's fears and alleviate misjudgments about the quality of a life lived with disabilities.

As a person with multiple sclerosis, I do welcome advancing scientific research that may extend and improve my productive and interactive life. But not at the expense of another human life.

(over)

Every life, no matter how it has come into being, deserves the same respect and dignity. Cloning must be unequivocally condemned because the value of a life is not measured in how long it has existed, but in the very nature of life itself. Therefore, a day-old embryo is just as valuable as a six-month-old fetus, which in turn is just as valuable as a two-year-old child.

When we deny the inherent dignity of human life, when we view the unborn as "products" to be harvested and sold, we have moved toward the sacrificing of one life for the benefit of those who consider their existence more important than the ethical guidelines which have guided principled societies of the past.

We all face the possibility of disease, but that possibility is less frightening than a world in which, as a matter of medical intervention, one life can be casually eliminated in order to offer a few additional months of "normality" to another.

Thank you for listening, and again, I urge you to ban all human cloning in Wisconsin.

Donna Arciszewski
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UW Alumni for Life

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Testimony of Rebecca (Lindstedt) Sande before the
Assembly Public Health Committee / Senate Judiciary Committee
In favor of Assembly Bill 104 and Senate Bill 45

May 20, 2003

Chairman Zien, Chairman Hines and Committee members:

Good afternoon. Thank you for the opportunity to speak on behalf of UW Alumni for Life in favor of Assembly Bill 104 and Senate Bill 45, the Comprehensive Human Cloning Ban.

UW Alumni for Life is a diverse group of UW-Madison alumni opposed to the deadly research on human embryos being conducted at our alma mater. We have a 21-member advisory board that includes some of your colleagues in the State Legislature, as well as alumni with legal and scientific, business and public policy backgrounds.

AB 104 and SB 45 would prohibit the creation of human embryos through cloning for any purpose. It prohibits cloning for "reproductive" purposes, which enslaves human beings by making them subject to the designs and desires of others, and it also prohibits "therapeutic" cloning – which is a complete misnomer as it is hardly therapeutic for the tiny human being who is killed through the extraction of his or her stem cells. Let us be clear, however, that the process of cloning is one and the same in both instances.

With the recent announcement that Stanford University is cloning human embryos for medical experimentation, it is easy to imagine that UW researchers would soon follow suit. Not everyone associated with the UW believes this is a good thing. UW Alumni for Life is here today to say that we must not permit this in Wisconsin.

During our tenure at the UW, we walked Bascom Hill and attended classes in Bascom Hall. On the entrance to that building is etched the dictum to "sift and winnow" for truth.
Students at UW-Madison have always taken that dictum to heart, and the UW is known for its campus activism on behalf of human rights. We know, beyond a shadow of a doubt, that life begins at fertilization. Scientists who pull stem cells from cloned human embryos know that as well.

Unfortunately, the truth about the humanity of these tiny embryos is discarded when their lives are sacrificed in the name of scientific progress.

One of the unfortunate lessons of the last century is that innocent human life must not be sacrificed for the benefit of others. The research talent at the UW should be spent in the service of and not at the expense of human life. We must recognize the personhood of our embryonic brothers and sisters. Let our sifting and winnowing for truth not be clouded by our passions but guided by fact and reason. Thank you.

Testimony of David A. Prentice, Ph.D.
Professor of Life Sciences, Indiana State University
Adjunct Professor of Medical and Molecular Genetics, Indiana University School of Medicine
Founding Member, Do No Harm: The Coalition of Americans for Research Ethics

Wisconsin Senate Judiciary, Corrections and Privacy Committee and
Wisconsin State Assembly Public Health Committee
Hearing on ban on human cloning and parthenogenesis (SB 45 and AB 104)
May 20, 2003

Mr. Chairman, distinguished Members of the Committee, thank you for the opportunity to testify today regarding the important issue of human cloning.

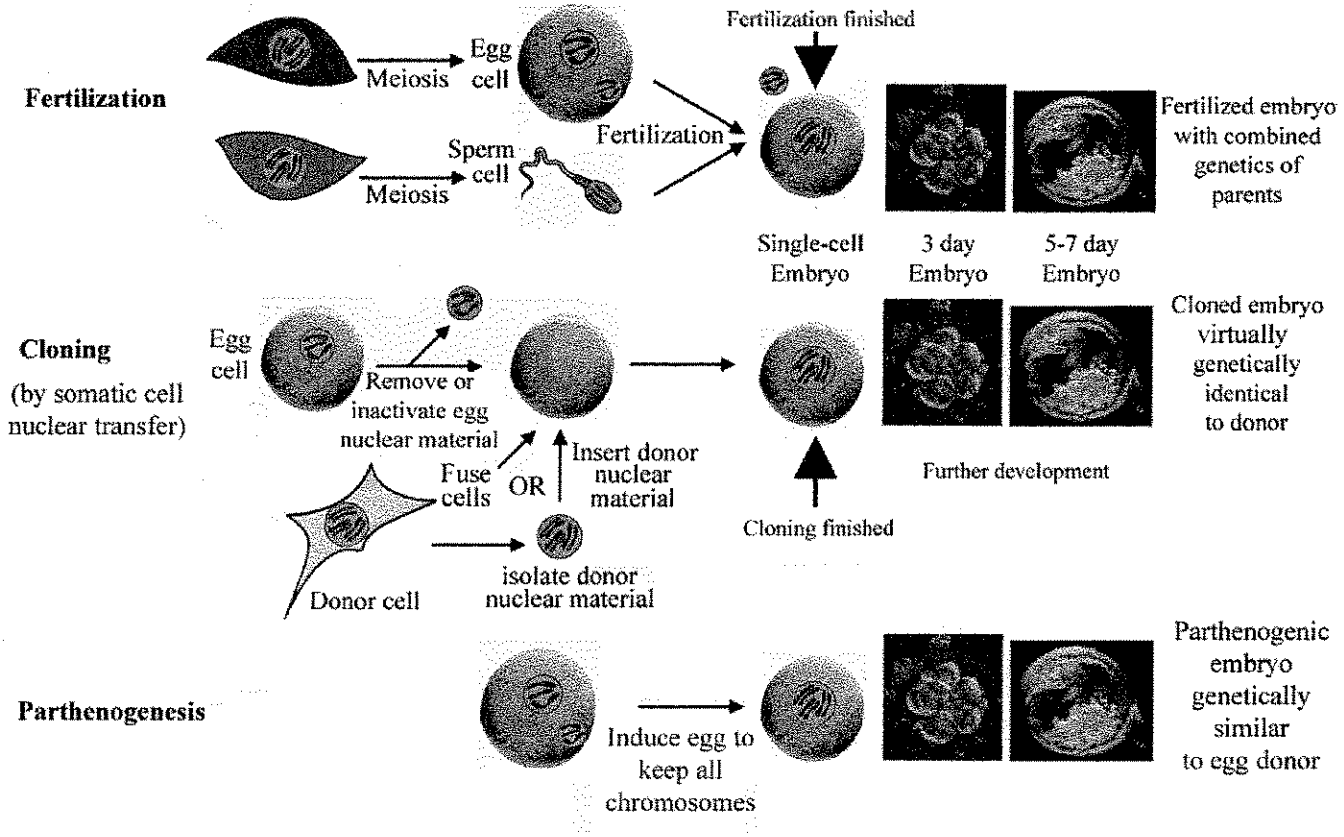
Mark Twain noted, "There is something fascinating about science. One gets such wholesale returns of conjecture out of such a trifling investment of fact." Regarding human cloning, a great deal of conjecture, as well as false hope, has arisen out of a total lack of fact in the science. We need to examine the facts carefully, and not be misled by the conjecture.
Human cloning is human asexual reproduction. It is accomplished by the technique of somatic cell nuclear transplantation (SCNT)—introducing the nuclear genetic material from one or more human somatic (body) cells into a fertilized or unfertilized egg cell whose nuclear genetic material has been removed or inactivated, producing a human embryo who is virtually genetically identical to an existing or previously existing human being.

Proponents of human cloning hold out two hopes for its use: (1) creating live born children for infertile couples or those grieving over the loss of a loved one, so-called "reproductive cloning" (live birth cloning), and (2) promises of medical miracles to cure diseases by harvesting embryonic stem cells from cloned embryos created from patients, euphemistically termed "therapeutic cloning" (more properly termed experimental cloning.)

First let us be clear on the terms. All human cloning is reproductive, in that it creates – reproduces – a new developing human intended to be virtually identical to the cloned subject. In point of fact, both "reproductive" and "therapeutic" cloning use exactly the same techniques to create the clone, and the cloned embryos are indistinguishable. The process, as well as the product, is identical. The only distinction is the purpose for use of the embryo—either transfer to a uterus in the hopes of a live birth, or destruction in the hopes of a medical miracle.

The technique of cloning is finished once that first cell, the one-celled embryo (zygote) is formed. Anything beyond that step is simply growth and development. And despite the attempts to employ various euphemisms, scientifically, genetically, what is created is a human being; its species is *Homo sapiens*, it is neither fish nor fowl, monkey nor cow—it is human. The use of disingenuous euphemisms to describe the embryo as something other than an embryo likewise are not scientific, and diverge from the accepted definitions as put forth by the National Academy of Sciences, the National Institutes of Health, and others, including well-known proponents of human cloning.

Fertilization, Cloning (somatic cell nuclear transfer), and Parthenogenesis Produce Embryos



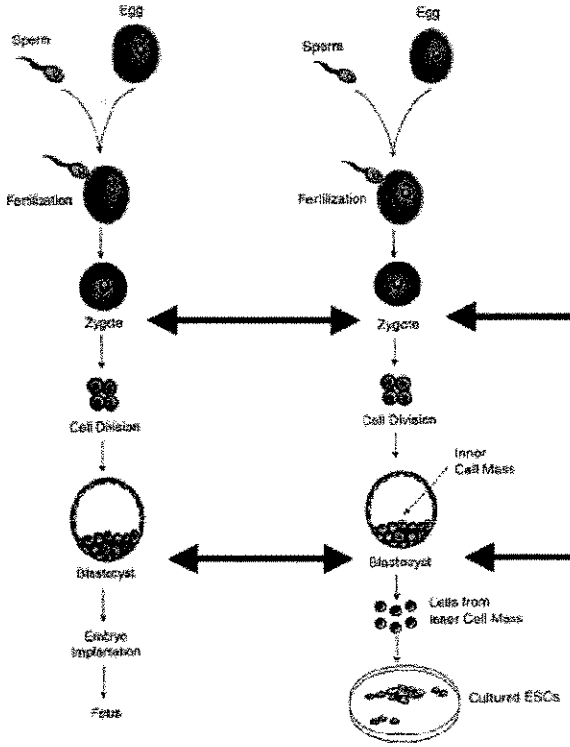


Figure 1 Stages of Development of the Human Embryo

Figure 2 Isolation and Culture of Human ESCs from Blastocysts

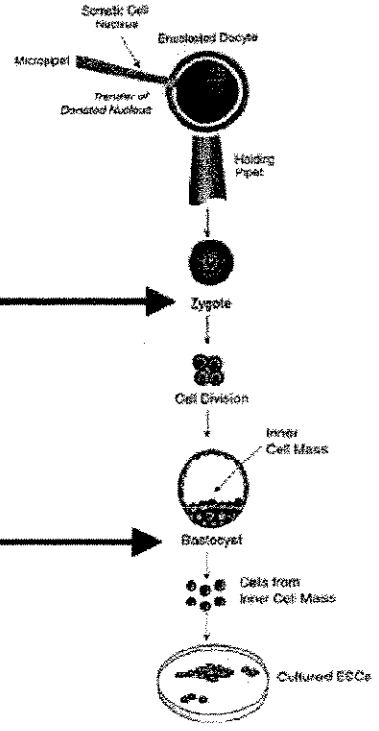
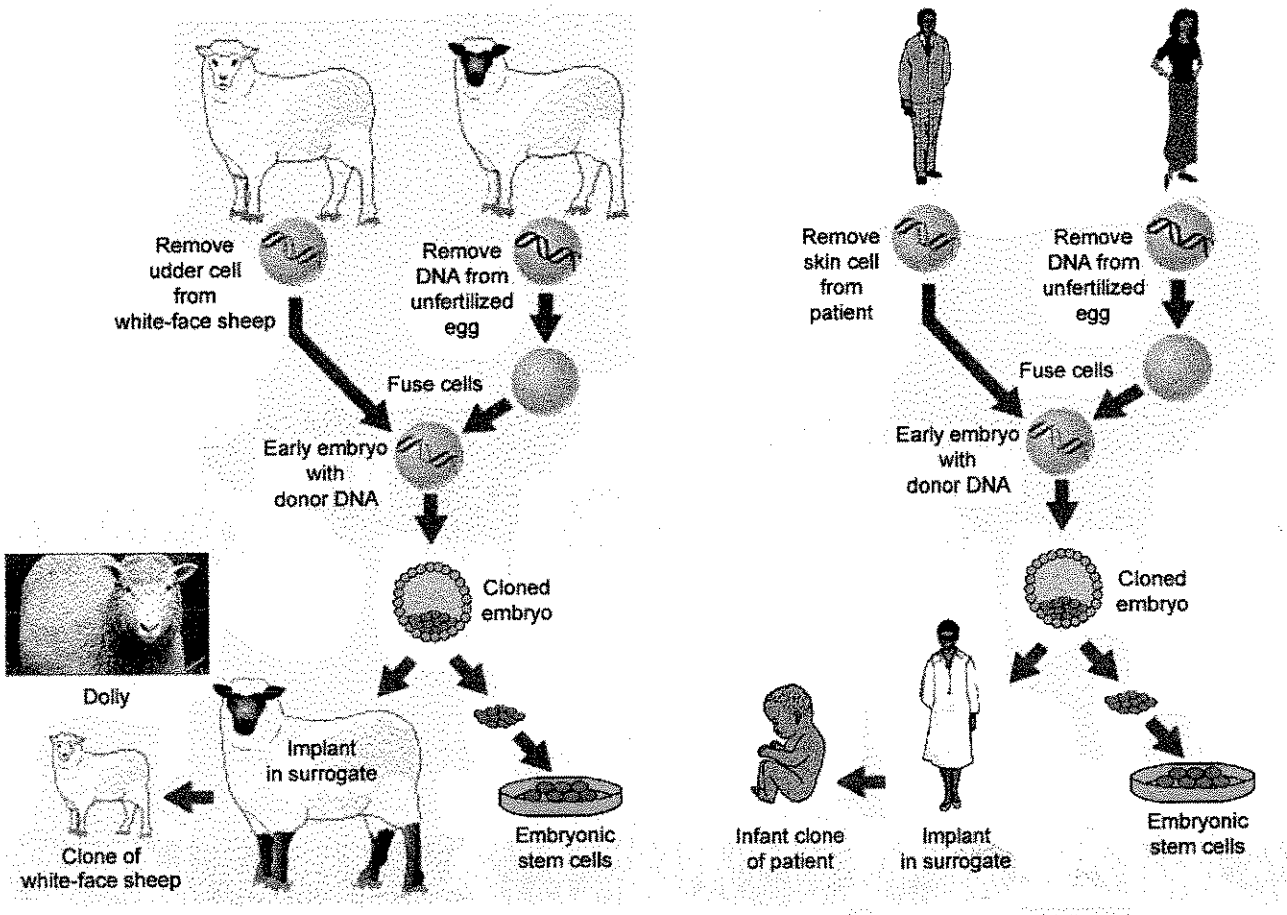


Figure 4 Somatic Cell Nuclear Transfer (SCNT).

[From: Stem Cells and the Future of Regenerative Medicine, Report of the National Academy of Sciences and the Institute of Medicine, National Academy Press, Washington, DC, Sept. 2001; Pg. 10, 11, 26]

Cloning (somatic cell nuclear transfer) produces a cloned embryo that can be transferred to a uterus ("reproductive cloning") or destroyed for embryonic stem cells ("therapeutic cloning"). The cloning technique is finished once the cloned embryo is produced.



<u>Reproductive, or live birth, cloning should be banned</u>. It constitutes unethical human experimentation. It has an enormous failure rate—95-99% of clones die before or soon after birth. In 1997, out of 277 cloned embryos, one Dolly the sheep was produced, and even this "successful" clone was beset with abnormalities—she developed early onset arthritis, lung disease, and was put down in February 2003. In 2001 a group at the Whitehead Institute achieved 5 born mice from 613 cloned embryos, and all of the born mice showed genetic abnormalities. The numbers are problems seen in clones are similar for all other species that have been cloned.

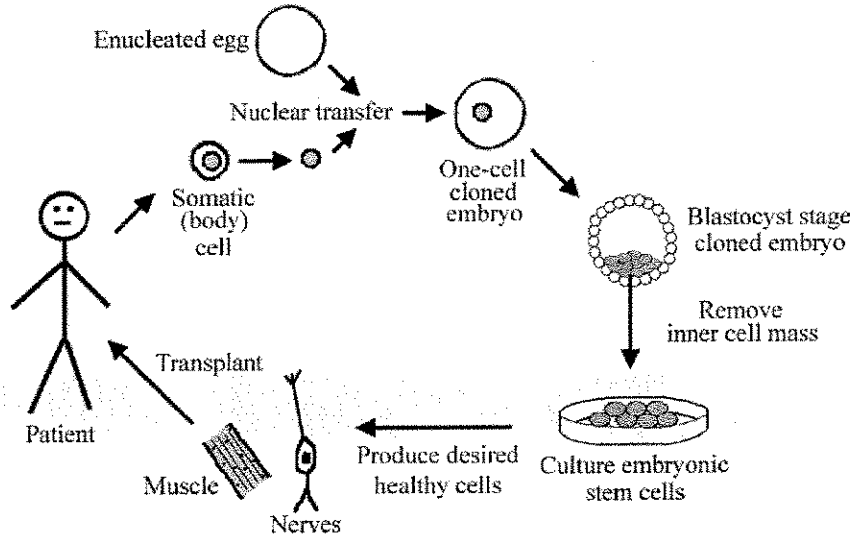
Ian Wilmut, creator of the cloned sheep Dolly, has stated that there are no normal clones, and notes, "There is abundant evidence that cloning can and does go wrong and no justification for believing that this will not happen with humans." ("Gene defects emerge in all animal clones", Sunday Times of London, April 28, 2002)

The reported births of cloned children by Clonaid and the Raelian cult is highly suspect—no proof has been provided for the claims. Nonetheless, given the results for all animal clones, we can expect that of those few cloned humans who survive to birth, most will die shortly thereafter and the others be plagued by abnormalities due to the cloning process. In addition, the surrogate mothers of clones experience physiological problems; because of the clone's abnormalities, carrying a clonal pregnancy to term will pose unique threats to the woman involved.

Therapeutic, or experimental, cloning should be banned. This, too, constitutes unethical human experimentation. No human cloning is "therapeutic" cloning. In medical ethics, "therapeutic research" is defined as research that could provide therapeutic benefit to the individual subjected to research risks. Thus "therapeutic cloning" is obviously not therapeutic for the embryo—the new human is created specifically to be destroyed as a source of cells or tissues.

> "Moreover, because therapeutic cloning requires the creation and disaggregation ex utero of blastocyst stage embryos, this technique raises complex ethical questions."
> "Unlike much stem cell research, which can use spare embryos remaining from infertility procedures, CRNT [cell replacement through nuclear transfer, aka therapeutic cloning] requires the deliberate creation and disaggregation of a human embryo."
> **Robert P. Lanza, Arthur L. Caplan, Lee M. Silver, Jose B. Cibelli, Michael D. West, Ronald M. Green**; "The ethical validity of using nuclear transfer in human transplantation"; *The Journal of the American Medical Association* 284, 3175-3179; Dec 27, 2000.

THEORETICAL CONCEPT OF "THERAPEUTIC CLONING"



Creating new human life solely to destroy it for the potential benefit of others is unethical. It turns human life into a commodity, creating a caste system of lesser humans for scientific sacrifice, what the renowned biochemist Erwin Chargaff calls "a kind of capitalist cannibalism."

Human experimental cloning is completely unnecessary for medical progress. *Theoretically* the embryonic stem cells from the cloned human embryo might be used to generate matched tissues for transplant into the patient from whom the embryo was cloned. However, the theory is not supported by any of the scientific literature.

Numerous promising alternatives do exist, in particular adult stem cells and other non-embryonic stem cells such as umbilical cord and placental stem cells. While the public has heard little about their successes, it is adult stem cells that have already shown effectiveness in treating disease. These successes have been shown in an avalanche of published scientific papers over the last several years, for conditions such as diabetes, Parkinson's, stroke, heart disease, spinal cord injury, and many other diseases. And, adult stem cell successes are not limited to animal research alone, but include successful treatments in human patients, against cancer, multiple sclerosis, lupus, arthritis, for repair of cartilage damage, immune deficiencies, sickle cell anemia, growth of new corneas to restore sight to blind patients, growth of new blood vessels to rescue legs from gangrene, repair of stroke damage, repair of

heart damage, and successful treatment of Parkinson's disease. These successes, using adult stem cells from the patients themselves, are available for producing the therapies about which cloning advocates can only speculate.

Despite the hype surrounding them, embryonic stem cells have significant disadvantages for potential treatment of disease, including the tendency to form tumors and the lack of genetic stability. However, even for embryonic stem cells, alternatives to cloning exist to prevent transplant rejection, including genetic engineering of stem cells to match patients (a possibility for either embryonic or adult stem cells), and co-transplant of blood cells to develop tolerance in the patient to other transplanted cells and organs (this has already shown success with adult stem cells). Both methods were proposed in 2001 by Dr. James Thomson, who first isolated human embryonic stem cells. Dr. Thomson also noted in his paper that therapeutic cloning has an unlikely chance of clinical use:

> "Furthermore, the poor availability of human oocytes, the low efficiency of the nuclear transfer procedure, and the long population-doubling time of human ES cells make it difficult to envision this [therapeutic cloning] becoming a routine clinical procedure even if ethical considerations were not a significant point of contention."
> Odorico JS, Kaufman DS, **Thomson JA**, "Multilineage differentiation from human embryonic stem cell lines," *Stem Cells* 19, 193-204; 2001

Dr. Thomson published a paper on 10 February in which he has accomplished initial genetic engineering experiments with human embryonic stem cells.
(TP Zwaka and JA Thomson; "Homologous recombination in human embryonic stem cells"; *Nature Biotechnology* Advanced Online Publication, published online 10 February 2003)

In an interview with Reuters, Dr. Thomson's co-author notes that this technique would bypass cloning as a method to produce matching stem cells for patients:

> "The method could also be used, Zwaka said, to create "universal" donor batches, or cell lines, of cells. The genes that cause the body's immune system to reject foreign tissue could be removed. "You could transplant this line into any patient," Zwaka said. This could bypass the need for therapeutic cloning -- another promising but unproved method that involves taking a cell from a patient using cloning technology to make a very early embryo, and then extracting the cells from it for a personalized transplant."
> CNN/Reuters; "Scientists replace human stem cell genes"; Monday, February 10, 2003 Posted: 9:52 AM EST
> http://www.cnn.com/2003/HEALTH/02/10/stem.cells.reut/index.html

A ban only on transfer of cloned embryos to a uterus is unenforceable. The embryo at that stage, whether produced by cloning or by the old-fashioned method of fertilization, is the same—embryos produced by the different methods of cloning and fertilization could not be distinguished under the microscope. The U.S. Department of Justice testified in a hearing before the U.S. House of Representatives that because of this it would be virtually impossible to enforce a ban only on implantation of cloned embryos.

> "The prohibited activity "transfer of an embryo to a uterus" is an activity that is otherwise permitted now in all states and is performed thousands of times a year in fertility clinics. Entrusted with enforcing such a limited ban, law enforcement would be in the unenviable position of having to impose new and unprecedented scrutiny over doctors in fertility clinics and/or research facilities to ensure that only fertilized embryos were being transferred to would-be mothers.

> Additionally, at the point when embryo transfer occurs...there does not seem to be any reliable means for determining the difference between a fertilized embryo and a cloned embryo. Therefore it is not clear how, upon hearing that someone may be engaging in the activity prohibited under the Act, law enforcement personnel could determine that it was taking place, even if they were present and observing the activity firsthand."
> Statement by Daniel J. Bryant, Assistant Attorney General, U.S. Department of Justice; Testimony before House Government Reform Committee on Human Cloning; May 15, 2002.

Moreover, **allowing "therapeutic" cloning while trying to ban reproductive cloning is unfeasible, and will simply hasten development of the process supposedly to be banned, reproductive cloning**. Again, honest proponents of cloning have noted this themselves:

> "It is true that the techniques developed in CRNT [cell replacement through nuclear transfer, aka therapeutic cloning] research can prepare the way scientifically and technically for efforts at reproductive cloning."
> **Robert P. Lanza, Arthur L. Caplan, Lee M. Silver, Jose B. Cibelli, Michael D. West, Ronald M. Green**; "The ethical validity of using nuclear transfer in human transplantation"; *The Journal of the American Medical Association* 284, 3175-3179; Dec 27, 2000.

The American Society for Reproductive Medicine (ASRM), the largest professional organization with expertise in reproductive technologies, says that SCNT is simply the procedure that clones embryos for WHATEVER purpose (whether for starting a pregnancy or destroying for research). And ASRM concedes that if cloning for research is allowed, that research will be used to refine the process and will make it easier for people to perform "reproductive" cloning:

> "If undertaken, the development of SCNT for such therapeutic purposes, in which embryos are not transferred for pregnancy, is likely to produce knowledge that could be used to achieve reproductive SCNT."
> The Ethics Committee of the American Society for Reproductive Medicine; "Human somatic cell nuclear transfer (cloning)"; *Fertility and Sterility* 74, 873-876; November 2000.

Any human cloning also poses potential significant health risks to women. The National Academy of Sciences January 2001 report on cloning also spoke of the risk to women's health from cloning:

> "Because many eggs are needed for human reproductive cloning attempts, human experimentation could subject more women to adverse health effects -- either from high levels of hormones used to stimulate egg production or because more women overall would be sought to donate eggs, which involves surgery with its own inherent risks."

But since the same procedure is used to create embryos in therapeutic cloning, the same problem applies. In fact, the problem will be even greater, because the procedure used to create embryonic stem cell lines is itself inefficient. An enormous supply of human eggs will need to be made available to treat even a small group of patients, subjecting a large population of women of childbearing age to unethical health risks inherent in harvesting the necessary quantities of eggs for cloning. A calculation based on the published scientific literature for cloning of animals and derivation of embryonic stem cells, both extremely inefficient procedures, reveals that to use therapeutic cloning to treat just one patient group, the 17 million diabetes patients in the U.S., will require at least 850 million human eggs, or approximately 85 million women of childbearing age to "donate" eggs. As the NAS panel points out, this will subject a large number of women to adverse health risks. The result will be that human eggs will also become a commodity, with the resultant exploitation of disadvantaged women in this country and abroad.

It is important to note that this significant risk to women's health posed by any attempts at human cloning have led to pro-choice groups such as the Boston Women's Health Collective and individuals such as the noted feminist Judy Norsigian, author of "Our Bodies, Ourselves", to join the call for a complete ban on all human cloning.

Furthermore, numerous proponents of embryonic stem cell research besides Dr. Thomson have pointed out that therapeutic cloning will be too costly and inefficient, and is unlikely for medical use—those who still support it are relying on obsolete information.

Dr. Alan Trounson, Australia's leading embryonic stem cell expert makes the same points:

> "However, it is unlikely that large numbers of mature human oocytes would be available for the production of ES cells, particularly if hundreds are required to produce each ES line. The technical capability for nuclear transfer would also need to be widely available and this is unlikely. In addition, epigenetic remnants of the somatic cell used as the nuclear donor can cause major functional problems in development, which must remain a concern for ES cells derived by nuclear transfer."
> "Although it is possible to customize ES cells by therapeutic cloning or cytoplasmic transfer, it would appear unlikely that these strategies will be used extensively for producing ES cells compatible for transplantation."
> **Alan O.Trounson**, "The derivation and potential use of human embryonic stem cells", *Reproduction, Fertility, and Development* 13, 523-532; 2001

Alan Trounson, Australian embryonic stem cell expert and a leader in the field worldwide, also says that stem cell research has advanced so rapidly in the past few months that therapeutic cloning is now unnecessary. "My view is there are at least three or four other alternatives that are more attractive already," he said.

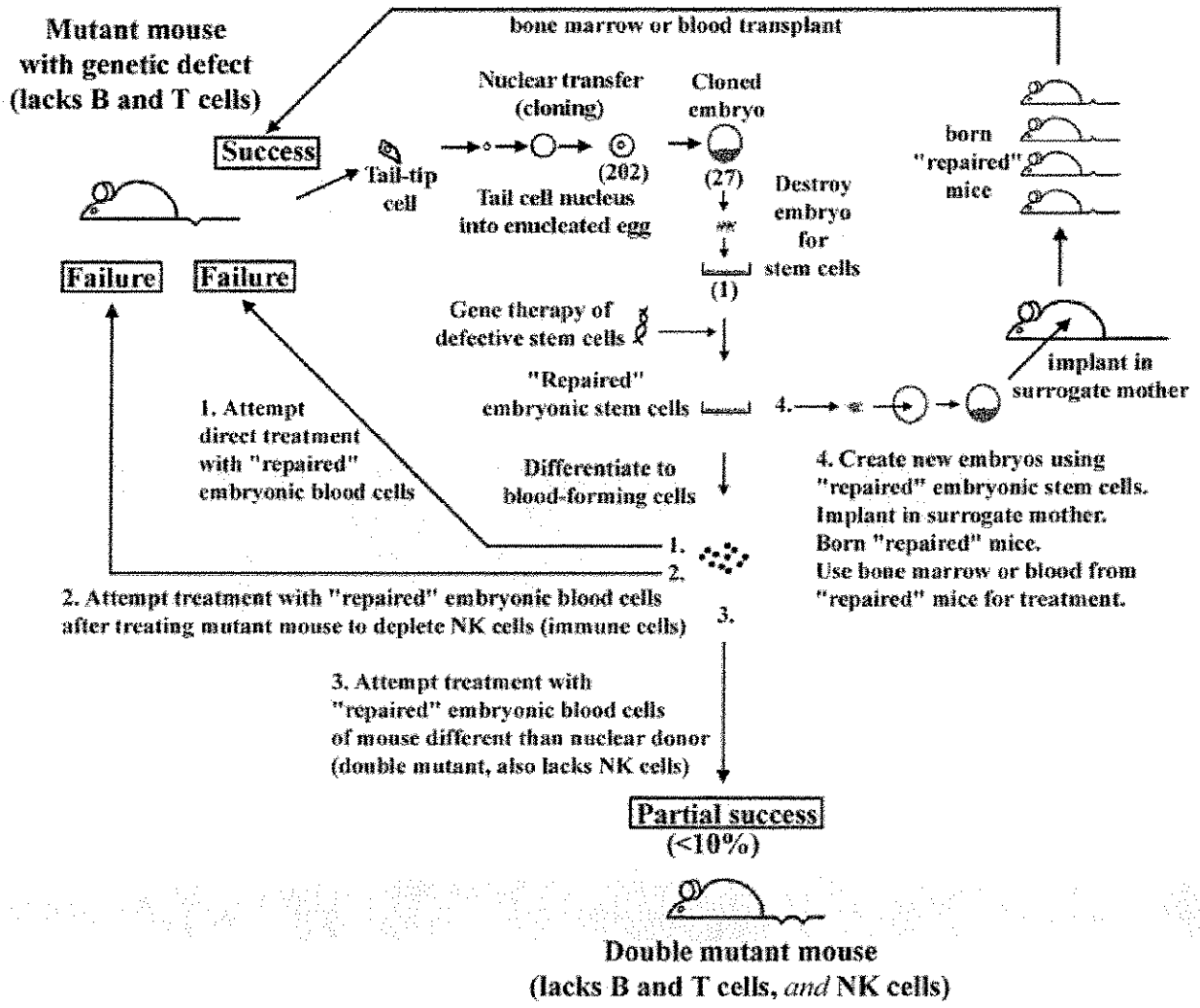
Trounson abandoned his call for therapeutic cloning, saying scientific breakthroughs mean there is now no need for the controversial technique.
Professor Trounson said therapeutic cloning faced logistical problems, and that other techniques were showing great promise and offered better options. "I can't see why, then, you would argue for therapeutic cloning in the long term because it is so difficult to get eggs and you've got this issue of (destroying) embryos as well."
"Stem-cell cloning not needed, says scientist", The Age (Melbourne), pg. 2, July 29, 2002;
"Stem-cell research outpaces cloning", The Australian, pg. 3, July 29, 2002;
"Therapeutic cloning no longer necessary: expert", AAP Newsfeed, July 29, 2002

Dr. Trounson supported passage of Australia's current law banning all human cloning.

Thomas Okarma, chief executive officer, Geron Corporation says: "The odds favoring success are vanishingly small, and the costs are daunting." "It would take thousands of [human] eggs on an assembly line to produce a custom therapy for a single person. The process is a nonstarter, commercially." (Denise Gellene, "Clone Profit? Unlikely", Los Angeles Times, May 10, 2002)

A scientific report in 2002 that purported to show success of therapeutic cloning to treat a genetic defect in mice actually was a failure in terms of the use of therapeutic cloning; indeed, the only real success in the experiment was achieved by bringing cloned mice to birth and using the born mouse bone marrow adult stem cells to treat the disease. It should also be noted that the similar genetic defect in humans, severe combined immunodeficiency syndrome ("boy in the bubble disease"), has been cured in several infants since 2000 using gene therapy of the infants' own bone marrow adult stem cells.

THERAPEUTIC CLONING UNSUCCESSFUL



In scientific understatement, the authors, including **Dr. Rudolf Jaenisch**, a proponent of therapeutic cloning, note:

> "Our results raise the provocative possibility that even genetically matched cells derived by therapeutic cloning may still face barriers to effective transplantation for some disorders."

(W.M. Rideout et al., "Correction of a genetic defect by nuclear transplantation and combined cell and gene therapy," *Cell* 109, 17-27; 5 April 2002 (published online March 8, 2002)

While some have suggested the experiment showed "proof of principle" for therapeutic cloning, the experiment actually shows that therapeutic cloning does not result in the theoretical match of tissues for the patient:

> "Jaenisch addressed the possibility that ES clones derived by nuclear transfer technique could be used to correct genetic defects in the hematopoietic system…"
>
> "<u>However, the donor cells, although derived from the animals with the same genetic background, are rejected by the hosts</u>."

R.Y.L. Tsai, R. Kittappa, and R.D.G. McKay; "Plasticity, niches, and the use of stem cells"; *Developmental Cell* 2, 707-712; June 2002.

Another report in 2002 claimed success at implanting cloned tissues into cattle. However, these results did not use embryonic stem cells or therapeutic cloning at all, as admitted by the authors themselves in their paper. Instead, the cloned embryos were implanted and gestated up to 8 weeks, and then the cloned fetuses were aborted and formed tissues harvested.

> "Because cloned cells were derived from early-stage fetuses, this approach is not an example of therapeutic cloning…"
> Robert Lanza *et al.*; "Generation of histocompatible tissue using nuclear transplantation," *Nature Biotechnoology* 20, 689-696; July 2002 (published online June 3, 2002)

A recent press release from this same group (Advanced Cell Technology) involved gestating the cloned embryos and fetuses for several months before "harvesting" the tissues. These results imply that reproductive cloning should be allowed, so that we can provide born cloned individuals to serve as tissue donors; obviously this is a horrific and inhumane proposal.

The assertion that cloning is the only method for preventing immune rejection of transplanted embryonic stem cells is completely false. In an article published March 18, 2002 (Abate, San Francisco Chronicle), researchers with Geron Corp. and with Advanced Cell Technologies admit that there are ways to prevent rejection of transplanted cells without therapeutic cloning, but that "that message has not gotten out," and that "the need for cloning to overcome immune system rejection has been overstated." The report goes on to note **"the scientific community has put out the message that a ban on therapeutic cloning will prevent researchers from solving the immune-system problem—an argument that seems at best a stretch, and at worst, a deception."**

Other scientists have admitted in testimony that therapeutic cloning will not prevent transplant rejection of the cloned tissues:

> "There is no question in my mind that the possibility exists that if you are doing an egg donor, and nuclear transfer into an egg, that there possibly exists that that cell -- that the embryonic stem cells derived from that could be rejected. Absolutely."
> (**Dr. John Gearhart**; transcript of the April 25, 2002 meeting of the President's Council on Bioethics; p.47; http://www.bioethics.gov/meetings/200204/0425.doc)

> "I should say that when you put the nucleus in from a somatic cell, the mitochondria still come from the host." He concluded, "And in mouse studies it is clear that those genetic differences can lead to a mild but certainly effective transplant rejection and so immunosuppression, mild though it is, will be required for that."
> (**Dr. Irving Weissman**, Stanford, before the President's Council on Bioethics on February 13, 2002)

Finally, it should be emphasized that the proposed ban on human cloning does not restrict any vital or viable medical research. Cloning and nuclear transfer techniques for production of DNA, other molecules, cells other than human embryos, tissues, organs, plants, and animals are all allowed. The proposed prohibition only restricts human cloning, for which there have been no federal funds and for which there will be no federal funds in the foreseeable future. Five states now ban human cloning for any purpose (MI, VA, IA, AR; ND) and numerous other states ban research that destroys human embryos (including LA, ME, MA, MI, MN, ND, PA, RI, SD). In terms of the effects of such bans on economic development, it is illustrative to note that PA, which passed its ban in the 1990's, is ranked 3rd in the nation in biotechnology investment, and MI, which banned embryo destruction in 1978 and all human cloning in 1998, is considered one of the major growth sites for biotechnology in the U.S.

In summary, human cloning is unsafe, unethical, and unnecessary. There are no valid or compelling grounds—ethical, scientific, or medical—to proceed with human cloning. A comprehensive ban on all human cloning, provided by passage of the bill under consideration, is the only sufficient answer.

Thank you for the opportunity to provide testimony on this important issue, and I would be pleased to answer any questions.

Testimony of Rev. Tadeusz Pacholczyk, Ph.D., Ethics Committee, St. Anne's Hospital, Caritas Christi Health Care System, Fall River, Massachusetts.

Wisconsin State Assembly – Public Health Committee Hearing on Ban on Human Cloning (SB 45 & AB 104) May 20, 2003

Good afternoon. My name is Father Tad Pacholczyk. I did my doctoral work in neuroscience at Yale University, where I focused on cloning genes which are expressed in the human brain. I also worked for several years as a molecular biologist at Massachusetts General Hospital/Harvard Medical School, before going to Rome to do advanced work in theology and in bioethics.

Isn't it true to say that most of us want sick people to be cured? Isn't it also true that most of us want to see science continue to march onward and conquer disease? And isn't it true that most of us want to see the likes of a Christopher Reeve get up out of their wheelchairs and walk again? Of course we do. And the Catholic Church does too. Indeed the Church is among the very first to desire that Christopher Reeve walk again, because part of the Church's mission is to bring healing. The Church runs an international conglomeration of hospitals, nursing homes, and hospice care facilities to provide care and medical help to the sick and the handicapped, and the afflicted. Healing has always been part of her mission. So why do so many people, Catholic and non-Catholic alike, draw a clear line in the sand when desperate people like Mr. Reeve start telling us that we should support embryonic stem cell research and therapeutic cloning?

The reasons are fairly straightforward, and I would like to invite you to use your imagination for a moment to conduct a

thought experiment with me, which may serve to help clarify those reasons. Suppose, hypothetically, that when Mr. Reeve was born back in 1952, he also happened to have an identical twin brother who was born at the same time, a twin brother we'll call James. Suppose further that James grew up and led an ordinary life, working as a plumber, while Christopher went on to Hollywood to become the superstar actor. Suppose that Christopher still had his very unfortunate fall and ended up paralyzed. Suppose further that scientists one day announced a new scientific discovery to cure spinal cord damage. To achieve this cure, however, it would be necessary to sacrifice his twin brother James in order to remove special groups of cells in his brain for nerve cell transplants into Christopher's damaged spinal cord. The tissue would need to come from his identical twin, to assure there would be no tissue rejection, since identical twins can transplant organs between each other and those organs will not be rejected. Now suppose that one evening on Larry King Live, right on national television, Christopher stated that he absolutely wanted to do this procedure. Suppose he proclaimed that in the name of science, medical progress, and the advancement of knowledge, he felt it was not just a good idea, but it was his moral duty to make use of his brother's tissues in this way, and that nobody should impose their beliefs on him about taking another human life. All of us, of course, would be aghast at this proposal. His brother James would probably be the most livid of all, and we can imagine him strutting onto the Larry King Live Show the next evening to vigorously denounce his brother's immoral and absurd proposal.

Let's change the scenario slightly, again using our imaginations. Suppose, hypothetically, that when Christopher and James were born, while they were still newborn twin babies, James was taken and placed into liquid nitrogen using a newly developed process for freezing and preserving living human babies. He was cryopreserved like baseball great Ted

Williams, except that he was alive when he was frozen. That way he could be thawed out and continue growing into an adult at a later date when his parents had saved up enough money to pay for his college. Now suppose that Christopher meanwhile grew up and became an adult while his baby brother James was still frozen. Suppose he ended up paralyzed from the accident as before, and now insisted that his twin brother be thawed out and sacrificed in order to disaggregate his brain tissue and harvest his cells. Even though everybody would like Christopher to walk again, Americans would be horrified by his proposal to use his newborn brother as a source for spare body tissues. This time, of course, James would be too small to walk onto the Larry King Show in order to defend himself. Perhaps somebody would put him in a baby stroller and roll him into the studios after he had been thawed out, and place him before the cameras to remind the viewers what was at stake. James of course wouldn't be able to speak on his own behalf; the best he might be able to do would be to cry a little and wave his arms. He would be quite dependent on the legal protections and sanctions afforded by laws aimed at protecting human life, especially newborn human life.

Now let's modify the scenario one last time with a slightly different twist. This time, let's suppose that Christopher Reeve was already a paralyzed adult, and that he never had an identical twin brother. Instead, scientists decide to produce his twin brother James by cloning, by producing an embryo with the same genes as Christopher's. That cloned embryo would be his identical twin. This is what cloning does. Cloning does not make xerox copies of people, contrary to the popular myth. Rather, cloning makes identical twins, and it does so by making an embryo in a way that is different from how nature does it. Christopher would be much older than his embryonic twin brother James, but they would still be twins genetically. If James were placed into a womb and allowed to be born and to become an adult, Christopher and James

should be able to exchange organs without rejection just as if they had been naturally born twins. Let's suppose, however, that James was never placed into a woman's uterus, but instead that he was cryopreserved to store him as a frozen embryo for the future. If Christopher were to suggest that James his cloned brother should be thawed and then destroyed to harvest his immune compatible stem cells, we can only hope that Larry King's audience would see what was really going on here. This time, however, James could not be placed into a baby stroller and rolled into the studio for a photo-op. This time, James in the earliest stages of his existence would be utterly defenseless on the laboratory bench before the menacing hands of the scientist who was going to dissect out his stem cells. This time, he couldn't even utter a cry in his own defense or wave his arms. This time, he might not have the protection of laws and legal structures unless we who are gathered here in this Assembly today take the courageous step and do our duty of protecting those who are the weakest and most vulnerable members of our human family.

Indeed, unless we take legal steps to assure that the rich, the powerful, and the self-interested are <u>not</u> allowed to run roughshod over embryonic humans, we will never be worthy of the claim that ours is a civilized society. We can never allow for the sanctioned creation of a subclass of human beings, made up of those still in their embryonic or fetal stages, who can be freely exploited and discriminated against by those fortunate enough to have already passed beyond those early stages.

Our existence as human beings is a continuum that extends all the way back to our lowly origins as that humble ball of cells we refer to as an embryo. Every person in this room was once an embryo, and that is an affirmation which has nothing to do with religion, nothing to do with belief systems, and nothing

to do with imposing anything on anyone. The statement that each of us was once an embryo is a statement of simple biological fact. It is also a statement of fact that if any one of us had been disaggregated to get at our embryonic stem cells while we were still embryos, we would no longer exist, and we would not be able to participate in these hearings today. In other words, an extremely grave injustice would have been carried out against us in the name of science and in the name of progress. As a former embryo myself, I am grateful that I was never offered up on the altar of science in that manner. The bottom line here is remarkably simple: it is invariably immoral to take the life of another innocent human being, no matter how small or powerless he or she may be, no matter how different he or she may look from you and me. We all looked that way a few years ago. We all were that weak and powerless ourselves not so very long ago. A truly just society, which we all aspire to create and live in, can never allow the mighty and the powerful to exploit the weak and the powerless with impunity.

Therapeutic cloning manipulates human beings and violates their dignity by creating them for the express and premeditated purpose of destroying them by extracting their stem cells. We consciously choose in this way to exploit powerless human beings as factories for their bodily tissues. *That is why therapeutic cloning and embryonic stem cell extraction are invariably and without exception immoral kinds of research activity, which should never be permitted in a civilized society.* We can only hope that modern science will not collaborate in the immoral project of constructing a world where some humans enter the world with saddles on their backs, while others wear boots and spurs.

Science offers people like Christopher Reeve many promising avenues in the quest for a cure, including a wide range of alternative stem cell sources, such as those from placentally

derived stem cells, umbilical cord stem cells, and adult stem cells of various types. Recently another type of cell known as the olfactory ensheathing glial cell, has been isolated from inside the nose, inside the nasal cavity, and has been shown in preliminary studies to help paralyzed animals and humans when transplanted into their spinal cords. Practically every week, new studies are published which demonstrate successful therapies both in humans and animals for a wide range of ailments using cells which don't require the destruction of the most defenseless and vulnerable members of the human species. We can all support these exciting and forward-looking avenues of research with a clear conscience, and our laws need to promote precisely that kind of good science, and to ban the immoral and unsavory practices of therapeutic cloning and embryonic stem cell extraction. Thank you very much.

Wisconsin Council of Catholic Women

Founded 1915
Miss Mary Connor, Honorary Founder

Jan Holzbauer
5009 Flad Avenue
Madison, WI 53711

May 20, 2003

TO: Senator Dave Zien, Chair;All Committee Members
Senate Judiciary, Corrections and Privacy Committee
FROM: Jan Holzbauer, Chair
WCCW Legislative Committee Jan Holzbauer

Since its inception in 1915, the WCCW has been an ardent pro-life advocate.

REpresenting Catholic womens' clubs, Daughters of Isabella, Catholic Daughters of the Americas and Catholic Jr. Leagues throughout the state, members have actively promoted and supported a culture of life.

In 1973, when Roe V Wade created a new constitutional "right" the WCCW warned of the slippery slope of denigrating life values.

As we approach the absolute abyss of moral turpitude, the WCCW urges your committee to support S45 which would ban both reproductive and therapeutic cloning.

We are aware of and accordance with the pro-life organizations dedicated to opposition to a "clone and kill" mentality and suggest a recent article on ethics in the National Catholic Reporter worthy of consideration. The article states, "To act morally and ethically, we need knowledge about ourselves, about the particular case, about the particular context and what would count as a good outcome. Ethics is an art, not a science. Yet choosing moral means to an end is necessary since, as Mahatma Gandhi said, 'means are ends in the making'".

Do not "bow down to the bottom line, or choose to do evil out of some tragic necessity."

SB-45

Written Statement of Testimony
of
Claire Thuning-Roberson, Ph.D.

Before the Wisconsin Senate Judiciary, Corrections and Privacy Committee and the Assembly Public Health Committee

May 20, 2003

I thank the Chairs and their committees for the opportunity to speak today so that I may provide you with information that will enable you to make well-informed decisions.

My 35 years of experience in research and industry has focused on cell and tissue culture and developing products for clinical use both as a scientist and businessperson. My professional positions have included:

- Past Chairman, BioFlorida, the BIO state affiliate
- Former Director of the Goodwin Institute for Cancer Research
- Founder & CEO of Goodwin Biotechnology, a manufacturer of recombinant proteins for clinical trials
- VP Product Development, Sunol Molecular Corporation, developing monoclonal antibodies
- Member of the Scientific Advisory Boards at Florida Atlantic University and James Madison University, Virginia

I do not represent any organization, but rather, myself and other scientists and physicians known to me who also shares my views. I support a ban on human somatic cell nuclear transfer (SCNT) whether for reproduction or research.

Cloning is a very difficult and complex issue for our country, for humanity. Ethical and public policy decisions must be based on objective scientific facts and decision-makers must be fully informed before attempting to rule on it. Therefore, I would like to clarify the misconceptions expressed in the press and by some legislators around the country, the partial and sometimes skewed information provided by some of my fellow colleagues, as well as bring to light the little publicized risks and alternatives. I will speak only to objective scientific or business facts, not to subjective opinion.

Clarification:

- Human cloning is asexual reproduction, i.e. it produces an embryo the same as sexual reproduction but without the use of a sperm. The result is not an unfertilized egg or activated oocyte as some have stated. The product of both sexual and asexual reproduction is an embryo. The development of identical twins is another example of asexual reproduction, and no one will refute that "twinning" results in two embryos that develop into newborns. President Clinton's National Bioethics Advisory Commission in 1997 explicitly acknowledged that an embryo results from cloning. The question of when a human begins to exist is strictly a scientific one that is answered in any embryology textbook and defined by the international Nomina Embryologica Committee, that the human embryo is a human being because it possesses an internal code for self-actualization and is an organism with an independent inherent teleology to develop into a human adult and, therefore, is physiologically alive and genetically human. The question of when a human person begins to exist is a philosophical and theological one that I will not address here.

- Therapeutic Cloning and Reproductive Cloning are exactly the same. The operative word is "cloning". The National Academy of Sciences cloning panel in January 2002 explained that both concepts use the identical cloning process and result in embryos that can be theoretically implanted in the uterus for continued development. The destiny of the clones is

what differentiates the two terms, destroying the clones in the first case by harvesting stem cells, or implanting them *in utero* for development of a newborn, in the latter case.

Risks:

What is little publicized and down-played are the serious risks and unintended consequences posed by human cloning.

- **Random, widespread genetic flaws**: Scientists agree on the high probability that human cloning will produce children that are stillborn, unhealthy, severely malformed, or disabled based on animal experiments to date in mammals such as sheep and cows. Experts such as Ian Wilmut (creator of the cloned sheep, Dolly) and Rudolph Jaenisch (MIT, one of the founders of transgenic science) conclude that these outcomes are the result of faulty reprogramming of the genome resulting in abnormal gene expression which may result in genetic abnormalities in tissues or cells derived from human clones. These flaws, which are thought to be caused by missing interactions between sperm and egg, are intrinsic to cloning. One of these flaws, imprinting, is known to cause cancer and late-onset disease. In developing "Dolly", only 29 of the 277 eggs injected with adult DNA successfully survived a few days implantation after the development of the embryonic stage used for therapeutic cloning. Dr. Dominko, who conducted primate-cloning research at the Oregon Regional Primate Research Center, states that of particular concern are embryos that appear healthy but at the genetic level are a "gallery of horrors." Dr. Bryan Cowan testified before Congress on behalf of the American Society for Reproductive Medicine that "because the safety and efficacy of the (SCNT) procedure had not been established, it would be unethical at this time to attempt human cloning." Dr. Jonathan Van Blerkom who works with human embryonic stem cells at the University of Colorado supports a blanket ban on all human cloning stating that "until you really understand the underlying biology of what you're dealing with in a very comprehensive way, it's crazy, it doesn't make any sense" to approve any human cloning. Basically, lousy embryos will likely yield lousy stem cells.

- **Imperfect genetic match:** Mr. Reeves and others cite the need for SCNT because as he testified "implantation of human embryonic stem cells is not safe (from rejection) unless they contain the patient's own DNA." Rejection of incompatible tissues **is not** overcome by therapeutic cloning. Dr. Irving Weissman, world-renowned immunologist at Stanford who supports therapeutic cloning, claims that it does not solve the immune rejection problem. Residual components from the egg called mitochondria DNA can cause an immune response. Weissman adds that "in mouse studies it is clear that those genetic differences can lead to a mild but certainly effective transplant rejection." He goes on to say "because therapeutic cloning requires the creation and disaggregation *ex utero* of embryos, this technique raises complex ethical questions."

- **Exploitation of women:** Therapeutic cloning is also a women's health issue. Judy Norsigian, Founder and Director of the Boston Women's Health Book Collective and co-author of Our Bodies, Ourselves, testified before Congress that she and other who are pro-choice" and support embryonic stem cell research using embryos in IVF clinics for example, have joined with other renowned individuals and organizations calling for an immediate halt to any forms of human cloning. The number of eggs required for research as well as therapies, if achieved, will be enormous even if cloning efficiencies are improved. A woman can provide about 10 to 12 eggs from one fertility procedure. Drugs used to enhance female egg production carry significant safety risks, including loss of fertility and increased cancer risk. The removal of these eggs requires invasive surgery. Yet many economically challenged women will face these risks to earn the four thousand dollars that a company like Advanced Cell Technology currently pays for eggs for their human cloning research. This company used 71 eggs from 12 donors before generating the first embryo that eventually died. Even with improvements that would result in one embryo from one egg, use of the technology for just one disease such as diabetes will depend on millions of women each

year undergoing substantial health risks. The unlikelihood of many repeat donors will lead to donation of eggs for money, thereby exploiting women with limited financial resources, commodifying women's eggs and compromising their reproductive autonomy. These and other unknown risks at this time represent a few of the unintended consequences of therapeutic cloning.

It is our responsibility as a society to protect its citizens through oversight and the ability to control science. We have always done this, when we said that using prisoners or mentally compromised individuals for testing new drugs was illegal. IRBs are set in place to be watchdogs for patient's rights and FDA expects no less. We are dealing with the welfare of not only the embryo which many believe is human, but also with the welfare of women who will be used as tools in this research endeavor.

- **Unaffordable:** James Thomson, who discovered embryo stem cells, stated that the poor availability of human oocytes, the low efficiency of the nuclear transfer procedure, and the long population-doubling time of human ES cells make it difficult to envision therapeutic cloning becoming a routine clinical procedure. This may mean that if this approach would ever work, such therapy would only help those individuals who are able to afford an expensive treatment and the majority of patients will be excluded, as reported by Great Britain's Royal Society.

- **Not appropriate for genetic disorders:** Therapeutic cloning is touted as the cure for a long list of diseases and conditions. Yet the National Research Council states that "it might not be appropriate to transplant such cells (derived from cloning) into a person with a genetically based disease, since the cells would carry the same genetic information." For example, Juvenile Diabetes, Sickle Cell Anemia Muscular Dystrophy, and more.

- **Overstated:** Furthermore, many scientists believe the current state of embryonic stem cell research is overstated. Much more is to be learned before human embryo cloning can even be justified from a scientific perspective. Yet, the hope of therapeutic cloning would seem to be growing with all the advances being reported in the press. This promise is much further from reality than ever acknowledged. On April 11, 2003, it was reported in the peer-reviewed journal, Science that the difficulty in cloning primates is far greater than in lower animals and explains inability to clone primates, even after many attempts. It went on to add that important proteins that enable cells to equally divide the chromosomes are removed with the egg's nucleus in primate cloning. Dr. Jaenisch went on to say regarding the future of SCNT that "there may not be normal clones."

Therefore, the benefits of therapeutic cloning with or without risks is not just around the corner. There are other more advanced alternatives that receive little to no attention in the claim that therapeutic cloning is necessary and it alone offers unique cures.

Medical Advancement and Alternatives:

When articles speak of therapeutic cloning being crucial to medical research for Parkinson's disease, spinal cord injury, diabetes, and heart disease, they fail to mention the clinical trials showing early success using the alternatives of adult stem cells and regenerative medicine for Parkinson's disease, spinal cord injury, diabetes, and heart disease. The claim is *untrue* that these alternatives offer limited options. This is refuted by the extent of clinical development for multiple diseases.

- **Diseases being treated in the clinic**:
  1. Parkinson's disease – patient's own brain stem cells, 80% reduction of patient's symptoms in one year (Celmed Biosciences in Canada, completed Phase 1 studies)
  2. Spinal cord injury (Princess Alexandra Hospital in Brisbane, Italy, China, Portugal)

3. Diabetic circulation problems - blood vessel formation (Yamaguchi University School of Medicine, Japan)
4. Neurological effects of stroke reversed (University of Pennsylvania)
5. Juvenile diabetes - >100 patients insulin-independent (Edmunton Protocol, Canada)
6. Heart disease – myocardial tissue regeneration (Bioheart, Phase 3)
7. Sickle cell anemia – cured (France)
8. Multiple sclerosis – reversed (Canada, China)

- Numerous tissues have been successfully derived from adult stem cells, making this a very viable option for curing many diseases.

Enforcement:

- The United States is one of very few countries considering therapeutic cloning. Over 40 Countries of the Council of Europe, including Russia and Turkey, have adopted a prohibition on creating embryos for research or reproductive purposes, 23 of them signing the Council of Europe's 1998 protocol to ban all human cloning. They have recognized the inherent problems with all human cloning as well as that a modified banning, i.e. banning reproductive but not therapeutic cloning, is problematic to enforce. Assistant Attorney General Daniel Bryant, Office of Legislative Affairs testified before the Subcommittee on Criminal Justice, Drug Policy and Human Resources in May last year to this effect adding that prohibiting the transfer of an embryo, difficult to distinguish from IVF or SCNT, to a uterus, an activity that is otherwise permitted in fertility clinics, would be a formidable task in light of the number of embryo transfers performed in clinics across the country every year. Indeed, allowing therapeutic cloning will make reproductive cloning more likely to occur. He stated that "anything short of an outright ban would present other difficulties to law enforcement" and be easily undermined. For example, the language in S. 2076 prohibits clonal implantation if it were done "for the purpose of creating a cloned human being." This ambiguous language would not prohibit other purposes such as growing a clone in utero for research use at any time during its 9-month gestation and, thus, permit the slippery slope to eugenics and reproductive cloning.

- These fears have proven well-founded, as legislation has been proposed in four states (withdrawn, in New Jersey when this point became known) that would have allowed the cloning of humans "through the embryonic, fetal, and newborn stages" provided the clones were *not* allowed to live beyond this point. Some notable scientists have even indicated that human cloning can provide scientists with the capability to develop and study human disease models, going far beyond what the general public has envisioned.

Economic Impact:

Some have suggested that therapeutic cloning is needed for cell-based biotech to thrive. These claims are not supported by the facts.

- Due to a shortage of funds, Advanced Cell Technology, America's premier cloning corporation, has reduced its workforce in its therapeutic cloning program.
- PPL Therapeutics, the Scottish biotech firm that created Dolly the sheep, has decided to close its stem-cell (therapeutic cloning) operations as being "unprofitable."
- Michigan, emerging leader in biotech industry growth, has banned all human cloning.
- Australia, recently cited by the journal *Science* as an "island of stability and growth" in the generally lackluster worldwide cell-based biotech market, has banned all human cloning. Most notably, Australia's *embryonic* stem cell research industry is thriving.
- Stem cell and regenerative research are making significant strides at the major universities and medical centers.

Diverting federal funds from human adult and embryonic stem cell research will delay approval of therapies that are already showing promise. Research dollars are very dear, and even investors

recognize betting on a more sure thing in that the major number of stem cell companies are focused on adult stem cell research, not embryonic cloning.

Ethical Considerations:

Unproven theories that sound good until one considers the facts and the unethical way in which therapeutic cloning is being sold to the public:

- Though ACT and PPL patents for SCNT clearly describe the creation of an embryo, yet ACT's scientific and bioethics board thought it prudent to use a less inflammatory term than an embryo in any press releases.
- The decrying of reproductive cloning while maintaining an interest in circumventing the spirit of the law to use it for research purposes is deceptive.
- It is not only unethical, but borderline criminal to hold out a promise to desperate patients without full disclosure of the high probability for failure, the enormous lead time required, and the availability of stem cell and tissue regeneration therapies currently in human trials.

In Conclusion:

The risk/benefit ratio is way too high when one considers that even if we were to achieve some success after years of research and a considerable financial investment; the risks are still there: health issues for and exploitation of women, inappropriateness for genetic diseases, genetic flaws intrinsic to the system, ethical considerations regarding the human embryo, and the real possibility of leading to reproductive cloning, and all of this in the face of a very viable alternative.

The House and Senate Bills:

- do not ban embryonic or adult stem cell research,
- do not ban the use of umbilical cord blood, fetal tissue,
- do not criminalize procurement of treatment from human cloning in another country, if it should ever become available,
- do not block cures for life-threatening diseases since many of these are already being addressed with adult stem cells or regenerative medicine,
- only ban human cloning,
- protect women from exploitation for a risky, unproven technology,
- protect us from a law enforcement quagmire, and
- protect us from an unproven technology that ushers in the risk of genetic manipulation with other known and unknown risks.

We scientists are passionate about the research we do, but preservation and protection of the right to conduct scientific investigation cannot ignore protection of human beings from risks and unintended consequences when the risk/benefit ratio is so high. Please be assured that we scientists will continue to find ways to cures diseases and advance the medical health of mankind, with or without the use of cloning. If our mission is the advancement of life, we must not jeopardize it in the name of progress.

Thank you again for your time, attention, and the opportunity to provide testimony on the ethical and public policy implications of human cloning for any purpose.